MicroTaper™ NV

Non-Vascular Safety Introducer Set

INSTRUCTIONS FOR USE

Rx ONLY

Caution: Federal Law (USA) restricts the use of this device for sale by or on the order of a physician.

WARNINGS

- Device should be used for non-vascular procedures only. Do not use for venous or arterial access.
- Contents supplied STERILE using an irradiation process. Do not use if sterile barrier is damaged. Inspect prior to use to verify that no damage has occurred in shipping.
- For single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure, which, in turn, may result in patient injury, illness, or death.
- Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to patient injury, illness, or death.
- Once engaged, do not attempt to override the needle's locking mechanism. Reuse or reprocessing will compromise the structural integrity of the device and/or lead to device failure, which, in turn, may result in patient injury, illness, or death.
- Failure to fully engage the needle's proximal hub until it locks may result in the needle tip being exposed, potentially resulting in an accidental needle stick injury, which may cause the transmission of infectious disease(s).
- When the guidewire is placed in the patient's body, it should be manipulated while under high-quality fluroscopic guidance.

DEVICE DESCRIPTION

The MicroTaper™ NV Non-Vascular Safety Introducer Set contains:

- 1 — 0.018-inch (0.46 mm) / 0.035-inch (0.89 mm) Tapered Guidewire, Angled, Nitinol
- 1 — 21-gauge (0.9 mm) Tapered Needle, 18-gauge (1.27 mm) Max Outside Diameter, Echogenic

INTENDED USE / INDICATIONS FOR USE

The MicroTaper™ NV Non-Vascular Safety Introducer Set facilitates introduction and placement of a guidewire. The MicroTaper™ NV Needle incorporates a blunting mechanism to reduce the risk of accidental needle stick injury.

CONTRAINDICATIONS

None known.

PRECAUTIONS

- This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of percutaneous catheters should be employed.
- Advancement and/or withdrawal of the guidewire should be smooth and without resistance. Do not use excessive force. If resistance is felt, carefully remove the wire and needle as a unit.
- Do not attempt to disengage the needle's locking mechanism.
- Use the device prior to the "Use By" date specified on the package.
- This device has not been evaluated for use in the vasculature.

POTENTIAL ADVERSE EVENTS

Potential risks exist for serious complications to include:

- Perforation of a vessel or viscus
- Laceration of a vessel or viscus
- Bleeding
- Wire or catheter embolism
- Extravasion
- Hematoma
- Hydrothorax
- Inflammation, necrosis, or scarring
- Risks normally associated with percutaneous interventional procedures
- Pain in region
- Skin infection
- Edema

These and other complications are well documented in medical literature. Use of the MicroTaper™ NV Non-Vascular Safety Introducer Set should be reserved to persons knowledgeable of the risks involved and qualified in the procedures.

HOW SUPPLIED

- Contents supplied STERILE using an irradiation process.
- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible.
- Store in a cool, dry, dark place.

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OPERATIONAL INSTRUCTIONS

1. Prior to use, flush the needle with saline or heparinized saline.
2. Remove protective sheath (see Figure 1).
3. Place the Needle Introducer into the target anatomy by grasping the ***Main Body***. Opacify or sample to verify needle tip location.
4. Carefully advance the Tapered Guidewire through the Needle Introducer to the depth indication mark (see Figure 2). Remove Clip.

Caution: Do not advance beyond the depth indication mark. Needle and guidewire damage may occur.
Caution: The guidewire should not be withdrawn through the needle. If the guidewire must be withdrawn while still inside the needle, simultaneously remove both the needle and the guidewire as a unit to prevent damage to the guidewire.

5. Grasp the ***Main Body*** of the Needle Introducer with one hand and twist the ***Proximal Hub*** clockwise with the other hand until an audible click is heard. Audible click indicates the blunting mechanism is activated (see Figure 3).

Caution: Do not attempt to disengage the safety mechanism.

6. Continue advancing the Tapered Guidewire to desired placement (see Figure 4).

Caution: Do not advance or withdraw the guidewire against resistance. Fix the cause of resistance before continuing.

7. Withdraw the Needle Introducer, leaving the Tapered Guidewire in place (see Figure 5).
8. Utilize guidewire for placement of further diagnostic or interventional devices.
9. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

SYMBOLS KEY

REF	Catalogue Number
LOT	Lot Number
QTY	Quantity
	Use By Date
Rx Only	Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.
	Single use only. Do not reuse.
	Consult instructions for use.
STERILE R	Sterilized using irradiation.
	Do not use if package is damaged.
	Keep away from sunlight.
	Non-pyrogenic
	Manufacturer

Figure 1: MicroTaper™ NV Needle Introducer

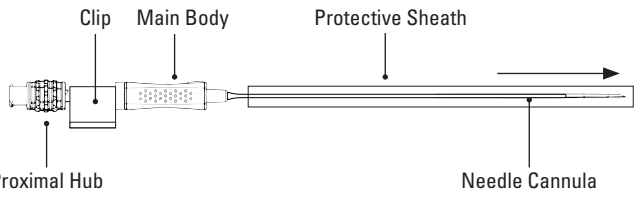


Figure 2: Guidewire Advancement to Depth Indication Mark

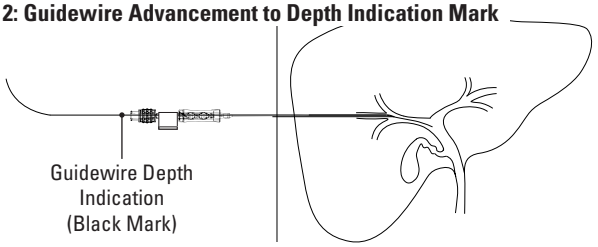


Figure 3: Engage Main Body and Proximal Hub

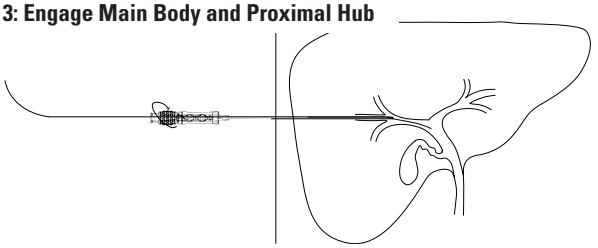


Figure 4: Guidewire Placement

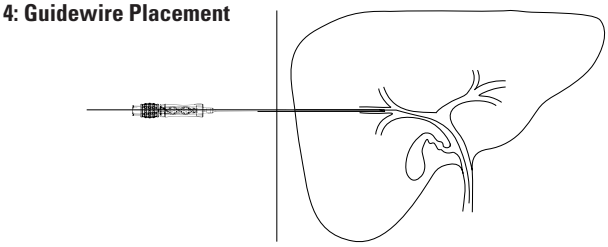
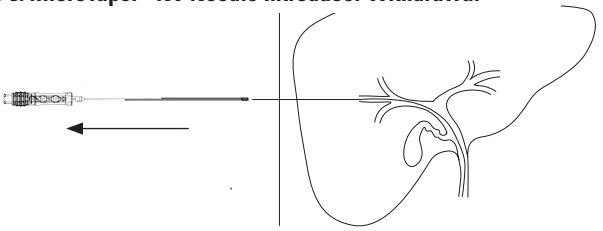


Figure 5: MicroTaper™ NV Needle Introducer Withdrawal



WARRANTY

Summit Access, LLC warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Summit Access's control directly affect the instrument and the results obtained from its use. Summit Access's obligation under this warranty is limited to the replacement of this instrument and Summit Access shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Summit Access neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. This instrument is not designed for or intended to be reused, reprocessed, re-sterilized, modified or altered in any way, and Summit Access assumes no liability with respect to instruments treated or handled in such manner, and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.