Technical Guide

Trulife's Pressurecare products are Class 1 medical devices manufactured in Ireland in conformity with the Medical Devices Regulation.

The Oasis, Oasis +, Elite and Azure ranges are manufactured to the ISO 13485 standard, each carrying the CE quality mark and are guaranteed against manufacturing defects for 2 years.

Pressurecare products have been subjected to a series of rigorous tests to ensure that the materials used in their manufacture provide the optimal level of benefits to the anaesthetised patient to ensure compatibility with everyday use in the operating room environment. The results of these tests are outlined in the following pages.

Section 1 – Pressure Mapping

Test 1 – Interface Pressure

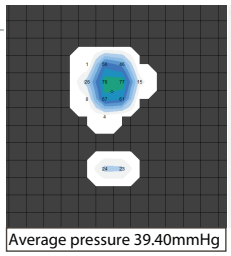
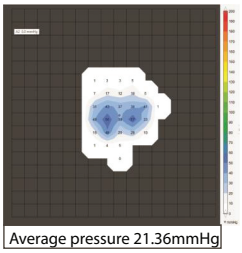
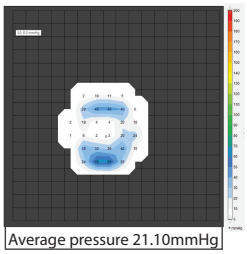
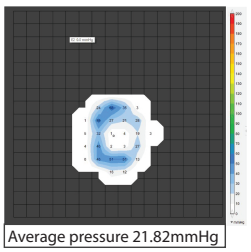
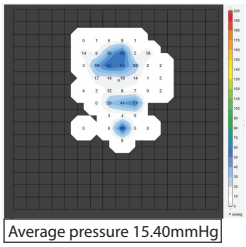
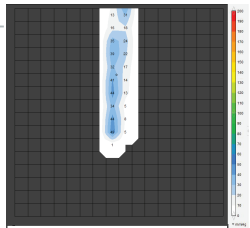
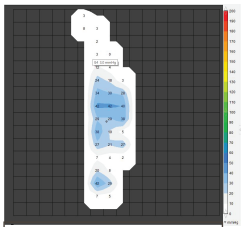
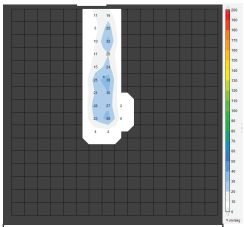
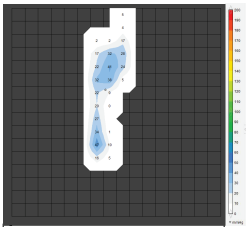
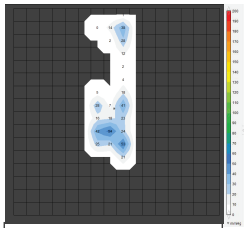
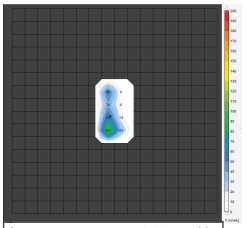
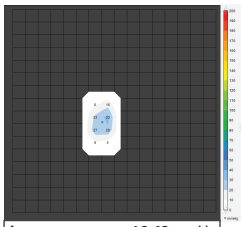
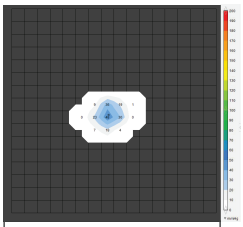
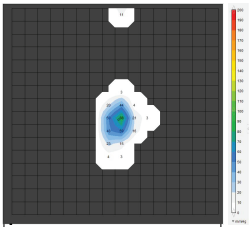
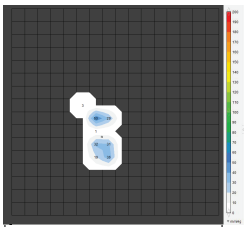
Pressure, the amount of force exerted on a given area, is often measured in millimetres of mercury (mmHg). When a force or pressure greater than normal capillary pressure is exerted on a body over time, this can restrict blood flow to the area and cause serious tissue damage. It is important therefore, to reduce this pressure particularly at the more susceptible parts of the body. Our gel pads help relieve pressure by increasing the area of contact between the body part and the supporting surface (i.e. Trulife Pressurecare Products).

We use Force Sensitive Applications (FSA) to evaluate our products for their pressure relieving capabilities. FSA is essentially a clinical tool to allow us to evaluate and map the interface pressure between a person and the support surface (i.e. product) they are lying on. The Pressure Mapping System is a versatile tool that provides accurate information in an easy to interpret graphical format.

When interpreting the Interface Pressure Maps, the lower the average interface pressure, the higher the degree of pressure relief of the product.

Trulife Pressurecare products are tested to the equivalent weight of a 90kg individual.This is based on the average weight of individals in the United States as determined by the National Health Statisics Report (2018).

The below Pressure Mapping was performed using a percentage of the overall body weight of a 90kg person depending on the body part being reference. All tests are run for a minimum of 5 hours.

	SUPPORT SURFACE WITH NO PROTECTION	SUPPORT SURFACE WITH AZURE GEL PAD	SUPPORT SURFACE WITH ELITE GEL PAD	SUPPORT SURFACE WITH OASIS GEL PAD	SUPPORT SURFACE WITH OASIS+ GEL PAD
HEAD	 Average pressure 39.40mmHg	 Average pressure 21.36mmHg	 Average pressure 21.10mmHg	 Average pressure 21.82mmHg	 Average pressure 15.40mmHg
ARMS	 Average pressure 24.18mmHg	 Average pressure 18.49mmHg	 Average pressure 18.86mmHg	 Average pressure 18.39mmHg	 Average pressure 20.69mmHg
HEELS	 Average pressure 40.98mmHg	 Average pressure 18.63mmHg	 Average pressure 16.15mmHg	 Average pressure 24.41mmHg	 Average pressure 25.29mmHg

Section 2 – Product Care & Durability

Test 1 – Disinfecting and Cleaning

The Trulife range is easy to clean/ disinfect between surgical cases and is more hygenic than many disposable foam options which can facilitate bacterial growth by absorbing fluids. The disinfectant market is a very diverse one comprised of a number of suppliers. Thus, testing types of chemistries, rather than brands is the most logical approach.

If there is something specific that you wish to confirm please contact your local distributor.

Main Chemistry	Cleaner (manufacturer)
Alcohol	Mikrozid
Chlorine	Milton
Hydrogen Peroxide	Incidin OxyFoam S
Ammonia	Sani-Cloth AF Universal Wipe
Sodium Hydroxide	Terminator
Sodium Gluconate	Sani- Cloth detergent Wipes

Please note that it is not advisable to soak the Oasis, Oasis+, Elite and Azure pads in a cleaning solution overnight as this may affect the long-term durability of the products. Products should be wiped clean only. Always follow manufacturing guidelines for cleaning solution dilution ratios.

Test 2 – Autoclave sterilisation (Oasis+ range only)

The Oasis+ products have been tested for Autoclave sterilisation.

Autoclave testing protocol was defined by Trulife and tested by an independent testing lab. Protocol based on accepted international sterilisation standard in consultation with Tallaght (AMNCH) hospital according to HSE Code of Practice for Decontamination of RIMD, Version 1.0.

The tests reported no discernible change in appearance, no degradation and no contaminations from the products after 24 Autoclave Sterilisation Cycles at 134 °C and 3 minutes. As part of Trulife's testing protocol products used for Autoclave testing were lifecycle and pressure map tested pre and post autoclave cycles for comparison results. No change in function or performance was recorded.

Test 3 – Temperature Test

Thermal stability is very important when the material is in contact with the body, as the temperature of the body and its environment is continually changing.

The test replicates the treatment that Trulife's Pressurecare range would receive in a hospital setting when placed in a preheated oven for a period of time to heat it up prior to it being used under a patient. The temperature of the product is monitored while heating in the oven and while cooling down to room temperature. The test results indicate that it takes a minimum of 30 minutes to heat the product from a temperature of 20˚C / 68°F to 40˚C / 122°F. In isolation, the product will not return to room temperature for at least 3 hours. This time will vary according to room and patient temperature.

Tests were performed by the Research& Development Laboratory of Trulife.

The Trulife products may be preheated to 40 degrees, or heated to body temperature, in an oven or used in conjunction with a heating mattress. Please follow instructions of the oven or mattress manufacturer as appropriate. (Refer to good clinical practices).

Test 4 – Storage Temperature Test

Tests were performed by the Research and Development Laboratory of Trulife Ireland investigating the effect of hot and cold temperatures on Trulife's Pressurecare Products when stored at temperatures of 40ºC / 104º F and -20ºC / -4º F for 30 days. The results of the test indicate without any deterioration in their condition, damage is unlikely to occur as a result of storage temperatures within these ranges. Always ensure the product has returned to room temperature before use.

Test 5 – Conductivity Test

Modern surgical procedures, including High Frequency Techniques, require the interface pad to be non-conductive. According to BS 2050 (Specification for Electrical Resistance of conducting and anti-static products made from flexible polymeric material), accessory pads can be classed as non-conductive if their surface resistance is greater than 106 ohms. Trulife Pressurecare products were tested at the National Electronics test centre at Eolas in Glasnevin using a HP 4329A High Resistance Meter and a HP16008A Resistivity Cell according to the procedure laid down in BS2050.

Results showed the Trulife Pressurecare pads to be within the non-conductive range with values from 3.0 x 109 to 2.3 x 1013 ohms.

Test 6 – Lifecycle/ Durability Test

Silicone shows resistance to wear and tear which is important for the long term life of the products.

When used in a normal environment a Trulife Pressurecare product is repeatedly compressed and relaxed when a patient is placed on and removed from the pad.

The Lifecycle test assesses the impact of a weighted plate being applied to and removed from the products continuously at a predetermined rate dependent on the size and specific application of the product. It is carried out at room temperature in an enclosed area.

The results show that Trulife products pass durability tests to the equivalent of 5 years of use.

Test 7 – X-Ray Attenuation

The Trulife Oasis, Elite and Azure products are x-ray translucent, meaning they are almost entirely transparent to radiation. However, higher radiation levels may be needed to achieve this. (See table below)

Attenuation Assessment			
Product	**Product Tested: Materials & Thickness**	**Exposure Factor's during Test's**	**Product Attenuation in mm of Aluminium**
OA030	10mm thick, silicone		2-4mm
OA212	75mm thick,silicone		> 10mm Aluminium
EL012	At centre, 10mm silicone & foam		2-4mm
	At edge, 50mm silicone & foam		4-6mm
EL141	At centre, 40mm silicone & foam		4-6mm
	At edge, 140mm silicone & foam	100kVp, 40mAsec's	> 10mm
EL216	75mm thick, silicone & foam		6-8 mm
AZ500	60mm, 2 types of silicone		> 10mm
AZ600	10mm, 2 types of silicone		2-4mm
FP012	75mm silicone, foam & fabric		2-4mm
FP050	90mm silicone, foam & fabric		2-4mm

Trulife Pressurecare products are nonconducting, nonmetallic and nonmagnetic and are suitable to be used in environments that require these specifications.

Section 3 - General Information

Pressure Relieving Properties of Silicone Gel

The material used in the Trulife range is a medical grade silicone; it is one of the most similar synthetic materials to human tissue. This means that pressure is relieved by the slight movement of the silicone gel and resulting dissipation of pressure/force across the product.

Skin Compatibility

Silicone is widely acceptable to most biomedical applications and poses no risk to the user.

Irritancy potential tests were performed by CYTOX, Gottleib-Keim-Strabe 60, 95448 Bayreuth, Germany. The tests were carried out in accordance with ISO 10993-10 and ISO 10993-1 which require clinical trials to be conducted in accordance with the principles of good clinical practice.

All Pressurecare products have passed these tests.

Bacteriological Data

Silicone is an elastomer which provides a unique balance of chemical and mechanical resistance and due to its pure state displays exceptional biocompatibility.

Suppliers of the materials used to manufacture Oasis, Oasis+, Elite and Azure Gel Pads have confirmed that these materials are inorganic and hydrophilic, thus not an ideal material for biotics.

Latex & Phthalates

Trulife Pressurecare products are not made with natural rubber latex or come into contact with any latex products throughout the manufacturing process. Pressurecare product do not contain phthalates, they are not a specified part of our products.

General Use

PLEASE NOTE:

- Due to our manufacturing process a slight variation in colour may occur between individual products.
- Product dependent a tolerance of +/- 10mm is applied to all product dimensions.
- The position of the model in certain images is intended to display the products only and may not be surgically accurate in all cases.
- We offer a guideline to help select products for different surgical positions. Please refer to good clinical practices when selecting products.

WHAT IF THE PRODUCT GETS CUT?

In the event of the product being cut, it is recommended that the product be discarded to avoid the risk of infection.

For the Oasis + range, If the product is cut, it is safe to use as long as the area in question can be cleaned.

DO THE PRODUCTS CARRY A GUARANTEE?

All products are guaranteed against manufacturing defects for a period of 2 years.

Conclusion

Silicone has been a world leader in the medical industry and will continue to be a prominent material in the future.

Trulife uses it in its manufacturing, as the properties and adaptability far exceeds any other material in its field including polyurethanes.This is mainly due to its pressure relieving quality and its compatibility with skin.

The Trulife Pressurecare range is a simple and cost effective solution with a comprehensive offering to cover all surgical procedures.