

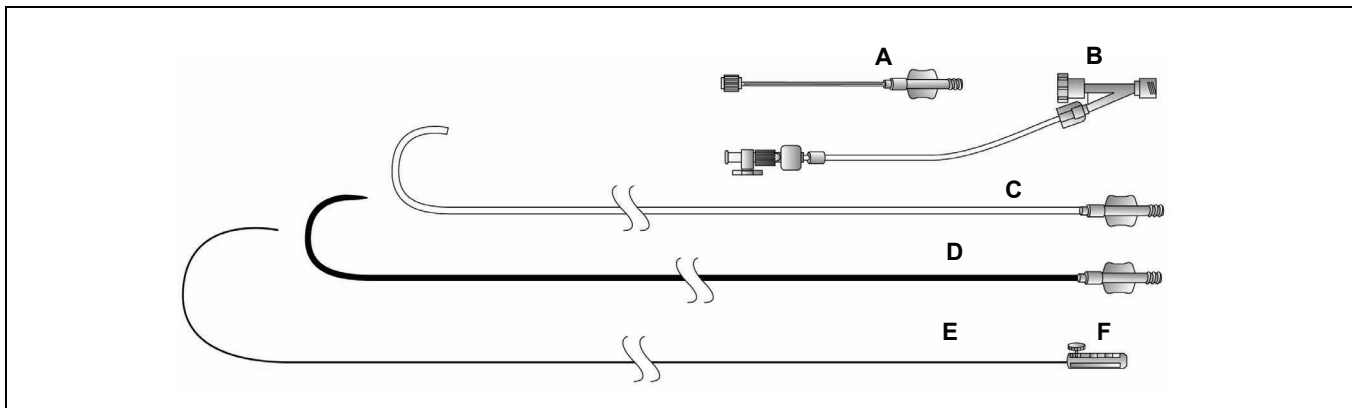
**AMPLATZER®**

# 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

- Use on or before the last day of the expiration month noted on the product packaging.
- The delivery system 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.

STERILE EO



R Only



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- Do not use the delivery system if the packaging sterile barrier is open or damaged.
- 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.
- 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.

**Precautions**

- Store in a dry place.
- This delivery system should only be used by physicians who have been trained in transcatheter techniques. The physician should determine which patients are suitable candidates for procedures using this delivery system.
- 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 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<br>19 mm          | 20–24 mm | 26–30 mm | 32-38 mm |
| AMPLATZER Multi-fenestrated ASD (Cribriform) Occluder | ---                       | ---      | 18 mm<br>25 mm<br>30 mm | 35 mm    | ---      | ---      |
| AMPLATZER Muscular VSD Occluder                       | 4–10 mm                   | 12 mm    | 14 mm<br>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<br>8/6 mm<br>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<br>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.
5. 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.
6. Turn the rotating luer on the dilator clockwise to lock the components together.
7. Advance the dilator and sheath over the guidewire until the sheath is positioned according to the device's instructions for use.
8. 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.
9. Allow blood backflow to purge any air from the sheath.
10. 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.
11. Capture the device in the loader according to the device's instructions for use.
12. 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.

13. Position, deploy, and detach the device according the device's instructions for use.
14. When the procedure is complete, slowly 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 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.







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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<br>(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  |
| <b>R</b> Only   | Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner). |
| <b>CE</b> 0473  | Indication of conformity with the essential health and safety requirements set out in European Directives              |