


MANUFACTURED BY:
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IMPORTANT: PLEASE READ

 For detailed information on correct & safe device use, please consult the Surgical Manual.

DESCRIPTION

The table system provides a reusable versatile platform for a variety of spinal surgeries. It offers patient support in a supine, lateral and prone position while being able to securely transition the patient from one orientation to the other.

INDICATIONS FOR USE

The Southern Medical Modular Table System is an operating table intended for the surgical interventions for procedures that include:

- Anterior/Posterior Cervical Procedures
- Anterior/Posterior Fusion
- Decompressions
- Disc Arthroplasty Procedures
- IDET Surgeries
- Kyphoplasty
- Laminectomies
- Osteotomies
- Surgical Correction of Deformities

CONTRAINDICATIONS

- Patients with known or probable intolerance to the materials used in the manufacture of this device
- Use with accessories/components from other manufacturers.
- Grossly distorted anatomy.
- Patients exceeding the weight limit (250kg)
- Disruption to the power supply.
- Any case not described in the indications for use.
- Use by untrained or non-medical personnel.
- Use in a setting other than a surgical theatre.

RISKS & UNDESIRABLE SIDE-EFFECTS

- Leakage & spillage onto the floor
- Small parts can be lost
- Caution must be taken while equipment is in use – moving parts.
- Fuse burnout/ table unable to hold charge
- Electrical failure
- Accessories falling off because of a failure in clamping mechanism and/or human error
- The lateral tilt of the tabletop may cause the fasteners to loosen. The table may tilt to one side and not stay level, and potentially fall over.
- Damage to the lifting column will result in the table not being able to raise and lower properly, which could in turn do more damage to the table and patient. A table with a damaged lifting column should be taken out of service immediately.
- Cosmetic damage to the theatre tables' frames and accessories.
- Due to patients weighing it down, the table's strength may start to show signs of weakness and drift may occur.
- Lateral tilt can put a lot of stress on a table, especially if the patient is at max weight. There are essentially three issues that can happen: (1) failure to return to normal level, (2) not reaching the maximum degree or (3) tilting more than intended. In the third case, the issue is mechanical, and the table should be removed from use until serviced.
- More frequent may be required when patients that are consistently close to the maximum allowable weight (250kg).
- Calibration may be required for moving parts.
- Once the cord or buttons are damaged, the hand control loses most functionality, rendering the table virtually useless

MANUFACTURER SERVICE PLAN

A Service Plan applies to the Galen Modular Table System and Accessories purchased from Southern Medical.

This service includes the following:

- Maintenance of all moving parts.
- An evaluation of the electrical system and controls.
- Assessment of carbon fiber components.
- Wear assessment of accessories, caster wheels, attachment pins, covers, brake pads, etc.



Southern Medical will perform an end of warranty service. This will be free of charge apart from the call out fee, which is determined by geographical location. After the end of warranty service is complete, a report which details the condition of all physical parts evaluated during the service.

WARNINGS & PRECAUTIONS: CORRECT & SAFE USE



The device should only be used by qualified medical personnel with knowledge of the correct and safe use of the device and associated accessories. Refer to the Surgical Manual provided by Southern Medical (Pty) Ltd. If uncertain, please contact a Southern Medical Representative. The device is intended to be used in a surgical theatre.

Regular maintenance may be required to correct/prevent some of the possible adverse events.

ITEMS REQUIRING REPAIR

During the warranty period, Southern Medical will repair or replace products or parts of a product that proves defective because of improper material or workmanship, under normal use and maintenance. If the warranty period has expired, a quotation to replace or refurbish the item will be provided. Theatre beds requiring repair must be removed from use until evaluated.

STORAGE

There are no special storage instructions. Storage conditions must not lead to degradation or damage to the theatre bed and accessories. Handle with care.

RECCOMENDATIONS FOR END OF WARRANTY SERVICE

The warranty period for Galen-MTS and Accessories purchased from Southern Medical is eighteen (18) months from the date of delivery. A replacement physical good or part assumes the remaining warranty from the original delivery date. At end of Warranty, it is recommended that table and accessories are serviced annually.

LIMITS & EXCLUSIONS

The limited warranty applies to physical parts, and only for physical parts, of the Galen-MTS and Accessories purchased from Southern Medical. Components subject to be worn during normal use such as cushions, trimmings, labeling, cables, etc., are excluded from this warranty.

The warranty is void if the Galen-MTS or Accessories are subjected to mishandling, misuse, neglect, accident, improper maintenance, improper operation or application, or improperly repaired or serviced by the customer or by an unauthorized service technician. Warranty or repair service is available from Southern Medical.






LIABILITY & DAMAGES

Southern Medical is not liable to buyer, seller or any customer of buyer for loss of profit, loss of revenue, loss of use, cost of downtime, or any other incident or consequential damage, personal injury, loss of health or death whether in an action in contract or tort, arising out of or related to the Galen-MTS and Accessories. Southern Medical's liability for damages for any cause whatsoever shall be limited to repair or replacement, at the discretion of Southern Medical, of the defective parts or components.

REPORTING

Any device-related adverse events must be reported to the manufacturer as soon as possible.

DESCRIPTIONS OF SYMBOLS USED IN PACKAGING

MANUFACTURER		CATALOGUE NUMBER	
CONSULT INSTRUCTIONS FOR USE		CAUTION	
DATE OF MANUFACTURE		LOT NUMBER	