

5.1

ENGLISH

1. Obstructions Form in The Chest Tube

6.1

ENGLISH

1. Chest Tube Free Of Obstructions
2. Proximal End
3. When Placed, Return Shoulder Guide To Proximal End And "Click" Into Position
4. Stride Guide Fully Retraction
5. Drainage Material Flows To Drainage Container

- Do not incinerate
- Use by
- Lot
- Batch code
- Sterilization using ethylene oxide
- Do not reinsert
- Manufacturer
- Consult Instructions for Use
- Catalog number
- Not reusable
- Contact
- Do not use if package is damaged

CAUTION:
 (REF) (U.S.A.) See website this device to use by or in the order of a physician.

REF
 ONLY

The PleuraFlow® System with FlowGuide®
 For Single Use Only. Made in the U.S.A.

PLEURAFLOW
 ACTIVE CLEARANCE TECHNOLOGY

ENGLISH The PleuraFlow® System with FlowGuide®
 For Single Use Only. Made in the U.S.A.

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REF
 ONLY

PL02 Rev. C
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1.1

ENGLISH

1. Proximal
2. PleuraFlow Chest Tube
3. Distal
4. Proximal End (Connects To PleuraFlow Chest Tube)
5. StrideFlow Guide Tube
6. Distal End (Only From Patient)

2.1

ENGLISH

1. Must Cut On Cut-Line

3.1

ENGLISH

1. PleuraFlow Chest Tube
2. Proximal End
3. PleuraFlow Clearance Apparatus
4. Distal End
5. Drainage Container
6. Drainage Tubing

4.1

ENGLISH

1. Clearance Loop is Advanced To Top Tip when Not in Use
2. Stride Guide is in The Retard Position

ENGLISH **Instructions for Use**

DESCRIPTION
 The PuruFlow System with PuruGrip incorporates a Clearance Apparatus intended to prevent ongoing and additional PuruFlow Chest Tube injury and/or PuruFlow Chest Tube injury after cardiovascular surgery and trauma.

The primary components of the system are the PuruFlow Chest Tube and the PuruFlow Clearance Apparatus (PCA). The PuruFlow Chest Tube is a silicone chest tube connected with PuruGrip. It is designed to be connected to the PuruFlow Chest Tube and the PuruFlow Chest Tube. The PuruFlow Clearance Apparatus is designed to prevent ongoing and additional PuruFlow Chest Tube injury and/or PuruFlow Chest Tube injury after cardiovascular surgery and trauma. When indicated, the Clearance Wire and Loop is advanced and inserted into the PuruFlow Chest Tube using a separate Sterile Guide. The indication of the Clearance Wire and Loop is advanced and inserted into the PuruFlow Chest Tube using a separate Sterile Guide. The indication of the Clearance Wire and Loop is advanced and inserted into the PuruFlow Chest Tube using a separate Sterile Guide. The indication of the Clearance Wire and Loop is advanced and inserted into the PuruFlow Chest Tube using a separate Sterile Guide. The indication of the Clearance Wire and Loop is advanced and inserted into the PuruFlow Chest Tube using a separate Sterile Guide.

INDICATIONS
 The PuruFlow System is indicated for use during endovascular surgical procedures and chest trauma. It is intended to prevent ongoing and additional PuruFlow Chest Tube injury and/or PuruFlow Chest Tube injury after cardiovascular surgery and trauma. It is intended to prevent ongoing and additional PuruFlow Chest Tube injury and/or PuruFlow Chest Tube injury after cardiovascular surgery and trauma. It is intended to prevent ongoing and additional PuruFlow Chest Tube injury and/or PuruFlow Chest Tube injury after cardiovascular surgery and trauma. It is intended to prevent ongoing and additional PuruFlow Chest Tube injury and/or PuruFlow Chest Tube injury after cardiovascular surgery and trauma.

CONTRAINDICATIONS
 The PuruFlow System is contraindicated for patients with a history of intolerance to implantable silicone materials. The device should not be used on patients with the following conditions:

SET UP INSTRUCTIONS
 Read the package for damage before opening.

Preparation:
 - Open the PuruFlow and define the contents to be sterile field using aseptic technique.
 - Inspect thoroughly, ensuring that it is undamaged or otherwise damaged. If there are any damage, replace with a new device.

Inserting the PuruFlow System
 Insert the PuruFlow Chest Tube into the pleural or mediastinal space according to standard methods. The PuruFlow Chest Tube should be inserted into the pleural or mediastinal space according to standard methods. The PuruFlow Chest Tube should be inserted into the pleural or mediastinal space according to standard methods. The PuruFlow Chest Tube should be inserted into the pleural or mediastinal space according to standard methods.

CAUTION
 Do not attempt to remove the PuruFlow Chest Tube until the Chest Tube has been inserted into the pleural or mediastinal space. Do not attempt to remove the PuruFlow Chest Tube until the Chest Tube has been inserted into the pleural or mediastinal space. Do not attempt to remove the PuruFlow Chest Tube until the Chest Tube has been inserted into the pleural or mediastinal space.

USE OF THE CLEARANCE APPARATUS
 Only qualified healthcare providers should operate the device. When it is indicated to use the PuruFlow Chest Tube, the Sterile Guide is designed from the proximal opening and inserted into the PuruFlow Chest Tube. The Sterile Guide is designed from the proximal opening and inserted into the PuruFlow Chest Tube. The Sterile Guide is designed from the proximal opening and inserted into the PuruFlow Chest Tube.

TROUBLE SHOOTING

If a chest tube is placed on the Clearance Wire and Loop, steps should be taken to dislodge the chest tube into the pleural space:

- 1. Gently separate the wire through the PuruFlow Chest Tube or Guide Tube while advancing the Clearance Wire and Loop.
- 2. Apply the wire back and forth to dislodge any fibrin webbing that may have formed between the Clearance Wire and Loop and the PuruFlow Chest Tube and Guide Tube.
- 3. Gently lay the Sterile Guide against the distal connector.
- 4. Advance the Clearance Wire and Loop through the Clearance Wire and Loop, which is then inserted into the PuruFlow Chest Tube and Guide Tube.
- 5. Advance the Clearance Apparatus towards the chest tube until the Clearance Wire and Loop is inserted into the PuruFlow Chest Tube using standard methods.
- 6. If the Clearance Wire and Loop is inserted into the PuruFlow Chest Tube, the Clearance Wire and Loop can be inserted into the PuruFlow Chest Tube using standard methods.
- 7. If the Clearance Wire and Loop is inserted into the PuruFlow Chest Tube, the Clearance Wire and Loop can be inserted into the PuruFlow Chest Tube using standard methods.
- 8. If the Clearance Wire and Loop is inserted into the PuruFlow Chest Tube, the Clearance Wire and Loop can be inserted into the PuruFlow Chest Tube using standard methods.
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PLURISLOW SYSTEM CHEST TUBE CLEARANCE APPARATUS REMOVAL
 Removal and insertion require the following steps:
 - Gently the PuruFlow Chest Tube near the insertion site using a slow, steady motion, remove the Chest Tube from the chest.
 - CAUTION: Care should be taken during chest tube removal from the patient to avoid damaging the Chest Tube. Care should be taken during chest tube removal from the patient to avoid damaging the Chest Tube. Care should be taken during chest tube removal from the patient to avoid damaging the Chest Tube.

SUGGESTED PLURISLOW CHEST TUBE MAINTENANCE
 The PuruFlow Chest Tube should be replaced in accordance with standard institutional protocols. Suggested PuruFlow Chest Tube maintenance is as follows:
 - Change Chest Tube: Assess the integrity of the Chest Tube at least every 24 hours for a maximum of 30 days, or as instructed by the manufacturer.
 - Change Sterile Drainage according to institution protocol.

COMPATIBILITY
 The PuruFlow System with PuruGrip is only compatible with PuruFlow Chest Tubes. Compatibility with other drainage tubes has not been established.
 - Refer to product label for device dimensions.

CAUTIONS OF USE
 - Maximum for PuruFlow Chest Tube is 5 days.
 - Maximum for PuruFlow Chest Tube is 5 days.
 - If the PuruFlow Chest Tube is still needed, but the Clearance Apparatus is not, the Clearance Apparatus can be removed and discarded, and the Chest Tube can be used. Assess the integrity of the Clearance Wire and Loop into the Chest Tube prior to removing the Clearance Apparatus. The Chest Tube may then be connected to the drainage tubing and used as the standard method.

WARNINGS
 Do not attempt to remove the PuruFlow Chest Tube until the Chest Tube has been inserted into the pleural or mediastinal space. Do not attempt to remove the PuruFlow Chest Tube until the Chest Tube has been inserted into the pleural or mediastinal space. Do not attempt to remove the PuruFlow Chest Tube until the Chest Tube has been inserted into the pleural or mediastinal space.

PRECAUTIONS
 Insertion or removal of this device is only to be done by qualified health professionals. Insertion or removal of this device is only to be done by qualified health professionals. Insertion or removal of this device is only to be done by qualified health professionals.

CONTRAINDICATIONS
 Inserting the PuruFlow Chest Tube and utilizing the Clearance Apparatus may result in any of the following complications:
 - Hemorrhage
 - Pleural Effusion
 - Pneumothorax
 - Infection
 - Discomfort
 - Chest Tube Displacement
 - Chest Tube Occlusion
 - Chest Tube Blockage
 - Chest Tube Leakage
 - Chest Tube Dislodgement or Removal
 - Chest Tube Infection
 - Chest Tube Obstruction
 - Chest Tube Displacement

HOW SUPPLIED
 The PuruFlow System is provided sterile and will remain so as long as the package is unopened and undamaged. Do not re-sterilize.

STERILIZATION
 Handle with care. The System should be stored in an area with good ventilation under good conditions that protect from excessive temperature and humidity and from light.

CAUTION
 Product (P) is a medical device that is to be used by or on the order of a physician. The instructions for use do not override clinical practice by qualified individuals.