Cat. **50-7000B**

PleurX™ Pleural Catheter Kit

For Pleural Placement Only
Sterile
For Single Use Only

Product and packaging do not contain natural rubber latex.

Instructions for Use

USA Rx Only

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

SafetyGlide is a trademark of Becton Dickinson, Inc.

Point-Lok is a registered trademark of Smiths Medical, ASD, Inc.

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

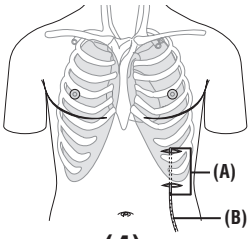
PleurX is a trademark or registered trademark of CareFusion Corporation, or one of its subsidiaries.

CareFusion
1500 Waukegan Road
McGaw Park, IL 60085 USA
361-26801 • 2012-04

CareFusion

DEHP
Contains phthalates

Diagram



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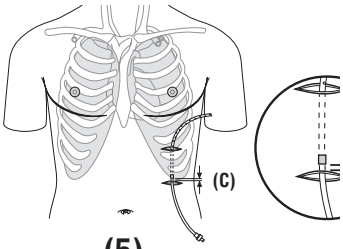

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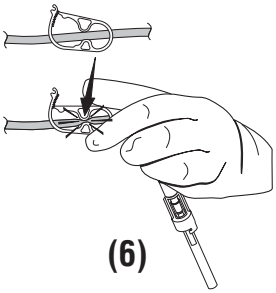

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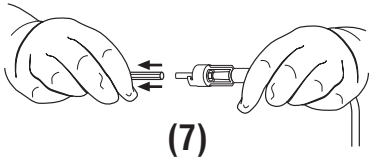

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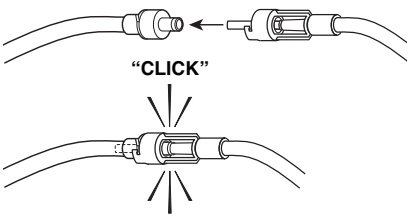

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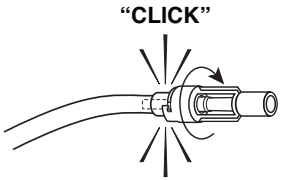

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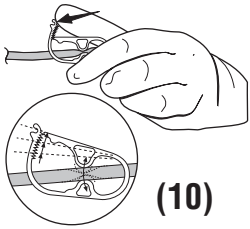

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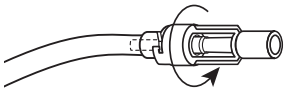

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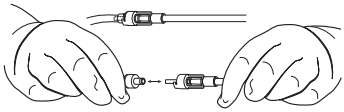

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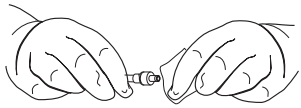

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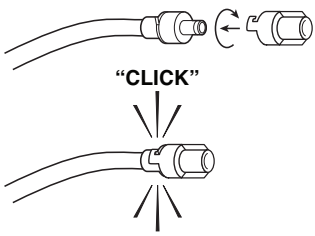

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Instructions for Use

Kit Contents

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 Ga. x 1 ½" (3.8 cm)
1 SafetyGlide Needle, 25 Ga. x 1" (2.5 cm)
1 CSR Wrap

Placement Components

1 PleurX Pleural Catheter, 15.5 Fr.
1 Safety Scalpel
1 Guidewire Introducer with Needle
2 Syringes, 10 ml
1 Point Lok Sharps Safety Device
1 J-tip Guidewire
1 Forceps
1 Dilator, 8 Fr.
1 Dilator, 12 Fr.
1 Peel-Away Introducer, 16 Fr.
1 Tunneler

Closing Components

1 Tweezer
1 Silk Suture, 2-0 Straight Needle
1 Absorbable Suture, 3-0 Curved Needle

Drainage Components

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

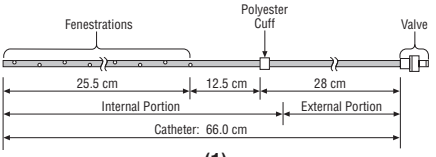
Dressing Components

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

PleurX Pleural Catheter Description

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. 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 or vacuum bottles provided by CareFusion.

PleurX Pleural Catheter



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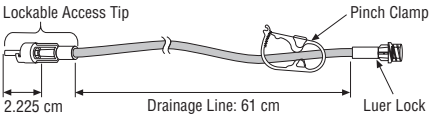
PleurX Lockable Drainage Line



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Indications

The PleurX Pleural Catheter Kit (Cat. 50-7000B) and the PleurX Drainage Kits (REF 50-7500 series and REF 50-7510 series) are 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:

1) the palliation of dyspnea due to pleural effusion
2) providing pleurodesis (resolution of the pleural effusion)

Contraindications

Use of the PleurX Pleural Catheter Kit and the PleurX Drainage Kit is contraindicated in the following situations:

1. When there is a shift ≥ 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.

Warnings

Do not put anything except the access tip of the lockable drainage line or PleurX Vacuum Bottles into the PleurX Catheter valve since this 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 non-functional product or contribute to cross contamination.

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

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

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

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

Exercise care when placing 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.

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

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.

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

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

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.

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

When connecting to a vacuum bottle, make sure the pinch 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.

When draining with glass vacuum bottles, do not use a needle larger than 17 Ga. If wall suction is used, it must be regulated to no greater than (-)60 cm H_2O.

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.

Make sure that the valve and 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 set to avoid potential contamination.

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

It is normal for the patient to feel some discomfort or pain when draining fluid. If discomfort or pain is experienced when draining, clamp the drainage line to slow or stop the flow of fluid for a few minutes. Pain may be an indication of infection.

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 lung or liver, hypotension/circulatory collapse, wound infection, empyema and infection in the pleural cavity.

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

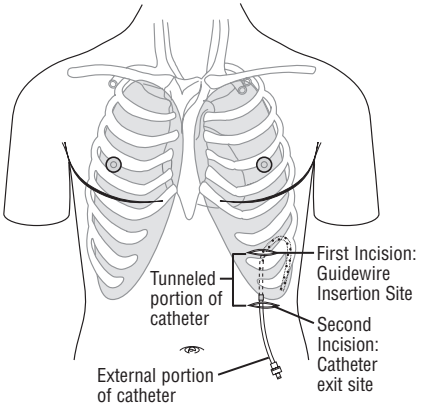
Sterility

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.

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. Catheter 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.

Suggested Placement Procedure



(3)

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. **Diagram (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 Ga. needle to the syringe and raise a skin wheal. Aspirate additional Lidocaine into the syringe and use the 22 Ga. 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.
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. **See Diagram (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. Attach the fenestrated end of the catheter onto the tunneler.

Caution: Exercise care when placing 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 contaminates.

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

14. 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. **See Diagram (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. **See Diagram (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.

15. Dilate the insertion site over the guidewire utilizing the 8 Fr. and 12 Fr. dilators.
16. Thread the 16 Fr. peel-away introducer sheath over the guidewire into the pleural cavity.
17. Remove the guidewire and dilator as a unit, leaving the 16 Fr. peel-away introducer 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.

18. 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.
19. 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.

20. Close the incision at the guidewire insertion site.
21. 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.

Drainage Procedure

The drainage procedure can be performed using:

a) PleurX Vacuum Bottle(s)

b) PleurX Lockable Drainage Line with other vacuum bottle(s) or

c) 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.

1. Clamp the drainage line completely closed using the pinch clamp found on the tubing. **See Diagram (6)**

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

Caution: When connecting to a vacuum bottle, make sure the pinch 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. If using wall suction, attach the 5-in-1 adapter to the Luer fitting on the drainage line. If using a vacuum bottle other than PleurX, attach a 17 Ga. needle to the Luer fitting on the drainage line.

Caution: When draining with glass vacuum bottles, do not use a needle larger than 17 Ga. If wall suction is used, it must be regulated to no greater than (-)60 cm H_2O.

3. Connect the drainage line to the vacuum/suction source.
4. Hold the drainage line near the lockable access tip and remove the protective cover by twisting it and gently pulling. Take care to avoid contaminating the lockable access tip. **See Diagram (7)**

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.

5. Continue holding the catheter near the valve. Carefully insert the lockable access tip into the catheter valve and advance it completely into the valve. You will feel and hear a click when the lockable access tip and valve are securely connected. **See Diagram (8)**

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 set to avoid potential contamination.

6. If desired, lock the access tip to the catheter valve by twisting the access tip until you feel and hear a second click. **See Diagram (9)**

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

7. Release the pinch clamp on the drainage line to begin drainage. You can reduce the flow rate by squeezing the clamp partially closed. **See Diagram (10)**

Caution: It is normal for the patient to feel some discomfort or pain when draining fluid. If discomfort or pain is experienced when draining, clamp the drainage line to slow or stop the flow of fluid for a few minutes. Pain may be an indication of infection.

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.

8. If you need to change to a new vacuum bottle or suction source for any reason, squeeze the pinch clamp on the drainage line completely closed. Remove the drainage line from the vacuum/suction source and connect to a new vacuum bottle or suction source. Release the pinch clamp to resume draining.
9. When flow stops or the desired amount of fluid has been removed, squeeze the pinch clamp on the drainage line completely closed. **See Diagram (6)**
10. If locked, twist the lockable access tip to unlock it from the catheter valve. **See Diagram (11)**

11. Ensure the drainage line has been unlocked. With the drainage line in one hand and the catheter valve in the other hand, pull the lockable access tip out of the valve in a firm, smooth motion. **See Diagram (12)**
12. Clean the catheter valve with an alcohol pad. Do not try to push anything through the valve as damage to the valve may occur. **See Diagram (13)**.

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

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

13. Place the valve cap over the catheter valve and twist it clockwise until it clicks into the locked position. **See Diagram (14)**
14. Clean around the catheter site.
15. Place the foam catheter pad around the catheter.
16. Wind the catheter into loops and place it over the foam pad.
17. Cover the catheter with gauze pads and secure with the self-adhesive dressing.
18. Disconnect the drainage line from the glass vacuum bottle or suction source. Dispose of the used drainage line and/or used vacuum bottles in accordance with applicable local, state, and federal regulations. Used product may present a potential biohazard.

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. [1]

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.

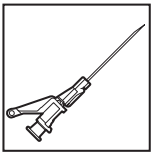
Contains Phthalates. The benefit of treatment outweighs the remote possibility of exposure to phthalates.

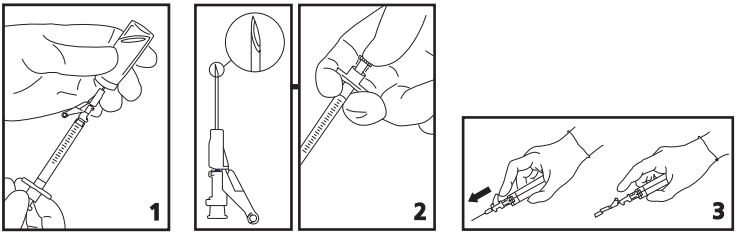
[1]Putnam JB Jr, Light RW, Rodriguez RM, et al. A Randomized Comparison of Indwelling Pleural Catheter and Doxycycline Pleurodesis in the Management of Malignant Pleural Effusions. Cancer 1999; 86; 1992-1999.

ADDENDUM ONE P/N DG205107 8024001 Rev. 2009-06

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**

BD, Franklin Lakes, NJ 07417 USA

ADDENDUM TWO P/N 1016262

POLYSORB™ - Coated, Braided Synthetic Absorbable Sutures

Description

POLYSORB™ sutures are composed of LACTOMER™ glycolide/lactide copolymer which is a synthetic polyester composed of glycolide and lactide (derived from glycolic and lactic acids). POLYSORB™ sutures are prepared by coating the suture with a mixture of a caprolactone/glycolide copolymer and calcium stearoyl lactylate. POLYSORB™ sutures are colored violet to increase visibility and are also available undyed.

POLYSORB™ sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) except for minor variations in suture diameter.

Maximum Suture Oversize in Diameter (mm) from U.S.P.

U.S.P. Size	U.S.P. Size Designation (mm)	Maximum Overage (mm)
3-0	0.20 - 0.249	0.050

Rx Only

For Single Use.

Prior to use see instructions.

Indications

POLYSORB™ Sutures are indicated for use in soft tissue approximation or ligation and ophthalmic surgery, but not in cardiovascular or neural tissue.

Actions

POLYSORB™ sutures elicit a minimal acute inflammatory reaction in tissue, which is followed by a gradual encapsulation of the suture by fibrous connective tissue.

Progressive loss of tensile strength and eventual absorption of POLYSORB™ sutures occurs by means of hydrolysis, where the LACTOMER™ glycolide/lactide copolymer is broken down to glycolic and lactic acids which are subsequently absorbed and metabolized by the body. Absorption begins as a loss of tensile strength without appreciable loss of mass. Studies indicate tensile strength averages for POLYSORB™ sutures are approximately 140% of U.S.P. and E.P. minimum knot strength initially, are approximately 80% at two weeks and in excess of 30% at three weeks post implant. Absorption of POLYSORB™ sutures is essentially complete between the 56th and 70th day.

Contraindiction

POLYSORB™ sutures, being absorbable, should not be used where extended approximation of tissue is required.

Warnings

Do not resterilize. Sterile unless packaging has been opened or damaged. Discard open, unused sutures. Store at room temperature. Avoid prolonged exposure to elevated temperatures.

In surgery of the urinary or biliary tracts, care should be taken to avoid prolonged contact of this, or any other, suture with salt solutions, as calculus formation may result.

Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing POLYSORB™ sutures for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As any foreign material in the presence of bacterial contamination may enhance bacterial infectivity, acceptable surgical practice must be followed with respect to drainage and closure of contaminated or infected wounds.

The use of this suture may be inappropriate in patients with any conditions which, in the opinion of the surgeon, may cause or contribute to delayed wound healing.

As this is an absorbable suture material, the use of supplemental nonabsorbable sutures should be considered by the surgeon in closure of the abdomen, chest, joints or other sites subject to expansion or requiring additional support.

Precautions

In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments, such as forceps or needle holders. 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.

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

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

Adverse Reactions

Adverse effects, which may be associated with the use of this product, include: wound dehiscence, failure to provide adequate wound support in sites where expansion, stretching, or distention occur, failure to provide adequate wound support in patients with conditions which may delay wound healing, localized irritation when skin sutures are left in place greater than 7 days, calculi formation when prolonged contact with salt solutions occurs, enhanced bacterial infectivity, minimal acute inflammatory reaction, and transitory local irritation.

How Supplied

POLYSORB™ sutures are available in U.S.P. sizes 2 (5 metric) through 8-0 (0.4 metric). They are available undyed (natural) or violet colored. The sutures are supplied sterile, in pre-cut lengths and ligating reels, non-needled or affixed to various needle types using both permanent and removable needle attachment techniques. The sutures are available in box quantities of one, two, and three dozen.

Excerpt from: **POLYSORB™**

www.syneture.com

ADDENDUM THREE P/N 03-3318R6

SILK SUTURE - Non-Absorbable Surgical Suture, USP 2-0 Braided, Black

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 coated with fully refined paraffin. 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.

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.

Contraindictions

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. Do not reuse. Do not use if package is damaged.

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 materiel 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.

Caution: Refer to accompanying documents.

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 bloodborne pathogens.

Sterility

Silk sutures are sterilized by gamma radiation. 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), coated with fully refined paraffin. 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
Surgical Specialties Corporation, Reading, PA 19606 USA
SHARPOINT™ is a trademark of Surgical Specialties Corporation
LOOK™ is a trademark of Surgical Specialties Corporation

ADDENDUM FOUR P/N CLA318 Rev.001

Portex® Point-Lok® - SHARPS SAFETY DEVICE (STERILE)

Read Completely Before Use

Description

The Portex® Point-Lok® needle protection device is designed to provide needle stick protection utilizing a simple one-handed technique. The design will accommodate most style needles in the size range of 16 to 30 gauge.

The Point-Lok® device will help users to comply with the following OSHA rules and regulations:

(OSHA Rules and Regulations on Bloodborne Pathogens)*
Needle Sticks:

"(A) Contaminated needles ... shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure."

"(B) Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique."

Exposure to contaminated blood:

"(XI) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splash, spray, splattering, and generation of droplets of these substances."

**U.S. Labor Occupational Safety and Health Administration, OSHA Rules and Regulations Of Bloodborne Pathogens 29CFR1910.1030*

Indications For Use

This device is intended as a single use needle protection device, which covers the end of the needle after use to help prevent needle sticks. This device is designed for use with 16 gauge through 30 gauge needles.

Contraindications

None known.

Warnings

A needle stick with a contaminated needle may cause infectious diseases.

Intentional misuse of the Point-Lok® needle protection device may result in a needle stick with a contaminated needle.

Bent or damaged needles cannot be properly secured in this device. If the needle is bent, do not try to straighten the needle or attempt to engage the needle into this protective device. The Point-Lok® device may not properly contain a bent and / or damaged needle. If a bent or damaged needle was forced in to this device, it could cause a needle to protrude through the device, which could result in a contaminated needle stick.

Do not ever attempt to place needle into Point-Lok® device while holding the device. This may result in an accidental needle stick injury.

Use this device only on a flat, secure, sturdy surface when attempting to engage needle in the Point-Lok® device. Attempting to do so otherwise could possibly lead to a contaminated needle stick.

Do not forcibly insert needles into Point-Lok® device as this may lead to accidental penetration of base unit and could result in an accidental needle stick injury.

Precautions

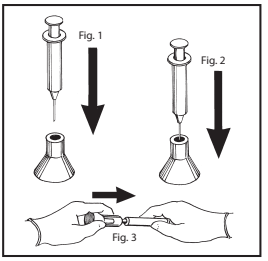
The Point-Lok® device is not considered to be a final sharps container and should be properly disposed of in an approved sharps collection container.

Any attempts to remove needle from syringe with the unwinder device, should be done very gently to avoid splattering, spraying, or generation of droplets from the syringe.

Instructions For Use

Place the Point-Lok® needle protection device only on a secured flat surface.

Immediately after use of needle, gently insert exposed needle into the Point-Lok® device opening at top of the Point-Lok® device.
See illustration (Fig.1)



Push needle into the top opening until it is fully inserted into Point-Lok® device. This action will seal the needle tip and lock the needle firmly into the Point-Lok® device. (Fig.2)

Once the Point-Lok® device is properly engaged with needle, the needle may be removed from the syringe with the Point-Lok® unwinder device. (Optional/Fig.3)

While firmly holding the Point-Lok® device base, slide the unwinder off the Point-Lok® device and engage it with the lugged needle Luer. Safely and gently unscrew the needle from the syringe. (Fig.3) The unwinder is intended *only* for use with needles that have lugged Luers.

After use, place sharps in a suitable sharps container. Dispose of contaminated product in a safe manner according to Centers for Disease Control and Prevention, USA and Federal/State/Local regulations (EPA, OSHA) and health care facility guidelines or local equivalent.

Attention, See instructions for use. Do not reuse. Latex Free.

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. Sterilized using ethylene oxide.

Excerpt from: Portex® Point-Lok®
Smiths Medical ASD, Inc., Keene, NH 03431 USA
www.smiths-medical.com
The product described is covered by U.S. Patent Nos. 5,395,338, 5,417,659 & 5,601,532.
Portex & Point-Lok are trademarks of the Smiths-medical family of companies.