Approved by: O. Gunning 30/07/2020
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Risk Management Report
Benefit-Risk Analysis Report

Project Title: Silicone Breast Forms
Project Description: Breastcare Silicone breast form range
Project Leader: Elle Coughlan

Purpose and Scope:

This Risk Management Report covers the Benefit-Risk analysis of Trulife Breastcare Silicone product range. The report aims to establish if there is a positive Benefit-Risk ratio for Silicone BP products and has the Risk Management Plan been effectively implemented in accordance with the EU Medical Device Regulation 2017/745.

Intended Use

Breastcare Prosthesis are designed to be used as a replacement of a natural breast.

Characterization of the Disease:

A mastectomy is a surgical procedure to remove tissue from a breast as a way to treat or prevent breast cancer. Another option for early-stage breast cancer is breast conserving surgery (lumpectomy) which is when only the tumour is removed from the breast.

There are several different types of mastectomy surgeries:

Total Mastectomy: the entire breast is removed including the nipple, areola and skin; some underarm lymph nodes may be removed also.

Skin Sparing Mastectomy: most of the skin of the breast is left intact and only the breast tissue, nipple and areola is removed. Implants and tissue from other parts of the body can be used for reconstructive surgery.

Nipple Sparing Mastectomy: breast tissue is removed but skin, nipple and areola are left and can be followed with breast reconstruction.

Modified Radical Mastectomy: total mastectomy with the removal of the lymph nodes under the arm

Radical Mastectomy: an extensive surgery that removes the entire breast, underarm lymph nodes and pectoral (chest wall) muscles under the breast.

Double (bilateral) Mastectomy: both breasts are removed as a precaution for high risk patients of getting breast cancer.

Nature of the Treatment and Use of the Device:
Trulife Silicone breast forms are designed to be used in the replacement of a natural breast. The breast form can either be placed directly against the chest wall or in the pocket of a mastectomy bra. Suited for patients with failed reconstructions or some breast tissue remaining and only a partial breast form is needed, a silicone breast form shell can be used to fill out were natural breast tissue is missing. Patients should be sized by a trained fitter for product sizes.
Summary of Alternative Treatments:
Alternatively, to a silicone breast form, breast reconstructive surgery is an option for some patients when some breast tissue remains or a skin transplant from another part of the body is used. This alternative is not always an option and can result in extensive scaring, hard immovable implants and uneven breast balance between the patient's reconstruction and remaining natural breast.
Benefits of Treatment using the Device:
Using a Trulife Silicone breast form gives the user a choice in choosing a form that fits their needs. The range covers different footprint shapes, fullness, densities, skin tones, and nipple/ areola sizes. By using a silicone breast form this gives the user an alternative to reconstructive surgery and allows them to choose a breast form that is soft at touch and is comforting to sit against surgical scar tissue of the chest wall.
Risks Associated with Device Use:
Risks Associated with the use of a Trulife Silicone Breast form has been recorded in the Risk Management file SRD22 for Silicone Breast forms in accordance with Trulife procedure RD11 Risk Management. For this device the risks identified were of potential skin irritancy due to the materials being used and the product being in direct contact with the user's skin. The maximum severity associated with the use of these devices is Rated with a Severity = 4. Non-significant skin rash, slight patient discomfort. Customer complaints matrix for 2020, shows there have been no reports or injury associated with the use of these devices in 2020. Potential risks associated with the device are evaluated to implement suitable risk controls is reducing their likelihood of occurrence.
Risk Reduction
The risks associated with using these products were analysed using for SRD22 – Risk Management File in accordance with Trulife Risk Management procedure RD11. All risks associated with the device as evaluated through an FMEA analysis and controls are implemented to reduce the risk as far as possible by means of Safe Design and Manufacture, Protection and Information for Safety, where applicable.
Post Market Data:
Post Market data from Breastcares Silicone breast forms has been documented in the Post market Surveillance Report SQM73. The report has the following conclusions: 1. The Post Market Surveillance of Breastcares Silicone Breast form range were successfully completed. 2. The Post Market Surveillance report shows that the Silicone Breast forms are safe and effective

products and no corrective actions are required based on the data reviewed as part of this study.

3. The articles and reports assessed for the literature search were positive towards the use of External Breast prosthesis in place of a natural breast after mastectomy procedures. The psychological benefits of using external breast prosthesis are evident in the literature reviewed.
4. Overall customer feedback on the quality and need for a Trulife Silicone Breast forms was positive.
5. On review of customer complaints, warranty covers were the main source of complaint. The threshold set for warranty returns was exceeded in 2020, Target set at 0.12% and the end of 2020 coming in at 0.5%. The warranty complaints for 2020 will be reviewed to identify the cause to the high returns rates.
6. Searched on MAUDE and MHRA databases did not reveal any incidences of adverse events from these devices.
7. The studies reviewed show that using silicone breast prosthesis can have a positive psychological and physical benefit to its users.

A review of the information in the Post Market Surveillance report has identified no new or unrecognized risks and no risks that are no longer acceptable.

Benefit-Risk Analysis

The risks associated with the use of Trulife Silicone Breast form are evaluated at having a low to moderate severity rating with a low likelihood of occurrence. The residual risks after risk controls have been implemented are viewed against the benefits of using the products over alternative methods of breast symmetry and balance. The risk information has been taken from the Silicone Breast Forms Risk Management file SRD22 and the benefits have been taken from Clinical Evaluation Report SRD39. FMEA analysis of each risk is reduced as far as possible by implemented controls. The risk is reduced and deemed acceptable by Trulife, resulting in the benefits of using the device to outweigh any residual risks.

Stakeholder Perspectives

Trulife has been developing breast forms for over 60 years and the range of products has grown extensively with an increasing demand from customers and the advances in new materials and manufacturing processes creating a need for product development. Continual feedback from customers is encouraged and suggestions enhancing product performance and safety have been taken on board which is evident from the product developments documented.

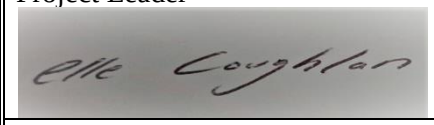
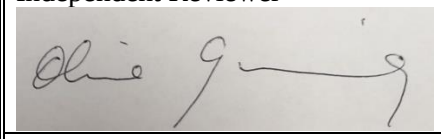
Benefit-Risk Summary:

Benefits of using Trulife Silicone Breast forms far outweigh the risks associated with the use of the device. No reports of products negatively impacting on patient safety. The research conducted as part of the Post-Market Surveillance of all Silicone breast forms has identified many reports which show the benefits of using external breast prostheses for patients who have had a mastectomy.

Conclusions and Recommendations:

1. Benefits of using a Silicone Breast form outweigh its risk; therefore, a positive Benefit-Risk ratio has been achieved.
2. The continual use of any Silicone Breast forms has not resulted in any adverse events or a need for corrective action.

Prepared by: Katie Smullen & Elle Coughlan Date: 27.04.2021

Approvals:	**Date:**
Project Leader 	30.04.2021
Independent Reviewer 	30.04.2021
Marketing / Clinical 	30.04.2021

Clinical Evaluation Plan

Device name: Breastcare Silicone Breast Forms
Date: 22.04.2021

Identification of GSPR that requires support from clinical data

As a general requirement of the GSPR a device shall be safe and effective and not compromise the clinical condition or the safety of patients. Supporting clinical data from the Clinical Evaluation Report will assess the devices safety and performance and that any residual risks associated with the device can be comparable to a high level of safety to the user.

1.0 Scope of Clinical Evaluation

1.1 General Details

Identification of device(s)

<table>
<tr><td>Devices covered in report</td><td>The Silicone breast form range are categorized into product ranges as follows:
- Lightweights
- Traditional
- Recovery
- Partials
- 100% Silicone

Full list of products can be found in the device DOC.</td></tr>
<tr><td>Name of device or product family</td><td>Breastcare Silicone Breast Forms</td></tr>
<tr><td>Dimensions, sizes</td><td>
<table>
<tr><th>Code</th><th>Name</th><th>Size</th><th></th><th></th><th></th></tr>
<tr><td>151</td><td>Subline Aris</td><td>3-14</td><td>473</td><td>Silk Teardrop</td><td>1-14</td></tr>
<tr><td>152</td><td>Sublime Sensation</td><td>XS-XL</td><td>475</td><td>Silk A Supreme</td><td>1-14 L&R</td></tr>
<tr><td>822</td><td>Recover-Shell</td><td>S-XL</td><td>476</td><td>Silk Connect</td><td>1-10</td></tr>
<tr><td>509</td><td>E Supreme</td><td>1 -17</td><td>478</td><td>Silk Xtend</td><td>1-14 L&R</td></tr>
<tr><td>503</td><td>A Supreme</td><td>1 -14 L&R</td><td>477</td><td>Silk Flex</td><td>1-14</td></tr>
<tr><td>508</td><td>Symphony</td><td>1 -14</td><td>481</td><td>Silk Ultima Triangle</td><td>1-14</td></tr>
<tr><td>641</td><td>Tropez</td><td>1-14</td><td>485</td><td>Silk Curve</td><td>2-14</td></tr>
<tr><td>533</td><td>Triangular Partial</td><td>3-9</td><td>490</td><td>BodiCool Triangle</td><td>1-14</td></tr>
</table>
</td></tr>
</table>

	531	Partial	1-12	495	BodiCool Wave Triangle	1-17
	571	Bella	3-14	496	BodiCool Wave Teardrop	1-14
	701	Duette Triangle	1-14	110	Impressions Shell	S-XL
	545	Evenly You Triangle Plus	3-9	101	Impressions II	2-12
	471	Silk Triangle	1-17	102	Impressions II Encore	4-12
	483	Silk Encore Triangle	1-17	356	Teardrop Partial Encore	1-11
	472	Silk Triangle Plus	1-17	497	BodiCool Assymetrical	2-10 L&R
	153	Cara		498	Asymetrical	2-10 L&R
				535	Tri- Partial Encore	3-9

Accessories	Breast form COOLMAX fabric covers for Traditional, Silk and Impressions Breast forms.  Cool Pad and Comfort Pad only for Cara Breast form. 
Classification of device	Breast Prosthesis are classified as Class 1 non- active, non-invasive devices according to the MDR 2017/745

1.2 Manufacturer

Legal Manufacturer	Trulife Airton

1.3 Device Description

Physical description of device, incl images or drawings if applicable	Trulifes Silicone Breast forms are all manufactued using medical grade silicone. Each product is moulded by either filling the mould directly with silicone and sugar beads or filling a PU film bag with silcone and leaving it to set in a mould for the desired shape.   A selection of products have additional features such as an adhesive backing or comforable back. 
Technology used	RF Welding is used to create the PU film bags for the filled breast form products. The heat moulding is used for the 100% silicone products, silicone is directly dispensed into the mould and heated to cure into shape.
Packaging variations and sizes	

Packaging for PU Film and Silicone Gel products

This packaging consists of a card box and a plastic cradle to hold the product in place. The plastic cradle comes in a range of sizes to fit the products.

Packaging for Silicone Products

This packaging consists of a hard card box and a card cradle that can be cut to size depending on the product.

	Cara Packaging  This packaging consists of a hard card box and a grey foam insert. The accessories and stored under the foam support.

1.4 Intended Purpose

Intended use in alignment with IFU	Breastcares Prosthesis are designed to be used as a replacement of a natural breast.
Contraindications	None
Warnings	None
Precautions	none

1.5 Intended Target Groups

Intended users	Patients who have had a mastectomy or lumpectomy and are in need of prosthesis designed to replace a natural breast or breast tissue.

1.6 Clinical Benefits of Device

Intended clinical benefits to patient	Trulife Silicone breast forms are intended to provide symmetry between the patient's natural breast and the surgical side by providing a natural drape and fullness much like a natural breast would.

1.7 Clinical Outcomes of using device

Using a Trulife Silicone Breast Form gives the patient a more symmetric appearance to their chest and provides fullness and balance in place of a natural breast.

2.0 Device Safety and Performance

2.1 Methods of examining aspects of clinical safety and performance

Feedback	Customer questionnaires are sent out to retrieve back feedback on how the device is performing and is it continuing to provide a safe and effective purpose as intended.
Trialled Samples	Panel fitting events are arranged to trial the products with users and receive feedback on their experience and on how the product preforms.

2.2 Methods for determining residual risks

Risks are determined to be reduced as far as possible when the probability of occurrence can be shown to have been reduced due to controlled measures put in place.

2.3 Side effects

No known side effects to using Breastcares Silicone Breast Forms

2.4 Parameters for acceptability of benefit risk ratio

Acceptability of Benefit-Risk Ratio	Risk will only be accepted when it has been demonstrated that the benefits of device use outweigh the risks associated with the device. Risks will only be submitted to Benefit-Risk analysis when these risks have been reduced As Far As Possible given the generally accepted state of the art.

Reference to risk management document: SRD22- Risk Management File can be located in the devices Technical file.

2.5 Identification of benefit-risk issues related to specific components such as pharmaceuticals, non-viable human or animal tissues

Breastcare products do not contain any specific components such as pharmaceutical or non-viable human or animal tissues.

2.6 Clinical Investigations development plan

Breastcare products are Class 1 devices that are not required under the MDR 2017/745 to perform Clinical Investigations.

2.7 Device Changes

Any modifications made to the device since last report?	No modifications have been made to these devices since being launched onto the market.

3.0 Clinical Evaluation

3.1 Literature Search Protocol

Data retrieved from literature .i.e. device equivalence, acceptance of articles, which databases will be used.	
The PubMed (Medline) and Science Direct databases were used to retrieve literature sources and were accepted as article and reports that are relatable to the purpose and objectives of Breastcare products.	
Period covered by search	2000-2021
Literature sources used	1. School of Nursing and Midwifery Karachi, Pakistan 2017 - Women Experiences of Using External Breast Prosthesis after Mastectomy, Zohra Asif Jetha. 2. The Breast Journal 2009, - Long-term role of external breast prostheses after total mastectomy, Simone W. Glaus, Volume 15 no. 4, pp 385-393. 3. Indian Journal of Surgical Oncology 2015, - Pattern of External Breast Prosthesis Use by Post Mastectomy Breast Cancer Patients in India: Descriptive Study from Tertiary Care Centre, D. Ramu, Volume 6 no. 4, pp 374-377. 4. Journal of Biomedicine and biotechnology 2017, - Can the Weight of an External Breast Prosthesis Influence Trunk Biomechanics during Functional Movement in Post mastectomy Women, Katerzyna Hojan. 5. Polish journal of surgery 2015, - Why women who have mastectomy decide not to have breast reconstruction? Tomasz Zielinski, Volume 86 no.10, pp 451-455.
Included filters for search	Full articles Review articles Literature findings are in English Clinical studies
Excluded filters for search	Abstracts Non-English language reports or articles

	Reported outcomes that are not relevant to the purpose of literature review search
keywords	External Breast Prosthesis Mastectomy Prosthesis

3.2 Clinical Data Generated by Manufacturer

List of clinical data documents	Validation Report Clinical Evaluation feedback Post Market Surveillance Report Vigilance Report Trend Report

3.3 Appraisal of data

The data obtained through literature searches evaluated to determine their suitability for establishing the safety and performance of the device. Data will be evaluated for its suitability through a series of questions that are asked about the literature towards its suitability to the medical device safety and performance.

Completed by: Katie Smullen & Elle Coughlan Date: 23.04.2021

Customer Information - BreastCare

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Appendices
Appendix (A) Declaration of Conformity
Appendix (B) ISO Certificate
Appendix (C) BreastCare IFU
Appendix (D) BreastCare Catalogue

Section 1 – Manufacturers Details

1.1 Declaration of Conformity

An EU Declaration of Conformity (DoC) is a mandatory document that declares, as a medical device manufacturer, we are in conformity with the regulations as set out in MDR 2017/745. Our EU Declaration of Conformity for our BreastCare products can be found in Appendix (A). This includes the company's information, the name of the devices and their codes, their Basic UDI, intended use, the classification and rule, a statement taking responsibility for the products, and a signature on behalf of Trulife

1.2 Quality Management System

Trulife has been assessed and deemed to comply with the requirements of EN ISO 13485:2016. A copy of this certificate can be found in Appendix (B) of this document.

1.3 Information supplied by the Manufacturer – Labelling and Packaging

Examples of our standard product labelling and packaging can be seen in the images below. Our Instructions for Use (IFU's) can be found in Appendix (C). The IFU contains the basic operational "how to" information as well as any cautions and other general or device specific information. The IFU includes the regulatory steps that must be taken should any serious adverse incident take place with the product, or should patient safety be compromised.

All labels and packaging are compliant to EN ISO 15233-1 Medical Devices Symbols and the EU MDR 2017/745.

Any changes to labelling or packing are carried out as per our internal document control procedures. This ensures that the labels and packaging received by the customer have been reviewed and approved for use.

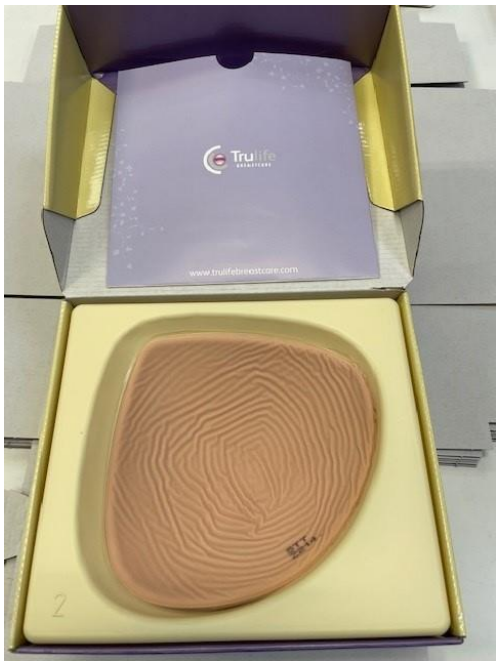

Image of Inner Packaging of BreastCare products

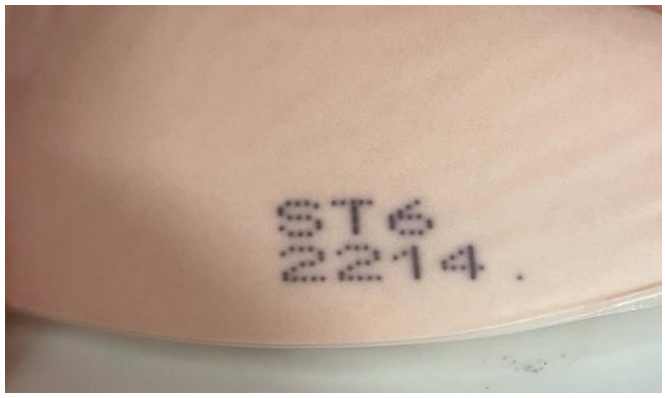

Image of Transfer on BreastCare products

Image of Outer Labels on BreastCare products

1.4 Risk Management

Trulife's risk management process is performed in accordance with the methodology described in ISO 14971:2019. Trulife has the relevant product expertise and historical experience to assign the appropriate risks to the products and risks identified during risk management determine internal and external testing requirements. All risks are reduced as far as possible and have an acceptable benefit-risk level.

1.5 General Safety and Performance Requirements

Our products achieve the intended performance and are designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.
The General Safety and Performance Requirements in accordance with Annex I of the European Medical Device Regulation 2017/745, for the BreastCare product range has been evaluated and is documented in our technical documentation.

Section 2 Product Design, Specification and Manufacture

2.1 Product Design

The Design History File retains all pertinent project data, (i.e. design verifications and validations, design transfer etc.) to demonstrate compliance with the design plan and all applicable regulations. The design control process ensures confidence that our products are safe, reliable, efficacious and meet all regulatory requirements prior to release for market. This is initiated for the following situations;

- The design and development of new products
- Changes to existing products following post market feedback
- Publication of the new or revised harmonised standards

2.2 Product Specification and Manufacture

Specification

For the complete range of Trulife BreastCare products and specifications, please refer to our catalogue in Appendix (D) and/or www.trulife.com

Manufacture

The BreastCare Product range are made up into three main families. The name of each family and an overview of the manufacturing steps to make these products are listed below.

P.U film and Silicone

- Sheets of polyurethane film are heat sealed to form the shape of the product of a particular size.
- The formed bag is then filled with silicone gel (Two- part addition cure gel).
- The neck of the bag is heat sealed.
- The product is moulded and cured for 4 hours.
- The product is inspected and trimmed.
- The product is then packed.

100% Silicone

- BP mould is filled with silicone to create a skin layer.
- After curing, mould is then filled with sugar bead and closed for filling.
- Mould is filled again with more silicone into the sugar beads.
- Once cured, product is demoulded, inspected and sent to be washed.
- The product is placed into an over to dry overnight.
- The product is then inspected, trimmed, and packed.

Foam

- Foam blocks are positioned onto a dye board that is the template for the BP size to be cut.
- Foam block and dye board are rolled through a cutting machine.
- Excess foam separates from the BP shape.
- Weighted BP's have silicone paste PU bag inserted into cut out at back of the BP.
- Plugs for the back of weight BPs are cut out of the same foam using a clicker tool.
- Glue is added to the back of the weighted PU bag and plug is pressed into place.
- The product is weighted, inspected, and trimmed.
- The product is then packed.
- Unweighted products, after cutting are inspected, trimmed and then packed.

All of Trulife products are non-sterile, latex free and do not contain phthalates. All raw materials used in BreastCare products comply with the requirements of the REACH Regulation and the RoHS Directive.

2.3 Routine Production

All inspection and test procedures carried out in the production area are in accordance with ISO 13485:2016. These procedures, work sheets etc. and the training associated with the proper performing of these tasks form part of the ISO 13485:2016 quality management system.

2.4 Traceability

All products are printed with a four-digit Lot number in YY/WW format. This ensures that all materials that were utilised in the manufacture of the product are traceable. Once packed, the Lot number and Date of Manufacture (DoM) are printed on the product packaging label and incorporated in a fourteen-digit G.T.I.N barcode. This allows for continued downstream traceability of our products throughout the supply chain.

2.5 Shelf Life and Product Life Cycle

Our BreastCare products are guaranteed for a period of two years from date of manufacture. Based on relevant durability testing, the product life cycle for BreastCare products is five years.

Section 3 Testing

3.1 Physical Testing (Internal)

BreastCare products are tested to verify all products meet their intended use. Our design inputs and product risk analysis dictate what testing is required. All testing carried out is documented.

Push Pull

The Push Pull test is used to determine the durability of a product and to stimulate the daily handling of a breast form being fitted in and removed from a bra pocket. BreastCare products are repeatedly compressed and pulled to demonstrate the placing and removing of the product from a bra.

Temperature Storage

The temperature that a product can be stored in is very important for product durability. Our products are tested in both freezer (-20°C) and oven temperatures (200°C) to ensure no permanent changes to the products occurs.

Panel Fitting

This test is used to evaluate the overall product characteristics with a target market group. Panel fitting us performed to gain feedback on the products performance and fit. The patient is given the breast corm to wear as they would their own breast form for a period of time. The feedback is reviewed towards product safety and performance validation.

Altitude

To determine if our silicone breast forms can withstand high altitudes, our altitude tests are conducted. Air travel is a popular mode of product transport that can have an effect on the products material behaviour at high altitudes.

Cleaning Test

Ease of cleaning is an important feature of Trulife products. The disinfectant cleaner market is very diverse with a wide range of cleaning solutions and suppliers. Therefore, we test the main chemistries found in a selection of cleaners. When testing a range of chemistries, we assess their effort on the products physical composition to ensure no damage occurs to the product. A list of recommended tested chemistries is available. Trulife products are recommended to be cleaner with a damp cloth of diluted cleaning solution and should not be submerged into any liquids, as this may affect the long-term durability of the products.

3.2 Biocompatibility Testing (External)

Irritation / Cytotoxicity Tests

Only in certain circumstances are we prepared to perform cytotoxicity and/or skin irritation tests for ISO 10993. Typically, these tests are not performed for low risk, non-invasive medical devices. Third party test facilities used by Trulife to carry out this external testing are ISO/IEC 17025 approved.

3.3 Clinical Evaluation Procedure

Trulife perform clinical evaluations to demonstrate the safety and effectiveness of our product throughout the collection, analysis and assessment of clinical data relating to the BreastCare product range. (Annex I MDR 2017/745)

This procedure is carried out during the validation phase of the design and development process prior to launching the medical device on the market.

Only products that are clinically evaluated and approved are launched onto the market.

3.4 Post Market Surveillance

The purpose of Post Market Surveillance (PMS) is to identify previously unrecognised adverse effects, as well as positive effects and to ensure that our products continue to be safe and effective on the market. Our PMS system consists of three main areas;

1. Customer Complaints, Trend Reports and Reportable Incidents
2. Direct feedback from customers
3. Review of published information

As per EU MDR 2017/745 Articles 83-86, Trulife's PMS procedure documents all post market surveillance activities.

3.5 Complaints Handling

Our complaints procedure complies with the requirements for handling complaints and processing incidents that are reportable to a regulatory body. The Quality Department performs regular trend analysis of reported incidents to provide useful information about the company's products and for the potential initiation of corrective / preventative actions.

Our customers complete an SQM4 Complaints Description Worksheet, stating if a patients safety was at risk, and email it to Quality_Department@trulife.com