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Authorised by: M. Dempsey 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.

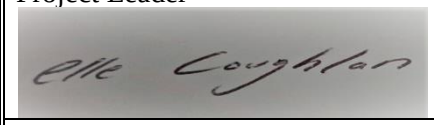
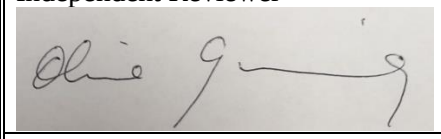
Benefit-Risk Summary:

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
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