

## Self-Retaining Ureteral Stents: Analysis of Factors Responsible for Patients' Discomfort

### Purpose

To determine factors affecting patients' discomfort during the period self-retaining ureteral stents are in place.

**Patients and Methods:** Between April 2001 and May 2003, 58 male and 42 female patients underwent temporary double-pigtail stenting. The indications were endopyelotomy in 39 patients, ureteroscopy in 32, laparoscopic pyeloplasty in 18, and endoureterotomy in 11. The stents were silicone in 56 patients and Percuflex in 44. The median stenting period was 8 weeks (range 4-16 weeks). Patient discomfort was evaluated by a questionnaire conducted by the physician before stent removal. Tested variables were patients' sex, side of the stent, urine culture, stent material, stent length and diameter, and stenting duration. The site of the upper coil (renal pelvis or calix), the site of the lower coil (in the same side or crossing the midline), and the shape of the lower coil (complete circle or not) were also tested. Univariate and multivariate analysis were carried out to determine significant independent variables, with  $P < 0.05$  being significant.

**Results:** Of the total, 59 patients experienced discomfort consisting of dysuria, urgency, urge incontinence, loin pain, suprapubic pain, frequency, nocturia, or gross hematuria or some combination. Significant factors associated with discomfort were a positive urine culture, crossing of the lower end of the stent to the opposite side, caliceal position of the upper coil, and longer stenting duration.

**Conclusion:** Proper positioning of the coils of the stent, eradication of infection, and shorter stenting duration are advised to decrease patient discomfort during the period of ureteral stenting.

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The study is an evaluation of self-retaining ureteral stents composed of one of two materials, silicone or Percuflex, from two manufacturers, analyzed for factors responsible for patient discomfort.

#### Coloplast Key Takeaways

- Stent material composition is a key factor that affects patient discomfort.
- The stents in the study were made of silicone (Coloplast) and Percuflex (Boston Scientific).
- Symptoms of discomfort led to the limitation of the normal daily activities in 38.0% of patients in the study.

### Imajin® Silicone Double Loop Ureteral Stent Kit BRIEF STATEMENT

#### Indications

The Silicone double loop ureteral stents are intended for adult and pediatric (children and adolescents) patients for drainage of the upper urinary tract over fistulas or ureteral obstacles and/or for healing of the ureter. These stents may remain implanted for up to 12 months.

#### Contraindications to the medical device

- Do not attempt stent placement in a patient with suspected ureteral avulsion.
- Allergy to any component of the device.
- Violent sports or strenuous physical activities are not recommended during stenting period. The practice of sport should be evaluated by the physician.
- Do not use, when, in the judgement of the physician, such a procedure would be contrary to the best interest of the patient.

#### Contraindications to the endourological procedure

- Untreated progressive infections of the upper urinary tract.
- Uncontrolled haemostasis disorder (relative contraindication).

- The safety of some endourological procedures should be evaluated in pregnant women.

#### Warnings & Precautions

These devices must only be used by trained and experienced physicians. Formation of knots in lengthy stents have been reported as adverse events and may require surgical intervention to remove them.

#### Potential Complications

The following events have been reported with double loop ureteral stents although their occurrence greatly depends on patients' medical conditions. Adverse events include but are not limited to: pain, discomfort, sexual dysfunction, infection (e.g., urinary tract infection, pyelonephritis, severe infection, sepsis), tissue lesion (e.g., mucosal irritation, erosion, laceration, perforation of the renal pelvis, ureter or bladder), urinary symptoms (e.g., frequency, urgency, dysuria...), migration, encrustation, obstruction, hematuria, hemorrhage, fragmentation, reflux, knot, and hydronephrosis.

Some other events may be related to the procedure, particularly if the devices are not used as recommended amongst which:

- related to the guidewire: perforation of the urinary tract or close organs, bleeding, hemorrhage, mucosal irritation, tissue lesion, breakage, foreign object in the body, infection, guidewire knotting or looping or kinking, guidewire entrapment, or ureteral avulsion.

- related to the pusher: mucosal irritation, perforation, foreign object in the body, infection or prolonged procedure in case of difficult detachment from the stent.

#### Advice to Patients

The physician should educate the patients on their implanted stent, potential side effects, and the need for regular monitoring.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at [www.coloplast.com](http://www.coloplast.com).

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

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