

TorqVue® 2 Delivery Sheath

Instructions for Use

Device Description

The AMPLATZER TorqVue 2 Delivery Sheath is designed to provide a pathway through which a device may be delivered. The delivery sheath consists of 2 components.

- A. The single lumen sheath is radiopaque for visibility under fluoroscopy.
- B. The dilator, which advances through the sheath, eases penetration of tissue and facilitates passage of the sheath through the vessel to the intended site.

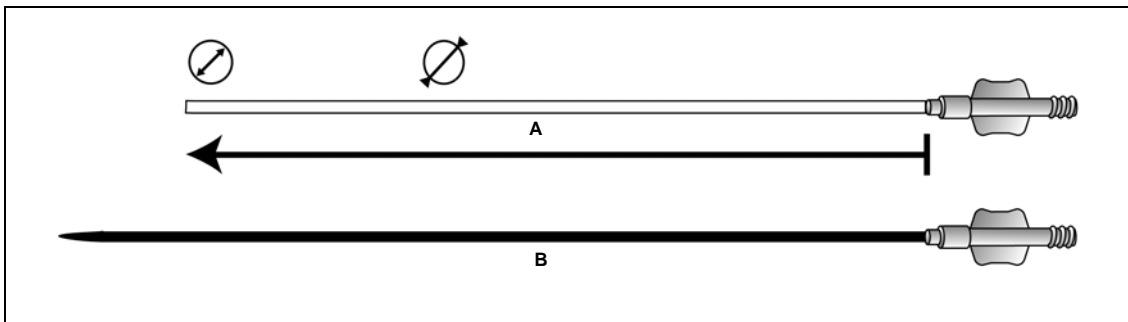


Figure 1. AMPLATZER TorqVue 2 Delivery Sheath components

Table 1. Sheath dimensions

REF	Fr	mm (in)	mm (in)	cm
9-TV2-05F120	5	1.82 (0.072)	2.51 (0.099)	120
9-TV2-06F120	6	2.11 (0.083)	2.79 (0.110)	120
9-TV2-07F120	7	2.44 (0.096)	3.17 (0.125)	120

Indications and Usage

The AMPLATZER TorqVue 2 Delivery Sheath is intended to provide a pathway through which devices are introduced within the peripheral vasculature.

Contraindications

None known.



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Warnings

- Do not use the sheath or dilator if the packaging sterile barrier is open or damaged.
- Use on or before the last day of the expiration month noted on the product packaging.
- Do not use a power injection syringe to inject contrast solution through the sheath.
- The device is sterilized using ethylene oxide and is for single use only. Do not reuse or resterilize. Attempts to resterilize the device may result in device malfunction, inadequate sterilization, or patient harm.
- Remove the dilator and sheath from the patient slowly to prevent an ingress of air.

Precautions

- Store in a dry place.
- Use standard transcatheter techniques when using AMPLATZER products.
- This delivery sheath should only be used by physicians trained in transcatheter techniques. The physician should determine which patients are suitable candidates for procedures using this delivery sheath.
- The physician should exercise clinical judgement in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this delivery sheath.
- Use caution when advancing the dilator and sheath to avoid damaging tissue and vessels or interfering with previously implanted medical devices.
- Prolonged procedures may result in increased exposure to anesthesia, contrast media, and/or radiation.

Potential Adverse Events

Potential adverse events that may occur during or after a procedure using this sheath include, but are not limited to:

- Air embolism
- Bleeding
- Death
- Fever
- Foreign material embolic event
- Infection
- Peripheral embolism
- Peripheral pulse loss
- Stroke
- Thrombus formation
- Tissue trauma/damage
- Transient ischemic attack
- Vascular access site complications
- Vessel trauma/damage

Device Compatibility

Refer to the instructions for use provided with the device to determine delivery sheath compatibility.

Directions for Use

Materials recommended for use with the delivery sheath:

- 0.035-inch guidewire
- Hemostasis valve

Procedure

CAUTION: When placing a device using an AMPLATZER TorqVue 2 Delivery Sheath, refer to the instructions for use provided with the device.

1. Select the appropriate size delivery sheath for the device that will be introduced through the sheath. See Table 1 to determine the appropriate size.
2. Place a 0.035-inch guidewire according the device's instructions for use.
3. Prepare the components for use:
 - Inspect the sterile pouch and verify that it is unopened and undamaged. Do not use the components if the sterile barrier has been compromised.
 - Gently open the sterile pouch and inspect the components for damage. Do not use damaged or kinked components.
 - Flush the components with sterile saline.
 - Wipe the dilator and sheath with sterile gauze dampened with sterile saline to remove any foreign material.
4. Insert the dilator into the sheath. You may encounter resistance as the dilator reaches the distal end of the sheath because the tip of the sheath is tapered.
5. Turn the rotating luer on the dilator clockwise to lock the components together.
6. Advance the dilator and sheath over the guidewire.
7. Turn the rotating luer on the dilator counterclockwise to unlock the components. Remove the dilator from the sheath.

WARNING: Remove the dilator slowly to prevent an ingress of air.

8. Remove the guidewire.
9. Connect a hemostasis valve to the sheath to prevent excessive bleeding or air embolism.

10. Deliver the device according to the device's instructions for use.
11. When the procedure is complete, remove the sheath.

WARNING: Remove the sheath slowly to prevent an ingress of air.

Disposal

- Dispose of all packaging materials as appropriate.
- Dispose of delivery systems and accessories per standard solid biohazard waste procedures.

Warranty













AGA Medical Corporation warrants to buyer that, for a period equal to the validated shelf life of the product, this product shall meet the product specifications established by the manufacturer when used in accordance with the manufacturer's instructions for use and shall be free from defects in materials and workmanship. AGA Medical Corporation's obligation under this warranty is limited to replacing or repairing at its option, at its factory, this product if returned within the warranty period to AGA Medical Corporation and after confirmed to be defective by the manufacturer.




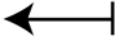



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Symbol Definitions

The following symbols may appear on the device packaging.

Symbol	Definition
	Manufacturer
	EU authorized representative
	Reference number
	Product serial number
	Product lot number
	Use by date (Use on or before the last day of the expiration month noted on the product packaging.)
	Do not reuse
	Sterilized using ethylene oxide
	Consult operating instructions
	Keep dry
	Do not use if package is damaged
	Latex free

	Inner diameter
	Outer diameter
	Length
	Usable length
	Recommended delivery sheath/catheter dimensions
	Indication of conformity with the essential health and safety requirements set out in European Directives
	Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).