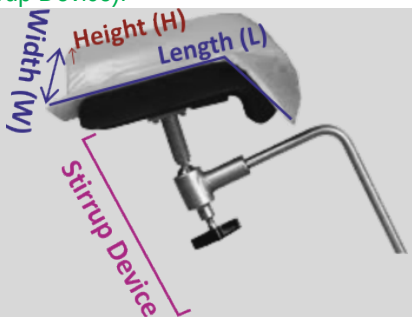
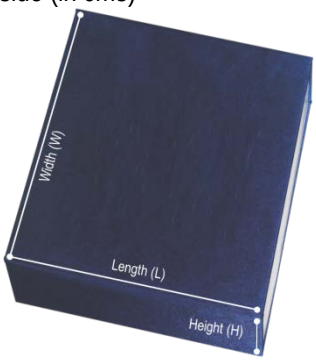
Technical Specification of Operation Theatre Positioning Devices

Crutch Stirrup Pad Medium Green No Film

	Generic / Technical Specifications	Compliance Statement(s)
Name of Item	Crutch Stirrup Pad Medium Green No Film	Crutch Stirrup Pad Medium Green No Film 
Technology/ Product Specifications		
Product Category	As mentioned in catalogue or website: otcare.co.in	Crutch Stirrup Pad(s)
Purpose of Product	As defined in catalogue	o Designed to fit both Lloyd Devices & various types of stirrups/ leg-holders to relieve pressure from nerves and allows blood flow especially during lithotomy procedures o Protect against frictional impact, shear force and nerve injury. o It is provided as 01 pair per pack (without any Stirrup Device).
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	C3I Gel
Generic Technology Name	C3I Gel (CC+) or C3I Gel	C3I Gel
Brand Name or OEM	Whether the item is required with/ without Brand Name i.e. OEM	Without Brand Name: OEM or optional as per buyer
Color of Product	Sapphire Blue/ Emerald Green/Custom Color	Green Emerald
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	EGR-NF-CSP-M

Size of Item, Number of Items Per Pack	Neonatal/ Small/ Medium/ Adolescent/ Large/ Adult/ Extra Large/ Standard Size	Medium (M), Pair Per Pack
Dimensions of Item	As mentioned in catalogue specific to item with definition of each annotation used.	L*W*H (in mm) = 400 X 250 X 10 wherein L = Length; W = Width; H= Height.
Dimensional marking of item	Grey Image of Product Item with specific marking of each dimension	
Dimension of Pack (Wooden: Cardboard Box)	Dimension of Wooden: Cardboard Box (Length X Breadth X Height) from exterior side (in cms)	 NA
Dimensional Marking of Pack (Wooden: Cardboard Box)	Marking of Exterior Length, Breadth and Height of Wooden: Cardboard Box (in cms)	NA
Net weight of Item	Weight of item (in grams) without any accessories or packing	1800 grams
Gross Weight (Item with Wooden: Cardboard Box)	Gross weight inclusive of item, its accessories and Wooden: Cardboard box used for packing (in grams)	1800 grams
Specification (with optional choices)		
Pandemic Resilience Ability: Prevent Spread of Infection	Specialized Gel Technological Variant with Covid Coat+ (sustainable solution that is tested against hospital pathogens responsible for Hospital Associated Infections)	No
Packaging: Internal Environment	Option 1: Viscoelastic Gel with Covid Coat+ (with/ without) film based item should have	No accessory items are provided in the

assurance and accessories inside pack	anti-microbial sticker, air clean pouch and 50 ml of Covid Coat+ solution. Option 2: C3I Gel (with/ without film) doesn't contain any accessory items	box.
Compliance Statement with AST SOPS (Digital Access) (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	No such access of such information provided in the pack.
Barcodes (optional)	Option 1: Bar codes specifying item information should be available outside box. Option 2: No Barcode is provided on the pack.	No barcode specifying company information is provided on the box.
Acceptance Test Procedures Compliance (optional)	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	User Manual is not provided with Testing Kit in this pack.
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.	No User Manual is provided with Packaging Kit.

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	Latex, Plasticizer, Phalates, Silicone and Polyurethane Free Gel.
	Material to be Phalates free	
	Material to be Polyurethane Free	
	Plasticizer & silicone 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 (≥ 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 ^{0}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^{0}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 ¾ of Shelf Life	Remaining Shelf Life at the time of Supply should be 3/4 th	As per date of manufacturing, the remaining shelf life of provided item is ≥ 3/4th 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-riddent, 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.