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)

Devices covered in report	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.
Name of device or product family	Breastcare Silicone Breast Forms
Dimensions, sizes	

Code	Name	Size	Code	Name	Size
151	Subline Aris	3-14	473	Silk Teardrop	1-14
152	Sublime Sensation	XS-XL	475	Silk A Supreme	1-14 L&R
822	Recover-Shell	S-XL	476	Silk Connect	1-10
509	E Supreme	1 -17	478	Silk Xtend	1-14 L&R
503	A Supreme	1 -14 L&R	477	Silk Flex	1-14
508	Symphony	1 -14	481	Silk Ultima Triangle	1-14
641	Tropez	1-14	485	Silk Curve	2-14
533	Triangular Partial	3-9	490	BodiCool Triangle	1-14

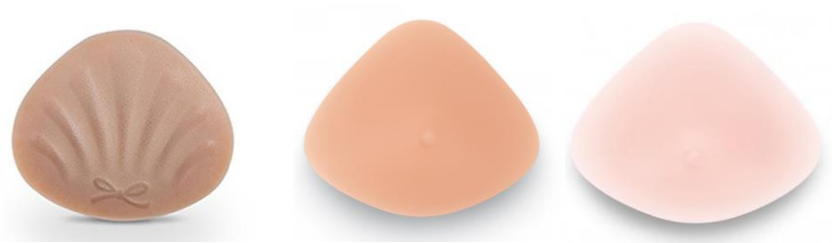
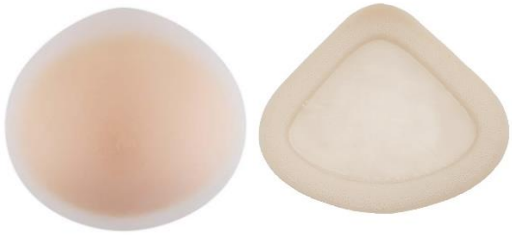
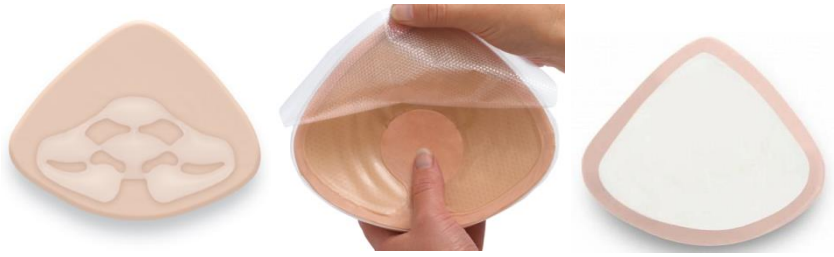
	531	Partial	1-12	495	BodiCool Wave Triangle	1-17
	571	Bella	3-14	496	BodiCool Wave Teardrop	1-14
	701	Duette Triangle	1-14	110	Impressions Shell	S-XL
	545	Evenly You Triangle Plus	3-9	101	Impressions II	2-12
	471	Silk Triangle	1-17	102	Impressions II Encore	4-12
	483	Silk Encore Triangle	1-17	356	Teardrop 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

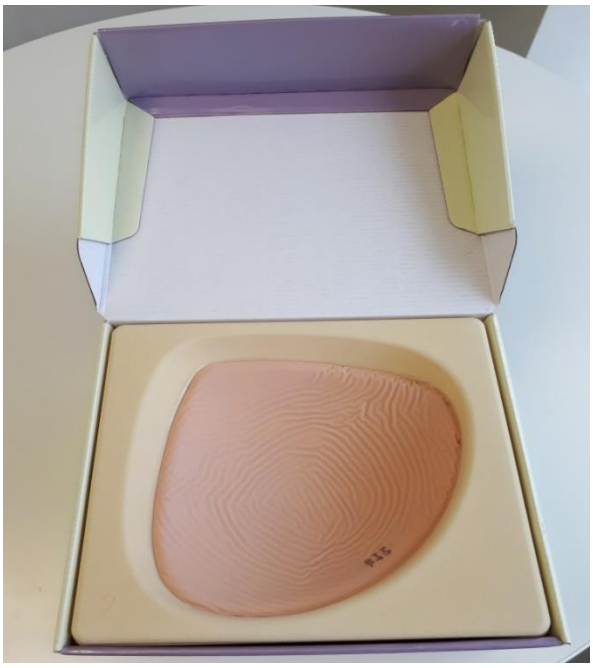
1.2 Manufacturer

Legal Manufacturer	Trulife Airton

1.3 Device Description

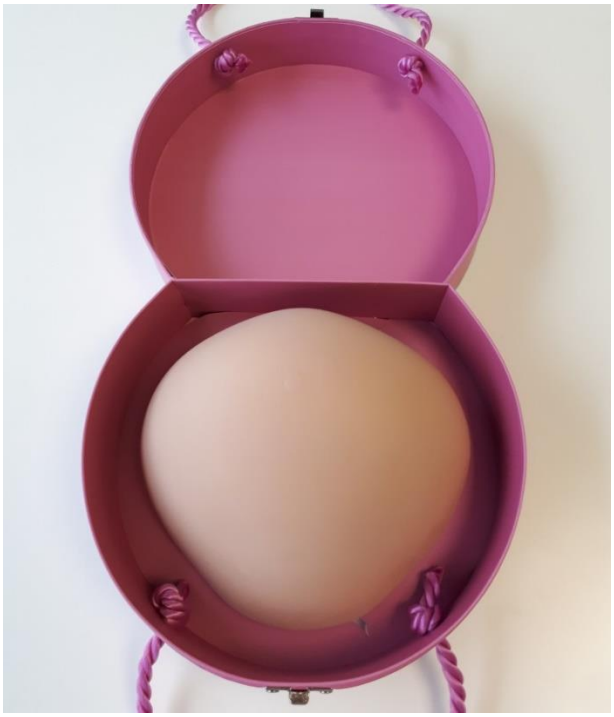
Physical description of device, incl images or drawings if applicable	Trulifes Silicone Breast forms are all manufactued using medical grade silicone. Each product is moulded by either filling the mould directly with silicone and sugar beads or filling a PU film bag with silcone and leaving it to set 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

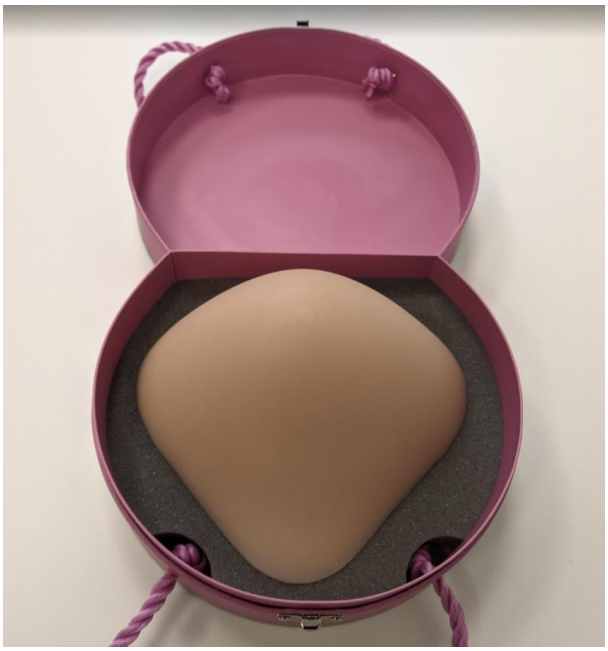


This packaging consists of a card box and a plastic cradle to hold the product in place. The plastic cradle comes in a range of sizes to fit the products.

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