translumina
LIMITLESS POSSIBILITIES

TRANS-INTRO

Femoral
INTRODUCER SHEATH
Set
Instructions for use

Manufacturing Facility

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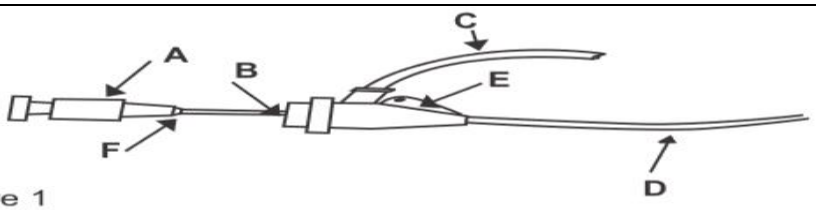

Figure 1

A. Vessel Dilator
B. Haemostasis Valve
C. Side port Extension
D. Cannula
E. Suture Collar
F. Snap-Fit Ring

PRODUCT DESCRIPTION

The 'TRANS-INTRO' is a Sheath Introducer System.

DEVICE COMPONENT DESCRIPTION

Introducer Sheath

An introducer sheath facilitates percutaneous entry of an intravascular device. Colour coding below indicates the French size of the largest intravascular device that will pass through the introducer sheath.

The availability of French sizes may vary according to product line. Please refer product catalogue for availability.

French	Colour
4 (1.35 mm)	Red
5 (1.65mm)	Grey
6 (2.0mm)	Green
7 (2.3mm)	Orange
8 (2.7mm)	Blue

Dilator

A vessel dilator facilitates the percutaneous entry of the Introducer sheath by forming an atraumatic transition from the skin, through the subcutaneous tissue to the vessel. Trans intro contains one dilator.

Mini-Guide wire

A mini-guide wire is provided for maintaining access to the puncture site after removal of the needle and the insertion of Introducer sheath. Trans Intro contains one Mini-Guide wire

Puncture Needle

A puncture needle provides access to the vessel and serves as a pathway for the introduction of guide wire. Trans Intro contains one puncture Needle.

INDICATIONS

The Introducer sheath is indicated for use in arterial and venous procedures requiring percutaneous introduction of intravascular devices.

CONTRAINDICATIONS

None known

WARNINGS

For single use only. Do not re-sterilize or re-use. Structural integrity and/or function may be impaired through cleaning, re-sterilization or reuse and may cause adverse patient reactions. Accordingly, Translumina Therapeutics LLP will not be responsible for any direct or consequential damages or expenses resulting from reuse of the introducer sheath.
This product is designed and intended for single use. It is not designed to undergo reprocessing and re-sterilization after one use.
Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labelling/use information all of which present a potential risk to patient safety.
Do not use with Ethiodol or Lipiodol contrast media, or other such contrast media, which incorporate the components of these agents.
Do not leave an introducer sheath in place for extended periods of time without a catheter or an obturator to support the catheter wall.

PRECAUTIONS

- Store in a dry, dark cool place.
- Do not use if package is open or damaged.
- Check expiry date prior to using product.
- Do not re-sterilize. Exposure to temperatures above 50°c may damage the catheter sheath and components.
- Do not expose to organic solvents, e.g. alcohol.
- If increased resistance is felt upon insertion of the Introducer sheath, investigate the cause before continuing. If the cause of the resistance cannot be determined and corrected, discontinue the procedure and withdraw the introducer sheath.

COMPLICATIONS:

- Air embolism
- Infection
- Intimal tear
- Hematoma at the puncture site
- Perforation of the vessel wall
- Thrombus formation.

RECOMMENDED PROCEDURE

1. Remove Introducer Sheath from package using sterile technique.
2. Remove air from Introducer Sheath by flushing with heparinised saline or suitable isotonic solution.
3. Insert the vessel dilator through the Introducer Sheath's haemostasis valves, snapping it into place at the hub (figure 1). Flush with heparinised saline or suitable isotonic solution.
4. Introduce the cannula of an angiographic needle into the vessel using aseptic technique. Holding the needle in place; insert the flexible end of the guide wire through the needle and into the vessel. If a J tip is used, slide the guide wire introducer over the J to straighten it for insertion. Gently advance the guide wire to the desired depth.

Note: Refer to product labelling for the guide wire size that is compatible with the system components.
Note: If a needle with a metal cannula is used, do not withdraw the guide wire after it has been inserted as it may damage the guide wire.

5. Holding the guide wire in place, withdraw the needle and apply pressure to the puncture site until the Introducer Sheath is inserted into the vasculature.
6. Thread the Sheath/dilator assembly over the guide wire, grasping the sheath close to the skin to prevent buckling. Using a rotating motion, advance the assembly through the tissue and into the vessel.
7. Detach the vessel dilator from the Introducer Sheath by releasing the snap – fit ring at the hub. Withdraw the guide wire and dilator. To avoid damage to the Introducer sheath tip, do not withdraw the dilator until the Introducer Sheath is in the vessel.
8. Aspirate from the side port extension to remove any potential air. After aspiration and flushing, consider establishing a heparinised solution or suitable isotonic solution or suitable via the side port extension. The addition of a heparinised saline drip via the side port can help in the prevention of thrombus formation.
9. Introduce the selected catheter into the Introducer Sheath using one of the following methods:
   a. Straighten the catheter tip by hand
   b. Insert a guide wire into the catheter until the tip is straight.

Note: Hold the sheath in place when Inserting, Positioning, or removing the catheter. The suture collar may be used as a temporary suture site.
Note: If there is a reduction in the valve haemostasis, insert the tip of the vessel dilator into the valve and withdraw it slowly.
Note: When measuring right atrial pressure or determining cardiac output by thermo dilution methods. Temporarily discontinue infusion through the side port extension to help prevent errors in hemodynamic measurement.

10. To exchange catheters, slowly withdraw the catheter from the Introducer Sheath and repeat the insertion procedure.
11. Remove the sheath when clinically indicated by placing compression on the vessel above the puncture site, and slowly withdraw the Introducer Sheath. Discard the sheath as per safe hospital practices.

Important: Upon removing any Introducer Sheath, aspirate via the side port extension to collect any fibrin that may have been deposited within or at the tip of the sheath.

Obturator insertion and withdrawal:

1. Flush the Introducer Sheath with heparinized saline. holding the Introducer Sheath in place, slide the obdurate through the haemostasis valve pushing the snap –fit ring into place A heparinized solution or suitable isotonic solution infused through the side port extension is recommended.

Note: Use an obturator that is one French size smaller than the Introducer Sheath to allow for flushing, infusion, and pressure monitoring. Refer to table in Obturator section under system components /Description.

2. To remove, hold the Introducer Sheath in place, releasing the snap-fit ring, and withdraw.
3. Discard the sheath and obturator accordingly.

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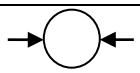
SYMBOLS

Description	Symbol
Introducer sheath set Length	
Introducer sheath set Diameter	
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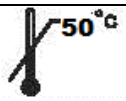
Storage condition	
Manufactured Date	 YYYY MM
Expiry Date	 *YYYY MM*
Sterile and Method of sterilization	
Single use only & do not re-sterile	
Medical Device	

Description	Symbol
Guide wire Diameter	0.038inch
Name of Manufacturer	
Content	
Read the documents/Instruction for use	
Do not use if package open or damaged	
Keep away from direct sun light	
Keep dry	
Caution/Warning	
Pyrogen free	
Single Sterile barrier system