

Cat. **50-7000B / 50-7700**

# **PleurX™ Pleural Catheter Kit**

For Pleural Placement Only

Sterile

For Single Use Only



Not made with  
natural rubber  
latex.

## **Instructions for Use**

**USA** Rx Only

For product inquiries or technical assistance,  
please call (800) 653-6827

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Filter Straw is a registered trademark of B. Braun, Inc.

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### **CareFusion**



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2015-08



# **CareFusion**



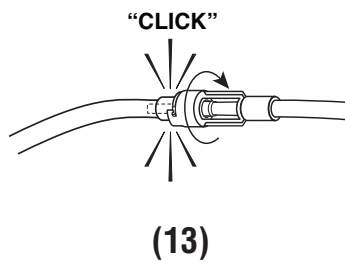
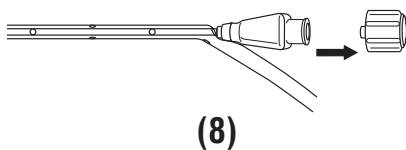
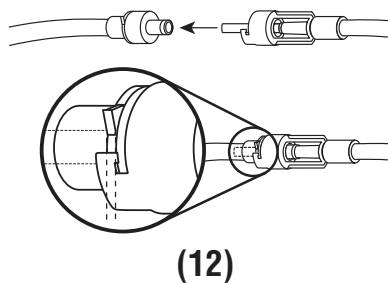
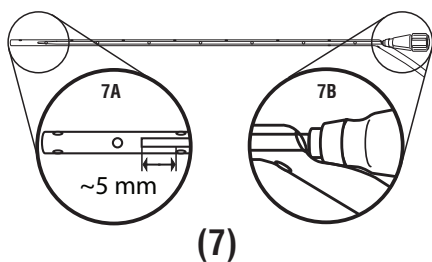
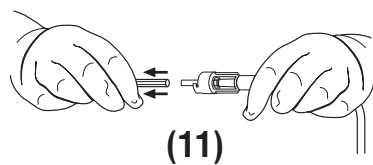
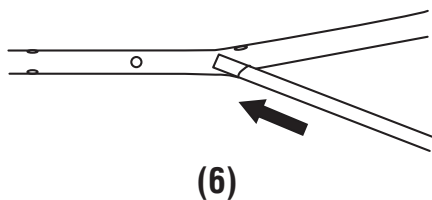
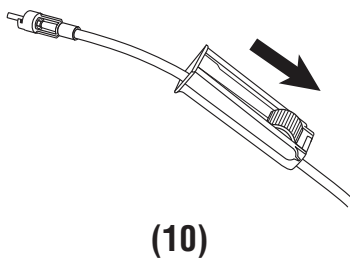
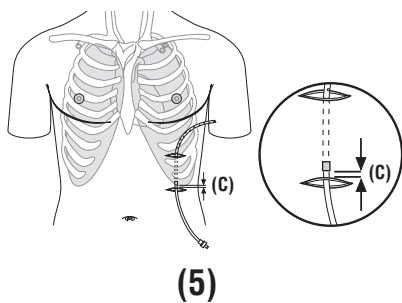
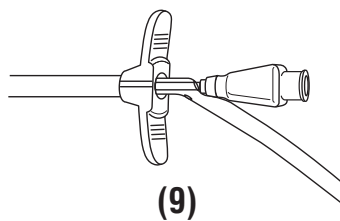
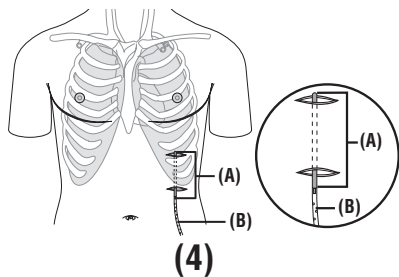
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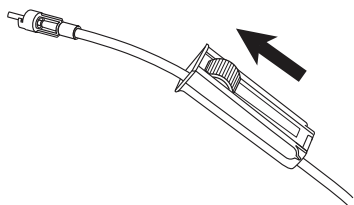
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# Figure

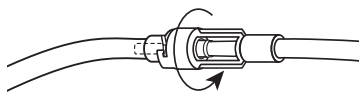


**Figure**

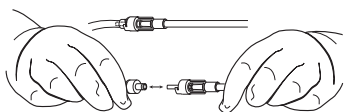




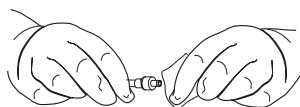
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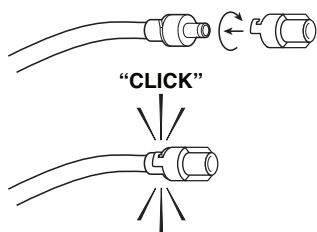
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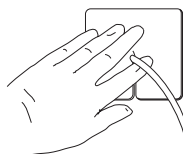
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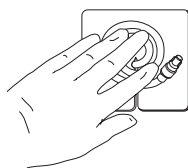
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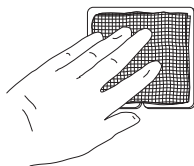
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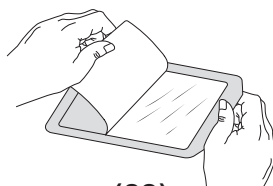
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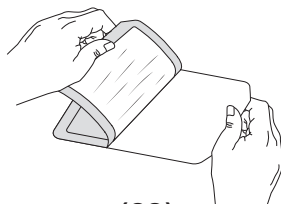
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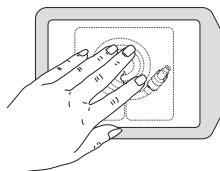
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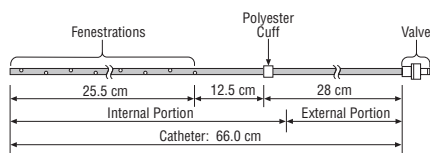
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## PleurX Pleural Catheter Procedure

### Product Information

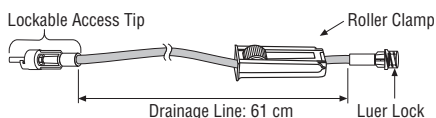
The PleurX Pleural Catheter consists of a fenestrated silicone catheter with a valve mechanism and a polyester cuff. A barium sulfate stripe runs the entire length of the catheter. **(Figure 1)** The valve is designed to prevent the passage of air or fluid in either direction unless it is accessed with the specifically matched drainage line, access kit, or vacuum bottles provided by CareFusion. The PleurX Pleural Catheter is designed exclusively for use with the PleurX vacuum bottle, glass vacuum bottles, and the lockable drainage line for connection to wall suction or portable suction.

### PleurX Pleural Catheter



(1)

### PleurX Lockable Drainage Line



(2)

### Indications for Use

The PleurX Pleural Catheter System is indicated for intermittent, long term drainage of symptomatic, recurrent, pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of the underlying disease. The devices are indicated for the palliation of dyspnea due to pleural effusion and providing pleurodesis (resolution of the pleural effusion). The Drainage Line is used to drain fluid using standard wall suction, water seal drainage system, vacuum bottle, or other appropriate method.

### Contraindications

Use of the PleurX Pleural Catheter System is contraindicated in the following situations:

1. When there is a shift  $\geq 2$  cm in the mediastinum towards the ipsilateral side of the effusion.
2. When the pleural cavity is multi-loculated, and the drainage of a single loculation would not be expected to provide relief of dyspnea.
3. When there is a coagulopathy.
4. When the pleural cavity is infected.
5. When the effusion is known to be chylous.

The catheter insertion stylet is not designed for use in the arterial system or as a hemostatic device.

### Warnings

Do not put anything except the access tip of the lockable drainage line, access kit, or PleurX Vacuum Bottles into the PleurX Catheter valve since any other device could damage the valve. A damaged valve may allow air into the body or let fluid leak out through the valve when not draining.

### Cautions

For single use only. Re-use may result in a nonfunctional product or contribute to cross contamination.

Sterile technique must be used when placing and draining the catheter.

The fenestrations must be entirely within the pleural space to avoid leakage into the tunnel tract. Take patient size, tunnel length, and the catheter length into account when placing the catheter.

Individuals with severe skin pathology overlying the favored implantation site (e.g. tumor invasion / psoriasis) should receive alternative treatment to relieve symptoms.

### Sterility

This product has been sterilized. It is for single use only and is not to be resterilized. Do not use if package is damaged. CareFusion will not be responsible for any product that is resterilized, nor accept for credit or exchange, any product that has been opened but not used.

### PleurX Catheter Tray Supplies

#### Preparation Components

- 2 ChloraPrep® 10.5 ml Applicators with Hi-Lite Orange™ Tint
- 1 Fenestrated Drape
- 1 Filter Straw
- 3 Lidocaine HCl 1%, 5 ml Ampules
- 1 SafetyGlide Needle, 22 G x 1 1/2" (3.8 cm)
- 1 SafetyGlide Needle, 25 G x 1" (2.5 cm)
- 1 Blue Wrap

#### Placement Components

- 1 PleurX Pleural Catheter, 15.5 Fr
- 1 Safety Scalpel
- 1 Guidewire Introducer with Needle
- 2 Syringes, 10 ml
- 1 Needle Foam Stop
- 1 J-tip Guidewire
- 1 Forceps
- 1 Dilator, 12 Fr
- 1 Peel-Away Introducer, 16 Fr
- 1 Tunneler
- 1 Catheter Insertion Stylet

#### Closing Components

- 1 Tweezer
- 1 Silk Suture, 2-0 Straight Needle
- 1 Absorbable Suture, 4-0 Curved Needle

#### Drainage Components

- 1 Drainage Line with Lockable Access Tip
- 1 Needle, 17 G x 1" (2.5 cm)
- 1 5-in-1 Drainage Line Adapter
- 1 Alcohol Pad
- 1 Valve Cap

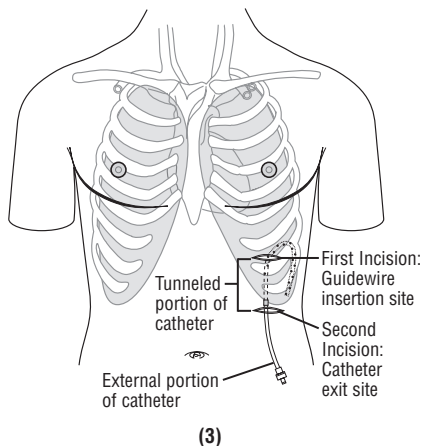
## Dressing Components

- 6 Gauze Pads, 4" x 4" (10.2 cm x 10.2 cm)
- 1 Foam Catheter Pad
- 1 Self-Adhesive Dressing

## General Guidelines

1. The procedure for pleural placement can be performed using local anesthetic and sedation. However, depending on patient needs, it may be performed using alternative approaches to anesthesia or sedation.
2. Use of image guidance may aid in the accuracy and safety of catheter placement. Care should be taken to identify and avoid contact with vasculature near the guidewire insertion site.
3. Guidewire placement site selection should be based upon patient anatomy and presentation with consideration given to any possible adhesions or loculated pockets of fluid.
4. Consideration should be given to the patient's ease of access in determining the location of the catheter exit site.
5. The fenestrated end of the catheter may be cut shorter depending on an individual patient's anatomy. **Note:** Leave at least one fenestration present on the catheter.
6. When using the drainage line, it may be used to drain at a suction level of -60 cm H<sub>2</sub>O or less for as long as it takes to drain 1,000 ml of fluid from the chest per day. The volume of fluid removed should be based on the individual patient's status and the risks for over draining, including reexpansion pulmonary edema in the chest.

## Suggested Placement Procedure



Proper medical and surgical procedures are the responsibility of the physician. The appropriateness of any procedure must be based upon the needs of the patient. **Figure (3)** illustrates the placement of the PleurX Pleural Catheter, as described in the following procedure.

1. Position the patient appropriately to access the desired guidewire insertion site.
2. Identify the appropriate intercostal space for guidewire placement. The guidewire is typically placed in the sixth or seventh intercostal space. Ultrasound can be used to confirm the guidewire insertion site.
3. Identify the location of the catheter exit site, which is usually approximately 5 cm inferior and lateral to the guidewire insertion site.
4. Surgically prep both sites utilizing the ChloraPrep® applicators. **Refer to the ChloraPrep insert for further information.**
5. Place the fenestrated drape with the opening located over the planned insertion and tunneling sites.

**Caution:** Use the filter straw for aspiration only. Do not use for injection.

**Note:** Utilize a filter straw when aspirating Lidocaine into the syringe.

6. Aspirate the Lidocaine HCl 1% into a syringe. Attach the 25 G needle to the syringe and raise a skin wheal. Aspirate additional Lidocaine into the syringe and use the 22 G needle to complete infiltration of the access site and tunnel track. **Refer to Addendum for additional product information.**

**Caution:** Care must be taken when inserting the guidewire introducer needle to avoid puncturing or lacerating the lung or liver.

7. Insert the guidewire introducer with needle, attached to a syringe, through the desired intercostal space and just over the lower rib.
8. Ensure free aspiration of pleural fluid, then remove the needle and syringe, leaving the guidewire introducer in place.
9. Insert the guidewire through the introducer, advancing it well into the pleural cavity.

**Caution:** Do not allow the guidewire to inadvertently advance totally within the patient. Ensure that the guidewire exits the proximal end of the needle, dilator, sheath or stylet prior to and during placement of each component.

10. Remove the introducer, leaving the guidewire in place.

**Caution:** If the needle is left in place with the guidewire introducer, damage to the guidewire may result if withdrawn through the needle.

11. Make a 1 cm incision at the guidewire insertion site.
12. Make a second 1-2 cm incision approximately 5 cm inferior and lateral to the guidewire insertion site. This incision will be the catheter exit site. Consider the patient's ease of access in determining its location. **(Figure 3)**

**Note:** A smaller incision may provide better security of the catheter.

**Note:** Take care to ensure that the tunnel track has been anesthetized.

13. The fenestrated end of the catheter may be cut shorter depending on an individual patient's anatomy. If desired, cut a portion of the fenestrated end of the catheter by using a scalpel to make a straight cut between fenestrations. Leave at least one (1) fenestration on the catheter.

14. Attach the fenestrated end of the catheter onto the tunneler.

**Caution:** Exercise care when handling the catheter to prevent it from coming into contact with surfaces such as drapes or towels. Silicone rubber is highly electrostatic and attracts airborne particles and surface contaminants.

**Caution:** Use rubber-shod instruments when handling the catheter. Possible cuts or tears can occur if rubber-shod instruments are not used.

15. Pass the tunneler **(A)** and catheter **(B)** subcutaneously from the second incision up to and out through the first incision at the guidewire insertion site. **(Figure 4)** Continue to draw the catheter through the tunnel until the polyester cuff lies inside the tunnel, about 1 cm **(C)** from the second incision. **(Figure 5)** Disconnect the tunneler from the catheter.

**Note:** If the cuff is advanced further into the tunnel, it can make later removal of the catheter difficult.

**If using the catheter insertion stylet, follow these instructions (steps 16-21) and continue to step 26:**

**Caution:** Do not use the catheter insertion stylet if the PleurX Catheter has been trimmed to accommodate patient anatomy.

16. Insert the tip of the catheter insertion stylet through the first fenestration of the catheter (closest to the cuff) and advance it into the catheter toward the tip (away from the cuff). **(Figure 6)** Ensure that the base of the stylet hub is pushed all the way up against the catheter, **(Figure 7B)**, such that the tip of the catheter insertion stylet is just past the 3rd to last fenestration near the tip of the catheter. **(Figure 7A)** Set the catheter and stylet aside.

**Note:** If placing the catheter over the guidewire, turn the yellow cap counterclockwise to remove it from the stylet. **(Figure 8)**

**Note:** For steps 17-19, ensure the guidewire exits the proximal end of the dilator, sheath, or stylet prior to and during placement.

17. Dilate the insertion site over the guidewire utilizing the 12 Fr dilator.

18. Thread the 16 Fr peel-away introducer over the guidewire into the pleural cavity.

19. Remove the guidewire and dilator as a unit from the sheath. Leave the sheath in place. **Note:** If placing the catheter over the guidewire, only remove the dilator. Thread the catheter with the stylet over the guidewire.

**Caution:** Place a thumb over the end of the sheath as the dilator is removed to avoid air entering the pleural cavity. Care must be taken not to bend or kink the sheath. Damage to the sheath may prevent passage of the catheter.

20. Advance the catheter with stylet through the sheath all the way until the hub of the stylet is at the top of the sheath. **(Figure 9)**

21. Pull the stylet out of the catheter. Continue pushing the catheter into the sheath advancing it until all the fenestrations are within the pleural cavity. This can be verified using fluoroscopy as the fenestrations are located along the barium sulfate stripe. **Note:** If placing the catheter over the guidewire, remove the stylet and the guidewire as a unit out of the catheter. **If not using the catheter insertion stylet, follow these instructions (steps 22-25) and continue to step 26:**

**Note:** For steps 22-23, ensure the guidewire exits the proximal end of the dilator or sheath prior to and during placement.

22. Dilate the insertion site over the guidewire utilizing the 12 Fr dilator.

23. Thread the 16 Fr peel-away introducer over the guidewire into the pleural cavity.

24. Remove the guidewire and dilator as a unit from the sheath. Leave the sheath in place.

**Caution:** Place a thumb over the end of the sheath as the dilator is removed to avoid air entering the pleural cavity. Care must be taken not to bend or kink the sheath. Damage to the sheath may prevent passage of the catheter.

25. Insert the fenestrated end of the catheter into the sheath advancing it until all the fenestrations are within the pleural cavity. This can be verified under fluoroscopy as fenestrations are located along the barium sulfate stripe.

26. After the catheter has been positioned, crack the sheath handle in half.

27. Peel away the sheath while ensuring the catheter remains in place. Adjust the catheter so that it lies flat in the tunnel without any kinks.

**Caution:** Do not use forceps on the introducer to break the handle and/or peel the sheath.

28. Close the incision at the guidewire insertion site.

29. Close the incision site around the catheter and suture the catheter to the skin taking care not to restrict the diameter of the catheter. This suture is intended to remain in place at least until there is tissue ingrowth around the cuff. **Refer to Addendum for additional product information.**

**Caution:** Exercise care when placing ligatures to avoid cutting or occluding the catheter.

**Note:** After suturing, Dermabond™ Topical Skin Adhesive (not included) may be applied topically over the guidewire insertion site and catheter exit site. This may aid in preventing leakage by assisting in wound closure. Follow the instructions for use provided by the manufacturer.

### Drainage Procedure

The drainage procedure can be performed using:

- a) PleurX Vacuum Bottle(s)
- b) PleurX Lockable Drainage Line with glass vacuum bottle(s) or with wall suction

If using PleurX Vacuum Bottle(s), refer to PleurX Drainage Kit Instructions for Use to perform the drainage procedure.

**Caution:** Re-expansion pulmonary edema may occur if too much fluid is removed too rapidly. Therefore, it is recommended to limit the initial drainage to no more than 1,500 ml. The volume of pleural fluid removed should be based on the patient's individual status.

**Caution:** Potential complications of access and drainage of the pleural cavity include, but may not be limited to, the following: re-expansion pulmonary edema, pneumothorax, laceration of the lung or liver, hypotension/circulatory collapse, wound infection, empyema and infection in the pleural cavity.

### Connect the Drainage Line to Wall Suction

**Caution:** Keep the valve on the PleurX Catheter and the lockable access tip on the drainage line clean. Keep them away from other objects to help avoid contamination.

**Caution:** If wall suction is used, it must be regulated to no greater than -60 cm H<sub>2</sub>O, or to drain no more than 400 ml of fluid per minute. (-60 cm H<sub>2</sub>O = -1.7 in Hg = -0.8psi)

1. Close the roller clamp completely by rolling the wheel on the roller clamp toward the suction source. **(Figure 10)**

**Caution:** The roller clamp must be fully closed to occlude the drainage line. When not connected to a suction source, make sure the roller clamp is fully closed; otherwise the drainage line may allow air into the body or let fluid leak out.

2. Attach the 5-in-1 adapter to the Luer fitting on the drainage line.
3. Connect the 5-in-1 adapter to the suction source.
4. Remove the cover from the lockable access tip by twisting it and pulling gently. Discard the cover. **(Figure 11)**
5. Insert the lockable access tip on the drainage line securely into the catheter valve. You will feel and hear a click when the lockable access tip and valve are securely connected. **(Figure 12)**
6. If desired, lock the access tip to the catheter valve by twisting the access tip until you feel and hear a second click. **(Figure 13)**

**Caution:** Make sure that the valve and the lockable access tip are securely connected when draining. If they are accidentally separated, they may become contaminated. If this occurs, clean the valve with an alcohol pad and use a new drainage line to avoid potential contamination.

**Caution:** Precautions should be taken to ensure the drainage line is not tugged or pulled.

### Connect the Drainage Line to Glass Vacuum Bottle(s)

**Caution:** Keep the valve on the PleurX Catheter and the lockable access tip on the drainage line clean.

Keep them away from other objects to help avoid contamination.

**Caution:** When draining with glass vacuum bottles, do not use a needle larger than 17 G.

1. Close the roller clamp completely by rolling the wheel on the roller clamp toward the glass vacuum bottle. **(Figure 10)**

**Caution:** The roller clamp must be fully closed to occlude the drainage line. When not connected to a glass vacuum bottle, make sure the roller clamp is fully closed; otherwise the drainage line may allow air into the body or let fluid leak out.

**Caution:** When connecting to a glass vacuum bottle, make sure the roller clamp on the drainage line is fully closed. Otherwise, it is possible for some or all of the vacuum in the bottle to be lost.

2. Attach a 17 G needle to the Luer fitting on the drainage line.
3. Connect the 17 G needle to the glass vacuum bottle.
4. Remove the cover from the lockable access tip by twisting it and pulling gently. Discard the cover. **(Figure 11)**
5. Insert the lockable access tip on the drainage line securely into the catheter valve. You will feel and hear a click when the lockable access tip and valve are securely connected. **(Figure 12)**
6. If desired, lock the access tip to the catheter valve by twisting the access tip until you feel and hear a second click. **(Figure 13)**



**Caution:** Make sure that the valve and the lockable access tip are securely connected when draining. If they are accidentally separated, they may become contaminated. If this occurs, clean the valve with an alcohol pad and use a new drainage line to avoid potential contamination.

**Caution:** Precautions should be taken to ensure the drainage line is not tugged or pulled.

### Drain Fluid

1. Roll the wheel on the roller clamp away from the suction source to begin drainage. **(Figure 14)**
2. When fluid begins to drain, you may roll the wheel on the roller clamp toward the suction source to slow the flow of fluid.

**Caution:** It is normal for the patient to feel some discomfort or pain when draining fluid. If discomfort or pain is experienced when draining, roll the wheel on the roller clamp towards the suction source to slow or stop the flow of fluid for a few minutes. Pain may be an indication of infection.

3. When fluid flow stops or the desired amount of fluid has been removed, completely close the roller clamp by rolling the wheel on the roller clamp toward the suction source. **(Figure 10)**
4. If you need to change the glass vacuum bottle / canister / water seal device or suction source for any reason, remove the drainage line from the suction source and connect to a new suction source. Roll the wheel on the roller clamp away from the suction source to resume draining.

### Finish Drainage

1. If locked, twist the lockable access tip to unlock it from the catheter valve. **(Figure 15)**
2. Ensure the drainage line has been unlocked. Pull the lockable access tip out of the valve in a firm, smooth motion. Set the used drainage line down. **(Figure 16)**
3. Clean the catheter valve with an alcohol pad. Discard the alcohol pad. Do not try to push anything through the valve as damage to the valve may occur. **(Figure 17)**

**Caution:** The alcohol pads are flammable. Do not expose the pads to an open flame.

4. Place the new valve cap over the catheter valve and twist it clockwise until it clicks into its locked position. **(Figure 18)**

### Place the Self-Adhesive Dressing

1. Clean around the catheter site.

**Note:** Make sure the exit site and skin around the catheter are dry before completing the dressing procedure.

2. Place the foam catheter pad around the catheter. **(Figure 19)**
3. Wind the catheter into loops and place it over the foam pad. **(Figure 20)**
4. Cover the catheter with up to four (4) gauze pads **(Figure 21)**
5. The self-adhesive dressing has three (3) layers:
  - a. printed liner
  - b. clear wound dressing
  - c. center panel and frame backing
6. Remove and discard the center panel from the backing of the self-adhesive dressing. **(Figure 22)**
7. Peel the printed liner from the self-adhesive dressing, exposing the adhesive surface. **(Figure 23)**
8. Center the self-adhesive dressing over the gauze pads and press it down. **(Figure 24)**

**Note:** Do not stretch the self-adhesive dressing during application.

9. Slowly remove the frame while smoothing down the self-adhesive dressing edges. **(Figure 25)**
10. Smooth the entire self-adhesive dressing from the center toward the edges using firm pressure to enhance adhesion.
11. Disconnect the drainage line from the glass vacuum bottle or suction source.

**Note:** Dispose of the used drainage line and/or used glass vacuum bottles in accordance with applicable local, state, and federal regulations. Used product may present a potential biohazard.

**Note:** The Ethicon BioPatch™ (not included) is compatible for use with the PleurX Catheter. If using BioPatch, the disc should be placed on the skin first, before the foam pad and other dressing materials.

Follow all instructions for use provided by Ethicon and CareFusion.

## Spontaneous Pleurodesis with the PleurX

Patients who drain regularly every day or every other day may achieve pleurodesis. In a multi-center clinical trial, drainage of the effusion at least once every other day resulted in approximately half of the patients achieving spontaneous pleurodesis with a mean time to catheter removal of 29 days.<sup>1</sup>

## Pleurodesis Procedures with PleurX

The PleurX Catheter is compatible with Talc and Bleomycin (not included).

### Talc Slurry / Bleomycin

Use the Catheter Access Kit (REF 50-7280) to access the catheter and instill the pleurodesing agent. The locking access tip with needleless access valve should be removed immediately after completion of the procedure.

Perform the procedure per the pleurodesis agent's instructions for use and your institution protocol.

### Talc Poudrage

The PleurX catheter can be used in place of the chest tube for post-surgical drainage of a talc poudrage.

**Note:** The poudrage should not be sprayed through the PleurX catheter. Perform the procedure per the Talc instructions for use and your institution protocol.

## Subsequent Drainage Procedures

Subsequent drainage procedures are to be performed using the PleurX Drainage Line, PleurX Vacuum Bottle, or the PleurX Drainage Kits. Each drainage kit contains the necessary drainage line, vacuum bottle, and other necessary items to perform the drainage procedure.

**It is vital that patients and/or caregivers are carefully instructed on how to use the kit to drain the pleural cavity. The person(s) responsible for drainage must be able to demonstrate they are capable of performing the procedure.**

**If the patient/caregiver is not able or willing to perform the drainage, a medical professional should perform the drainage.**

**It is recommended that the patient is periodically contacted or seen by a clinician to evaluate treatment regimen and evaluate catheter's functional status.**

## Catheter Removal Procedure

It may be appropriate and/or necessary at a later date to remove the PleurX Pleural Catheter. Three successive attempts to drain fluid that result in less than 50 ml of fluid removed may indicate one of the following:

- pleurodesis has been achieved
  - the catheter is loculated away from the fluid
  - the catheter is occluded
1. Place the patient appropriately to access the catheter insertion site.
  2. Aseptically clean the patient's chest around the catheter insertion site.
  3. Anesthetize the site.
  4. Remove any remaining sutures securing the catheter.
  5. Using forceps, dissect around the cuff to free it from the ingrowth. Ensure that the cuff is completely free within the tunnel.
  6. Grasp the catheter in one hand and pull with a firm, constant pressure.
  7. Cover the site as appropriate.

Contains Phthalates. The benefit of treatment outweighs the remote possibility of exposure to phthalates.

**Note:** Not made with natural rubber latex.  
The PleurX Catheter is MR Safe.

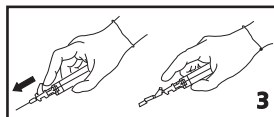
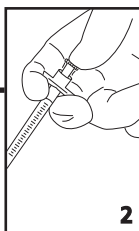
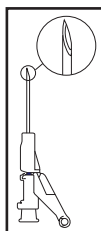
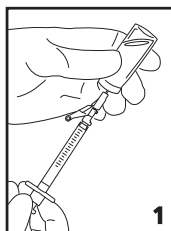
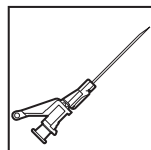
1Putnam JB Jr, Light RW, Rodriguez RM, et al. A Randomized Comparison of Indwelling Pleural Catheter and Doxycycline Pleurodesis in the Management of Malignant Pleural Effusions. Cancer 1999; 86; 1992-1999.

## ADDENDUM ONE

P/N DG205108 8036300 Rev. 2012-02

### BD SafetyGlide™ Needle

1. Push firmly when attaching the needle to the syringe.  
Draw up Medication in accordance with established protocol.
2. Administer Medication in accordance with established protocols. For user convenience, the needle “bevel up” position is oriented to the lever arm as shown.



Bevel Up = Lever Arm Up

Activated after use.

3. Activate Safety Mechanism immediately after removal from patient by pushing lever arm completely forward until needle tip is completely covered. Visually confirm that the lever arm has fully advanced and the needle tip is covered. If unable to activate, discard immediately into an approved sharps collector.

Discard after single use in an approved sharps container in accordance with applicable regulations and institutional policy.

Use one handed technique and activate away from self and others.

Activation of the protective mechanism may cause minimal splatter of any fluid that is remaining on the needle after injection.

Non-pyrogenic. Do not use if individual packaging is damaged.

Do not Reuse. For Single Use.

### Caution

Where local and/or institutional procedures permit/require transportation of the filled syringe, use a passive recapping technique to cover the needle before transporting to the point of administration. USA only: OSHA standards require that such recapping must be accomplished using a one handed technique. DO NOT hold the needle shield during the recapping process.

To help avoid HIV (AIDS), HBV (Hepatitis) and other infectious diseases due to accidental needlesticks, activate the protective mechanism immediately after use.

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

Do not autoclave BD SafetyGlide™ Needle before use.

**Caution:** Reuse may lead to infection or other illness/injury.

Excerpt from: **BD**

SafetyGlide is a trademark of Becton, Dickinson and Company. ©2006 BD www.bd.com  
This product is covered by U.S. Patent numbers 5,348,544.

**BD**, Franklin Lakes, NJ 07417 USA

**POLYSYN™ - Absorbable Surgical Suture, USP (Violet and Clear)****Description**

POLYSYN™ (Polyglycolic Acid) suture is a synthetic absorbable, sterile, surgical suture composed of a homopolymer of glycolic acid. POLYSYN™ (Polyglycolic Acid) is supplied as either a braided multifilament or as a monofilament suture. POLYSYN™ (Polyglycolic Acid) is provided dyed (violet) or undyed (clear) as well as coated or uncoated. The pigment for the violet dye is D&C Violet #2. The substances contained in the coating and suture are noncollagenous and nonantigenic. POLYSYN™ (Polyglycolic Acid) suture meets all the requirements established by the United States Pharmacopeia (USP) for synthetic absorbable surgical suture.

Rx Only

**Indications**

POLYSYN™ (Polyglycolic Acid) suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

**Actions**

POLYSYN™ (Polyglycolic Acid) suture elicits a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of POLYSYN™ (Polyglycolic Acid) synthetic absorbable sutures occurs by hydrolysis, where the polymer degrades to glycolic acid which is subsequently absorbed and metabolized by the body. Absorption begins as a loss of tensile strength without appreciable loss of mass. Implantation studies in animals indicate that POLYSYN™ (Polyglycolic Acid) suture retains at least 50% of its original tensile strength at two weeks post implantation, with approximately 20% remaining at three weeks. Absorption of POLYSYN™ (Polyglycolic Acid) synthetic absorbable suture is essentially complete between 50 and 90 days.

**Contraindications**

This suture, being absorbable, should not be used where extended approximation of tissue is required.

**Warnings****Do not resterilize. Discard open, unused sutures and associated surgical needles.**

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing POLYSYN™ (Polyglycolic Acid) synthetic absorbable sutures for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the *in vivo* performance (under ACTIONS section) when selecting a suture for use in patients. The use of this suture may be inappropriate in elderly, malnourished or debilitated patients, or in patients suffering from conditions which may delay wound healing.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculi formation. As an absorbable suture, POLYSYN™ (Polyglycolic Acid) may act transiently as a foreign body. Acceptable surgical practice should be followed for the management of contaminated or infected wounds. As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of sites which may undergo expansion, stretching, or distension or which may require additional support.

## Precautions

Care should be taken to avoid damage when handling. Avoid crushing or crimping the suture material with surgical instruments, such as needle holders and forceps.

Infections, erythema, foreign body reactions, transient inflammatory reactions, and in rare instances, wound dehiscence are typical or foreseeable risks associated with any suture and hence are also potential complications associated with POLYSYN™ (Polyglycolic Acid) suture.

The surgeon should avoid unnecessary tension when running down knots to reduce the occurrence of surface fraying and weakening of the strand.

Under some circumstances, notably orthopedic procedures, immobilization of joints by external support may be employed at the discretion of the surgeon.

Avoid prolonged exposure to elevated temperatures.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.

Adequate knot security for synthetic absorbable sutures, which are coated to enhance handling characteristics, requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.

## Adverse Reactions

Adverse effects associated with the use of this device may include, wound dehiscence; failure to provide adequate wound support in closure of sites where expansion, stretching or distension occur etc., unless additional support is supplied through the use of nonabsorbable material; failure to provide adequate wound support in elderly, malnourished, or debilitated patients, or in patients suffering from conditions which may delay wound healing; tissue granulation or fibrosis, wound suppuration and bleeding as well as sinus formation; wound infection, minimal acute tissue inflammatory response characteristic of foreign body response; localized irritation when skin sutures are left in place for greater than seven (7) days; calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs; and transitory local irritation at the wound site.

Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of blood borne pathogens.

## Sterility

POLYSYN™ (Polyglycolic Acid) is sterilized using ethylene oxide. Do not resterilize. Do not use if the package is opened or damaged. Discard opened unused sutures. Do not use after expiration date.

## How Supplied

POLYSYN™ (Polyglycolic Acid) synthetic absorbable surgical sutures are available sterile as braided multifilament dyed, (violet) and undyed (clear) coated strands in USP sizes 8-0 through 2 (metric sizes 0.4 through 5) in a variety of lengths affixed to various needle types. POLYSYN™ (Polyglycolic Acid) synthetic absorbable sutures are also available sterile as monofilament uncoated, dyed (violet) and undyed (clear) strands in USP sizes 9-0 and 10-0 (metric 0.3 - 0.2) in a variety of lengths affixed to various needle types.

Excerpt from: Surgical Specialties Corporation

Surgical Specialties Corporation, Corredor Tijuana-Rosarito 2000,  
#24702-B, Ejido Francisco Villa, Tijuana, B.C., C.P. 22235

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**SILK SUTURE - Non-Absorbable Surgical Suture, USP, (Black, White, Blue)****Description**

Silk suture (Black, White) is a non-absorbable, sterile, surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species *Bombyx mori*, (*B. mori*) of the family Bombycidae. In the United States, Silk suture is provided dyed (black) or undyed (white). The pigment for the black dyed suture is Hematein (Logwood Tree) Black. Silk suture is wax coated. Silk suture is available as either braided or twisted monofilament strands. The product meets all the requirements established by the United States Pharmacopeia (USP) for Non-absorbable Surgical Suture.

Outside the United States only, virgin Silk suture is available in sizes 8-0 (metric 0.4) and 9-0 (metric 0.3) dyed blue with methylene blue. Virgin Silk suture dyed blue is not available for sale in the United States, and is available for export outside the United States only.

Rx Only

**Indications**

Silk suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures.

**Actions**

Silk suture elicits an acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. While Silk suture is not absorbed, progressive degradation of the proteinaceous silk fiber in vivo may result in gradual loss of the suture's tensile strength over time.

**Contraindications**

The use of this suture is contraindicated in patients with known sensitivities or allergies to Silk. Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, Silk suture should not be used where permanent retention of tensile strength is required.

**Warnings**

**Do not resterilize. Discard open, unused sutures and associated surgical needles.**

Users should be familiar with surgical procedures and techniques involving Silk sutures before employing Silk sutures, for wound closure, as risk of wound dehiscence may vary with the site of application and the suture material used. Physicians should consider the in vivo performance (under ACTIONS section) when selecting a suture for use in patients. The use of this suture may be inappropriate in elderly, malnourished or debilitated patients, or in patients suffering from conditions which may delay wound healing.

As with any foreign body, prolonged contact of any suture with salt solutions, such as those found in the urinary or biliary tracts, may result in calculus formation.

Acceptable surgical practice should be followed with respect to drainage and closure of infected or contaminated wounds.

## **Precautions**

Care should be taken to avoid damage when handling. Avoid crushing or crimping the suture material with surgical instruments, such as needle holders and forceps.

Infections, erythema, foreign body reactions, transient inflammatory reactions and in rare instances wound dehiscence are typical or foreseeable risks associated with any suture and hence are also potential complications associated with Silk suture.

Acceptable surgical practice must be followed with respect to drainage and closure of infected wounds.

To avoid damaging needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half (1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to lose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

As with any suture material, adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.

## **Adverse Reactions**

Adverse effects associated with the use of this suture may include, wound dehiscence; gradual loss of tensile strength over time; allergic response in patients that are known to be sensitive to silk; calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs; infected wounds; minimal acute inflammatory tissue reaction; and pain, edema and erythema at the wound site.

Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in the transmission of blood borne pathogens.

## **Sterility**

Silk sutures are sterilized by gamma radiation. Do not reuse. Do not resterilize. Do not use if the package is opened or damaged. Discard opened unused sutures. Do not use after expiration date.

## **How Supplied**

Braided Silk suture is available sterile in USP sizes 8-0 through 5 (metric 0.4 through 7) in both dyed (black) and undyed (white), wax coated. Silk suture is supplied sterile in pre-cut lengths, both needled and non-needled and affixed to various needle types. Twisted Silk suture is available in USP size 9-0 (metric 0.3) dyed black.

Excerpt from: Angiotech

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