
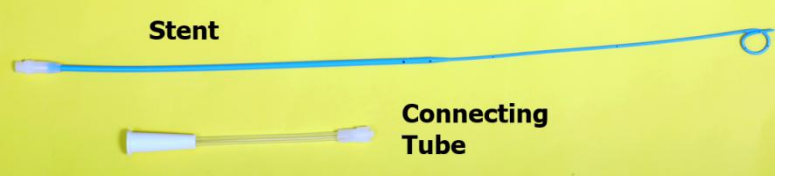






**DEVON INNOVATIONS PRIVATE LIMITED
BANGALORE**

Endopyelotomy Stent - With/without Hydrophilic coated

VARIANTS:

| Product Name | Variant Name | Packing | Image |
|---|----------------------------------|-----------------|---|
| Endopyelotomy Stent-With/without Hydrophilic coated | Endopyelotomy Stent (External) | With Packing |  |
| | | Without Packing |  |
| | Endoureterotomy Stent (Internal) | With Packing |  |
| | | Without Packing |  |

INTENDED PURPOSE:

Used for temporary internal drainage from the Ureteropelvic junction to the bladder. In case of Hydrophilic coated, it is to improve the ease of insertion.

MEDICAL INDICATIONS:

a. Endopyelotomy Stent (External):

- Extrinsic compression of ureter
- Ureteral incision
- Ureteropelvic junction incision
- Stricture dilatation

b. Endoureterotomy Stent (Internal):

Endoureterotomy Stent has been employed to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions. These stents may be placed using endoscopic techniques. In case of Hydrophilic coated, it is to improve the ease of insertion.

TARGET PATIENT POPULATION:

Paediatric and Adult

INTENDED USERS:

Urologist



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CLINICAL BENEFITS:

- Shorter operative time
- Decreased morbidity
- Safe and effective procedure for UPJ (ureteropelvic junction) obstruction
- Minimally invasive treatment
- Long-term success rate
- Symptomatic improvement
- Improved drainage
- Reduced postoperative pain
- Faster convalescence
- No complications during the postoperative period

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE REFERRED:

The link for the Summary of Safety and Clinical Performance (SSCP) is provided below:

<https://devoncath.com/Endopyelotomy-stent-SSCP.pdf>

SPECIFICATION:

a. Endopyelotomy Stent (External):

| Feature | Specifications |
|-------------|----------------|
| Size (F) | 4-14 |
| Length (cm) | 5-28 |

b. Endoureterotomy Stent (Internal):

| Feature | Specifications |
|-------------|----------------|
| Size (F) | 4-14 |
| Length (cm) | 5-28 |

Guidewire Compatibility

| Type | Straight/J tip/ Zebra Crossing | | |
|-----------|--------------------------------|---------------------|-----------------------|
| Material | Stainless steel 304/Nitinol | | |
| Dimension | Stent Size | Guidewire size (In) | Guidewire length (cm) |
| | 4F | 0.025" | 80-400 |
| | 5F | 0.035" | 80-400 |
| | 6F | 0.038" | 80-400 |
| | 7F | 0.038" | 80-400 |
| | 8F | 0.038" | 80-400 |
| | 9F | 0.038" | 80-400 |
| | 10F | 0.038" | 80-400 |
| | 12F | 0.038" | 80-400 |
| 14F | 0.038" | 80-400 | |



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SHELF LIFE:

The Endopyelotomy Stent has a shelf life of 5 years.

IMPLANT CARD:

The required details should be filled in on the enclosed implant card. This card must be handed over to the patient, who should keep it safely for future reference and present it to any urologist when needed.

RESIDUAL RISKS:

- Urinary Tract Infection, Sepsis
- Stent migration, Urinary incontinence
- Contamination or Deterioration of product
- Procedural trauma
- Toxic to environment
- Stent fragmentation, Ureteral avulsion
- Haematuria
- Tissue damage
- Delay in procedure, Inconvenience to the user
- Pain, Bleeding
- Irritation

CONTRAINDICATIONS:

The use of Endopyelotomy stents should be reconsidered if the following conditions exist:

- Contra-indicated surgical candidate
- Unexplained hematuria
- Unrepaired ureteral avulsion

PRECAUTIONS:

- Carefully read all instructions for use and product labeling. The device shall only be applied for its intended use, and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.
- All Health care professionals is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.
- Prior to and during use, inspect the device packaging and product integrity. Do not use the device if the packaging is damaged, opened, or if the product shows any visible defects, as this may compromise sterility and patient safety.
- Ensure proper placement of the stent to avoid migration, kinking, or incomplete drainage.

CAUTIONS:

- The sale of this device is restricted by or on the order of a Urologist.
- Stent placement must be performed only by a qualified urologist. Use by untrained or unauthorized personnel may result in complications such as stent migration.



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WARNING:

- Endopyelotomy Stent are intended for single use only.
- Patients should be advised to immediately report symptoms such as flank pain, fever, hematuria, or difficulty urinating.
- The device materials include polyurethane and hydrophilic coating (for coated stents). Patients may experience allergic or hypersensitivity reactions to these materials.
- **Duration of Use / Expected Lifetime**
 - The stent should not remain indwelling for more than three (3) months. These stents are not intended as permanent indwelling devices
 - Do not use device if there is any indication that the sterility of the device has been compromised
- **Patient Follow-up**
 - Periodic clinical evaluation is recommended to monitor the patient condition and the position/function of the stent.
- **Adverse effects:**
 - Use of this device should be based upon consideration of risk-benefit factors as they apply to your patient. Informed consent should be obtained to maximize patient compliance. Follow up procedures.
- **Reuse**
 - Reusing single-use stents can lead to urinary tract infections in patients.

UNDESIRABLE SIDE EFFECTS:

A slight risk of incontinence (leaking of urine). These side effects are usually due to the stent being inside the bladder and causing irritation. They will disappear when the stent is removed.

POTENTIAL ADVERSE EVENTS:

Migration, sepsis, Encrustation

DIRECTIONS FOR USE:

- Open the package carefully to avoid damaging the stent. Incorrect removal of the stent from the package may lead to contamination or product deterioration.
- This procedure can be performed using either the retrograde or antegrade technique.
- Select the appropriate stent size for the patient. Using an incorrect size may result in stent displacement or shortening, which can cause Stent Migration.

a) Endopyelotomy Stent (External):

- Place the stent over previously placed guide wire.
- Advance the stent into the collecting system to the bladder. Check position of the larger diameter ureteral portion of the stent. Assure that it is placed within the ureteropelvic junction, to prevent post-operative structuring.
- Remove the guide wires slowly. Check for at least a full coil in the bladder, and that the larger stent section is located in ureteropelvic junction. This should be confirmed fluoroscopically.



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b) Endoureterotomy Stent (Internal):

- Pass the guidewire tip beyond the obstruction into the renal pelvis.
- Estimate the proper stent length using a baseline pyelogram; add 1 cm to that estimated ureteral measurement. Accurate measurements enhance drainage efficiency and patient comfort.
- Pass the stent over the guide wire through the cystoscope.
- Advance the stent into the ureter with the stent positioner, under direct vision. Hold the guidewire in position to prevent advancement of the guidewire into the renal parenchyma.
- Watch for the distal end of the stent at the ureterovesical junction. At that point, halt Advancement of the stent.
- As the guide wire is removed hold the stent in position with the positioner.
- The stent pigtail will form spontaneously, carefully remove the positioner.

Note: During the implantation procedure, the device is intended to be used in conjunction with ancillary devices such as a guidewire, positioning sleeve/positioner to facilitate placement of the stent and achieve the intended clinical function of the device. These ancillary devices are not supplied with this product and must be procured separately as compatible CE-marked devices.

POST IMPLANTATION CARE FOR SURGEON/PATIENT:

Following implantation of an Endopyelotomy Stent (internal or external), the patient should be monitored for complications such as flank pain, hematuria, fever, or signs of infection; advised to maintain hydration, avoid strenuous activity, follow prescribed medications, and attend scheduled follow-ups to ensure proper stent function and timely removal.

MATERIAL USED:

Polyurethane

STERILITY:

These stents are supplied in a package which is sterilized by using Ethylene Oxide. Do not use the stent if the package is damaged. If used it leads to Urinary Tract Infection.

STORAGE CONDITION:

Keep in a cool and dry place. Store the Stents at temperatures between 5°C to 40°C. Do not expose to direct sunlight.

MR SAFE:

The device is made of non-metallic polyurethane and is safe for use in the MR environment.

DISPOSITION:













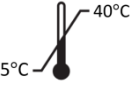









The product shall be disposed as per medical device disposal regulation.

NOTE:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established;



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| SYMBOL | DESCRIPTION | SYMBOL | DESCRIPTION |
|---|----------------------------------|---|--|
|  | MANUFACTURER |  | AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY |
|  | DATE OF MANUFACTURE |  | USE-BY DATE |
|  | BATCH CODE |  | COUNTRY OF MANUFACTURE |
|  | STERILIZED USING ETHYLENE OXIDE |  | DO NOT RESTERILIZE |
|  | DO NOT USE IF PACKAGE IS DAMAGED |  | SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING INSIDE |
|  | KEEP AWAY FROM SUNLIGHT |  | KEEP DRY |
|  | TEMPERATURE LIMIT |  | DO NOT RE-USE |
|  | CONSULT INSTRUCTIONS FOR USE |  | CAUTION |
|  | MEDICAL DEVICE |  | UNIQUE DEVICE IDENTIFIER |
|  | PATIENT IDENTIFICATION |  | PATIENT INFORMATION WEBSITE |
|  | HEALTH CARE CENTRE OR DOCTOR |  | DATE |





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