**ACCESS PORT**

**CE marking:** 2000 Products references: IVT XXXX / IVP XXXX / IVM XXXX / VSP XXX / VPP XXX / IAT XXXX / IAP XXXX / ASP XXXX / APP XXXX

Product sterilized by ethylene oxide
Sterile product as long as the packaging hasn’t been opened damaged or brake. Single use product

**WARNING:**
- Don’t resterilize
- Store in a cool and dry place with ambient temperature. Avoid extreme temperatures (<5°C and >+35°C) and humidity
- Conserve in the original packaging
- Read carefully instructions before use
- Shelf life – Use before expiration date indicated on the package

**ACCESS PORT DESCRIPTION AND USE:**
The FB Medical access ports are totally implantable vascular access devices designed to provide repeated access to the vascular system for the delivery of medications, intravenous fluids, parenteral nutrition solutions, and blood products. They are also indicated for the withdrawal of blood sample. Port access is performed by percutaneous needle insertion using a Huber needle.

**CONTRAINDICATIONS:**
The FB Medical access port with catheter is contraindicated for implantation whenever:
- Use in the superior vena cava, or any other vessel of the central circulatory system. The central circulatory system consists of the following vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens up bifurcatio aortae, arteriae coronorae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteria cerebral, truncus brachiocephalicus, venae cordis, venae pulmonales, superior vena Cava, vena Cava inferior.
- The presence of infection, bacteraemia, or septicemia is known or suspected
- Burned area
- The patient’s body size is insufficient to accommodate the size of the implanted port or catheter
- The patient is known or is suspected to have, an allergic reaction to the materials
- Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site
- Local tissue factors will prevent proper device stabilization and/or access
- Fast irradiation of prospective insertion site, cutaneous metastases
- Severe chronic obstructive lung disease exists

**PRECAUTIONS:**
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and application local, state and federal laws and regulations.
- Hold thumb over exposed opening of sheath to prevent air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
- Avoid vessel perforation.

- **FB Medical access ports are intended for use in venous or arterial circulation: internal and external jugular, subclavian, brachial, cephalic veins, axillary or hepatic artery. They are not intended to be used in epidural or intrathecal.**
- **All FB Medical access systems ports are supplied in double sterile packages. Examine the package carefully prior to opening to confirm sterility. If package is opened or damaged do not use the device.**

**Pinch-off prevention:** Catheters placed percutaneously or through a cut down, into the subclavian vein, should be inserted at the junction of the outer and middle thirds of the clavicle, lateral to the thoracic outlet. The catheter should not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and the clavicle, which can cause damage and even severance of the catheter. A radiographic confirmation of catheter placement should be made to ensure that the catheter is not being pinched by the first rib and clavicle.

**Pinch-off prevention:**

- **Signs of pinch-off:**
  - **Clinical:**
    - Difficulty with blood withdrawal
    - Resistance to infusion of fluids
    - Patient position changes required for infusion of fluids or blood withdrawal
  - **Radiologic:**
    - Grade 1 or 2 distortion on chest X-ray.
    - Pinch-off should be evaluated for degree of severity prior to explanation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently. There are grades of pinch-off that should be recognized with appropriate chest X-ray as follows:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Severity</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No distortion</td>
<td>No action</td>
</tr>
<tr>
<td>1</td>
<td>Distortion present without luminal narrowing</td>
<td>Chest X-ray should be taken every one to three months to monitor progression of pinch off to grade 2 distortions. Shoulder positioning during chest X-ray should be noted as it can contribute to changes in distortion grades.</td>
</tr>
<tr>
<td>2</td>
<td>Distortion present with luminal narrowing</td>
<td>Removal of the catheter should be considered.</td>
</tr>
<tr>
<td>3</td>
<td>Catheter transaction or fracture</td>
<td>Prompt removal of the catheter.</td>
</tr>
</tbody>
</table>
CAUTION:
- Only qualified persons should implant, manipulate and remove these devices.
- When utilizing the Arm Placement via Brachial/Basilic approach, the port should not be placed in the axillary cavity.
- Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.
- If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to help prevent the needle from damaging or shearing the guidewire.
- Prior to advancing the catheter lock, ensure that the catheter is properly positioned. A catheter not advanced to the proper region may not seat securely and lead to dislodgment and extravasation. The catheter must be straight with no sign of kinking. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter.

Precautions:
- Follow universal precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, notes, precautions and instructions for all infusates as specified by their manufacturers.
- Precautions are intended to help avoid catheter damage and/or patient injury.

Prior to placement:
- Inspect kit or presence of all components
- Fill the device with sterile heparinised saline or normal saline solution to help avoid air embolism.
- When using an introducer kit, verify that the catheter fits easily through the introducer sheath.

During placement:
- Do not allow accidental device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.
- Do not perforate, tear or fracture the catheter when using a guide wire.
- Do not use the catheter if there is any evidence of mechanical damage or leaking.
- Do not bend catheter at sharp angles during implantation. This can compromise catheter patency.
- Carefully follow the connection given in these instructions to ensure proper catheter connection and to avoid catheter damage.
- Do not occlude or cut catheter when using sutures to secure catheter.
- When using peel-away introducers:
  - Carefully insert the introducer and catheter to avoid inadvertent penetration to vital structures in the thorax.
  - Avoid blood vessel damage by maintaining a catheter or dilator as internal support when using a peel-away introducer.
  - Avoid sheath damage by simultaneously advancing the sheath and dilator as a single unit using a rotational motion.

After placement:
- Do not use the device if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism and surgical removal.
- Accessories and components with Luer Lock connections should be used with this device.
- If signs of extravasations exist, discontinue injections. Begin appropriate medical intervention immediately.
- DO NOT USE A SYRINGE SMALLER THAN 10CC! Infusion pressure greater than 25 psi (172kPa) may damage blood vessels and viscus and is not recommended.
- Use only Huber needles with the port.
- Choose a needle length based on reservoir depth, tissues thickness, and the thickness of any dressing beneath the bend of the needle. Too short a needle will compress the tissue and bandage which may cause the needle to back out of the reservoir. Too long a needle may create a lever action which can cause needle instability.
- Confirm correct positioning of the needle within the port reservoir by aspiration of blood before infusion of any substance. If there is doubt regarding proper needle placement, perform a radiographic dye procedure to confirm placement.
- Do not reuse Huber needle. Tip deformation may tear or damage the port septum.

IMPLANTATION INSTRUCTIONS:
The following suggestions for surgical insertion are provided as an aid to facilitate safe and prolonged use of the titanium port. Since the reservoir body may be placed in a number of areas of the body and the catheter in a variety of vessels, use the surgical procedure and the sterile technique which best suits your experience and needs and is appropriate for the patient.

IMPLANTATION PREPARATION:
1. Select implantation procedure to be used (upper arm, cut down or percutaneous).
2. Select the site for port placement.
3. Inspect kit or presence of all components
4. Fill the device with sterile heparinised saline or normal saline solution to help avoid air embolism.
5. Carefully follow the connection given in these instructions to ensure proper catheter connection and to avoid catheter damage.
6. Do not occlude or cut catheter when using sutures to secure catheter.
7. Carefully insert the introducer and catheter to avoid inadvertent penetration to vital structures in the thorax.
8. Avoid blood vessel damage by maintaining a catheter or dilator as internal support when using a peel-away introducer.
9. Avoid sheath damage by simultaneously advancing the sheath and dilator as a single unit using a rotational motion.

Note:
- The port site should be distal to the vein insertion site in upper arm placements.
- The infraclavicular fossa is a satisfactory site, but the actual site will vary based on individual patient factors. Port pocket site selection should allow for port placement in an anatomic area that provides good port stability, does not interfere with patient mobility (if arm placement, consider arm and elbow movement), does not create pressure points, and does not interfere with clothing. Consider the amount of cutaneous tissue over the port septum as excessive tissue will make access difficult. Conversely, too thin a tissue layer may lead to port erosion. A tissue thickness of 0.5 cm to 2 cm is appropriate.
- Perform adequate anaesthesia.
- Create sterile field and open tray.
- Surgically prep and drape the implantation site.
- Using flush connector, flush catheter with heparinized saline and clamp the catheter closed several centimetres from the distal (port) end.
- Clamp catheter segments that will be cut off prior to attachment. Tunnel catheter from the pocket to the venous entry site.

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INSTRUCTION FOR USE

CUT-DOWN PROCEDURE:
1. Place patient in the Trendelenburg position with head turned away from the intended venipuncture site. Use a cut-down incision to expose the entry vein of choice.
2. Perform vessel incision after vessel is isolated and stabilized to prevent bleeding and air aspiration.
3. Insert the tapered end of the vein lifter through the incision and advance it into the vessel.
4. With the vein lifter in position, slide the catheter tip into the grooved underside of pick and advance the catheter tip into the vessel.
5. Withdraw the vein lifter.
6. Advance the catheter into the vessel to the desired infusion site.

Note: Catheters must not be positioned in the central circulatory system. Verify correct catheter tip position, using fluoroscopy, or appropriate technology. Do not occlude or cut catheter when using sutures to secure catheter.

PERCUTANEOUS PROCEDURE,
1. Place patient in the Trendelenburg position with head turned away from the intended venipuncture site.
2. Locate desired vessel using a small gauge needle attached to a syringe. Note: The subclavian vein is entered percutaneously at the point that identifies the junction of the outer and middle thirds of the clavicle. Refer to the “warnings” section covering catheter Pinch-off.
3. Attach introducer needle to the syringe and insert into vessel alongside the small gauge needle. Remove small gauge needle.
4. Aspirate gently as the insertion is made. If the artery is entered, withdraw the needle and apply manual pressure for several minutes. If the pleural space is entered, withdraw the needle and evaluate patient for possible pneumothorax.
5. When the subclavian vein has been entered, remove the syringe leaving the needle in place. Place a finger over the hub of the needle to minimize blood loss and the risk of air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
6. Straighten “J” tip of guidewire with tip straightener and insert tapered end of tip straightener into the needle.
7. Remove the tip straightener and advance the guidewire as far as appropriate for the procedure. Verify correct positioning, using fluoroscopy, or appropriate technology.
8. Gently withdraw and remove needle. Caution: If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to help prevent the needle from damaging or shearing the guidewire.
9. Make a small (approx. 1 cm wide) incision parallel to the clavicle with the guidewire at the center of the incision to permit introduction of vessel dilator and sheath introduction of vessel dilator and sheath introducer.
10. Advance the vessel dilator and sheath introducer as a unit over the exposed wire using a rotational motion. Advance it into the vein as unit, leaving at least 2 cm of sheath exposed. Warning: Avoid vessel perforation

NOTE: to avoid damaging the sheath tip, it must not let the sheath advance over the vessel dilator. The sheath and dilator must be grasped as one unit. If the incision is too small, enlarge it.
11. Release the locking mechanism and gently withdraw the vessel dilator and “J” wire, leaving the sheath in place.
12. Warning: Hold thumb over exposed opening of sheath to prevent air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva manoeuvre.
13. Insert catheter into the sheath. Advance the catheter through the sheath into the vessel to the desired infusion site. Catheters should be positioned with the catheter tip at the junction of the superior vena cava and the right atrium.
INSTRUCTION FOR USE

ACCESS PORT

14. Verify correct catheter tip position using fluoroscopy, or appropriate technology.

15. Grasp the two handles of the peel-away sheath and pull outward and upward at the same time.

16. Peel the sheath away from the catheter completely. Make sure the catheter is not dislodged from vessel.

CATHETER TUNNELLING PROCEDURE:

1. Create a subcutaneous pocket using blunt dissection.
   - Note: Do a trial placement to verify that the pocket is large enough to accommodate the port and that the port does not lie beneath the incision.

2. Create a subcutaneous tunnel from the venous site to the port pocket site using tunneler or long forceps per the following:
   a. Make a small incision at the venous entry site.
   b. Insert tip of tunneler into the small incision.
   c. Form tunnel by advancing tip of tunneler from the venous entry site to the port pocket site.
      - Caution: Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.
   d. Remove catheter lock from the catheter.
   e. Attach end of catheter onto the tunneler barb with a twisting motion. Note: Barb threads must be completely covered by the catheter to adequately secure the catheter as it is pulled through the tunnel. A suture may be tied around the catheter between the tunneler body and the large barb to hold it more securely.
   f. Pull the tunneler through to the port pocket site while gently holding the catheter.
      - Note: The catheter must not be forced.
   g. Place catheter lock back onto catheter.
   h. Cut the catheter to the proper length at a 90° angle, allowing sufficient slack for body movement and port connection.

Connect catheter to port:

1. Flush all air from the port using a 10ml syringe with a Huber needle filled with heparinised saline (100 USP U/ml). Insert the Huber needle through the septum and inject the fluid while pointing the port stem upward.

2. Cleanse all system components with irrigation solution.

3. Connect catheter to port

   - Caution: Prior to advancing the catheter lock, ensure that the catheter is properly positioned. The catheter must be straight with no sign of kinking. A catheter not advanced to the proper region may not seat securely and lead to dislodgement and extravasation. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter.

   1. Align Port cannula with catheter lumen

   2. Advance Catheter to this region (about 1-2 mm)

   WARNING: For plastic port, be careful not to force laterally on the cannula as it may cause damage. Advancing catheter and ring in a straight line.

   3. Advance catheter lock:
      - For titanium port, finish locking by screwing the ring until it touch the port.
      - For plastic port, advance catheter lock until it touch the port

   NOTE: If the catheter and lock are connected and then disconnected, the catheter end must be re-trimmed to ensure a secure re-connection.

   - Place the port in the subcutaneous pocket away from the incision line and secure to underlying fascia using one non-absorbable, monofilament suture per suture hole. This will reduce the risk of port migration and the possibility of it flipping over. Leave sufficient slack in the catheter to permit slight movement, and verify that the catheter is not kinked.

   - After suturing the port in the pocket, flush the wound with an appropriate antibiotic solution.

   - Conduct flow studies on the catheter using a Huber needle and 10ml syringe to confirm that the flow is not obstructed, that no leak exists and that the catheter is correctly positioned.

   - Flush and heparin lock the port system as described under heparin lock procedure.

   - Close the incision site, so that the port does not lie beneath the incision.

   - Apply dressing according to hospital practice.

Implantation of Arterial Port

The common hepatic artery is the most common location for intra-arterial catheter placement, with the port body placed on either side of the lower rib cage. Other sites may be used depending on the organ targeted for drug delivery. It may be necessary to determine the catheter insertion site by direct visualization due to variations in patient anatomy.

1. Clamp gastroduodenal artery on either side of chosen entry site.
2. Trim catheter to necessary length ensuring that at least two suture beads are left on catheter.
3. Insert catheter into artery through small arteriotomy. Beaded catheter is advanced up to, but not into, lumen of common hepatic artery.
4. One fixation suture is placed around artery just behind bead at catheter tip; another suture is placed around second bead just outside arteriotomy.
5. Follow guidelines for port pocket formation as outlined previously.
**Implantation of Peritoneal Port**

1. Follow the guidelines for port body placement as outlined previously. The peritoneal catheter is tunneled to 3-5 cm below the umbilicus. This area is preferred due to its relative avascularity and reduced fascia resistance.
2. Make a 3-4 cm midline vertical incision. Incise fascia. Identify and separate subcutaneous tissue and pre-peritoneal fat. Grasp peritoneum with hemostat or forceps. Elevate and carefully incise under direct vision.
3. Insert index finger into peritoneal incision to check for adhesions.
4. Insert catheter into selected area, usually pelvic gutter region. Place purse-string suture around catheter to prevent leakage though not too tight as to occlude catheter. Once placement is accomplished, cuffed portion of catheter can be sutured into place above or at level of peritoneal incision.

**Caution:** To avoid injection into subcutaneous tissue, ensure that all catheter holes remain within the peritoneal cavity.

5. Attach an anti-coring needle to a 50 ml syringe filled with saline. Flush system with saline solution and immediately aspirate to confirm that flow is not obstructed and that no leaks exist.
6. Attach an anti-coring needle to a 10 ml syringe of normal saline. Penetrate septum and flush system.

**USE AND MAINTENANCE INSTRUCTIONS**

**Site preparation**

Always inspect and aseptically prepare the injection site prior to accessing the port.

**Equipment:**
- Alcohol wipe
- Antiseptic swabs (3)
- Sterile gloves

**Procedure:**
1. Explain procedure to patient. Warn of needle prick sensation. (Sensation of needle insertion decreases over time. Use of a topical anaesthetic may be appropriate.)
2. Wash hands thoroughly
3. Put on sterile gloves
4. Paint area with alcohol wipe starting at the port and working outward in a spiral motion over an area 4-5 inches in diameter.
5. Repeat step 4 with antiseptic swabs three times

**Accessing FB Medical implanted ports**

**Equipment:**
- Huber needle
- Syringe, 10 ml or larger

**Procedure:**
1. Perform aseptic site preparation
2. Utilizing a sterile glove hand, locate septum by palpation.
   a. Locate base of port with non-dominant hand.
   b. Triangulate port between thumb and first two fingers of non-dominant hand. Aim for center point of these three fingers.
3. Insert needle perpendicular to port septum. Advance needle through the skin and septum until reaching bottom of reservoir.
4. Verify correct needle placement by fluid aspiration.
5. Always flush the port following injection.
6. Perform heparin lock procedure or positive pressure

**Note:** it is recommended that the dressing and infusion components be changed every 24-48 hours during infusion therapy.

**Caution:** check with concerned laboratory the compatibility with drugs or substances which could come into contact with the access port and its catheter

**Bolus injection procedure**

**Equipment:**
- Huber needle
- 10 ml Syringe filled with sterile normal saline
- Extension set with clamp

**Procedure:**
1. Explain procedure to patient and prepare injection site.
2. Attach Huber needle to extension set and 10 ml syringe filled with sterile normal saline. Expel all air and clamp extension.
3. Aseptically locate an access port.
4. Flush port with 10 ml sterile normal saline. Clamp the extension set and remove the syringe.
5. Connect syringe containing the drug to extension set. Release clamp and administer injection.
6. Examine the injection site for signs of extravasation; if noted, immediately discontinue the injection and initiate appropriate intervention.
7. When the injection is completed, clamp the extension set.
8. Flush after each injection with 10ml of sterile normal saline to help prevent interaction between incompatible drugs.
9. Perform heparin lock procedure or positive pressure

**NOTE:** The needle hub should not be left open to air while it is in the port. Do not manipulate the needle once it is in the septum.
INSTRUCTION FOR USE

ACCESS PORT

Continuous Infusion procedure

Equipment:
- Prescribed I.V. solution
- Extension set with clamp
- 10 ml syringe filled with sterile normal saline
- Huber needle
- I.V. pole & I.V. pump (if ordered)
- Transparent dressing
- Antibacterial ointment
- 2 in. x 2 in. gauze pads

Procedure:
1. Explain procedure to patient and prepare injection site.
2. Attach Huber needle to extension set and 10 ml syringe filled with sterile normal saline. Expel all air and clamp the extension set.
3. Aseptically locate and access port.
4. Apply antibacterial ointment to injection site and place a rolled gauze pad under needle hub. Secure needle with transparent dressing to help prevent inadvertent dislodgement.
5. Open clamp and flush port with sterile normal saline. Clamp extension set and remove syringe.
6. Connect fluid delivery system (I.V. set or infusion pump as indicated).
7. Release clamp and initiate infusion. Examine the infusion site for signs of extravasation; if noted, or if patient experiences pain, immediately discontinue infusion and initiate appropriate intervention.
8. When infusion is completed, clamp extension set and then remove the fluid delivery system.
9. Flush after each infusion with 10 ml sterile normal saline to help prevent interaction between incompatible drugs.
10. Perform heparin lock procedure or positive pressure.

Blood sampling procedure:

Equipment:
- Huber needle
- 10 ml syringe filled with sterile normal saline
- Extension set with clamp
- Sterile normal saline

Procedure:
1. Explain procedure to patient and prepare injection site.
2. Attach a 10ml syringe filled with sterile heparinised saline to needle.
3. Aseptically locate and access port.
4. Flush the system.

Heparin lock procedure

To help prevent clot formation and catheter blockage, implanted ports with catheters should be filled with sterile heparinised saline after each use. If the port remains unused for long time, the heparin lock should be changed at least once every four weeks.

Recommended flushing volumes:

<table>
<thead>
<tr>
<th>PROCEDURE VOLUME</th>
<th>FLUSHING VOLUMES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Port not in use</td>
<td>5 cc heparinized saline</td>
</tr>
<tr>
<td>After each infusion of medication</td>
<td>10 cc sterile normal saline Then 5 cc heparinized saline</td>
</tr>
<tr>
<td>After blood withdrawal</td>
<td>20 cc sterile normal saline Then 5 cc heparinized saline</td>
</tr>
</tbody>
</table>

Equipment:
- Huber needle
- 10 ml syringe filled with sterile heparinised saline (10 to 1000 U/ml) *

*NOTE: Other concentrations of heparinised saline (10 to 1000 U/ml) have been found to be effective. Determination of proper concentration and volume should be based on patient’s medical condition, laboratory tests, and prior experience.

Procedure:
1. Explain procedure to patient and prepare injection site.
2. Attach a 10ml syringe filled with sterile heparinised saline to needle.
3. Aseptically locate and access port.
4. Flush the system.

De-accessing FB Medical implanted ports – positive pressure

To reduce potential for backflow into the catheter tip and possible catheter clotting, always remove a Huber needle slowly, while injecting the last 0.5ml of solution. Stabilize the port with two fingers during needle withdrawal.

FLUSHING VOLUMES

- Port not in use: 5 cc heparinized saline
- After each infusion: 10 cc sterile normal saline
- After blood withdrawal: 20 cc sterile normal saline

Equipment:
- Huber needle
- 10 ml syringe filled with sterile heparinised saline

*NOTE: Other concentrations of heparinised saline (10 to 1000 U/ml) have been found to be effective.

Determination of proper concentration and volume should be based on patient’s medical condition, laboratory tests, and prior experience.

Procedure:
1. Explain procedure to patient and prepare injection site.
2. Attach a 10ml syringe filled with sterile heparinised saline to needle.
3. Aseptically locate and access port.
4. Flush the system.
Use of fibrinolytic agent for catheter obstruction

Use a fibrinolytic agent such as urokinase may clear obstructed catheters when gentle irrigation and aspiration have failed. The following procedure may be employed on the order of a physician. Additional instructions provided by the drug manufacturer should be followed.

Equipment:
- Huber needle
- 10 ml syringe containing port priming volume of a fibrinolytic agent
- 20 ml syringe filled with sterile normal saline.

Procedure:
1. Explain procedure to patient and prepare the injection site.
2. Aseptically locate and access the desired septum with needle attached to 10 ml syringe, void of air and filled with port priming volume of fibrinolytic agent.
3. Gently instil urokinase solution. Use a gentle pull-push action on the syringe plunger to maximise solution mixing within port and catheter.

**WARNING:** Occluded catheters may not accept all of the solution. If strong resistance is felt, do not attempt to force into catheter.

4. Leave solution in place for 15 minutes.
5. Attempt to aspirate urokinase and clots.
6. If the clots cannot be aspirated, repeat procedure.
7. Once the blockage has been cleared, flush catheter with at least 20 ml of sterile normal saline.
8. Perform heparin lock procedure.

Single use Medical Device

FB Medical systems products are single use devices and should never be reimplanted or resterilized. Reuse carries with it the attendant concern a cross infection regardless of the cleaning or sterilization method. Resterilization of incompletely cleaned devices may not be effective. **Any device that has been contaminated by blood should not be reused or resterilized.**

Possible complications

The use of a subcutaneous port provides an important means of venous access for critically ill patients. However, the potential exists for serious complications, including the following:

- Air embolism
- Bleeding
- Brachial plexus injury
- Cardiac arrhythmia
- Catheter or port erosion through the skin
- Catheter embolism
- Catheter or port occlusion
- Catheter or port-related sepsis
- Catheter damage or breakage due to compression between the clavicle and first rib
- Catheter tamponade
- Device rotation or extrusion
- Endocarditis
- Extravasation
- Fibrin sheath formation
- Hematoma
- Hematorax
- Hydrothorax
- Intolerance reaction to implanted device
- Inflammation, necrosis, or scarring of skin over implant area
- Laceration of vessels or visscus
- Perforation of vessels or visscus
- Thoracic duct injury
- Risks normally associated with local and general anesthesia, surgery and post-operative recovery
- Spontaneous catheter Tip malposition or retraction
- Vascular thrombosis
- Vessel erosion

These and other complications are well documented in medical literature and should be carefully considered before placing the port. Placement and care of the implanted port should be performed by persons knowledgeable of the risks involved and qualified in the procedures.
N'utilisez que des aiguilles à points de Huber
Use only Huber needles

Ne pas utiliser de seringues de moins de 10 ml
Don't use syringe under 10 ml

Apporter et faites remplir ce carnet lors de chaque injection dans la chambre
Provide and make completing this book at each injection in the port

A L’ATTENTION DU MEDECIN OU DE L’INFIRMIERE
TO THE DOCTOR OR NURSE

Les chambres implantables ISO Med permettent les injections médicamenteuses, de fluides, y compris de grosses molécules, la transfusion de sang et dérivés, la nutrition parentérale (cathéters veineux), les prélèvements sanguins.
ISO Med’s access ports allow medications injections fluids, including large molecules, the transfusion of blood products, parenteral nutrition (venous catheter), blood samples.

Procédure / Procedure:
1. Aseptiser le site / Perform aseptic site preparation
2. Localiser la base de la chambre avec la main non dominante.
3. Maintenir la chambre entre le pouce, l’index et le majeur de la main non dominante.
4. Trianguler l’aiguille perpendiculairement au septum de la chambre.
5. Avancer l’aiguille au travers de la peau et du septum jusqu’à ce qu’elle bute contre le fond de la chambre.
6. Insérer l’aiguille perpendiculaire au septum de la chambre.
7. Avancer l’aiguille au travers de la peau jusqu’à ce qu’elle Bute contre le fund de la chambre.
8. En cas d’obstruction, en cas d’injection de produit excessif, en cas de remplacement du cathéter, ou en cas de lésion du septum ou de blessure de la peau, ou en cas de pansement, il est recommandé de retirer l’aiguille tout d’abord et de changer le cathéter, ou de changer l’ensemble du système de protection des tissus, ou de changement du pansement.

Volumes de rinçage recommandés / Recommended flushing volumes:

<table>
<thead>
<tr>
<th>Volumes de rinçage</th>
<th>Fluide recommandé</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 ml de sérum physiologique</td>
<td>Saladage du cathéter</td>
</tr>
<tr>
<td>5 ml d’héparine</td>
<td>Saladage du cathéter</td>
</tr>
<tr>
<td>10 ml de sérum physiologique</td>
<td>Saladage du cathéter après l’examen des suites de l’ouverture du port</td>
</tr>
<tr>
<td>20 ml de sérum physiologique</td>
<td>Saladage du cathéter après l’examen des suites de l’ouverture du port</td>
</tr>
</tbody>
</table>

Clôture de l’accès à une chambre implantée – pression positive
De-accessing an implanted port – positive pressure

Pour réduire le risque de reflux sanguin dans l’extrémité du cathéter et la formation d’un caillot dans le cathéter, il est préférable de retirer l’aiguille de Huber lentement tout en injectant 0.5ml de solution. Stabiliser la chambre avec deux doigts pendant le retrait de l’aiguille.

Note: Durant le traitement, il est recommandé de changer les pansements et composants d’injection toutes les 24-48 heures.
Note: it is recommended that the dressing and infusion components be changed every 24-48 hours during infusion therapy.
CONTRE INDICATIONS:
Certains solvants organiques ont été identifiés comme étant incompatibles à haute concentration :
- Diméthyl –Sulfoxide
- Amines aromatiques
- Dichlorométhane
- Chloroforme
- Phénol 5%

CONTRAINDICATIONS:
Some organic solvents were identified as being incompatible with a high concentration:
- Dimethyl –Sulfoxide
- Amines aromatiques
- Dichlorométhane
- Chloroforme
- Phenol 5%
ISO Med a mis au point sous la marque FB Medical une technologie qui permet de réaliser une injection ou une perfusion grâce à une simple ponction sous-cutanée.

Cette technique simple et fiable vous évitera des ponctions veineuses douloureuses et difficiles, et apportera une nette amélioration de votre confort tout en continuant vos traitements, aussi fréquents soient-ils.

Ce dispositif appelé «chambre à cathéter implantable» est réalisé en titane ou POM. Extrêmement léger, il vous permettra de mener une vie normale.

La chambre est mise en place au cours d'une petite intervention chirurgicale.

Votre chirurgien et votre infirmière vous expliqueront et vous informeront du lieu d'implantation choisi.

Vous aurez donc une petite cicatrice (3 à 4 cm) fermée par des points de suture. Ces fils seront enlevés selon les indications de votre chirurgien, (généralement vers le 7ème jour).

Les jours suivant l'implantation, l'infirmière, pour l'entretien du site, effectuera des rinçages quotidiens.

Nous vous recommandons de bien vouloir observer ses gestes et sa technique, cela vous aidera éventuellement à seconder votre infirmière à domicile.

**CHAQUE JOUR :**
- VÉRIFIER LA ZONE D'IMPLANTATION
- DÉPISTER TOUTE ROUGEUR OU INFLAMMATION LOCALE
- DÉPISTER TOUTE ZONE DOULOUREUSE À LA PALPATION

**EN CAS DE PROBLÈME :**
- CONSULTER IMMÉDIATEMENT LE SERVICE QUI VOUS SOIGNE !!!
- APRÈS LA TOILETTE, SÉCHER SOIGNEUSEMENT LA PEAU ET PRATIQUER UNE DÉSINFECTION LOCALE.

Ces quelques précautions vous permettrons de poursuivre votre traitement avec un maximum de confort, d'efficacité et sécurité.