Breeze® Centesis Drainage Catheter

PRODUCT DESCRIPTION:

The Breeze® Centesis Drainage Catheter is a short term drainage catheter with stainless steel needle and vent plug.

INDICATIONS FOR USE:

The Breeze® Centesis Drainage Catheter is intended for the percutaneous drainage of fluids.

INTENDED USE:

Short-term percutaneous fluid aspiration.

POTENTIAL COMPLICATIONS:

- Skin Infection
- Pain in region
- · Non-targeted catherization
- Bleeding
- Injury to other organs

PRECAUTIONS:

Do not leave in patient longer than 24 hours.

WARNINGS:

- Do not use if the package is damaged or open. (Q)
- Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only
- Product is sterile in unopened, undamaged package. STERILIZED BY ETHLENE OXIDE STERILEEO
- For Single use only. DO NOT REUSE. Re-Use may lead to infection or illness/injury.
- Do not resterilize.
- End caps are not intended to be punctured with a needle.

INSTRUCTIONS FOR USE:

1. Remove catheter and needle from protective cover.

- 2. Insert catheter where the fluid buildup exists using standard insertion technique.
- 3. Verify accuracy of placement by visually evaluating the fluid gathered in the clear proximal hub or using cross sectional imaging.
- 4. When catheter is in appropriate position remove needle from catheter.
- 5. Attach device with current ISO standard luer fitting to catheter hub to remove fluid.
- 6. Following the procedure gradually withdraw the catheter and dress the site accordingly.

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	5.3.2	Keep Away from Sunlight $*$	5.1.4	Use By Date *	5.1.6 REF	* Catalogue Number
5.3.4	Keep Dry *			5.1.5	Lot Number *	5.2.6	Do Not Resterilize *
5.2.8	* Do Not Use if Package is Damaged			5.4.2	Do Not Re-use *	Rx Only	Prescription Use Only**
5.2.3 STERILEEO	Sterilized Using Ethylene Oxide *			5.4.3	* Consult Instructions for Use		

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

*** FDA guidance Use of Symbols in Labeling.

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