

**Trans- Needle  
Introducer Needle  
*Instructions for use***

**Manufacturing Facility**



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**PRODUCT DESCRIPTION**

Trans-Needle is an Introducer needle.

**DEVICE COMPONENT DESCRIPTION**

A hypodermic needle is a hollow needle commonly used with a syringe to inject substances into the body or extract fluid from it. They may also be used to take liquid samples from the body, for example taking blood from a vein in venepuncture. Large bore hypodermic intervention is especially useful in catastrophic blood loss or shock.

A hypodermic needle is used for rapid delivery of liquids, or when the injected substance cannot be ingested, either because it would not be absorbed, or because it would harm the liver. There are many possible routes for an injection.

The hypodermic needle also serves an important role in research environments where sterile conditions are required. The hypodermic needle significantly reduces contamination during inoculation of sterile substrates.

**INTRODUCER NEEDLE- Product Matrix with Product Reference No.**

Ref No.	Nominal Introducer Length (cm)	Nominal Introducer Needle	Diameter (G)
NELE 1807	07	18	0.038"/0.97mm
NELE 2104	04	21	0.021"/0.53mm
NELE1807 P	07	18	0.038"/0.97mm

**INDICATIONS**

Indicated for the hypodermic Needle is indicated when blood flow must be detected for percutaneous vessel cannulation. The vessel must be of a calibre which would normally be punctured with a needle and/or catheter of this size or larger.

**CONTRAINDICATIONS**

The use of the balloon is contraindicated for:

The Smart Needle is a delicate instrument which must be handled with care. Protect the tip from impact.

Prior to use of this device, all equipment to be used for the procedure should be carefully examined.

Verify that the luer connections between the needle and probe and between the catheter and needle, if applicable, are snug and that the size is appropriate for the vessel to be accessed.

**WARNINGS**

Before withdrawing the needle and/or probe assembly in a central venous puncture, the patient should suspend respiration to prevent the introduction of air into the venous system.

**PRECAUTIONS**

Store at room temperature. Do not use if package is open or damaged. Inspect all components prior to use.

**INSTRUCTION FOR USE**

To use the Smart Needle Device you will need the following:

- Smart Needle Vascular Access Device
- For Salinger technique – bare needle and guide wire
- For ONC placement – Over-the-Needle Catheter Introducer
- Smart Needle Monitor
- Small volume syringe (10cc or smaller)
- Sterile, normal saline
- Sterile bowl or cup

1. Insert the tip of the needle a short distance into the subcutaneous tissue. (A 45° – 60° angle to the vessel will produce the strongest Doppler signal.)
2. Express a small amount of saline (1/2cc or smaller) through the tip of the needle to clear any air bubbles existing on the tip of the probe.
3. Using the tip of the needle as a pivot point, slowly move the needle in a circular slow, sweeping motion, listening for the desired flow signal.
4. Identify the vessel by location and sound wave form. Arterial flow may be identified as a pulsatile, higher frequency sound. Venous flow may be identified as a windy, lower frequency sound. Venous flow may also exhibit some degree of palpability and may be influenced by the respiratory cycle. This phenomenon is especially true for those veins in close proximity to the heart, such as internal jugular and subclavian veins.
5. If blood flow is not detected, advance the needle further and continue scanning the area, listening for the desired Doppler signal. (If required, more saline (1/2 cc or less) may be injected through the needle to clear any residual air trapped on the tip of the probe.)
6. Once the initial Doppler signal is detected, STOP! Scan the area until the intensity of the signal is maximized. Advance the needle further in that direction (approximately 1-2mm) and STOP again. Scan the area until the signal is maximized.
7. Once the needle penetrates the vessel, a marked increase in the signal intensity occurs. Due to the compromised needle lumen with the probe in place, backflow will not be as brisk as with traditional punctures.
8. Once the needle tip is within the vessel, the needle angle may be decreased to facilitate advancement into the vessel. If the audio signal decreased with repositioning, the needle should be advanced or retracted until the audio signal is strong again. For Smart Needle

models equipped with a catheter, once the catheter has been adequately placed within the vessel, the needle and probe are withdrawn by pulling the luer connector from the hub to permit passage of a guide wire, catheter or infusate. For models without a catheter, the probe is withdrawn to permit passage of a guidewire, catheter or infusate, once the needle has been adequately placed within the vessel. The ONC may be connected to an intravenous drip or capped and periodically flushed to maintain patency.

9. Once satisfactory position is assured, advance the guide wire or suitable catheter into the vessel per standard technique.

10. Withdraw the needle, and insert the catheter or sheath over the guidewire using standard technique.









**Adverse effects:**










The potential complications related to the use of the introducer include, but are not limited to the following: Air embolism, wound infection, intimal tear, subclavian artery puncture, pneumothorax, subclavian vein thrombosis, bleeding, cardiac arrhythmia, hematoma formation, haemothorax, hydrothorax, thoracic duct injury, vessel erosion.

**PACKAGING**

- **Sterile:** This device is sterilized with ETO gas and is non-pyrogenic.
- **Contents:** One Trans-Needle, Introducer Needle.
- **Storage:** Store below 40 °C & keep away from direct light & humidity.

**SYMBOL**

Description	Symbol
Reference No.	
Batch No.	
Gauge size	XXX G
Manufactured Date	 YYYY MM
Use By	 YYYY MM
Sterile and Method of sterilization	
Single use only & do not re-sterile	
Storage condition	
Medical Device	

Description	Symbol
Name of Manufacturer	
Content : Trans-Needle	
Read the documents/Instruction for use	
Do not use if package open or damaged	
Keep away from direct sun light	
Keep dry	
Warning / Attention: See Instructions for Use	
Pyrogen free	
Single Sterile barrier system	

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