

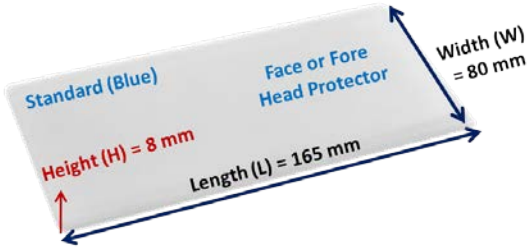



Technical Specification of Operation Theatre Positioning Devices

Face/ Fore Head Protector Standard Blue No Film



| | Generic / Technical Specifications | Compliance Statement(s) |
|--|---|---|
| Name of Item | Face/ Fore Head Protector Standard, Blue No Film | Face/ Fore Head Protector Standard, Blue No Film |
|  | | |
| Technology/ Product Specifications | | |
| Product Category | As mentioned in catalogue or website: otcare.co.in | Face/ Fore Head Protector(s) |
| Purpose of Product | As defined in catalogue | <ul style="list-style-type: none"> Protect the patient's fore head/ facial contours from pressure caused by endotracheal tubes Universal protector and it can be used at any similar body site. |
| Product Design (with markings) | Product Image with marking of dimensions |  |
| Material | Medical Grade cured gel which doesn't flow out | Yes |
| Type of Gel Technology | Viscoelastic Gel with Covid Coat+ (Anti-microbial coating) or C3I Gel | Viscoelastic Gel with Covid Coat+ (Anti-microbial coating) |
| Generic Technology Name | C3I Gel (CC+) or C3I Gel | C3I Gel (CC+) |
| Brand Name or OEM | Whether the item is required with/ without Brand Name i.e. OEM | With Brand Name: Medigel® |
| Color of Product | Sapphire Blue/ Emerald Green/Custom Color | Sapphire Blue |
| Type of Construction | Film/ No Film (single continuous phase) | No Film (Single Continuous Phase) |
| Specifications of Item /Variant | | |
| Item Code | As per listed SKU Code | SBL-NF-FHP-SD |
| Size of Item, Number of Items Per Pack | Neonatal/ Small/ Medium/ Adolescent/ Large/ Adult/ Extra Large/ Standard Size | Standard (SD), Piece Per Pack |
| Dimensions of Item | As mentioned in catalogue specific to item with definition of each annotation used. | L*W*H (in mm) = 165 X 80 X 8 mm, wherein L= Length; W= Width; H= Height. |

| | |
|---|--|
| Dimensional marking of item | <p>Grey Image of Product Item with specific marking of each dimension</p>  |
| Dimension of Pack (Wooden: Cardboard Box) | <p>Dimension of Wooden: Cardboard Box (Length X Breadth X Height) from exterior side (in cms)</p>  <p>Box Number 1: 18.7 X 19.1 X 6.3 cms</p> |
| Dimensional Marking of Pack (Wooden: Cardboard Box) | <p>Marking of Exterior Length, Breadth and Height of Wooden: Cardboard Box (in cms)</p> |
| Net weight of Item | <p>Weight of item (in grams) without any accessories or packing</p> <p style="text-align: right;">200 grams</p> |
| Gross Weight (Item with Wooden: Cardboard Box) | <p>Gross weight inclusive of item, its accessories and Wooden: Cardboard box used for packing (in grams)</p> <p style="text-align: right;">526 grams</p> |
| Specification (with optional choices) | |
| Pandemic Resilience Ability: Prevent Spread of Infection | <p>Specialized Gel Technological Variant with Covid Coat+ (sustainable solution that is tested against hospital pathogens responsible for Hospital Associated Infections)</p> <p style="text-align: right;">Yes</p> |
| Packaging: Internal Environment assurance and accessories inside pack | <p>Option 1: Viscoelastic Gel with Covid Coat+ (with/ without) film based item should have anti-microbial sticker, air clean pouch and 50 ml of Covid Coat+ solution.</p> <p>Option 2: C3I Gel (with/ without</p> <p style="text-align: right;">Each box contains ENSHIELD (anti-microbial) sticker, Air clean pouch, user manual and 50 ml of Covid Coat+ (anti-microbial) solution as accessory items to Positioning Device.</p> |



| | | |
|---|---|---|
| Compliance Statement with AST SOPS (Digital Access) (Optional) | film) doesn't contain any accessory items | QR Code specifying Compliance Statements (generic/ specific to product) is available on Signage Information Sticker affixed on Internal Surface of Each Item's Pack. |
| Barcodes (optional) | Option 1: Compliance Statement (Generic)/ Specific to Product should be provided in physical or digital format ensuring patient safety as per laid down Guidelines by Association of Surgical Technologist(s) SOPs for Positioning Devices Option 2: No such access of information provided with pack | Visible bar codes describing item, pricing and company name etc., are provided on each item's pack. |
| Acceptance Test Procedures Compliance (optional) | Option 1: Bar codes specifying item information should be available outside box. Option 2: No Barcode is provided on the pack. Option 1: User Manual provides description of ATPs which minimally suffice testing parameters to establish (a) environmental friendly material; (b) elastomerism; (c) hydrophobicity; (d) cold tolerance; (e) impact resistance and; (f) destructive testing, thereby ensuring the nature of gel technology to support the requirements of operation theatre positioning device Option 2: User Manual is not provided with testing Kit | ATPs cover burn test, elastomeric stretching test, Cold Crack Resistance, Moisture Resistance and others to self-authenticate supplied material's quality assurance. ATPs are provided as part of User Manual. |
| User/ Technical / Maintenance manuals to be supplied in English & Hindi in hard and soft Copy | Option 1: Bilingual (in physical and digital copy) User Manual with third optional language (digital access) as per specific provision of order only (if provided) should be available. Option 2: No User Manual is provided with Packaging Kit. | User Manual in bi-lingual (English and Hindi) format; as well as digital access to third language (optional-needs to be specifically mentioned in order) as per choice of customer are provided as part of packing kit. User manual describes Acceptance Test Procedures, Technical and Maintenance Procedures of OT Positioning Devices. |



Manufacturing Certifications and Product Standards

Operation Theatre Positioning Devices

| | Generic / Technical Specifications | Compliance Statement(s) |
|---|---|---|
| Product Standard Certification | CE or any other standard (if applicable) Certification Number, Date | CE Certification Number: CE-97801 Date: 09-04-2021 to 08-04-2024 |
| Manufacturer's Quality Standard | ISO 9001: 2015 and ISO 13485: 2016 as well as any other standard with its number and date | ISO 9001: 2015 Cert No : 305021041024Q Date: 10-04-2021 ISO 13485: 2016 Cert No: MD-9014121 Date: 09-04-2021 |
| Certification regarding chemical inertness | REACH standard assuring Gel free from any hazardous /environment degrading constituents Cert Number & Date | REACH Cert No: CH:TX: 1142028342 Date: 29-09-2020 |
| GMP Certification | Standards for Global Manufacturing Practices- Best Practices adopted for development of medical devices i.e. WHO: GMP Cert No and Date | WHO: GMP Cert No: UQ-901241 Date: 09-03-2021 to 08-03-2024 |
| QCI Certification | Certification issued by Quality Council of India (QCI) for adoption of best quality practices in development, occupational hygiene, management, safety and other aspects. | QCI Cert No: VA-452406728758919 Date: 27-7-2021 to 26-07-2024 |



Technical Specifications: Material, Technology, Packaging, Purchase & Site Utilities

Operation Theatre Positioning Devices

| | Generic / Technical Specifications | Compliance Statement(s) |
|---|---|--|
| Category | Health Care Device/ Non-Health Care Utility Device/ Both | Health Care Device |
| Toxin Free Composition | Material to be Latex free Material to be Phalates free Material to be Polyurethane Free Plasticizer & silicone free Gel | Latex, Plasticizer, Phalates, Silicone and Polyurethane Free Gel. |
| Human Safe | Material to be non toxic, Skin compatible and inert | Compatible with skin even during long duration usage while in direct contact with skin during surgeries |
| Eco-friendly and Recyclable | Material shall be eco-friendly and recyclable | Gel material is REACH certified, thus environment friendly as well can be recycled. |
| Elasticity of Material (Elastomeric Cushioning) | Item is designed to evenly distribute the body pressure to prevent circulatory disturbance and pressure ulcer at the bony prominences | Elastomeric Cushioning Gel complies with minimum requirement of Elongation strain withstands ability ($\geq 500\%$) while simultaneously Shore A value limits to Zero. |
| Elongation Strain Ability (%) | Elastomeric Ability is estimated as elongation strain withstands ability with minimum of 500%. | 543% |
| Soft Cushioning | Material having Shore A value limits to zero | Item's material has Shore A value limits to Zero indicating its extreme softness preventing pressure sore |
| Conforming Ability (Complete/ Partial) | Device should be able to complement body's contours completely | Complete: Designed according to body contours to prevent intra operative skin injuries and to avoid respiratory or nerve injuries |
| Non-Leaky | Material should not flow on prick | Elastomeric Gel is closed cell structure that doesn't leak out when pricked or punctured. |
| Density | 0.3 to 0.9 g/cc "Optimal value attributes towards strength of Positioning Device to hold body weight while not losing flexibility" | Density of material used in development of item has density of 0.8 g/cc (4.9 lb/foot). |
| Compression Set in | Should be least so that it does not get | 3.3 |

| | | |
|---|--|--|
| Material (%) | compressed with time. | |
| Repeated Usage : Bottom Out Resistance Ability | Device should be reusable and should not bottom out on repeat usage | Organic, inert & reusable which don't bottom out on repeated usage due to high density with least compression set. |
| Weight bearing capacity of the gel pad/ device (in Kg) | ≥200 Kg | Item is able to hold 200 Kg of patient's weight at vertical angle of placement. |
| Rebounding Capacity | Device should not be immersive and rebound in less than 1 second | Item has high rebounding capacity, on withdrawal of external pressure, in less than fraction of second it rebounds, thereby, preventing pressure due to any bony prominence. |
| Intrinsic Impact Resistant Ability | Impact Resistant ability is linked to its tensile strength with optimal core value of 10 Kg/ cm ³ . | Gel material used in development of item complies with requirement of optimal core value of Tensile strength of 10 Kg/ cm ³ . |
| Tensile Strength of the technology (Kg/ cm ³) | Optimal core value of 10 Kg/cm ³ | 11.4 Kg/ cm ³ |
| Crush Strength | No permanent deformation even after n = 1000 crushing cycles at 1600 psi. | Yes, material complies with such requirement for Crush Strength. |
| Uniform Pressure Distribution | Complete / Partial | Complete pressure re-distribution realized as tear strength ranges from 1.0 -4.5 kN/m and also reduces capillary interface pressure thereby preventing bed sores, pressure, shear and frictional impact during prolonged surgeries |
| Tear Strength (kN/m) | Should be in range of 1-4.5 kN/m | 4.17 |
| Capillary Interface Pressure Reduction Ability | Able to reduce capillary interface pressure to 32 mm Hg or less | Yes, it complied with this requirement. |
| X- Ray Observation Compatibility | Device should be translucent to X-ray. | Item is translucent to X-ray |
| Non-Conductive Material | Device should be non-conductive | Item is non-conductive, an essential property for its utility in magnetic environment as well as doesn't produce static charge. |
| C ARM / MRI Compatible | Device should be compatible for usage in C Arm and MRI | Item is compatible for usage in C ARM and MRI sections of hospital due to its non-conductivity. |
| Range of the usage temperature(in °Celsius) | 12-40°C | Item is maximally effective in this ambient range of 12-40°C. |
| Cold Crack Resistance | The material should not melt, harden, | Gel Material used in this item is able to |



| | | |
|--|--|--|
| | freeze or crack under standard operating conditions and withstand upto -30°C during storage / transit | withstand up to -30°C with no cracks. |
| Non-supportive to microbial growth | Hypoallergenic/ non-toxic & doesn't support any microbial growth | Gel material by its intrinsic composition doesn't support any microbial growth. |
| Anti-Microbial Coating | Standard anti-microbial coating is required as per Infection Control Guidelines of Hospital. | Item is coated with anti-microbial coating to prevent growth of opportunistic pathogens |
| Washability | Positioning Device can easily be cleaned using standard operating room/ hospital based detergents. | Easily cleaned using Standard Hospital Detergents, instruction manual is provided in every pack as well as available digitally with QR code on each pack. |
| Hot Operation Theatre Compatible | Positioning Device that can be used directly with partially contaminated victim of Chemical and Radiological Emergency for Emergency Surgeries in Hot OTs | Compatible for decontamination procedures to remove C& R agents being hydrophobic with closed cell structure (moisture resistant) |
| Hydrophobic | The material should be Hydrophobic | Material dose not absorb any water, chemical or fragrance etc |
| Leakage proof | The material should be leakage proof | Material, being closed cell structure, is leakage proof & moisture resistant |
| Unusual Movement Resistance of OT Table: Adhesion of Material | Velcro to be provided for adhesion. | Device is provided with Stick on Surface that can be attached to Velcro to affix device on OT Table preventing unwanted movement of device during Prolonged Surgeries. |
| Packaging Material | | |
| Complimentarily of Pack Size, Material, Strength with Item | Suitable packing to withstand transit and accommodate the size of device to be provided | Wooden Box complement to weight of item with size dimensions for ease of fitting with least possible movement during transit |
| The type of the inner wall of the packing box | The inner walls are laminated coating to prevent any direct contact with absorbent material or if lamination is restricted in region specific regulation on plastic, butter paper is used. | Inner walls of Wooden Box are laminated to prevent any direct contact with absorbent material or otherwise product is wrapped in butter paper if region specific restrictions don't allow use of laminated sheets. |
| Ultraswachh Disinfection /Sterilization or Gamma Irradiation Sterilization Compatible | Boxes can be sterilized using DRDO's Ultraswachh Sterilization Unit(s) as well as Gamma Irradiation for safety of packaged material for direct utility in OT facility | Gel Technology is compatible for both DRDO's Ultraswachh Sterilization Procedures as well as Gamma Irradiation. User can decide as per available hospital infrastructure. |
| Purchase Information | | |
| Warranty in years(For manufacturing defects) | 01 year of comprehensive warranty applicable from Date of Delivery for | Company provides 01 year of comprehensive warranty applicable from |



| | | |
|--|---|---|
| | any manufacturing defects. | Date of Delivery for any manufacturing Defects as per T&C applied in Manufacturing Warranty Agreement, digitally accessible from Signage Information Sticker (if available as per option selected). |
| Shelf Life (in years) | Shelf life of item provided should be minimum of 5 years or more. | Shelf Life of item provided in the lot is ≥ 5 years applicable from date of manufacturing. |
| Residual Shelf Life (in years) – Not Less than $\frac{3}{4}$ of Shelf Life | Remaining Shelf Life at the time of Supply should be $\frac{3}{4}$ th | As per date of manufacturing, the remaining shelf life of provided item is $\geq \frac{3}{4}$ th of applicable Shelf Life of 5 years from Date of Manufacturing. |
| Certifications & Reports | Copies of reports and certifications to be furnished to buyer on demand | All information i.e. certification/ relevant documentation (reports) in terms of digital copy accessible via QR codes labeled on packs. Specific confidential certifications are provided in physical copies as per requirement furnished by Buyer. It includes GST Certification, MSME Registration with UAN, Vendor Registration with Government Agency (if any), Trademark Registration/ Application (as applicable, if any) and other Company specific documentation requisite for legalized production of items. |
| Web Authentication of Material Batch | Bath Certification for Supplied Lot should be available online for web based authentication by Buyer. | QR Code with digital access to 'batch certificate' for particular lot Quality Assurance is available outside Item's Pack. |
| Sites of Application Information | | |
| Applications (Health Purposes) | Operation Theatres, Intensive Care Units, X-ray, MRI, Special Wards for Comatose/ Semi-Comatose Patients, Rehabilitation Centres for Elderly, Residential Usage for Bed Ridden for Comatose, Semi-Comatose / Non-Comatose Patients. | Item can be deployed in Operation Theatres, ICUs, X-ray diagnostics, MRI, Eye Clinics, Special Wards for both comatose, semi-comatose and regular patients, rehabilitation centres for elderly, special children and persons suffering from specific problems, effectively useful in household for all types of bed-ridden, morbid patients including comatose and sem-comatose patients. In addition, health parlors with massages and physiotherapy clinics as well as reception of emergency trauma centers, based on functionality of item, it can be used. |