

## **Biosoft® Duo Double Loop Ureteral Stent**

### **BRIEF STATEMENT**

#### **Physician Facing**

#### **Indications**

Biosoft duo Double Loop Ureteral Stents can be used for:

- Drainage of the upper urinary tract over fistulas or ureteral obstacles
- Healing of the Ureter

Target population are Patients requiring ureteral stenting for drainage and/or healing of the ureter.

Duration of Use: Biosoft duo Double Loop Ureteral Stent may remain implanted for up to 6 months.

#### **Contraindications**

Untreated progressive infection of the upper urinary tract.

These devices may particularly contain traces of silicone resulting from the manufacturing process. The evaluation of the allergic background of a patient is the health care 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.

Reuse of this single use product may create a potential risk to the user.

Formation of knots in lengthy stents have been reported as adverse events and may require surgical intervention to remove them.

If the stent is intended to remain implanted for more than seven days, remove the withdrawal thread prior to implantation.

#### **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 guidewire: ureteral perforation, or burns when in contact with an electrosurgical equipment.

The risks and benefits of using Biosoft Duo 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](http://www.coloplast.com).

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

Minneapolis, MN

12/07/2021

PM-19611