

INNOVATIVE SEATING SOLUTIONS



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Trulife Group

Trulife is an internationally based and managed group engaged in the creation, development, manufacture and marketing of niche healthcare products. In addition to wheelchair cushions the Group activities encompass Orthopaedics, Prosthetics, Breastcare and Gel positioners for use in the operating room.



Prevention is Better than Cure

Pressure sores are areas of damaged skin and tissue that develop when prolonged periods of uninterrupted pressure cuts off the circulation to vulnerable parts of the body. Without adequate blood flow, the affected tissue dies.



People who are most vulnerable to the onset of pressure sores include those living with paralysis or using a wheelchair and any person with impaired mobility sensation.

1. "Pressure sores can develop quickly, progress rapidly and are often difficult to heal. Yet health experts say many of these wounds don't have to occur. Key preventive measures can maintain the skin's integrity and encourage healing"



Aside from causing serious discomfort to the sufferer and distress to the carer, the cost of treatment can be debilitating to the healthcare industry.

In the US

2. "The mean length of stay for hospitalizations specifically for pressure sores was 13 days, and the average charge was nearly \$37,800"

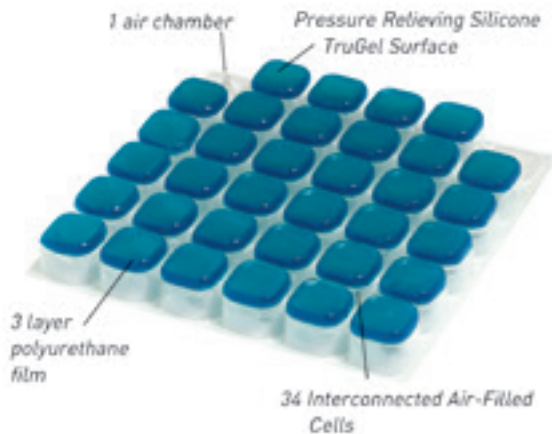
3. "An estimated 2 million adult workdays are lost each year because of chronic ulcers. The cost to manage these ulcers is excessive. Although the direct cost to heal pressure ulcers is elusive, the national cost is estimated at between \$1.68 billion and \$6.8 billion annually." (in the US)

The Relax range offers a wide variety of pressure relieving cushions for wheelchair users and people of restricted mobility who are at increased risk of developing pressure sores. The range has been designed to re-distribute weight and provide exceptional pressure relief and optimum comfort at an affordable cost, bringing a better quality of life to the user.

1. 1998-2006 Mayo Foundation for Medical Education and research (MFMER) "Pressuresores"

2. Agency of Healthcare Research and Quality "Hospitalizations related to Pressure Sores, 2003"

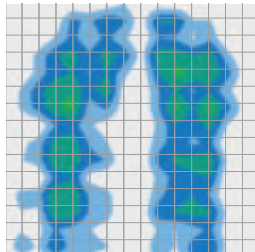
3. Yale School of Nursing "Incidence of Pressure Ulcers Reduced by up to 87 Percent Using Skin Care Prevention Systems According to Yale Clinical" Press Release, 3rd July 2007



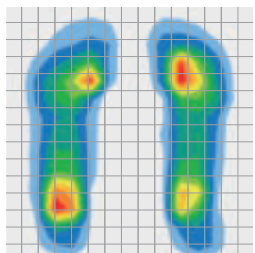
Features & Benefits

The unique combination of **Air** and silicone **Gel** (TruGel) offers pressure relief and comfort.

- **34 interconnected cells** allows movement of air, enhancing the capillary function.
- **Silicone-based TruGel**
 - Enhances pressure redistribution
 - Minimizes the effects of shear and friction
 - Is impact dampening
 - Has a positive effect on skin temperature.
- The Gelcell is made up of 3 layers of polyurethane (PU) film making it highly durable and difficult to puncture. If it is punctured the user will sit on a layer of gel, which still provides pressure relief.
- Highly durable.
- Easy to use and clean.
- Includes an outer cover, first-aid Kit and pump (see pages 12 & 13).



Pressure diagram with Gelcell cushion



Pressure diagram without wheelchair cushion

Relax Gelcell with standard black waterproof cover

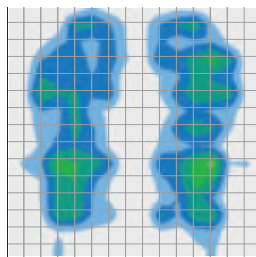
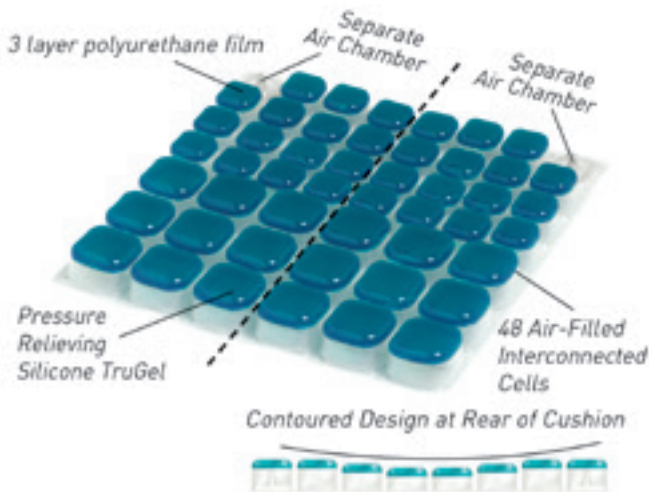
Product Code	Dimensions* (Width x Length x Height)	Cushion Weight
RG004-1514	38cm x 36cm x 4cm / 15" x 14" x 1.5"	1.4kg/3.1lb
RG004-1616	40cm x 40cm x 5cm / 16" x 16" x 2"	1.5kg/3.3lb
RG004-1717	43cm x 43cm x 5cm / 17" x 17" x 2"	1.6kg/3.5lb
RG004-1816	45cm x 40cm x 5cm / 18" x 16" x 2"	1.6kg/3.5lb
RG004-1818	45cm x 45cm x 5cm / 18" x 18" x 2"	1.7kg/3.7lb
RG004-2018	50cm x 45cm x 5cm / 20" x 18" x 2"	1.9kg/4.2lb

Relax Gelcell with breathable/spacer cover (not waterproof)

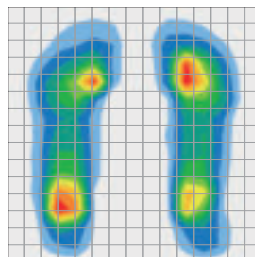
Product Code	Dimensions* (Width x Length x Height)	Cushion Weight
RG002-XXXX	Sizing information above	Cushion weights information above

The weight limit for the Gelcell cushion is 130kg/287lbs

*A tolerance of +/- 10mm is applied to dimensions



Pressure diagram with Gelcell G2 cushion



Pressure diagram without wheelchair cushion

Features & Benefits

- Two separate **air chambers** provide greater stability and pressure redistribution for buttocks and Ischial Tuberosities.
- Air cushion enhances capillary function.
- **Silicone-based TruGel**
 - Enhances pressure re-distribution
 - Minimises the effects of shear forces
 - Has a positive effect on skin temperature
 - Silicone gel is impact dampening.
- The cells are **contoured** towards the rear, promoting good postural tilt.
- When pressure is applied, air circulates to each cell in both chambers distributing weight evenly. This process reduces high pressure concentrations around bony prominences, preventing skin breakdown.
- The Gelcell is made up of 3 layers of polyurethane (PU) film making it highly durable and difficult to puncture. It is easy to wipe clean and suitable for incontinent users.
- Lightweight and easy to transport.
- Easy to inflate and adjust.
- Includes outer cover, First Aid Kit and Pump (see pages 12 & 13).

“Positive test results let us assume that the cushion not only offers good pressure distribution but also reduces shearing stresses”

Independent test report by Woltemade Seniorenurlab, Germany

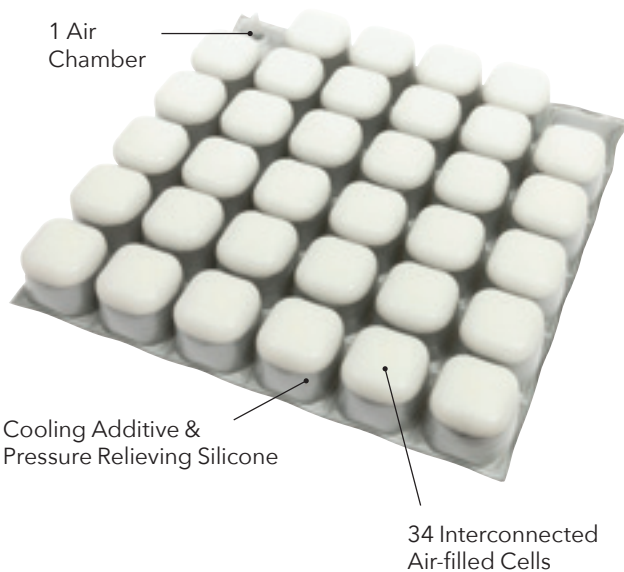
Product Code	Dimensions* (Width x Length x Height)	Cushion Weight
RG005-1414	36cm x 36cm x 4cm / 14" x 14" x 1.5"	1.3kg/2.9lb
RG005-1515	38cm x 38cm x 4cm / 15" x 15" x 1.5"	1.3kg/2.9lb
RG005-1616	40cm x 40cm x 4cm / 16" x 16" x 1.5"	1.5kg/3.3lb
RG005-1618	40cm x 45cm x 4cm / 16" x 18" x 1.5"	1.6kg/3.5lb
RG005-1717	43cm x 43cm x 4cm / 17" x 17" x 1.5"	1.6kg/3.5lb
RG005-1816	45cm x 40cm x 4cm / 18" x 16" x 1.5"	1.6kg/3.5lb
RG005-1818	45cm x 45cm x 4cm / 18" x 18" x 1.5"	1.6kg/3.5lb

The weight limit for the Gelcell G2 cushion is 130kg/287lbs

*A tolerance of +/- 10mm is applied to dimensions



COOLCELL



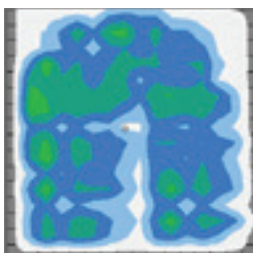
Features & Benefits

A Cooling Additive called "TruCool Gel" uses absorption technology to draw heat away from the users body.

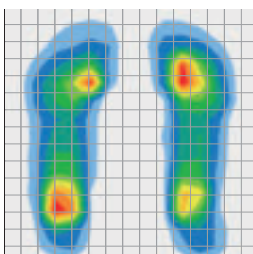
The unique combination of Air and silicone Gel(Trugel) offers pressure relief and comfort to the high-risk user.

- 34 interconnected cells allow movement of air enhancing the capillary function.
- **Silicone Gel (Trugel)**
 - Enhances pressure redistribution
 - Minimizes the effects of shear and friction
 - Is impact dampening
 - Has a positive effect on skin temperature.
- Highly durable.
- Easy to use and clean.
- Includes an outer cover, first-aid Kit and pump.

We recommend using the spacer fabric cover as it will further enhance airflow. For additional incontinence protection, the standard black cover is available. See page 12 & 13.



Pressure diagram with CoolCell cushion



Pressure diagram without wheelchair cushion

Coolcell with standard black waterproof cover

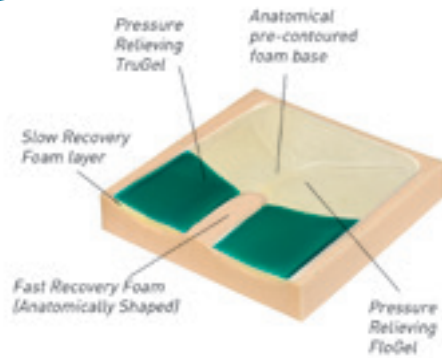
Product Code	Dimensions* (Width x Length x Height)	Cushion Weight
RC004-1616	40cm x 40cm x 5cm/ 16" x 16" x 2"	1.5kg/3.3lb
RC004-1717	43cm x 43cm x 5cm/ 17" x 17" x 2"	1.6kg/3.5lb
RC004-1816	45cm x 40cm x 5cm/ 18" x 16" x 2"	1.6kg/3.5lb
RC004-1818	45cm x 45cm x 5cm/ 18" x 18" x 2"	1.7kg/3.7lb

Coolcell with breathable/spacer cover (not waterproof)

Product Code	Dimensions* (Width x Length x Height)	Cushion Weight
RC002-1616	40cm x 40cm x 5cm/ 16" x 16" x 2"	1.5kg/3.3lb
RC002-1717	43cm x 43cm x 5cm/ 17" x 17" x 2"	1.6kg/3.5lb
RC002-1816	45cm x 40cm x 5cm/ 18" x 16" x 2"	1.6kg/3.5lb
RC002-1818	45cm x 45cm x 5cm/ 18" x 18" x 2"	1.7kg/3.7lb

The weight limit for the Coolcell cushion is 130kg/287lbs.

*A tolerance of +/- 10mm is applied to dimensions



Features & Benefits

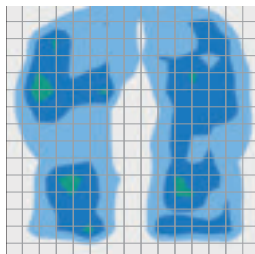
- **TruGel** and **FloGel** work together effectively to provide excellent pressure relief and weight distribution.
- Anatomically contoured **Gel** and **Foam** combination allows for greater circulation and weight distribution.
- The high channels are lined with **TruGel** and the Ischial area is lined with **FloGel** which is set on a viscoelastic foam giving greater comfort and seating stability.
- The clear protective polyurethane film coating is easy to wipe clean and is suitable for incontinent users (not illustrated).
- Highly durable.

Relax Duogel with standard black cover

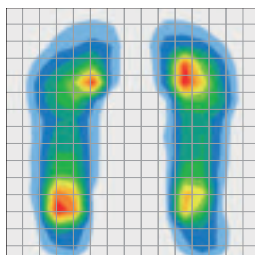
Product Code	Dimensions* (Width x Length x Height)	Cushion Weight
RD003-1414	36cm x 36cm x 8cm / 14" x 14" x 3"	1.2kg/2.7lb
RD003-1514	38cm x 36cm x 8cm/ 15" x 14" x 3"	1.3kg/2.9lb
RD003-1517	38cm x 43cm x 8cm / 15" x 17" x 3"	1.8kg/4.0lb
RD003-1616	40cm x 40cm x 8cm/ 16" x 16" x 3"	1.8kg/4.0lb
RD003-1618	40cm x 45cm x 8cm/ 16" x 18" x 3"	1.9kg/4.2lb
RD003-1717	43cm x 43cm x 8cm/ 17" x 17" x 3"	1.9kg/4.2lb
RD003-1719	43cm x 48cm x 8cm / 17" x 19" x 3"	2.0kg / 4.4lb
RD003-1816	45cm x 40cm x 8cm/ 18" x 16" x 3"	1.9kg/4.2lb
RD003-1818	45cm x 45cm x 8cm/ 18" x 18" x 3"	2.0kg/4.4lb
RD003-1820	45cm x 50cm x 8cm/ 18" x 20" x 3"	2.1kg/4.6lb
RD003-2018	50cm x 45 cm x 8cm/ 20" x 18" x 3"	2.1kg/4.6lb
RD003-2020	50cm x 50cm x 8cm/ 20" x 20" x 3"	2.5kg/5.5lb
RD003-2218	55cm x 45cm x 8cm/ 22" x 18" x 3"	2.8kg/6.2lb
RD003-2418	60cm x 45cm x 8cm/ 24" x 18" x 3"	3kg/6.6lb

The weight limit for the Duogel cushion is 130kg/287lbs

*A tolerance of +/- 10mm is applied to dimensions



Pressure diagram with Duogel cushion



Pressure diagram without wheelchair cushion

"The Duogel significantly outperformed the other market leader in each of the interface pressure indices selected for evaluation"

Interface Pressure Comparison of Wheelchair Cushions Report, TranScience Inc. P.2

Relax Duogel with wipeable black cover

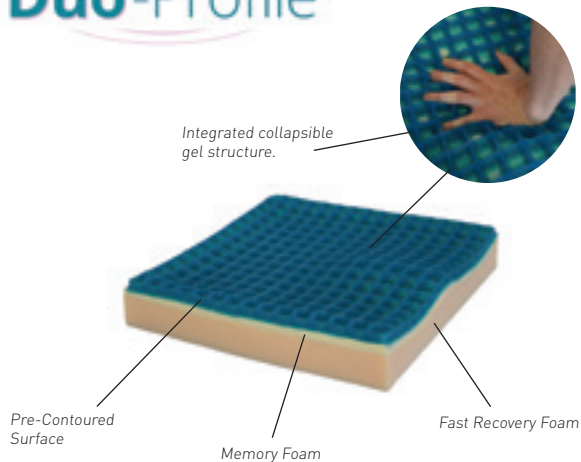
Product Code	Dimensions* (Width x Length x Height)	Cushion Weight
RD006-XXXX	Sizing information above	Weight information above

Duogel with wipeable black cover available in all sizes



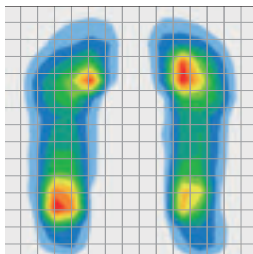
DUO-PROFILE

Duo-Profile

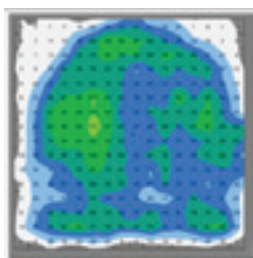


Features & Benefits

- Offers a pre-contoured surface giving excellent hip and leg alignment.
- 3 Layered Design
 - The base is Fast Recovery Foam
 - The mid-section is Slow Foam/ Memory Foam
 - The top layer is Medical Grade Silicone.
- The Duo-Profile uses a collapsible gel topper. This unique design allows you to quickly immerse into the cushion, while conforming to your shape.
- Silicone gel is
 - Impact dampening
 - Minimizes the effects of shear forces
 - Has a positive effect on on skin temperature and is highly durable.
- Includes outer cover (See page 12&13).



Pressure diagram without wheelchair cushion



Pressure diagram with RELAX Duo-Profile

Relax Duo-Profile with standard black cover

Product Code	Dimensions* (Width x Length x Height)	Cushion Weight
RDP003-1616	40cm x 40cm x 8cm / 16"x16" x 3"	1.8Kg/4.0lb
RDP003-1717	43cm x 43cm x 8cm /17"x 17" x 3"	1.9Kg/4.2lb
RDP003-1816	45cm x 40cm x 8cm / 18"x 16" x 3"	1.9Kg/4.2lb
RDP003-1818	45cm x 45cm x 8cm / 18" x 18" x 3"	12Kg/4.4lb

The weight limit for the Duo-Profile is 130kg/287lbs
 *A tolerance of +/- 10mm is applied to dimensions

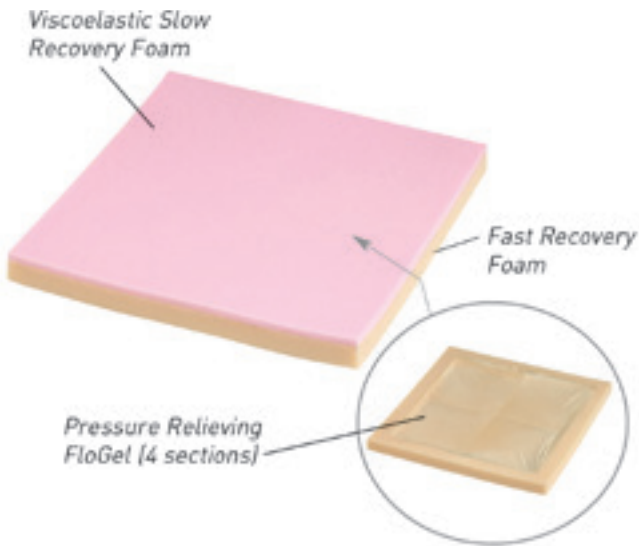
"The combination of foam & gel can be effective in preventing both skin changes and pressure sore formation"

2008 Perioperative Standards and Recommended Practices AORN, Inc



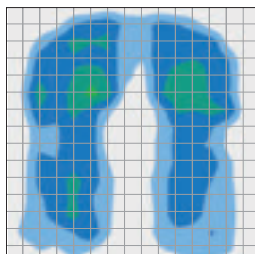


Trio

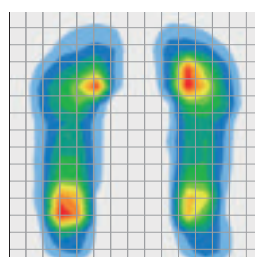


Features & Benefits

- Specially designed to conform to the shape of the user, increasing surface area and relieving pressure. Cushion consists of a **Viscoelastic upper layer with FloGel in the centre and a recovery foam base.**
- No front or back.
- **FloGel helps prevent bottoming out, offers more comfort and pressure relief.**
- Clear protective (PU) film coating is easy to wipe clean and is suitable for incontinent users.
- Lightweight and easy to transport.
- Highly durable.
- Includes outer cover (See page 12&13).



Pressure diagram with Trio cushion



Pressure diagram without wheelchair cushion

Product Code	Dimensions* (Width x Length x Height)	Cushion Weight
RT001-1416	36cm x 40cm x 4cm / 14" x 16" x 1.5"	1.2kg/2.7lb
RT001-1616	40cm x 40cm x 4cm/ 16" x 16" x 1.5"	1.3kg/2.9lb
RT001-1717	43cm x 43cm x 4cm/ 17" x 17" x 1.5"	1.4kg/3.1lb
RT001-1816	45cm x 40cm x 4cm/ 18" x 16" x 1.5"	1.5kg/3.3lb
RT001-1818	45cmx 45cm x 4cm/ 18" x 18" x 1.5"	1.6kg/3.5lb

The weight limit for the Trio cushion is 80kg/176lbs

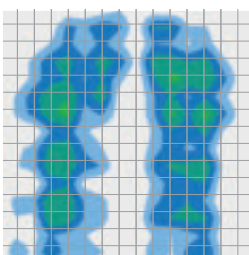
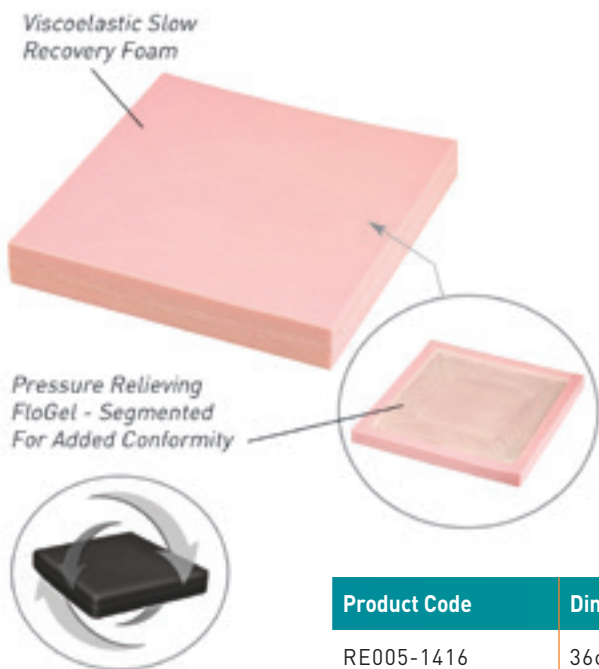
*A tolerance of +/- 10mm is applied to dimensions

"An ultra light cushion that benefits from four sections of FloGel being positioned into a polyurethane base with a viscoelastic foam upper layer. Specifically designed to conform to the shape of the user, increasing surface area and relieving pressure"

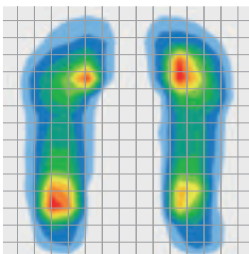
Pressure Sores: Easier to Prevent Than Heal. Able Magazine.



Easy



Pressure diagram with Easy cushion



Pressure diagram without wheelchair cushion

Features & Benefits

- **Fully Rotational** - No top, bottom, front or back.
- Ideal pressure relieving cushion for use in the nursing home environment.
- The Easy cushion has a layer of FloGel sandwiched between an upper and lower layer of **viscoelastic foam**.
- The combination of pressure relieving **FloGel** and **viscoelastic foam** facilitates effective pressure re-distribution while allowing the patient to immerse themselves comfortably into the cushion.
- Conforms to the shape of the user, increasing surface area and relieving pressure.
- Clear protective polyurethane film coating is easy to wipe clean and is suitable for incontinent users.
- Lightweight and easy to transport.
- Includes outer cover (See page 12&13).

Product Code	Dimensions* (Width x Length x Height)	Cushion Weight
RE005-1416	36cm x 40cm x 5cm / 14" x 16" x 2"	1.7kg/3.8lb
RE005-1418	36cm x 45cm x 5cm / 14" x 18" x 2"	1.8kg/4.0lb
RE005-1616	40cm x 40cm x 5cm / 16" x 16" x 2"	1.8kg/4.0lb
RE005-1717	43cm x 43cm x 5cm / 17" x 17" x 2"	1.9kg/4.2lb
RE005-1816	45cm x 40cm x 5cm / 18" x 16" x 2"	1.9kg/4.2lb
RE005-1818	45cm x 45cm x 5cm / 18" x 18" x 2"	2.0kg/4.4lb
RE005-1820	45cm x 50cm x 5cm / 18" x 20" x 2"	2.1kg/4.6lb
RE005-2020	50cm x 50cm x 5cm / 20" x 20" x 2"	2.2kg/4.8lb
RE005-2218	55cm x 45cm x 5cm / 22" x 18" x 2"	2.3kg/5.0lb

The weight limit for the Easy cushion is 130kg/287lbs

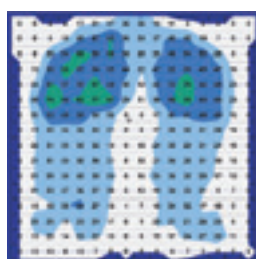
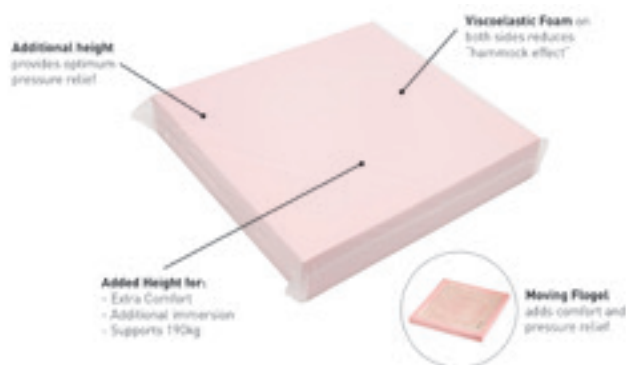
*A tolerance of +/- 10mm is applied to dimensions

"The gel in the Easy cushion has the effect of reducing the risk of the cushion bottoming out whilst maintaining effective pressure re-distribution"

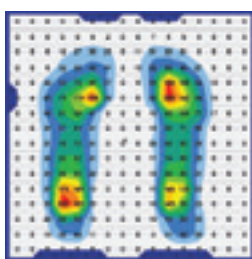
International Journal of Rehabilitation, Volume 13, Issue 1, 2005



Easy **HIGH** Profile



Pressure diagram with Easy High Profile cushion



Pressure diagram without wheelchair cushion

Features & Benefits

- **Fully Rotational** - No top, bottom, front or back.
- High density viscoelastic foam with silicone fluid gel at its core, provides superior pressure re-distribution and immersion.
- Silicone oil is centered between the two layers of slow foam, it contains preformed channels to make sure the oil is evenly distributed.
- Conforms to the shape of the user, increasing surface area and relieving pressure.
- Thanks to additional height and materials, the Easy High profile offers pressure relief for **up to 190kg**.
- Increased depth of memory foam and silicone oil allows for greater immersion and comfort.
- Combination of materials reduces 'hammock' effect.
- Ideal for a patient requiring additional stability, and/or greater cushion depth in their wheelchair.
- Includes outer cover (See page 12&13).

"A combination of foam and gel can be effective in preventing both skin changes and pressure sore formation"

2008 Perioperative Standards and Recommended Practices. AORN, Inc.

Product Code	Dimensions* (Width x Length x Height)	Cushion Weight
REH005-1616	40cm x 40cm x 8.5cm / 16" x 16" x 3.3"	1.8kg/4.0lb
REH005-1717	43cm x 43cm x 8.5cm / 17" x 17" x 3.3"	2.0kg/4.4lb
REH005-1816	45cm x 40cm x 8.5cm / 18" x 16" x 3.3"	2.1kg/4.6lb
REH005-1818	45cm x 45cm x 8.5cm / 18" x 18" x 3.3"	2.5kg/5.5lb
REH005-1820	45cm x 50cm x 8.5cm / 18" x 20" x 3.3"	2.6kg/5.7lb
REH005-2020	50cm x 50cm x 8.5cm / 20" x 20" x 3.3"	3.0kg/6.6lb

The weight limit for the Easy cushion is 190kg/418lbs

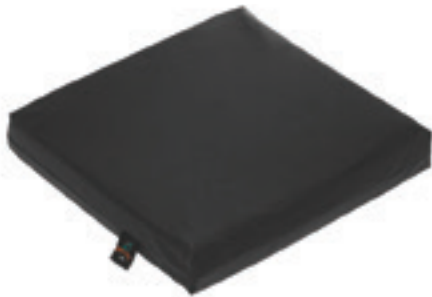
*A tolerance of +/- 10mm is applied to dimensions



COVERS & ACCESSORIES

Our Relax range of wheelchair cushion covers are all designed to offer protection to the user and the product.

The covers are either breathable or fluid repellent, stretchable and hand washable. A cover is included with each cushion, but they are also available to purchase separately.



Wipeable Black Outer Cover

Available with:

Easy (Also available for Duogel on request)

Materials:

Topside and Underside: Polyurethane transfer coating on a weft knitted polyester fabric.

Features:

Water resistant wipe down cover
Easy to clean & maintain

Standard Black Outer Cover

Available with:

Duogel, Gelcell, Gelcell G2, CoolCell, Trio

Materials:

Topside: Weft knitted polyester fabric with a polyurethane transfer coating on inner side.

Underside: Anti-slip nylon coated with flame retardant PU, which has been treated with a biocide.

Features:

Water resistant and easy to wash
High Grip /Anti-slip surface

Codes & Sizes:

**Duogel/
Duo-Profile**

DWC003-1414
DWC003-1514
DWC003-1517
DWC003-1616
DWC003-1618
DWC003-1717
DWC003-1719
DWC003-1816
DWC003-1818
DWC003-1820
DWC003-2018
DWC003-2020
DWC003-2218
DWC003-2418

**Easy
Wipedown**

EC004-1416
EC004-1418
EC004-1616
EC004-1717
EC004-1816
EC004-1818
EC004-1820
EC004-2020
EC004-2218

**Easy High Profile
Wipedown**

ECH005-1616
ECH005-1717
ECH005-1816
ECH005-1818
ECH005-1820
ECH005-2020

Codes & Sizes:

**Duogel/
Duo-Profile**

DC003-1414
DC003-1514
DC003-1517
DC003-1616
DC003-1618
DC003-1717
DC003-1719
DC003-1816
DC003-1818
DC003-1820
DC003-2018
DC003-2020
DC003-2218
DC003-2418

Gelcell G2

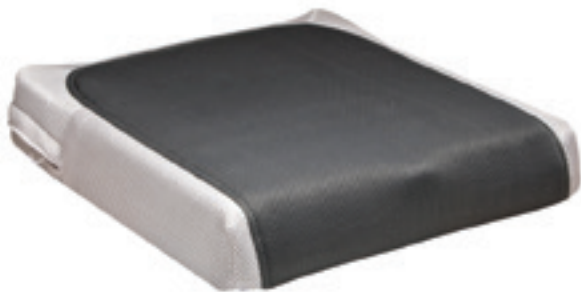
GC005-1414
GC005-1515
GC005-1616
GC005-1618
GC005-1717
GC005-1816
GC005-1818

Gelcell, CoolCell

GC004-1514
GC004-1616
GC004-1717
GC004-1816
GC004-1818
GC004-2018

Trio

TC001-1416
TC001-1616
TC001-1717
TC001-1816
TC001-1818



Spacer Fabric Cover

Available with:

Gelcell & CoolCell

Materials:

Topside: Spacer fabric material enhances redistribution of pressure peaks and dispersion of air and water.

Underside: Anti-slip nylon polyurethane griplock.

Features:

- Excellent dispersion of air and moisture
- Enhances redistribution of pressure peaks
- Millions of microfilaments act as miniature pressure springs
- Highly durable
- Washable at 60°C
- High grip/anti-slip surface

Codes & Sizes:

Gelcell, CoolCell

- CC002-1514
- CC002-1616
- CC002-1717
- CC002-1816
- CC002-1818
- CC002-2018



Handi Pump

Aerogel dual action Handi Pump

Available with:

Gelcell, Gelcell G2, CoolCell

Code: AP001

Repair Kit

Available with:

Gelcell, Gelcell G2, CoolCell

Code: RPK005

The repair kit should be used as a temporary solution only.





The cushions in the Relax range have been subjected to a series of rigorous tests to ensure that the materials used in their manufacture provide the optimal level of support and pressure relief to cushion users.

The results of these tests are outlined in the following pages.

Trulife's Relax range of wheelchair cushions are Class 1 medical devices manufactured in Ireland in conformity with the Medical Devices Directives Annex VII SI252 (93/42/EEC) as amended by Directive 2007/47/EC.

The Relax range is manufactured to ISO 13485:2016 standards, with each product carrying the CE quality mark and guaranteed against manufacturing defects for 2 years.



TEST 1: INTERFACE PRESSURE

Pressure, the amount of force exerted on a given area, is often measured in millimeters 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.

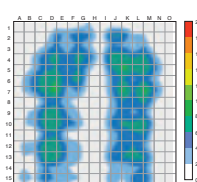
Trulife's Relax cushions help relieve pressure by increasing the area of contact between the body part and the supporting surface (i.e. Relax Cushions). The materials used in the Trulife Relax range are of medical grade and are softer than both skin and underlying tissue. This means that pressure is relieved by the slight movement of the silicone gel and resulting dissipation of pressure/force across the product.

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 sitting on. The Pressure Mapping System is a versatile tool that provides accurate information in an easy to interpret graphical format.

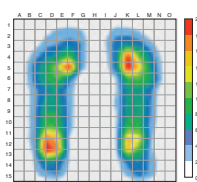
The pressure maps illustrated here are for visual aid purposes only. More comprehensive maps are available upon request.

PRESSURE MAPPING SUMMARY - RELAX RANGE

Relax Gelcell Cushion

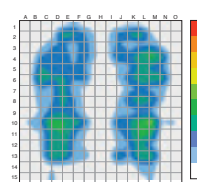


Pressure diagram with Gelcell cushion

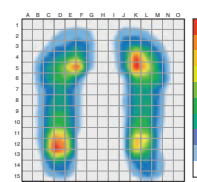


Pressure diagram without wheelchair cushion

Relax Gelcell G2 Cushion

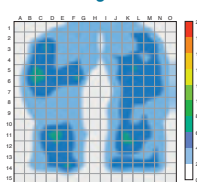


Pressure diagram with Gelcell G2 cushion

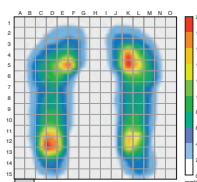


Pressure diagram without wheelchair cushion

Relax Duogel Cushion

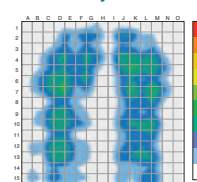


Pressure diagram with Duogel cushion

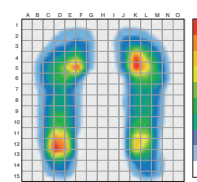


Pressure diagram without wheelchair cushion

Relax Easy Cushion

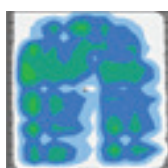


Pressure diagram with Easy cushion

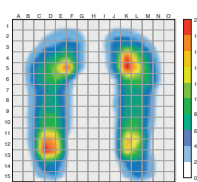


Pressure diagram without wheelchair cushion

Relax CoolCell Cushion

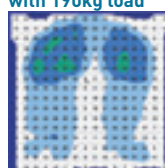


Pressure diagram with CoolCell cushion

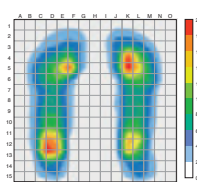


Pressure diagram without wheelchair cushion

Relax Easy HP Cushion with 190kg load



Pressure diagram with Easy HP cushion

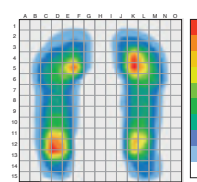


Pressure diagram without wheelchair cushion

Relax Trio Cushion



Pressure diagram with Trio cushion



Pressure diagram without wheelchair cushion



SECTION 2 - PATIENT COMPATIBILITY TEST

TEST 1: SKIN COMPATIBILITY

The silicone and foams used in the Relax range are widely acceptable to biomedical applications and pose no cytological risk to the user.

Irritancy potential 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.

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

Our foam and gel cushions are covered in a layer of film which also provides excellent biocompatibility to the end user.

TEST 2: BACTERIOLOGICAL DATA

Suppliers of the materials used to manufacture Relax cushions have confirmed that these materials do not support microbiological growth.





TEST 1: DISINFECTANT REPORT / CLEANING

All outer covers can be washed at 60°C and include a weft-knitted polyester fabric coating.

The Trulife Relax range is easy to clean & disinfect between uses. The interior cover/Polyurethane film can be cleaned with mild disinfectants or detergents as outlined below.

- Phenolics
- Quaternary ammonia
- Quaternary ammonia and alcohol blends (Alcohol, chlorine) This list covers the major families of detergents.

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	Glucoprotamin, alcohols	Yes	200 to 1
Pursept (Corrosive)	Ethanol, glyoxal, quaternary compounds	Yes	100 to 1
Cutasept F (Bode)	Alcohol, propan-2-ol	No	-
Cutasept G (Bode)	Alcohol, propan-2-ol, quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl, chlorides	No	-
Milton	Sodium hypochlorite, chlorine	Yes	100 to 1
Terminator One-Step	Quaternary based	No	-
Mikrozid (S&M)	Ethanol, propanol	Yes	5 to 1
Bacillol AF (Bode)	Ethanol, propanol	No	-
Bigusept Fluid (Bode)	Alcohol	No	-
Virkon	Potassium peroxomonosulphate, sulphamic acid, sodium alkyl benzene sulphonate	Yes	100 to 1



SECTION 3 - GENERAL USE OF WHEELCHAIR CUSHIONS

TEST 2: FLAMMABILITY TEST

External Flammability tests were carried out in accordance with BS EN 1021-1 & BS EB 1021-2 on cushions and covers.

TEST 3: ISO 16840-2 (GELCELL AND DUOGEL)

Trulife are certified for ISO 16840-2, which specifies apparatus, test methods and disclosure requirements for wheelchair seat cushions intended to maintain tissue integrity and prevent tissue trauma.

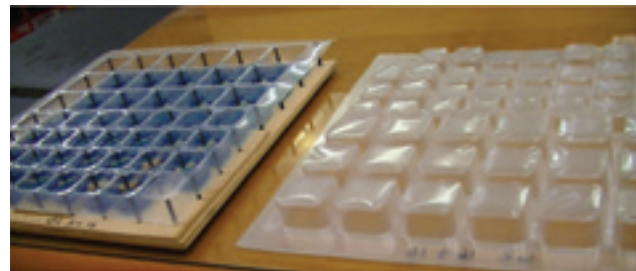
ISO 16840-2 certification was awarded to Gelcell and Duogel cushions, having passed the following tests:

- Impact Dampening (shock absorption)
- Friction (cover)
- Friction (whole cushion)
- Heat & water vapour (moisture management)
- Load-deflection and hysteresis (resistance to bottoming out)
- Recovery (maintenance of shape)
- Loaded contour depth (resistance to bottoming out)
- Horizontal and Lateral stiffness (resistance to shear)
- Water Strike (suitability for incontinent users)

Further information on testing and certification is available if required.

TEST 4 - FREEZING TEST / HEAT TEST

Tests were performed on Trulife's Relax range investigating the effect of freezing temperatures and excessively warm temperatures on product integrity and function. When stored at temperatures of -15°C / 0°F for 7 days and also 40°C for 7 days, no deterioration in the condition of the cushions was observed. The results of the test indicate that damage is unlikely to occur as a result of freezing temperatures or excessively warm conditions. We conclude that the products can be cooled to -15°C or heated to 40°C without any adverse effects.



Gelcell G2 manufacturing



Trulife commissioned TranScience Inc. in the United States to carry out independent testing on the Relax Wheelchair Cushion range.

The principal findings confirmed the high performance status of the Relax Wheelchair Cushions.

DUOGEL

The Duogel cushion is currently competing against another market leader, against which it was rigorously tested in the independent tests carried out by TranScience Inc.

The tests included Repeated Mapping and 60 Minute Trials.

The results show that, over time, the Duogel proves to be the more effective anti-decubitus cushion:

“The Duogel significantly outperformed the other market leader in each of the interface pressure indices selected for evaluation”

“Mean pressure was significantly less on the Duogel than the market leader” (Fig.1)

“Mean support area on the Duogel was significantly greater than on the other market leader” (Fig 2)¹

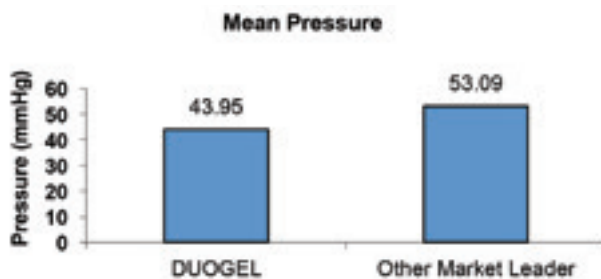


Figure 1: Mean Pressure- Duogel vs Other Market Leader

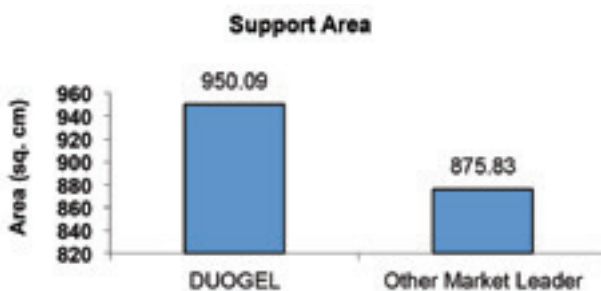


Figure 2: Support Area- Duogel vs. Other Market Leader

GELCELL

The Gelcell cushion is also competing with the market leader in its class.

Again, the independent tests were carried out between the Gelcell and another market leader and many of the results proved positive in the Gelcell's favour:

“The other market leader had significantly higher peak pressures than the GelCell” (Fig. 3)²

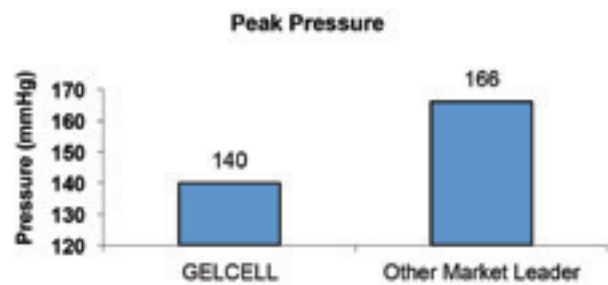


Figure 3: Peak Pressure- Gelcell vs. Other Market Leader

Testing, analysis and reporting were carried out by Richard Barnett, Ph.D. and Charlie Lachenbruch, Ph.D.

¹ Interface Pressure Comparison OF Wheelchair Cushions” Report, April 25, 2001, TranScience Inc. P.2



Trulife commissioned Woltemade Seniorenurlaub in Germany to carry out independent testing on Gelcell and Gelcell G2 Cushions.

GELCELL

The cushion “Gelcell” by the company Trulife was tested. The Gelcell cushion was tested during a period of 12 weeks.

The test persons spent a few hours (approx. 4-5 hours) daily in wheelchairs and care chairs.

Altogether four patients with the following illnesses tested the cushion: hypertonia, degenerative spinal-suffering, cerebral-sclerosis, relapsing urinary tract infection, condition after Total Prosthetic Replacement, carcinomas and diabetes mellitus type 2, condition after apoplectic insult. The four patients were in an extremely bad state of health and were very restricted in their mobility. The decubitus risk was determined with the Braden Scale. All patients showed a high to very high risk. Two of the patients had a decubitus of second degree in the sacral region. These were slightly infected however they were free from necrotic skin.

TEST CONCLUSIONS

The following observations were made. Wound healing of the decubitus patients was successful, with wounds improving. Inflammation diminished and the wounds became clearly smaller. High-risk patients showed completely intact skin, and the patients themselves were satisfied with seat comfort.

The cushion is easily cleaned, and the anti-slip base was noted as being effective. The flexible cover does not show any formation of wrinkles.

The micro-climatic conditions seem to be relatively good and/or sufficient, because increased sweating of the patients could not be observed.

It was noted that some practice was required in order to inflate the cushion to the necessary level. Additionally the air pressure in the cushion must be examined before each use.

Overall the cushion is recommended for the prevention and therapy of decubitus ulcers.

DUOGEL

The Duogel cushion was tested by five residents in our houses for a period of three weeks the nursing staff got the results shown below.

TEST CONCLUSIONS

Three residents each had a pressure sore in category I, II and IV (EPUAP) in the sacral region. The start of wound healing could even be observed for the category IV pressure sore. During the whole time of use our residents had no new pressure induced skin lesions, so the effectiveness of the cushion could be proven.

From the results and experience gained during the use of the test cushion, we evaluate the product as appropriate in accordance with the indications of the manufacturer for use in pressure sore management (decubitus prophylaxis and therapy). The use of the cushion can be advocated both for domestic as well as for hospital applications.

SECTION 4 - INDEPENDENT TEST 3 (UK)



Trulife commissioned Occupational Therapy Independent Practitioner Christine Turner, based in the UK, to carry out independent testing on the Relax range.

Her conclusions are summarised in the table below:

- * low performance ** medium performance
- *** high performance **** exceptional performance

Cushion	Gelcell	Gelcell G2	Duogel Contour	Easy	Trio
Materials used	Air/gel	Air/gel	Gel/PU & Visco foam	Gel/VE foam	Gel/PU & Visco foam
Cushion weight	1.3kg	1.3kg	2kg	1.5-1.7kg	1.4-1.5kg
Max. User weight	130kg	130kg	130kg	130kg	80kg
Level of Wheelchair Dependency	****	****	****	***	***
Ease of Standing Transfer	***	***	**	***	***
Sitting Stability	***	***	***	**	***
Postural Positioning	**	**	****	**	**
Pressure Re-Distribution	****	****	***	**	**
Shear Force Reduction	***	****	**	**	**
Deformity Accommodation/Correction	**	**	***	**	**
Heat Reduction	****	****	***	**	**
Moisture Management	****	****	***	**	**
Ease of Maintenance/ application	****	****	***	****	***



SECTION 5 - DURABILITY TEST

TEST 1: POUNDING LIFE CYCLE TEST AND REPEATED PRESSURE MAPPING

Silicone and foams show resistance to weathering which is important for the long term life of the products. Under normal conditions of use a Trulife Relax product is repeatedly compressed and relaxed when a patient sits on and off a cushion.

The life cycle test assesses the impact of a human representation being applied to and removed from the cushion 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.

Trulife require a product to undergo a minimum of 9,130 cycles at a rate of 10 cycles per minute without showing any signs of damage. This represents approximately 2.5 yrs of usage.

Once the cushion has undergone the life cycle test, it is again pressure mapped to evaluate the effect the life cycle test has had on the internal structure of the cushion and if it could potentially cause any risk to the user.

TEST 2: ALTITUDE TEST

Physical stability is very important when the cushion is in contact with the body. As Trulife cushions are often shipped overseas, it is necessary to replicate the environment to which the product may be exposed whilst in transit.

When testing a new silicone, the product is placed into a known environment and the pressure of this environment is reduced to 0.6 mbar to simulate an altitude of approximately 6000m for 60 minutes. A comparison product is used after the test to establish if any abnormalities are visible 24 hours after the test. If the silicone shows no abnormalities the material is deemed suitable for use in the Relax range.

TEST 3: ADHESION TEST

When properly adhered to the external polyurethane film, silicone offers excellent pressure relieving qualities and reduced shear forces. We test the adhesion of silicone to film using two methods, to ensure the adhesion has been successful.

TEST 3A - COMPRESSION TEST

The silicone is repeatedly compressed physically in the same area under controlled conditions. Afterwards the area compressed is visually inspected for silicone delamination, gel discolouration and silicone oil being released between silicone and film.

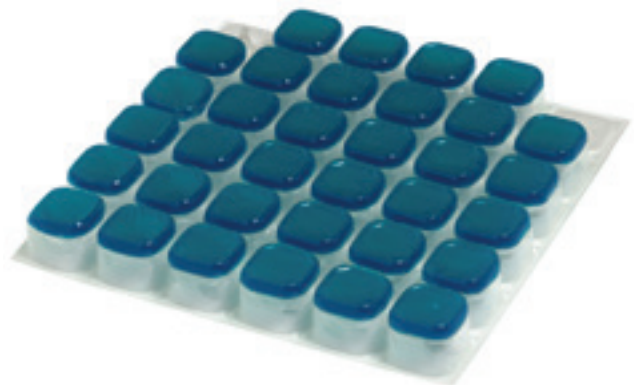
TEST 3B - PEEL TEST

The film is pierced open and the silicone is physically peeled away from the film. The film is observed for traces of silicone that may remain on it. Trulife's internal protocols and procedures are used to determine if the silicone has passed the peel test and if it can therefore be utilized as a component in a Relax cushion.

TEST 4 - JOURNEY HAZARD

The exterior packaging of Trulife's Relax range needs to be robust and strong enough to protect the cushion and facilitate worldwide delivery.

Journey hazard testing is carried out by shipping product to, and back from a specified overseas destination (usually within the Trulife Group). Afterwards, the cushion and other materials are inspected for any signs of damage. If the packaging, cushion and other materials show no signs of damage, the journey hazard test is deemed to have been passed.



Gelcell cushion [RG004]



Trulife's goal is to achieve excellence in our products through innovation and quality for the customer and end user.

Prior to the market release of a new cushion, samples and prototypes of a proposed design are reviewed in conjunction with occupational therapists, physiotherapists, seating specialists and users to ensure the product offers effective pressure relief and functions as intended.

Trulife values feedback from the patients and healthcare professionals who use our products. If you have any questions or feedback, please don't hesitate to contact your local distributor.

Q: How do I care for my Relax wheelchair cushion?

Care instructions are included with every Relax product. This instruction pamphlet contains all the information you will need to care correctly for your cushion and its cover.

Q: How much should the air cushions (Gelcell, Gelcell G2 and CoolCell) be inflated?

It is important not to over-inflate the air cushions, as this could damage the integrity of the individual cells. For inflation guideline please refer to instruction pamphlet with your product.

Q: How long will the air cushion stay inflated?

The air cushions underwent cyclic loading testing of 70kg for 300,000 cycles and did not deflate. This is more than an air cushion would have to withstand in a lifetime. However, it is highly recommended to check the level of inflation on a regular basis.

Q: What happens if the valve is opened accidentally?

The air cushions will not release air if the valve is accidentally opened, as pressure needs to be applied to the valve (i.e. squeezed) before air will be released.

Q: Will the air cushions burst easily?

When used correctly, the air cushions should withstand normal day to day usage and should not burst. The air cushions are made up of 3 layers of a durable polyurethane film. Together these have a thickness of approximately 1mm, which would be hard to burst. If any damage occurs (e.g cut, crack or tear) the product should be replaced. A repair kit is available but should only be used as a temporary solution.

Q: How should the air cushions be placed in my wheelchair?

The valve of the air cushion should be placed toward the back of the wheelchair.

Q. What happens to air cushions during a flight?

During a flight a user may see an increase in volume of the air in the cushion as there is an increase in altitude. If this does occur, the valve may need to be squeezed and re-inflated to equalise the pressure. For inflation guidelines please refer to the instruction pamphlet with your product.

Q: Is my Relax cushion under warranty?

All Relax cushions have undergone rigorous testing and are manufactured to ISO 13485:2016 standards, each carrying the CE Quality mark and are guaranteed against manufacturing defects for 2 years.

Q: What is the weight limit of the Relax Cushion?

Weight limits are indicated on the Relax Wheelchair Cushion Cover and in this catalogue.

Q: What weight is used in your illustrated Pressure Mapping?

80kg is the weight used. It is important to note that pressure relief will be compromised as weight increases.



Trulife Ireland

Ireland

Tel + 3531 4511755

Email: info@trulife.com



www.trulife.com