

Brief Summary Document

Overview

Product

Gateway™ Advantage Y-Adapter – IFU 51556761

Rx Statement

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a skilled and licensed practitioner with experience in urological endoscopic procedures.

The use of this device should be restricted to use by or under the supervision of physicians trained in urological endoscopic procedures.

Prior to use, please refer to all applicable “Instructions for Use” for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.

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.

PRECAUTIONS

- 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. Improper connections between the Y-Adapter and the endoscope, or between the irrigant tubing and the luer seal, may result in leaks and user exposure to biohazardous material.
- Improper seal or closure of the Tuohy Borst valve around urological devices may result in backflow and user exposure to biohazardous material.
- Always drain the Y-Adapter after use. Failure to do so may result in user exposure to biohazardous material.
- The Gateway Advantage Y-Adapter may be used in endourological procedures involving lasers. Laser fibers should not be used in conjunction with urological devices that have not been indicated for use with laser fibers.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with procedures where the Gateway Advantage Y-Adapter is used may include, but are not limited to, the following:

- Allergic reaction
- Infection
- Inflammation

Adverse events may require additional medical or surgical intervention.

There are currently no known **CONTRAINDICATIONS** or **WARNINGS** associated with the use of this device.