‘No-Touch’ Breast-Implant Insertion Device

By

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DECLARATION

I, Shaa'ista Ameen, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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DEDICATION

To my parents

Anisa Kasoojee & Hassan Ameen

ACKNOWLEDGEMENTS

I would like to sincerely thank my lecturer and supervisor **A. Prof George Vicatos** for the immense amount of time spent on mentoring me over these past few years. I have thoroughly enjoyed learning from you and the guidance you have given me has been absolutely invaluable. Thank you Sir.

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ABSTRACT

Capsular Contracture (CC) has been identified as the major cause of breast-implant failures and subsequent discomfort, pain and shape deformation following cosmetic breast implantation procedures. It has been documented that CC is primarily due to bacteria which are transmitted in the breast-cavity through conventional implantation. A 'no-touch' implant insertion technique has therefore been identified as the optimal method in potentially reducing CC rates. This describes an implant delivery without the implant ever touching: gloves (even during post-insertion implant orientation assessments), retractors or the patient's skin and breast-tissue; which is inherently unachievable with the traditional finger-manipulation method. To date, the most significant improvement in the insertion process has been a 'minimal-touch' technique, i.e. with the Keller-Funnel. This study was therefore in the design and development of a safe 'no-touch' insertion device for the delivery of silicone breast-implants. Parameters included a horizontal 45 mm incision, which can stretch up to a maximum vertical central distance of 35 mm.

The proposed design featured a positive-displacement method with: (a) pressurized air as the insertion 'force', (b) an inverting-bag (partially inserted with the implant) to eliminate direct glove/implant contact, and (c) a built-in retractor with a breast-cavity air-removal path to reduce implant insertion resistance due to trapped air. The implant, in the device, remains closed to the environment and separated from the wound margin thus, eliminating skin/implant contact and further providing wound protection. Finally, the design employed an eccentric funnel shape for device use at the inframammary incision site with a suggested subpectoral or submuscular pocket placement, i.e. to eliminate breast-tissue/implant contact. Through experimentation with various implant sizes, device dimensions were suitable for implant-volumes up to 428.57 cm^3.

A 1 bar air supply was used to test the prototype and prove the concept on a silicone cast breast-model. Leverage of the built-in retractor efficiently opened the incision for device placement multiple times and, the successful insertions of the implants and inverting-bag into the breast-model indicated that a 'no-touch' technique was achievable. This was at a maximum insertion time of 4.2 seconds, amongst eight implants ranging from 242 to 428.57 cm^3. However, the continued post-insertion air supply resulted in inflation of the inverted bag in the breast. This is at a high risk of developing a thoracic wall deformity and/or embolism. Suggestions were made to improve the design and eliminate this fault.

The proposed 'no-touch' technique was successfully proven in vitro with significantly reduced insertion times. However, this is subject to breast-model evaluations and a greater insertion

resistance may be experienced in a real breast. The development of a device with an air supply safety cut-off and a sensitive air pressure transducer is recommended.

Where appropriate, this dissertation uses the APA (American Psychological Association) reference style.

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NOMENCLATURE AND ACRONYMS

Roman Symbols

A	area, m^2
A_t	tensile stress area (thread), m^2
a	ellipse major radius, m
B, C	equation constants
b	ellipse minor radius, m
D	linear mass density, denier
D_t	thread major diameter, m
d (Ø)	internal diameter, m
F	force, N
g	gravitational acceleration, m/s^2
m	mass, kg
P	pressure, Pa
PCD	pitch circle diameter (thread), m
r	radius, r
t	thickness, m
W	weight, N

Greek Symbols

σ	stress/strength, Pa

Subscripts

c	circumferential
i	inner
max	maximum
o	outer
p	plunger
r	radial
req	required
T	total
TS	tensile

Acronyms

CC	Capsular Contracture
HDPE	High Density Polyethylene
SF	Safety Factor
SLS	Selective Laser Sintering

GLOSSARY

600 D polyester fabric	a woven polyester fabric composed of a polyester thread with a linear mass density (denier) of 600
air embolism	air bubble trapped in a blood vessel – through undetected blood vessel cuts or, diffusion into blood vessels due to an internal pressure increase
antimicrobial	drugs used to treat microbial (i.e. bacterial) infections – antibiotics
breast augmentation	aesthetic breast enlargement procedure
breast reconstruction	breast implantation following: mastectomy, trauma or development abnormalities
capsular contracture	an immune system response to the breast implant
capsulectomy	corrective procedure for the removal of a capsule around and implant
capsulotomy	'cutting' (open) or 'breaking' (closed) of a capsule around an implant
denier	the mass (in grams) per 9000 m of (a fabric material) thread, i.e. the linear mass density of a thread
extracellular matrix	sticky network of non-living tissue secreted by cells
fibroblast	collagen secreting connective tissue cell
gel-bleed	the diffusion of silicone particles through the implant shell
gel-fracture	damage to the gel-structure of a silicone breast-implant, causing shape deformation
hematoma	a collection of stagnant blood
hypertrophic	an excessive growth (i.e. of the capsule around an implanted prosthesis)
implant integrity	implant shell and gel-structure quality
modulation	morphological fluctuation/change of a cell in response to environmental change
myofibroblast	fibroblast with smooth muscle characteristics
mastopexy	breast lift or reshaping procedure
pneumothorax	air between the lungs and chest cavity due to damage to the parietal pleura
shell rupture	damage to the elastomer shell of a breast-implant
subclinical infection	an infection absent of clinical (observable) symptoms

1. INTRODUCTION

Capsular contracture (CC) has been the most common and persistent postoperative complication associated with breast implantation surgeries. This occurs when the otherwise normal formation of a fibrous capsule, around an implanted foreign object, tightens and squeezes the implant. The breast consequently becomes unnaturally hard, painful and distorted (Pittet, Montandon, & Pittet, 2005). Despite implant improvements, CC has continued to occur at high rates, often requiring corrective surgeries at increased risks and costs. The reported rate of CC occurrence has varied between 10-30% within the first five postoperative years (Mofid, 2011) and is estimated to be inevitable by the 25th year after implantation if there is no complication history (Grigg, Bondurant, Ernster, & Herdman, 2000). This is also at the risk of even higher reoccurrence rates following implant replacement treatments.

While the etiology of CC remains unclear, investigations have strongly led to the 'infectious theory' (Pittet et al., 2005). This describes the primary cause of CC to be due to a bacterial multiplication process in the breast pocket environment, particularly with 'skin' bacteria which have gained access in the breast-cavity. A 'no-touch' implant insertion technique has been hypothesised as the optimal method in significantly reducing future complication rates thus, indicating a required improvement in the insertion process. By definition, the 'no-touch' technique refers to a direct implant insertion into the breast-pocket without the implant being touched by: instruments, drapes, gloves, or the patient's skin and breast-tissue (Moyer, Ghazi, Saunders, & Losken, 2012).

1.1. Problem Statement

To significantly reduce insertion related bacterial contamination in breast implantation procedures, increasing attention had been on the development of 'no-touch' breast-implant insertion devices. This stems from the inherent inability in achieving the required 'no-touch' technique with the traditional finger-manipulation method of insertion. Also inherent to the finger-manipulation method is the potential: (a) compromise to implant integrity (i.e. with regards to the implant shell and gel-structure) and (b) adverse effect on wound healing. This is due to the distribution of uneven forces on the implant and, the high degree of tissue trauma at the wound by the passing implant, respectively. To be surgically adopted, the use of a device is therefore required to significantly reduce complication rates and promote safer and faster procedures in comparison to the traditional method of insertion. Consequently, further

requirements include: (a) implant integrity maintenance, (b) wound margin protection, and (c) a simple and easy to use design.

To date the gold stand of devices, with a purpose to reduce the above stated complication, is the 'minimal-touch' technique introduced by the Keller-Funnel (Moyer et al., 2012). This implant push-device (i.e. a device employing a positive implant displacement method) is the only device that has been introduced to market with the aim of reducing skin/implant contact, while providing a more even distribution of insertion forces to the implant. Due to the limitations introduced by the 'minimal-touch' technique of the Keller-Funnel, there exists a need for the design and development of a breast-implant insertion device that achieves a true 'no-touch' technique and meets requirements that will positively influence its appeal to the industry. This is particularly for the insertion of prefilled silicone-gel implants.

1.2. Aim and Objectives

The aim of this study is to design and develop a silicone breast-implant insertion device that demonstrates (*in vitro*) the 'no-touch' technique and, is also conducive to safe implant and breast handling. To be surgically adopted, the proposed device design must be simple, easy to use and able to achieve the desired outcome in a timely manner.

The objectives of this study (with *in vitro* visible evaluations) are therefore:

1. To be able to insert prefilled silicone breast-implants through a 45 mm incision length that is stretchable (centrally) to a maximum perpendicular distance of 35 mm[1].
2. To eliminate skin/implant contact throughout insertion.
3. To eliminate the need for an external retractor (to the device) to hold the incision open for implant delivery, i.e. for the elimination of additional surgical instrument contact on the implant surface.
4. To eliminate direct glove/implant contact throughout insertion and (post-insertion) correct implant placement verification.
5. To eliminate breast-tissue/implant contact prior to final placement.
6. To demonstrate a safe positive-displacement method with regards to:
    - 6. a. maintaining implant integrity of the implant shell and gel-structure.
    - 6. b. safe breast handling.
7. To be ergonomically conducive to the workable surgical space and overall handling of the device as an instrument at the incision site.

[1] Incision dimensions provided by project initiator, Dr Nicholas Kairinos – Plastic Surgeon

1.3. Scope and Limitations of Study

A major scope of this study is to bring forth and understand (from literature) the causes of CC which led to the current necessity worldwide to develop a 'no-touch' insertion technique. Thereafter, this study is in the design and development of a silicone breast-implant insertion device that visibly demonstrates a 'no-touch' technique and, also ensures in an atraumatic implant and breast handling delivery during breast implantation surgeries. This 'no-touch' technique is consequently, verified by the observations of silicone breast-implant insertions into a breast-model. Implant integrity is verified via post-insertion visible inspection of the implant for evidence of shell rupture and/or gel-fracture.

This device is particularly designed for an incision length of 45 mm. It is therefore part of the scope to use the proposed insertion device to determine the maximum insertable implant volume for a 45 mm breast incision. Final device material selections and the ergonomics of prototype device assembly procedures, which do not influence the concept to be proven, are beyond the scope of this study.

The limitations of this study are:

1. The small sample-size of silicone breast-implants (donated to this study) which are composed of implants of varying: size, gel-type, shape and surface finish, introduce a number of variables which cannot be compared conclusively. This sample-set is also composed of both permanent and sizer breast-implants, which differ with regards to the thickness of the implant shells and cohesiveness of the gel.
2. The 'no-touch' proof of concept will be limited to *in vitro* testing only and therefore, bacterial contamination testing will not be carried out.

1.4. Structure of Dissertation

To fully determine design considerations and essential device features a background of the surgical procedure is provided, followed by a literature review on: the current body of evidence and understanding of CC, the traditional finger-manipulation method and, existing device designs. Based on these findings, device concepts are explored, critically analysed and followed by prototype development in the final design of the prototype. The proposed device concept is thereafter proven according to breast-model evaluations.

2. BACKGROUND

For centuries various attempts have been made to enhance the shape and size of the female breast. Surgical interventions became apparent in the 1880's with the insertion of ivory, metal, glass and rubber implants. These insertions required painful procedures which often failed aesthetically and resulted in multiple medical complications (Sarwer, Nordmann, & Herbert, 2000). The direct injection of materials such as petroleum jelly and silicone liquid (amongst others) into the breast-tissue were later introduced. However, complications remained severe and in some cases even resulted in breast loss or death (Grigg et al., 2000). The potential success and safety of breast implantation procedures only became apparent in 1963, following the invention of silicone elastomer shell implants filled with either a saline solution or silicone-gel material (Sarwer et al., 2000). While the popularity of breast implantations have increasingly grown since the introduction of this type of implant, there remains a number of postoperative complication associated with the procedure (Tweed, 2003).

This background provides an overview on the breast implantation procedure and associated postoperative complications. Prior to this, an overview on the popularity and an average patient description is provided.

2.1. Popularity of Breast Implantation Surgery

The use of breast-implants are the core components in breast augmentation and reconstructive surgeries for cosmetic enlargements (Grigg et al., 2000) and following mastectomies, trauma or development abnormalities (Fleming Fallon, 2013), respectively. In 2013, breast augmentation became the most popular cosmetic procedure performed by plastic surgeons worldwide, with over 1.7 million procedures reported to the International Society of Aesthetic Plastic Surgery (2014). This was a significant increase since the 1.2 million reported in 2010 (International Society of Aesthetic Plastic Surgery, 2011). South African statistics are not readily available however, trends in South Africa have been determined to follow closely to those reported in the United States of America (USA) (Finance Health Finance, 2013). As shown in Figure 2.1, despite a slight reduction during a recession period (i.e. between 2007 and 2009), a steady increase in these procedures have been observed in the USA (Smith, 2011).

The number of breast implantation surgeries have continued to increase over the past ten years (Marcotte, 2013). In 2013, The American Society of Plastic Surgeons (2014) reported a total of 290 224 augmentations, performed by their members. This represented a 1% increase since 2012, and a 37% increase since 2000. A total of 95 589 reconstructive procedures were also

reported by these members in 2013, representing a 4% increase since 2012 and 21% increase since 2000. This supports the greater popularity of breast augmentations compared to reconstructive procedures (Rohrich, 2000). However, these totals are most likely an underestimate since; reported rates correspond to the procedures performed by the members of a specific association.

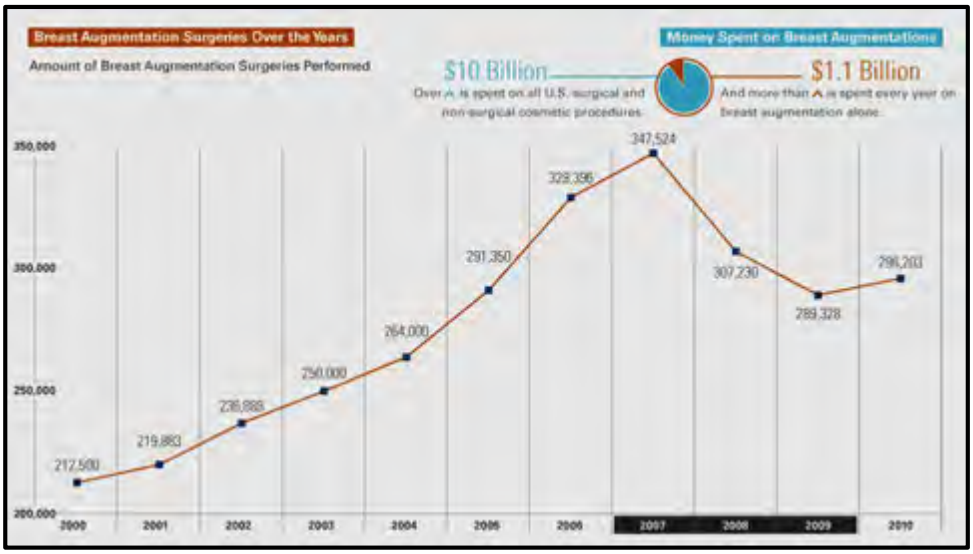

Figure 2.1: USA breast augmentation trend (2000 - 2010) (Smith, 2011)

2.2. Patient Description

Improvements in technologies and subsequent decrease in costs has increasingly attracted individuals from less wealthy backgrounds to undergo these surgeries (Shaw, 2013). The average patient is of a middle to upper-middle socio-economic status (Sarwer et al., 2000). Breast implantation patients are primarily women however, in 2013, 12 reported augmentations were performed on men in the United Kingdom (The British Association of Aesthetic Plastic Surgeons, 2014). Nonetheless, this patient analysis is with regards to the female patient.

Both physical and psychological benefits have been observed in women following this type of procedure (Independent Review Group, 1998). According to the Independent Review Group (1998), the typical breast implantation patient is a women that:

- Is dissatisfied with the shape and size of the natural breast (i.e. feelings of inadequacy).
- Has a congenital defect or absence of one or both breasts.
- Experienced a decrease in breast size after pregnancy or with increasing age.
- Has undergone a mastectomy for treatment of cancer.

The average augmentation patient is approximately 31 years of age and is often married with children (Sarwer et al., 2000). In 2013, according to The American Society of Plastic Surgeons (2014), augmentation patients were predominantly younger than reconstructive patients.

2.3. Breast Implantation Surgery

Prior to breast pocket dissection and implant insertion, preoperative surgical planning involving an evaluation of the patient's breast-tissue, anatomy, desired physical outcome and preference is required. Collectively, these evaluations influence the surgical procedure (Allergan, 2009). An overview of the surgical variables and procedure is herein provided.

2.3.1. Surgical Variables

The surgical procedure is determined according to three variables, these include the chosen:

- Implant type: filler material (saline/silicone); surface finish (textured/smooth); shape (round/anatomical); and size.
- Implant pocket placement: subglandular, subpectoral or submuscular.
- Incision site: periareolar, inframammary, transaxillary or transumbilical.

Implant related (sub) variables are as indicated above. Of interest (at this stage) is the implant filler material, i.e. saline and silicone-gel. Unlike saline implants, silicone-gel implants are delivered prefilled (Hidalgo, 2000), so as to prevent gel-leakage concerns. Silicone-gel implants consequently require larger incision lengths and more time for insertion (Preissman, 2012). In retrospect, a silicone-gel implant can require incision lengths of up to 60 mm compared to 30 mm for a saline implant of an identical final volume (Abell, Muhanna, & David, 2007). And, the associated increase in insertion times increases the procedure costs, as well as complication risk (Keller & Senn, 2013). In 2013, The American Society for Aesthetic Plastic Surgery (2013) reported the use of silicone-gel implants in 75% of augmentations, representing a 3% increase since the previous year (The American Society for Aesthetic Plastic Surgery, 2012). This has been determined to be due to the more natural appearance and softer feel of the breast with silicone-gel implants (Grigg et al., 2000). *Unless otherwise stated, concern is with the insertion of silicone-gel implants and is herein referred to as silicone implants.*

An implant pocket is essentially created behind the breast-tissue or pectoral muscles (i.e. subglandular, subpectoral or submuscular pocket placements). Where, subpectoral is a combination of the subglandular and submuscular placements, and is often refer to as a dual-plane placement (Hidalgo, 2000). Pocket plane selection largely depends on: the patient's body type, amount of available soft tissue (for coverage) and, the specifics of the implant to be inserted (American Society of Plastic Surgeons, 2005). Anatomically, large blood vessels and

nerves are found between the breast-tissue and muscles. Consequently, submuscular and subpectoral pocket dissections tend to draw less blood (Camirand, Doucet, & Harris, 1999). However, the detachment and mobilization of muscles are required, which may (postoperatively) result in excessive pain and/or implant displacement with submuscular placements – due to the muscular compression on the implant (Spear, Bulan, & Venturi, 2004). Refer to APPENDIX A, Figure A.1 for an illustration of these placements.

Incision site selection is based on the: size of the nipple, inframammary fold definition, presence of congenital breast abnormalities (tuberous breast) and the need for a mastopexy (breast lift/reshaping) (Hidalgo, 2000). Regardless of the selected pocket plane, augmentations are ideally carried out through incision sites that will minimize the visibility of the resultant scar (Zochowski, 2014). There exists four potential incision sites (as shown in Figure 2.2) however; silicone implant insertions are not possible through the transumbilical site. There also exists implant control difficulties and potential placement inaccuracies with insertions through the transaxillary site (Hidalgo, 2000). The most frequently used site is the inframammary incision (Moyer et al., 2012). This accounts for between 70-80% of all breast implantation procedures (Arbor, 2013). Preference with this incision site is mainly due to: the simplicity and versatility of this site, greater control over implant placement, the reduced need for breast-tissue violation and effectively concealed incision lines (Spear, Bulan, et al., 2004). However, in the case of a simultaneous mastopexy, the periareolar incision is used for insertion (Jacobson, Gatti, Schaffner, Hill, & Spear, 2012).

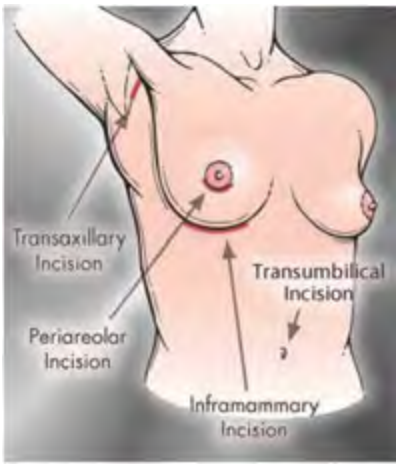

Figure 2.2: Incision sites (Perez, 2013)

2.3.2. Surgical Procedure

After preoperative planning, an incision is made at the selected incision site, followed by dissection of the selected pocket plane. Traditionally, the implant is forced through the relatively small incision and into the breast-cavity with the fingers, whilst the rest of the hand

applies pressure on the implant so as to prevent it from sliding back out (Abell et al., 2007) – this is the finger-manipulation method of insertion. Stainless steel retractor/s are used throughout insertion (and pocket dissection) to stretch and hold the incision open (Ledergerber, 1998). Sizers may be used, prior to insertion of the permanent implant, to assist the surgeon in evaluating if the selected implant will achieve the desired surgical outcome, or if another implant size/type should be used (Adams, 2008).

The average length of an augmentation procedure is between 1-2 hours (The American Society for Aesthetic Plastic Surgery, 2012). For silicone implants, insertions with the traditional finger-manipulation method generally takes 5-15 minutes per an implant for even a highly skilled surgeon (Keller & Senn, 2013). This technique often becomes more difficult with larger implants and/or smaller incisions (Abell et al., 2007). Following insertion, the surgeon feels for correct implant placement and orientation with the tip of the fingers. Postoperatively, patients often have a drainage tube in place (for a few days) to drain any fluids that may have collected in the breast (Allergan, 2007). Figure 2.3 shows the insertion of a silicone implant through a periareolar incision at the aid of the traditional finger-manipulation method.

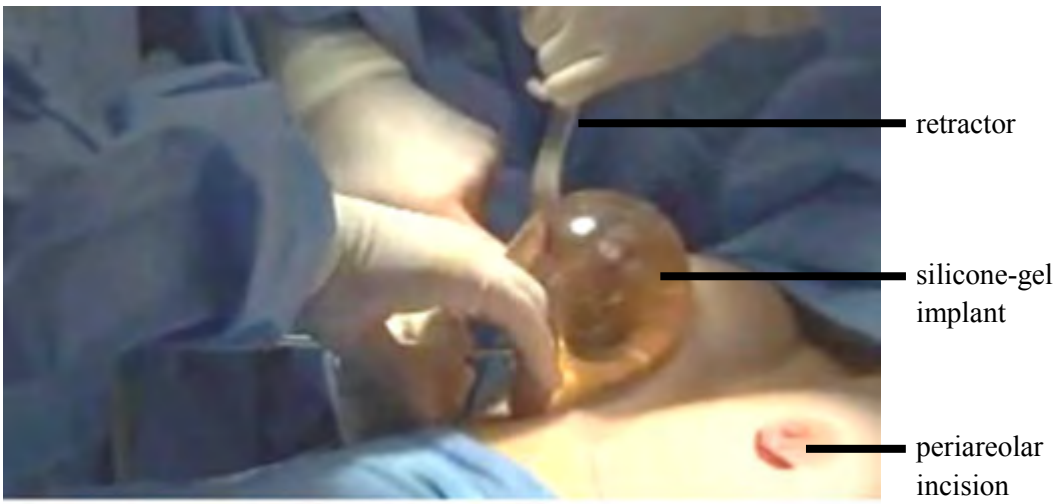

Figure 2.3: Traditional finger-manipulation method of insertion (KellerFunnel, 2012)

2.4. Complications Associated with Breast Implantation Surgery

Postoperative complications vary from mild to severe, all of which may result in reoperation combined with an implant removal (Tweed, 2003). Complications that are not medically related, but require reoperation, include: implant displacement, implant rotation, wrinkling/rippling and, discomfort or breast hardness due to an inadequate pocket dissection (Sarwer et al., 2000). These complications result in patient dissatisfaction and often are due to the inexperience of surgeons. Of more concern are complications such as: shell rupture, silicone gel-bleed,

hematoma, clinical infection and capsular contracture (CC). These are local complications (Grigg et al., 2000).

Reoperation following breast implantation has been reported in 17% of procedures within the first postoperative year (Moyer et al., 2012) and 25% after five years (Tweed, 2003). Considering the popularity of breast implantation surgeries, the risk of reoperation potentially affects a large number of women. In 2013 alone, The American Society of Plastic Surgeons (2014) reported a total of 23 770 implant removals (by their members) however, no indication was provided as to why these implants were removed. Nonetheless, a decrease in complication rates have been observed as the silicone breast-implant has evolved. There have been five generations of silicone implants since 1963 – each representing an attempt at further reducing complication rates. Changes in the manufacturing process of the implant have been with regards to the: shell, gel-structure and shape (i.e. from 1st generation smooth, round, high gel-bleed implants to 5th generation textured, anatomical and more form-stable cohesive gel implants) (Moyer et al., 2012). Where, gel-bleed refers to the diffusion of non-cross linked silicone particles through the elastomer shell, in the absence of a shell rupture (Pittet et al., 2005).

The most common and persistent complication associated with breast implantation surgery is CC. This occurs when the otherwise normal formation of a fibrous capsule, around an implanted foreign object, tightens and squeezes the implant. As a result, the breast becomes unnaturally hard, distorted and/or painful (Pittet et al., 2005). The occurrence of CC, and the potential influence of the other local complications, is therefore of concern with this surgical procedure and, in the development of a suitable breast-implant insertion device (Maxwell & Gabriel, 2009).

3. LITERATURE REVIEW

To determine the design requirements for a breast-implant insertion device, this literature review investigates: the requirements for the prevention of capsular contracture (CC) and the inherent contribution of the traditional finger-manipulation method to this and other associated complications. This is followed by an analysis on existing insertion devices and essential aspects for prototype development.

3.1. Capsular Contracture

Within two to three weeks following implantation, the natural immune response results in an acellular and avascular collagenous sheath encapsulation of the implant (Mcgrath & Burkhardt, 1984). This is a normal scar tissue which also forms around implanted cardiac pacemakers and orthopaedic prostheses (Pittet et al., 2005). A contracture is regarded as an abnormal progression of this natural immune response to the biologically inert and non-toxic breast-implant. Physically, CC occurs when the scar tissue tightens and squeezes the deformable breast-implant into a hard spherical mass. This is in an attempt to reduce the implant surface area via a radial force (Camirand et al., 1999).

Contractures have been observed to develop weeks to years after surgery, bilaterally or unilaterally, and to varying degrees of severity (Allergan, 2007). On average, between Ersek (1991) and Hipps, Raju, & Straith (1978), 50% of contractures have occurred unilaterally following bilateral implantations. The severity of a contracture is measured according to the Baker Classification Scale (described in Figure 3.1).

Baker Classification Scale

Grade I – The implanted breast is as soft as a normal breast.

Grade II – The breast is not as soft and the implant can be palpated (but not visible).

Grade III – The breast is firmer and the implant can be easily palpated with visible distortion.

Grade IV – The breast is firm, tender, hard, cold, painful and distorted.

Figure 3.1: Baker Grade Classification (Grigg et al., 2000)

This scale is entirely based on the appearance and feel of the breast (Grigg et al., 2000). Despite the inherent subjective nature of the Baker Grade system, this remains the most popular and practical method in externally assessing breast firmness (Tamboto, Vickery, & Deva, 2010). Baker Grade III/IV evaluations are generally considered as severe contractures (Grigg et al., 2000) and, Grade II as mild, indicating the onset of a contracture (Marques et al., 2010). Figure 3.2 shows the effect of severe CC on the appearance of the breast.

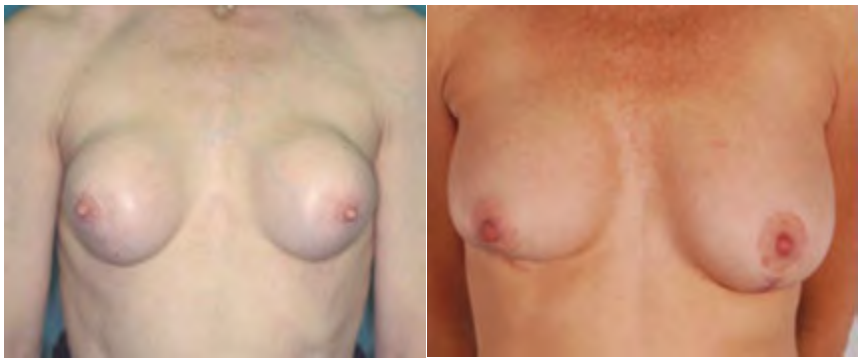

Figure 3.2: Baker Grade IV bilateral contracture *(left)* (Pittet et al., 2005)**, right breast unilateral contracture *(right)*** (Spear et al., 2011)

3.1.1. Capsular Contracture Occurrence Rates

The reported CC incidence has significantly varied between studies.

- Manufacturers have reported the incidence of Grade III and IV contractures to be between 10-30% within the first five postoperative years (Mofid, 2011).
- In literature this has ranged between 0-74% (Hester et al., 2012) and,
- Between 0.6-100% of patients (Tamboto et al., 2010).

This variation is primarily due to the anecdotal nature of most studies (Gabriel et al., 1997), refer to APPENDIX B.1, Table B.1 for other reported CC occurrence rates. While some studies continue to report high rates, contracture rates with newer 5th generation implants have reportedly been 6-times less than those reported with older generation (high gel-bleed) implants (Adams, 2009). A 100% contracture rate was also consistently reported following the injection of silicone-liquid into the breast (Grigg et al., 2000), see section 3.1.3.

Approximately 90% of contractures have been reported between the first (Jacombs et al., 2012) and third (Ersek, 1991) postoperative year. The remainder of which have occurred more than 10 years later (Adams, 2009), refer to Table B.2 for other reported time-to-contracture rates. It has been determined that, even in the absence of other complications, all implanted breasts will

develop a severe contracture by the 25th postoperative year (Grigg et al., 2000). This indicates a progressive phenomenon (Sarwer et al., 2000). Consequently, the risk of CC development continues to exist as long as the implant remains in the breast (Jacombs et al., 2012).

3.1.2. Potential Etiology of Capsular Contracture

The exact cause of CC remains unknown (Preissman, 2012) however, studies have collectively indicated a multifactorial etiology (Adams, 2009). Factors that have been observed to influence CC development have included:

- The type of surgery (augmentation vs. reconstructive)
- Patient's age at implantation
- Chosen surgical variables (section 2.3.1)

} Surgery related

- Clinical infection
- Hematoma
- Gel-bleed (with/without shell rupture)

} Other local complications

With regards to the type of surgery, lower CC rates have consistently been reported with augmentation procedures (Adams, 2009), refer to Table B.3 for reported rates. While, reconstructive patients are generally older than augmentation patients, a more significant difference between the two types of surgeries is the increased surgical complexity required with a reconstructive procedure rather than the patient's age at implantation (Handel et al., 1995).

The influence of surgical variables on CC rates is illustrated in Figure 3.3. Regardless of the higher CC rates reported with silicone implants (Mckinney & Tresley, 1983), these remain the preferred type of prosthesis (section 2.3.1). With regards to surface-finish, texturing has been observed to delay CC development rather than reduce the occurrence however, this advantage has been observably limited to subglandular placements (Handel et al., 1995). And, an increase in complication rates with volumetrically larger implants have been found (Somogyi & Brown, 2015). Irrespective of the implant type, subpectoral placements have yielded even lower CC rates. However, the incision site has been determined to have the greatest impact on CC development (H. Becker & Springer, 1999), see section 3.1.4. In addition to the conclusive cautions associated with anecdotal studies, surgeons may also be more skilled with certain surgical variables thus, potentially influencing reported rates and observations (Handel et al., 1995). Refer to Table B.4 – B.7 for reported CC rates associated to surgical variable selections.

With regards to local complications, Sarwer et al. (2000) reported an incidence of 3% for both clinical infections and hematomas. While this occurrence may appear insignificant, this potentially affects a large number of women (section 2.1). Nonetheless, it is evident that the

incidence of clinical infections and hematomas cannot compare to reported CC rates (Pajkos et al., 2003). Hematomas usually occur within an acute postoperative period (American Society of Plastic Surgeons, 2005) but have been determined to influence the risk of contracture by a factor of 2 (Mofid, 2011) and by a factor of 3 (Wixtrom, Stutman, Burke, Mahoney, & Codner, 2012). Hematomas have also been found to influence the occurrence of clinical infections (Courtiss, Goldwyn, & Anastasi, 1979). Hipps et al. (1978) reported that 86% of hematomas and 75% of clinical infections in their study later developed CC. It is likely that the reported incidence of infections and hematomas are an underestimate since, contractures are only recognized once the breast has already become firm. Furthermore, in keeping with CC occurrence, infection and hematoma rates have been higher following reconstructive procedures (Pittet et al., 2005).

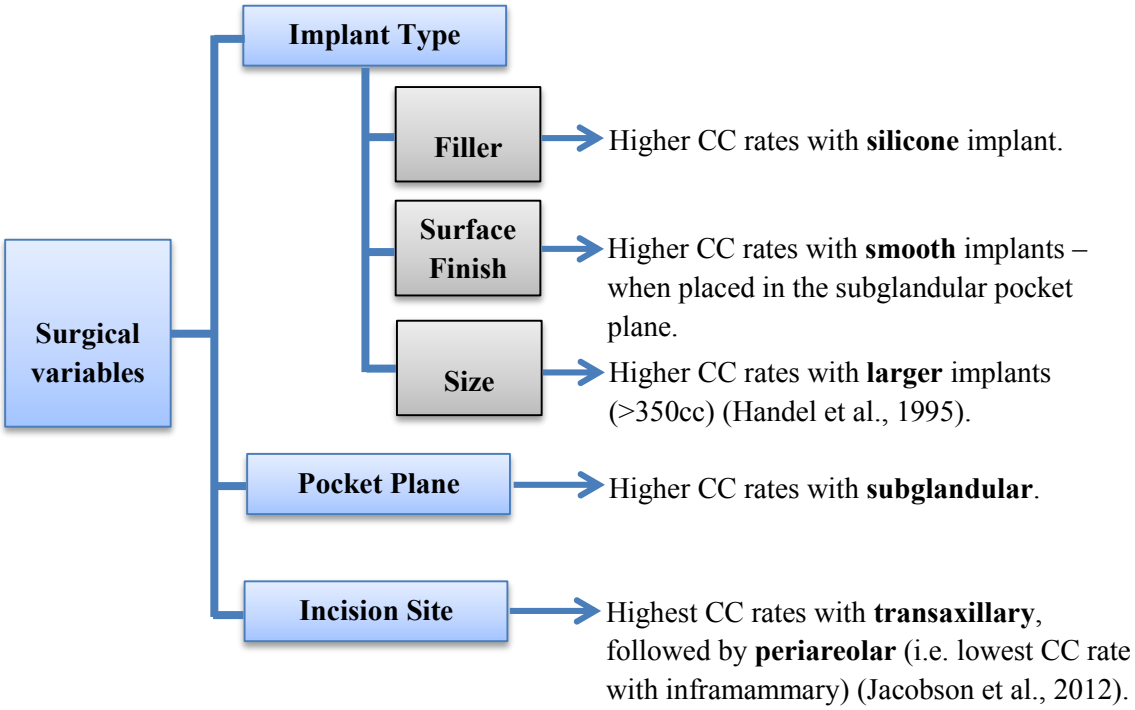

Figure 3.3: Effect of surgical variables on capsular contracture occurrence

The contribution of gel-bleed (with/without shell rupture) stems from the observed decrease in CC rates as the gel-filler has become more cohesive (section 2.4). Silicone implant shell rupture is usually absent of symptoms however, 'loose' silicone particles have reportedly produced similar symptoms to contractures (i.e. breast firmness, distortion and pain) (Allergan, 2009). This has created confusion between gel-bleed causing CC and CC contributing to shell rupture and gel-leakage. In either case there are 'loose' silicone particles inside the breast-cavity. Should this theory be true and the 'loose' silicone particles are a potential cause of CC, then

contractures with saline implants are attributed to the shedding of the silicone elastomer shell over time (Adams, 2009).

Other factors that have influenced CC occurrence have also included: tissue trauma during/after surgery (Adams, 2009), the presence of talcum powder (from gloves) or any other irritants in the breast-cavity (Camirand et al., 1999) and, the surgeon's technical skill (Jacobson et al., 2012). To gain a better understanding of CC development, it is believed that the early inflammatory response on the cellular level may be the key to understanding the etiology of CC (Adams, 2009) and, potentially lead to innovative preventative solutions (Maxwell & Gabriel, 2009). As a result, two theories have attempted to explain the development of contractures: the hypertrophic scarring and infectious theory (Pittet et al., 2005).

3.1.3. The Hypertrophic Scarring Theory

The hypertrophic scarring theory attributes the abnormal progression of the immune response to the presence of 'loose' silicone particles in the breast-cavity, i.e. gel-bleed. This presences was observed to directly influence the thickness of the capsule (Domanskis & Owsley, 1976) – as a result of an excessive collagen fibre deposition (Ersek, 1991). This theory was supported by the decrease in CC rates with saline implants and the progression of silicone implant generations (Siggelkow, Faridi, Spiritus, Klinge, & Rath, 2003). This also explains the 100% contracture rates reported with the injection of silicone-liquid into the breast (section 3.1.1) since, excessive gel outside the capsule has also been observed to develop lumps (Independent Review Group, 1998). With regards to Baker Grade Classification, this theory therefore describes a direct relationship between CC severity and the thickness of the capsule (Domanskis & Owsley, 1976).

The capsule thickness and CC severity have been observed to increase with the implantation duration (demonstrating the progressive phenomenon of CC) but, severe contractures have not always shown evidence of thicker capsules compared to corresponding non-contracted capsule specimens (Siggelkow et al., 2003). This indicated a lack of correlation between capsule thickness and CC severity (Mofid, 2011). Furthermore, gel-bleed as a contributing factor does not account for the occurrence of unilateral contractures following bilateral implantations (Burkhardt, 1981). The decrease in CC occurrence with newer generation implants is therefore, due to the resistance of capsular compression by the more form-stable gel-filler material (Spear, Bulan, et al., 2004) hence, resulting in less firmness and lower Baker Grade evaluations.

A more consistent finding with CC severity (and the associated increase in pain) has been the increase in: plasma cells, inflammatory cell infiltrates and fibroblast populations (Gayou, 1979). This suggests the development of CC to be influenced by bacterial contamination (Mcgrath &

Burkhardt, 1984). The hypertrophic scarring theory is further contradicted by the reported lack of correlation between: inflammation and capsule thickness; and inflammatory cell infiltrates and 'loose' silicone particle presence (gel-bleed) (Siggelkow et al., 2003). Regardless, factors that influence capsule thickening are problematic since, the breast pocket is dissected according to the (exact) dimensions of the implant.

3.1.4. The Infectious Theory

The infectious theory attributes the progression of the immune response to the presence of a subclinical infection (Mofid, 2011). CC severity is therefore as a result of a subclinical bacterial multiplication process (Rieger et al., 2013), which is responsible for the increase in inflammatory cells (Pittet et al., 2005). This subclinical growth has been observed to be due to a biofilm formation around the implant, which is composed of multiple microorganisms embedded in an extracellular matrix (Tamboto et al., 2010). Once established, an antimicrobial resistant environment is created around the implant and the biofilm continues to thrive on the attachment of other bacterial species (Bartsich, Ascherman, Whittier, Yao, & Rohde, 2011).

Biofilm formations have been reportedly responsible for approximately 80% of infections in the body (Wixtrom et al., 2012). With regards to CC, Coagulase-negative *Staphylococci* species, specifically *Staphylococcus epidermidis*, has been determined as the primary biofilm causative microorganism (Courtiss et al., 1979). *S. epidermidis* is naturally found just below the outer-most layer of the skin (Adams, 2009). The breast ducts have also been found to harbour and extrude this bacterium into the surgical field thus, skin/implant contact and breast-tissue violation contribute to this bacterial contamination (Abell et al., 2007). Even after surgery, the breast ducts create a passage for bacterial seepage into the breast (Wixtrom et al., 2012).

Other bacterial species also responsible for this biofilm formation include: *Propionibacterium acnes* naturally found in the sebaceous glands and on the skin (Bartsich et al., 2011) and, *Bacillus* species naturally found in the environment (Pajkos et al., 2003). Collectively, these bacterial species have potential access to the implant surface and breast-cavity throughout the procedure. The continuous rubbing of the implant against the skin frees the underlying bacterial species since, preoperative skin preparation only covers the outermost layer of the skin (Adams, 2009). Surgical glove and instrument contact with the patient's skin and breast-tissue (and then onto the implant) have also been determined as other sources of bacterial contamination (Abell et al., 2007). This bacterial development and growth of a subclinical infection, over prolonged periods, explains the progressive phenomenon of contractures (Mofid, 2011). The local nature of CC is further explained by the local tissue invader characteristic of *S. epidermidis* (Shah,

Lehman, & Tan, 1981) however, an untreated contracture increases the risk of a thoracic wall deformity, i.e. pneumothorax (Asplund, Gylbert, & Jurell, 1990).

Histologically, the contraction of the surrounding capsule is due to the modulation of active fibroblasts into myofibroblast (Domanskis & Owsley, 1976). The orientation of these myofibroblasts and collagen fibres in the capsule has been observed to influence capsule compression and therefore, contracture severity. Contaminated implants with severe contractures have featured densely packed concentrically orientated, thick bundles of collagenous fibres. And, non-contaminated implants have featured loosely packed parallel orientated components (Shah et al., 1981). This indicates a fibril orientation contribution to capsule contraction (Hester et al., 2012); however, the identification of myofibroblasts in both contracted and non-contracted capsules confirm that all capsules contract to some degree (Miller, 1981).

This infectious theory for CC development has been further supported by the reported CC etiological agents (section 3.1.2), refer to Table 3.1. It is evident that clinical infections and hematomas contribute to the subclinical reaction. With regards to surgical variables, the reduced benefit of texturing following subpectoral placements is due to the greater benefit of a muscular barrier between the implant and the breast-tissue (Shah et al., 1981). This benefit is however short-lived following an incision that requires a passage through bacteria laden regions, i.e. the breast-tissue or sweat glands (H. Becker & Springer, 1999). In retrospect, the greater the degree of ductal system disruption the greater the amount of breast-pocket bacterial contamination (Jacobson et al., 2012), regardless of good surgical techniques (Wiener, 2008). The influence of trauma to the breast during/after surgery on CC development is therefore due to the spread of additional bacteria from the breast ducts, especially with subglandular placements (American Society of Plastic Surgeons, 2005). Furthermore, the occurrence of unilateral contractures following bilateral implantations significantly supports this theory – making systematic or implant related causes unlikely with regards to CC development (Rieger et al., 2013).

The lack in permanent relief after treatment for CC has further supported the infectious theory. These treatment methods have included both surgical and non-surgical interventions. However, surgical interventions are usually required in the case of severe contractures (Pittet et al., 2005), refer to APPENDIX B.2 for an overview of CC treatment methods. Due to the strong bacterial attachment on the contracted implant and breast-cavity, the most widely recommended treatment is an implant replacement with a pocket change (American Society of Plastic Surgeons, 2005). CC reoccurrence rates have however been between 17.4% (Handel et al., 1995) to 53.4% (Hester et al., 2012). This risk of reoccurrence also increases with repeated treatments (Barnsley, Sigurdson, & Barnsley, 2006). Furthermore, surgical treatments are at the

risk of additional complications such as: hematoma, infection, implant damage and malposition (Reid, Greve, & Casas, 2005). It is evident that CC preventative measures would be most advantageous (Mofid, 2011). Figure 3.4 shows the outcome of a capsulectomy following a severe contracture.

Table 3.1: The infectious theory and potential CC etiological agents

Etiological Agent	Capsular Contracture influence – based on the Infectious Theory
Clinical Infection	*Staphylococcus aureus* is the primary bacterium cultured from clinical infection samples (Courtiss et al., 1979). This bacterium is also found on the skin (Bartsich et al., 2011) thus, clinical infections proceed sub-clinically, developing into contractures – even after treatment (Wixtrom et al., 2012).
Hematoma	This rich source of iron is nutritional to the growth of biofilms and bacterium such as *S. aureus* (Wixtrom et al., 2012) resulting in CC and clinical infections, respectively. The drains required for hematoma removal also introduce additional bacteria into the breast-cavity (Hipps et al., 1978).
Gel-bleed	The higher CC rates with older generation implants are likely due to the more inadequate pocket irrigation solutions used in previous years. This is in conjunction with the capsule compression resistance offered by newer generation gel-fillers. Nonetheless, irrigation solutions still do not provide the required broad-spectrum coverage (Adams, 2009).
Type of Surgery	The higher CC rates with reconstructive procedures are due to the greater degree of breast-tissue manipulation and violation (Bartsich et al., 2011).
Implant Type	The higher CC rates with silicone-filled implants are due to the greater degree of skin/implant contact with the insertion of these prefilled implants (Embrey et al., 1999). This also explains the higher CC rates reported with larger implants (Bartsich et al., 2011).
	Histologically, the lower CC rates with textured implants has been observed to be due to sample similarities with non-contracted capsules (Ersek, 1991). This observation also verifies the delay in CC development with textured implants since, orientation is related to the degree of contamination (Shah et al., 1981). Furthermore, smooth implant surfaces are more conducive to bacterial adherence (Embrey et al., 1999).
Implant Placement	The lower CC rates with subpectoral/submuscular placements are due to: the muscular barrier between the implant and bacteria laden ducts (Shah et al., 1981) and, better vascularity – an antibacterial benefit (Mcgrath & Burkhardt, 1984). This placement is also at the reduced risk of blood vessel dissection – conducive to hematoma prevention (Camirand et al., 1999).
Incision Site	The lowest CC rates with inframammary incisions are due to dissection and implant insertion travelling deep to the bacteria laden breast-tissue (Shah et al., 1981). This site also avoids the sweat glands (Jacobson et al., 2012).

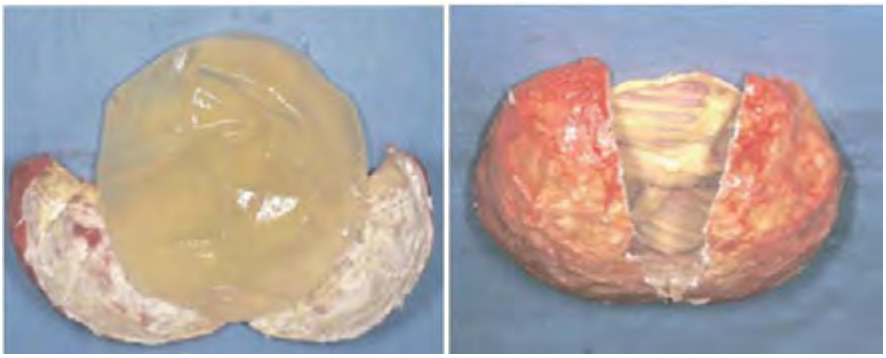

Figure 3.4: Grade IV capsule removal following an open capsulectomy (Pittet et al., 2005)

3.1.5. Recommendations in the Prevention of Capsular Contracture

Based on the infectious theory, CC development is evidently affected by the surgical technique more than implant related characteristics (Mofid, 2011). This has further been supported by the abandonment of preventative techniques that have aimed to alter the construction of the capsule around the implant – i.e. postoperative massage/expansion exercises (Allergan, 2009), steroid use (Hipps et al., 1978) and vitamin E consumption (Uzunismail, Duman, Perk, Findik, & Beyhan, 2008). In the prevention of bacterial contamination a number of recommendations to the traditional surgical procedure have been practiced and are described in Table 3.2.

CC rates have reportedly reduced following the practice of these recommendations however, the risk continues to exist (Marques et al., 2010). This is due to the unavoidable bacterial contamination with the traditional surgical procedure. With reference to Table 3.2, the surgical gloves continue to transfer bacteria onto the implant from the skin and breast-tissue, even after insertion and with multiple glove changes (Moyer et al., 2012). The use of multiple retractors is also at an increased risk of bacterial contamination, due to the increased instrument/implant contact. The implant remains exposed to environmental bacteria throughout insertion and triple antibiotic irrigations still do not provide the require coverage (Adams, 2009). Consequently, CC prevention has remained a medical challenge (Mendes, Viterbo, & DeLucca, 2008).

Considering pocket dissection relies on the surgeon's technical skills (Table 3.2 – no. 4 & 10), increasing attention has been on the insertion process and the development of breast-implant insertion devices that will significantly reduce, if not eliminate, insertion related bacterial contamination (Moyer et al., 2012). While prevention of subclinical infections is of primary concern, CC remains an interplay between any factors that promote a foreign body reaction and/or local chronic inflammation (Spear, Seruya, Clemens, Teitelbaum, & Nahabedian, 2011). For a device to be surgically adopted, the proposed insertion technique must therefore address all other potential CC contributing factor, i.e. including the presence of 'loose' silicone particles

in the surrounding capsule (Hester et al., 2012). This requires a thorough analysis of the traditional finger-manipulation method, prior to an investigation on essential design features for a device to achieve the desired insertion.

Table 3.2: Recommendation to surgery – capsular contracture prevention

	Recommendation to Surgery	
1	**Limited implant handling and contact** (with the skin and breast-tissue)	To reduce environmental bacterial contamination, the implant is also only removed from the packaging and sterilized at the time of insertion (H. Becker & Springer, 1999).
2	**Inframammary incision site**	Advantageously, this is the most widely used site (section 2.3.1). In conjunction with a mastopexy, a second incision is recommended at the areolar, with insertion through the inframammary incision – indicating the significance of CC prevention over multiple scars (Wiener, 2008).
3	**Submuscular/Subpectoral placement**	However, this is largely patient dependant (section 2.3.1).
4	**Bloodless pocket preparation**	So as to prevent hematomas by achieving meticulous homeostasis (Wixtrom et al., 2012). A minimized dissection into the breast is also beneficial (Pajkos et al., 2003).
5	**Pocket irrigation with triple antibiotic solution**	This irrigation solution has observably achieved the greatest reduction in CC rates (Adams, 2009).
6	**Use of nipple shields**	This includes any method in the blockage of nipple leakage contamination during surgery (Wixtrom et al., 2012).
7	**Sterile surgical environment**	Skin sterilization (Adams, 2009).
8	**Glove change**	Due to extensive skin and breast-tissue contact on the surgeon's gloves throughout pocket dissection, glove change is recommended with each insertion (Adams, 2009).
9	**Proper retraction during insertion**	So as to reduce skin/implant contact by keeping the wound open throughout insertion (H. Becker & Springer, 1999). The use of multiple retractors with several assistants has also been recommended (Bell & McKee, 2009).
10	**Quick procedures**	This has a direct impact on the degree of bacterial contamination. Longer procedures also adversely affect healing (Adams, 2009) and increase the cost of surgery (Keller & Senn, 2013).

3.2. Analysis of the Traditional Finger-Manipulation Method

The traditional finger-manipulation insertion method is analysed in terms of: the infectious theory (i.e. bacterial contamination.), potential 'loose' silicone particle sources (i.e. shell rupture and gel-bleed) and other adverse effects of this insertion method (i.e. implant shape deformation and wound infection).

3.2.1. Bacterial Contamination

The infectious theory describes a 'no-touch' insertion technique as the optimal method in effectively reducing bacterial contamination. Where, 'no-touch' implies a direct implant insertion into the breast-cavity without the implant ever touching: instruments, drapes, gloves, or the patient's skin and breast-tissue (Moyer et al., 2012). This technique is unachievable with the traditional finger-manipulation method (Zochowski, 2014). The implant also remains open to environmental bacteria throughout insertion and, the insertion of sizers increase breast-cavity contamination prior to the placement of the permanent implant. It has been shown that proper tissue-based analysis and careful planning can reduce the need for Sizers in 99% of cases however, this is highly reliant on the surgeon's skills (Adams, 2008).

In an attempt to assist with the insertion of textured implants, the use of a BIOCELL Delivery Assistant Sleeve has demonstrated a 'no-touch' insertion (Castello et al., 2014). This sleeve protects the implant from bacterial attachments throughout insertion however, the rubbing of the skin and freeing of bacteria inherent to the traditional insertion method still significantly results in breast-cavity contamination, (refer to APPENDIX C.1).

3.2.2. Shell Rupture and Gel-Fracture

Silicone implant integrity refers to the integrity of the shell and gel-structure, damage to these components consequently result in shell rupture and gel-fracture, respectively (Moyer et al., 2012) as shown in Figure 3.5. Compromise to the implant integrity is at the risk of a permanent implant shape deformation, adversely affecting the appearance of the breast and/or contributing to the presence of 'loose' silicone particles in the capsule. Advantageously, the presence of 'loose' silicone particles is insignificant with 5th generation implants, even in the case of a rupture, i.e. the cohesive gel-filler does not run out (Spear, Howard, et al., 2004).

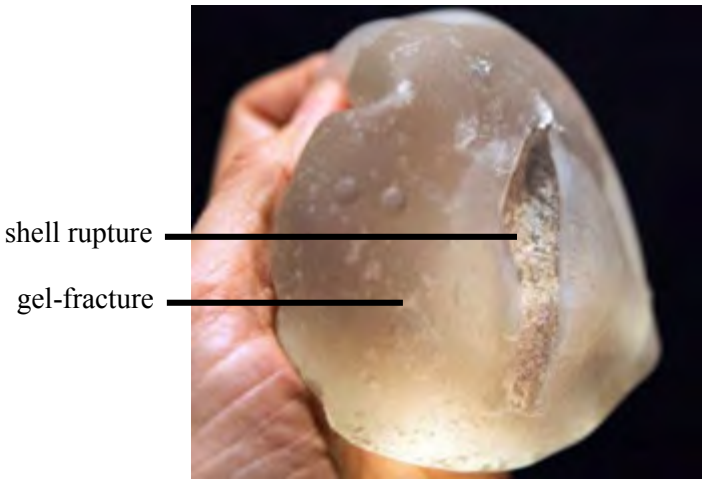

Figure 3.5: A ruptured silicone breast-implant with gel-fracture (The Health Coach, 2012)

Shell rupture has been observed to occur following the development of a tear from an area of minor damage and, gel-fracture is as a result of the increased insertion difficulty with more cohesive gel-filled implants (Allergan, 2007). With regards to the traditional insertion method, the implant integrity is adversely affected by:

- Uneven force distributions on the surface of the implant throughout insertion (Preissman, 2012), i.e. the excessive manipulation with extreme variability in finger pressure (Abell et al., 2007).
- The forcing of an implant through too small of an incision length (American Society of Plastic Surgeons, 2005).
- Sharp instrument and implant contact – specific to shell rupture (Preissman, 2012).

In the maintenance of implant integrity, manufactures strongly recommend an even distribution of forces over the implant surface throughout insertion. This is since highly localised stress on the implant has the potential to strain the shell past the point of elasticity, weakening the shell and making it more prone to gel-bleed and rupture. The increased difficulty with insertion of 5th generation implants also result in finger fatigue within a shorter period (Keller Medical Inc., 2011). Implant shell wear over time (following a traditional insertion), is unavoidable and implant manufacturers recommend a replacement every ten years (Independent Review Group, 1998). This has been supported by the reported average implant age of 11 years at the time of rupture. It is therefore evident that the traditional insertion method is not beneficial to long-term silicone implant integrity (Allergan, 2009).

3.2.3. Wound Damage/Infection

Inherent to the traditional finger-manipulation method is also the excessive frictional abrasion of the wound margin by the passing implant (more so with textured implants). This traumatizes the skin and occasionally causes the wound to tear, effectively increasing the scar length and risk of wound infection (Abell et al., 2007). Longer incision lengths are beneficial in preventing wound margin damage however, preference is with short incision lengths which promote faster healing and prevent unsightly scarring (Anderson & Hunt, 2014). In addition, the high coefficient of friction between the implant and stainless steel retractor is also a source of insertion resistance (Abell et al., 2007).

3.2.4. Overall Required Improvements

It is evident that the quality of the surgical technique delivered by the surgeon is directly related to the overall success of the procedure; in that, the process determines: the patient's experience, reoperation rates and recovery (Adams, 2009). Furthermore, the popularity of breast

implantation procedures relies on: improved procedure safety, availability to more individuals, and advancements in technology (Rohrich, 2000). In addition to a 'no-touch' insertion technique (without breast-cavity contamination), an atraumatic implant delivery requires attention (Ledergerber, 1998). Quicker procedures (Keller & Senn, 2013) and minimal incision lengths are also desirable (Bracaglia, Gentileschi, & Tambasco, 2012).

3.3. Analysis of Existing Breast-Implant Insertion Devices

The requirements for a breast-implant insertion device, as an improvement to the traditional finger-manipulation method, includes (from section 3.2):

1. A 'no-touch' insertion technique (without the freeing of skin bacteria), requiring an elimination of:
    - 1.1 Direct glove/implant contact
    - 1.2 Skin/implant contact
    - 1.3 Breast-tissue/implant contact
    - 1.4 Instrument/implant contact
2. An even distribution of insertion forces on the implant – to maintain implant integrity.
3. Wound margin protection – to prevent wound damage/infection and implant resistance.
4. A closed device – for protection from environmental bacteria.

Other beneficial requirements for an insertion device also include (from section 3.1.5 & 3.2):

5. Usability at the inframammary incision site.
6. An elimination of direct glove/implant contact after insertion – which is required to feel for correct implant placement.
7. Shorter insertion times – compared to 5-15 minutes (section 2.3.2).
8. Shorter incision lengths.

Amongst the attempts made in the design of insertion devices, none have successfully achieved all the above requirements or, in most cases, evidence of a successful insertion. Regardless, existing designs provide essential background for future developments. Based on the method of insertion employed, these designs feature either an implant push- or pull-device. Where, a push-device briefly compresses (flattens) the implant and a pull-device briefly elongates the implant during insertion (Abell et al., 2007). While it is an objective (section 1.2) to design an implant push-device, implant pull-devices are also analysed for the purpose of determining design features that are essential to a successful insertion. Two pull-devices have been identified: propulsion (Abell et al., 2007) and suction from within the breast (Kairinos, 2011). And, three push-devices have been identified: plunger (Shiao, 1993), air/fluid pressure (Ledergerber, 1998)

and hand manipulation (Keller & Senn, 2013). *The following analysis on existing insertion devices is with regards to the requirements listed above.*

3.3.1. Implant Pull-Devices

Abell et al. (2007) proposed a propulsion system for the insertion of silicone implants, (refer to APPENDIX C.2.1, Figure C.2). This device features the use of a: flexible carrier-bag and, a rigid funnel with an attached winding cylinder and crank. Compared to the traditional finger method, this method of insertion is at an increased insertion difficulty – i.e. if insertion is even possible. As the implant is propelled into the breast, the carrier-bag consequently rubs against the wound margin. This action could also result in an early device detachment from the incision site. Nonetheless, the rigid funnel component is emphasised as the most appropriate shape in reducing the cross-sectional area of a prefilled silicone implant, for insertion through the relatively small incision length. This is at a larger inlet diameter compared to the outlet diameter, which is dimensioned to fit at a specified incision length.

The suction system proposed by Kairinos (2011) featured a more conducive device shape for use at the inframammary incision site (section 3.3, no. 5), i.e. an eccentric funnel as demonstrated in Figure 3.6 & 3.7. While *in vitro* prototype testing was successful, immediate tissue collapse was observed following *in vivo* testing[2]. Nonetheless, the 'built-in' retractor of this device eliminates the need for external retractors (section 3.3, no. 1.4) and assists in device placement and attachment at the incision site thereby, also providing the required wound margin protection (section 3.3, no. 3). However, for the suction application, this featured 'built-in' retractor travels deep into the breast which may become problematic upon post-insertion device removal.

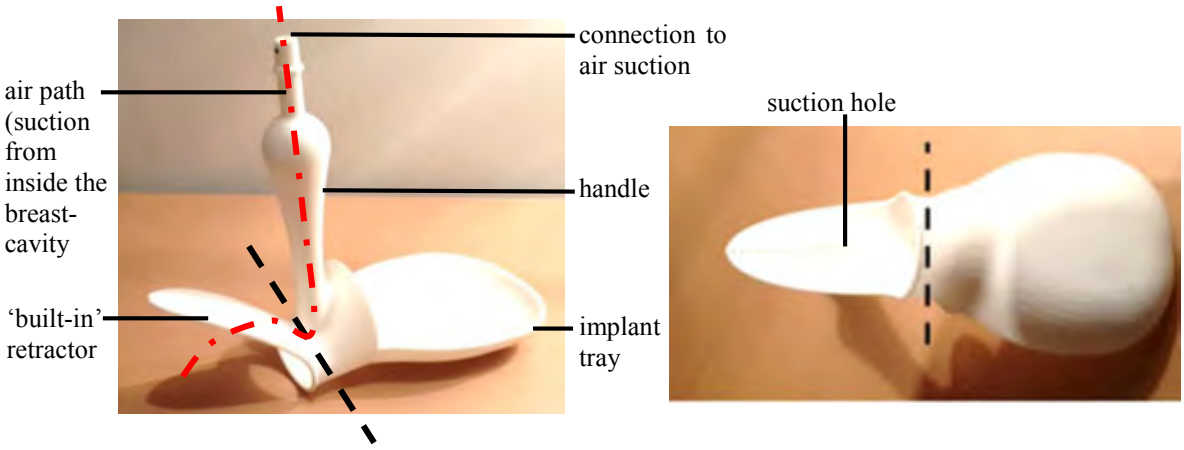

Figure 3.6: Implant Suction Device by Kairinos (2011) **– everything to the left of the *black dashed line* enters the breast cavity and the *red dashed line* represents the air path.**

[2] Information directly from A. Prof George Vicatos and Dr Nicholas Kairinos

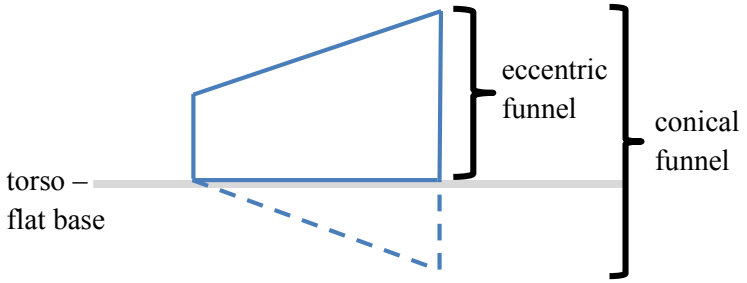

Figure 3.7: Schematic of an eccentric funnel compared to a conical funnel

Upon insertion, the tube through the built-in retractor with holes on the underside (Figure 3.6) also provides a natural air-removal passage, (for the air naturally occupying the breast-cavity after dissection). With the use of drains (without suction), Savaci & Tosun (2004) found that breast-cavity air-removal throughout insertion reduced implant insertion resistance consequently, reducing insertion times (section 3.3, no. 7) and incision lengths (section 3.3, no. 8). While rare in surgery (National Health Service, 2013), inadequate air-removal throughout insertion is also at the risk of developing an air embolism in response to an increasing breast-cavity pressure, a risk which increases with longer surgical procedures (Hsu, Basu, Venturi, & Davison, 2006). Traditionally, this air-removal would be achieved through gaps created by the external retractor between the implant and wound margin. An additional insertion device requirement is therefore:

> Breast-cavity air-removal throughout insertion – so as to reduce insertion resistance and prevent an air embolism occurrence.

3.3.2. Implant Push-Devices

The plunger system proposed by Shiao (1993) in a single use device, features a constant diameter injection barrel with a steep funnel towards the outlet of the device, (refer to APPENDIX C.3.1, Figure C.4). The implant is manually pushed through the device via the plunger (section 3.3, no. 2). This concept demonstrates a ‘no-touch’ insertion technique (section 3.3, no. 1) with the implant closed to the environment (section 3.3, no. 4). However, a prefilled silicone implant insertion through the steep funnel at the device outlet may be difficult, simultaneously causing damage to the implant. It would be easier (requiring less manual force) to push the implant through a gradual decrease in cross-sectional area. Furthermore, following insertion, the expanded flaps in the breast are potentially at the risk of injuring the wound margin upon withdrawal of the device. In addition to the ergonomics of using the device, in the patent application by Shiao (1993) it was recommended that disposability of this device could reduce the risk of bacterial contamination.

In an attempt to reduce insertion difficulty by providing an atraumatic implant delivery, Ledergerber (1998) proposed an insertion device that employs air/fluid to push the implant into the breast-cavity (section 3.3, no. 2) – refer to APPENDIX C.3.2, Figure C.5. It is evident that seals would be essential to prevent the air/liquid from escaping the device and entering the breast. This is achieved by the use of an expandable structure that fills with the air/liquid consequently, pushing the implant. This structure would be required to be appropriately durable and highly elastic however, the device walls are required to be inelastic. While it was not an aim to provide a 'no-touch' insertion, the implant is closed to the environment (section 3.3, no. 4) and, the wound margin is protected (section 3.3, no. 3) by a rigid collar at the incision site.

The only device that has been successfully launched to market is the Keller-Funnel which employs hand-manipulation (opposed to finger-manipulation) to force the implant into the breast (Moyer et al., 2012). This is a compact disposable cone-shaped NYLON bag with a hydrophilic inner coating, (refer to APPENDIX C.3.3, Figure C.6). Due to the slippery inner coating and improved distribution of insertion forces (section 3.3, no. 2), use of the Keller-Funnel has reportedly reduced: incision lengths (section 3.3, no. 8), insertion times to 3-20 seconds per an insertion (section 3.3, no. 7) and, trauma to the wound/implant (Keller & Senn, 2013). Preissman (2012) reported insertions of 500 cm^3, 400 cm^3, 550 cm^3 and 400 cm^3 implants through periareolar incisions of 30 mm, 40 mm, 50 mm and 55 mm, respectively. However, no indication was provided regarding the type of gel contained within these implants (i.e. a soft/hard gel-filler), nor was there any indication regarding the surface finish and/or shape of these implants. These are relevant since, increased difficulties have been experienced with the insertions of textured and anatomical implants (Castello et al., 2014). Furthermore, Moyer et al. (2012) reported a 'minimal-touch' technique with the insertion of implants (ranging from 300-600 cm^3) through a 50 mm inframammary incision on a cadaver. This lack in a 'no-touch' technique has observably been due to:

- An exposed portion of the implant at the device outlet (prior to insertion) – potential skin/implant contact (Moyer et al., 2012).
- The required use of external retractors to hold the breast-cavity and incision open (Preissman, 2012).
- Device handling difficulty (especially at the incision site). This is due to the slippery interior and lack of device attachment at the wound margin, i.e. slip of the device may result in skin/implant contact (Anderson & Hunt, 2014).

In an attempt to address the required use of external retractors and the lack of device attachment at the wound with the Keller-Funnel, Anderson & Hunt, (2014) designed a rigid collar with attachable retractors for use with the funnel. The retractors are physically held at the incision

site, followed by attachment of the collar and funnel, (refer to APPENDIX C.3.3, Figure C.7). Conversely, this collar with separate attachable retractors increases: the number of steps and complexity to the insertion process, the required assistance and the device thickness at the incision site. Nonetheless, a short retractor length is described as adequate for holding the incision and breast-cavity open; hence, allowing for an easier device removal after insertion (section 3.3, no.1.4). The rigidity of the collar also requires this component to be available in a range of sizes, dimensioned so as to fit at a specified incision length and to accommodate a range of implant-volumes. In contrast, the Keller-Funnel on its own is a one size fits all device, since the user cuts along indicia at the outlet to match a specific incision length and implant-volume (Keller & Senn, 2013).

Zochowski (2014) also described a range of features in the design of an insertion device that eliminates skin/ instrument/ and glove/implant contact. To achieve this, the primary focus was in the placement and attachment of the device at the incision site, (refer to APPENDIX C.3.4, Figure C.8). Of interest is the use of an inverting-bag to eliminate post-insertion direct glove/implant contact (section 3.3, no. 6). This bag, with the implant contained within, inverts about a plane of attachment as the implant and bag are inserted into the breast. For this application, the inverting-bag is required to be open at only one end. However, no indication is provided as to how this bag is attached to the device.

It is evident that none of the existing insertion devices eliminate implant and breast-tissue contact throughout insertion. While the use of a 'built-in' retractor can open the breast-cavity and lift a portion of the breast-tissue, an inframammary incision site (section 3.3, no. 5) with a subpectoral/submuscular placement would be the most effective at reducing this contact (section 3.3, no.1.3) – Table 3.2.

3.4. Prototype Development

The development of a 'no-touch' insertion device relies on features that eliminate the undesired implant contact, as well as other design aspects essential to a successful insertion as discussed in section 3.3. For the purpose of prototype development, a summary concerning breast-implant insertion and essential prototype aspects for an insertion device is herein provided.

3.4.1. Summary

1. Theoretically, the prevention of CC is in an elimination of breast-cavity and implant bacterial contamination, i.e. predominantly from skin and environmental bacteria. This also includes (to a lesser degree) factors that influence the thickening of the capsule surrounding the implant, i.e. 'loose' silicone presence outside of the implant.

2. With regards to surgical variables, the inframammary incision avoids bacteria laden tissue and has had the greatest impact on CC reduction. While pocket placement is largely patient dependant, the submuscular plane is also best suited to reducing breast-tissue/implant contact.
3. Increasing attention has been on the insertion process since; pocket dissection relies on the technical skills of the surgeon.
4. Analysis of the traditional finger-manipulation method of insertion has revealed that bacterial contamination is unavoidable with this method. This insertion method is also at the risk of compromising implant integrity and, promoting wound infection due to the rubbing of the passing implant against the wound margin.
5. Analysis of existing breast-implant insertion devices has revealed that a positive-displacement method (implant-push device) is more conducive to a successful insertion. This is at the aid of either a hand-manipulation technique or fluid/air insertion pressure. These insertion methods also deliver the implant with a more even distribution of insertion forces on its surface.
6. Essential insertion device features have include:
    - A gradually decreasing eccentric funnel shape, (to adequately reduce the cross-sectional area of the implant for insertion through the relatively small incision length and for device placement at the inframammary fold).
    - A built-in retractor with a breast-cavity air-removal tube, (to open and hold the incision, to eliminate the use of additional external retractors and to remove the presence of air in the breast-cavity).
    - A closed device, (for implant protection against skin and environmental bacteria).
    - An inverting-bag, (to eliminate post-insertion direct glove/implant contact).
    - Placement and attachment of a rigid component through the incision site, (for wound margin protection).

3.4.2. Essential Aspects of the Prototype

It is evident from section 3.3, that a positive-displacement method is more conducive to a successful insertion. This is particularly following comparisons between the Keller-Funnel and the suction device by Kairinos (2011) which has been proven unable to achieve an insertion into the breast-cavity. The outlet of this suction device does however demonstrate an effective means of eliminating the need for an additional external retractor to open the incision. At the same time, although the proposed suction technique was not successful, the same holes that were meant to provide suction could also allow for a natural escape of trapped air in the breast upon insertion. Also, from the design concepts by Ledergerber (1998) and Zochowski (2014),

other elements which will be developed in the prototype of this study include: aspects of an orifice at the incision site, fluid/air pressure as the positive-displacement method and an inverting-bag. The design aspects of this prototype will be discussed extensively in section 4.

4. FINAL DESIGN OF THE PROTOTYPE

4.1. Design Statement

As it was mentioned in the problem statement (section 1.1), the inability in achieving a 'no-touch' insertion with the traditional finger-manipulation method has sparked various methods in designing breast-implant insertion devices. This is particularly for the insertion of silicone implants in breast implantation procedures. The limitations of existing insertion device concepts have yielded the need for the development of a single device that eliminates direct implant contact with: gloves and the patient's skin and breast-tissue throughout insertion, as well as the need for additional external retractors. This device is also required to meet other requirements including: implant integrity maintenance; wound margin protection; safer and faster procedures; and a simple and easy to use design.

4.2. Design Considerations

The design considerations were established according to the analysis of the traditional finger-manipulation method (section 3.2) and existing insertion device concepts (section 3.3). These considerations were subdivided into constraints, criteria (for surgical appeal) and requirements for a potentially successful 'no-touch' insertion.

The requirements for a 'no-touch' insertion device and (potentially) applicable device features found in literature are tabulated and 'cross-linked' in Table 4.1. These requirements describe a 'closed' implant push-device with a built-in retractor for: (a) device placement at the wound, (b) holding the incision and breast-cavity open and (c) providing a means for breast-cavity air-removal upon insertion (via the built-in retractor). An inverting-bag is described as potentially effective in preventing post-insertion direct glove/implant contact. And, an eccentric funnel shape is described as suitable for the device usability at the inframammary incision site, this being the surgical variable evaluated as most effective in reducing bacterial contamination (section 3.1.5).

In the design of the proposed device, the design constraints included:

- The insertion of prefilled silicone implants.
- Insertion through an incision length of 45 mm stretchable (centrally) a maximum perpendicular distance of 35 mm, (as shown in Figure 4.1).

Table 4.1: Design features based on device requirements

Device Requirements		Design Features
Insertion force direction	An implant push-device	A positive displacement mechanism via: ➢ Hand manipulation ➢ Plunger system ➢ Air/fluid pressure (requires seals)
'No-Touch' insertion technique (reduction/ elimination of):	Glove/implant contact	An implant-holder that keeps the implant closed to the environment and skin throughout insertion. *This includes protection against drawing freed 'skin' bacteria into the breast-cavity.*
	Skin/implant contact	
	Instrument/implant contact	A 'built-in' retractor able to: ➢ Open the incision without assistance from additional external retractors. ➢ Hold the breast-cavity open without assistance from external retractors. *Breast/implant contact would be further reduced with a subpectoral/submuscular placement.*
	Breast-tissue/implant contact	
Elimination of bacterial contamination after insertion	Direct glove/implant contact after insertion	An inverting-bag, i.e. a bag open on only one end.
Implant Integrity (reduced trauma to the implant)	Even distribution of insertion forces on the implant	Implant push-device. Using: ➢ Air/fluid pressure ➢ Hand manipulation A low coefficient of friction between implant and device walls.
Reduced implant insertion resistance	Wound margin protection (due to friction at the wound)	➢ A rigid device well fitted within the wound margin. ➢ Well lubricated on the inside of the device (i.e. low coefficient of friction)
	Breast-cavity air-removal	Achieved via: ➢ Drainage tubes ➢ Holes on the underside of a 'built-in' retractor
	Frictional force between the implant and instruments	A 'built-in' retractor that is well lubricated.
Surgical variable – incision site	Device usability at the inframammary fold	Device able to rest on the torso and fit at this incision site – i.e. an eccentric funnel shape with a gradual eccentric-funnel angle.

For the device to be surgically adopted the device criteria included:

- A simple design that is easy to use (user-friendly), i.e. few operational steps; no more than one assistant; ergonomically favourable.

- A safer and faster insertion method (shorter insertion times).
- Reliability, i.e. in reproducing the desired insertion.

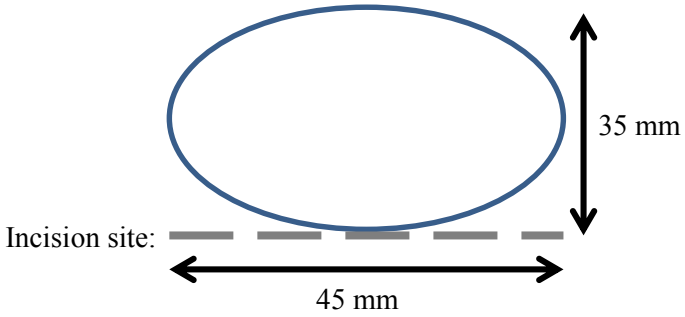

Figure 4.1: Schematic diagram of (stretched) incision dimensions

4.3. Design Concept

The device concept was developed according to the requirements and associated features described in Table 4.1. Various design concepts have been considered which ultimately led to the final concept described in this section.

For the required positive implant-displacement method (objective no. 6, section 1.2), air pressure was chosen over hand-manipulation and a plunger system. This was since hand-manipulation would essentially result in the design of additional components to the Keller-Funnel (i.e. with a flexible implant-holder component) rather than the design of an entirely unrelated device, (refer APPENDIX D.1). It was also likely that the user may resort to the finger-manipulation method towards the end of the insertion process – so as to push the end portion of the implant through the device. And, the plunger system was evaluated as impractical since, the flat surface of the plunger (required to prevent point loads on the implant) was not conducive to the required funnelling of the device (section 3.3.2). Prior to insertion, the plunger also increases the length of the device which results in a bulkier device. Furthermore, it was predicted that a significant manual force may be required to push the implant with a plunger, (refer to APPENDIX D.2).

Considering the essential device aspects identified in section 3.4, to achieve the desired insertion with an inverting-bag component and air as the insertion force, the proposed concept was made up of three designed components (herein referred to as: nozzle, mid-funnel and implant-holder), as shown in Figure 4.2. The steps for the operation of this device concept were as follows:

1. The implant is placed into the inverting-bag.
2. The inverting-bag with the implant is placed into the implant-holder.

3. The implant-holder is attached to the mid-funnel-component with the open end of the inverting-bag threaded through and wrapped around the outside of the mid-funnel-component.
4. The mid-funnel-component (with attached implant-holder) is attached into the nozzle-component aided by the guide-knob and lock, consequently holding the inverting-bag against the Plane of Inversion.
5. Once the components are securely attached to each other, the device is inserted through the incision site aided by the built-in retractor (with leverage at the device handle) until the device outlet securely lines the margin of the wound.
6. The air supply is attached to the implant-holder and the push-button on the handle is used to control the air supply required to push the implant through the device.
7. Following insertion, the mid-funnel-component is detached from the nozzle-component so as to release the inverted bag.
8. The nozzle-component is removed (without pulling the inverted bag out).
9. If the surgeon is required to feel for correct implant placement and orientation, the fingers are inserted through the inverted bag and into the breast-cavity – eliminating direct glove/implant contact.
10. The inverted bag is gently pulled out of the breast and the incision is closed.

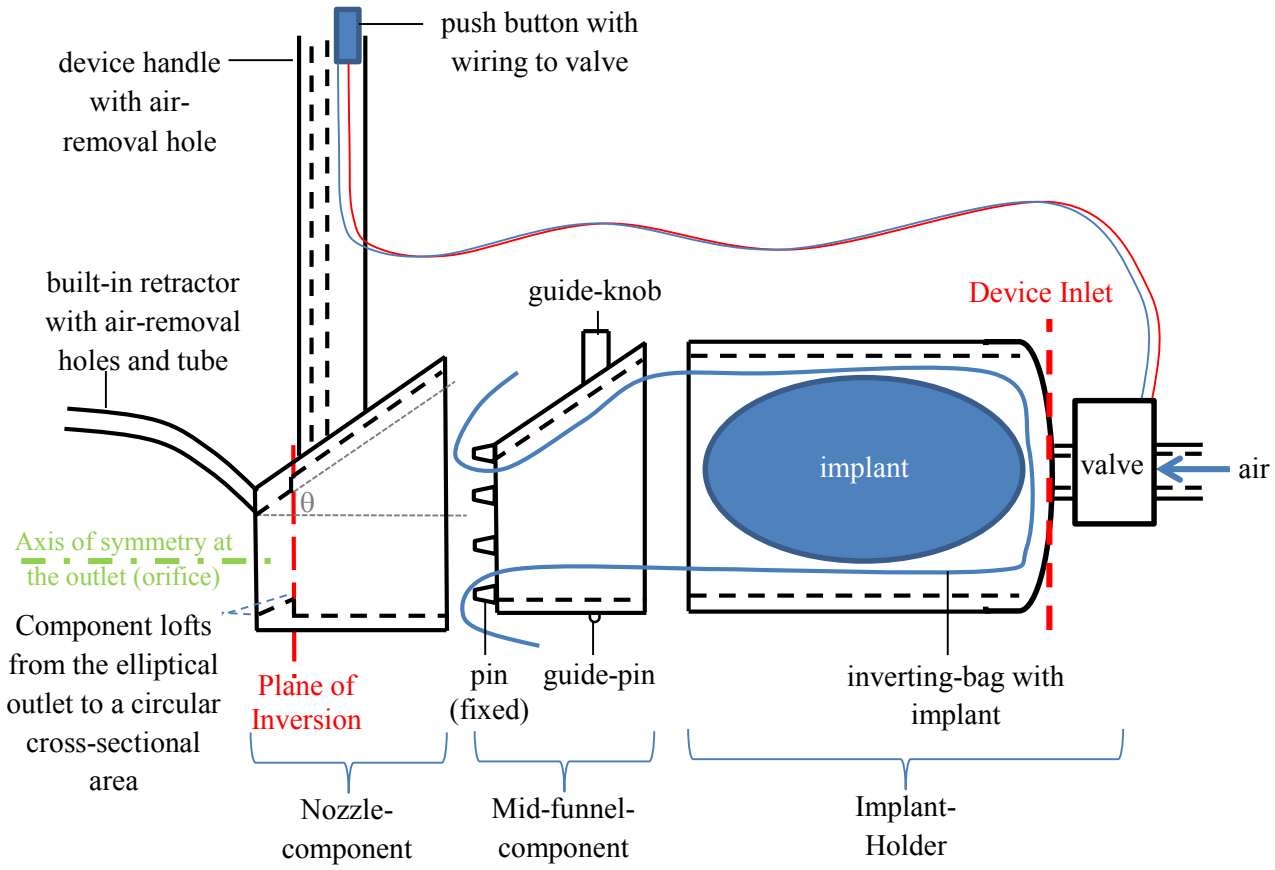

Figure 4.2: Schematic diagram of the insertion device design concept

Compared to the Keller-Funnel (section 3.3.2) the proposed concept is more complex in terms of its operation however, theoretically this design could be at a significant advantage with regards to the 'quality' of the insertion, i.e. a further bacterial contamination reduction (if not elimination) and wound margin protection.

A closed device was essential for the application of air pressure – this was in addition to the benefits of a closed device with regards to bacterial contamination (section 3.3.2). This air supply would be blocked from entering the breast-cavity by the inverting-bag wrapped around the exterior of the mid-funnel-component (section 4.3, step no. 3), thereby, creating an air seal. The required breast-cavity air-removal (upon insertion) would however be achieved via the built-in retractor and out through the device handle as described in section 3.3.1. Due to the insertion of this retractor into the breast-cavity, it was also essential for the edges of the retractor to be rounded so as to prevent potential tissue trauma due to sharp corners. A short built-in retractor was determined as applicable to this design since; a longer retractor was more conducive to a suction system and increased device removal difficulties following insertion (section 3.3.2). The device handle of this concept therefore had three functions: to maintain stability and device control (with leverage), to provide a breast-cavity air-removal passage and to provide the point of air supply control (push button).

With reference to Figure 4.2, the requirement of the outlet of the **nozzle-component** was to match the elliptical shape of the wound (as shown in Figure 4.1). However, a circular profile throughout the device was evaluated as more conducive to simpler machining needs and component attachment methods, i.e. for threads, clips or bi-unit fittings. Consequently, the (required) elliptical outlet of the nozzle-component was designed to 'loft' towards a circular section at the Plane of Inversion and continued with circular sections throughout the remainder of the device. The insertion device also needed to rest on the patient's chest for use at the inframammary incision. To address this requirement the circular sections were eccentric instead of following a right conical geometric configuration for the funnel (as demonstrated in Figure 3.7). To hold the inverting-bag, the **mid-funnel-component** was designed to fit into the nozzle-component thus, requiring both these components to be eccentric funnel shaped. Compared to living-hinge type pins (described in APPENDIX D.1), the fixed pins (on the mid-funnel-component) were evaluated as a simple design conducive to device preparation (holding the bag and preventing it from slipping) and post-insertion inverting-bag release (see section 4.3, step no. 7).

The **guide-knob and pin** on the exterior surface of the mid-funnel-component were designed to guide and lock this component into the nozzle-component, since rotation was not possible between these two eccentric funnel shaped components. This was with corresponding **'guide'**

paths on the nozzle-component. Following insertion, the guide-knob was required to be conducive to the detachment of the mid-funnel and nozzle components. Thus, a two-way guide was designed, which was more applicable than a bi-unit fitting (APPENDIX D.1) or one-way guide (APPENDIX D.3). The combination of the two-way guide and fixed pins on the mid-funnel-component were therefore essential for an easy inverting-bag release (see section 4.3, step no. 7).

The **implant-holder** was cylindrical having one end closed with a dome-shape cap, which features an attachment for the air supply. The internal diameter at the implant-holder delivery end was designed to match that of the mid-funnel-component inlet, since a smooth transition of the implant through the device was required. Due to this, rigidity was required at the ends of the implant-holder. Consequently, an implant-holder constructed from a fabric material (similar to the Keller-Funnel) was not conducive to this application, since a more complicated design would be required which also defeats the purpose of a compactable device with the use of fabric (APPENDIX D.4).

The required device dimensions were determined prior to material evaluations for prototype development. Where, material evaluations were so as to verify device thicknesses according to the insertion air pressure and the selected material. The internal device dimensions were according to the required insertable implant-volume-range suitable for the 45 mm incision. And, a prototype development analysis was carried to determine final dimensions and function-related features.

4.4. Dimension Specifications

Component dimensions were determined according to the required thickness and internal parameters of the prototype since, these parameters provided the device boundaries for insertions through the specified 45 mm incision (section 4.2). While the device was required to fit through the incision, the thickness of the device affected the outlet dimensions. To ensure an adequate implant volume-range was still insertable through the specified incision length, the outlet of the device was designed to resemble an incision of 40 mm – i.e. proportionally, stretchable (centrally) a maximum perpendicular distance of 30 mm (minor elliptical diameter). Device thickness was also partially specified for the nozzle and mid-funnel components according to functional requirements.

At the author's discretion, an eccentric-funnel angle, θ of 38.63° (see APPENDIX E.1) was used, i.e. a gradual funnel (section 4.2). Based on this angle and the thickness requirements, the device parameters were defined according to the required implant-holder dimensions. An implant evaluation was therefore carried out to determine a suitable implant-holder size.

4.4.1. Implant Evaluation

To determine the diameter of the implant-holder, adequate of holding the implant without damaging it, a set of experiments were performed starting with a 50 mm (inner) diameter pipe and a 280 cm^3 textured implant. As finger-manipulation was difficult and there existed a risk of tearing the implant against the sharp edges of the pipe, the implant was pulled into the pipe. Within a week following placement in the pipe, an implant failure was observed (i.e. rupture and gel-leakage). It was therefore evident that the implant-holder dimensions were required to be adequately sized according to an easy implant placement, into the device, by the user at the time of surgery.

Consequently, to determine the required implant-holder parameters for a range of silicone breast-implants[3], cylindrical 'mock'-holders were constructed at varying internal diameters and lengths, as it is shown in Figure 4.3. The dimensions of the mock-holder suitable for housing the implants provided the required internal diameter and length of the implant-holder component. The internal diameters of these mock-holders were chosen to match potential diameters of the funnel-shaped mid-funnel-component, (refer to APPENDIX E.1). The mock-holders were constructed from 600 D polyester fabric which was glued to machined plastic rings. The internal diameters of these cylinders ranged from 70.5 to 90.5 mm.

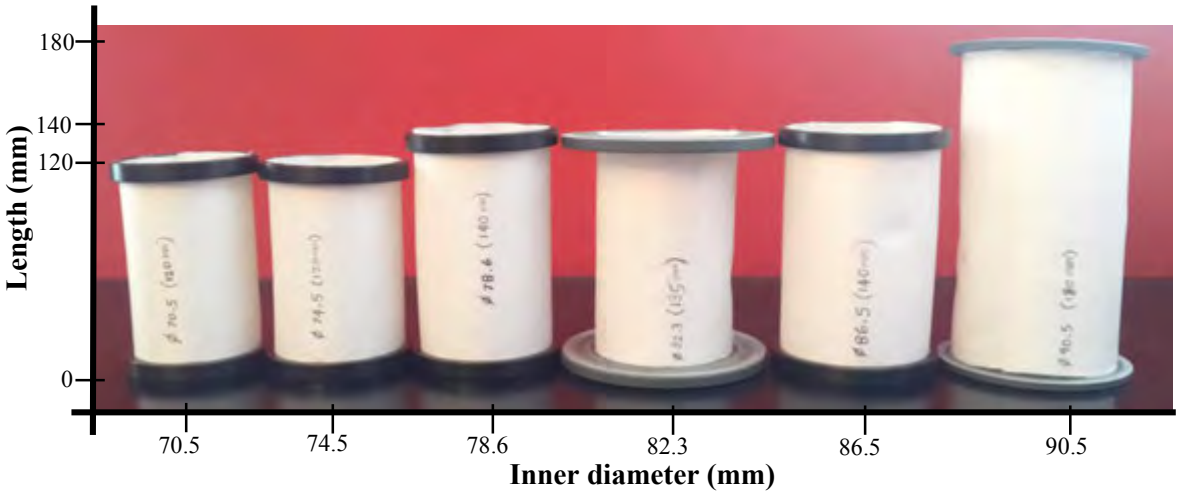

Figure 4.3: Implant 'mock' holders from a diameter of 70.5 mm to 90.5 mm

While smaller implants easily fit into larger implant-holders, Table 4.2 shows the dimensions measured for the implant-holder according the implant volumes tested, (refer to Table E.1 for the specifications of these implants and implant-holder dimensions evaluated for each implant).

[3] A total of 17 preliminary silicone-gel implants (ranging from 133.33 – 580.95 cm^3) were received from Mr Craig McLuckie at Allergan Pharmaceuticals Ltd (Pty) in Midrand, Johannesburg. Refer to APPENDIX G.2, Table G.1, for the specifications of these implants.

The appropriate implant-holder diameter was based on an easy hand manipulation of the implant into the holder and, the required length was based on allowing a small portion of the implant to stick out of the holder, at the author's discretion. Device sizes for the 45 mm incision were classified according to the implant-holder size, from small to extra-large.

Table 4.2: Results from implant 'mock' holder test

Implant volume-range (cm^3)	Appropriate implant-holder internal diameter (mm)	Required (internal) implant-holder length (mm)	(45 mm incision) Device size
133 – 243	70.5	70	Small
295 – 395	78.5	85	Medium
428 – 467	82.5	90	Large
500 – 581	90.5	100	Extra-Large

4.4.2. Prototype Internal Dimensions and Size Classification

To determine an appropriate insertable implant volume-range through the device, reported Keller-Funnel incision lengths (per implant volume-range) were used as a guide in the selection of the implant-holder size from section 4.4.1. This was since the Keller-Funnel has reportedly reduced bacterial contamination by 50% (section 3.3.2). Consequently, the Keller-Funnel was considered as the reference for implant-volumes and incision lengths.

In section 3.3.2, it was reported that a 500 cm^3 implant passed through a 30 mm periareolar incision with a Keller-Funnel insertion. However, there was no mention regarding the type of implant used. It was therefore assumed that such an implant must have been soft gel-filled or alternatively, a greater hand-manipulation force was exercised on the Keller-Funnel. This stems from the 400 cm^3 implant insertion through a 40 mm incision that was also reported (see section 3.3.2).

The Keller-Funnel is a flexible NYLON bag while the prototype is an inflexible fixed-dimension device, and due to the experiment described in section 4.4.1 with a 50 mm pipe, concerns about the integrity of the implant passing through a small outlet set the limit to a 40 mm by 30 mm elliptical shape orifice. For these arguments and in order for the device to be able to deliver all types of implants (hard and soft gels) and in order to reduce the number of parameters in the experimentation, the prototype was designed according to the 'medium' sized device (Table 4.2). This was regarded as equivalent to the reported Keller-Funnel insertion of a 400 cm^3 implant through a 40 mm incision (section 3.3.2).

From Table 4.2, a 78.5 mm internal implant-holder diameter (length = 85mm) was determined as appropriate for the prototype. The required device dimensions were therefore determined from Figure E.1 according to the 78.5mm diameter. This described an internal device length of 150 mm, i.e. from mid-funnel-component inlet to device outlet (65mm) plus implant-holder length (85mm – Table 4.2). These dimensions were assumed as conducive to the device application and surgical environment.

The curve of the built-in retractor was determined according to the dimensions of the (medium device size) implant volume-range established in section 4.4.1. This shape is that of the implant inside the breast-cavity after insertion and it is assumed safe for both the implant and breast-tissue. With reference to Table E.1, while the 395 cm^3 implant was volumetrically larger than the 380.95 cm^3, the base and projected contour dimensions of the 380.95 cm^3 implant were slightly larger. Therefore, the dimensions used to model the built-in retractor were taken from the supplied specifications of the 380.95 cm^3 implant, as shown in Figure E.2 (APPENDIX E.3). Due to the benefit of shorter built-in retractors with regards to post-insertion device removal (section 3.3.2) and suggestions from Dr N. Kairinos[4], a 20 mm (horizontal length) retractor was regarded as sufficient for this prototype.

The above dimensions and observations were used to guide the prototype design and development.

4.5. Prototype Design and Development

The aim of building the prototype device was to prove the concept described in section 4.3. Based on the dimensions described in previous sections, the mechanical properties of the selected materials were used to verifying the wall thicknesses of the prototype components under the application of a pre-selected air pressure.

4.5.1. Prototype Design Concept

In section 4.3, four basic components were discussed, which comprise the shape and functionality of the insertion device. These components (nozzle, mid-funnel, implant-holder and inverting-bag) are considered as the essential components of the device. The features and components that were not essential to proving the concept but were used for the purpose of the prototype design are described in Table F.1, APPENDIX F. These are the specifications of: attachments between designed components; air supply control and related components (valve, electrical supply etc.); and the material of the inverting-bag. While the latter was not essential to

[4] Plastic surgeon and project initiator

proving the concept, the thickness of this bag influenced the required space between the nozzle and mid-funnel components. Thus, an inverting-bag for the purpose of the prototype was according to the following inverting-bag requirements:

- Relatively thin, so as to allow the surgeon to adequately feel (through the bag) for implant wrinkles and correct placement.
- Flexible, i.e. conducive to the required inversion.
- Durable, with regards to the air pressure supply.
- Inelastic.

Due to the application of pressurized air as the positive-displacement force, components were designed having air seals between them. With reference to Figure 4.4, air seals were at: the circumferential taper around the mid-funnel and implant-holder components; a tightly held inverting-bag at the Plane of Inversion; and an NPT connection at the device inlet for the air supply attachment. To securely hold all the components together, strap handles on opposite sides of the nozzle-component were designed for an attachable strap to run from one handle, around the back of the implant-holder and to the other handle (Figure 4.4 (C)).

4.5.2. Prototype Material and Other Necessary Parts Selection

Material selections were required for the designed prototype components (nozzle, mid-funnel and implant-holder) and the inverting-bag. In addition to these essential components, a strap was used to hold the parts of the device together during experimentation. Also, in order to control the air supply standard pneumatic components were used such as, a valve and tubing. These are described in Table 4.4. Due to the aim of validating a breast-implant insertion device concept, the designed prototype components were developed from plastic materials, which were regarded suitable for the application at hand. Rapid prototyping with selective laser sintering (SLS) of fine powdered polyamide (NYLON 12, referred to as EOS PA2200)[5] was selected for the development of the geometrically complex nozzle and mid-funnel components. High density polyethylene (HDPE) was selected for the development of the geometrically simpler implant-holder-component. The engineering drawings of the individual designed prototype components and assembly of these components are shown in APPENDIX G.

Prior to development, the wall thicknesses of the designed components and the thread attachment between the mid-funnel and implant-holder-component (Table F.1) were theoretically verified according to a pre-selected insertion air pressure.

[5] At the Free State, Central University of Technology, Centre of Rapid Prototyping and Manufacturing (CRPM)

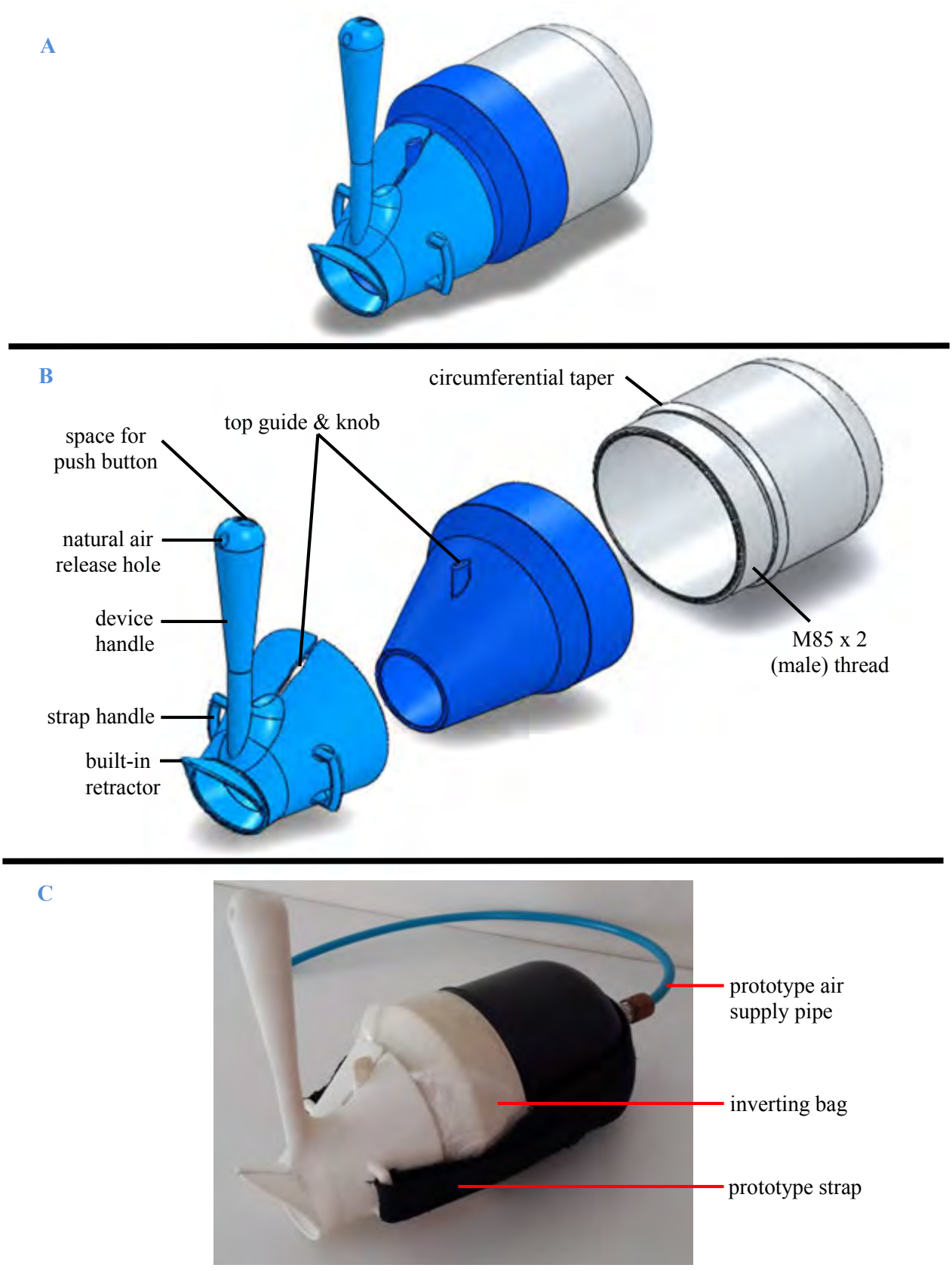

Figure 4.4: (*A*) CAD assembled device; (*B*) CAD exploded view; and (*C*) developed prototype

Table 4.4: Materials/Parts selected for prototype device components

Prototype Component	Selected Material/Part	Reason
Nozzle	Sintered Nylon12	Complex – rapid prototyping
Mid-Funnel	Sintered Nylon12	Complex – rapid prototyping
Implant-Holder	HDPE	Simple – standard machining
Inverting-Bag	Thin film polyethylene	*Bag requirements (section 4.5.1)*
Strap	Polyester 'seat belt strip' with Velcro (stitched accordingly)	To hold the prototype components together under the application of air pressure

4.5.3. Thickness and Thread Verifications – Internal Pressure Related Calculations

The air pressure, *P*, required for the insertion of the implant volume-range (section 4.4.2), could not be theoretically calculated. This was since implant properties were not available and extensive experimentation of these deformable implants would be required. It was assumed that a large insertion pressure may result in implant damage, device detachment from the wound and furthermore, it may be more difficult to maintain air seals and the speed of insertion. Therefore it was further assumed that 1 bar pressure would be suitable for the implant insertion. This pressure would provide an insertion force of approximately 484 N at the implant-holder internal diameter of 78.5 mm, (refer to APPENDIX H.1 for this calculation). Due to the application of air pressure, the wall thicknesses, *t* of the designed components (nozzle, mid-funnel and implant-holder) were verified according to pressure vessel analyses[6], as well as the coupling M85 x 2 thread between the mid-funnel and implant-holder (Table F.1, APPENDIX F). A safety factor (SF)[7] of 2 was used with pressure, *P*.

For wall thickness verifications, a thin-walled pressure vessel analysis was applicable if the ratio of the internal diameter, *d* to *t* was larger than 20, as shown in equation 4-1. However, both the sets of thin- and thick-walled pressure vessel equations (4-2 to 4-5) were suited to cylindrical vessels. To account for the funnelling of the device, various sections of concern were determined and analysed as separate cylinders. These sections included the: internal maximum (Ø 78.5 mm) and minimum (Ø 34.5 mm) diameters (Figure E.1); the elliptical device outlet; and the ellipsoidal end cap of the implant-holder.

For a thin-walled cylinder:

$$\frac{d}{t} \geq 20 \qquad (4\text{-}1)$$

[6] From: Strength of Materials for Technicians (Drotsky, 2011).
[7] From: Fundamentals of Machine Component Design (Juvinall & Marshek, 2006), pg. 255.

$$\sigma_{TS} = \frac{(p \times SF)d}{2t} \text{ (circular profile)} \quad (4\text{-}2)$$

$$\sigma_{TS} = \frac{(p \times SF)a^2}{2tb} \text{ (elliptical profile and end-cap[8])} \quad (4\text{-}3)$$

For a thick-walled cylinder:

$$\sigma_r = C - \frac{B}{r^2} \text{ and } \sigma_c = C + \frac{B}{r^2} \text{ (circular profile)} \quad (4\text{-}4)$$

$$\sigma_r = C - \frac{B}{(a \times b)} \text{ and } \sigma_c = C + \frac{B}{(a \times b)} \text{ (elliptical profile)} \quad (4\text{-}5)$$

The tensile strength, σ_{TS} of the concerned materials is shown in Table 4.5. To determine the constants C and B, these stress equations (4-4 and 4-5) were evaluated at the inner, *i* and outer, *0* radii of the components at the relevant sections of concern – with $\sigma_{ro} = 0$ and $\sigma_{ri} = p \times SF$.

Table 4.5: Tensile strength properties of sintered NYLON 12 (PA2200) and high density polyethylene (HDPE)

Material	Tensile Strength, σ_{TS} (MPa)
Sintered PA2200[9]	45 ± 3
HDPE[10]	32

In the case of a thin-walled vessel, the minimum required *t* due to the 1 bar insertion pressure was determined and compared to the designed thickness. For a thick-walled cylinder, the internal circumferential stress, σ_{ci} was determined and compared to the σ_{TS} of the selected component material. These results are shown in Table 4.6 for each sections of concern, with the detailed calculations in APPENDIX H.2. It was evident in all cases that the minimum required thicknesses were significantly lower than the designed thicknesses and, σ_{ci} were lower than σ_{TS} of the concerned components. Thus, verifying that the designed thicknesses for prototype development were sufficient to withstand the forces due to air pressure.

To verify the M85 × 2 threads, the maximum allowable internal pressure, P_{max} of this type of thread and for HDPE (Table 4.5) was determined according to equations 4-6 and 4-7.

For thread calculation at M85 × 2 (HDPE):

$$A_t = \frac{\pi}{4}[D_t - (0.938194 \times PCD)]^2 \quad (4\text{-}6)$$

[8] From: Analysis of Heads of Pressure Vessels (Lawate & Deshmukh, 2015).
[9] From: (Electro Optical Solutions, 2004) – as supplied by CPRM
[10] From: (AZO Materials, 2013)

$$\sigma_{TS} = \frac{F}{A_t} = \frac{(P \times SF)A}{A_t} \qquad (4\text{-}7)$$

It was found that the calculated P_{max} of almost 18 MPa was significantly larger than the 1 bar (1×10^5 Pa) insertion pressure, (refer to APPENDIX H.3). Thus, verifying that the threaded feature will withstand the applied forces.

Table 4.6: Pressure Vessel Analyses Results

Section of concern	Component	Designed thickness (mm)	d/t	Pressure Vessel Analysis	Results
Ø 78.5 mm	Mid-Funnel	2.9	26.9	Thin-Wall	Min. Thickness = 0.174 mm
	Implant-Holder	3.25	24.2	Thin-Wall	Min. Thickness = 0.245 mm
Ø 34.5 mm	Mid-Funnel	2.9	11.9	Thick-Wall	σ_{ci} = 141.56 Pa Which was significantly below σ_{TS} = 45 MPa
Device outlet: a = 20 mm b = 15 mm	Nozzle	2 2	20 15	Thin-Wall Thick-Wall	Min. Thickness = 0.0593 mm σ_{ci} = 133.35 Pa Which was significantly below σ_{TS} = 45 MPa
Ellipsoidal end-cap	Implant-Holder	4	20	Thin-Wall	Min. Thickness = 0.241 mm

4.5.4. Prototype Development

The built prototype was as shown in Figure 4.4 (C). Deficiencies in the prototype device were however observed and these were specific to the NYLON SLS manufactured components (i.e. nozzle and mid-funnel). This was with: (a) the blockage of the air-removal path by trapped loose NYLON powder and (b) the roughness of the surface of these components even after tumbling.

A flexible wire was pushed through the air-removal path from the tip of the retractor. According to Figure 4.5, a purposefully designed exhaust hole allowed any blockage due to trapped powder to be cleared[11]. This hole however, does not interfere with the passage of the implant and it is covered by the inverting-bag as it passes through the outlet. For the purposes of the prototype development, it was experimentally determined (see section 5.2) that an appropriate

[11] Blockage concern from: (Yang, Leong, Du, & Chua, 2002).

lubricant on the internal walls of the device components would effectively reduce the frictional resistance due to the rough surfaces[12].

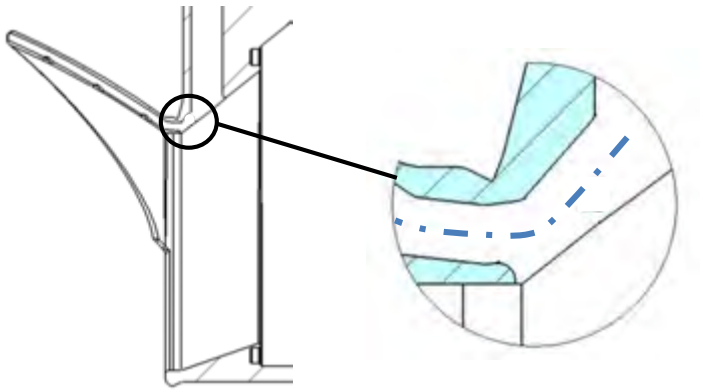

Figure 4.5: Cross-sectional view at the junction of the breast-cavity air-removal-tube from the retractor to device handle. (*Blue dashed line*) approximate centre line for the conceptual tube curve.

This prototype, with lubrication and an air supply, was therefore regarded as suitable for determining if the proposed concept (section 4.3) achieves the objectives of this study. This evaluation would however rely on an *in vitro* test that closely resembles the female breast and dissected breast-cavity environment.

[12] Two lubricants were used: K-Y Jelly and petroleum jelly. NYLON is chemically stable with both of these lubricants (Electro Optical Solutions, 2004).

5. EXPERIMENTAL INVESTIGATION

5.1. Objectives of Investigation

To prove (*in vitro*) the proposed 'no-touch' breast-implant insertion device concept (section 4.3), the investigation objectives for the medium device sized prototype (section 4.5) included:

1. A verification of the pre-selected 1 bar (gauge) insertion pressure (section 4.5.3).
2. Face validations of a safe 'no-touch' insertion into a silicone cast breast-model, with an elimination of post-insertion direct glove/implant contact, and which was verified by a plastic surgeon.

5.2. Insertion Air Pressure Verification – Plunger Test

For the verification of the 1 bar insertion pressure, a plunger test was used to determine the maximum force required to push implants passed the funnel section of the device. With this plunger test experiment, medium and small sized implants (Table 4.2) were tested for: (a) the adequate force to push the implant through the device, (b) surface lubrication and type of lubricant and (c) integrity of the implant passing through the device.

5.2.1. Test Setup and Process

A plunger with a platform for the placement of mass pieces was constructed for this test, as shown in Figure 5.1. The total weight of the mass pieces required to push any particular implant was used to determine the required force.

For this test, the device components were lubricated with K-Y Jelly (as mentioned in section 4.5.4). This was followed by preparation of the device as described in steps 1 to 4 of section 4.3. The inverting-bag was also included in this preparation of the device but, this was only for the purpose of conformity and not to observe if the desired inversion of the bag was achievable. The prepared device was supported upside-down and multiple mass pieces of 5, 10 and 19 kg were placed as needed on the mass-piece-platform (Figure 5.1). This was performed until movement of the plunger was observed and again if the plunger stopped moving before reaching the end of the stroke. The results are shown in Table 5.1.

Due to the limitations of a plunger with a funnel shaped device (described in section 4.3), the implants were not expected to completely pass through the outlet during this test. An evaluation of the modelled insertion device showed that the funnelled region had a volume[13] of 156.2 cm^3, consequently an equivalent volume was expected to remain in the device after the plunger

[13] SolidWorks verification of the volume

reached the end of the stroke. This is also evident in Figure 5.1 with only a portion of the implant observed through the device outlet. The implant was removed by pulling it out of the device, something that partially damaged the implants during this experiment (see Figure 5.2 and APPENDIX I, Figure I.1)

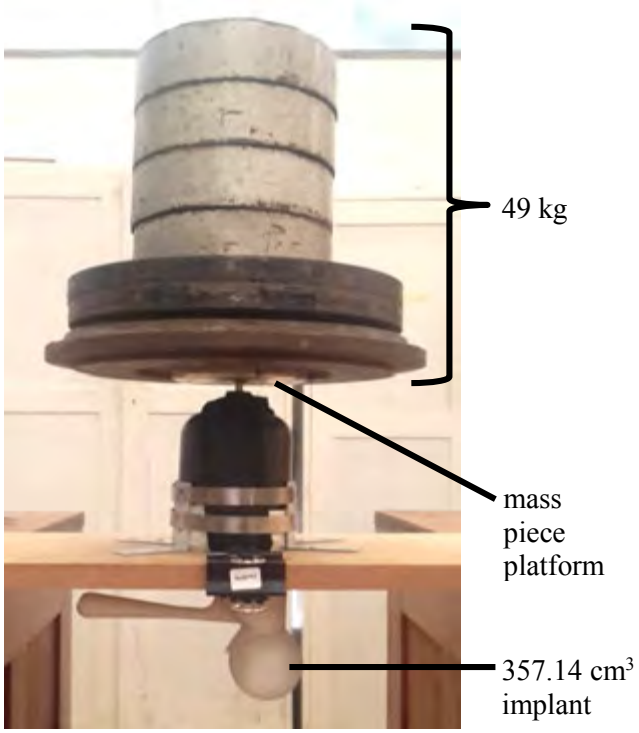

Figure 5.1: Plunger Test with the 357.14 cm^3 implant at the end of the stroke

The above mentioned process was repeated for each implant in this experiment. This included a total of seven implants (three from the small device-range and four from the medium device-range) as listed in Table 5.1. The implants that required the largest mass to be pushed through the device were used to calculate the required insertion air pressure.

5.2.2. Results and Observations

From Table 5.1, the largest required mass, m_{req}, to move the plunger to the end of stroke was 49 kg and was recorded for implants no. 10 (357.14 cm^3) and no. 11 (380.95 cm^3). Using equations 5-1 and 5-2 with this mass of 49 kg, the required insertion pressure was evaluated to be approximately 1 bar. Thus, verifying that the pre-selected 1 bar air pressure (section 4.5.3) would be sufficient for the implant insertions through the prototype device. Refer to APPENDIX I.1, Table I.1 for necessary constants and Table I.2 for the calculated insertion pressure of each implant in the plunger test.

$$F_T = (m_{req} \times g) + W_p \quad (5\text{-}1)$$

$$p = \frac{F_T}{A} \quad (5\text{-}2)$$

Table 5.1: Implants used for plunger test and results

	No.	Shell Type	Gel-Type	Volume (cm^3)	Shape	Mass Required, m_{req} (kg)	Plunge Period (i.e. until end of stroke)
small	1	Textured	Mod. Hard	133.33	Anatomical	10	10 seconds
	5	Smooth	Mod. Soft	180.95	Round	35	20 seconds
	7	Textured	Very Hard	238.10	Anatomical	45	30 seconds
medium	9	Smooth	Mod. Soft	295.24	Round	40	1.5 minute
	10	Textured	Very Soft	357.14	Round	49	30 seconds
	11	Smooth	Mod. Hard	380.95	Anatomical	49	3 minutes
	12	Smooth	Mod. Soft	395	Anatomical	29	30 seconds

From Table 5.1, it is also evident that m_{req} for implant no. 12 (395 cm^3) was less than all the implants in the medium device-range, as well as implants no. 5 (180.95 cm^3) and no. 7 (238.10 cm^3) of the small device-range. While a comparison between m_{req} of implant no. 11 and 12 are in keeping with the reported increase in insertion difficulties with harder gel-filled implants (section 3.2.2), theoretically m_{req} for implant no. 12 should not have been smaller than that of implant no. 10 (with a very soft gel-type) and no. 5 (with the same gel-type). A plausible explanation for this discrepancy was therefore in a greater (unintentional) amount of device lubrication used in the testing of implant no. 12, or that no. 12 was a sizer implant which tends to have a thinner, more deformable shell. Due to the damage caused to the implants by the pulling of the implants out of the device through the outlet (following the end of the stroke), this result could not be further verified with repeated plunger tests. The only way to remove the implant out of the device after the end of the stroke was by physically pulling it out. However, this had caused undesirable damage to the implants, specifically with implant no. 9, 11 and 12 which had shown shape deformation and gel-fracture, refer to Figure 5.2 and I.1 (APPENDIX I.1). The plunger test results and insertion pressure verification were therefore limited to one round of testing.

Other prototype-related observations were with regards to the:

1. Placement of the implant in the implant-holder.

It was observed that in coupling the mid-funnel to the implant-holder (with a screw fitting), the implant itself was rotated in the device. Consequently, correct implant orientation relative to the

outlet of the device was essential during device preparation, since this would directly affect the post-insertion orientation of the implant in the breast-cavity.

2. Use of K-Y Jelly directly on the NYLON components.

The thin water-based K-Y Jelly was not sufficient for the roughness of the NYLON components. In subsequent tests, a petroleum jelly lubricant was directly applied on the NYLON components and followed by a layer of water-based K-Y Jelly. This combination proved more effective than the petroleum jelly alone, especially with the material of the inverting-bag.

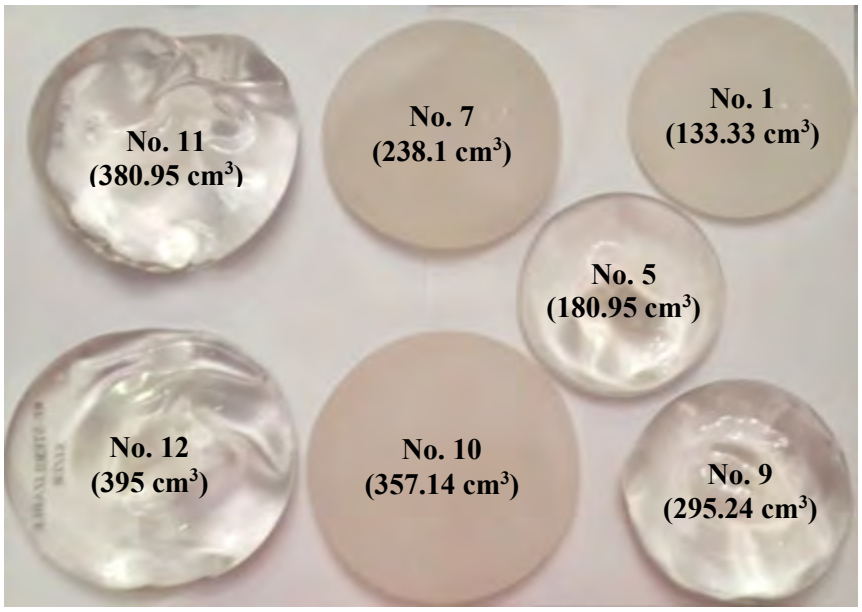

Figure 5.2: Condition of the implants in the plunger test subset after being manually pulled through the device outlet

5.3. Prototype Evaluation – In Vitro Breast-Model Test

For the face validation of the proposed insertion technique, a breast-model test was used to observe insertions with the medium device sized prototype. This was according to the visible observation (and feel) of a safe 'no-touch' insertion, an elimination of post-insertion direct glove/implant contact and the ergonomics of the device. A successful insertion was therefore achieved if the implant was inserted into the breast followed by the required inversion of the inverting-bag. And, a safe insertion was indicated by the maintenance of the implant integrity and the reaction of the breast-model to the insertion. The specifications and development of the breast-model, followed by the breast-model test setup and experimental results are herein provided.

5.3.1. Breast-Model Specifications and Development

For a reliable *in vitro* test, a portion of a female torso (breast-model) was required to closely resemble a human (female) breast with a breast-cavity. The breast-model requirements therefore included:

1. A 45 mm inframammary incision able to be stretched as shown in Figure 4.1.
2. Breast-cavity dimensions suitable for the placement of all the implants in the medium sized device-range (Table 4.2).
3. An air-tight breast-cavity.

The breast-model was constructed by the casting of a silicone material referred to as Dragon Skin®30. This followed from the evaluated suitability of this cast material for the development of face validation models[14]. Where, face validation is for the purpose of visible observation and 'feel', and not for the purpose of biomechanical tissue investigations[15]. This Dragon Skin®30 silicone could also be stretched from a 45 mm incision to the specified open (stretched) incision dimensions (requirement no. 1, *above*). Thus, the open (stretched) incision dimensions were more essential to this model than the exact matching of the material properties to that of human skin around the breast area.

To ensure all the implants in the medium sized device-range (requirement no. 2, *above*) were insertable into this model, the breast-cavity was dimensioned according to the implant with the largest base and projected contour in this range, i.e. implant no. 11 at 380.95 cm^3 (Table E.1). This was since the silicone material was not conducive to the required 'stretch' if this breast-cavity was constructed similar that of an empty real dissected breast-cavity prior to an implant insertion[16].

To ensure an air-tight breast-cavity (requirement no. 3, *above*), access to the breast-cavity was limited to the incision at the inframammary fold. Consequently, for post-insertion implant removal from the breast-model, the implant was required to be pulled back out through the inframammary incision. The developed silicone cast breast-model with the prototype device placed through the incision site is shown in Figure 5.3.

The breast-model visibly resembled a female breast and the incision could be stretched to accommodate the placement of the prototype (outlet). This breast-model was therefore regarded

[14] Used in the development of surgical training models (Cheung, Looi, Lendvay, Drake, & Farhat, 2014).
[15] Where, the mechanical properties of Dragon Skin®30 has been better suited to modelling epithelial tissue (Murray & Thomson, 2010) and muscular tissue (Sparks et al., 2015).
[16] Information provided by Prosthetic Artist, Miss Elani Allers – to whom the development of the silicone breast model was outsourced.

suitable for the face validations of the proposed concept. In order to repeat the experiment with the same size implant, the implant had to be removed by pulling it out through the incision. This caused damage to the implant (see discussion at section 5.3.3).

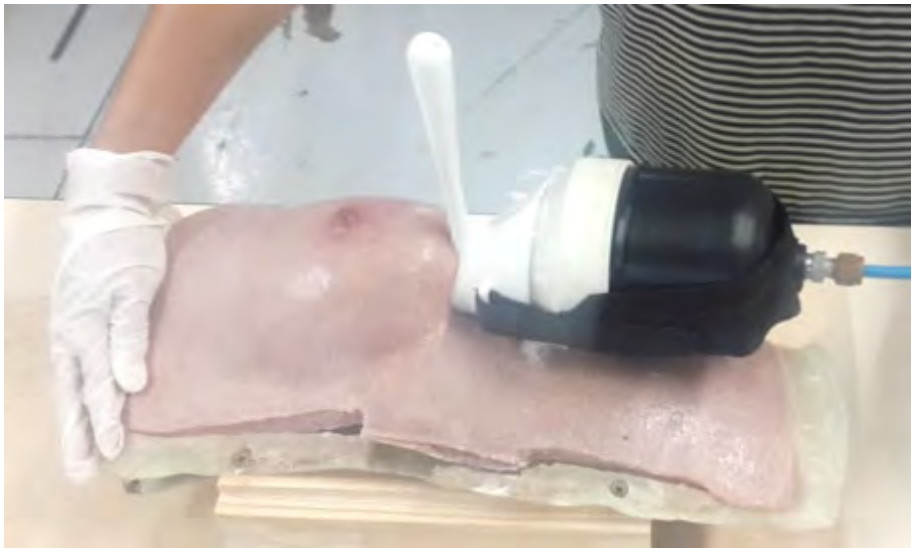

Figure 5.3: Prototype device inserted through the inframammary incision of the silicone cast breast-model

5.3.2. Test Setup and Process

For the prototype evaluation, insertions of eight implants into the breast-model were observed. Implants were supplied for this test by Allergan[17], but due to their cost, only one of each size was made available. However, implants no. 11 and 12 (Table 5.1 in section 5.2), which were used for the plunger test, were reused and therefore not new during the breast-model testing. Upon request, three additional implants (no. 18, 19 and 20) were received. While the implant-holder was designed to accommodate implant sizes up to 395 cm^3 (the decision made during the design stage of the device), it was found during experimentation that implant sizes of 400 cm^3 and 428.57 cm^3 could also be accommodated and therefore, were included in the testing. Table 5.2 shows the range of implants that were tested.

Device components were first lubricated as described in section 5.2.2 and assembled as described in steps 1 to 4 of section 4.3, ensuring at the same time that the orientation of the implant in the assembled device was correct. The components were then securely held together (for the purpose of the prototype) by a strap (Figure 4.4 (C)).

[17] From: Allergan Pharmaceuticals Ltd (Pty) in Midrand, Johannesburg.

Table 5.2: Implants used for the breast-model test arranged according to size and category

Classified range	No.	Shell Type	Gel-Type	Volume (cm^3)	Shape
Small	8	Textured	Mod. Soft	242.86	Anatomical
	18	Smooth	Mod. Hard	270	Anatomical
Medium	19	Textured	Mod. Soft	295.24	Round
	10	Textured	Very Soft	357.14	Round
	11	Smooth	Mod. Hard	380.95	Anatomical
	12	Smooth	Mod. Soft	395	Anatomical
	20	Smooth	Mod. Hard	400	Anatomical
Large	13	Textured	Very Soft	428.57	Round

The air-supply (set at 1 bar by the pressure regulator valve) was attached to the device as shown in Figure 5.4, and the outlet of the device was inserted through the inframammary incision of the breast-model as shown in Figure 5.3. The 1 bar air supply was passed through the device inlet until the implant had been inserted into the breast-cavity. An insertion was achieved according to one of two criteria: (a) the device felt empty (i.e. lighter by weight) or (b) the breast portion of the model was observed to have expanded. The insertion time was recorded from the point at which the valve was opened until either of the two criteria for insertion was met.

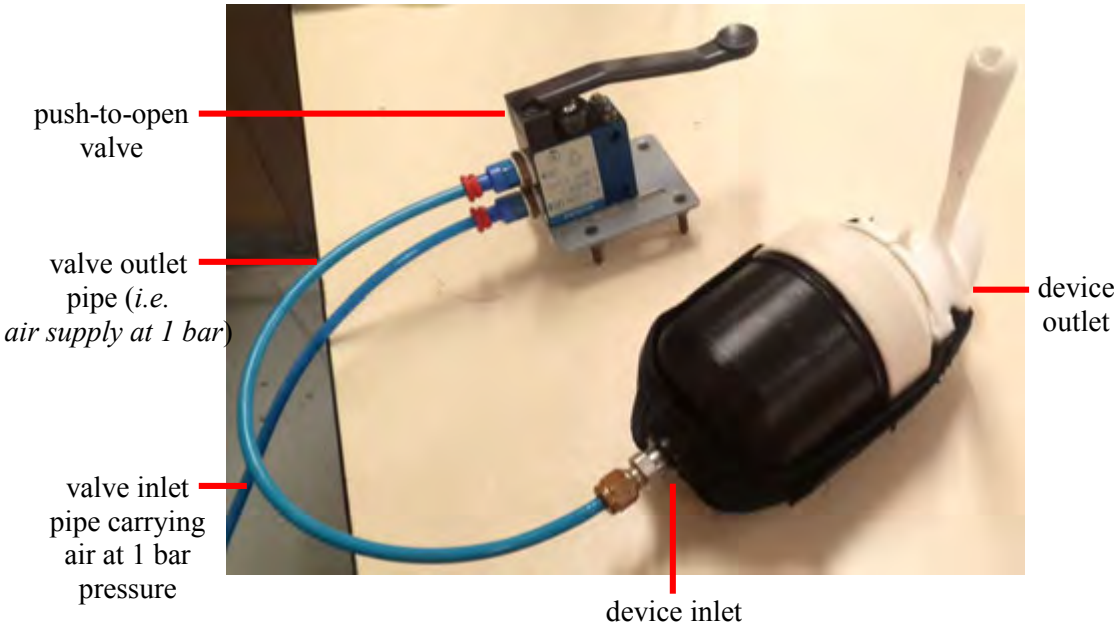

Figure 5.4: Prototype device setup prior to placement at the breast-model incision (the pressure regulator valve is not shown in this picture)

Following insertion, the prototype device was further evaluated according to steps no. 7 to 10 of section 4.3. Finally, the inserted implant was removed from the breast-model (as described in section 5.3.1) and inspected for any visible damage. This testing method was repeated for three successful insertions per implant.

5.3.3. Results, Observations and Discussions

The experimental procedure *in vitro* using the breast-model was particularly addressing the efficacy of the prototype conceptual design in using air to propel the implant through the outlet of the device into the breast-cavity, and concurrently to maintain no-touch conditions of the implant. Therefore, the data collected and the observations made address the following issues:

1. Time taken for the implant insertion.
2. Successful/not successful inversion of the inverting-bag and integrity of the inverting-bag (essential to the no-touch condition).
3. Ability to smooth the implant (and verify correct placement) in the breast-cavity through the inverting-bag and integrity of the implant after insertion.
4. Ergonomics of holding and manipulating the device.
5. Reliability of the procedure as a simulated surgical technique.

5.3.3.1. Insertion Times

The insertion times were recorded in Table I.3 (APPENDIX I.2) and are in Figure 5.5. On average, the insertion time for successful insertions in this test varied from 2.5 to 4.2 seconds. However, this timing has not been verified *in vivo* and therefore, cannot be used as a comparative measure with other devices.

5.3.3.2. Inversion and Integrity of the Inverting-Bag

During the first experiment, it was observed that the inverting-bags[18] tore and although the implants were inserted, the inverting-bag remaining in the device torn. Subsequent tests were performed with a thicker inverting-bag[19] but although it was inverted inside the breast-cavity, even these were found to be torn. The tearing was attributed to the air pressure, as a 'pop' sound was heard during insertion.

A total of 30 insertion attempts were made (Test 1: 12 attempts; Test 2: 9 attempts; Test 3: 9 attempts). In test 1, the thin inverting-bag was used and four attempts were unsuccessful due to bag rupture prior to implant insertion. In tests 2 and 3, the thicker inverting-bag was used and

[18] 0.05 mm (thick) polyethylene bag.
[19] 0.1 mm (thick) polyethylene bag

one attempt in each of tests 2 and 3 were unsuccessful due to bag rupture prior to implant insertion. In all the remaining 24 tests the inverting-bag was found torn in the breast-cavity and this was also attributed to the air pressure. Refer to Table I.3 for details on these inverting-bag tears.

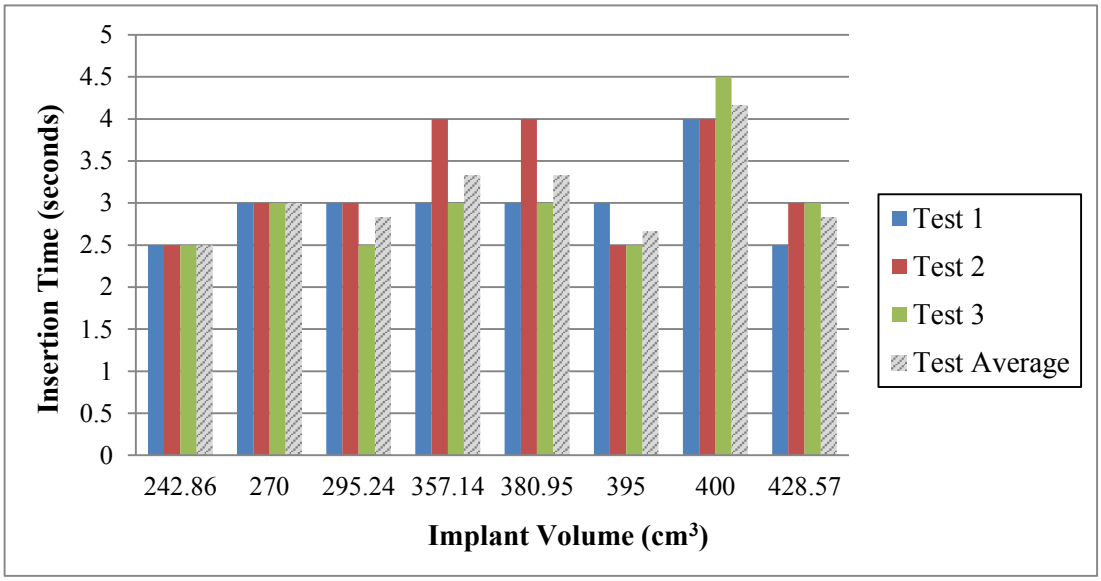

Figure 5.5: Bar graph showing silicone breast-model test results for all the successful insertions

5.3.3.3. Implant integrity

Post-insertion inspection revealed that implant no. 10 was inserted upside-down and no. 12 was orientated incorrectly. However, this was only observed with Test 1 insertions, after which adjustment to the assembly procedure of the device eliminated this problem. In all the tests in which inversion of the inverting-bag was successful the smoothing of the implant inside the breast-cavity was performed by a plastic surgeon (Dr N. Kairinos) who verified that: (a) the implant was orientated correctly and (b) that the no-touch condition procedure was successful.

It was also ascertained that apart from the already damaged implants no. 11 and 12 during the plunger test (see Table I.2) all other implants for all Tests 1, 2 and 3 were minimally damaged, not due to insertion but during implant removal from the breast-cavity. The damage was localised at the areas where the implant was squeezed past the relatively harder-than-human-tissue, silicone material of the breast-model, and of course due to the tight grip necessary to pull the implant out of the breast-cavity. The reuse of the implants did not affect any parameters of the experiment.

5.3.3.4. Ergonomics of the Prototype Device

While one of the indicators for the implant insertion was a slightly expanded breast, it was observed that a continued air-supply after insertion excessively expanded the silicone breast, as shown in Figure 5.6. This expansion was initially assumed to be due to a possible blockage of the retractor air-removal holes by the passing implant, as demonstrated in Figure 5.7. However, the tip of the air-removal-path was not blocked, as indicated by the red broken circle in Figure 5.7.

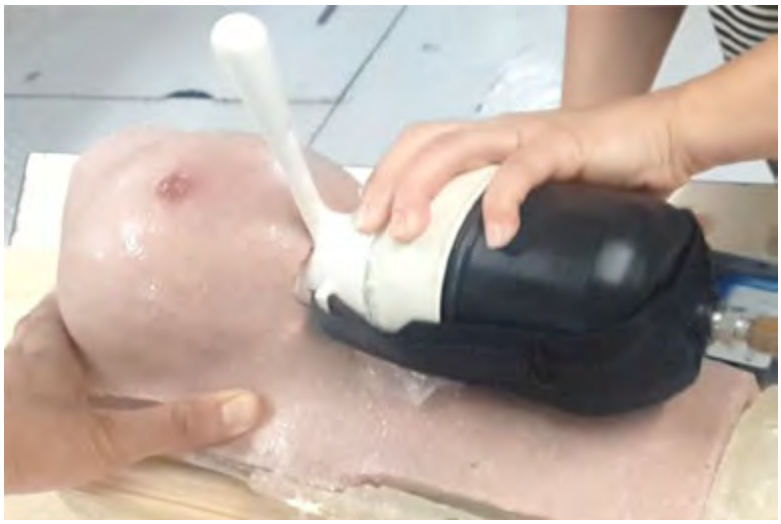

Figure 5.6: Excessive expansion of the silicone breast-model due to a continued air supply following insertion

Figure 5.7: Observation of the passing implant through the prototype. (*Red broken circle*) Open end of air-removal-tube through the built-in retractor

To determine if the blockage of the air-removal-path was responsible for the observed breast expansion, a drainage tube was inserted alongside the prototype device through the incision site. During insertion a minimal amount of air flow was felt through the drainage tube. This indicated that air from the air-supply did not enter the breast-cavity, since this air would have otherwise exited the breast through the drainage tube. Considering that the inverting-bag entered the breast-cavity too, the breast expansion was therefore confirmed to be due to the inflation of the inverted bag in the breast-cavity. This indicated a deficiency of the device to control the air supply, an issue which will be discussed in section 6.

Apart from the above issue against the functionality of the device, ergonomic related observations of the prototype included:

- The thread attachment between the mid-funnel and implant-holder components was not suitable to ensuring a correct implant placement in the assembled device (implant was found twisted).
- The handle on the nozzle-component was suitable for the leverage of the prototype through the incision site and provided an escape passage of the trapped air inside the breast-cavity, during implant insertion.

During assembly and dis-assembly of the prototype device:

- The attachment and detachment of the strap holding the components was time consuming and tedious.
- The inverting-bag thickness of 0.1 mm was suitable for assessing post-insertion implant placement/orientation[20].
- The overall size of the prototype was suitable for the torso of the breast-model as shown in Figure 5.3.
- The opaque materials used for the prototype device development were not conducive to accurately determining if the implant had been passed the mid-funnel and nozzle components.
- Air supply through an air pipe attached to the device may not be comfortable to the surgeon handling the device, it may cause concerns during the surgical procedure.
- For the purpose of the prototype device the control of the air supply was through a manually operated ON-OFF valve. As there was not visual confirmation that the implant was out of the device and inside the breast-cavity, it was not known when to

[20] Confirmed and recommended by Dr Nicolas Kairinos (Plastic Surgeon)

stop the air supply. This in turn was the main cause of inflating the inverted bag, the abnormal expansion of the breast-model and the rupture of the inverting-bag.

5.3.3.5. Reliability of the Experimental Investigation

The successful insertions into the breast-model and the breast-model for the *in vitro* evaluation of the prototype were confirmed by a plastic surgeon[21].

[21] Dr Nicholas Kairinos

6. CONCLUSIONS

The ‘no-touch’ insertion technique has been theoretically identified in literature as the optimal method in effectively reducing current capsular contracture (CC) rates via an elimination of insertion related bacterial contamination. The inability in achieving this ‘no-touch’ insertion with the traditional finger-manipulation method and, subsequent need for an insertion device was identified in the study problem statement (section 1.1). To be surgically adopted, this device is also required to promote safer and faster procedures and to be simple and easy to use. This is particularly for the insertion of prefilled silicone implants. The aim of this study was therefore, in the design and development of a silicone breast-implant insertion device that demonstrates (in vitro) a ‘no-touch’ technique without adversely affecting the integrity of the implant and the breast (section 1.2).

The proposed device concept was designed according to constraints, requirements and criteria established in section 4.2, which were based on the objectives of the study (section 1.2) and applicable design features found in literature (section 3.3). Following the conceptual design (section 4.3), an implant evaluation was carried out to determine internal prototype dimensions (section 4.4). The design and development of the prototype (section 4.5) was further based on component material selections and the necessary attachments between components. Following the verification of the pre-selected insertion force, i.e. air pressure at 1 bar (section 5.2), silicone implants were inserted into a silicone cast breast-model using the prototype device (section 5.3). The proposed device concept was therefore, evaluated with regards to the: ‘no-touch’ insertion achievement, positive-displacement method and relevant ergonomics of the prototype and, the limitations of this *in vitro* study were explored.

6.1. Insertion Times

The average insertion times of the three breast-model test rounds at the 1 bar (gauge) insertion air pressure ranged from 2.5 to 4.2 seconds (section 5.3.3.1). A statistical analysis was not carried out on these results, due to the small implant-sample size, which was composed of implants of varying: volume, shape, gel-type and surface finish. However, this variety of implants verified that consistent insertion was successfully achieved.

From the data collected, it is evident that both the implant volume and gel-type influence insertion time. This is in keeping with the increase in insertion difficulty with larger implants (section 2.3.2), as well as more cohesive gel-fillers (section 3.2.2), where insertion times are an indication of the insertion difficulty.

6.2. Insertion Air Pressure of 1 bar (gauge)

The maximum average insertion time of 4.2 seconds compared to the recorded plunge periods indicates a flaw in the plunger test used to verify the insertion force. The 1 bar insertion pressure (which was assessed as a safe pressure) verified that a 49 kg mass was required to plunge the 357.14 cm^3 and 380.95 cm^3 implants (Table 5.1) through a 78.5 mm diameter cylinder and the device outlet. The difference being in the relative short (30 seconds) and long plunge period (3 minutes) recorded for the 357.14 cm^3 and 380.95 cm^3 implants, respectively (section 5.2.1). While it was accurate to assume that the 1 bar pressure was sufficient for the 380.95 cm^3 implants in spite of the longer plunge period, experimentation showed that by using a different lubricant the insertion time was frictional-resistance-dependant and not on the type of implant. This suggests that the choice of device material is essential if sterile lubricants are used during implant/inverting-bag insertion.

Nonetheless, the short insertion times with the breast-model test results suggest that:

- A lower insertion pressure could be used with the insertion of implants up to 428.57 cm^3 (with a very soft gel) through a 45 mm incision and/or,
- A larger implant volume than 428.57 cm^3 (with a very soft gel) could be insertable through a 45 mm incision at a 1 bar insertion pressure – i.e. with the design of a larger implant-holder and corresponding dimensional increases on the mid-funnel-component.

While it appears that an insertion air pressure greater than 1 bar (gauge) is not necessary, an increase in this pressure may be at the risk of causing trauma to the breast-tissue.

6.3. Breast-Cavity Air-Removal Path

The device was designed having a built-in retractor and a handle incorporating a perforated tube at the underside of the retractor and connected to a tube through the handle. This design aspect successfully removed the air trapped inside the breast-cavity and let it escape through the passage inside the handle. As literature has indicated, trapped pressurised air inside the breast, due to implant insertion, could cause air embolism (section 3.3.1). Therefore, through the experiments in this study, this aspect of the device proved to be efficient. However, the extensive air-supply inflated excessively the breast-cavity of the model and unknowingly at the time of experimentation, this observation was thought to have occurred due to the blocked air-escape passage. It was proven later that the excessive breast inflation was due to the inverting-bag inflation inside the breast, which also caused rupture for the bag itself. Therefore, although the inverting-bag did not survive any testing of implant insertion, the breast inflation and bag

rupture indicated that a precise control of the air-supply is not only essential but detrimental to: (a) the health of the patient as besides air embolism, a more severe thoracic wall deformity is eminent, and (b) rendering the device and surgical methodology useless.

6.4. Achievement of the 'No-Touch' Insertion Technique and Safe Implant Handling

Theoretically, the successful insertions into the breast-model and visible maintenance of implant integrity (described in section 5.3.3) indicate that the proposed device concept provides a means for silicone breast-implant insertions with a 'no-touch' technique. As a result, this verifies the features for:

- Silicone breast-implant insertions through a 45 mm incision (objective no. 1).
- An elimination of skin/implant contact (objective no. 2).
- An elimination of an external retractor to hold the incision open throughout insertion (objective no. 3).
- An elimination of direct glove/implant contact (objective no. 4).
- An elimination of breast-tissue/implant contact (objective no. 5).
- Safe implant handling (objective no. 6.a).

6.4.1. Silicone Breast-Implant Insertions through a 45 mm Incision

The successful breast-model insertions verify the use of a funnel in reducing the cross-sectional area of prefilled implants, as suggested by Abell et al. (2007) in section 3.3.1. This is evidently also a standard feature in all the existing concepts investigated in section 3.3.

The successful insertion of the 428.57 cm^3 implant (section 5.3.3), is regarded as on par with the 400 cm^3 implant insertion reported with the Keller-Funnel through a 40 mm incision (section 3.3.2). This is considering that, while breast-model insertions were through a 45 mm incision, the actual proposed device outlet is equivalent to a 40 mm incision, as described in section 4.4.2. Consequently, this potentially indicates that minimal incision lengths (section 3.2.4) may be achievable with the proposed device concept, in comparison to the Keller-Funnel, which has the advantage in reduced incision lengths (section 3.3.2).

6.4.2. Elimination of Skin/Implant Contact

The closed nature of the proposed concept and device placement through the incision (as described in device operation step no. 5 in section 4.3), protects the implant from skin contact throughout insertion. While this is to prevent an implant contamination from skin bacteria, the

infectious theory (section 3.1.4) also describes a need for protection against environmental bacteria such as *Bacillus* species. Thus, the closed nature of the proposed device further protects against environmental contamination throughout insertion and is therefore, superior to the open implant tray of the suction system by Kairinos (2011) in Figure 3.6. However, the similarity of the proposed device outlet to that of the suction system and placement thereof is conducive to an elimination of skin contact at the wound margin. This stems from the evaluated bacterial contamination with the use of the Keller-Funnel to have been partially due to the lack of device attachment at the wound (section 3.3.2). Consequently, the rigid device outlet lining the wound is also essential to the elimination of skin/implant contact.

6.4.3. Elimination of an External Retractor

The successful prototype placement, attachment and removal in the breast-model test indicate that the built-in retractor was effective at eliminating the need for an external retractor to the device. According to suggestion by Dr Kairinos, a short length of the built-in retractor was incorporated in the design of the prototype. In comparison to Kairinos (2011) 'suction model' the shorter retractor serves to: (a) cause no injury to the soft tissues inside the breast and (b) facilitates easier removal from the breast at the end of insertion.

Conversely, the curve of the retractor was fixed according to the equivalent dome dimensions of the 380.95 cm^3 implant (section 4.4.2). Considering the open configuration of the empty cavity in the breast-model (section 5.3.1), it is unclear if this curve may become problematic with the insertion of smaller implants in a real breast (through the 45 mm incision, medium device size).

6.4.4. Elimination of Direct Glove/Implant Contact

The use of the inverting-bag for elimination of direct glove/implant contact was verified by the successful inversion and release of the bag following insertion (section 5.3.3). This inverting-bag feature was suggested by Zochowski (2014) however, no indication was provided as to how this bag is attached to the device (section 3.3.2). The proposed device concept therefore indicates that the operation of this bag relies on the attachment and detachment of one component into another with the bag trapped in between, which is achievable by a two-way guide and knob feature between the nozzle- and mid-funnel-components.

It is also evident that the strength of the inverting-bag is essential for a successful insertion with air pressure as the insertion force (i.e. with a maximum 0.1 mm bag thickness for post-insertion implant orientation assessments – section 5.3.3). While it was beyond the scope of this study to specify final component materials, successful bag inversions confirm the use of a bag that is: open on one end, relatively thin, flexible, durable and inelastic (section 4.5.2).

6.4.5. Elimination of Breast-Tissue/Implant Contact

The breast ducts have also been found to harbour and extrude skin bacteria (section 3.1.4) consequently, an elimination of breast-tissue/implant contact would be ideal. However, this relies on an elimination of breast-tissue violation with implant pocket and incision site selections that are deep to the breast-tissue – i.e. a submuscular/subpectoral pocket and inframammary incision (section 3.1.5). While the suggested pockets are also deep to large vessels for hematoma concerns (which is contributes to CC development), the implant pocket plane is largely patient dependant (section 2.3.1). Nonetheless, the inframammary incision has been the most effective surgical variable at reducing bacterial contamination (section 3.1.4) and the device was suitably designed for this site. The inframammary restriction is further validated by the suggested use of two incisions if a simultaneous mastopexy is required (Table 3.2). Thus, use at the inframammary site was achieved by the design of the eccentric shaped funnel. It is also assumed that the built-in retractor may assists with a potential reduction in breast-tissue contact, by opening the breast-cavity (in a real breast) and lifting a portion of the breast-tissue away from the implant (section 3.3.1).

The extent to which a potential reduction (if not elimination) in breast-tissue contact is achieved is unclear from the breast-model test. However, in conjunction to an inframammary incision, the short insertion times (Figure 5.5) would be beneficial to a reduction in breast-tissue contact. This stems from the predicted reduction in bacterial contamination with quicker procedures (Table 3.2).

6.4.6. Safe Implant Handling

Despite the designed maximum insertable implant volume of 395 cm^3 for the 45 mm incision, no visible post-insertion implant damage was observed with the breast-model test subset of up to 428.57 cm^3 (section 5.3.3). This potentially indicates a safe implant handling with the eccentric funnel angle and the even distribution of insertion forces offered by pressurized air. It is therefore evident that the proposed method of insertion may not be at the risk of permanently deforming the implant shape or weakening the implant shell for insertions of up to 428.57 cm^3.

In addition to the integrity of the implant, safe implant handling also involves the orientation of the delivered implant. Consequently, device attachments that require the rotation of components also require increased skill and time for device preparation, which may still not be conducive to an acceptable implant delivery (section 5.3.3). This is however, related to the ergonomics of device component attachments (which may change in future designs) and does not disprove the proposed concept.

6.5. The Positive-Displacement Method of Insertion

6.5.1. The 1 bar (gauge) Insertion Air Pressure and Benefits Thereof

Theoretically, the successful breast-model insertions (section 6.1) also imply that the positive-displacement, 1 bar air pressure was effective at pushing the implant and inverting-bag through the device and into the breast-cavity (objective no. 6.b, section 1.2). This further indicates that the seals created by the circumferential tapers and tightly held inverting-bag at the plane of inversion were also effective. In addition, the rigidity of the prototype materials provides the required inelastic nature for this application (section 3.3.2).

Other than a safe (implant handling) 'no-touch' technique, the appeal of the proposed device concept is also in a reduction in insertion difficulty, which is indicated by the recorded insertion times. The maximum insertion time in the breast-model test was recorded with the 400 cm^3 implant containing a hard gel and not the 428.57 cm^3 with a soft gel (section 5.3.3.1) – thus indicating a gel-type influence on insertion difficulty. This potentially verifies the assumed soft gel-filler with the reported Keller-Funnel 500 cm^3 implant insertion through a 30 mm incision (section 4.4.2). If this verification extends to the assumed hard gel-filler for the reported Keller-Funnel 400 cm^3 insertion through a 55 mm incision then, the proposed device concept may be superior to the Keller-Funnel with respect to a reduction in incision lengths. However, further studies would be required for this verification. Nonetheless, the maximum average insertion time of 4.2 seconds for the test subset is within the 3-20 seconds reported with the Keller-Funnel (section 3.3.2) and significantly below the 5-15 minutes reported with the traditional finger-manipulation method (section 2.3.2).

The short insertion times are most likely due to the more even distribution of forces offered by the proposed positive-displacement method. While the 1 bar insertion air pressure was subject to plunger test evaluations (regardless of its flaws, section 6.2), the 49 kg equivalence to this pressure (section 5.2.2) verifies the significant manual force predicted with the use of a plunger system (section 4.3) as a positive-displacement method.

6.5.2. Insertion Resistance Reduction with the Proposed Device Concept

The short insertion times indicate that insertion resistance is adequately overcome with the proposed device concept. This includes implant resistance due to friction and resistance due to air naturally trapped in the breast. Frictional resistance would have been overcome by the wound margin protection and internal lubrication of the device. While the amount of lubrication was not equivalent to the extremely slippery Keller-Funnel description (section 3.3.2),

satisfactory insertion times were recorded. The removal of trapped air from the breast is also essential, for which was achieved by the retractor air-removal path.

6.5.3. Breast Safety Concerns

The safety of the proposed positive-displacement method is potentially threatened by the observed inverted bag inflation (section 6.3). While the inflation of the inverted bag indicates that the air-supply seals are effective, it is evident that the expandable structure (Figure C.5) with a liquid/air supply proposed by Ledergerber (1998) is better suited to breast safety, as a liquid supply can be more accurately controlled than the air supply. However, this structure would not achieve the required inverting-bag inversion, which is essential to direct glove/implant contact elimination. Alternatively, a transparent device for visible insertion verifications and/or an air supply safety cut-off following insertion could be paramount to breast safety. This material change and the cut-off mechanism are beyond the scope of this study (section 1.3) nonetheless, these alternatives would not adversely affect the proposed 'no-touch' technique, but are essential to the safe insertion of the implant.

6.6. Overall Ergonomic Evaluation of the Insertion Device

Ergonomic evaluations that are detrimental to the proposed concept include the required handling of the device and the overall size relative to the torso of the breast-model (objective no. 7, section 1.2). Whereas, prototype related ergonomic evaluations include features that are not detrimental to proving the concept, i.e. the screw attachment between the device components, the prototype strap, material selection and the position of the air supply control (from Table 4.3). Consequently, these features are not herein discussed and therefore, the design specifications are not conclusive to these aspects of the device.

From section 5.3.3.4, it is evident that the device handle is suitable for the leverage of the built-in retractor, through the incision until the device outlet adequately lines the wound margin. Upon insertion, it is also assumed that device stability would be maintained at the handle. Since at the prototype design stage the air-control valve was external to the device, it caused undesirable effects in assessing the safe delivery of the implant. It is therefore concluded that a more ergonomically-correct positioning of the air valve at the top of the handle, and controlled by the surgeon's thumb, would provide dexterity as well as stability of the device during insertion. This potentially verifies the leverage and stability functions of the device handle (section 4.3).

6.7. Limitations of the Proposed Insertion Device Concept Evaluation

Due to the nature of the experiment to proving the concept, the *in vitro* testing posed limitations to the investigation of real bacterial reduction. In doing so, the proposed device was developed having considered aspects discussed in previous sections of this document and successfully delivered the conclusive results supporting the aim of this study.

It is anticipated that the *in vivo* study will explore the real-life concerns, when live breast-tissue during animal studies will show the efficacy of the device in time of insertion, bag inversion and integrity of both inverting-bag and implant. Therefore, considering the *in vitro* testing, the prototype device was designed specifically to investigate the proposed aim.

7. RECOMMENDATIONS AND FUTURE WORK

This study validates the proposed 'no-touch' breast-implant insertion device according to a prototype *in vitro* breast-model investigation. Recommendations for future device developments include:

- Sterilizable material selections, consisting of transparent rigid device components with a low coefficient of friction (against the breast-implant) and, a 0.1 mm thick inverting-bag durable to the 1 bar (gauge) insertion air pressure.
- An attachment of a pressurized air-supply canister to the device (instead of the use of readily available air-supply in theatre).
- A post-insertion air-supply safety cut-off mechanism.
- Direct clip-lock device component attachments.

The limitations of this breast-model investigation are in the inadequate implant insertion resistances and, inherent inability of biological related verifications of the proposed 'no-touch' technique. Consequently, the surgical validity of the proposed concept will be a study in a future work with *in vivo* investigations, for:

- Breast safety verifications, specifically with regards to breast-cavity air-removal through the built-in retractor.
- Biological 'no-touch' technique verifications, with regards to the amount of bacterial contamination following insertions using the proposed device compared to traditional as well as Keller-Funnel insertions.

APPENDIX A – Implant Pocket Planes

Breast pocket planes include: subglandular, submuscular and subpectoral (dual plane) – as shown in Figure A.1

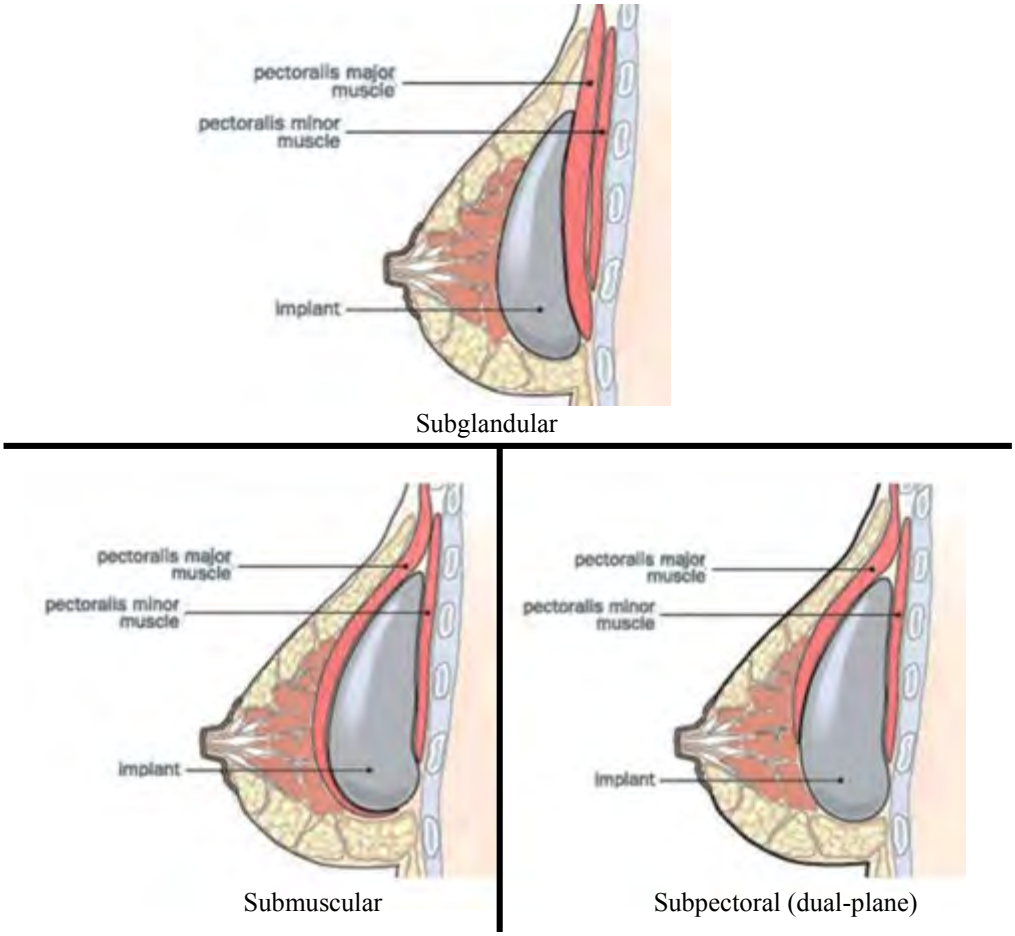

Figure A.1: Breast implant pocket locations (Poulin, 2008).

APPENDIX B – Capsular Contracture (CC)

B.1. Capsular Contracture Occurrence Rates

Table B.1: Capsular Contracture reported rates

(Reference)	Reported CC occurrence rates
(Hipps et al., 1978)	4 – 74%
(Shah et al., 1981)	40 – 50%
(Mcgrath & Burkhardt, 1984)	0 – 74%
(Gabriel et al., 1997)	17.5%
(Independent Review Group, 1998)	(1st & 2nd generation) 40 – 60%
(Sarwer et al., 2000)	10 – 70%
(Pajkos et al., 2003)	Up to 74%
(Barnsley et al., 2006)	15 – 45%
(Araco, Caruso, Araco, Overton, & Gravante, 2009)	1.3 – 30%
(Tamboto et al., 2010)	0.6 – 100%
(Mofid, 2011)	10 – 30%
(Hester et al., 2012)	0 – 74%
(Moyer et al., 2012)	5 – 74%
(Rieger et al., 2013)	30%
(Bergmann et al., 2014)	4 – 60%

Table B.2: Time-to-Contracture reported rates

(Reference)	CC Occurrence Rate (%)			
	1st post-operative year	2nd post-operative year	3rd post-operative year	After 3rd post-operative year
(Domanskis & Owsley, 1976)	40%- within 6 months	-	-	-
(Ersek, 1991)	33.33%	50%	Over 90%	Remainder
(Tweed, 2003)	-	25%	-	-
(Marques et al., 2010)	-	16% and 76% within 1.6 and 2 years, respectively	-	-
(Mofid, 2011)	58% - within 11 months	-	75%	Remainder (by 5 years)
(Jacombs et al., 2012)	Approx. 90%	-	-	-
(Somogyi & Brown, 2015)*	1.3%	-	-	7.4% (after 6 years)

*Predicted probability rates – based on a study of 1539 patients.

Table B.3: Reported capsular contracture rates following augmentation and reconstructive surgeries

(Reference)	CC Occurrence Rate (%)		Recon. To Augmentation
	Augmentation	Reconstructive	
(Gabriel et al., 1997)	6.5% - within a year 12% - by 5 years Avg. patient age: 31	21.8% - within a year 34% - by 5 years Avg. patient age: 49	3.3 times more 2.8 times more
(Grigg et al., 2000)	-	30 – 40%	-
(Reid et al., 2005)	4.6%	25%	5.4 times more
(Allergan, 2007) – *5 Year Allergan Core Study*	13.8%	7.6%	1.8 times less
(Adams, 2009)	15%	15 – 30%	2 times more
(Allergan, 2009) – 7 *Year Core Study*	15.5% Avg. patient age: 34	17.1% Avg. patient age: 48	1.1 times less
(Marques et al., 2010)	17.4% - within 3 years Avg. patient age: 31	47.7% - within 4 years Avg. patient age: 48.6	2.7 times
(Mofid, 2011)	30%	73%	2.4 times
(Brazin et al., 2014)	10%	More than 20%	2 times

Table B.4: Reported capsular contracture rates with saline and silicone implants

(Reference)	CC Occurrence Rate (%)		Commentary
	Saline Implant	Silicone Implants	
(Mckinney & Tresley, 1983)	24% CC rate Bilateral in 28.5% of contractures. Average implantation duration to contracture – 14.5 months.	36% CC rate Bilateral in 67.5% of contractures. Average implantation duration to contracture – 10.8 months.	No significant difference was determined with regards to the time of capsule formation.
(Asplund, 1984)	20%	54%	This followed reconstructive procedures over a 2 year follow-up period. However, results were from a small sample size.
(Handel et al., 1995)	7.1%- over a mean follow-up period of 6.7 months	5.6% - over a mean follow-up period of 13.8 months	No significant difference was determined following statistical analysis – result do not support lower CC rates with saline compared to silicone
(Embrey et al., 1999)	33%	68%	-

Table B.5: Reported capsular contracture rates with smooth and textured implants

(Reference)	CC Occurrence Rate (%)		Commentary
	Smooth Implants	Textured Implants	
(Ersek, 1991)	25.15% Bilateral contracture more common with smooth implants	2.5%	Results following implantation of 330 smooth and 122 textured implants, with not statistical analysis to account for the difference in the number of implants used.
(Handel et al., 1995)	19.5% Mean follow-up of 32.8 months	8% Mean follow-up of 10.7 months	Statistical analysis determined the reduced risk of CC with textured implants to be short lived – i.e. textured implants eventually approximate smooth implant CC rates.
(Spear, Howard, et al., 2004)	23 – 40%	2 – 29%	Subglandular placement in augmentation
(Barnsley et al., 2006)	-	-	A Meta-Analysis: CC rates were observed to be **5-times higher with smooth**, compared to textured implants. However, these results were from short follow-up studies, with no indication regarding placement.
(Mofid, 2011)	-	-	CC rates are **3-to-5-times higher with smooth implants** following subglandular placement.
(Hester et al., 2012)	-	-	Did not find a decreased CC rate with textured implants – no indication of implant placement.

Table B.6: Reported capsular contracture rates with subglandular and submuscular/subpectoral placements

(Reference)	CC Occurrence Rate (%)		Commentary
	Subglandular	Submuscular/ Subpectoral	
(Handel et al., 1995)	8.8%	6.9% (subpectoral)	This difference was not statistically significant. Furthermore, no indication of the incision site used was provided in this study.
(Grigg et al., 2000)	30%	10% (submuscular)	-
(Mofid, 2011)	-	-	CC rates are **8-times higher with subglandular** placement than submuscular/subpectoral

Table B.7: Reported capsular contracture rates with regards to incision site

(Reference)	CC Occurrence Rate (%)			Commentary
	Inframammary	Periareolar	Transaxillary	
(Wiener, 2008)	0.59% The interval to development of CC was on average 4.5 months	8.6% The interval to development of CC was on average 9.5 months	-	No statistical analysis was carried out. And, a significantly higher number of augmentations were performed at the inframammary site than the periareolar (338 vs. 92).
(Jacobson et al., 2012)	0.5% The interval to development of CC was on average 18.6 months	2.4% The interval to development of CC was on average 3 months	6.4% The interval to development of CC was on average 8.5 months	A statistically significant difference was only determined between the inframammary and transaxillary sites. However, very small sample size was used

B.2. Treatments for Relief of Capsular Contracture

Non-surgical treatments have included: closed capsulotomy; the consumption or pocket injection of leukotriene receptor antagonists (LTRAs) – particularly Zafirlukast (ZL); and the application of external ultrasound on the contracted breast. And, surgical treatments have included: open capsulotomy; capsulectomy; and the attachment of a shaped piece of acellular dermal matrix (ADM) to the pectoralis muscle/s.

High CC reoccurrence rates have been consistently reported following capsulectomies and both types of capsulotomies, with repeated procedures decreasing the chance of success (Grigg et al., 2000), refer to Table B.8 for reported reoccurrence rates following open/closed capsulotomies and capsulectomies. Closed capsulotomies have been largely abandoned due to the required excessive compression on the implant – increasing the risk of: hematoma and implant shell rupture (Mofid, 2011). With regards to the infectious theory, this 'breaking of the capsule' for relief of the contraction does not resolve the underlying subclinical infection hence, the observed high reoccurrence. This is also an applicable explanation for CC reoccurrence following open capsulotomies and capsulectomies (Adams, 2009). Where, cuts are made in the contracted capsule and the implant is reinserted with the cut capsule in an open capsulotomy – also for the relief of contraction. And, a capsulectomy requires the removal of the entire contracted capsule, followed by an implant reinsertion (Grigg et al., 2000). A further reduction in reoccurrence rates have been observed following an implant exchange with a pocket plane

change however, an elimination is desired (Mofid, 2011). Furthermore, replacements and capsulectomies required more than an hour of surgery time (Grigg et al., 2000).

Table B.8: Reported capsular contracture reoccurrence rates following open/closed capsulotomy and capsulectomy

(Reference)	CC Reoccurrence Rates (%)			Commentary
	Capsulotomy		Capsulectomy	
	Closed	Open		
(Vinnik, 1976)	25%			
(Hipps et al., 1978)	21%	11%	34%	No significant difference between treatments
(Handel et al., 1995)			17.4% - with implant change	
(Planas, Migliano, Wagenfuhr, & Castillo, 1997)	33%			Observed within a 1 year follow-up period.
(Embrey et al., 1999)	58%			
(Reid et al., 2005)		> 54%	21%	
(Hester et al., 2012)			53.4% - with implant and breast pocket change. 74% reoccurrence after capsulectomy.	Reoccurrences occurred 1month to 4 years following capsulectomy.

The use of LTRAs, external ultrasound and ADM in contracture treatment (and potentially prevention) have been largely anecdotal with short follow-up periods (Chun et al., 2010). Nonetheless, these methods aim to alter the capsule thickness thus, predominantly centred on the hypertrophic scarring theory. The application of external ultrasound from the immediate postoperative period has been observed to promote early stabilization of the healing process, by increasing cellularity, vascularity and subsequently, capsule thickness (Shah et al., 1981). However, with collagen fibre orientation described to be similar to those frequently reported around textured implants, which potentially indicates a delay in contractures (Mendes et al., 2008).

LTRAs (specifically ZL) have been observed to reduce capsule thickening by blockage of inflammatory cell mediators following the natural healing process, i.e. in the progression of a chronic inflammation (Moreira et al., 2009). Whereas, ADM has promoted the development of thinner capsules by providing a barrier (between the implant and surrounding tissue) that excludes inflammatory cells infiltrates in the natural healing process (Mofid, 2011). Conversely, the undesired systematic effect of ZL has resulted in liver failure etc. (Moreira et al., 2009) and is therefore not recommended (Adams, 2009). And, the insertion of ADM has significantly increased seroma and infection rates (Chun et al., 2010). According to the infectious theory, the

increase in clinical infections with ADM could be due to the increase in the pathogenic effect of *S. aureus* in the breast-tissue (Courtiss et al., 1979). Since, the exclusion of inflammatory cells reduces the ability of clinical infection prevention by the natural healing process and immune system. Furthermore, the ADM insertion process and increase in breast-tissue manipulation could result in an increase in bacterial contamination, i.e. due to the more complicated procedure (Chun et al., 2010). ADM is also expensive (S. Becker et al., 2009) and required a minimum 50 mm incision length (Baxter, 2003).

It is evident that the underlying biofilm formation and/or bacterial contamination are not treated with these CC treatment methods (Bartsich et al., 2011), since none of these methods have completely cured all contractures, nor have they proven to completely prevent contracture development (Adams, 2009).

APPENDIX C – Existing Implant Insertion Device Concepts

C.1. BIOCELL Delivery Assistant Sleeve

This sleeve creates a barrier between the implant and skin and, is open on both ends for the purpose of sleeve removal following insertion (Castello et al., 2014). Figure C.1 shows the insertion of an implant with this sleeve.

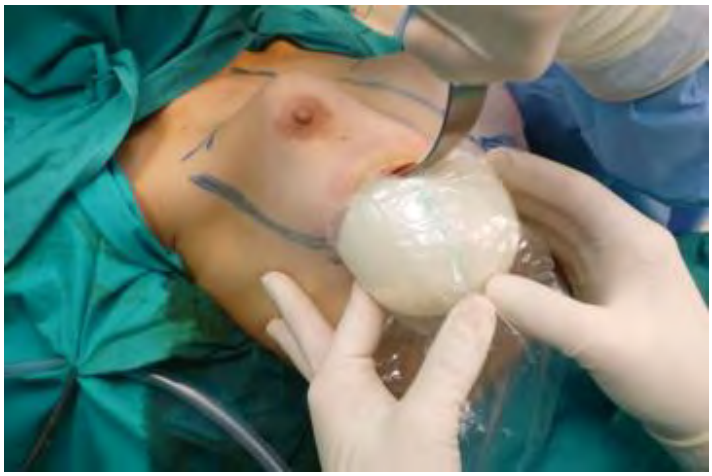

Figure C.1: Silicone implant insertion with a BIOCELL Delivery Assistant Sleeve (Castello et al., 2014)

C.2. Implant Pull-Devices

C.2.1. **Propulsion System** (Abell et al., 2007)

The propulsion system proposed by Abell et al., (2007) is as shown in Figure C.2.

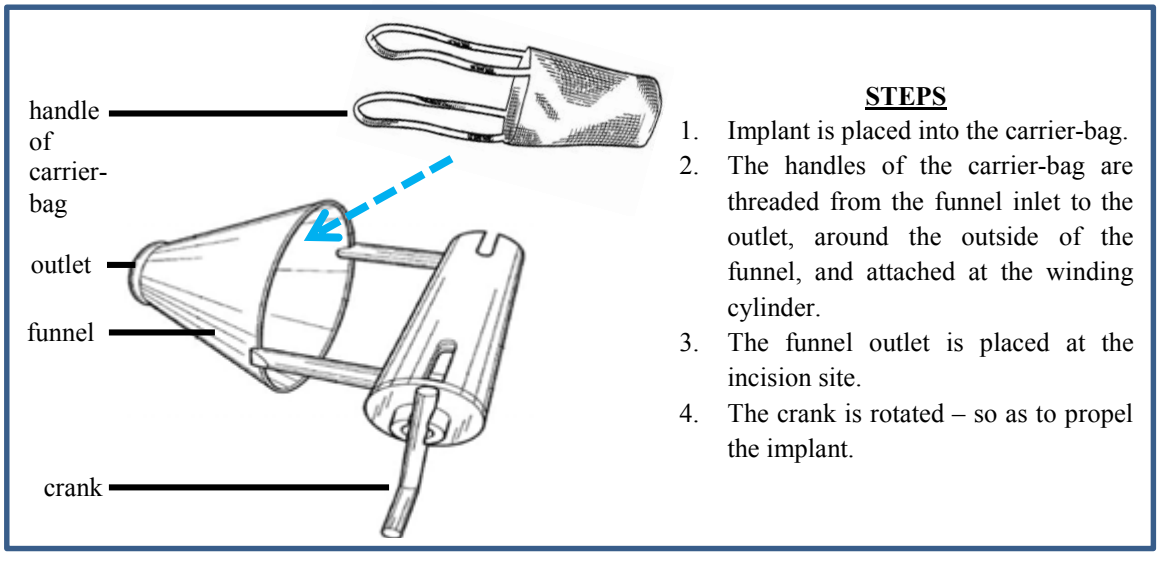

Figure C.2: Implant Propulsion Device (Abell et al., 2007)

While an insertion failure has been predicted, it is also evident that the implant could squeeze out the bag in the opposite direction, potentially resulting in an implant shape deformation. This is due to the use of a carrier-bag open at both ends. The crank and winding cylinder attachments may also result in a bulky device not suitable to the surgical environment. Furthermore, the conical funnel shape may become problematic for insertions through an inframammary incision, (as shown in Figure C.3).

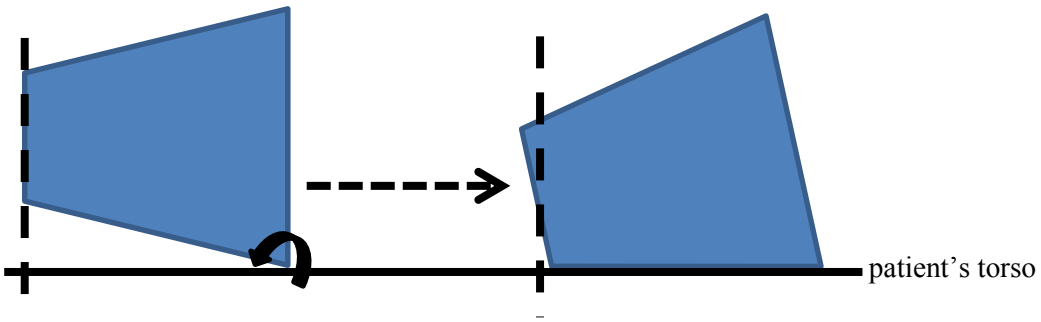

Figure C.3: Schematic representation of a rigid conical funnel and its attachment at the inframammary incision site (dashed line represent the plane of the inframammary incision)

C.3. Implant Push-Devices

C.3.1. Disposable Implant Injector (Shiao, 1993)

The injector and plunger system is as shown in Figure C.4.

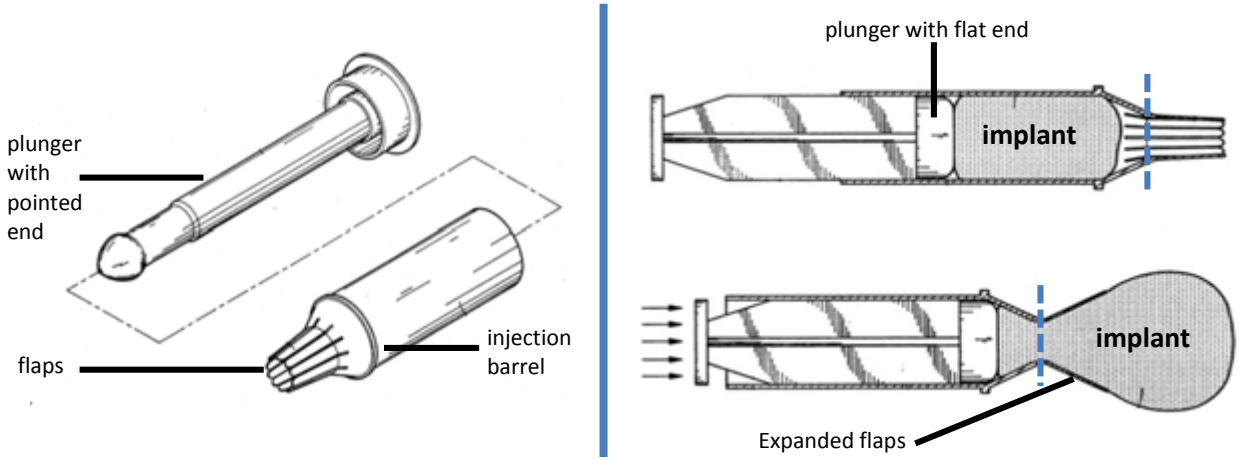

Figure C.4: Disposable Implant Injector (Shiao, 1993) – everything to the right of the *dashed line* enters the breast-cavity

While blunt, the end of the plunger applies a point load onto the implant shell which may adversely affect the implant integrity. Should a flat-end plunger be used, the implant may not be adequately pushed into the breast, since the plunger will not be able to travel through the decreasing cross-sectional area of the funnelled outlet.

C.3.2. **Breast Implant Introducer** (Ledergerber, 1998)

The aim of this design is primarily in an atraumatic implant delivery. This is by providing wound margin protection and a more even distribution of insertion forces on the implant. Of interest is the use of gas/saline to push the implant instead of a plunger, (shown in Figure C.5).

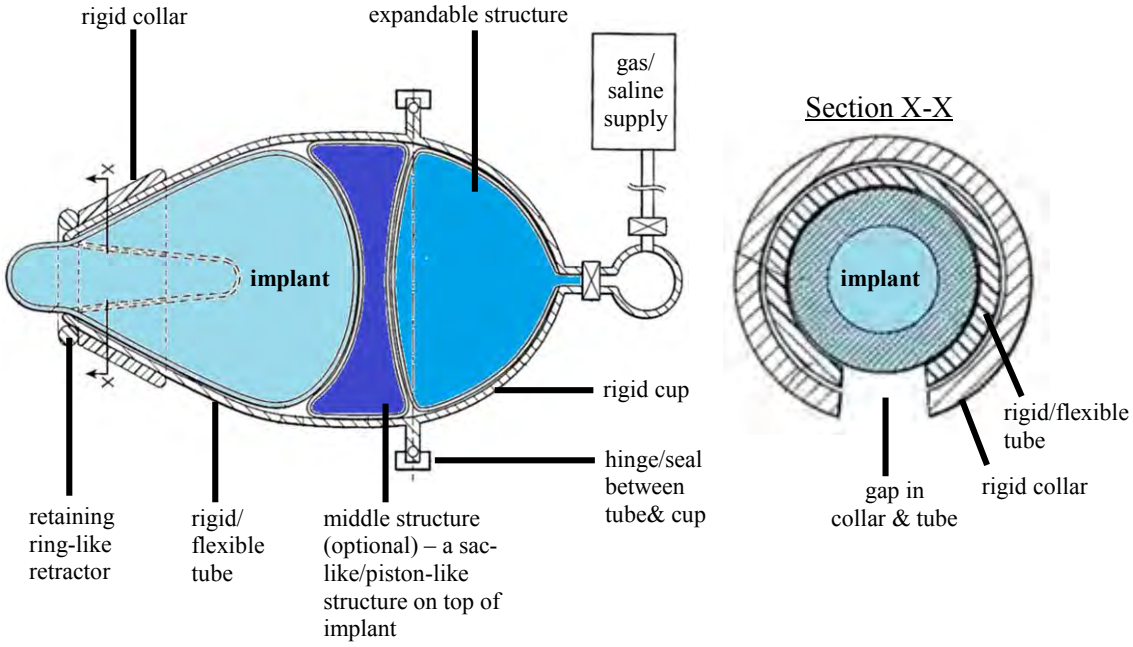

Figure C.5: Breast Implant Introducer (Ledergerber, 1998)

In this design (Figure C.5):

- A 'built-in' retractor is achieved by use of a retaining ring with hinge system. The ring is allowed to expand once the outlet of the device has been placed through the wound. This is meant to stabilize the device at the incision site and provide wound margin protection. However, an external retractor would still be required to initially open the incision for device placement.
- The rigid collar around the tube increases the thickness of the device. This may require a larger-than-normal incision length per implant-volume or, the forcing of a particular implant-volume through a smaller-than-normal orifice.

C.3.3. The Keller-Funnel

The Keller-Funnel is as shown in Figure C.6 and, the addition of rigid collar with attachable retractors designed by Anderson & Hunt, (2014) is as shown in Figure C.7.

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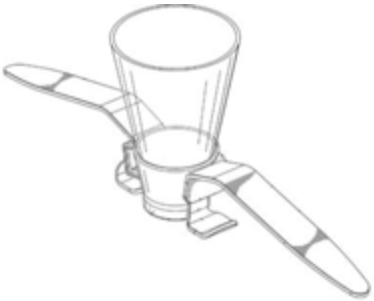
Figure C.6: The Keller Funnel (Jackson, 2013)



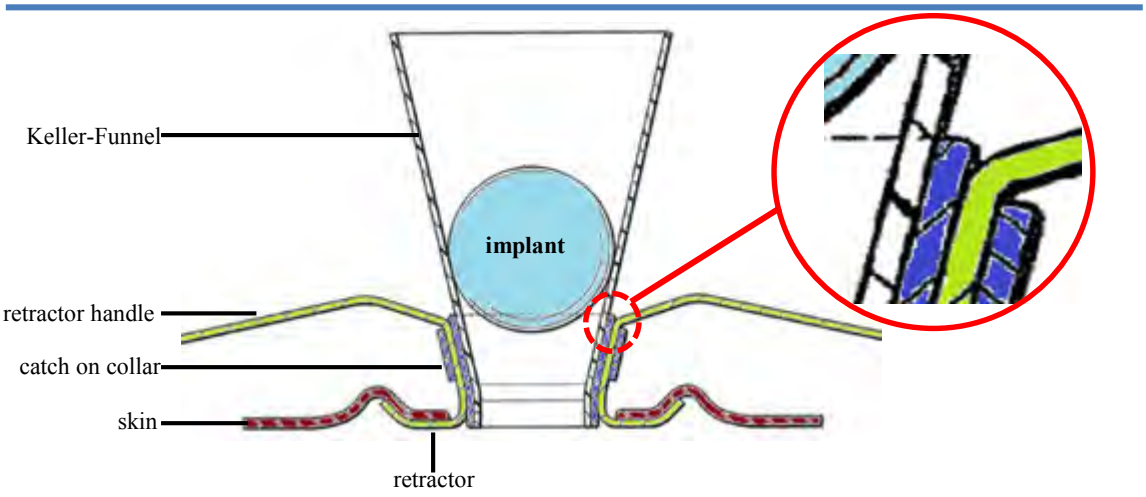


Figure C.7: Collar & Retractor attachment to the Keller-Funnel (Anderson & Hunt, 2014)

Insertion with the Keller-Funnel has reportedly delivered a 400 cm^3 silicone implant through a 35 mm incision length at 5% of the force normally required with the finger-manipulation method (Keller Medical Inc., 2009). However, no indication was provided regarding the method used to measure these forces.

C.3.4. Implant Insertion Device and Method of Use Thereof (Zochowski, 2014)

The design by Zochowski (2014) is as shown in Figure C.8.

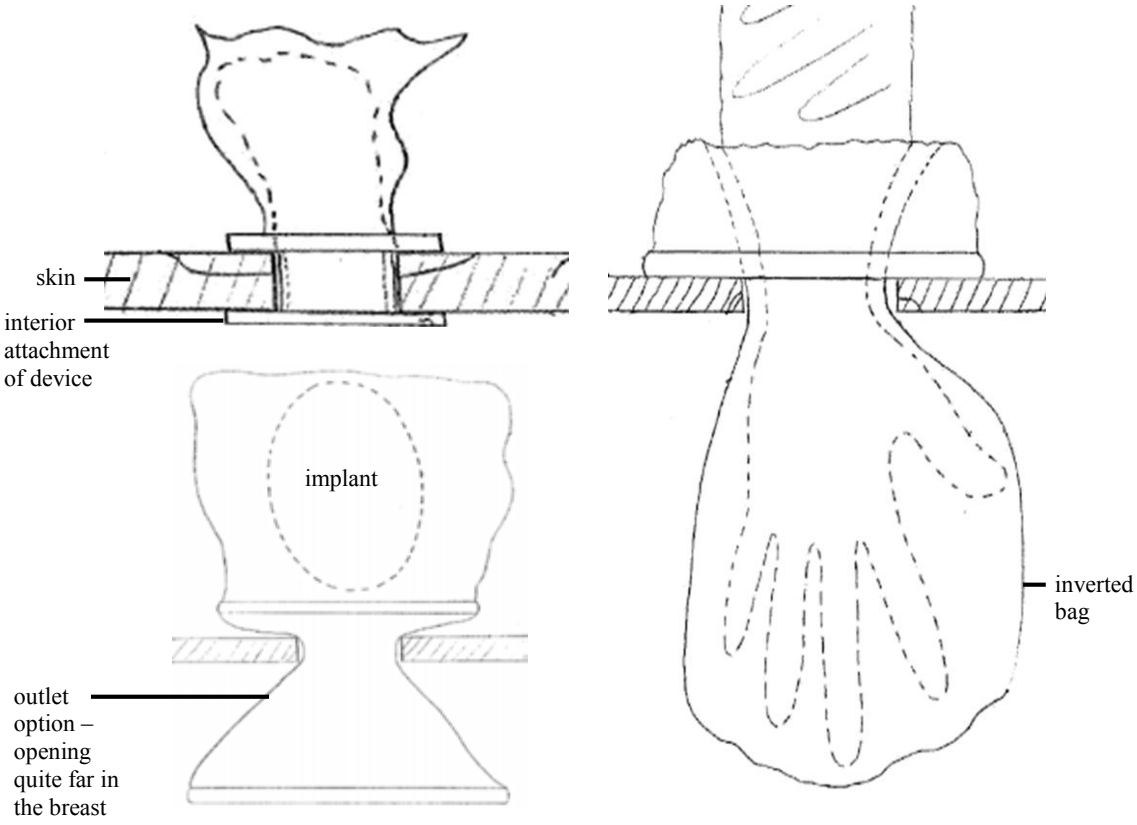


Figure C.8: Patent Application by Zochowski (2014).

A range of features are described by Zochowski (2014) in the attachment of this insertion device to the interior and exterior surfaces of the breast. This is so as to hold the incision open and stabilize the device. Alternatively, the outlet of the device can open up deep into the breast. This also provides wound margin protection. The implant is first placed into a bag that is either open on both ends or at just one end. The bag (with implant) is attached to the other components of the device and the user is required to push the implant into the breast-cavity by applying pressure on the bag (via the hands or an instrument). In the case of a bag with one open end, the bag is invertible and is partially inserted into the breast-cavity with the implant.

APPENDIX D – Device Concepts

D.1. Hand-Manipulation Concept

This conceptual design was made up of two designed components, i.e. the nozzle- and mid-funnel-component as shown in Figures D.1-D.3. The nozzle-component provides the required funnel shape and the mid-funnel-component is essentially described as a thick ring. For a positive-displacement at the aid of a hand-manipulation method, a bag-like implant-holder (to be attached to the mid-funnel-component) was required. This bag-like implant-holder would be closed on one end, due to the requirement of an inverting-bag (section 4.2). Following insertion, the user would be required to finger-push the bag-like implant-holder into the breast-cavity, i.e. so as to serve as the inverting-bag.

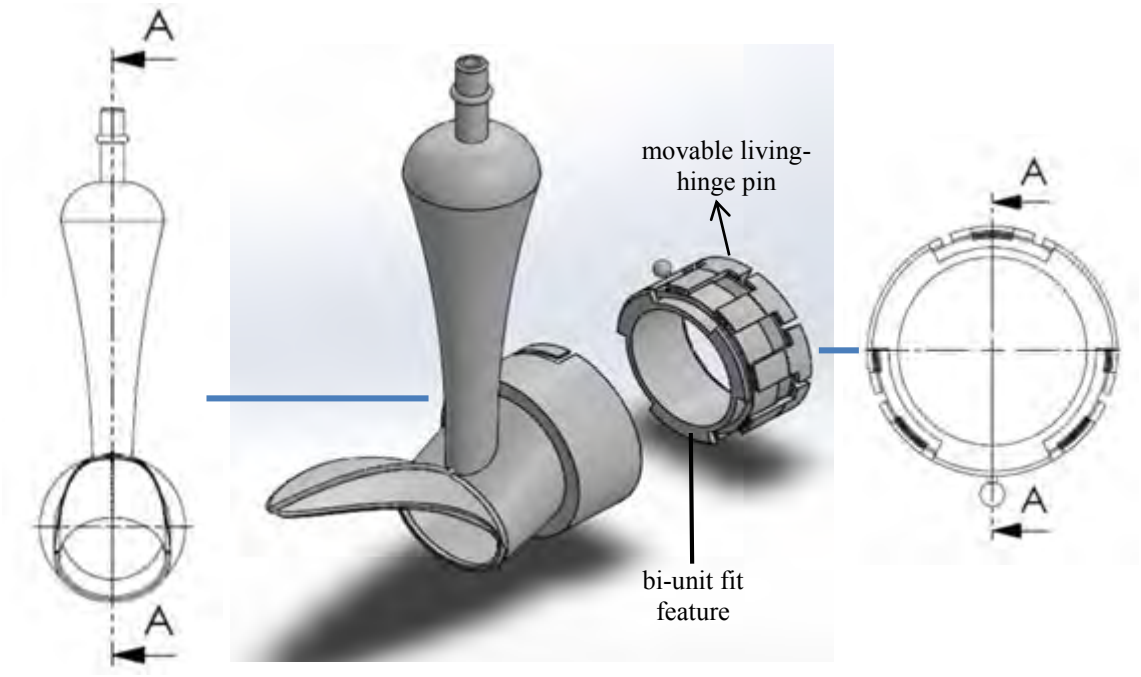


Figure D.1: Hand manipulation concept with front views of the insert- and end-component

An assistant may be required to maintain device stability during insertion in addition to preparing the device prior to insertion. Nonetheless, this design concept featured the use of living-hinge type pins to temporarily hold a bag-like component and a bi-unit lock mechanism for the device assembly. The knob on the mid-funnel-component was designed so as to assist with placement and rotation (along the guide path of the nozzle-component), which is necessary for the bi-unit lock. Since rotation of one component in another would be required for the bi-unit lock, this attachment would not be conducive to two eccentric funnel shaped components.

It is evident that difficulty may be experienced in holding the living-hinge pins (down) prior to the placement of the mid-funnel-component into the nozzle-component, since each pin functions separately. Furthermore, following insertion, a portion of the inverted implant-holder could easily be pulled out of the breast-cavity during the required pin release, i.e. due to the detachment of the mid-funnel-component from the nozzle-component.

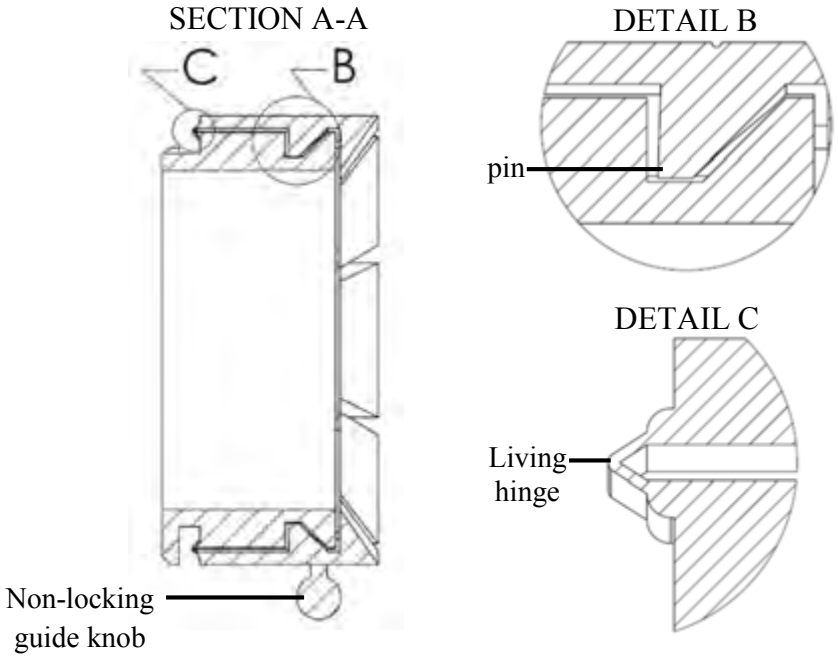


Figure D.2: Mid-funnel-component SECTION A-A, DETAIL B and DETAIL C views

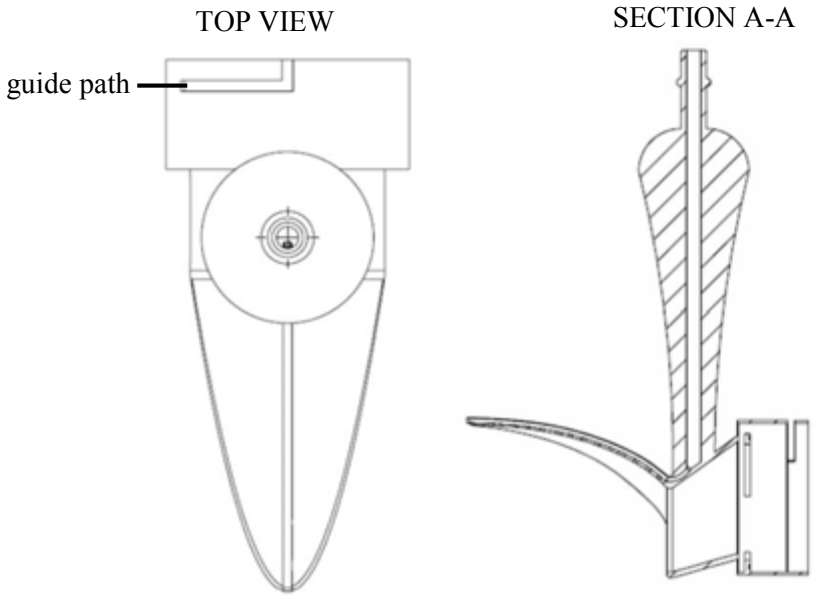


Figure D.3: Nozzle-component TOP VIEW and SECTION A-A

D.2. Plunger System

This conceptual design was made up of five designed components: nozzle, mid-funnel, implant-holder, plunger and plunger handle. With reference to Figure D.4, this design featured a horizontal device handle portion for stability as the user applies manual pressure on the plunger handle during insertion. To reduce insertion resistance, holes (just before the eccentric funnel portion) were required to allow for air release from the implant-holder as the implant is pushed through the device, since air would naturally be present in this space. A bi-unit lock was also featured in this design between the mid-funnel and implant-holder components.

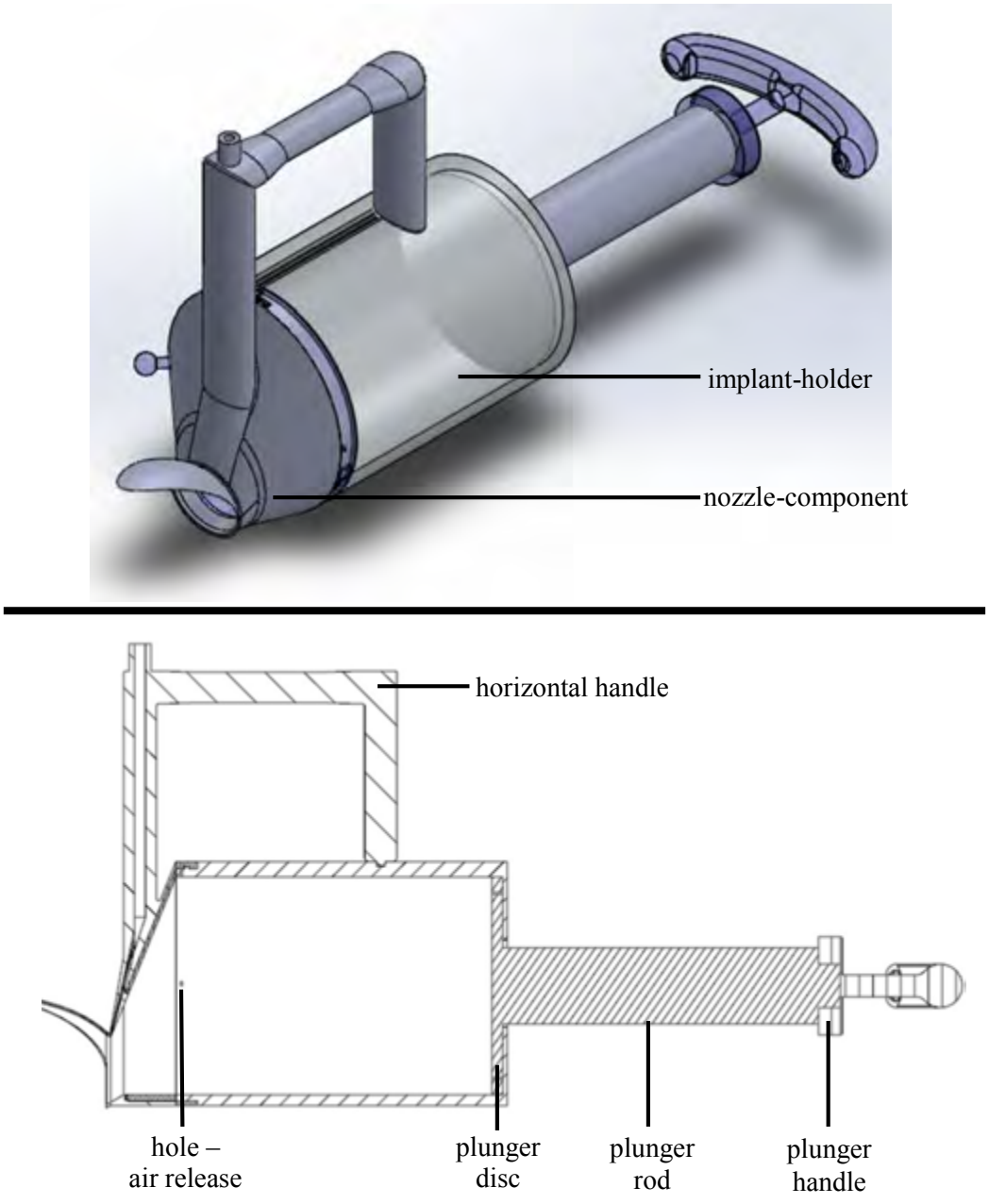


Figure D.4: Plunger system (*top*) isometric view of assembly, (*bottom*) cross-sectional view of assembly

It is evident that a steep eccentric funnel shape would be required for the face of the plunger to push the implant a sufficient distance through the device, since the plunger is suited to the constant diameter of the implant-holder. However, this was contradictory to the required gradual eccentric-funnel angle (section 4.2). Difficulty may also be experienced with the required inversion of the inverting bag, due to the flat face of the plunger.

D.3. One-Way Guide

This one-way guide and lock system would have been between the nozzle and mid-funnel-components (as shown in Figure D.5). The tear shaped guide-knob (on the mid-funnel-component) and corresponding shape in the guide-path does not allow for a detachment of these components following device assembly. Since, the rounded surface of the guide-knob against the relatively narrow neck of the guide-path was not conducive to an expansion of this neck should a detachment be attempted. Consequently, this type of lock design would not be conducive to the required post-insertion freeing of the inverting-bag.

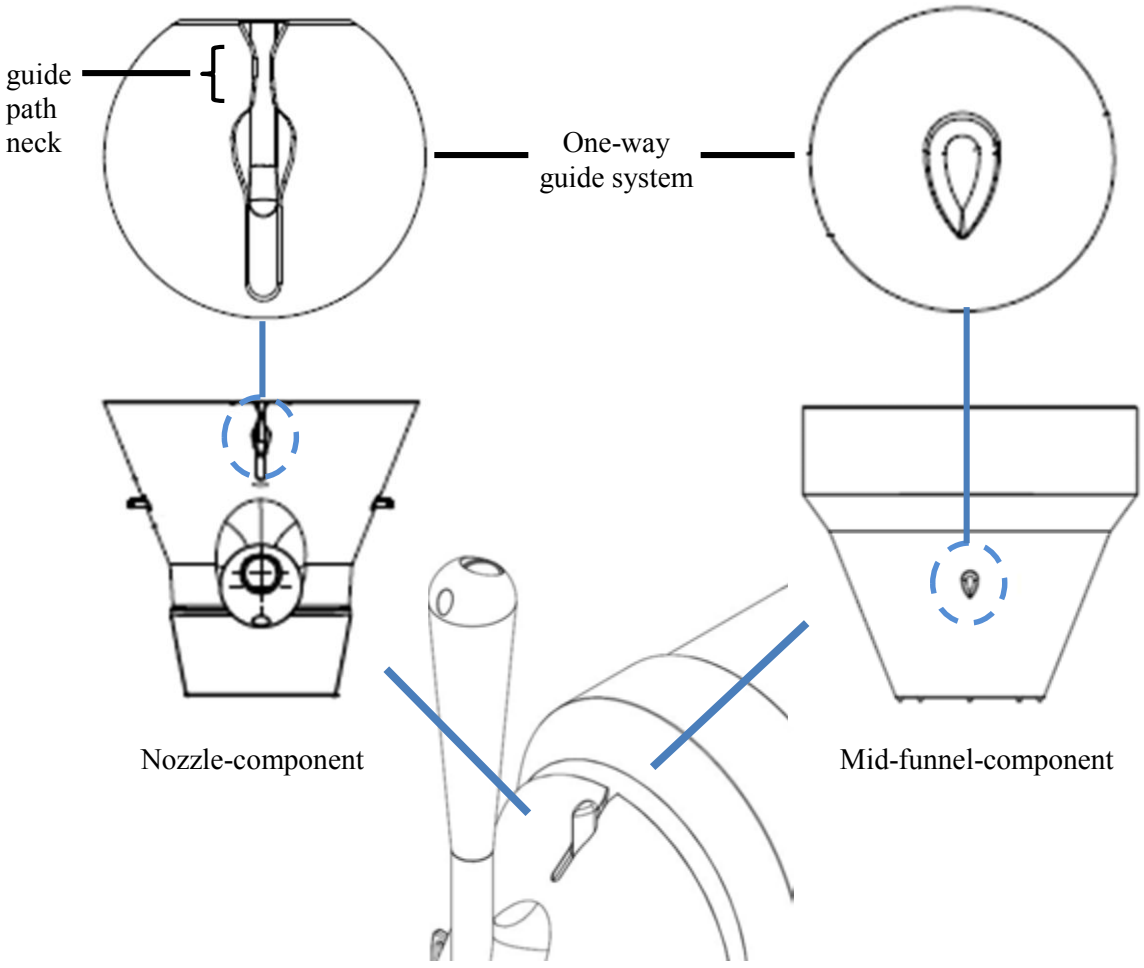


Figure D.5: One-way guide knob on nozzle- and mid-funnel-components

D.4. Fabric Implant-Holder Concepts

This concept was made up of 6 designed components (excluding the fabric): nozzle, mid-funnel, ring 1, ring 2, ring 3 and cap (as shown in Figure E.3). The rings and the mid-funnel-component were designed to trap and permanently hold the fabric with one of two methods. These included a one-way clip-lock or ultrasonic welding.

D.4.1. One-Way Clip Lock

This method for fabric entrapment was as demonstrated in Figure E.3. This type of lock relied on the mechanical properties of the component materials (specifically, material elasticity and tensile strength properties) since, rings that end up on top of other components (with the fabric in between) are required to briefly expand. However, based on the dimensional parameters of the device, too small of a workable space was available for the clip face to hold the fabric.

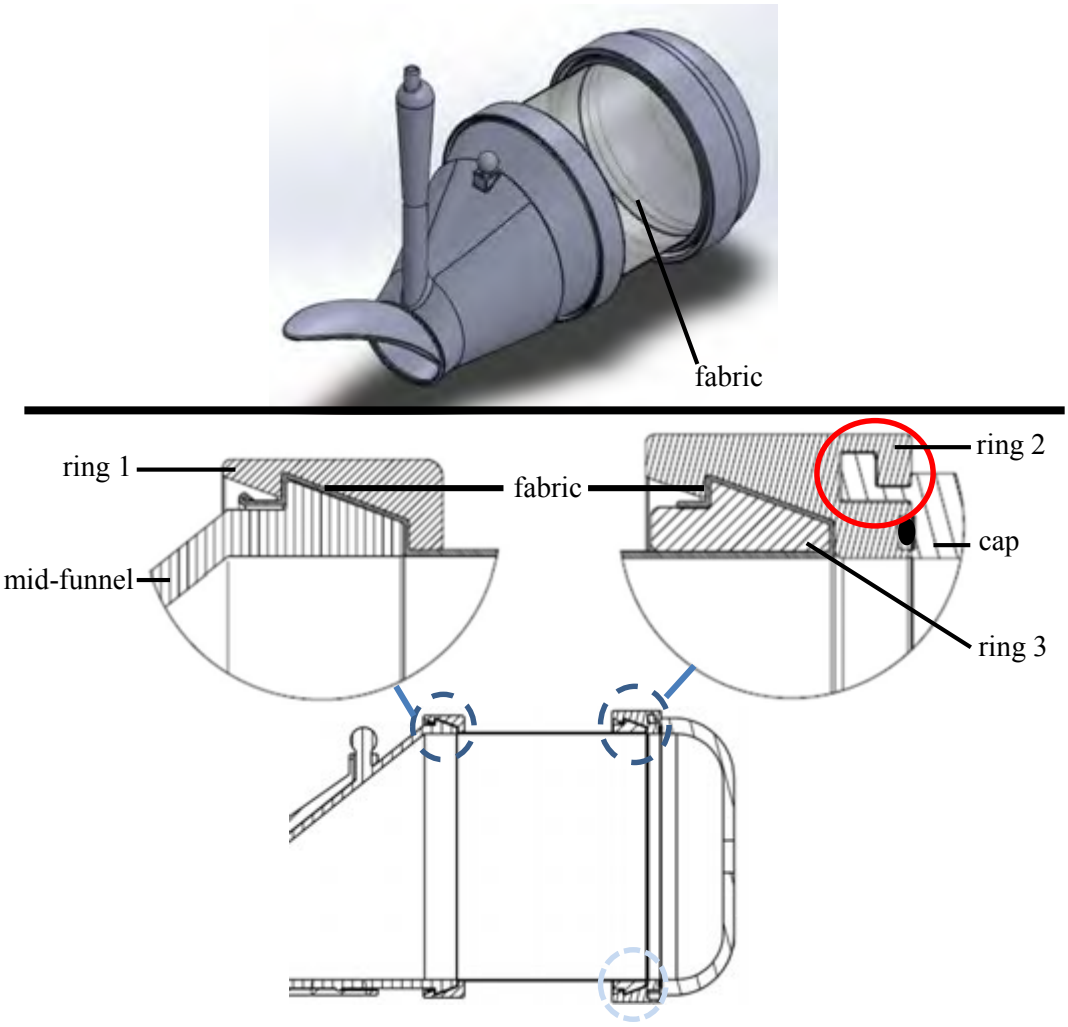


Figure D.6: Fabric Implant holder with one way clip system. (*Red circled region*) indicates the bi-unit lock between ring 2 and the cap component

D.4.2. Ultrasonic Welding

This type of fabric entrapment method required certain design consideration for the application of the ultrasound. For the application at hand, a near field shear joint design[22] was incorporated into the design of the device rings instead of the one-way clips, as shown in Figure E.4. Other considerations and requirements for this joining method would also be required with regards to the moisture content of the (selected) plastic and the joining of the same polymer types.

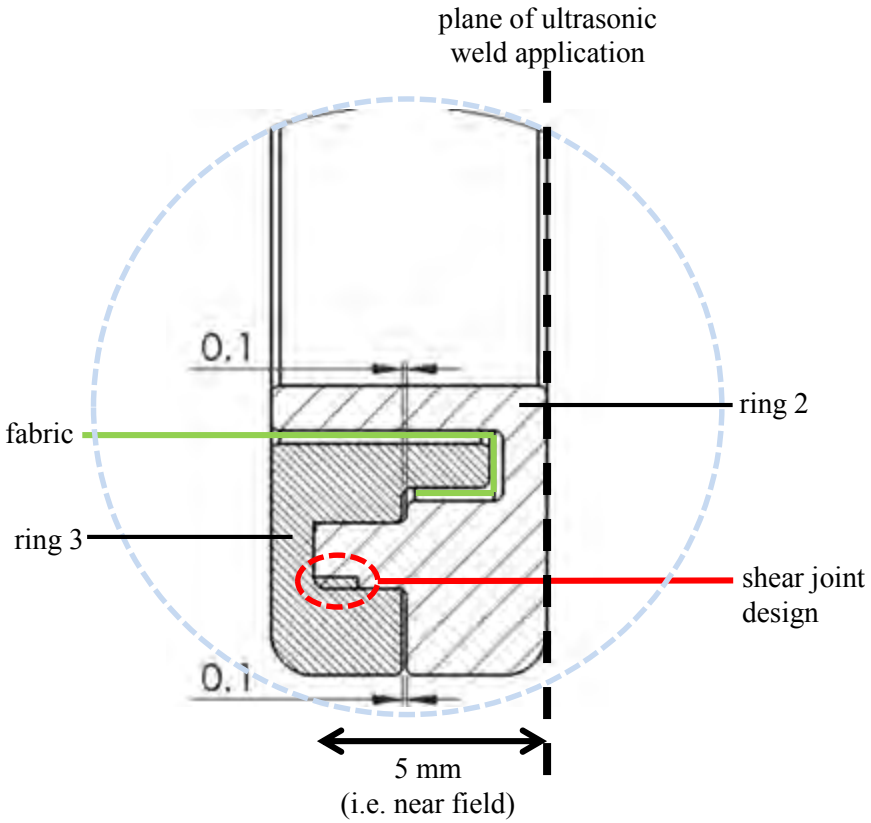


Figure D.7: Fabric system with ultrasonic weld considerations – from Figure E.3 (*light blue dotted margin*)

[22] Evaluated as an applicable design according to the Ultrasonic Plastic Joining guidelines for Branson equipment (Branson Ultrasonics Corporation, 2014) – which was made available from W. Lee Ultraplast (Pty) Ltd.

APPENDIX E – Implant Data and Dimensional Requirements

E.1. Implant Holder Evaluation

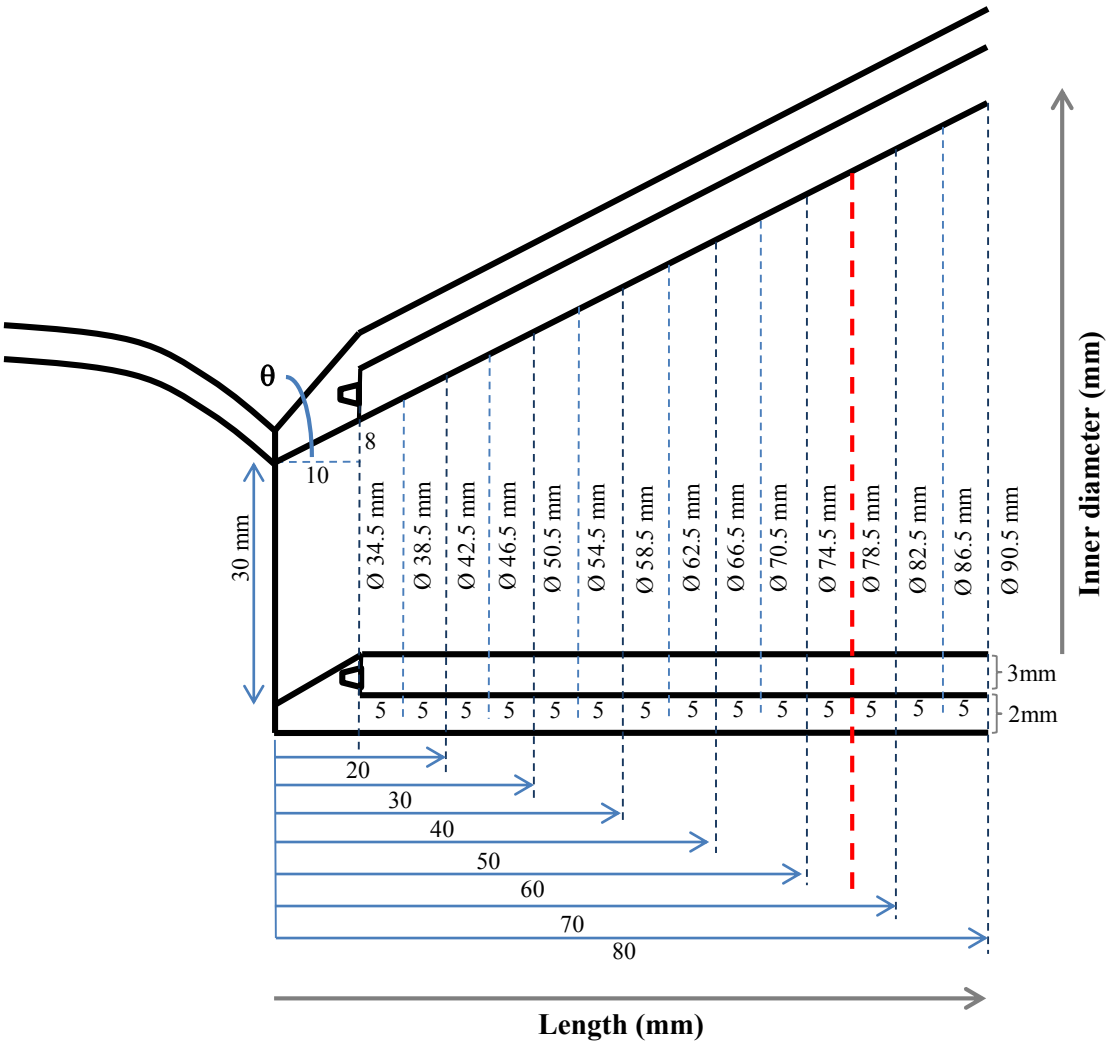


Figure E.1: Diagram of the mid-funnel- and nozzle-component used to determine the device internal diameters according to: the device outlet, eccentric-funnel angle (θ) equal to 38.63°, horizontal length from the outlet and component thicknesses (i.e. nozzle-component = 2mm and mid-funnel-component = 3mm). (*Red broken line*) experimentally determined dimensions.

E.2. Silicone-Gel Implant Data

Table E.1: Silicone implant data and implant evaluation results

No.	Mass (grams)	*Volume (cm^3)	Shell Type	Gel Type	Shape	Base Ø (mm)	Projection (mm)	(Anatomical) Height (mm)	Mock Holder Ø (mm)	Required holder length (mm)	Device Size
1	140	133.33	Textured	Mod. Hard	Anatomical	100	2.9	105	*70.5	45	SMALL
2	140	133.33	Smooth	Mod. Soft	Round	105	21	-	*70.5	45	SMALL
3	170	161.90	Textured	Mod. Soft	Anatomical	110	31	101	70.5	50	SMALL
4	175	166.67	Textured	Very Soft	Round	100	33	-	70.5	50	SMALL
5	190	180.95	Smooth	Mod. Soft	Round	100	38	-	70.5	55	SMALL
6	245	233.33	Smooth	Mod. Hard	Anatomical	115	42	106	70.5	60	SMALL
7	250	238.10	Textured	Very Hard	Anatomical	110	51	115	70.5	70	SMALL
8	255	242.86	Textured	Mod. Soft	Anatomical	115	46	106	70.5	70	SMALL
9	310	295.24	Smooth	Mod. Soft	Round	110	51	-	74.5	75	MEDIUM
10	375	357.14	Textured	Very Soft	Round	130	43	-	78.5	75	MEDIUM
11	400	380.95	Smooth	Mod. Hard	Anatomical	135	50	125	78.5	85	MEDIUM
12	414.75	395	Smooth	Mod. Soft	Anatomical	130	48	135	78.5	85	MEDIUM
13	450	428.57	Textured	Very Soft	Round	130	53	-	82.5	85	LARGE
14	490	466.67	Textured	Mod. Hard	Anatomical	145	58	122	82.5	90	LARGE
15	525	500	Textured	Very Soft	Round	130	63	-	90.5	95	EXTRA LARGE
16	560	533.33	Textured	Mod. Soft	Round	135	64	-	90.5	95	EXTRA LARGE
17	610	580.95	Textured	Mod. Soft	Round	170	36	-	90.5	100	EXTRA LARGE

*Volume (cm^3) $= \frac{Mass\ (grams)}{1.05}$

*While the smallest mock holder tested was at an internal diameter of 70.5 mm, by observation it is assumed that these implants would adequately fit inside a 66.5 mm diameter holder.

E.3. Retractor Dimensions

The retractor was dimensioned according to the curve of a 380.95 cm^3 implant with a round base Ø of 135 mm and projection of 50 mm (section 4.4.2 & Table E.1), as shown in Figure E.2.

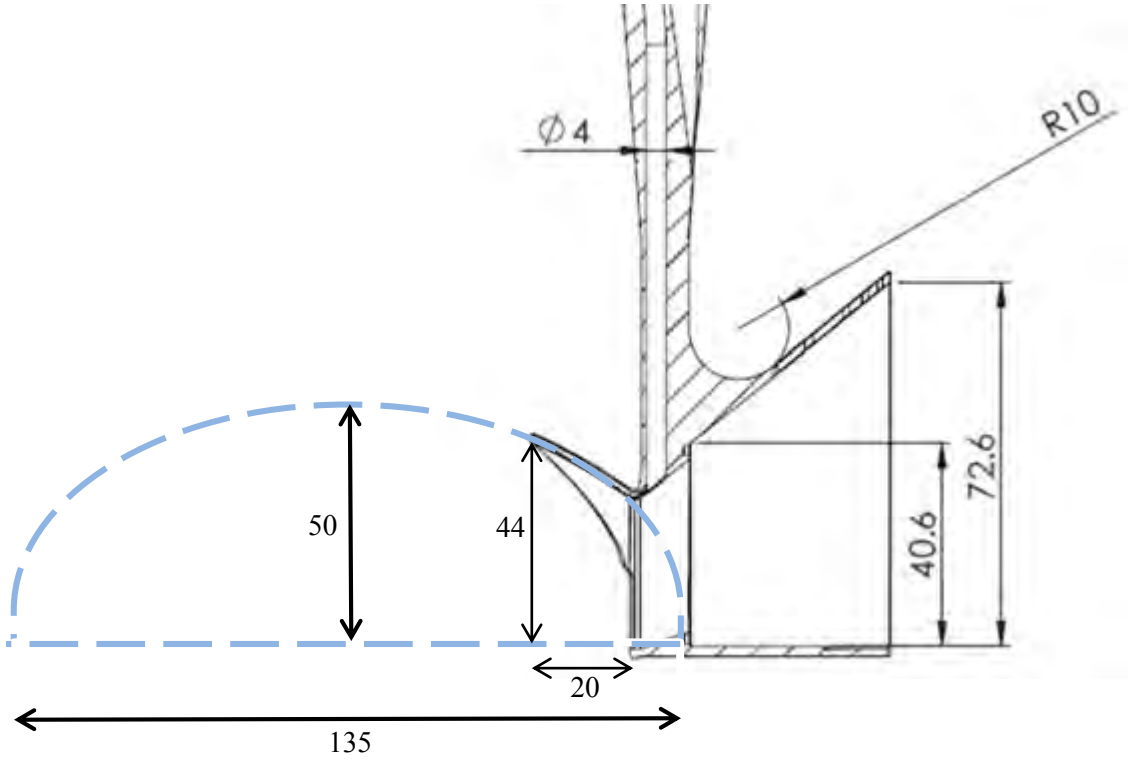


Figure E.2: Retractor dimensions according to a 380.95 cm^3 implant (blue dotted) with base of Ø 135 mm and projection of 50 mm (dimensions are in mm)

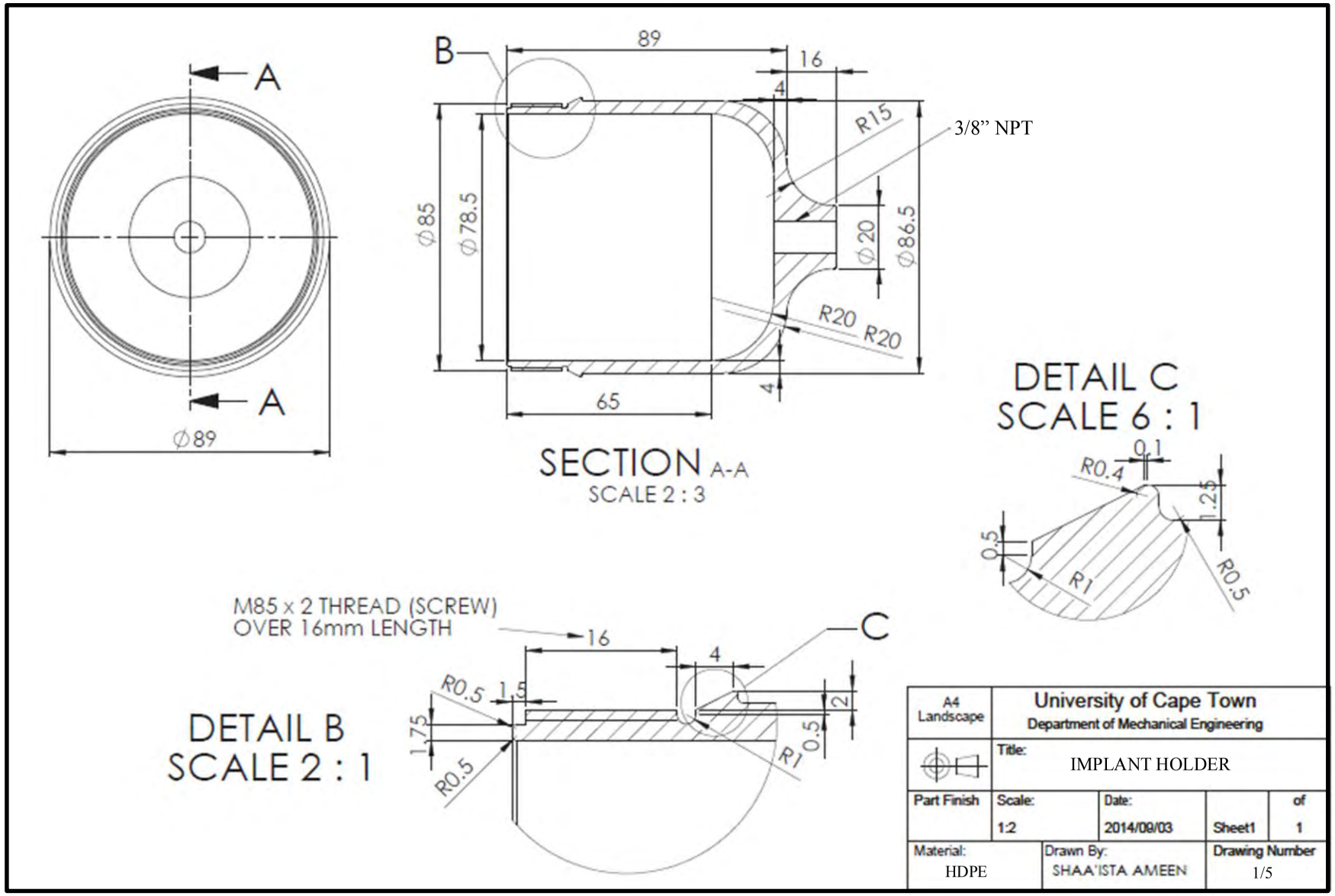
APPENDIX F – Prototype Design

Table F.1: Features/Components used for the purpose of the prototype that were not essential to proving the concept

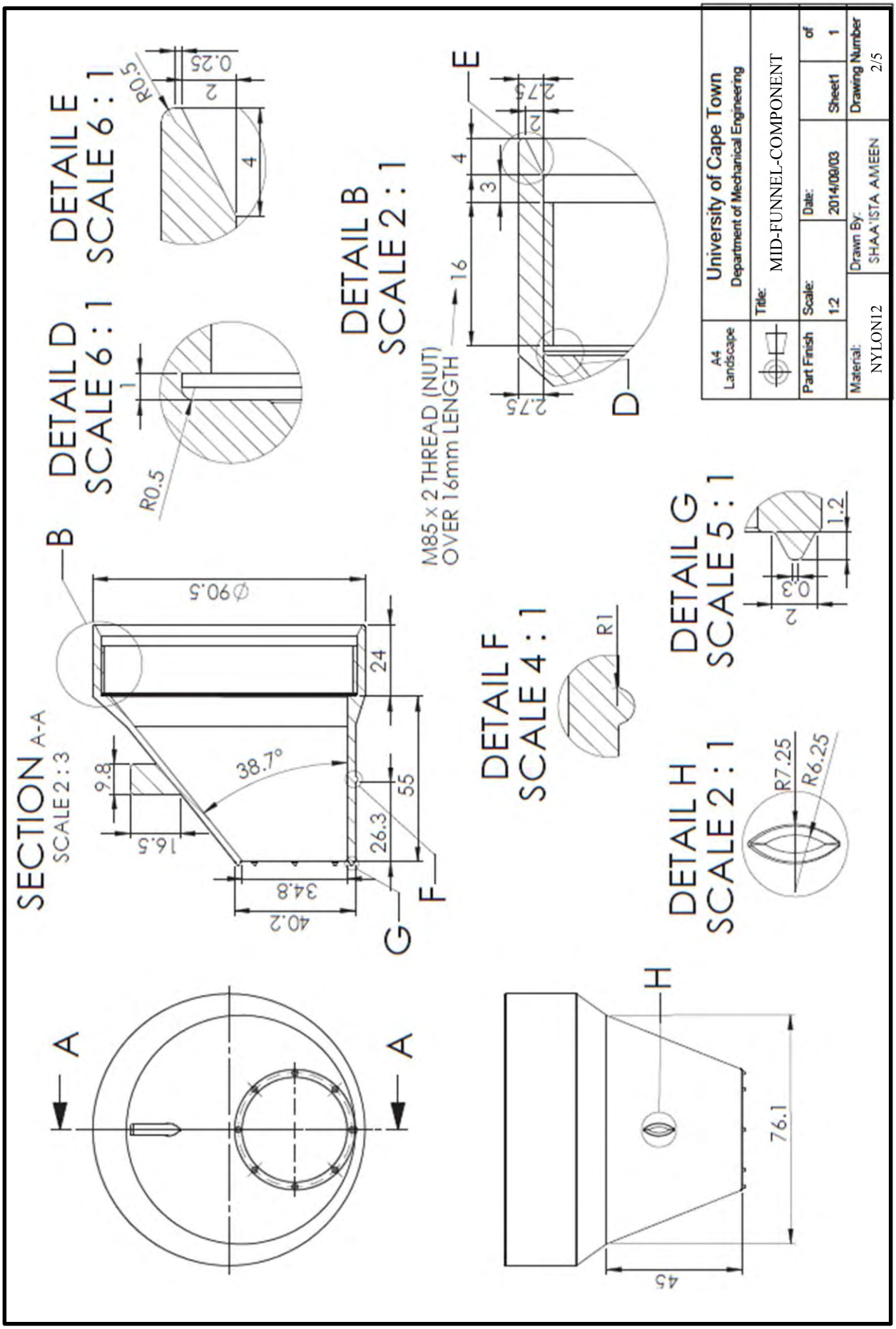
	Features/Components not essential to proving the concept		Feature/Components used for the purpose of the prototype
1	Attachment specifics of components (to each other) for device assembly	Mid-funnel- to implant-holder component	A standard M85 x 2 thread was determined as geometrically suitable. This allowed for a 3.25 mm minimum thickness of the implant-holder (at this site).
		Nozzle-component to the mid-funnel- and implant-holder components	Side handles were designed on the nozzle-component to accommodate a strap for holding the components of the device together upon insertion. This was also so as to ensure that the inverting-bag was securely held at the Plane of Inversion.
2	Additional components required for air supply control	Push-button control (with solenoid valve)	A manually operated (push-to-open) valve attached at the device inlet (via plastic piping). However, the presence of the push-button and wiring path was still considered in the design of the device handle.
		Valve connection (at the device inlet)	Due to the application of air pressure, a 3/8" NPT with the required fittings were used, i.e. with a female thread on implant-holder.
3	Specifics of the inverting-bag	With regards to the bag: • Material • Dimensions • Thickness	Thin film polyethylene bags (open on one end) were used for the inverting-bag – measured to be 0.05 mm in thickness. To account for an uneven wrapping of the inverting bag around the mid-funnel-component, a 0.2 mm gap was designed between the assembled nozzle and mid-funnel components. However, with no gap at the Point of Inversion

APPENDIX G – Engineering Drawings

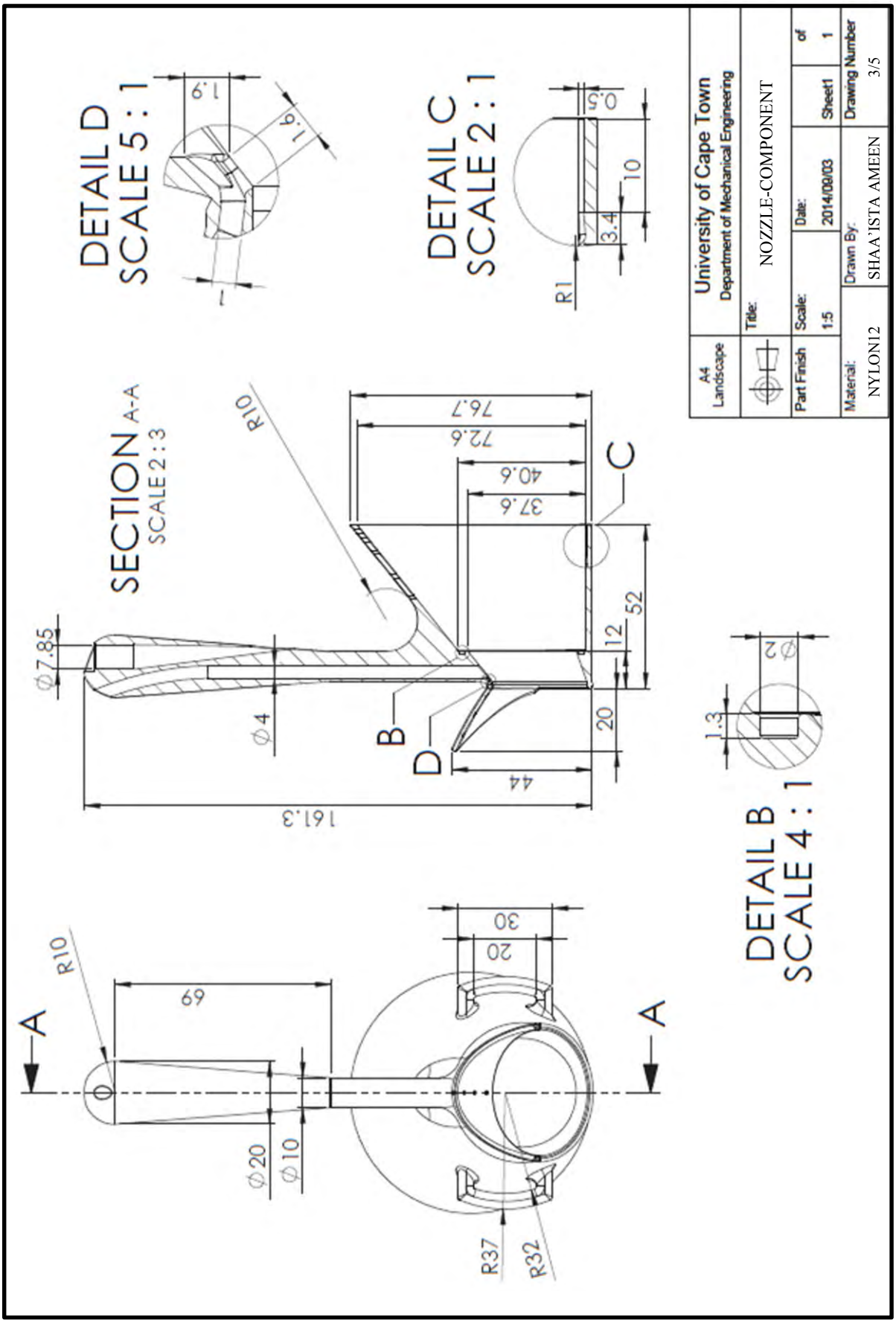
G.1. Implant-Holder

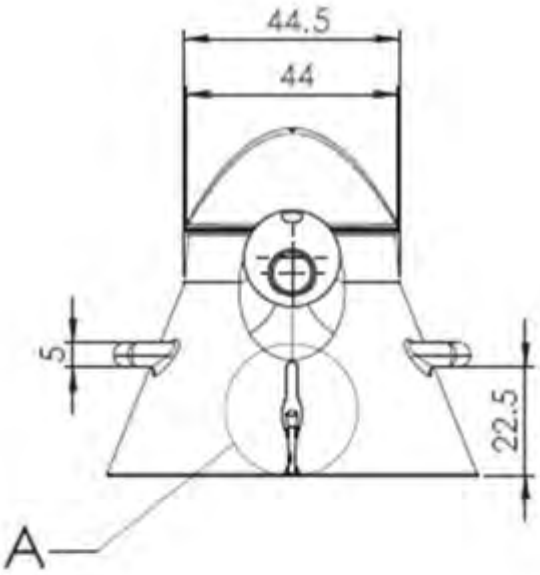


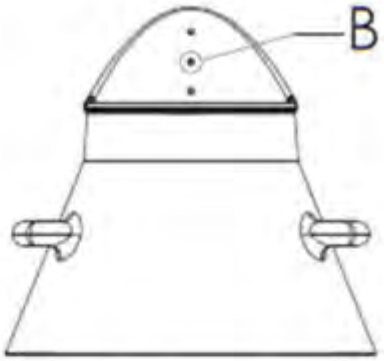
G.2. Mid-Funnel-Component



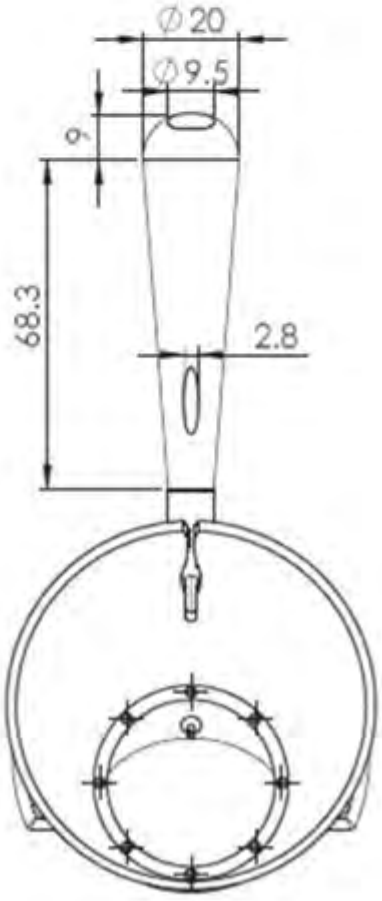
G.3. Nozzle-Component



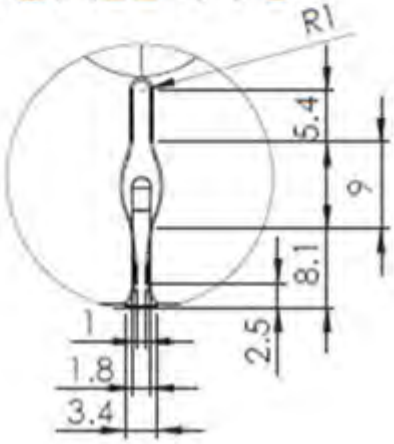




DETAIL B
SCALE 5 : 1

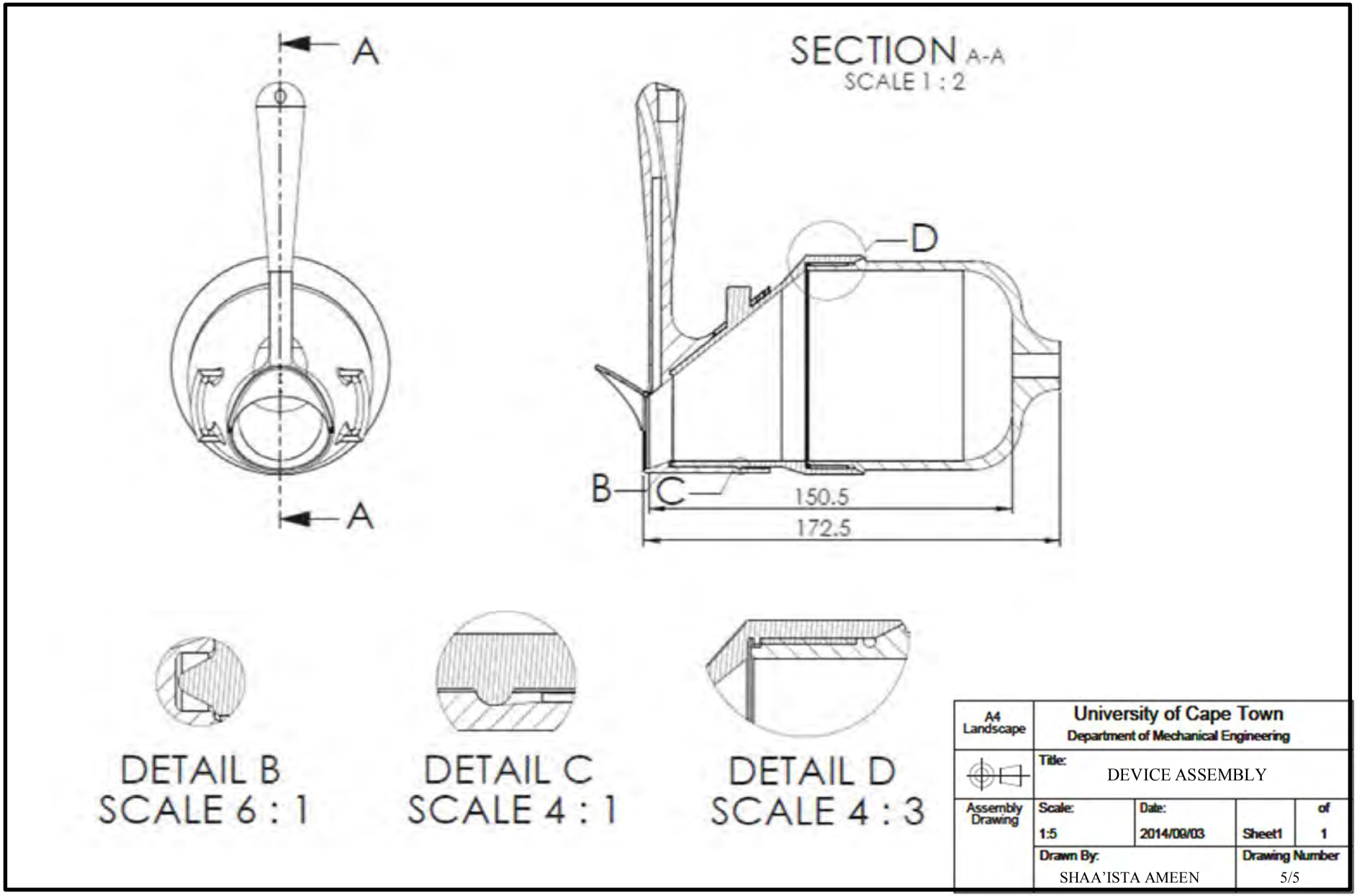


DETAIL A
SCALE 4 : 3



A4 Portrait	University of Cape Town Department of Mechanical Engineering			
	Title: NOZZLE-COMPONENT			
Part Finish	Scale: 1:2	Date: 2014/09/03	Sheet1	of 1
Material: NYLON12	Drawn By: SHAA'ISTA AMEEN		Drawing Number 4/5	

G.4. Device Assembly



APPENDIX H – Thickness and Thread Calculations

H.1. Force Provided By 1 bar Air Pressure

The force due to a 1 bar air supply at the cross-sectional area of the implant-holder was:

$$F = P \times A$$

Therefore,

$$F = (1 \times 10^5) \times \frac{\pi \times 0.0785^2}{4}$$

$$= \underline{483.98\ N}$$

H.2. Component Thickness Verifications

The tensile strength values used in the following calculations for sintered NYLON 12 (PA2200) and HDPE components were from Table 4.5.

H.2.1. Circular Thin-Walled Pressure Vessels Analysis

From equation 4-2 (rearranged):

$$t = \frac{Pd}{2\sigma_{TS}}$$

For sintered NYLON 12 (mid-funnel-component at Ø 78.5 mm):

$$t_{0.0785} = \frac{(1 \times 10^5) \times 2 \times 0.0785}{2 \times (45 \times 10^6)}$$

$$= \underline{1.74 \times 10^{-4}\ m}$$

For HDPE (implant-holder at Ø 78.5 mm):

$$t_{0.0785} = \frac{(1 \times 10^5) \times 2 \times 0.0785}{2 \times (32 \times 10^6)}$$

$$= \underline{2.45 \times 10^{-4}\ m}$$

H.2.2. Circular Thick-Walled Pressure Vessel Analysis

From equation 4-4 considering the internal, *i* and outer, *o* stresses at the corresponding radii:

$$\sigma_{ri} = C - \frac{B}{ri^2} \quad \text{(H-1)}$$

$$\sigma_{ro} = C - \frac{B}{ro^2} \quad \text{(H-2)}$$

$$\sigma_{ci} = C + \frac{B}{ri^2} \quad \text{(H-3)}$$

$$\sigma_{co} = C + \frac{B}{ro^2} \quad \text{(H-4)}$$

Due to the internal insertion pressure, *P*:

- Internal radial stress, $\sigma_{ri} = P \times SF$
- Outer radial stress, $\sigma_{ro} = 0$
- Internal circumferential stress, $\sigma_{ci} = \sigma_{TS}$ (of material)
- Outer circumferential stress, σ_{co}

For sintered NYLON 12 (mid-funnel-component at Ø 34.5 mm):

Solving for constants C and B from equation H-1 and H-2, with $r_o = 20.15$ mm (i.e. t = 2.9 mm)

$$1 \times 10^5 \times 2 = C - \frac{B}{0.01725^2}$$

$$B = C - (1 \times 10^5 \times 2 \times 0.01725^2)$$

$$B = C - 59.51 \quad \text{..... (1)}$$

And, $$0 = C - \frac{B}{0.02015^2}$$

$$B = (4.06 \times 10^{-4})\, C \quad \text{..... (2)}$$

Therefore, substituting B of (2) into (1)

$$C = 59.53$$

$$B = 0.024$$

Substituting C & B into equation H-3

$$\sigma_{ci} = 59.53 + \frac{0.024}{0.01725^2}$$

$$\underline{\sigma_{ci} = 141.56 \text{ Pa}}$$

H.2.3. Elliptical Thin-Walled Pressure Vessel Analysis

From equation 4-3 (rearranged):

$$t = \frac{Pa^2}{2b\sigma}$$

For sintered NYLON 12 (nozzle-component outlet):

$$t_{ellipse} = \frac{(1 \times 10^5) \times 2 \times 0.02^2}{2 \times 0.015 \times (45 \times 10^6)}$$

$$= \underline{5.93 \times 10^{-5} \text{ m}}$$

For HDPE ellipsoidal End-Cap (implant-holder):

$$t_{end\ cap} = \frac{(1 \times 10^5) \times 2 \times 0.03925^2}{2 \times 0.02 \times (32 \times 10^6)}$$

$$= \underline{2.41 \times 10^{-4} \text{ m}}$$

H.2.4. Elliptical Thick-Walled Pressure Vessel Analysis

From equation 4-5 considering the internal, *i* and outer, *o* stresses at the corresponding radii:

$$\sigma_{ri} = C - \frac{B}{(a_i \times b_i)} \quad \text{(H-5)}$$

$$\sigma_{ro} = C - \frac{B}{(a_o \times b_o)} \quad \text{(H-6)}$$

$$\sigma_{ci} = C + \frac{B}{(a_i \times b_i)} \quad \text{(H-7)}$$

$$\sigma_{co} = C + \frac{B}{(a_o \times b_o)} \quad \text{(H-8)}$$

Where, σ_{ri}, σ_{ro}, σ_{ci} and σ_{co} were as described in APPENDIX H.2.2.

For sintered NYLON 12 (nozzle-component outlet):

Solving for constants C and B from equation H-5 and H-6, with t = 2 mm

$$1 \times 10^5 \times 2 = C - \frac{B}{(0.02 \times 0.015)}$$

$$B = C - (1 \times 10^5 \times 2 \times 0.0003)$$

$$B = C - 30 \quad \ldots\ldots (3)$$

And, $$0 = C - \frac{B}{0.022 \times 0.017}$$

$$C = (3.74 \times 10^{-4})\ A \quad \ldots\ldots (4)$$

Therefore, substituting B of (4) into (3)

$$C = 60.02$$

$$B = 0.022$$

Substituting C & B into equation H-7

$$\sigma_{ci} = 60.02 + \frac{0.022}{0.02 \times 0.015}$$

$$\underline{\sigma_{ci} = 133.35 \text{ Pa}}$$

H.3. Thread Verification

For HDPE M85 × 2 thread:

From equation 4-6

$$A_t = \frac{\pi}{4}[0.085 - (0.938194 \times 0.002)]^2$$

$$= 5.427 \times 10^{-3}\ m^2$$

From equation 4-7 (rearranged):

$$P = \frac{\sigma_{TS} \times A_t}{A \times SF}$$

$$P = \frac{(32 \times 10^6) \times (5.427 \times 10^{-3})}{\frac{\pi 0.0785^2}{4} \times 2}$$

$$= \underline{17.94 \times 10^6 \text{ Pa}}$$ - This is larger than the 1 bar internal pressure. With the higher tensile strength of the NYLON 12 (mid-funnel-component), this thread will also be effective in withstanding the internal pressure.

APPENDIX I – Experimental Investigation Results

I.1. Plunger Test

Table I.1: Relevant plunger test constants

Plunger mass, m_p	kg	0.3
Plunger weight, W_p	N	2.943
Implant-holder internal Ø, d	m	0.0785
Implant-holder cross-sectional area, A	m^2	4.8398×10^{-3}

Table I.2: Plunger test results

No.	Shell Type	Gel Type	Volume (cm^3)	Shape	Mass Required, m_{req} (kg)	Total force, F_T (N)	Require Pressure, P_{air} (bar)	Comment
1	Textured	Mod. Hard	133.33	Anatomical	10	101.043	0.208774	Very quick plunge (10 seconds). No sign of the implant through the device outlet. No implant damage observed.
5	Smooth	Mod. Soft	180.95	Round	35	346.293	0.715508	Quick plunge (20 seconds). Very slight implant damage.
7	Textured	Very Hard	238.10	Anatomical	45	444.393	0.918202	Quick plunge (30 seconds). Slight implant damage
9	Smooth	Mod. Soft	295.24	Round	40	395.343	0.816855	Much longer plunge period than no. 7 (1.5 minutes). Implant shape deformation and gel fracture.
10	Textured	Very Soft	357.14	Round	49	483.633	0.999279	Quick plunge (30 seconds). Very slight implant damage
11	Smooth	Mod. Hard	380.95	Anatomical	49	483.633	0.999279	Much longer plunge period than no. 10 (3 minutes). Implant shape deformation and gel fracture.
12	Smooth	Mod. Soft	395	Anatomical	29	287.433	0.593892	Quick plunge (30 seconds). Implant shape deformation and gel fracture.

From Table I.1:

$$W_p = m_p \times g \quad \text{(I-1)}$$

$$A = \pi d^2 \quad \text{(I-2)}$$

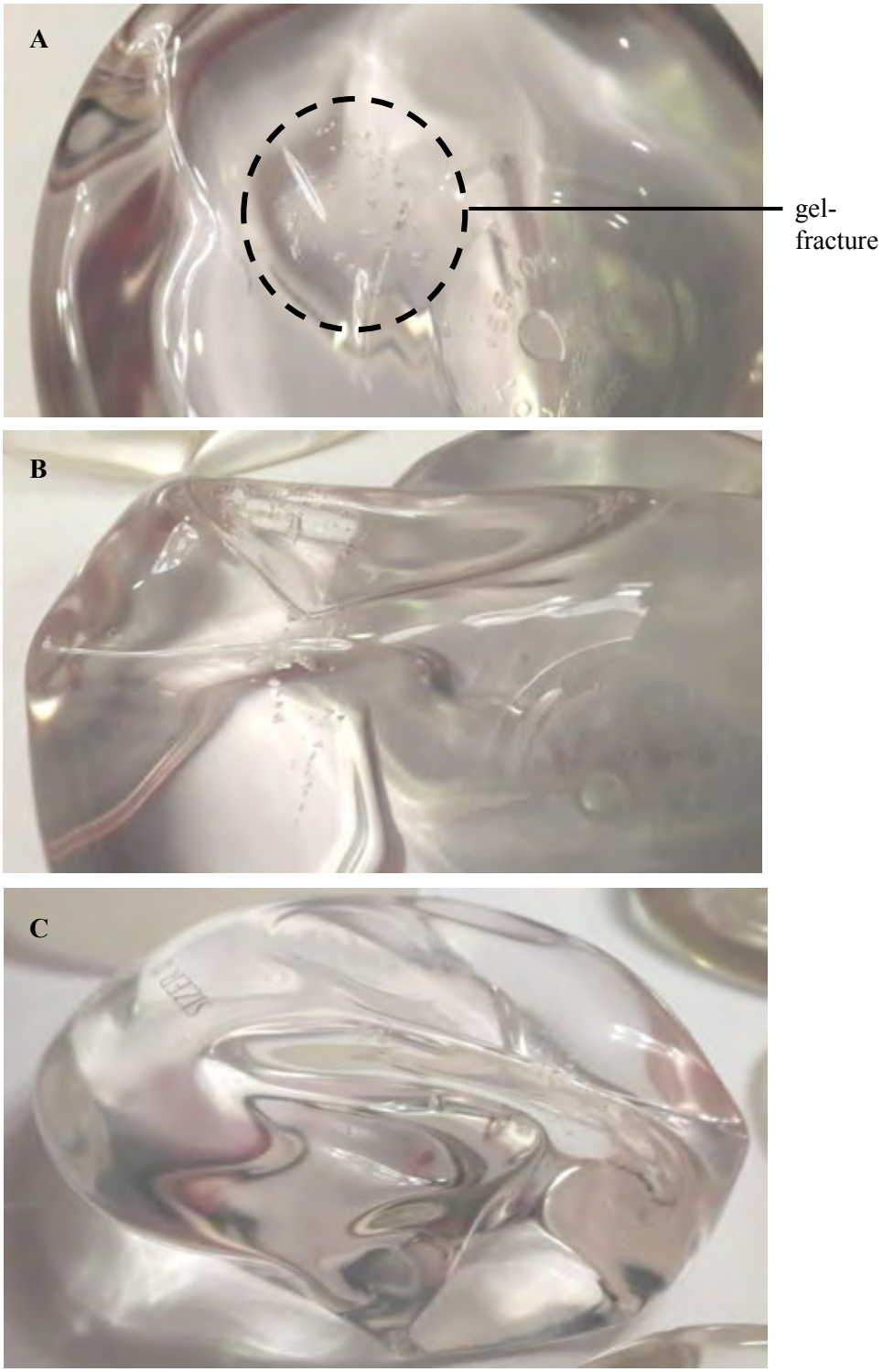


Figure I.1: Post-plunge damage of (A) implant no. 9 (295.24 cm^3), (B) implant no. 11 (380.95 cm^3) and (C) no. 12 (395 cm^3)

I.2. Silicone Breast-Model Test

Table I.3: Silicone breast-model test results

No.	Shell Type	Gel Type	Volume (cm^3)	Shape	Insertion Time (seconds)				Comments
					Test 1	Test 2	Test 3	Average	
8	Textured	Mod. Soft	242.86	Anatomical	2.5	2.5	2.5	2.5	Slight damage on implant at the point at which the implant was grabbed for removal from the breast model.
18	Smooth	Mod. Hard	270	Anatomical	3	3	3	3	Slight damage on implant due to grip for removal from the breast-model.
19	Textured	Mod. Soft	295.24	Round	3	3	2.5	2.8	Slight damage on implant due to grip for removal from the breast-model
10	Textured	Very Soft	357.14	Round	3	4	3	3.3	**Test 1**: a 'pop' sound was heard just before the implant was inserted. The implant was inserted up-side down. **Test 3:** 1st try unsuccessful, inverting-bag tore.
11	Smooth	Mod. Hard	380.95	Anatomical	3	4	3	3.3	**Test 1**: 1st try 'pop' sound with unsuccessful insertion, inverting-bag was torn. 2nd try 'pop' sound with successful insertion, inverting-bag was torn.
12	Smooth	Mod. Soft	395	Anatomical	3	2.5	2.5	2.7	**Test 1**: slight 'pop' with successful insertion. Inverting bag tore and implant orientation was slightly incorrect. **Test 2:** 1st try unsuccessful, inverting-bag tore with no 'pop' sound.
20	Smooth	Mod. Hard	400	Anatomical	4	4	4.5	4.2	Slight damage on implant due to grip for removal from the breast-model.
13	Textured	Very Soft	428.57	Round	2.5	3	3	2.8	Slight damage on implant due to grip for removal from the breast-model.

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