

AMPLATZER®

TorqVue® DX Catheter

Instructions for Use

Device Description

The AMPLATZER TorqVue DX angiographic catheters are single-use, sterile, non-pyrogenic, disposable intravascular catheters.

Indications and Usage

Angiographic catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Angiographic catheters with marker bands may also be used for anatomical measurements.

Contraindications

None known.

Warnings

- Angiographic catheters are single use.
- Recommended guidewire size: see the individual catheter label.
- Guidewire use has been associated with greater incidence of thrombus formation.

Precautions

- Do not use if package is opened or damaged.
- Do not use after expiration date.
- Do not autoclave.
- Carefully remove the catheter from the package by grasping the hub and slowly withdrawing it from the package.
- If resistance is felt when removing the guidewire from the catheter, remove the guidewire and catheter as a unit to prevent potential damage to the vessel wall.
- Flush all devices entering a blood vessel with sterile heparinized saline or similar isotonic solution before use.

Adverse Events

Angiographic catheters should be used by physicians familiar with percutaneous catheter introduction. Complications which may be associated with the use of angiographic catheters include, but are not limited to, the following:

- Thrombus formation/emboli
- Air embolism
- Hematoma at the puncture site
- Arterial wall damage
- Plaque dislodgement
- Myocardial infarction
- Cardiac arrhythmias
- Infection
- Perforation of the vessel wall
- Allergic reaction to contrast media
- Vascular occlusion
- Vascular spasm
- Stroke and death



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Directions for Use

1. A coated guidewire is recommended for use with angiographic catheters.
2. Introduce the catheter into the blood vessel using vascular entry technique of choice.

Sterile and non-pyrogenic in unopened and undamaged inner package. Store in a cool dry place.

Disposal

The IFU is recyclable. 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 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
	Length

CM	Centimeter
F	French size
PSI	Recommended pressure limit
GW	Recommended guidewire
CT	Contents
SH	Side holes
FLO	Flow rates and pressures. Flow rates achieved at 10.4 cP. Individual results may vary.
R Only	Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
CE 0473	Indication of conformity with the essential health and safety requirements set out in European Directives