TITANIUM BARBED CONNECTOR
INSTRUCTIONS FOR USE

INTENDED USE:

- To provide a secure connection between two peritoneal dialysis catheters.

DESCRIPTION:

- Implantable titanium double-ended barbed connector that is fully MRI compatible

POTENTIAL COMPLICATIONS:

- Disconnection
- Infection
- Leakage
- Occlusion

WARNINGS:

- Federal Law (USA) restricts the device to sale by or on the order of a physician.
- Do not resterilize by any method.
- This device is for Single Use Only.
- Re-Use may lead to infection or illness/injury.
- The manufacturer shall not be liable for any damages caused by re-use or resterilization of the device.
- Contents sterile and non-pyrogenic in unopened, undamaged package.
  STERILIZED BY ETHYLENE OXIDE STERILE EO
- Do not use if any sign of product damage is visible.
- Do not use if package is opened or damaged.

INSTRUCTIONS FOR USE:

- Connect barbed connector to each end of the catheter.
- Push barbed connector so that catheter ends are over the barbs.
- Barbed connector should fit tightly between both catheter ends.
- Tug gently to ensure the connection is secure.
- Sutures may be tied around each catheter over the grooves of the connector.
- Visually inspect for catheter damage before use.

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.

MRI Safety Information

Non-clinical testing has demonstrated that the X-Series Peritoneal Catheter is MR Conditional. A patient with this device can be safely scanned in an MR system with the following conditions:

- Static magnetic field of 1.5T and 3.0T.
- Maximum spatial gradient field of 19 T/m (1900 G/cm).
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 2.7 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends up to 6.1cm when imaged with a gradient echo pulse sequence in a 3.0T MR system.

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 LOT	Batch/Lot Number *	5.1.6 REF	Catalogue Number *
5.2.8	Do Not Use if Package is Damaged *		
5.1.2 EC REP	Authorized Representative in the European Community *		
5.2.3 STERILE EO	Sterilized Using Ethylene Oxide *		
MR	MR Conditional - 3 Tesla ****		

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

***** FDA guidance Use of Symbols in Labeling.**

******This Symbol is in accordance with ASTM F 2503-13**

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATEMENT, 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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EC REP

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