CLINICAL ARTICLE SUMMARY

# Effects of Silicone Hydrocoated Double Loop Ureteral Stent on Symptoms and Quality of Life in Patients Undergoing Flexible Ureteroscopy for Kidney Stone: A Randomized Multicenter Clinical Study

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## ABSTRACT

**Purpose:** We compared the hydrocoated silicone stent (Coloplast Imajin® hydro) to Percuflex™ Plus stent (Boston Scientific) in terms of patient comfort and quality of life after flexible ureteroscopy for stone disease over a 5-week prospective follow-up.

**Materials and Methods:** This is a multicenter, single-blind, prospective, randomized trial of 141 patients treated with flexible ureteroscopy for renal stones. Primary outcome was Ureteral Stent Symptom Questionnaire (USSQ) Body Pain Index recorded before Double-J® stent removal at day (D) 20. Secondary endpoints were USSQ scores at intermediate dates (D2, D7, D20) and 2 weeks after stent withdrawal (D35), occurrence of adverse events and stent encrustation.

**Results**: The trial was completed by 113 (80.1%) patients. Mean (SD) USSQ body pain scores were 25% lower at D20 for the silicone stent at 18.7 (11.4) vs 25.1 (14.2) (p=0.015). No difference in terms of adverse events and safety profile was observed. USSQ urinary symptoms scores at D2, D7 and D20 were lower in the silicone stent group at 26.4 (7.7) vs 31.8 (8.1) at D20 (p <0.001). The use of USSQ self-questionnaires was associated with a limited number of missing or incomplete answers.

**Conclusions**: The primary results of this large sample prospective randomized controlled study comparing the silicone Imajin hydro stents to the Percuflex™ Plus stent show that silicone stents are associated with significantly less patient discomfort. We would recommend their use in patients who require stenting for stone disease.

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## COLOPLAST KEY TAKEAWAYS

- Patients implanted with a silicone Imajin® Hydro ureteral stent had a mean body pain score of 18.7 compared to 25.1 for patients implanted with the Percuflex™ plus stent from Boston Scientific according to the USSQ body pain index. This represents a difference of 6.4 points or 25% reduction in pain score in favor of the Imajin Hydro ureteral stent from Coloplast.
- Patients implanted with a silicone Imajin® Hydro ureteral stent scored their day 20 urinary symptoms at 26.4 compared to 31.8 for patients implanted with the Percuflex™ plus stent from Boston Scientific according to the USSQ body pain index. This represents a difference of 5.4 points or 17% reduction in urinary symptom score in favor of the Imajin Hydro ureteral stent from Coloplast.
- Silicone stents are associated with significantly less patient discomfort and the authors of this clinical study would recommend the use of silicone stents in patients who require stenting for stone disease

**Indications:** Drainage of the upper urinary tract over fistulas or ureteral obstacles. Healing of the Ureter. Cicatrisation stent.

**Contraindications**: Untreated progressive infection of the upper urinary tract. Any known allergies to the medical device materials. These devices may particularly contain traces of silicone resulting from the manufacturing process. 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**: Reuse of this single use product may create a potential risk to the user. Reprocessing, cleaning, disinfection, and sterilization may compromise product characteristics which in turn create an additional risk of physical harm to or infection of the patient. Formation of knots in lengthy stents have been reported as adverse events and may require surgical intervention to remove them.

**Adverse Events:** 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 guidewire: ureteral perforation or burns when in contact with an electrosurgical equipment. The risks and benefits of using Imajin® Silicone Hydrocoated Double Loop Ureteral Stent Kits should be considered in patients.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, and precautions 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.

Complications from the use of this device should be brought to the attention of your Coloplast representative and your physician.

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

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