

Pressurecare

Pressure Relief & Patient Positioning



Supine / Trendelenburg / Prone / Lateral / Lithotomy / Paediatrics

Preventing Pressure Sores – **The Goal is ZERO**

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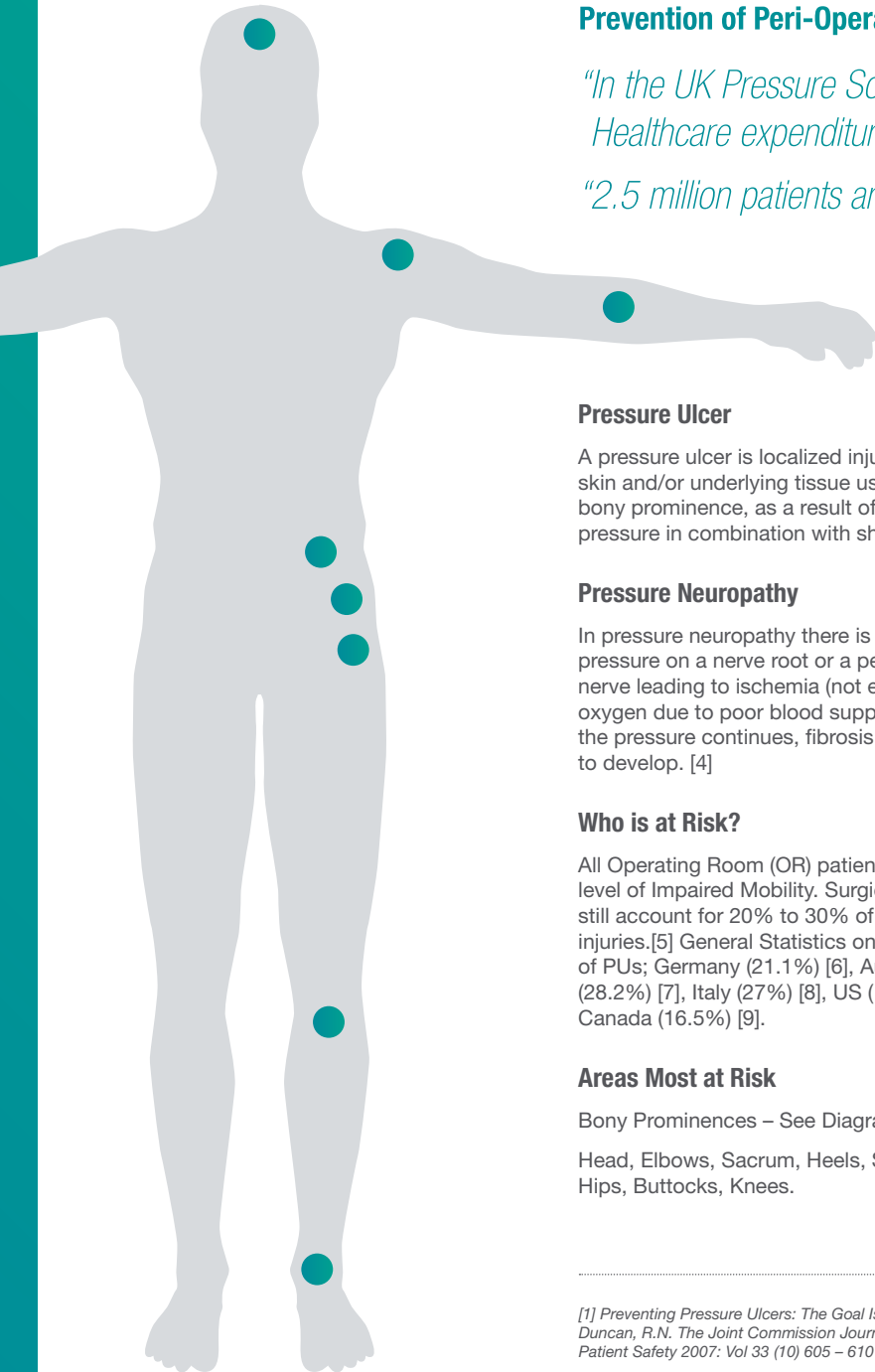
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Pressurecare



Prevention of Peri-Operative Pressure Injury Definition:

“In the UK Pressure Sores absorb around 4% of the National Healthcare expenditure” [1]

“2.5 million patients are treated for pressure sores in the USA” [2]

Pressure Ulcer

A pressure ulcer is localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear [3]

Pressure Neuropathy

In pressure neuropathy there is excessive pressure on a nerve root or a peripheral nerve leading to ischemia (not enough oxygen due to poor blood supply). If the pressure continues, fibrosis tends to develop. [4]

Who is at Risk?

All Operating Room (OR) patients due to level of Impaired Mobility. Surgical patients still account for 20% to 30% of all pressure injuries.[5] General Statistics on Prevalence of PUs; Germany (21.1%) [6], Australia (28.2%) [7], Italy (27%) [8], US (11.5%) [9], Canada (16.5%) [9].

Areas Most at Risk

Bony Prominences – See Diagram

Head, Elbows, Sacrum, Heels, Shoulders, Hips, Buttocks, Knees.

Aetiology: What happens?

- Prolonged Pressure
- Pressure on Blood Capillaries / Nerves
- Ischaemia & lack of Oxygen
- Skin Breakdown or Nerve Compression
- Pressure Ulcer / Neuropathy

Principles of Safe Positioning

- Level of prolonged pressure on bony prominences and nerve endings
- Avoid Circulatory and Respiratory Insufficiency
- Attain Optimal Surgical Position Safely
- Facilitate Role of Anaesthetist

Intervention - Pressure Injuries can be prevented! Use Preventative measures! Educate Staff!

Trulife offers an Extensive Range of Equipment for Pressurecare Management in the OR

The prevention of pressure injury assumes a fundamental role in health services economics and management. [10]

[1] Preventing Pressure Ulcers: The Goal Is Zero K. Duncan, R.N. The Joint Commission Journal on Quality and Patient Safety 2007: Vol 33 (10) 605 – 610

[2] The Cost of pressure ulcers in the UK G. Bennett, C. Dealey, J. Posnett age and ageing: Vol 33 (3) 230 – 235

[3] www.epuap.org www.npuap.org

[4] www.medterms.com

[5] Patient Positioning: Education is key. www.surgicalproductsmag.com. 2010. Claire Williams Tager

[6] Lahmann N. et al., J. Ostomy/Wound Management. 52: 20-33, 2006. [

[7] Gardner A. et al., J. Wound Practice and Research. 17:134-145, 2009

[7] Lahmann N. et al., J. Ostomy/Wound Management. 52: 20-33, 2006

[8] Capon A. et al., J. Advanced Nursing. 58: 263-272, 2007

[9] Healthcare Management Council Inc. HMC: Hospitals lose \$2 Million in errors yearly. March 5, 2010. Assessed March 11, 2010 from: <http://www.hmc-benchmarks.com/2010/03/hmhospitals-lose-2-million-in-errors-yearly/>

[10] ECONOMIC EVALUATION OF PREVENTION OF PRESSURE ULCERS IN INTENSIVE CARE UNITS Andrade, Melanie 1*, Nogueira, Fernanada 2, Morais, Ernesto 3: EPUAP Annual Meeting 2011

Trulife Ranges

The incidence of OR-acquired pressure sores can be significantly reduced by using the most effective pressure relieving and positioning devices available and by employing a few basic concepts in positioning care. Education of OR staff is paramount.

The Trulife Pressurecare Ranges were developed as a result of our commitment to provide improved levels of pressure care products to both patients and healthcare systems. Vast amounts of in-depth research have gone into the development of each range. The Trulife Pressurecare range offers a simple and cost effective solution with a comprehensive offering to cover all surgical procedures.

Why select the Trulife Range?

- Re-distributes weight effectively
- Helps prevent Decubitus Ulcers and Nerve Injury
- Helps promote Optimal Positioning
- Reusable
- Cost Saving
- Medical Grade Silicone
- Extensive offering
- Easy to Clean
- Biocompatible
- Made in Ireland

SURGICAL POSITIONS

PRODUCTS ARE SUITABLE FOR:

- S Supine
 - P Prone
 - L Lithotomy
 - LL Lateral
 - P Paediatrics
- *Indicates use



OASIS THE ORIGINAL SILICONE SOLUTION

The Oasis range is an extensive range of reusable 100% silicone gel pads. The silicone we use is softer than both skin and underlying tissue. This means that pressure is relieved by the slight movement of the silicone gel and resulting dissipation of pressure/force across the product. It is the first range of products launched by Trulife in the OR field and remains a market leader in gel pads and positioners.



OASIS ELITE LIGHTWEIGHT & PRE CONTOURED

The Oasis Elite range combines silicone gel and light weight foam with a precontoured surface to provide superior pressure relief and patient protection in the OR. Anatomical pre-contouring facilitates greater conformity between gel and body shape; weight is then redistributed over a larger area. Oasis Elite products are more than 50% lighter than comparable gel-only products.

They are designed for stability, easier handling and manipulation by medical personnel during preparation and surgery.



AZURE REDEFINING PRESSURECARE

The Azure range redefined pressurecare. Each product consists of two independent silicone layers that work in combination allowing the moulded products to conform to the users shape in a more contoured and less structured manner, resulting in effective protection against nerve damage and skin breakdown. Azure has set a whole new standard of protection in the OR.



OASIS + A REVOLUTION IN PRESSURECARE

The Oasis + products are made from a medical grade siloxane elastomer. Additional durability is ensured because the products have no outer film, making this an entirely unique product range. The shape and design of the product promotes the ultimate in pressure relief.

The material has hypoallergenic and anti slip properties helping to provide comfort and support to the patient.

Table Pad Protection

OASIS STANDARD OPERATING TABLE PADS



These Oasis table pads provide protection over the entire surface area of the operating table and are recommended for use with patients in all positions. The pads are flexible, soft, comfortable and versatile and distribute weight evenly over the entire surface area.



Code	Description	Dimensions
OA032	Full Length Table Pad	1800 x 520 x 10mm

OASIS PERINEAL TABLE PAD



The Oasis Perineal Pad provides excellent protection to the sacral area, a point of maximum pressure. It is essential for all patients in the lithotomy position.

Code	Description	Dimensions
OA040	Perineal Table Pad	520 x 520 x 10mm

OASIS ELITE TABLE PADS



The Oasis Elite Pads can be used to protect the body in all surgical positions. The ultra light weight pad consists of a foam base and a gel top, allowing for easy carrying and manipulation by OR staff.

Code	Description	Dimensions
EL031	¾ Length Table Pad	1150 x 520 x 20mm

OASIS + UNIVERSAL PROFILE PAD

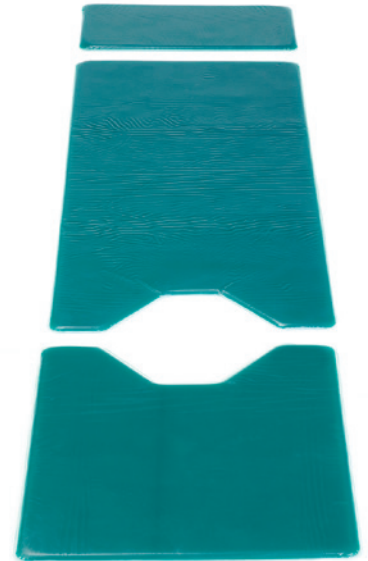


The Oasis+ Universal Profile Pad is made from medical grade siloxane elastomer with no outer film ensuring exceptional durability. Ergonomically designed for additional comfort and support, its anti-slip properties allow it to be used in a variety of positions including shallow Trendelenburg.

- Universal use
- Lightweight
- Fully autoclavable
- Easy to Clean
- Helps prevent pressure sore formation

Code	Description	Dimensions
OP041	Profile Pad	520 x 520 x 9mm

OASIS 3 PIECE OPERATING TABLE PAD



The Oasis 3 Piece Operating Table Pad is designed for use on sectioned tables. The set consists of a head section, torso section and a foot section, with the latter two having a perineal cutout. The product provides a high degree of flexibility, versatility and protection during a variety of surgical procedures, particularly in the areas of Orthopaedics and Urology. Can also be used as a standard full length table pad.

Code	Description	Dimensions
OA036	Head Section	225 x 500 x 10mm
OA037	Torso Section	990 x 500 x 10mm
OA038	Foot Section	500 x 500 x 10mm

*Surgical patients
account for 20%
– 30% of all
pressure injuries*



Head & Neck Protection

OASIS ELITE CLOSED HEAD RING



S L LL P

Unique gel & foam combination conforms comfortably to the patient's head, this head ring is suitable for use in many surgical procedures.



Code	Description	Dimensions
EL011	Infant/Adolescent	140 x 34mm
EL012	Adult	200 x 50mm

OASIS ELITE PRONE HEAD REST



P P

Developed in conjunction with the Operating Staff at a leading hospital, the Oasis Elite Prone Head Rest is anatomically designed so that the patient's head can comfortably rest face down with respiratory tubes in place. The unique design provides excellent support, stability, comfort and protection during surgery in the prone position, with openings on both sides. The product is lightweight, durable and easy to handle.

Code	Description	Dimensions
EL142	Adolescent/Adult	273 x 220 x 135mm
EL141	Adult	280 x 240 x 140mm

OASIS ELITE OPEN HEAD RING



P LL P

Combination of gel and foam provides stability and protection to the patient's face during surgery. An opening allows for intubation.



Code	Description	Dimensions
EL021	Infant/Adolescent	140 x 34mm
EL022	Adult	200 x 54mm

OASIS + HEAD & NECK SUPPORT



S

The Oasis + Head & Neck support is ergonomically designed to support the head and neck. The product has anti slip properties designed for additional safety. Proving popular in ENT for septoplasty, some cases of laryngoscopes and thyroidectomy.



Code	Description	Dimensions
OP151	Adult	264 x 220 x 64mm

OASIS ELITE SUPINE HEAD REST



S P

This Supine Head Rest is ideal for positioning the patient during eye surgery and other supine procedures. Ergonomically shaped to position the patient's head, while effectively protecting against the onset of pressure sores.

Code	Description	Dimensions
EL152	Adolescent/Adult	275 x 230 x 65mm
EL151	Adult	275 x 237 x 90mm

OASIS CLOSED HEAD RING



S L LL P

Available in a wide variety of size options, the Oasis Closed Head Ring protects the head, neck and ears during all types of surgery and is suitable for use in many procedures.



Code	Description	Dimensions
OA010	Neonate/ New born	90 x 20mm
OA011	Infant/ Adolescent	140 x 35mm
OA012	Adolescent/ Adult	200 x 45mm

OASIS OPEN HEAD RING



P LL P



Soft, comfortable and durable, the Oasis Open Head Ring supports the patient's face, while allowing easy access for intubation during surgery.

Code	Description	Dimensions
OA020	Neonate/ New born	90 x 22mm

Arm & Elbow Protection

OASIS ELITE CONTOURED ARMBOARD PAD



S P L LL

This anatomically shaped armboard pad is designed to provide added support and stability to the arm in a variety of procedures.

Code	Description	Dimensions
EL401	Adult	510 x 155 x 40mm
EL402	Adolescent/Adult	395 x 140 x 40mm

OASIS ELITE ARMBOARD PAD



S P L LL P

This flat armboard pad has a slight indentation to cradle the arm and provide effective pressure relief during various surgical procedures.

Code	Description	Dimensions
EL072	Adolescent/Adult	600 x 125 x 20mm

OASIS ARMBOARD PADS



S P L LL P

Oasis Armboard Pads provide the necessary protection whenever the arm is extended on an armboard. Suitable for all types of armboards.

Code	Description	Dimensions
OA071	Infant/ Adolescent/Adult	600 x 200 x 10mm

OASIS ULNAR / BRACHIAL NERVE PROTECTORS



S L LL P

The Oasis Ulner / Brachial Nerve Protectors are essential for providing protection to the sensitive areas of the elbows and arms.

Code	Description	Dimensions
OA061	Adolescent/Adult	460 x 210 x 8mm

OASIS + LONG ARMBOARD PAD



S P L LL P

The Long Armboard Pad completely relieves pressure on the elbow with a full recess. It can also bend and conform to different arm positions. Raised sides provide defined support. Rollable, to facilitate a neutral hand position if desired.

Code	Description	Dimensions
OP101	Adult	500 x 161 x 40mm

OASIS + SHORT ARMBOARD PAD



S P L LL P

Ergonomic support, with a subtle recess to cradle the arm. The Short Armboard Pad can bend and conform to different arm positions. The product is also rollable, to facilitate a neutral hand position if desired.

Code	Description	Dimensions
OP070	Adult	395 x 134 x 10mm

Body Protection

AZURE SACRAL PROTECTOR



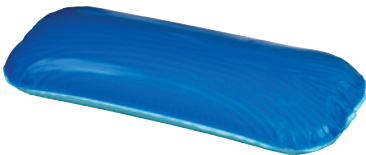
S L P

The Sacral area is an area of serious risk if left unprotected. The Azure Sacral protector has been designed to provide support in the supine and lithotomy positions by relieving pressure and focussing on peripheral support.



Code	Description	Dimensions
AZ300	Adolescent/Adult	400 x 380 x 25mm
AZ301	Adult	450 x 445 x 30mm

AZURE UNIVERSAL POSITIONER



S P LL P

This versatile and lightweight product can be used to position and protect the patient in variety of surgical procedures.



Code	Description	Dimensions
AZ500	Adolescent/Adult	425 x 155 x 60mm

OASIS ELITE PRONE POSITIONER



P

The Prone Positioner gel and foam combination has been designed to provide effective positioning to the patient during surgical procedure in the prone position. For best protection, it is recommended to be used in conjunction with the Prone Head Rest.



Code	Description	Dimensions
EL903	Adult	610 x 530 x 130mm

OASIS ELITE PRONE LATERAL POSITIONING SYSTEM



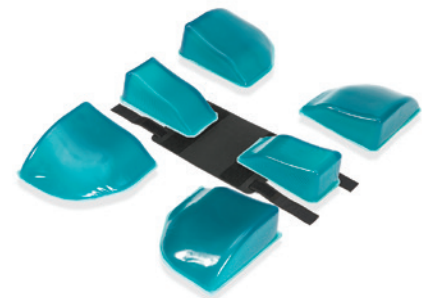
P LL

The Prone/Lateral Positioning System from Trulife is the result of extensive research into the needs of Operating Room personnel for patients during surgical procedures in the prone/lateral position. Designed with both patient and surgical staff in mind, this system offers the ultimate pressure relieving protection and effective positioning all in one.

Code	Description	Dimensions
EL905	Oasis Elite Prone/Lateral Positioning System	675 x 500 x 100mm

Replacement Parts Available:

EL906	Upper Left Section/Lower Right Section	275 x 250 x 100mm
EL907	Upper Right Section/Lower Left Section	275 x 250 x 100mm
EL908	Mid Left Section/Mid Right Section	125 x 250 x 100mm
EL912	Base Plate	500 x 500 x 6mm



Body Protection

OASIS ELITE LATERAL POSITIONER



LL P

This positioning device permits a safe, quick and easy transition from supine to lateral. The patient's lower shoulder fits into the integral channel to provide exceptional patient comfort and nerve protection. The Lateral Positioner is designed for use in hip replacement, shoulder, kidney and other procedures. The built-in headrest and auxiliary support assists in proper spinal alignment and surgical site access.



Code	Description	Dimensions
EL900	Adolescent/Adult	720 x 500 x 160mm

OASIS ELITE DOME POSITIONER



S P P

This lightweight positioner can be used to position and protect the patient during various surgical procedures in all positions. It can be used in many different applications.

Code	Description	Dimensions
EL210	Adolescent/Adult	350 x 150 x 75mm

OASIS FLAT BOTTOM CHEST ROLLS

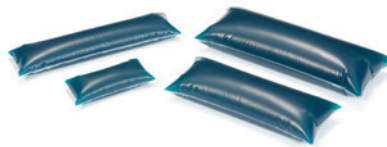


S P L LL P

These 100% silicone gel chest rolls provide excellent positioning and stability and are available in a wide variety of sizes.

Code	Description	Dimensions
OA211	Adult	305 x 95 x 75mm
OA212	Adult	405 x 95 x 75mm
OA213	Adult	505 x 92 x 75mm

OASIS UNIVERSAL PATIENT POSITIONERS



S P L LL P

These 100% silicone positioners are suitable for safe and effective positioning during all surgical procedures.

Code	Description	Dimensions
OA050	Infant/Adolescent/Adult	150 x 60 x 40mm
OA051	Infant/Adolescent/Adult	330 x 70 x 50mm
OA052	Adolescent/Adult	290 x 100 x 60mm
OA053	Adolescent/Adult	345 x 120 x 70mm

OASIS ELITE FLAT BOTTOM CHEST ROLLS



S P L LL

Chest Rolls provide excellent support and stability. The unique gel and foam combination means they are up to 75% lighter than comparative gel products, allowing for easy manipulation and handling by OR staff.

Code	Description	Dimensions
EL215	Adult	400 x 140 x 110mm
EL216	Adult	505 x 140 x 110mm
EL217	Adult	405 x 150 x 150mm
EL218	Adult	510 x 150 x 150mm

OASIS ELITE POSITIONERS PRONE PAD



P

The Prone Pad facilitates easy ventilation, and eliminates pressure on the abdomen, during long cases in prone. Recommended for Laminectomy procedures and surgery to the back of the legs. This is an improvement on the EL914 for a better fit with the EL141, and also a better anatomical fit for both female and male genitalia.



Code	Description	Dimensions
ELP914	Adult	480 x 1014 x 140mm



TO SEE MORE
SCAN HERE

OASIS ELITE TRENDLENBURG SYSTEM



S

The Oasis Elite Trendelenburg System has been developed to overcome the challenges faced in the Trendelenburg position, primarily patient slippage, nerve injury and the formation of decubitus sores.

Key Features

- Suitable for up to 40° Trendelenburg
- Holds patient securely in lateral tilt
- Dual-layer viscoelastic foam and integrated gel structure
- Reusable, durable and easily cleaned
- Carbon composite shoulder supports for steep Trendelenburg
- Rapid setup
- Restraint - Free



Code	Description
ELTS20	Elite Trendelenburg System 20°

Suitable for surgeries using up to 20° tilt

Includes:

1. TR012 - Trendelenburg Headrest
2. ELT900 - Elite Trendelenburg Positioner
3. ELT015 - ET Anti-Slip Mat

Code	Description
ELTS40	Elite Trendelenburg System 40°

Suitable for surgeries using up to 40° tilt

Includes:

1. TR012 - Trendelenburg Headrest
2. ELT900 - Elite Trendelenburg Positioner
3. ELT015 - ET Anti-Slip Mat
4. ELT21 - ET Shoulder Support x2
5. ELT22 - ET Arm Retainer x2
6. ELT23 - ET L-Bracket x2
7. ELT24 - ET Clamp x2
(need to specify US, UK, EU)

OASIS ELITE LATERAL PARK BENCH POSITIONER



LL

The Park-bench position is a modification of the Lateral position. This position provides the surgeon with better access to the Posterior Fossa in the Skull.

Code	Description	Dimensions
EL913	Adult	520mm x 413mm x 230mm



Leg & Knee protection

OASIS ELITE KNEE PAD



The Knee pad is used for various procedures in the prone position to protect the knees against pressure damage and the onset of pressure sores.



Code	Description	Dimensions
EL401	Adult	510 x 150 x 40mm
EL402	Adolescent/Adult	395 x 140 x 40mm

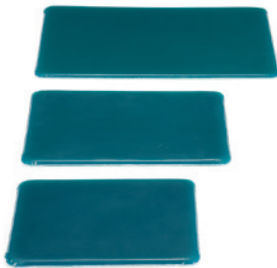
OASIS ELITE LATERAL LEG POSITIONER



This product is used to position the legs in a lateral position for kidney surgery and hip surgery. In addition to comfort, it facilitates optimal surgical positioning. This positioner also allows for knee and hip flexion. To use: Place patient on side, place upper limb on top (gel part of the product), and place lower limb underneath ledge.

Code	Description	Dimensions
EL800	Adult	650 x 400 x 230mm

OASIS CRUTCH STIRRUP PADS



The Oasis Crutch Stirrup Pads are designed to fit most types of stirrups. Supplied in pairs, they come in a variety of sizes.



Code	Description	Dimensions
OA090	Adolescent/Adult	320 x 220 x 10mm
OA091	Adolescent/Adult	395 x 245 x 10mm
OA092	Adolescent/Adult	520 x 300 x 10mm

Ankle, Heel & Foot Protection

AZURE HEEL PROTECTOR



S P

The heel area is one of extreme risk during any surgical procedure and special attention should be given to avoid any unnecessary damage. These lightweight protectors provide heel protection as well as stability and support. Supplied in pairs.



Code	Description	Dimensions
AZ401	Infant/ Adolescent/Adult	190 x 175 x 30mm

OASIS + HEEL PROTECTOR



S P

A broad base and raised sides provide stable support and pressure relief for the heel area.

- Non Slip base and top
- Durable and resistant to tear
- Ergonomically designed

Code	Description	Dimensions
OP132	Adult	127 x 162 x 71mm

OASIS ELITE HEEL PADS



S P

The Oasis Elite Heel Pads provide support and maximum protection for the heels, even during the longest surgical procedures. They support the Achilles and effectively remove pressure from the heels. Supplied in pairs, the products are lightweight and easy to use.



Code	Description	Dimensions
EL130	Adolescent/Adult	180 x 100 x 70mm

OASIS HEEL & ANKLE PROTECTOR



S L LL P

These unique pads are designed to fit around the heel and ankle like a boot with Velcro attachment. They provide protective padding for the heel when the patient is in the supine or lateral positions. Can also be used as a protector for the ankle and foot when using conventional ankle strap stirrups and lithotomy poles.



Code	Description	Dimensions
OA200	Adolescent/Adult	2540 x 120 x 10mm

Paediatric Products

OASIS ELITE TABLE PADS



EL031

OASIS STANDARD OPERATING TABLE PADS



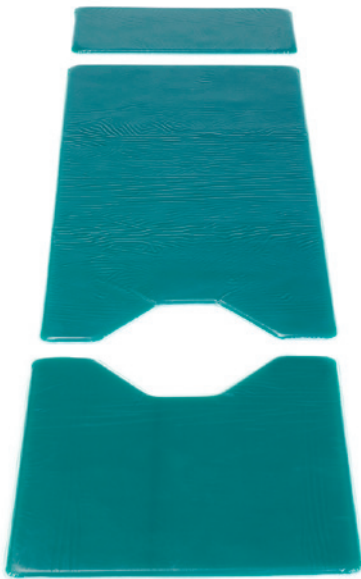
OA032

OASIS PERINEAL TABLE PAD



OA040

OASIS 3 PIECE OPERATING TABLE PAD



OA036 / OA037 / OA038

OASIS ELITE PRONE HEAD REST



EL142

OASIS ELITE SUPINE HEAD REST



EL152

OASIS ELITE CLOSED HEAD RING



EL011

OASIS ELITE OPEN HEAD RING



EL021

OASIS + UNIVERSAL PROFILE PAD



OP041

OASIS CLOSED HEAD RING



OA010 / OA011

OASIS OPEN HEAD RING



OA020

OASIS ELITE ARMBOARD PAD



EL072

OASIS + SHORT
ARMBOARD PAD



OP070

OASIS + LONG
ARMBOARD PAD



OP101

OASIS ARMBOARD PADS



OA071

OASIS ULNAR / BRACHIAL
NERVE PROTECTORS



OA061

OASIS ELITE KNEE PAD



EL402

AZURE SACRAL PROTECTOR



AZ300

AZURE UNIVERSAL
POSITIONER



AZ500

OASIS ELITE LATERAL
POSITIONER



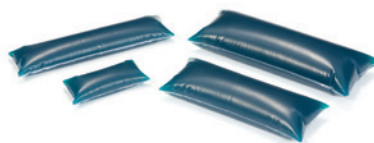
EL900

OASIS ELITE DOME
POSITIONER



EL210

OASIS UNIVERSAL
PATIENT POSITIONERS



OA050 / OA051 / OA052 / OA053

Paediatric Products

AZURE HEEL PROTECTOR



AZ401

OASIS ELITE HEEL PADS



EL130

OASIS HEEL & ANKLE PROTECTOR



OA200

OASIS + HEEL PROTECTOR

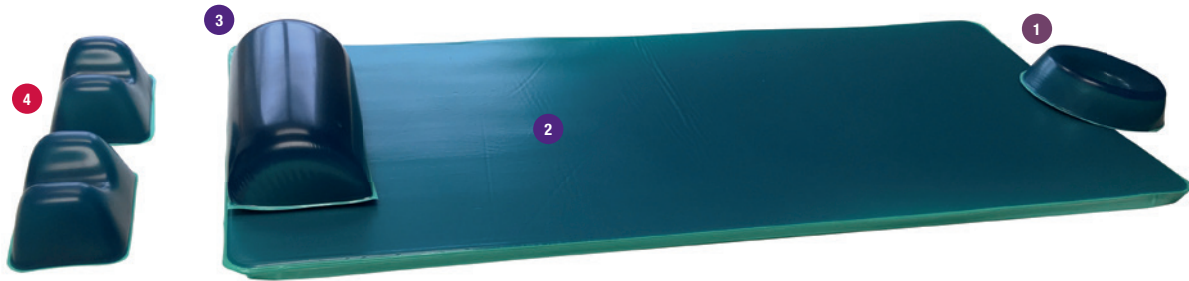


OP132

The principles of paediatric positioning to prevent pressure sores are the same, the affects are not only life altering but life threatening.



Supine Positioning Set



SPS001 Supine Positioning Set

- | | |
|---|------------------------------------|
| 1 | EL012 Elite Closed Head Ring Adult |
| 2 | EL031 Elite 3/4 Table pad |
| 3 | EL210 Elite Dome Positioner |
| 4 | EL130 Elite Heel Pads x 2 |

Prone Positioning Set



PPS001 Prone Positioning Set

- | | |
|---|------------------------------------|
| 1 | EL141 Elite Prone Headrest Large |
| 2 | ELP914 Elite Positioners Prone Pad |
| 3 | EL072 x 2 Elite Armboard Pad Long |
| 4 | EL401 Elite Knee Pad |
| 5 | EL210 Elite Dome Positioner |

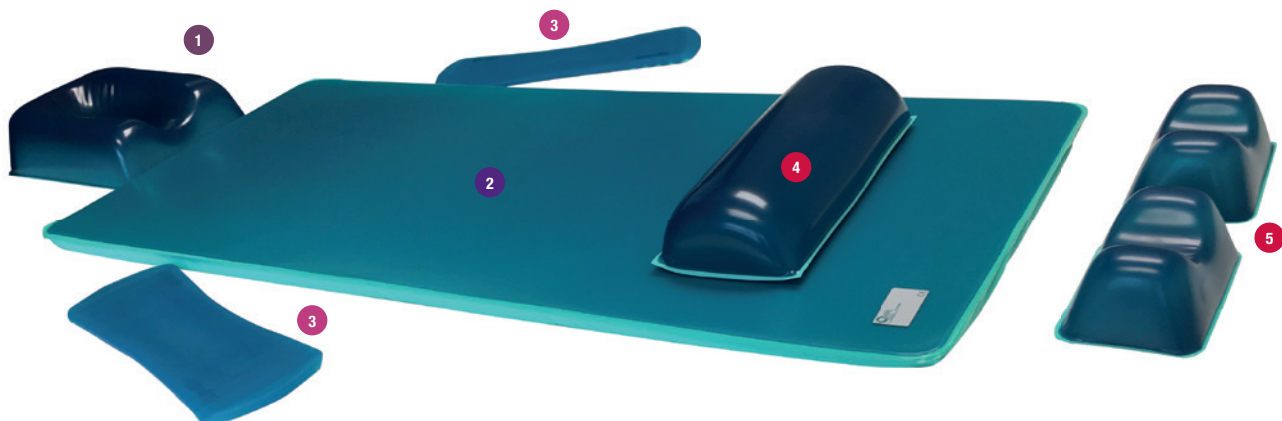
Lateral Positioning Set



LPS001 Lateral Positioning Set

- 1 EL022 Elite Open Headring Adult
- 2 EL402 Elite Contoured Armboard Pad
- 3 EL031 Elite 3/4 Table Pad
- 4 EL900 Elite Lateral Positioner
- 5 EL800 Lateral Leg Positioner
- 6 OA200 Oasis Heel and Ankle Protector x 2

Cardiovascular Positioning Set



CPS001 Cardiovascular Positioning Set

- 1 EL151 Supine Head Rest
- 2 EL031 3/4 Table pad
- 3 OP070 Oasis + Arm Pads
- 4 EL210 Dome Positioner
- 5 EL130 Elite Heel Pads

Accessories

FIRST AID REPAIR KIT



OA005

OEACARD CARD



OEACARD12

CAR PHONE MAT



OP001

Technical Guide

Trulife's Pressurecare range are Class 1 medical devices registered in Ireland and in conformity with the Medical Devices Directives S1252 (93/42/EEC) as amended by Directive 2007/47EC.

The Oasis, Oasis +, Elite and Azure ranges are manufactured to ISO 13485:2012 standards, 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.



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Trulife is committed to providing improved levels of pressure care products to both patients and healthcare systems so that pressure injuries can be eradicated. Vast amounts of in-depth research have gone into the development of each range

Section 1 – Patient Protection Test

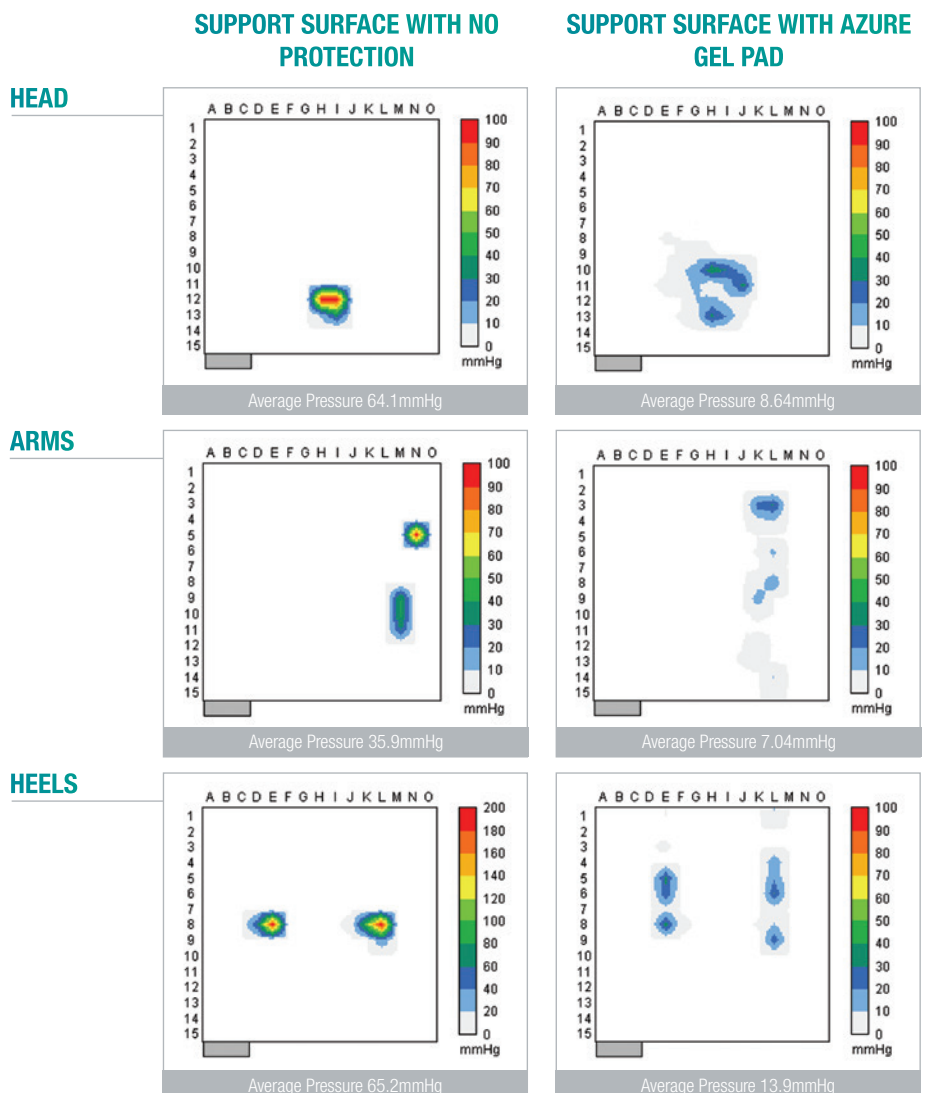
Test 1 – Interface Pressure

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 Pads).

We use Force Sensitive Applications (FSA) to evaluate our products for their pressure relieving capabilities. FSA is essentially a clinical tool that allows 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.

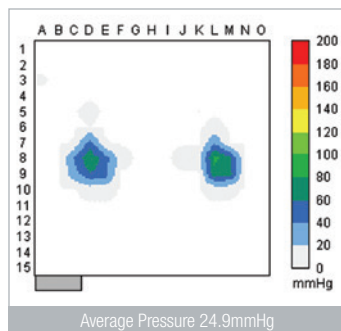
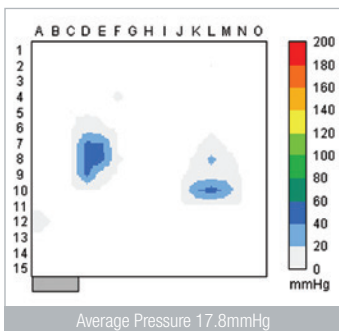
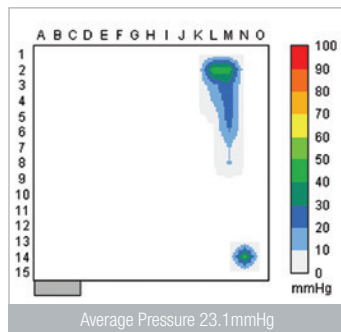
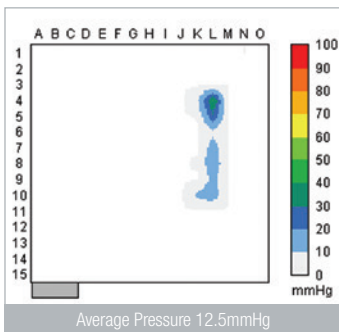
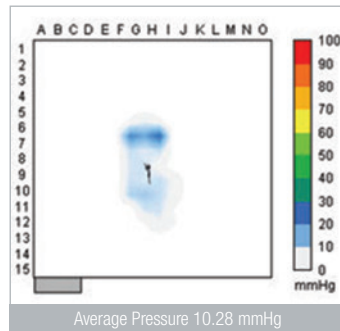
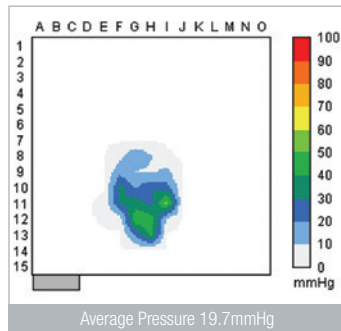
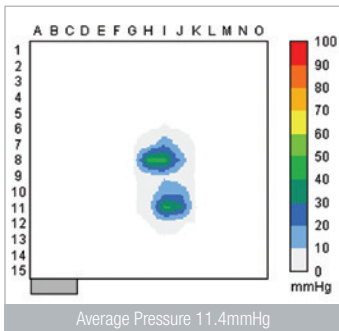
When interpreting the Interface Pressure Maps, the lower the average interface pressure, the higher the degree of pressure relief of the product. For more detailed testing information, please contact your distributor.



Tested in accordance with protocol for interface pressure management Ref: FSAT.0017

Studies comparing the pressure-reducing abilities of standard foam procedure bed mattresses to gel mattresses (i.e. visco-elastic polymer) have found gel mattresses to be more effective ¹

¹2011 Perioperative Standards and Recommended Practices AORN "Recommended Practices for Positioning the Patient in the Perioperative Practice Setting"



Section 1 – Patient Protection Test

Test 2 – Pressure Relieving Properties of Silicone Gel

The material used in the Trulife range is a medical grade silicone; it is softer than both skin and underlying tissue. This means that pressure is relieved by the slight movement of the silicone gel and resulting dissipation of pressure/force across the product.

Silicone Gel Versus PU/Polymer Gel

Tests were carried out on Trulife’s products by the School of Physics, Dublin Institute of Technology, Kevin Street, Dublin, Ireland. They studied the ‘cushioning’ / pressure relieving properties of six product samples made using different types of films and silicone fillings. The test samples were flat, donut and heel pad shapes filled with either silicone or polyurethane gel and using films of various thicknesses.

The results of these tests show that the flat, silicone filled samples had superior pressure relieving properties when compared with specimens made from polyurethane gel.



Other studies support the benefits of gel. The recommended practices from AORN state that “foam and gel mattresses are effective for preventing both skin changes and pressure sore formation”³

³ 2008 Perioperative Standards and Recommended Practices AORN
“Recommended Practices for Positioning the Patient in the Perioperative Practice Setting”

Section 2 – Patient Compatibility Test

Test 1 – 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. Suppliers of the materials used to manufacture Trulife's Pressurecare products have confirmed that these materials do not support microbiological growth.

Test 2 – 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 do not support microbiological growth.

Test 3 – Plasticizer & Fibreglass Content

Suppliers of the materials used to manufacture Oasis, Oasis+, Elite and Azure gel pads have confirmed that these materials are plasticizer and fibreglass free.



Section 3 – General Use of Gel Pads in an operating room environment

Test 1 – Disinfectant Report

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

- Phenolics
- Quaternary ammonia
- Quaternary ammonia and alcohol blends (Alcohol, chlorine)

This list covers the major families of detergents.

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

Cleaner/Disinfectant (Manufacturer)	Main Chemistry	Tested	Mix Ratio
Santex A	Water, Sulphates	no	-
Safeseat	Ethanol	no	-
Incidur Spray (Henkel Hygiene GmbH)	Aldehydes, alcohols, quaternary compounds	yes	neat
Incidin Plus (Acidic)	Glucoprotamin, quaternary ammonium	yes	200 to 1
Pursept (Corrosive)	Ethanol, Glyoxal, Quaternary Compounds	yes	100 to 1
Cutasept F (Bode)	Alcohol, porpan	no	-
Cutasept G (Bode)	Alcohol, porpan	no	-
Milton (Sodium hypochlorite, chlorine)	Sodium hypochlorite, chlorine	yes	100 to 1
Terminator New Century Sales		no	-
Mikrozid (S&M)	Ethanol, propanol	yes	5 to 1
Bacillol AF (Bode)	Ethanol, propanol	no	-
Bigusept Fluid (Bode)	Alcohol	no	-
Vikron	Potassium Peroxomonosulphate, Sulphamic Acid, Sodium alkyl benzene sulphonate	yes	100 to 1

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.

Test 2 – Flammability Test

Flammability tests were carried out by BTTG Fire Technology Services, Atlantic St, Broadheath, Attrinchau WA14 5DW, UK, in accordance with section 2 of BS 7175. Results indicate that when tested against this standard for ignitability in its “as received” condition, Trulife’s Pressurecare range are fire rated as self-extinguishing.

Test 3 – 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.

Note: number of cycles based on customer feedback regarding number of cycles products may be subjected to (max of once a month for 2yr warranty = 24cycles)

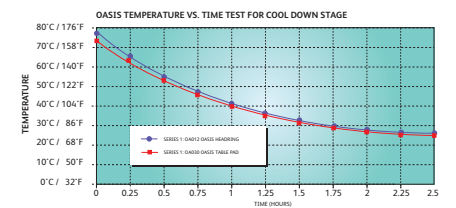
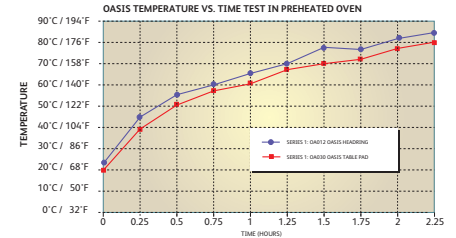
Test 4 – Temperature Test

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 50°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 Ltd, Dublin 24, Ireland.

The Trulife Pads 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). Please follow oven or mattress manufacturer instructions.



Section 3 – General Use of Gel Pads in an operating room environment

Test 5 – Freezing Test

Tests were performed by the Research and Development Laboratory of Trulife Ltd, Dublin 24, Ireland investigating the effect of freezing temperatures on Trulife’s Pressurecare Products when stored at temperatures of -18°C / 0° F for 7 days without any deterioration in their condition. The results of the test indicate that damage is unlikely to occur as a result of freezing temperatures. We recommend that the products can be cooled to -12°C without any adverse effects.

Test 6 – 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 7 – X-Ray Attenuation

The Trulife Oasis, Elite and Azure pads are x-ray translucent, however, higher radiation levels may be needed (See table below).

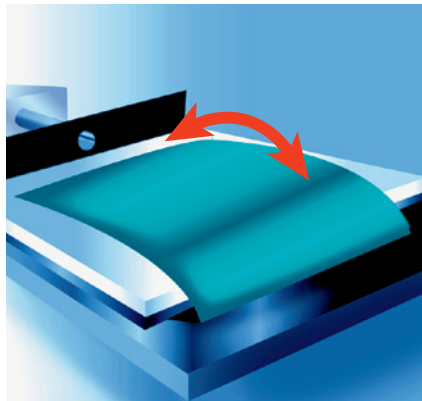
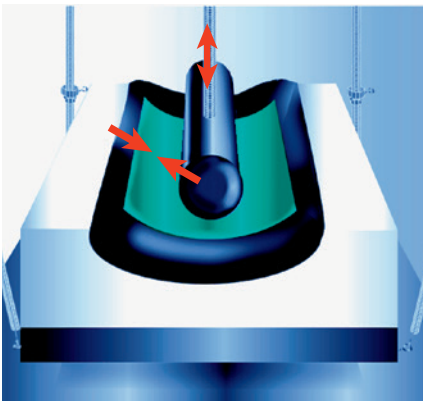
Attenuation Assessment			
Product	Product Tested: Materials & Thickness	Exposure Factor's during Test's	Product Attenuation in mm of Aluminium
OA030	10mm thick, silicone	100kVp, 40mAs	2-4mm
OA212	75mm thick, silicone		> 10mm Aluminium
EL012	At centre, 10mm silicone & foam		2-4mm
	At edge, 50mm silicone & foam		4-6mm
EL141	At centre, 40mm silicone & foam		4-6mm
	At edge, 140mm silicone & foam		> 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

Test 8 – MRI

For medical implants and devices, the objectives of Magnetic Resonance Imaging (MRI) testing determines the presence of magnetic field interactions, heating, and artifacts in association with the use of an MRI system. Accordingly, assessments of magnetic field interactions (deflection angle and torque), MRI-related heating, and artifacts were conducted at 3-Tesla on the Trulife range. The Trulife Pressurecare range does not cause significant signal loss or distortion during MRI imaging and is considered to be an acceptable device that may be used for patient positioning or patient comfort migration.

Project Conducted by: Frank G. Shellock, Ph.D. President and CEO
Shellock R & D Services, Inc.

For more detailed testing information, please contact your local distributor.



Section 4 – Durability Tests

Test 1 – Compression Test

Silicone shows resistance to weathering 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.

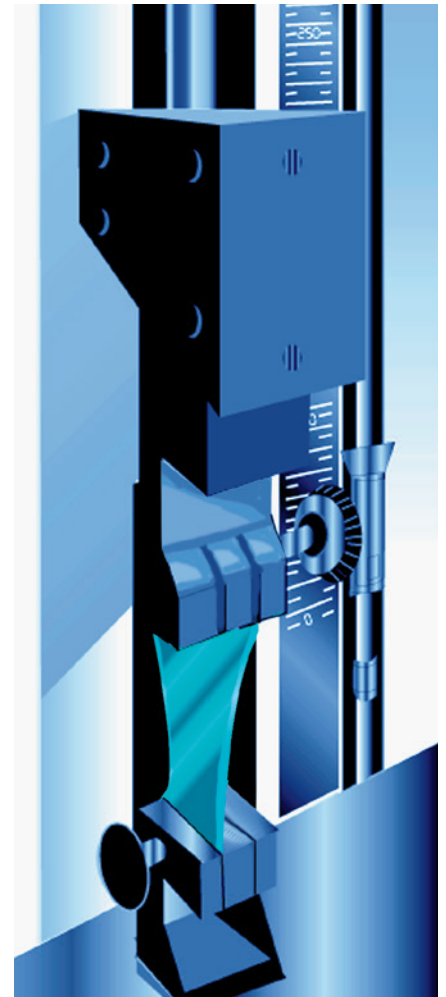
The compression test assesses the impact of a static bar being applied to and removed from the products continuously at a predetermined rate dependent on the size and specific application of the product. It is carried out at room temperature in an enclosed area.

We require a product to undergo a minimum of 20,000 cycles at a rate of 15 cycles per minute without showing any signs of damage to successfully pass this test. Over a 2 year life span, this would simulate 27 compressive actions on the product for each day of the year.

Test 2 – Dynamic Roll Test

During normal use, the gel pads are likely to be pulled, pushed and rolled into position on an operating table. The Dynamic Roll Test assesses the likelihood of the silicone separating from the film during normal positioning and storage over the life of the product. During this test, the product is attached to a jig in a flat position and is subjected to a rolling action which effectively folds it in half and then rolls it back to its original flat position.

The machine runs at 10 cycles per minute and the test is continued for a minimum of 5000 cycles. It is carried out at room temperature in a controlled environment. This is an accelerated test which simulates the product manipulation and positioning for each day of usage. A product is expected to withstand this treatment without showing any signs of damage before being added to the Trulife Pressurecare range.



Test 3 – Stress Test

In the marketplace, Trulife's Pressurecare Range is likely to be pulled and manipulated repeatedly during everyday use. This will create high local stresses in a product and will have a tendency to encourage the separation of film and gel. The Stress Test measures the degree of adhesion between the film and gel of the Trulife Pressurecare Range and therefore enables us to confidently predict the ability of the product to perform its function over the required lifetime.

A sample piece is subjected to a 50 Newton Load cell on a Lloyd PVM3 Tensile Tester as illustrated in the diagram. This machine runs at a speed of 200 mm per minute and the test is conducted at room temperature. The force, extension and appearance of the sample are recorded over a 5 minute test period. A minimum value of 30 Newtons is required for a product to pass this test.

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?

While a repair kit is available, in the event of the product being cut, it is highly 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.

Summary

Re-distributes weight effectively

High load-bearing capacity

Supports weight without bottoming out

Silicone performs most like human skin

Medical Grade Silicone is highly durable and chemically stable compared to many other gels

Over time its mechanical properties (softness etc) are likely to last much longer

Easily cleaned

X-ray translucent*

*Oasis+ Range has not been X-ray or MRI tested.

Reusable

Acceptable for use with MRI*

Fibre glass and plasticizer free

Does not support bacterial growth

Shock-absorbing

Pads may be heated to body temperature 40°C

The products can be cooled to -12°C

High tensile strength and elasticity

Hypoallergenic

Reduce heat and friction

Can be moulded into any shape or form

Non-conductive

Cost effective

Won't leak, flow or bottom out

Easily repaired if cut

Fire rated as self-extinguishing

Does not harden over time

Retains it's original shape after deformation

Resistant to UV light

Market Leader in many Countries

Helps prevent Decubitus Ulcers and Nerve Injury



Hospital comments on the Trulife Pressurecare Range

Trulife Gel Positioners are indispensable products in the positioning of patients in the Operating Room. The positioners protect the patient from pressure sores and nerve injuries. They are kind to the skin because they are latex free.

The positioners are x-ray translucent, therefore, there is no need to remove them from the patient during surgery. The products are easy to clean and very hygienic, which helps the staff.

We are very happy with the Trulife Gel Positioners because they make our team's job easier.

**Hospital Bielanski, Anesthesiology and Intensive Care Department,
Warszawa, Agnieszka Bartczak, Ward Nurse**

The Trulife Gel Positioners, which we are pleased to buy from the company Empireum, provide our patients with comfort and eliminate the dangers of pressure sores during long and difficult surgeries. They allow the correct positioning of the patient and are hygienic.

Due to the material they are made from, they are easy to clean using standard detergents and disinfectants. They are light to lift and feel nice to touch. We are happy with Trulife Gel Positioners and we are looking forward to further fruitful cooperation with Trulife.

**Z poważaniem, Institute of Psychiatry and Neurology
Neurosurgery clinic**

In order to correctly position patients in the Operating Room I use Trulife Gelpads on a daily basis. These products meet all the requirements a positioning pad has to fulfil.

They are easy to use and give the patient great protection. Furthermore, all pads are latex free, radiograph radiolucent, easy to disinfect, robust and easy to repair.

Trulife offers an extensive range of gelpads to suit every patient's position. Even extreme positions like positioning an adipose patient, prone and lateral positions are safe and possible.

Katrin Schmidt, Fachkrankenschwester für Anästhesie und Intensivmedizin

'Trulife Gelpads offer patients a pleasant positioning experience. The soft and warm pads reduce the fear and the pain of the patient and distract him/her from the operation.

With manifold systems and correct frameworks we can position the patient quickly and professionally so that we save time and follow-up costs caused by decubitus. I use the Trulife Gelpads because they suit every position and I don't have to use different systems.

Sabine Graf-Redecker, Fachkrankenschwester für Anästhesie und Intensivmedizin

Index

TABLE PAD PROTECTION

Code	Description	Dimensions (mm)	Page
EL031	Oasis Elite ¾ Length Table Pad	1150 x 520 x 20	6
OA032	Oasis Full Length Table Pad	1800 x 520 x 10	6
OA036	Oasis Head Section	225 x 500 x 10	6
OA037	Oasis Torso Section	990 x 500 x 10	6
OA038	Oasis Foot Section	500 x 500 x 10	6
OA040	Oasis Perineal Table Pads	520 x 520 x 10	6
OP041	Oasis + Universal Profile Pad	520 x 520 x 9	6

HEAD & NECK PROTECTION

Code	Description	Dimensions (mm)	Page
EL142	Oasis Elite Prone Head Rest Medium	273 x 220 x 135	8
EL141	Oasis Elite Prone Head Rest Large	280 x 240 x 140	8
EL011	Oasis Elite Closed Head Ring Adolescent	∅140 x 34	8
EL012	Oasis Elite Closed Head Ring Adult	∅200 x 50	8
EL021	Oasis Elite Open Head Ring Adolescent	∅140 x 34	8
EL022	Oasis Elite Open Head Ring Adult	∅200 x 54	8
EL152	Oasis Elite Supine Head Rest Adolescent	275 x 230 x 65	9
EL151	Oasis Elite Supine Head Rest Adult	275 x 237 x 90	9
OP151	Oasis+ Head & Neck Support	264 x 220 x 64	9
OA010	Oasis Closed Head Ring Paediatric	∅90 x 20	9
OA011	Oasis Closed Head Ring Adolescent	∅140 x 35	9
OA012	Oasis Closed Head Ring Adult	∅200 x 45	9
OA020	Oasis Open Head Ring Paediatric	∅90 x 22	9

ARM & ELBOW PROTECTION

Code	Description	Dimensions (mm)	Page
EL401	Oasis Elite Contoured Armboard Pad	510 x 155 x 40	10
EL402	Oasis Elite Contoured Armboard Pad	395 x 140 x 40	10
EL072	Oasis Elite Armboard Pad Long	600 x 125 x 20	10
OA061	Oasis Ulnar/Brachial Nerve Protectors (L)	460 x 210 x 8	10
OA071	Oasis Armboard Pads	600 x 200 x 10	10
OP070	Oasis + Short Armboard pad	395 x 134 x 10	10
OP101	Oasis + Long Armboard pad	500 x 161 x 40	10

BODY PROTECTION

Code	Description	Dimensions (mm)	Page
AZ300	Azure Sacral Protector Small	400 x 380 x 25	11
AZ301	Azure Sacral Protector Large	450 x 445 x 30	11
AZ500	Azure Universal Positioner	425 x 155 x 60	11
EL905	Oasis Elite Prone Positioning System	675 x 500 x 100	11
EL903	Oasis Elite Prone Positioner	610 x 530 x 130	11
EL900	Oasis Elite Lateral Positioner	720 x 500 x 160	12
EL210	Oasis Elite Dome Positioner	350 x 150 x 75	12
EL215	Oasis Elite Flat Bottom Chest Rolls	400 x 140 x 110	12
EL216	Oasis Elite Flat Bottom Chest Rolls	505 x 140 x 110	12
EL217	Oasis Elite Flat Bottom Chest Rolls	405 x 150 x 150	12
EL218	Oasis Elite Flat Bottom Chest Rolls	510 x 150 x 150	12
OA211	Oasis Flat Bottom Chest Rolls	305 x 95 x 75	12
OA212	Oasis Flat Bottom Chest Rolls	405 x 95 x 75	12
OA213	Oasis Flat Bottom Chest Rolls	505 x 92 x 75	12
OA050	Oasis Universal Patient Positioners	150 x 60 x 40	12
OA051	Oasis Universal Patient Positioners	330 x 70 x 50	12
OA052	Oasis Universal Patient Positioners	290 x 100 x 60	12
OA053	Oasis Universal Patient Positioners	345 x 120 x 70	12
ELP914	Oasis Elite Positioners Prone Pad	480 x 1014 x 140	13
EL913	Oasis Elite Lateral Park Bench Positioner	520 x 413 x 230	13
ELTS20	Elite Trendelenburg System 20°		13
ELTS40	Elite Trendelenburg System 40°		13
SPS001	Supine Positioning Set		19
PPS001	Prone Positioning Set		19
LPS001	Lateral Positioning Set		20
CPS001	Cardiovascular Positioning Set		20

LEG & KNEE PROTECTION

Code	Description	Dimensions (mm)	Page
EL800	Oasis Elite Lateral Leg Positioner	650 x 400 x 230	14
EL401	Oasis Elite Knee Pad	510 x 155 x 40	14
EL402	Oasis Elite Knee Pad	395 x 140 x 40	14
OA090	Oasis Crutch Stirrup Pads	320 x 220 x 10	14
OA091	Oasis Crutch Stirrup Pads	395 x 245 x 10	14
OA092	Oasis Crutch Stirrup Pads	520 x 300 x 10	14

ANKLE, HEEL & FOOT PROTECTION

Code	Description	Dimensions (mm)	Page
AZ401	Azure Heel Protector	190 x 175 x 30	15
EL130	Oasis Elite Heel Pads	180 x 100 x 70	15
OA200	Oasis Heel & Ankle Protector	250 x 120 x 10	15
OP132	Oasis + Heel Protector	127 x 162 x 71	15