

Gateway™ Advantage Y-Adapter Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications for Use

The Y-Adapter is intended to prevent irrigant backflow while securing urological devices during urological endoscopic procedures. Irrigation may also be connected to the side port of the device. The Y-Adapter is supplied in a sealed pouch and is intended for single-use only.

Contraindications

None known

Warning

- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.
- For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/ or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Potential Adverse Events

None known

Precautions

- Use prior to the "Use By" date on the package.
- Do not overtighten the adjustable valve. Excessive tightening may inhibit the ability to manipulate the catheter, guidewire or other therapeutic device. Since therapeutic devices are fragile, exercise care during handling to reduce the possibility of accidental breakage. If resistance is felt during manipulation, discontinue further movement and determine the cause.
- Laser fibers should not be used in conjunction with urological devices that have not been indicated for use with laser fibers.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Caution: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.