Manufacturer

LOT Batch Code

Consult Instructions for Use

REF Catalog number

MR unsafe

Contents

Do not use if package is damaged

CAUTION
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician

℞ ONLY

THE ZIP

Accessory Shuttle for PleuraFlow® System

Manufactured for:
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℞ **ONLY**

GENERAL DESCRIPTION

THE ZIP is an accessory to the PleuraFlow System. It is a removable magnetic shuttle that is used to actuate the Clearance Wire and Loop of the PleuraFlow System. THE ZIP consists of a plastic housing containing shielded magnets. The housing is designed to snap onto the Shuttle Guide Tube of the PleuraFlow System and couple to the Internal Magnets contained within. Once coupled THE ZIP can be used to actuate the Clearance Wire and Loop within the PleuraFlow Chest Tube to proactively prevent and break up and clear any tube obstructions or clogging to keep the tube patent.

INDICATIONS

THE ZIP is an accessory of the PleuraFlow System family of products that is indicated for use during cardiothoracic surgical procedures and chest trauma. The PleuraFlow System's active clearance technology proactively removes clots formed inside the chest tube to prevent or minimize chest tube occlusion with clot. A patent chest tube enables evacuation of blood and fluid from the operative site after closure of the surgical wound and reduces retained blood. In the United States the product is indicated for adult and pediatric patients including infant, preadolescent and adolescent patients under clinical settings.

THE ZIP accessory is a non-sterile reusable hand-held external magnetic shuttle that can be used to couple to and move the Clearance Wire of the PleuraFlow® System *in place of* the integral shuttle when the user determines that additional magnetic coupling strength is needed. Same as the integral magnet, the magnets in THE ZIP are intended to facilitate coupling and are not intended to provide energy to the patient.

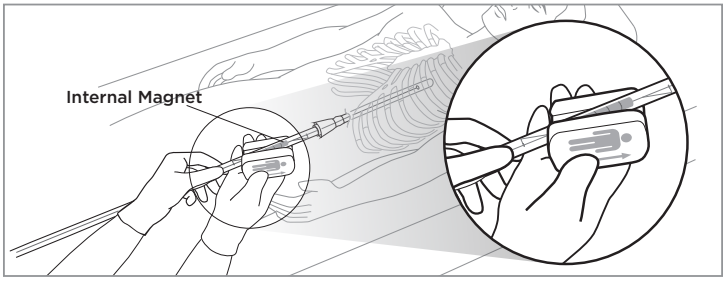
THE ZIP is reusable.

CONTRAINDICATIONS

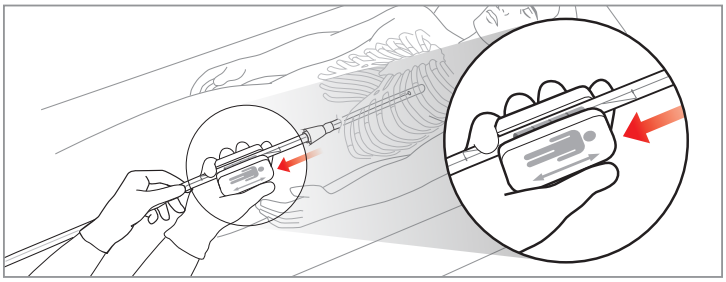
This product should not be used in proximity to an MRI.

INSTRUCTIONS

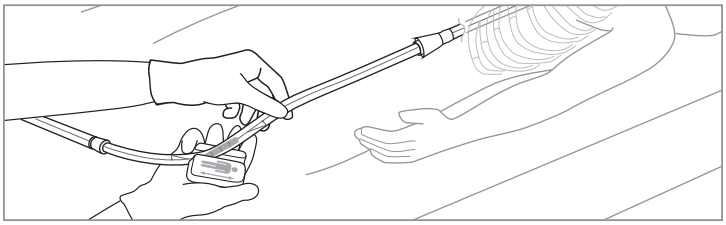
Step 1. Decouple the PleuraFlow System Shuttle from the Internal Magnet and attach THE ZIP onto the Clearance Apparatus over the Internal Magnet.



Step 2. Ensure that THE ZIP is fully engaged on the Internal Magnet of the Clearance Apparatus and that the patient symbol is aligned with the patient (head pointing towards head). Actuate by using THE ZIP to retract the Clearance Wire.



Step 3. Once the Clearance Wire has been successfully retracted, THE ZIP can now be removed. Clean THE ZIP in accordance with the IFU and return to its storage case.



Step 4. Refer to troubleshooting protocols in the PleuraFlow System IFU to ensure actuation schedule can be resumed. Once troubleshooting is completed, recouple the PleuraFlow System Shuttle and continue the actuation schedule.

WARNINGS

- Do not place THE ZIP within 6 inches of a medical device with conductive and/or magnetic parts. Some examples include: an implanted pulse generator, pacemakers, and implantable defibrillators. Users are advised to consult with respective device manual if it has conductive and/or magnetic parts.
- Do not use if in proximity to an MRI.
- Never move Clearance Wire and Loop against resistance without careful assessment of cause.
- THE ZIP is designed for use with the PleuraFlow System only
- Only a qualified healthcare practitioner should operate the device.
- Contains strong magnets, never attempt to disassemble or modify the device.

Refer to PleuraFlow System Instructions for Use for additional details on troubleshooting.

STORAGE

Handle with care according to institutional protocol. THE ZIP should be stored under good conditions that protect it from extremes of temperature.

INSTRUCTIONS FOR CLEANING

THE ZIP is supplied non-sterile and must not be sterilized by any sterilization method since it is not to be used sterile.

1. THE ZIP is supplied "non-sterile" and must be cleaned prior to initial use and after each use.
2. Remove THE ZIP from the storage case and visually inspect the device before use. Do not use if the device is damage.
3. The ZIP should be cleaned before initial use and between uses as follow:
   a. Wipe down all surfaces using 70% Isopropyl alcohol wipes.
   b. After use, wipe down all surfaces of THE ZIP using 70% Isopropyl alcohol wipes. Visually inspect the device for any debris and visible soil and repeat cleaning as necessary.
   c. Metal brushes and scouring pads must not be used during manual cleaning. These materials will damage the surface and finish of THE ZIP. If necessary, use only soft bristle nylon brushes to aid with manual cleaning.
   d. Allow the device to air dry then store the ZIP in the supplied storage case when no longer is use.

DISPOSAL

Dispose per institutional protocol for medical devices.

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

The Instructions for Use do not override clinical practice by qualified individuals.

DISCLAIMER OF WARRANTY

The following Disclaimer of Warranty Applies to United States Customers only:

ALTHOUGH THE CLEARFLOW MODEL PF-ZIP 1.5—The ZIP ACCESSORY SHUTTLE FOR PLEURAFLOW SYSTEM-- HEREAFTER REFERRED TO AS "PRODUCT" HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, IT IS SOLELY FOR USE WITH ALL MODELS OF THE PLEURAFLOW SYSTEM MODEL AND ONLY FOR USE BY TRAINED MEDICAL PROFESSIONALS WHO HAVE DETERMINED ITS USE TO BE APPROPRIATE. CLEARFLOW HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS PRODUCT IS USED. CLEARFLOW, THEREFORE DISCLAIMS ALL WARRANTIES, BOTH EXPRESS AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. CLEARFLOW SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND CLEARFLOW TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent Jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if the Disclaimer of Warranty did not contain the particular part or term held to be invalid.

SERVICE

ClearFlow trained employs and designees are available 24/7 by calling US Toll Free: (844) CLR-FLOW (257-3569); Outside USA: +1(714)916-5010; Support@clearflow.com.

For supplemental information, or to schedule an in-service contact your local ClearFlow representative.