

GlideThru™ Peel-Away Sheath/Dilator Introducer

Rx only.

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.

Clinical Benefits to be Expected:

Permits venous access for catheter introduction.

⚠️ General 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. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.
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. Clinicians must be aware of complications/undesirable side-effects associated with vascular access including but not limited to:
 - vessel perforation
 - sheath embolus
 - intravascular device related infection
 - mediastinal injury
 - air embolism
 - vessel wall damage/thrombosis
 - inadvertent arterial puncture
 - nerve damage
 - hematoma
 - hemorrhage
4. 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.
5. 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.

Precautions:

1. Do not alter the assembly except as instructed during procedure steps.
2. Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.
3. Use standard precautions and follow institutional policies for all procedures including safe disposal of devices.

A Suggested Procedure: Use sterile technique.

1. Ensure dilator is in position and locked to hub of sheath.
2. Thread peel-away sheath/dilator assembly over guidewire.
3. Grasping near skin, advance peel-away sheath/dilator assembly over guidewire with slight twisting motion to a depth sufficient to enter vessel.

4. If necessary, enlarge cutaneous puncture site with cutting edge of scalpel, positioned away from guidewire.

⚠️ Warning: Do not cut guidewire to alter length.

⚠️ Warning: Do not cut guidewire with scalpel.

- Position cutting edge of scalpel away from guidewire.
- Engage safety and/or locking feature of scalpel (when applicable) when not in use to reduce the risk of sharps injury.

⚠️ Precaution: Do not withdraw dilator until sheath is well within vessel to reduce risk of damage to sheath tip.

⚠️ Precaution: 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.
6. Holding sheath in place, remove guidewire and dilator as a unit (refer to Figure 1).

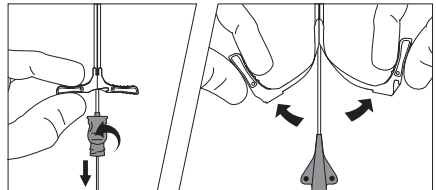


Figure 1

Figure 2

⚠️ Warning: Do not apply undue force on guidewire to reduce risk of possible breakage.

⚠️ Warning: Do not leave tissue dilator in place as an indwelling catheter. Leaving tissue dilator in place puts patient at risk for possible vessel wall perforation.

7. Quickly occlude sheath end upon removal of dilator and guidewire to reduce risk of air entry.

⚠️ Warning: Do not leave open dilators or sheaths uncapped in venous puncture site. Air embolism can occur if air is allowed to enter a vascular access device or vein.

8. Verify entire guidewire is intact upon removal.
9. Insert catheter through peel-away sheath to final indwelling position.
10. Withdraw peel-away sheath over catheter until sheath hub and connected portion of sheath is free from venipuncture site. Grasp tabs of peel-away sheath and pull away from the catheter (refer to Figure 2), while withdrawing from vessel until sheath splits down its entire length.

⚠️ Precaution: Avoid tearing sheath at insertion site which opens surrounding tissue creating a gap between catheter and dermis.








11. If catheter migrated during sheath removal, re-advance catheter to final indwelling position.

For reference literature concerning patient assessment, clinician education, insertion technique, and potential complications associated with this procedure, consult standard textbooks, medical literature, and Arrow International LLC website: www.teleflex.com

A pdf copy of this IFU is located at www.teleflex.com/IFU

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Symbol Glossary: Symbols are in compliance with ISO 15223-1. Some symbols may not apply to this product. Refer to product labeling for symbols that apply specifically to this product.

								
Caution	Medical device	Consult instructions for use	Do not reuse	Do not resterilize	Sterilized by ethylene oxide	Single sterile barrier system with protective packaging inside	Single sterile barrier system	
								
Keep away from sunlight	Keep dry	Do not use if package is damaged	Not made with natural rubber latex	Catalogue number	Lot number	Use by	Manufacturer	Date of manufacture

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