Pre-Procedure Preparation

1. Confirm the inner diameter (ID) of the sheath is compatible with maximum diameter of any instruments to be introduced.
2. Flush the sheath completely with heparinized saline (not supplied), using the side-port. Close the side-port after flushing by rotating the stopcock.
3. Flush the dilator with heparinized saline.
4. Fully insert the dilator into the sheath.

Directions for Use

Sheath Introduction

1. Employ the standard Seldinger technique to access the target vessel using a suitable needle.
2. Insert a guidewire (up to .038") into the vessel through the needle.
3. Leave the guidewire in place while removing the needle.
4. Insert the dilator/sheath assembly over the guidewire.
5. Advance the Intara™ Introducer Sheath into targeted vessel without occluding the vessel. Use fluoroscopic guidance when advancing, retracting, or manipulating kit components and accessories in the vasculature.
6. Remove the guidewire and dilator. Aspirate and flush through the sheath side-arm.
7. Insert appropriately sized devices as needed.

Sheath Removal

1. Insert a guidewire until its tip extends sufficiently beyond the tip of the sheath to arrive at a more malleable part of the wire.
2. Remove the sheath, while avoiding applying tension to hub during removal. If resistance is anticipated or encountered during the withdrawal of the sheath, consider reinserting the dilator and removing the sheath and dilator as a unit.
3. Remove the guidewire.

Storage and Handling Conditions

Store at controlled room temperature.

Disposal

After use, handle and dispose in accordance with hospitals policies and procedures concerning biohazard materials and waste.

Note:

In the event a serious incident related to this device occurs, the event should be reported to Argon Medical at quality.regulatory@argonmedical.com as well as to the competent health authority where the user/patient resides.

ARGON MEDICAL DEVICES

Intara™ Introducer Sheath

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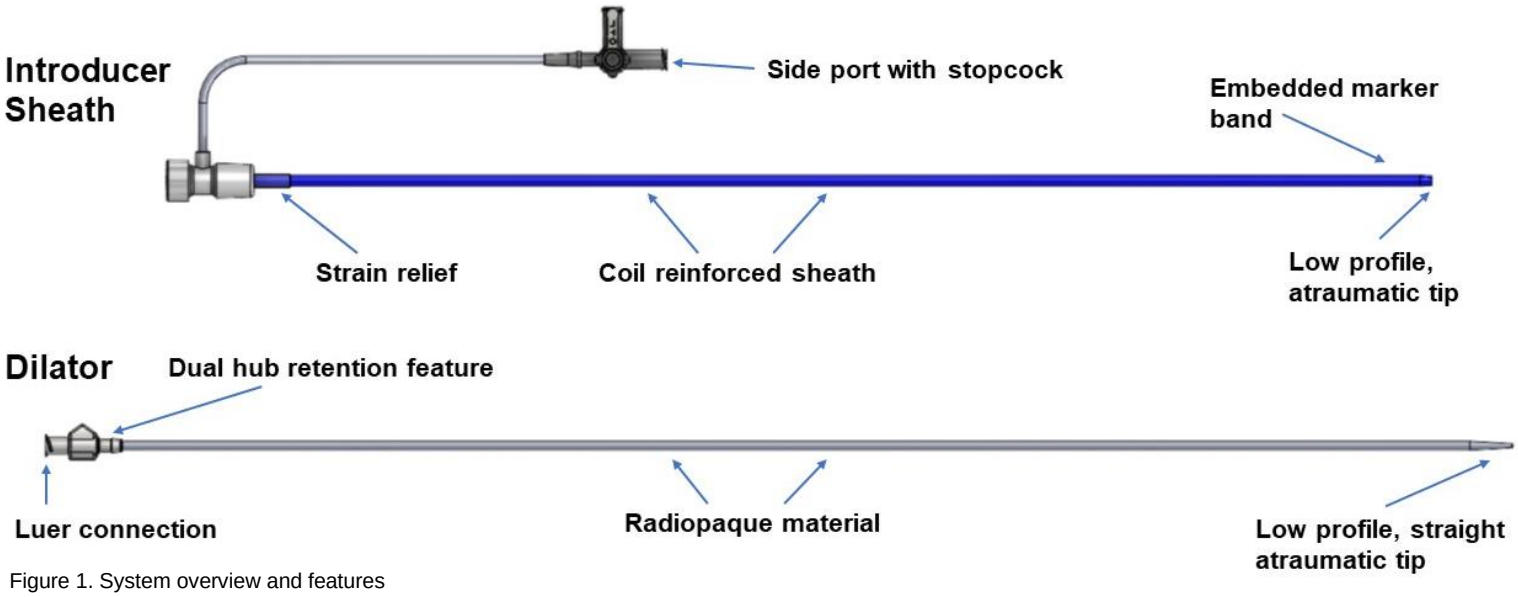

Figure 1. System overview and features

Device Description
The Intara™ Introducer Sheath is specifically engineered to act as a guiding or introducer sheath. The set comprises a sheath and a matching dilator, with the introducer sheath being reinforced and featuring a hub hemostasis valve. The product label contains information on the sheath's inner diameter, sheath's working length, and the dilator's inner diameter.

Intended Use/Purpose
The Intara™ Introducer Sheath is intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.

Intended Patient Population
Patients may be of any gender or age deemed to have appropriate vessel morphology for placement of a 10F sheath by the qualified clinician.

Indication for Use
The Intara™ Introducer Sheath is indicated for introduction of therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.

Intended Users
This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of vascular access sheaths should be employed.

Duration/Lifetime
The Intara™ Introducer Sheath is intended for continuous use less than 4 hours.

Clinical Benefits
The Intara™ Introducer Sheath provides an indirect clinical benefit to the patient by maintaining an access point into the vasculature for the introduction of other diagnostic and therapeutic devices, as well as the delivery of endoprosthetic shunts.

Risks and Side Effects:
- Pain and tenderness
- Extravasation
- Hematoma
- Vessel laceration
- Vessel perforation
- Infection
- Local pain/inflamation
- Cardiac arrhythmia
- Increased hepatic pressure
- Distal embolization

Contraindications
None known.

Warnings
- Contents are supplied sterile and are intended for single use only. Do not re-sterilize.
- Reuse or reprocessing has not been evaluated and may lead to its failure and subsequent patient illness, infection, or other injury.
- Do not use if package is open or damaged and if the expiry date has been exceeded.
- Do not continue to use if any of the components are damaged during the procedure.
- Resistance met while advancing the Intara™ Introducer Sheath should be investigated before continuing with advancement. Consider dilating any identified restrictions or adopting an alternative treatment strategy.
- Risks and benefits should be carefully assessed in pregnant patients as radiation from fluoroscopic imaging may endanger the fetus.
- The patient should be monitored (EKG, oximetry, blood pressure, pulse) during the procedure.
- Do not use the device or accessories after the expiration date.

Precautions
- Inspect package integrity and all set components prior to use.
- All interventional or diagnostic instruments used with this product should move freely through the valve and sheath to avoid damage.
- In the case of balloon catheterization, ensure that balloon is fully beyond the end of the sheath to prevent damage to sheath tip.
- Reinsertion of dilator prior to removal of introducer sheath increases the strength of the sheath. If resistance is anticipated or encountered during withdrawal of introducer sheath, consider carefully reinserting the dilator prior to continuing removal.
- When inserting, manipulating, or withdrawing a device through the sheath, always maintain sheath position.
- When puncturing, suturing, or incising the tissue near the sheath, use caution to avoid damaging the sheath.
- Do not attempt to heat or reshape the device.
- Do not use excessive force when advancing, retracting, or manipulating kit components and accessories.