Clinical Article Summary

# 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 Journal of Endourology 2006; 20:1



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<sup>®</sup> Silicone Hydro-Coated Double Loop Ureteral Stent Kit BRIEF STATEMENT

#### Indications

Silicone Hydro-Coated Double Loop Ureteral Stents are intended for: Drainage of the upper urinary tract over fistulas or ureteral obstacles. Healing of the Ureter

#### Contraindications

Untreated progressive infection of the upper urinary tract. The evaluation of the allergic background of a patient is the healthcare professional's responsibility. Do not attempt stent placement in a patient with suspect ureteral avulsion. Do not use, when, in the judgement of the physician, such a procedure would be contrary to the best interest of the patient.

### **Warnings and Precautions**

These kits 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 although their occurrence greatly depends on patients' medical conditions. Adverse events include but are not limited to: Migration or dislodgement, encrustation, infection, fragmentation, flank pain, mucosal irritation or inflammation, mucus secretion, frequency, urgency, dysuria, hematuria, reflux, stone formation, obstruction, erosion and perforation of the renal pelvis, ureter or bladder. Some events may be related to this procedure, amongst which those related to the quidewire: ureteral perforation, or burns when in contact with an electrosurgical equipment.

# Advice to the Patient

The physician must inform the patient of the risks associated with the use of the device

The risks and benefits of using ImaJin® Silicone Hydro-Coated Double Loop Ureteral Stent Kit should be considered in patients

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.

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

Minneapolis, MN February 21, 2023 PM 15976

