AMPLATZER™

TorqVue™ LP Delivery System

Instructions for Use

Device Description

The AMPLATZER™ TorqVue™ LP low-profile delivery system consists of a delivery catheter, loader, and hemostasis valve. Optional components of the AMPLATZER™TorqVue™ LP delivery system are a delivery wire and plastic vise. The delivery system is designed to provide a pathway through which devices are introduced into the chambers and coronary vasculature of the heart or into the peripheral vasculature. The body of the delivery catheter is radiopaque for visibility under fluoroscopy.

Note: Not made with natural rubber latex.

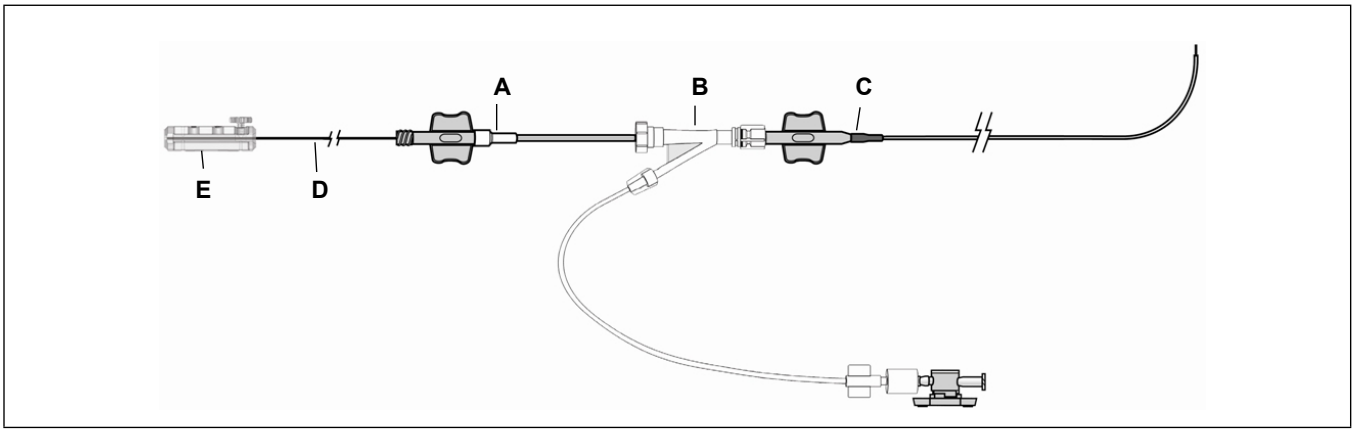

Figure 1. AMPLATZER™ TorqVue™ LP Delivery System components

A. Loader – Introduces a device into the delivery catheter.
B. Hemostasis valve with extension tube and stopcock – Allows flushing of the delivery system and controls back-bleeding.
C. Delivery catheter – Provides a pathway through which a device is delivered.
D. Delivery wire (optional) – Attaches to a device for controlling its movement through the delivery catheter.
E. Plastic vise (optional) – Attaches to the delivery wire, serving as a “handle” for detaching (unscrewing) the delivery wire from a device.

Indications for Use

The AMPLATZER™ TorqVue™ LP 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.

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AGA MEDICAL CORPORATION

Manufacturing facility:
AGA Medical Corporation
5050 Nathan Lane North
Plymouth, MN
55442 USA
+1.855.478.5833
+1.651.756.5833
sjm.com

Warnings

- 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.
- 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.

Precautions

- 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 judgement in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this delivery system.
- Use on or before the last day of the expiration month that is printed on the product packaging label.
- Use caution when advancing the sheath and dilator to avoid damaging tissue and vessels or interfering with previously implanted medical devices.
- Store in a dry place.

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 at the access site
- Brachial plexus injury
- Cardiac tamponade
- Death
- Dissection
- Endocarditis
- Hematoma
- Hemodynamic compromise
- Infection
- Myocardial infarction
- Perforation
- Peripheral pulse loss
- Stroke/transient ischemic attack
- Thrombosis
- Valve damage
- Vascular access site injury
- Vascular occlusion
- Vessel damage

Device Compatibility

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

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 the TorqVue™ LP Delivery System and AMPLATZER™ Devices

	Delivery System Sizes	
	4 Fr	**5 Fr**
AMPLATZER™ Vascular Plug	4 mm	6 mm 8 mm
AMPLATZER™ Duct Occluder II	03-04 mm 04-04 mm 03-06 mm 04-06 mm	05-04 mm 06-04 mm 05-06 mm 06-06 mm

Table 2. Delivery System Dimensions

Delivery system (catheter) size	Inner diameter of delivery catheter
4 Fr	1.17 mm (0.046 in)
5 Fr	1.50 mm (0.059 in)

Procedure

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

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

1. Select the appropriate delivery system for the device you be will using. Refer to Table 1 to select a delivery system by AMPLATZER™ device size, or refer to Table 2 to select the delivery system with a catheter that has the correct inner diameter as indicated in the device's instructions for use.
2. Prepare the delivery system for use:
   - Inspect the delivery system sterile pouch and verify that it is unopened and undamaged. Do not use the delivery system 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 delivery catheter with sterile gauze moistened with sterile saline to remove any foreign material.
3. Access the desired vessel.
4. Place a guidewire according to the device's instructions for use. (A 0.035-in [0.89-mm] or 0.038-in [0.97-mm] diameter guidewire is suggested for use with the TorqVue™ LP delivery system.)
5. Advance the prepared delivery catheter over the guidewire until the delivery catheter is positioned according to the device's instructions for use.
6. Remove the guidewire. Allow back-bleeding to purge any air from the delivery catheter.
7. Flush all parts of the hemostasis valve. Connect the distal end of the hemostasis valve to the delivery catheter. Remember to close the stopcock on the sidearm of the hemostasis valve.
8. Flush the loader with sterile saline.
9. Capture the device in the loader according to the device's instructions for use.
10. Insert the distal end of the loader into the proximal end of the hemostasis valve. Tighten the hemostasis valve to lock the components together. Advance the device into the delivery catheter.
11. Loosen the proximal end of the hemostasis valve and remove the loader. Retighten the hemostasis valve to minimize blood loss.
12. Position, deploy, and detach the device according the device's instructions for use.

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.

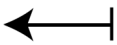
See the Terms and Conditions of Sale for further information.

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

	Quantity
Delivery System	Delivery System