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Operation theatre positioning devices

Technical Manual

Non leaky
(no release of any fluid)

Elastomeric Cushioning
(~2 times stretchability)

Natural Skin Touch
(Feel it yourself)

Organic -Environmental Friendly
(non toxic)

Stick On
(Self attached Device)

Moisture Resistant
(Dip water test)

Resilience Factor
(~2000 pounds, 900Kgs)

Nature Colour Variation
(Blue, Pink & Green)

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Surgical positioning especially during prolonged surgery is an important task preventing any pressure or illicit physiological response. The post anaesthetic positions during prolonged surgeries are linked to various factors such as the pressure application during surgery, thus (it is advisable to provide intermediate release of pressure); body physiology and age compatibility. Along with damage incurred by pressure, further shear and frictional impact also make patient's body vulnerable to bad sores. It might cause multiple pressure sores at various sites of the body. Proper patient positioning on the operating table (padded with organogel padding) is essential to allow optimal surgical exposure and to prevent neuromuscular injuries. Body parts i.e. eyes, ears, penis, scrotum, breasts, fingers etc are at risk of compression injury during such prolonged surgeries. Thus, this technical manual provides detail about medigel® operation theater positioning devices.

Instructions for Care

- ✓ Keep off sharp/pointed implements. Do not expose to heat or direct sunlight.
- ✓ The products can be disinfected with common available clinical disinfectants such as (Providone-Iodine Solution IP 5% w/v), (Isopropyl Alcohol IP 70% v/v), (Choloroxylenol IP 4.8% v/v, Terpeneol 9% v/v, Alcohol Absolute (Denatured) 13.1% v/v) and (Chlorhexidine Gluconate Solution IP 1.5% v/v, Cetrimide IP 3% w/v). Puff some standard hospital talcum powder before use.
- ✓ The products are easily cleaned using standard detergents.
- ✓ Do not autoclave it can be heated upto the temperature of maximum + 50° C and cooled upto the temperature of maximum -20° C.

Medigel® : Organic C₃I Gel Technology

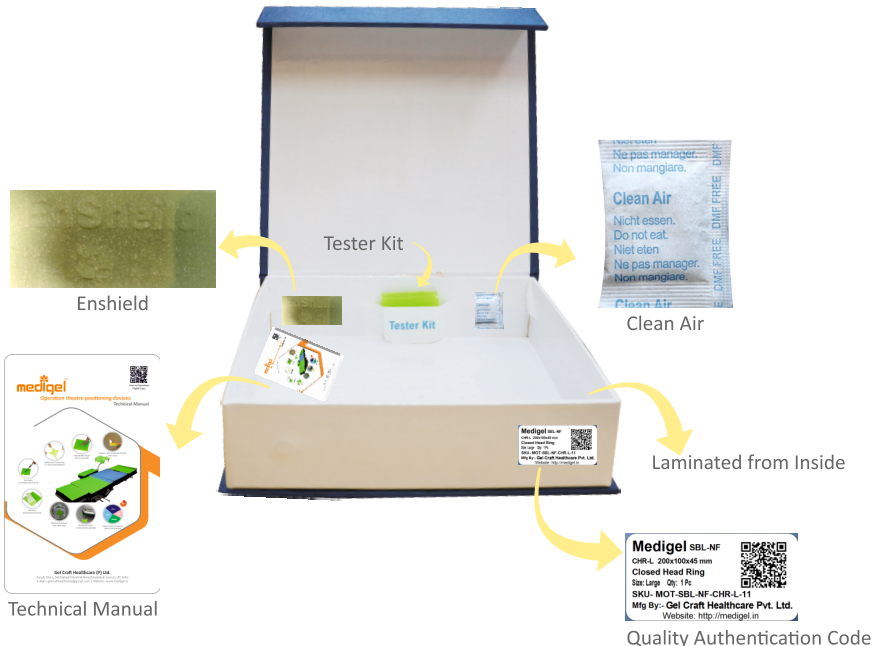
The Medigel®: Organic C₃I Gel Technology works on the principle of pressure redistribution. However, as per Newton's third law, every technology creates its own pressure as its nature of counter reaction to any surface. However, if the cushioning is supreme the pressure will immerse into the surface like memory foam and will be released slowly when the limb is removed. In such cases, due to lack of elastomeric distribution it may not be effective for positioning devices. On the other hand, only elastomerism can equalize the pressure, while in absence of cushioning damage to other nearby sites is observed, such as in latex based material. *An optimum of both such cushioning and elastomerism is essential for right pressure distribution with comfort to the site under stress.*

- ✓ Medigel® Mac Operation Theatre Positioning devices complied with SOPs laid down by Association of Surgical Technologists (AST-SOPs)

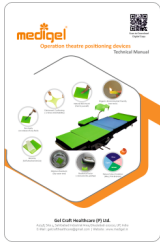
Medigel® : Organic C₃I Gel Technology vs. Other Technologies

Organic C ₃ I Gel Technology	Other Technologies
Single phase able to contour as well as provides cushioning along with elastomerism, makes it an ideal system for 100 % seamless pressure distribution.	Two phases in conjugation - one for cushioning material while other to develop contoured body part. Such technology has limitation that two phases of different nature cannot produce a seamless pressure distribution.
C ₃ I Gel Technology is organic in nature with artificial cushioning, comforting, able to be contoured into any desired shape & inert-ideal for operation theatre needs.	Foam and silicone gel combinations; jelly like material encapsulated in protective layer; 100% silicone gel pads have two phases which is a common limitation.
It can be cut into desired shapes, if need be.	Encapsulated Jelly based system cannot be cut as it will leak
Organic and natural skin touch, completely inert.	Synthetic in nature & 4% chances of any allergenicity in long term touch.
No leakage possible.	Some technologies leak if the upper protective layer breaks out.
Elastomerism and cushioning both allows complete pressure redistribution.	Cushioning with limited elastomerism allows incomplete pressure distribution.

Packaging Standards



Enshield



Technical Manual



Clean Air



Laminated from Inside



Quality Authentication Code

Irradiation Sticker
(Red Color indicates Irradiated Item)



Closed Box with Brand Name

Standards:

- The box is developed in accordance to the weight of the product.
- Each pack contains one sample of gel that is provided for performing Acceptance Test Procedures ensuring quality control.
- Box is irradiated (as exhibited by sticker outside).
- Inside air of the pack is protected by anti-mold solution Enshield and Clear Air system.
- QA Code provides batch number as per manufacturing standards of Gel Craft Healthcare (P) Limited (scan it to get relevant information).
- Outer box has original brand name.
- One copy of Technical manual is provided in each pack for instructions for care.

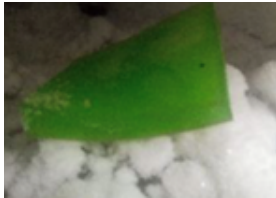
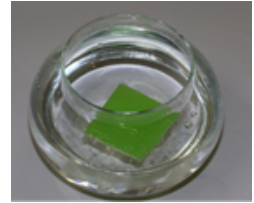
Note : The Inside Box is blue in colour (here shown in white for describing standards only)

Acceptance Test Procedures

Acceptance Test Products (ATPs) are laid down by Gel Craft Health Care (P) Limited to establish the authenticity of C₃I [Comforting, Cushioning, Conforming and Inert] gel products by pre-identified quality check procedures. With every product, a sample piece of C₃I gel material is provided for this sequential and destructive testing (as mentioned below). Destructive testing should not be used on the original item.

1. Moisture Resistant:

Dip the complete sample gel in the testing container filled with water and keep it for 1 hr to check impact. Wipe the sample prior to next test.

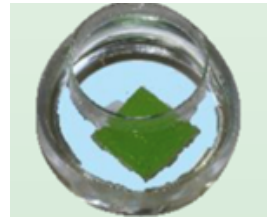


i. Cold Tolerance Testing:

Take the sample gel and keep it in the refrigerator (ice making section) for 1/2 hr, remove the sample, check its integrity after wiping it with clean cloth. Keep it at room temperature (~ 25°C) for 10 min prior to next testing.

ii. Clean Test:

Dip the sample in known detergents / mild soaps, remove it after a while, clean with clear water, keep it under running fan. Record the observations- time to self dry up; any change in its appearance or color; water retention or not. Wipe it prior to next testing procedure. You can also disinfect the sample with disinfection agents laid down in instructions to care.



iii. Resilience Test or Weight bearing capacity:

2000 pounds of weight to be placed on the sample piece (vertically downwards, as maximum load will be placed on the product). Remove it carefully after 15 min and note the observations: (a) time to achieve normal shape; (b) distortion on the surface (Repeat the process 5 times and check the observations).

iv. Elastomeric behavior or Stretchability Test:

To test the intrinsic property of elastomeric cushioning, hold the dried sample piece from both ends and stretch it twice its length (check whether it reached twice its length), slowly remove the tension induced (check how much time it will take to recover it to original shape). Ask other persons to hold two ends of the piece while you hold the other two and expand it slowly (check your observation, whether it expands extensively or not), remove the tension slowly and note how much time it will take to come back to normal state.



v. Prick Test:

To check robustness and leakage. This is destructive testing and should only be conducted once all the above-mentioned tests are completed. Take pointed pin with sharp end and pierce at the centre of the sample piece by vertically downward action, repeat it twice at 2 different positions. Check whether the sample piece leaks at any time.



vi. Burn Test:

Hold the pricked sample (previous test) in your left hand carefully and burn the sample from the opposite end (Observe the type and color of smoke, melting rate and residue falling on the ground). Remember, it would be extremely hot to touch the melted gel and you need to blow off the flames within few seconds of burning otherwise complete sample will be burnt in no time. Don't perform this procedure with silicone or latex containing sheet without any mask as a black toxic smoke and / or powdery residue (in case of silicone) will be observed.

Compare results with given table to self-authenticate that the supplied material is C3I gel.

Test	C ₃ I Gel	Silicone	Jelly filled films
Moisture Resistant	Completely Resistant	Resistant	Completely Resistant
Cold Tolerance Testing	Tolerant	Can't say, based on type	Outer plastic film might get hardened/ ruptured due to expansion of jelly
Clean Test	Yes	Yes	Yes
Resilience Testing	Extreme	Less	Least
Elastomeric Behaviour Testing	Extreme	Least	Nil
Prick or Leak Test	Don't Leak	Can't say, based on type	Leak if pricked.
Burn Test	White smoke with no odor, burns like candle or true gel	Black/mixed color smoke (toxic) with white powdery residue left	Plastic burning fumes with jelly burning as chemical burning material

पैकिंग मानक



गुणवत्ता प्रमाणिकरण को है



अंदर से परतदार

सूक्ष्म हवा



मानक:

बीएस की उपचार के अवयवों विकसित किया गया है।

प्रत्येक यूनिट में एक लैब का काम किया गया है जो गुणवत्ता नियंत्रण सुनिश्चित करने के लिए उपयुक्त प्रक्रियाएं प्रदान करने के लिए उपयुक्त है।

उत्पाद को विकसित किया गया है (जैसे कि बाहरी डिस्कॉर्न डिवाइस)।

यूनिट के अंदर का एंटी-मॉल्ड संभावित प्रभावित और निरंतर रूप से

गुणवत्ता प्रमाणिकरण को है लैब का प्रदान करने के लिए उपयुक्त प्रक्रियाएं प्रदान करने के लिए उपयुक्त है (जैसे कि गुणवत्ता प्रमाणिकरण को है लैब का प्रदान करने के लिए उपयुक्त प्रक्रियाएं प्रदान करने के लिए उपयुक्त है)।

बाहरी बीएस पर प्रमाणिकरण को है लैब का प्रदान करने के लिए उपयुक्त प्रक्रियाएं प्रदान करने के लिए उपयुक्त है।

विकसित डिस्कॉर्न (बाल रंग विकसित उपचार की प्रक्रिया है)



बैज के नाम सहित बीएस का उपयुक्त प्रक्रिया

नोट: बीएस के अंदर की प्रक्रिया को है लैब का प्रदान करने के लिए उपयुक्त प्रक्रियाएं प्रदान करने के लिए उपयुक्त है।

