

# Passport™ Balloon Catheter

## Prescriptive Information

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

### Intended Use/Indications for Use

The Passport Balloon Catheter is recommended for ureteral dilatation and dilating the intramural ureter and transureteroscopic ureteral dilatation. The use of the Passport Balloon Catheter with HydroPlus™ Coating is intended for ureteroscopes with a minimum working channel inside diameter of 3.4F (1.13 mm) or greater.

### Contraindications

This product is contraindicated in the presence of conditions which create unacceptable risk during catheterization.

### Warnings

For single use only. Do not reuse, reprocess or resterilize.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

### Adverse Events

The complications which may result from a balloon dilatation procedure include:

- Tissue trauma
- Tissue perforation

### Cautions

Cautions and Pre-Cautions can be found in the product labeling supplied with each device.

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