The comfortable way to manage stenosis

Designed for Maximum Resistance to Stenosis

- More resistant to extrinsic compression than conventional ureteral stent designs¹
- 12 Fr reinforced body for management of stenosis over the entire ureter
- Loops taper to 8 Fr, leaving less material in the bladder

Enhanced Patient Comfort

- Gold Standard Material for long-term stent placement
- Comprised of soft, smooth silicone material which has demonstrated greater patient comfort over Percuflex^{™2}
- · Long-term indwell for up to 12 months

Ease of Placement and Withdrawal

- Inserted and removed like a traditional double loop stent
- Paired with unique steerable positioner designed for precise stent placement



Ordering Information

Coloplast Interventional Urology Service Support 800-258-3476

Stenostent[®] Ureteral Stent

Diameter (Ch/Fr)	Length (cm)	ltem
12	16	AJ4W81
	24	AJ4W83
	26	AJ4W84
	28	AJ4W85
	30	AJ4W86

ImaJin[®] Stenostent[®] Silicone Double Loop Ureteral Stent Kit Brief Statement

Indications

Drainage of the upper urinary tract and/or ureteral healing during management of ureteral stenosis. Total enlargement of the stent diameter, for ureteral stenosis in adult and pediatric (children and adolescents) patients. Stenostent[®] Silicone double loop ureteral 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 and Precautions

These devices must only be used by trained and experienced physicians. Physicians must inform patients of the possible undesirable side effects.

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.

The risks and benefits of using ${\rm Imajin}^{\circ}$ Stenostent $^{\circ}$ Silicone 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.

 $\ensuremath{\textbf{Caution}}$: Federal law (USA) restricts this device to sale by or on the order of a physician.

Minneapolis, MN PM-15974 / February 21, 2023

1. Keller et al. Evaluation of ureteral stent resistance to extrinsic compression: The role of designs and materials. Journal of Urology. May 2020, Vol 203, No 4s. (e624-e625). 2. El-Nahas et al, Self-Retaining Ureteral Stents: Analysis of Factors Responsible for Patients' Discomfort. J of Endourology. Jan. 2006, 20(1):33-37.

Ostomy Care | Continence Care | Wound and Skin Care | Interventional Urology | Voice and Respiratory Care

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