AMPLATZER™

TorqVue™ 45° and 180° Delivery Systems

Instructions for Use

Device Description

The AMPLATZER™ TorqVue™ 45° and 180° Delivery Systems are designed to deliver AMPLATZER™ devices. The device and delivery system are shipped separately. The body of the sheath is radiopaque for visibility under fluoroscopy.

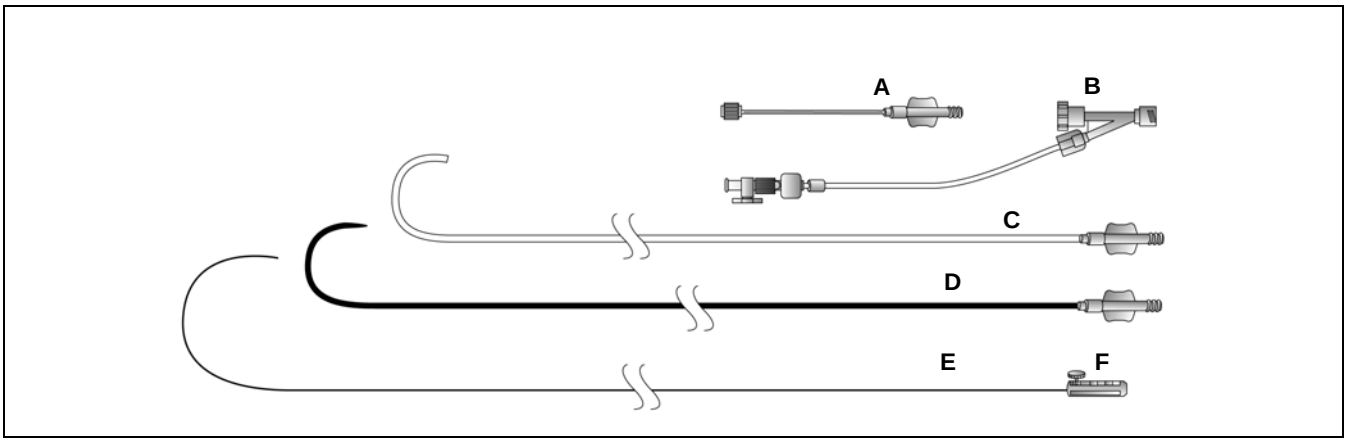

Figure 1. AMPLATZER™ TorqVue™ Delivery System Components

A. Loader – Introduces an AMPLATZER™ device into the sheath
B. Hemostasis valve with extension tube and stopcock – Allows flushing of the delivery system and controls blood backflow
C. Sheath – Provides a pathway through which an AMPLATZER™ device is delivered
D. Dilator – Eases penetration of tissue and minimizes vessel trauma
E. Delivery cable – Attaches to the device to control its movement through the sheath
F. Plastic vise – Attaches to the delivery cable and serves as a handle for disconnecting (unscrewing) the delivery cable from a device

Indications and Usage

The AMPLATZER™ TorqVue™ delivery system is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

Contraindications

None known.

Warnings

- The sheath is designed to be used with the loader. Do not attach a syringe directly to the sheath because the sizing is incompatible and may result in ingress of air or excessive bleeding.
- Use the hemostasis valve to impede the backflow of blood during the implant procedure.

STERILE EO

℞Only

LATEX
Does not contain natural rubber latex components

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- Do not use a power injection syringe to inject contrast solution through the sheath.
- Remove the dilator and sheath from the patient slowly to prevent an ingress of air.
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- This device was sterilized with ethylene oxide and is for single use only. Do not reuse or resterilize this device. Attempts to resterilize this device can cause a malfunction, insufficient sterilization, or harm to the patient.
- Do not use this device if the sterile package is open or damaged.

Precautions

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

Potential Adverse Events

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

- Air embolism
- Arrhythmia
- Arteriovenous fistulae
- Bleeding
- Brachial plexus injury
- Cardiac tamponade
- Death
- Dissection
- Endocarditis
- Hematoma
- Infection
- Myocardial infarction
- Perforation
- Peripheral embolism
- Peripheral pulse loss
- Stroke
- Thrombosis
- Tissue trauma/damage
- Valve damage
- Vascular occlusion
- Vessel trauma/damage

Device Compatibility

The AMPLATZER™ devices compatible with the TorqVue™ delivery system are identified in Table 1. and Table 2..

CAUTION: No devices other than those listed in these tables have been tested for use with the delivery system. Using untested devices with the delivery system may result in technical failures and/or adverse events.

Table 1. Compatibility Chart for TorqVue™ 45° Delivery System and AMPLATZER™ Devices

	45° Delivery System Sizes					
	6 Fr	**7 Fr**	**8 Fr**	**9 Fr**	**10 Fr**	**12 Fr**
AMPLATZER™ Septal (ASD) Occluder	4–10 mm	11–17 mm	18 mm 19 mm	20–24 mm	26–30 mm	32-38 mm
AMPLATZER™ Multi-fenestrated ASD (Cribriform) Occluder	––	––	18 mm 25 mm 30 mm	35 mm	––	––
AMPLATZER™ Muscular VSD Occluder	4–10 mm	12 mm	14 mm 16 mm	18 mm	––	––

Table 2. Compatibility Chart for TorqVue™ 180° Delivery System and AMPLATZER™ Devices

	180° Delivery System Sizes				
	5 Fr	**6 Fr**	**7 Fr**	**8 Fr**	**9 Fr**
AMPLATZER™ Duct (PDA) Occluder	5/4 mm	6/4 mm 8/6 mm 10/8 mm	12/10 mm	––	––

Table 2. Compatibility Chart for TorqVue™ 180° Delivery System and AMPLATZER™ Devices

	180° Delivery System Sizes				
	5 Fr	**6 Fr**	**7 Fr**	**8 Fr**	**9 Fr**
AMPLATZER™ Muscular VSD Occluder	4 mm	6–10 mm	12 mm	14 mm 16 mm	18 mm

Table 3. Delivery System Dimensions

Delivery system (sheath) size	Inner diameter of sheath	Outer diameter of sheath
5 Fr	1.83 mm (0.07 in)	2.51 mm (0.10 in)
6 Fr	2.11 mm (0.08 in)	2.79 mm (0.11 in)
7 Fr	2.44 mm (0.10 in)	3.18 mm (0.13 in)
8 Fr	2.69 mm (0.11 in)	3.45 mm (0.14 in)
9 Fr	3.00 mm (0.12 in)	3.81 mm (0.15 in)
10 Fr	3.30 mm (0.13 in)	4.14 mm (0.16 in)
12 Fr	3.99 mm (0.16 in)	4.80 mm (0.19 in)

Directions for Use

Materials recommended for use with the delivery system

Exchange-length 0.035-inch guidewire

Procedure

CAUTION: Refer to the instructions for use provided with the device when placing an AMPLATZER™ device using an AMPLATZER™ TorqVue™ Delivery System.

General instructions for the AMPLATZER™ TorqVue™ Delivery Systems are provided below.

1. Select the appropriate delivery system for use with the device being delivered. Refer to Table 1 and Table 2 to select a delivery system by AMPLATZER™ device size, or refer to Table 3 to select the delivery system with a sheath that has the correct inner diameter as indicated in the device's instructions for use.
2. Prepare the delivery system 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 all components with sterile saline.
   - Wipe the dilator and sheath with sterile gauze moistened with sterile saline to remove any foreign material.
3. Access the desired vessel.
4. Place the guidewire according to the device's instructions for use. Insert the dilator into the sheath. You may encounter resistance as the dilator reaches the distal end of the sheath because the end 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 until the sheath is positioned according to the device's instructions for use.
7. Turn the rotating luer on the dilator counterclockwise to unlock the dilator. Slowly remove the dilator from the sheath.

   WARNING: Remove the dilator slowly to prevent an ingress of air.
8. Allow blood backflow to purge any air from the sheath.
9. Attach the hemostasis valve to the proximal end of the loader and flush with sterile saline.

   CAUTION: Use the hemostasis valve to impede blood backflow during the implant procedure.
10. Capture the device in the loader according to the device's instructions for use.
11. Attach the distal end of the loader to the proximal end of the sheath. Turn the rotating luer on the loader clockwise to lock the components together. Remember to close the stopcock on the hemostasis valve.
12. Position, deploy, and detach the device according the device's instructions for use.
13. When the procedure is complete, slowly remove the sheath.

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

Disposal

- The instructions for use are recyclable. Dispose of all packaging materials appropriately.
- Dispose of delivery systems and accessories following 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.

EXCEPT AS EXPRESSLY PROVIDED IN THIS WARRANTY, AGA MEDICAL CORPORATION DISCLAIMS ANY REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

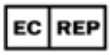
See the Terms and Conditions of Sale for further information.

State of California (USA) Only:

WARNING: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

Symbol Definitions

The following symbols may appear on the device packaging:

Symbol	Definition
	Manufacturer
	Contains phthalate
	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 instructions for use

	Keep dry
	Do not use if package is damaged
	Does not contain natural rubber latex components
	Inner diameter
	Outer diameter
	Length
	Usable length
	Recommended delivery sheath/catheter dimensions
	Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
	Indication of conformity with the essential health and safety requirements set out in European Directives
	Quantity
	Date of manufacture
Delivery System	Delivery System