# SafeSept BN Blunt Needle™

**Pressure Products, Inc.**
Customer Service
1861 N. Gaffey Street, Suite B
San Pedro, CA 90731 - USA
Tel +1-310-547-4973
Fax +1-310-547-4760
www.pressure-products.com

**PPMDM**
1 School Street
Morton, PA 19070 - USA
Tel +1-610-285-9858
Fax +1-610-285-9859

Pressure Products
Accessing the Heart of Innovation



The SafeSept Blunt Needle™ is a blunt stainless steel transseptal extended cannula with a plastic handle and hub designed to provide support to a transseptal introducer when used with a Transseptal Guidewire during a transseptal procedure. The distal end of the SafeSept Blunt Needle™ is curved to assist in orienting the device within the heart.

The outer diameter of the SafeSept Blunt Needle™ is designed to mate with the inner diameter of a standard dilator and extend out of the distal tip.

The proximal end of the SafeSept Blunt Needle™ has a pointer hub to indicate the curve direction of the Blunt Needle, and a 2-way stopcock handle and luer lock connection for flushing or aspiration.

## INTENDED USE

The SafeSept Blunt Needle™ is used to support a transseptal introducer when used in conjunction with a transseptal guidewire to create the primary puncture in the interatrial septum.

## INDICATIONS FOR USE

The SafeSept Blunt Needle™ is used in conjunction with a transseptal guidewire to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access. The SafeSept Blunt Needle is intended for single use only.

## CONTRAINDICATIONS

The use of the SafeSept Blunt Needle is contra-indicated in patients with the following conditions.

- Distorted anatomy due to congenital heart disease or other causes
- Significant chest or spine deformity
- The inability to lie flat
- Left atrial thrombus or tumor
- Dilated aortic root
- Previous patch repair of the interatrial septum
- Known or suspected myocardial infarction within the last two weeks
- Unstable angina
- Recent Pulmonary emboli
- Recent cerebral vascular accident (CVA)
- Patients who cannot tolerate anticoagulation therapy
- Patients with an active infection

## WARNINGS AND PRECAUTIONS

Single-Use Only: Do not re-use this device. After use thorough cleaning of biological and foreign material is not possible. Adverse patient reactions may result from re-use of this device.

- Do not use the Blunt Needle as the primary puncture device without first puncturing the septum with a Transseptal Guidewire
- Store in a cool, dark, and dry place
- Prolonged exposure to temperatures above 30° C (86° F) may damage the product
- Do not use if package is open or damaged in any way

## ADVERSE EVENTS

In addition to all of the complications associated with any transseptal cardiac catheterization, the following can occur during the use of the SafeSept Blunt Needle:

- Puncture of the atrial free wall
- Puncture of the aorta
- Puncture of the inferior vena cava
- Puncture of the coronary sinus
- Tamponade
- Hemothorax
- Arterial embolism from thrombus at the puncture site
- Pulmonary embolism
- Stroke
- Death
- Atrial arrhythmias
- Residual atrial septal defects

## INSTRUCTIONS FOR USE

*Follow standard transseptal technique:*

1. Per standard technique, aspirate and flush the transseptal system (including the Blunt Needle, dilator and sheath) before and after it is inserted into the right atrium.
2. After flushing, position the stopcock handle of the Blunt Needle so that it is in the closed position.
3. Advance the transseptal dilator fully into the transseptal sheath.
4. Advance the transseptal dilator and sheath assembly over the introducer guidewire to obtain venous access.
5. Remove the introducer guidewire from the dilator.
6. Aspirate and flush the dilator and ensure no air enters into the bloodstream.
7. Retract the dilator to accommodate the Blunt Needle curve which will allow the Blunt Needle curve to pass through the dilator and sheath hubs.
8. Gently advance the SafeSept Blunt Needle into the transseptal dilator allowing the Blunt Needle hub to rotate as it is advanced so as to avoid skiving the inside wall of the dilator. **Caution is to be used when inserting in the Blunt Needle into the dilator to avoid skiving. If resistance is met, withdraw the Blunt Needle and aspirate the Blunt Needle and dilator. Re-insert the Blunt Needle.**
9. Remove the protective tip cover and back the Transseptal Guidewire slowly into the guidewire tip straightener. Do not pull the Transseptal Guidewire completely out of the tip straightener.
10. Fully insert the tip straightener into the hub of the Blunt Needle.
11. Advance the Transseptal Guidewire until the tip enters the curved portion of the Blunt Needle (Printed markers are provided as a guide for common commercially available needle systems. The Transseptal Guidewire can generally be advanced to the first printed marker when using a Blunt Needle without a Y-adapter. Do not advance the guidewire beyond the tip of the Blunt Needle).
12. Tent the fossa ovalis with the transseptal dilator. The Blunt Needle tip position should be less than 0.5cm back from the tip of the dilator.
13. Under visual guidance, while tenting and maintaining constant force on the septum with the dilator, slowly advance the Transseptal Guidewire through the Blunt Needle, dilator, and across the interatrial septum, into the left atrium. Continue to advance into one of the pulmonary veins (The radiopaque coil on the guidewire should be seen to be within the left atrium and subsequently the pulmonary vein). **At no time should the guidewire be advanced or withdrawn when resistance is met without first determining the cause visually and taking remedial action. Confirm proper location of the Transseptal Guidewire prior to proceeding.**
14. The Transseptal Guidewire should be advanced approximately 7cm into the left atrium so that the entire radiopaque coil is across the septum and visible to ensure that the Blunt Needle tip does not engage the radiopaque coil during advancement.
15. Slowly advance the Blunt Needle through the dilator and over the Transseptal Guidewire across the septum. **Do not attempt to puncture the septum with the Blunt Needle without first puncturing with a Transseptal Guidewire. Do not hold or pin the Transseptal Guidewire when advancing the Blunt Needle.** If desired, measure pressures and/or inject contrast through the Blunt Needle before advancing the dilator and introducer sheath. Once the Blunt Needle tip position is confirmed in the left atrium, advance the dilator and introducer sheath over the Blunt Needle and Transseptal Guidewire into the left atrium.
16. Slowly remove the Transseptal Guidewire, Blunt Needle, and dilator as a unit, leaving the introducer sheath in place. **Do not remove the Transseptal Guidewire first, leaving the Blunt Needle tip exposed inside the left atrium. At no time should the introducer, Blunt Needle, or guide wire be advanced or withdrawn when resistance is met without first determining the cause visually and taking remedial action.**
17. After use, the Blunt Needle and Transseptal Guidewire may be a potential biohazard. Handle and dispose of it in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

| | |
|---|---|
| REF | Model Number |
| LOT | Lot Number |
| | Use Before |
| | Quantity |
| | Inner Diameter |
| | Outer Diameter |
| | Curve |
| | Length |
| | Manufacturing Date |
| Rx ONLY | CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician. |
| | Consult technical manual! |
| | Do not use if packaging is damaged! |
| | Keep away from sunlight |
| | Keep dry |
| 5° C 30° C | Temperature limitation |
| STERILE EO | Sterilized with ethylene oxide |
| | Single use only. Do not reuse! |
| STERILIZE | Do not resterilize! |
| | Manufacturer |
| | Distributor |