Instructions for Use
Reprocessed BRK and BRK-1 Transseptal Needle

Reprocessed Device for Single Use

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

DEVICE DESCRIPTION

The reprocessed BRK Transseptal Needle consists of a luminal stainless steel needle and solid stainless steel stylet. The distal section of the needle is curved to facilitate positioning within the heart when used with a St. Jude Medical transseptal introducer set. Within this curved section, there is an abrupt step down in the outer diameter of the needle to mate with the internal diameter of the dilator of a St. Jude Medical transseptal introducer set. The distal tip of the needle is beveled to facilitate the puncture process. The proximal end of the needle is configured with a pointer flange (indicating distal curve orientation) and is fitted with a 2-way stopcock to provide needle lumen access for aspiration, fluid injection/infusion, blood sampling, pressure monitoring, and stylet and/or guidewire insertion (0.014" maximum guidewire diameter for an 18 gauge needle). The stylet is straight and isodiametric throughout its length. The proximal end of the stylet is fitted with a curved clip to lock onto the proximal needle hub when inserted into the needle lumen. The stylet is designed to facilitate needle advancement within the dilator. The reprocessed needle is available in various useable lengths and distal curve configurations.

INDICATIONS FOR USE

The Reprocessed BRK Transseptal Needle is used to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access.

CONTRAINDICATIONS

- Previous interatrial septal patch or prosthetic atrial septal defect closure device.
- Any previous thromboembolic event.
- Known or suspected atrial myxoma.
- Known or suspected myocardial infarction within the last two weeks.
- Unstable angina.
- Recent Cerebral Vascular Accident (CVA)
- Patients who do not tolerate anticoagulation therapy.
- Patients with an active infection.

WARNINGS

- Do not alter this device in any way.
- Tactile feedback of reprocessed device may vary during use.

PRECAUTIONS

Special Patient Populations

Prior to the procedure, the patient must be hemodynamically stable. Certain conditions may require special consideration when using this product. These may include, but are not limited to:

- Rotated Heart
- Enlargement aortic root
- Marked right atrial enlargement
- Scoliosis/kyphosis
- Abnormal Left atrial geometry
- Congenital malformations
- Vascular malformations
- Inability to access the right atrium through the inferior vena cava

DIRECTIONS

The package label is detachable and may be affixed to the medical record of the patient.

Procedural Considerations

- Inspect the device and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the device is damaged or if the package is compromised, do not use the device. Return the device to Innovative Health. **Do not attempt to resterilize**.
- Carefully reading the Instructions before use of this device will help to reduce the potential dangers associated with the transseptal catheterization technique such as embolism or cardiovascular perforation.
- Only those physicians who are specially trained in transseptal procedures should use this device.
- Fluoroscopy should be used to confirm positioning throughout the procedure.
- Transseptal procedures should be performed only in facilities appropriately equipped and staffed to perform such procedures. Lab capabilities should include, but are not limited to:
    - Intracardiac pressure monitoring capabilities;
    - Systemic pressure monitoring;
    - Contrast media injection, and management of untoward reactions to contrast media;
    - Pericardiocentesis;
    - Surgical backup;
    - Anticoagulation therapy and monitoring
- Maintain monitoring of vital signs throughout the procedure.
- Inspect all components before use.
- Prior to inserting the device into the patient, pre-assemble sheath and dilator, advance the needle/stylet assembly through the dilator to check for excessive resistance as the tip of the needle advances through the curvature of the sheath/dilator assembly.
- During insertion, use caution not to create excessive bends in this device. This may inhibit advancement of the needle and may result in inadvertent needle puncture of the dilator/sheath assembly.
- During insertion, always use the stylet to facilitate needle passage through the dilator/sheath assembly. (Failure to use the stylet may inhibit advancement of the needle and may result in inadvertent needle puncture of the dilator/sheath assembly or skiving of material from the inner surface of the dilator).

POTENTIAL COMPLICATIONS

Complications that may occur during the use of this device include, but are not limited to:

- Air embolism
- Cardiac perforation
- Cardiac tamponade
- Conduction system disturbances such as SA node, AV node or HIS-Purkinje system block
- Hematoma or excessive bleeding at the vascular access site
- Reaction to contrast medium
- Stroke
- Thromboembolism
- Valvular damage
- Cardiac arrythmias

DIRECTIONS FOR USE - Transseptal Procedure

Note: Typical variations may occur within these steps, depending on available capabilities and operator preference. These optional steps will be listed as "OPT", and details discussed.

1. **Prepare and assemble equipment**
    - Prepare the transseptal catheter introducer set
        - Preparing the transseptal catheter introducer set requires the following items:
            - One transseptal sheath and dilator
            - One length-matching BRK Transseptal Needle, with a stainless steel stylet
            - One 0.032", 150-180 cm guidewire with a 3 mm 'J' tip
            - Syringes for aspiration and flushing
            - Sterile heparinized saline
        - Flush the dilator and the transseptal sheath with sterile heparinized saline.
        - After flushing, position the stopcock on the sidearm of the transseptal sheath so that it is in the dosed to the sheath position.
        - Insert the dilator fully into the transseptal sheath.
    - Prepare the BRK Transseptal Needle
        - Remove the stylet from the BRK Transseptal Needle and flush the needle with sterile heparinized saline.
        - Re-insert the stylet into the BRK Transseptal Needle and lock it onto the hub.
        - Insert the BRK Transseptal Needle and stylet into the sheath/dilator.

      Note: due to the stop feature of the dilator, when fully engaged, there will be a gap between the dilator hub and the needle pointer flange. (See Figure 1.)

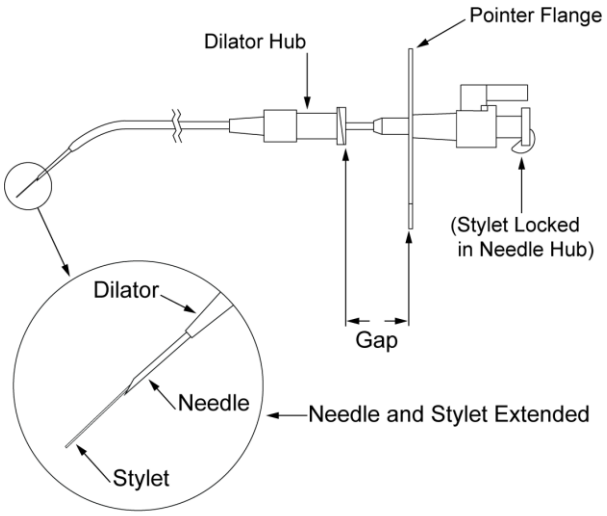


Figure 1

- Two measurements should be made:
  - Measurement 1. Withdraw the needle assembly until the tip of the stylet is just within the tip of the dilator. Measure the distance from the pointer flange and the dilator hub. Record this measurement for use during the procedure. (See Figure 2.)

Measurement 1

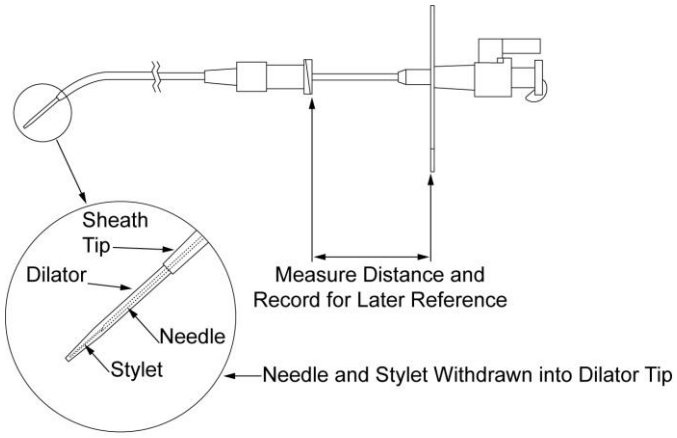


Figure 2

Measurement 2. Measure the distance between the pointer flange and the dilator hub with only the needle tip (without the stylet inserted) just inside the tip of the dilator. (See Figure 3)

Measurement 2

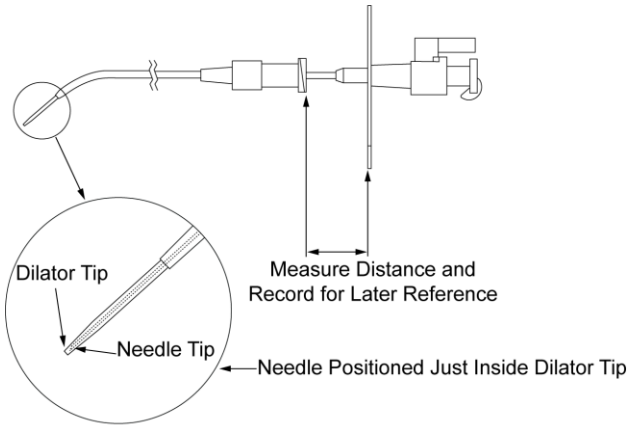


Figure 3

CAUTION: It is critical to maintain the distance between the pointer flange and the dilator hub during initial insertion into the sheath/dilator assembly. This ensures that the stylet does not extend beyond the dilator tip which could result in patient injury. Once the stylet is removed, it is critical to maintain the distance of the 2nd measurement to prevent patient injury with the needle tip until septal puncture Is desired.

- Remove the BRK Transseptal Needle from the dilator.
- Flush the needle again.
- Reinsert and lock the stylet.
- Flush the dilator again.

This completes the preparation.

2. **Advance sheath/dilator assembly into superior vena cava.**

   - Obtain femoral venous access (right femoral preferred). OPT: a larger *(≥ 2.5 French sizes greater than the transseptal introducer) standard length sheath may be used to obtain and maintain venous access for device exchange and hemostasis*.
   - Introduce a 0.032 inch, 150 -180 centimeter, 3 mm “J” tip guidewire into the superior vena cava (SVC).

     NOTE: 0.032" is the maximum guidewire diameter that can be used with the transseptal dilator.
   - Insert the transseptal sheath and dilator assembly into the vein over the guidewire and advance the assembly until the sheath tip is in the SVC. Orient the dilator tip medially.

3. **Position the BRK transseptal needle and stylet assembly inside the sheath/dilator assembly.**
   - Remove the guidewire from the dilator.
   - Fully aspirate and then flush the dilator with clean heparinized saline, ensuring that no air enters the bloodstream.

- Separate the sheath and dilator by withdrawing the dilator a distance sufficient to accommodate the needle curve. (See Figure 4) This will facilitate passage of the BRK Transseptal Needle curve through the rigid hubs of the dilator and sheath.

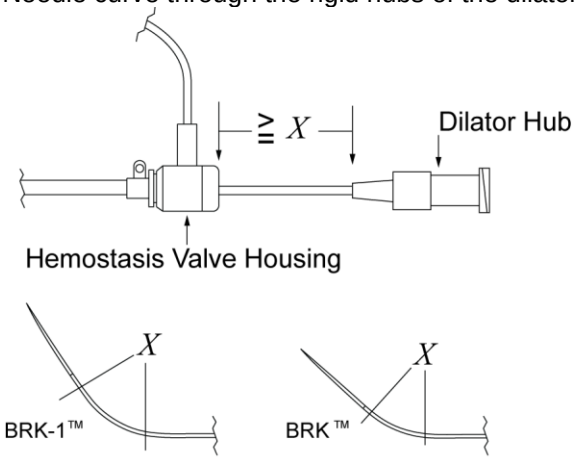


Figure 4

- Confirm that the stylet is locked onto the hub of the BRK Transseptal Needle.
- Insert the needle/stylet into the dilator, letting the needle rotate freely as it advances.
- After the needle curve is advanced beyond the hemostasis valve hub of the sheath, reconnect the sheath and dilator by sliding the sheath back over the dilator while maintaining the sheath tip position in the SVC (**Do Not** advance the dilator).
- Advance the needle and stylet until the pointer flange is the predetermined distance from the hub of the dilator (Measurement 1).
- Remove the stylet and set aside. (**Do Not** discard.)
- Turn the stopcock to the off position.
- With the stylet removed, advance the needle slightly until near the tip of the dilator (Measurement 2).
- Attach a syringe to the needle hub and aspirate until blood return is observed, then discard the syringe.
  NOTE: The use of a slip-lip (non-Luer-Lok) syringe may prevent aspirating air.
- Flush the needle with clean heparinized saline, ensuring that no air enters the bloodstream. Close the stopcock.
- OPT: Attach a 3-way rotating stopcock to the needle hub.
- OPT: Attach a syringe with radiopaque contrast media to the stopcock. Aspirate the BRK Transseptal Needle until blood return is observed. Then load the needle with the contrast media under fluoroscopic guidance.
- OPT: Connect a pressure monitoring line to the stopcock.
- OPT: Use a standard 3-port manifold setup to connect contrast, pressure and flush lines.

4. Engage the fossa ovalis.

- Visualize and identify anatomic landmarks.
  - Set the fluoroscopy unit to an appropriate angle parallel to the plane of the mitral valve and orthogonal to the plane of the septum. This will typically be approximately 30 to 40 degrees left anterior oblique (LAO).
- OPT: *During electrophysiology procedures, the coronary sinus and His bundle catheter positions can serve as useful anatomic landmarks. In the appropriate LAO view, the coronary sinus catheter will be seen in profile. In the appropriate right anterior oblique (RAO) view the His bundle catheter will appear in profile. The fossa ovalis is located at or*

slightly below the level of His bundle catheter and superior and posterior to the coronary sinus ostium.

- OPT: *Placing a pigtail angiographic/hemodynamic monitoring catheter in the non-coronary cusp of the aortic valve can serve as a useful anatomic landmark.*
- OPT: *Observe the pressure waveform being recorded through the BRK Transseptal Needle.*
- Adjust the pointer flange so that the needle is perpendicular to the fossa ovalis (typically between 3:00 and 5:00 o'clock, as viewed from the foot end of the patient). (See Figure 5.)

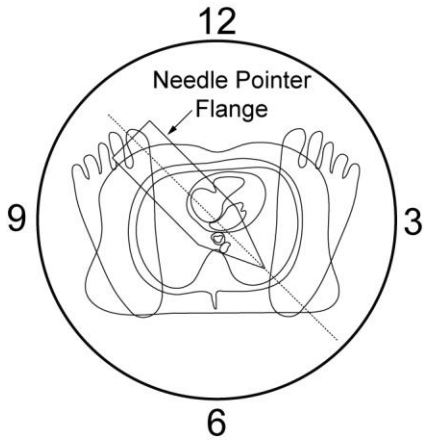


Figure 5

- Also, confirm that the needle tip is inside the dilator by fluoroscopy and by your previous measurements.
- After confirming that the tip of the needle is within the dilator, drag the entire sheath/dilator/needle assembly slowly. Prevent any movement of the assembly parts relative to each other. It is critical to maintain the previous orientation of the pointer flange while dragging assembly.
- In the LAO view (orthogonal to the interatrial septum) observe the tip of the dilator during the drag for abrupt medial (or rightward) movement, indicating the tip has engaged the fossa ovalis. (See Figures 6a, 6b. & 6c.)
  Note: If the fossa ovalis Is probe patent, the dilator tip will now move into the left atrium with ease.

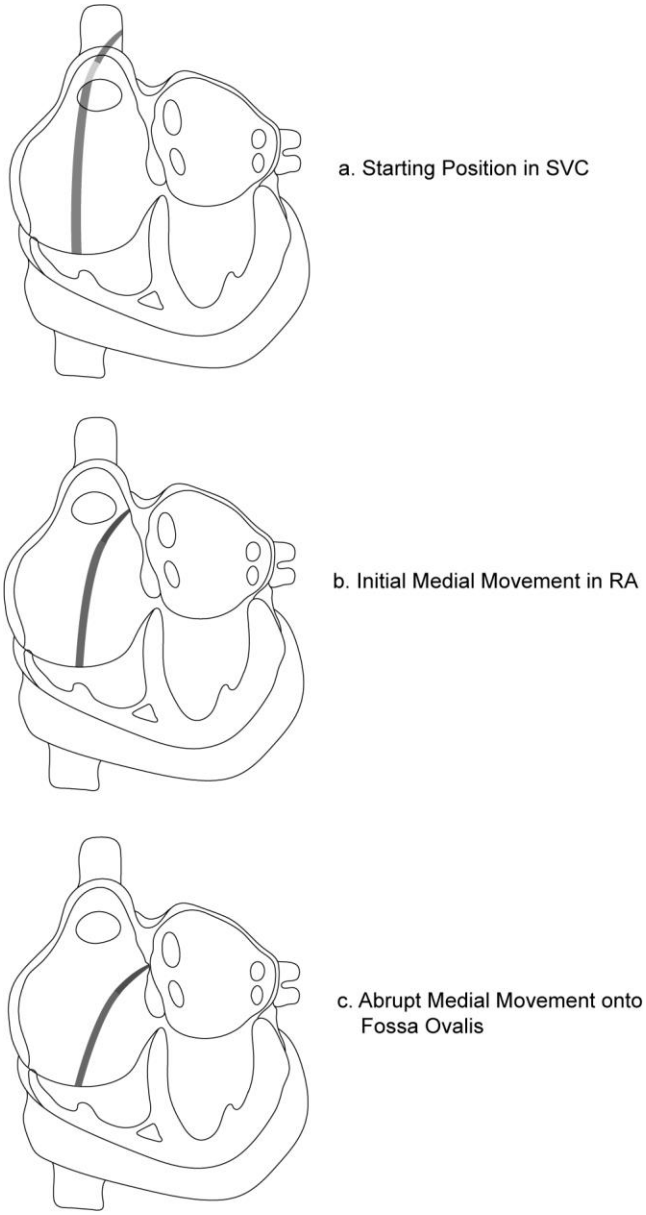


Figure 6

- OPT: *If pressure is being monitored through the needle, note that the pressure through the needle will not be accurate at this point, since the tip is against the fossa ovalis*.

5. Puncture the fossa ovalis with the BRK transseptal needle.

- Confirm the correct location of the sheath/dilator/needle assembly on the fossa ovalis before advancing the needle.
- Once the correct location is confirmed, extend the needle to full engagement within the sheath/dilator assembly and advance across the interatrial septum.
- OPT: *Under pressure monitoring, entry into the left atrium is confirmed when the pressure tracing shows a left atrial pressure waveform.*
- OPT: *Left atrial access can be confirmed via fluoroscopy with contrast injections.*

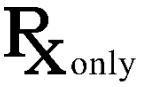
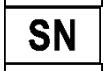
- If there is any resistance to needle advancement, retract the needle, re-evaluate the anatomic landmarks.
  CAUTION: If pericardial or aortic entry occurs, do not advance the dilator over the needle. If the needle has penetrated the pericardium or aorta, it must be withdrawn. Monitor vital signs closely.

6. **Advance the sheath/dilator assembly into the left atrium.**
   - While maintaining a fixed needle position within the left atrium, advance the sheath/dilator assembly fully over the needle into the left atrial cavity.

7. **Advance the sheath over the fixed dilator and needle into left atrium.**
   - Maintain the position of the needle and dilator across the septum.
   - While maintaining the dilator in a fixed location, advance the sheath fully over the dilator into the left atrial cavity.

8. **Withdraw the BRK transseptal needle and the dilator.**
   CAUTION: There is a risk of air infiltration when withdrawing objects from the hemostasis valve of the sheath. Take precautions to prevent air infiltration by withdrawing objects slowly to prevent vacuum buildup in the sheath and fluoroscopically monitor the sheath during ensuing device insertion for the presence of air.
   - Turn the needle stopcock to the off position and disconnect any attachments to the needle hub.
   - Remove the BRK Transseptal Needle from the dilator. The needle may be cleaned and set aside for repeat use in this procedure. Otherwise, discard by appropriate means for contaminated sharp objects.
   - Immediately attach a syringe to the dilator and aspirate. Continue aspirating blood while holding the sheath in position and withdrawing the dilator. The blood should be arterial blood.
   - Once the dilator is removed, aspirate blood through the side arm of the sheath, and then flush it with heparinized saline, taking care to avoid air bubbles.
   - The sheath is now in place in the left atrium.

EXPLANATION OF SYMBOLS

	Federal Law in the USA restricts this device to sale by or on the order of a physician
	Sterilized by Ethylene Oxide Gas
	Catalog Number
	Serial Number
	Lot Number
	Use by Date
	Do Not Reuse
	Do Not Resterilize
	Consult Instructions for Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight and Radioactive Sources
	Non-pyrogenic

As the reprocessor, Innovative Health is solely responsible for this device. All Original Manufacturer (OM) information is provided for device identification and may contain trademarks from third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with Ethylene Oxide (EO) gas. Even though the product is processed in compliance with all applicable laws and regulations relating to EO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with EO. The packaging may expose you to EO, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

Please refer to www.innovative-health.com for product warranty.