



GlideThru™ Peel-Away Sheath/Dilator Introducer

Indications for Use:

The Arrow® GlideThru™ Peel-Away Sheath/Dilator Introducer is used for percutaneous introduction of diagnostic or therapeutic devices into the vasculature.

Contraindications:

None known.

Warnings and Precautions

Warnings:

1. Sterile, Single use: Do not reuse, reprocess or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death.
 2. Read all package insert warnings, precautions, and instructions prior to use. Failure to do so may result in severe patient injury or death.
 3. Practitioners must be aware of complications associated with vascular access including but not limited to: vessel perforation, sheath embolus, intravascular device related infection, and mediastinal injury, air embolism, vessel wall damage/thrombosis, inadvertent arterial puncture, nerve damage, hematoma and hemorrhage.
 4. Do not leave open dilators or sheaths uncapped in venous puncture site. Air embolism can occur with these practices.
 5. Do not leave peel-away sheath/dilator in place as an indwelling catheter. Leaving peel-away sheath/dilator in place puts patient at risk for possible vessel wall perforation.
 6. Do not use excessive force when introducing guidewire, peel-away sheath over tissue dilator, or tissue dilator as this can lead to vessel perforation and bleeding.
2. Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.
 3. Use universal blood and body-fluid precautions in the care of all patients due to the risk of exposure to Human Immunodeficiency Virus (HIV) or other blood borne pathogens.
 4. Do not withdraw dilator until sheath is well within vessel to reduce risk of damage to sheath tip. Sufficient guidewire length must remain exposed at hub end of sheath to maintain a firm grip on guidewire.

A Suggested Procedure: Use sterile technique.

1. Ensure dilator is in position and locked to hub of sheath.
 2. Insert guidewire per manufacturer's instructions.
-  **Caution:** Maintain firm grip on guidewire at all times.
3. Thread tapered tip of peel-away sheath/dilator assembly over guidewire.
 4. Grasping near skin, advance peel-away sheath/dilator assembly over guidewire with slight twisting motion to a depth sufficient to enter vessel.

NOTE: A slight twisting motion of the peel-away may help sheath advancement.

- Pre-dilate puncture site, if necessary. Use scalpel positioned away from the guidewire to enlarge cutaneous puncture site, if necessary. **Do not cut guidewire.** Retract scalpel to the protected position.

 **Caution:** Do not withdraw dilator until sheath is well within vessel to reduce risk of damage to sheath tip. Sufficient guidewire length must remain exposed at hub end of sheath to maintain a firm grip on guidewire.

5. Check peel-away sheath placement by holding sheath in place, twist dilator hub counterclockwise to release dilator hub from sheath hub, withdraw guidewire and dilator sufficiently to allow blood flow.

Cautions:

1. Do not use if package has been previously opened or damaged.

6. Once proper peel-away sheath placement is confirmed, hold sheath in place and remove guidewire and dilator as a unit. Assess blood return is dark in color without pulsation.
 7. Quickly place finger or thumb over sheath end upon removal of dilator and guidewire to reduce risk of air entry.
 8. Verify entire guidewire is intact upon removal.
- ⚠ Warning: Do not apply undue force on guidewire to reduce risk of possible breakage.**
9. Insert catheter through peel-away sheath.
 10. Advance catheter to final indwelling position.
 11. Grasp tabs of peel-away sheath and pull apart, away from catheter, while withdrawing from vessel until sheath splits down its entire length.
 12. If catheter position has been displaced during sheath removal, re-advance it to appropriate indwelling position.
- If you have any questions, please contact Arrow International, Inc.**



Caution



Do not reuse



Do not resterilize



Sterilized
by ethylene oxide



Do not use
if package is damaged



Is not made with
natural rubber latex



Consult
instructions for use

Rx only.

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