

Single Action Pumping System Prescriptive Information

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.

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.

Indications for Use

For use with urological and/or endoscopic surgical procedures requiring continuous irrigation.

Contraindications

None known

Precautions

Do not use this product without reading and understanding the complete instructions enclosed herein.

Note: This product contains DEHP (Bis(2-ethylhexyl) phthalate). BSC has conducted a Chemical Safety Assessment of DEHP in this device based on currently known acceptable exposure limits for sensitive populations (children and pregnant/nursing women), and has determined that the potential exposure is below the known acceptable exposure limits for the device when used in accordance with the indications and instructions for use.

Potential Adverse Events

Any irrigation product may cause the following adverse tissue reactions.

- Hydro-nephrosis of the Urinary Tract.
- Excess Distention of the Kidney.