

STATLOCK® FOR TESIO® CATHETERS INSTRUCTIONS FOR USE

INTENDED USE:

- A stabilization device for Medcomp® Tesio® Hemodialysis catheter.





DESCRIPTION:

- The Statlock® stabilization device is designed as a stabilization device for use with Medcomp® central venous Hemodialysis catheters. **LATEX FREE**

PRECAUTIONS:

- Catheter should be sutured to the skin in situations where loss of adherence may occur such as with confused patient or nonadherent skin.
- The Statlock® stabilization device should be routinely inspected for adherence to the skin and connection to the catheter. Catheter position should be checked for proper placement.
- Alcohol and acetone may weaken the adhesive bond between the Statlock® stabilization device and skin. The structure of the foam or plastic components may be altered with application of alcohol or acetone. Care should be taken when high concentrations of acetone or alcohol are used when performing routine insertion site care and maintenance.
- Always place sterile adhesive strip over catheter or catheter hub to stabilize catheter during dressing change for the Statlock® stabilization device.
- Minimize catheter manipulation to maintain proper catheter tip position.

WARNINGS:

- Federal (USA) law restricts this device to sale or on the order of a physician.
- Product is sterile in unopened package.
STERILIZED BY ETHYLENE OXIDE 
- Single use only. DO NOT RE-USE. Re-use may lead to infection or illness/injury. 
- Do not use if package is damaged. 
- Do not resterilize. 
- Read instructions and precautions prior to use.

POTENTIAL COMPLICATIONS:

- Known tape or adhesive allergies
- Skin damage when removing device
- Device dislodgement

INSTRUCTIONS FOR USE:

- Cleanse and prepare targeted skin per agency protocol. Prep site with skin prep provided with the Statlock® stabilization device for enhanced adherence. Allow to dry thoroughly.
- Before adhering pad to skin, press red and blue Tesio® adaptors into the Statlock® stabilization device retainers on pad.
- Peel paper backing one side at a time and place pad onto skin.
- Complete insertion site dressing per agency protocol.
- Replace the Statlock® stabilization device dressing per agency protocol.
- Dispose of all equipment in appropriate containers.
- Statlock® stabilization device should be monitored daily and replaced at least every seven days.
- Discard biohazard according to facility protocol.

REMOVAL:

- Remove overlying dressing if the Statlock® stabilization device is covered.
- Place index finger and thumb of one hand on the Statlock® stabilization device pad at sides of retainer and gently lift red Tesio® adapter with other hand. Repeat to lift blue Tesio® adapter from retainer.
- Gently stroke the under surface with alcohol swab while lifting the Statlock® stabilization device pad.

Note: Apply adhesive strip to central venous catheter for added security during dressing changes involving the Statlock® stabilization device.

Medcomp® does not recommend a particular technique for the use of this device. The physician should evaluate their appropriateness according to individual patient conditions and his or her medical training and experience.











WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Medcomp® reserves the right to modify its products or contents without notice.

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5.1.1 	Manufacturer *	5.6.3 	Non-pyrogenic *
5.1.4 	Use-by Date *	5.3.2 	Keep Away from Sunlight *
5.4.2 	Do Not Re-use *	5.2.6 	Do Not Resterilize *
5.3.4 	Keep Dry *	Rx Only	Prescription Use Only ***
5.1.5 	Batch/Lot Number *	5.1.6 REF	Catalogue Number *
5.2.8 	Do Not Use if Package is Damaged *		
5.2.3 	Sterilized Using Ethylene Oxide *		

* This symbol is in accordance with ISO 15223-1.

*** FDA guidance Use of Symbols in Labeling.

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