PRESSURECARE

Technical Guide

Trulife

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INTRODUCTION

Trulife's Oasis, Elite and Azure products have been developed in conjunction with highly experienced operating room personnel resulting in products which can help protect the surgical patient from nerve damage and the development of pressure sores.

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, Elite and Azure ranges are manufactured to ISO 13485:2003 standards, each carrying the CE quality mark and are guaranteed against manufacturing defects for 2 years.

The Trulife Pressurecare range first launched in 1995 has become a market leader in many countries around the world. In the course of this development process, the Trulife 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.

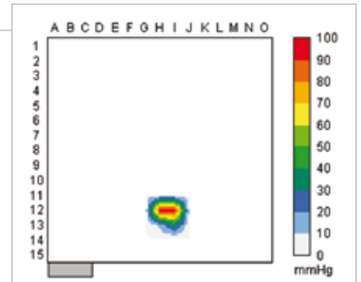
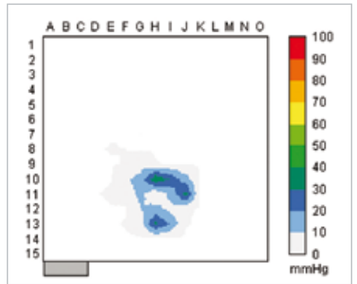
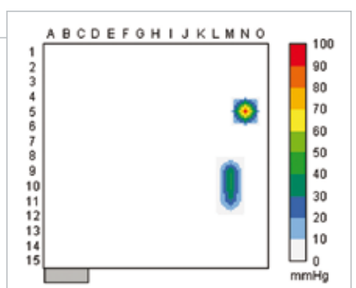
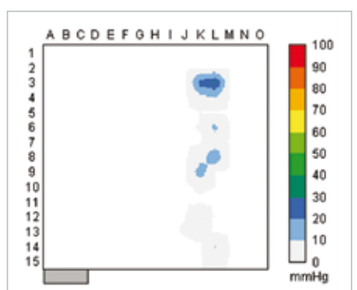
SECTION 1 PATIENT PROTECTION TEST

TEST 1.1 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.

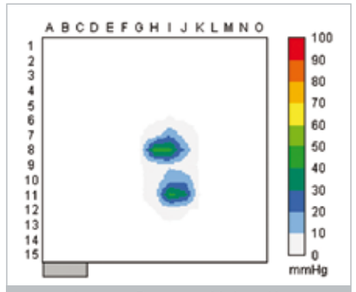
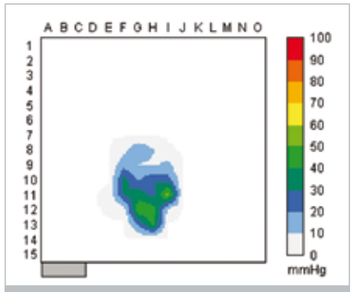
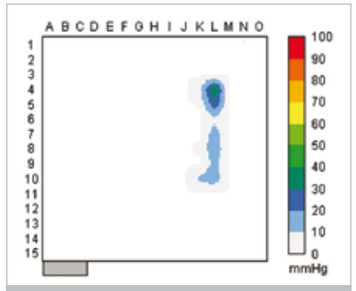
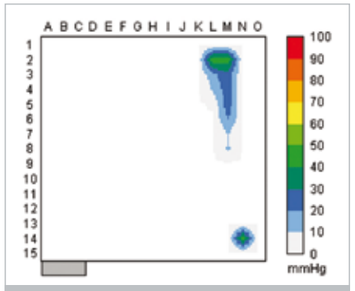
	SUPPORT SURFACE WITH NO PROTECTION	SUPPORT SURFACE WITH AZURE
HEAD	 Average Pressure 64.1mmHg	 Average Pressure 8.64mmHg
ARMS	 Average Pressure 35.9mmHg	 Average Pressure 7.04mmHg

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

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.***

"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.]

1. 2011 Perioperative Standards and Recommended Practices AORN
"Recommended Practices for Positioning the Patient in the Perioperative Practice Setting"

	SUPPORT SURFACE WITH OASIS ELITE	SUPPORT SURFACE WITH OASIS
	 Average Pressure 11.4mmHg	 Average Pressure 19.7mmHg
	 Average Pressure 12.5mmHg	 Average Pressure 23.1mmHg

2. 2011 Perioperative Standards and Recommended Practices AORN
J. & thomson et al. Pressure reduction products: making appropriate choices

> "Any positioning device used to reduce pressure on patient's body parts and prevent tissue damage should have the documented ability to reduce capillary interface pressures to 32mmHg or less[2]"

TEST 1.2 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 TESTS

TEST 2.1 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 (2009) and ISO 10993-1 (2009) 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 2.2 BACTERIOLOGICAL DATA

Silicone 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, Elite and Azure Gel Pads have confirmed that these materials are **latex free** and **do not support microbiological growth**.

TEST 2.3 LATEX CONTENT

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

SECTION 3 GENERAL USE OF GEL PADS IN AN OPERATING ROOM ENVIRONMENT

TEST 3.1 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, quatemany compounds	yes	neat
Incidin Plus (Acidic)	Glucoprotamin, quatermany ammonium	yes	200 to 1
Pursept (Corrosive)	Ethanol, Glyoxal, Quatermany 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 Centuary 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, Elite and Azure pads in a cleaning solution overnight as this may affect the long-term durability of the products.

TEST 3.2 FLAMMABILTY 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.**

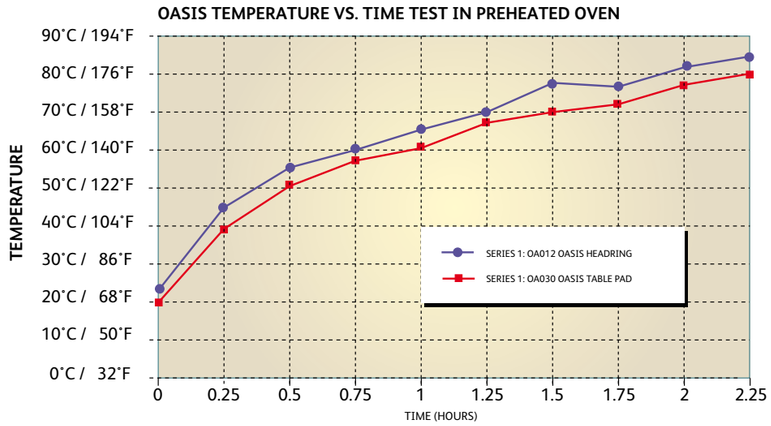
TEST 3.3 TEMPERATURE TEST

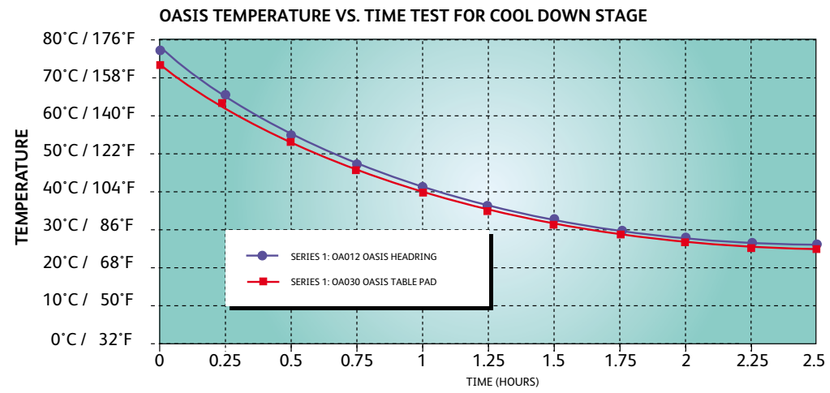
Thermal stability is very important when the material is in contact with the body, as the temperature of the body and its environment is continually changing.

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 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.





TEST 3.4 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 Operating Room Products when stored at temperatures of -18ºC / 0º 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 -12ºC without any adverse effects.

TEST 3.5 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 10^6 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 3.6 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, 40mAsec's	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 3.7 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. **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

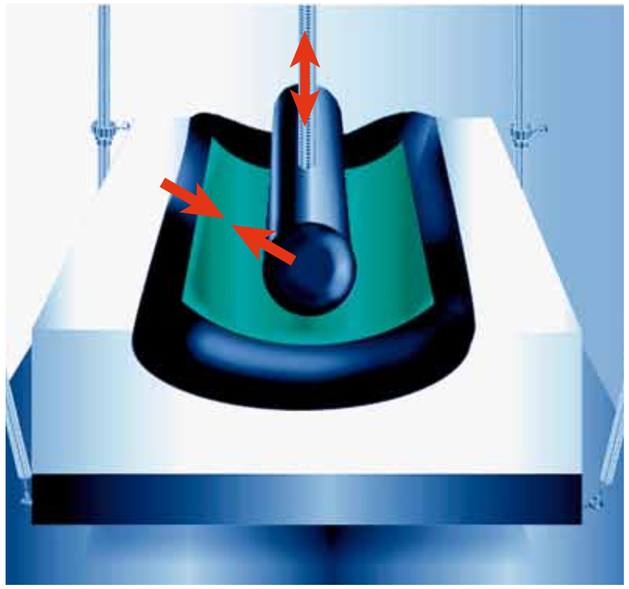
TEST 4.1 COMPRESSION TEST

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.

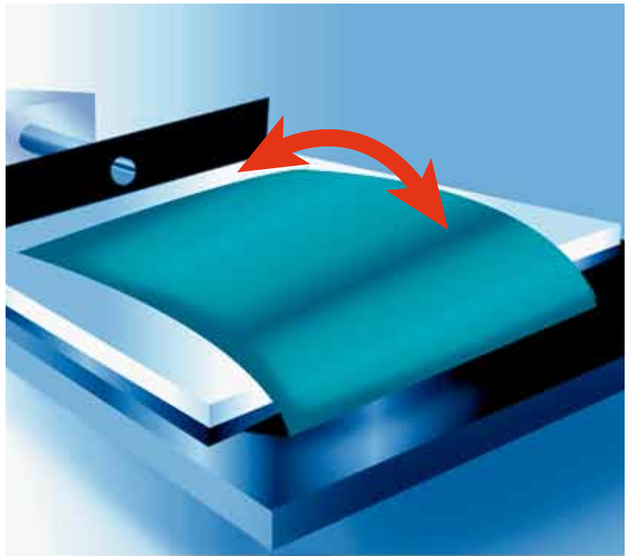
We require a product to undergo a minimum of **20,000 cycles at a rate of 15 cycles per minute** without showing any signs of damage to successfully pass this test. Over a **2 year life span**, this would simulate **27 compressive actions** on the product for each day of the year.



TEST 4.2 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 4.3 STRESS TEST

In the marketplace, Trulife's Gel 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 Operating Room 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.

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	♦ The products can be cooled to -12°C
♦ High load-bearing capacity	♦ High tensile strength and elasticity
♦ Supports weight without bottoming out	♦ Hypoallergenic
♦ Silicone performs most like human skin	♦ Reduce heat and friction
♦ Medical Grade Silicone is highly durable and chemically stable compared to many other gels	♦ Can be moulded into any shape or form
♦ Over time its mechanical properties (softness etc) are likely to last much longer.	♦ Non-conductive
♦ Easily cleaned	♦ Cost effective
♦ X-ray translucent	♦ Won't leak, flow or bottom out
♦ Reusable	♦ Easily repaired if cut
♦ Acceptable for use with MRI	♦ Fire rated as self-extinguishing
♦ Latex, fibre glass and plasticizer free	♦ Does not harden over time
♦ Does not support bacterial growth	♦ Retains it's original shape after deformation
♦ Shock-absorbing	♦ Resistant to UV light
♦ Pads may be heated to body temperature 40°C	♦ Market Leader in many Countries

Hospital comments on the Trulife Pressurecare Range

Pozycjonery żelowe są niezastąpionym produktem w pozycjonowaniu pacjenta na stole operacyjnym w każdej dogodnej pozycji. Dzięki swoim właściwościom przeciwdziałają powstawaniu odleżyn, oraz chronią przed ryzykiem podrażnienia nerwów.

Produkty te nie zawierają lateksu, który jest jednym z czynników alergennych. Pozycjonery są przezierne dla promieni RTG, dzięki czemu nie ma konieczności usuwania ich spod pacjenta podczas operacji. Powłoka, z której są wykonane pozycjonery jest łatwa do czyszczenia i dezynfekcji, co w dużym stopniu ułatwia pracę personelu.

Jesteśmy bardzo zadowoleni z pozycjonerów żelowych TRULIFE, znacznie ułatwiają one pracę naszego zespołu.

Agnieszka Bartczak, Ward Nurse
Anesthesiology and Intensive Care Department
Warszawa, Polska

Zespól bloku operacyjnego Kliniki Neurochirurgii chciałby podzielić się opinią na temat pozycjonerów żelowych. Pozycjonery żelowe, które mamy przyjemność kupować od firmy Empireum zapewniają naszym pacjentom ogromną wygodę i bezpieczeństwo podczas długotrwałych i ciężkich zabiegów operacyjnych. Dzięki temu, że umożliwiają właściwe ułożenie ciała poprzez odpowiednie dopasowanie to zapobiegają powstawaniu odleżyn.

Są łatwe do mycia i czyszczenia przy użyciu standartowych środków dezynfekcyjnych, lekkie i miłe w dotyku, wszystko to na pewnov jest ogromną zasługą materiału z którego są wykonane. Jesteśmy zadowoleni z zakupu wyżej wymienionych pozycjonerów i mamy nadzieję na dalszą owocną współpracę.

– Z poważaniem, Nurse
Neurosurgery Clinic
Polska

'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'.

Agnieszka Bartczak, Ward Nurse
Anesthesiology and Intensive Care Department
Warsaw, Poland

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 Powazanlem, Nurse
Neurosurgery Clinic
Poland

Die Anwendung der Lagerungshilfsmitteln der Firma Trulife ist ein wichtiger Bestandteil meiner täglichen Arbeit im OP zur optimalen Patientenpositionierung. Die Produkte entsprechen allen Anforderungen, die ein Lagerungshilfsmittel erfüllen muss.

Sie sind leicht anzuwenden und gewähren einen sicheren Dekubitusschutz. Desweiteren sind alle Lagerungshilfsmittel latexfrei, röntgenstrahlendurchlässig, gut zu desinfizieren, widerstandsfähig und reparaturfreundlich. Trulife bietet mit seinem umfangreichen Sortiment eine Lösung für nahezu jede Lagerung.

Auch Extremlagerungen, wie zum Beispiel die OP-Lagerung von Adipositaspatienten in Bauchlage oder Seitenlage sind sicher mit den Trulifeprodukten umzusetzen.

– Katrin Schmidt, Fachkrankenschwester für Anästhesie und Intensivmedizin
Deutschland

Eine angenehme Lagerung mit weichen, vorgewärmten Materialien nimmt dem Patienten im Vorfeld der Operation die Angst, lindert Schmerzen und lenkt vom Geschehen ab. Mit vielseitig einsetzbaren Systemen sowie gut ausgearbeiteten Standards können Lagerungen schnell und professionell durchgeführt werden, was zu einer erheblichen Zeitersparnis im OP führt und eventuelle Folgekosten durch Dekubiti reduziert.

Ich habe mich für das umfangreiche System von Trulife entschieden, weil ich damit jede Positionierung individuell durchführen kann.

Durch die Vielzahl der Polster habe ich für jede Lagerung eine Lösung und muss nicht verschiedene Systeme mischen.

– Sabine Graf-Redecker, Fachkrankenschwester für Anästhesie und Intensivmedizin
Deutschland

'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, Specialist Nurse,
Anesthesia and Intensive Care
Germany

'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, Specialist Nurse,
Anesthesia and Intensive Care
Germany

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www.trulife.com

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