

Percuflex™ Urinary Diversion Stent Set Prescriptive Information

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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.

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.

Intended Use/Indications for Use

For drainage following percutaneous, endoscopic, or operative procedures.

Contraindications

The Percuflex Urinary Diversion Stent is contraindicated for use with the following procedures and/or conditions:

- Poor Surgical Risk Patients
- Unexplained Hematuria
- Unrepaired Ureteral Avulsion

Warnings

None known.

Precautions

1. Recommended for single-use only.
2. Bending or kinking during or prior to placement could damage the integrity of the stent.
3. If resistance is encountered during advancement or withdrawal of the stent, **STOP. DO NOT CONTINUE** without first determining the cause of the resistance and taking remedial action.
4. Periodic visual, radiographic or isotopic examinations are recommended to evaluate stent efficiency and to observe for possible complications.

Note: Where long-term use is indicated, it is recommended that indwelling time not exceed 90 days. This stent should be evaluated by the physician on or before 90 days postplacement and at intervals.

5. Stents are not intended to be permanent implant devices.
6. The recommendations given are meant to serve only as a basic guide to the utilization of this set. The insertion of a ureteral stent should not be undertaken without comprehensive knowledge of the indications, techniques and risks of the procedure. Use of this device should be restricted to physician specialists in urologic procedures.

Adverse Events

Adverse events associated with urinary diversion stents include: Reflux-GU (e.g. ureteral reflux); Occlusion/Obstruction (e.g. catheter, stent); Migration (e.g. dislodgement); Hemorrhage; Infection (e.g. sepsis, peritonitis, urinary tract infection); Perforation (e.g. bladder, ureter, kidney, renal pelvis); Extravasation; Encrustation; Loss of renal function; Edema; Urinary symptoms (e.g. frequency, urgency, incontinence, dysuria, nocturia, hematuria); Pain/discomfort; Stent fragmentation; Fistula; Hydronephrosis; Stone formation; Tissue damage; Erosion.