AMPLATZER™

TorqVue™ Exchange Systems

Instructions for Use

Description

The AMPLATZER™ TorqVue™ Exchange Systems consist of a delivery sheath, dilator, loader, hemostasis valve, delivery cable, and plastic vise. The system components are identical to the AMPLATZER™ TorqVue™ Delivery System except that the dilator has a larger inner lumen to allow passage over a delivery cable. The body of the delivery sheath is radiopaque for visibility under fluoroscopy.

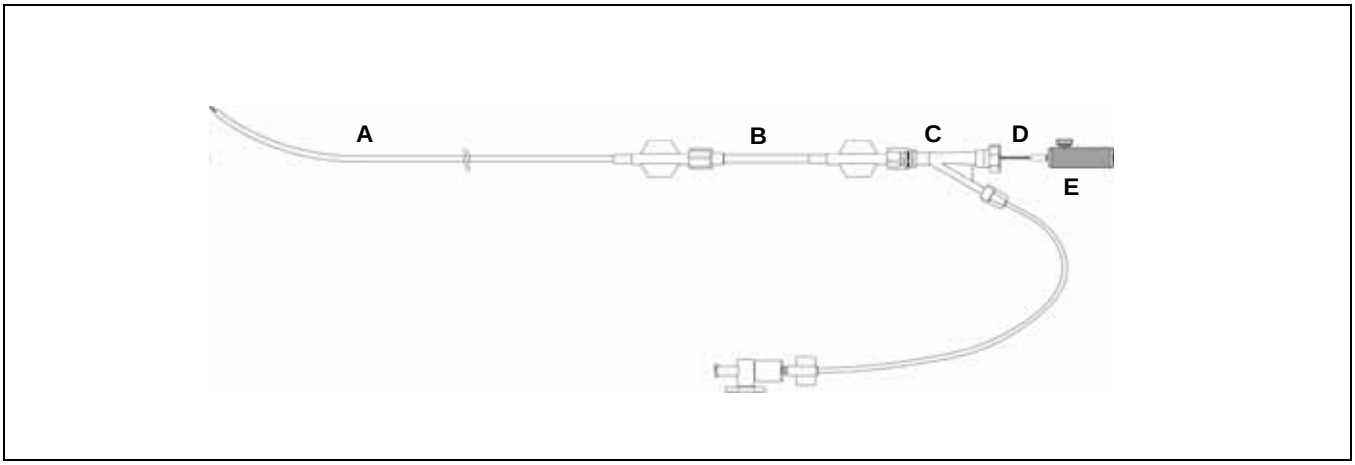

Figure 1. AMPLATZER™ TorqVue™ Exchange System Components (45° exchange system shown)

A. Delivery sheath – Provides a pathway through which a device is delivered.
B. Loader – Introduces a device into the delivery sheath.
C. Hemostasis valve with extension tube and stopcock – Allows flushing of the exchange system and controls back-bleeding.
D. Delivery cable – Attaches to an in vivo delivery cable to facilitate removal of a delivery sheath from a patient. Attaches to a device for controlling its movement through the delivery sheath.
E. Plastic vise – Attaches to the delivery cable, serving as a “handle” for detaching (unscrewing) the delivery cable from a device.
F. Dilator (not pictured) – Eases penetration of tissue.

Indications for Use

The AMPLATZER™ TorqVue™ Exchange System is intended for removal of a delivery sheath and subsequent exchange with a delivery sheath of equal or larger diameter.

Contraindications

None known.

STERILE EO

℞Only

LATEX
Does not contain natural rubber latex components

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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.
- The delivery sheath is designed to be used with the loader. Do not attach a syringe directly to the delivery sheath because the luer 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 delivery sheath.

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 judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this exchange 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 exchange 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
- Infection
- Myocardial infarction
- Perforation
- Peripheral pulse loss
- Stroke
- Thrombosis
- Valve damage
- Vascular occlusion
- Vessel damage

Procedure

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

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

1. Prepare the exchange system for use:
   - Inspect the exchange system sterile pouch and verify that it is unopened and undamaged. Do not use the exchange 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 sheath with sterile gauze moistened with sterile saline to remove any foreign material.
2. If the plastic vise is attached to the original delivery cable, remove the plastic vise.
3. Screw the distal end of the exchange system delivery cable to the proximal end of the original delivery cable.
4. Insert the dilator into the delivery sheath. You may encounter resistance as the dilator reaches the distal end of the sheath because the last few inches of the sheath are tapered. Turn the rotating luer on the dilator clockwise to lock the components together.
5. Remove the original delivery sheath from the patient.
6. Advance the exchange system delivery sheath and dilator assembly over the delivery cable until the delivery sheath is positioned according to the device's instructions for use

   CAUTION: If the distal tip of the sheath needs to be advanced into the left atrium of the heart, advance the delivery sheath and dilator assembly only as far as the vena cava before removing the dilator and purging air from the delivery sheath.
7. Remove the dilator and allow back-bleeding to purge any air from the delivery sheath.

   To recapture and remove a device:
8. Advance the delivery sheath to recapture the device within the sheath.

9. Retract the delivery cable to remove the device through the sheath.
10. Unscrew the exchange system delivery cable from the original delivery cable.

To place a new device:

11. Attach the hemostasis valve to the loader and flush with sterile saline.
12. Capture the device in the loader according to the device's instructions for use.
13. Attach the distal end of the loader to the proximal end of the delivery sheath, and turn the rotating luer on the loader clockwise to lock the components together. Remember to close the stopcock on the hemostasis valve.
14. 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 exchange 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.

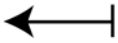
See the Terms and Conditions of Sale for further information.

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
	Hydrophilic coating

	Recommended delivery sheath/catheter dimensions
CE	Indication of conformity with the essential health and safety requirements set out in European Directives
℞Only	Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
	Quantity
	Date of manufacture
Exchange System	Exchange System