
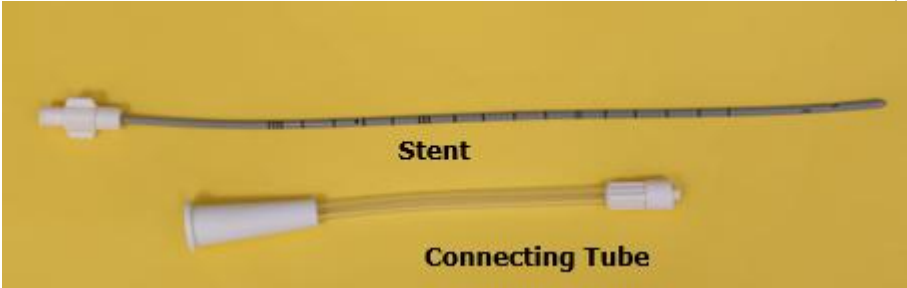




**DEVON INNOVATIONS PRIVATE LIMITED
BANGALORE**

Urethral Stents - With/Without Hydrophilic coated

Product Name	Packing	Image
Urethral Stents- With/without Hydrophilic coated	With Packing	
	Without Packing	

INTENDED PURPOSE:

Used for stenting the Urethra after Hypospadias or Epispadias repair and to provide postoperative drainage of the bladder. In case of Hydrophilic coated, it is to improve the ease of insertion.

MEDICAL INDICATIONS:

- Hypospadias or Epispadias repair
- Postoperative drainage of urine from the bladder

TARGET PATIENT POPULATION:

Paediatrics and Adults

INTENDED USERS:

Urologist

CLINICAL BENEFITS:

- Satisfactory stent drainage.
- Minimal local tissue reaction.
- Stenting can reduce early urethral strictures
- Reduced post-operative complications
- Easy to insert
- Provides better relief than surgery.
- Patient comfort
- Increased success rate
- Minimal complications during the removal
- Low incidence of failure.



**DEVON INNOVATIONS PRIVATE LIMITED
BANGALORE**

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE REFERRED:

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

https://www.devoncath.com/Urethral_stent_SSCP.pdf

SPECIFICATION:

Feature	Specifications
Size (F)	5,6,7,8,10,12,14,16
Length (cm)	20, 25

Guidewire Compatibility

Type	Straight/J tip/Zebra Crossing		
Material	Stainless steel 304/Nitinol		
Dimension	Stent Size	Guidewire size (In)	Guidewire length (cm)
	5F	0.035"	80-400
	6F	0.038"	80-400
	7F	0.038"	80-400
	8F	0.038"	80-400
	10F	0.038"	80-400
	12F	0.038"	80-400
	14F	0.038"	80-400
16F	0.038"	80-400	

SHELF LIFE:

The Urethral Stents 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
- Procedural trauma
- Contamination or Deterioration of product
- Toxic to environment
- Stent fragmentation, Ureteral avulsion
- Haematuria, Bleeding
- Tissue damage
- Delay in procedure, Inconvenience to the user



**DEVON INNOVATIONS PRIVATE LIMITED
BANGALORE**

CONTRAINDICATIONS:

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

- Contra-indicated surgical candidate
- Unexplained hematuria
- Unrepaired ureteral avulsion
- Contraindications specific to the antegrade technique
 - Active urinary tract infection
 - Severe bladder dysfunction
 - Uncontrolled coagulopathy or bleeding disorders

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 correct positioning of the stent to prevent migration or displacement.

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.

WARNING:

- Urethral Stents are intended for single-use only.
- In case of signs of urinary tract infection (fever, pain, burning sensation, hematuria), seek immediate medical attention.
- **Duration of Use / Expected Lifetime**
 - The stent should not remain indwelling for more than three (3) months. These stents are not indented 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.



**DEVON INNOVATIONS PRIVATE LIMITED
BANGALORE**

- **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.
- Insert a guidewire to facilitate accurate stent positioning.
- Advance the stent into the urethra into the bladder with the help of Guidewire.
- After completion of the corrective surgery for hypospadias or epispadias, the urethral stent should be securely sutured using absorbable suture to the external urethral meatus to ensure proper positioning and prevent displacement.
- The stent must be connected to the urine collection system or urine bag using the provided connecting tube.
- The stent remains in place for 30 to 35 days. During the healing process, the sutures are naturally absorbed, and the stent is typically expelled on its own during urination. If it is not expelled spontaneously, it must be removed by a urologist.

POST IMPLANTATION CARE FOR SURGEON/PATIENT:

After placement of a urethral stent, proper care is essential to ensure healing and prevent complications. The surgical site should be kept clean and dry, and the stent must be monitored for correct positioning. Patients should maintain good hydration and avoid strenuous activities. Pain and infection should be managed with prescribed medications, and any signs of fever, blockage, or dislodgement must be reported immediately.

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 infections.



**DEVON INNOVATIONS PRIVATE LIMITED
BANGALORE**

STORAGE CONDITION:

Keep in cool and dry place. store the Stents at temperatures between 5°C to 40°C. Do not expose to direct sun light.

MR SAFE:













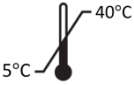





The device is made of non-metallic polyurethane and is safe for use in the MR environment.

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;

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



**DEVON INNOVATIONS PRIVATE LIMITED
BANGALORE**

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	PATIENT IDENTIFICATION		PATIENT INFORMATION WEBSITE
	HEALTH CARE CENTRE OR DOCTOR		DATE



Amstermed BV

Saturnusstraat 46-62, Unit 032,
2132 HB Hoofddorp
The Netherlands.

Email: info@amstermed.nl

Tel: +31 23 56 56 337



DEVON INNOVATIONS PRIVATE LIMITED

No:27A, Near State Bank of India, Electronic city Phase-I,
Hosur Road, Bangalore-560 100, India.

Phone: (080) 28522367, 28522368

Email: sales@devoncath.com

Website: <https://www.devoncath.com>