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BANGALORE**

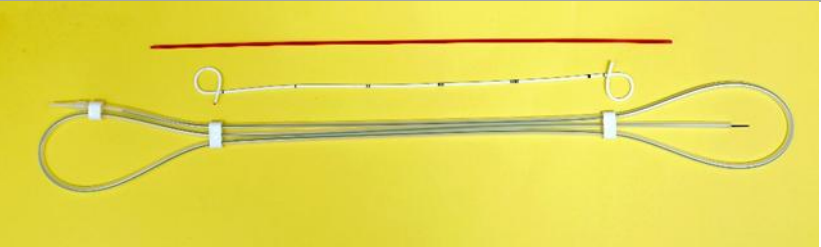
**Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated**

**VARIANTS:**

Product Name	Variant Name	Packing	Image
Ureteral Indwelling Pigtail Stent/Set- With/without Hydrophilic coated	Single pigtail stent	With Packing	
		Without Packing	
	Double Pigtail Stent	With Packing	
		Without Packing	
	Multi Length Stent	With Packing	
		Without Packing	
	Set	With Packing	



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Product Name	Variant Name	Packing	Image
		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:**

- Obstruction from urolithiasis
- Malignant obstruction (typically pelvis malignancies)
- Benign strictures
- Retroperitoneal fibrosis

**TARGET PATIENT POPULATION:**

Pediatric and adult

**INTENDED USERS:**

Urologist

**CLINICAL BENEFITS:**

- It promotes ureteral healing
- Prevents complications of ureteral obstructions
- Reduction of extravasations around ureter
- Morbidity is minimal
- Safe and useful to treat upper urinary tract diseases.
- Maintain renal function, relieve pain.
- Aid passage of upper urinary calculi after ureteroscopic lithotripsy
- Better surgical outcomes
- High success rate
- Reduces SRSs (Stent related symptoms)

**SUMMARY OF SAFETY AND CLINICAL PERFORMANCE REFERRED:**

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





[https://devoncath.com/Ureteral-Indwelling-stent-SSCP\\_20-Mar-2025.pdf](https://devoncath.com/Ureteral-Indwelling-stent-SSCP_20-Mar-2025.pdf)

**URETERAL INDWELLING PIGTAIL STENT SET COMPONENTS:**

The following accessory is supplied only along with Ureteral Indwelling Pigtail Stent Set.



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#	Accessory Name	Variant Name	Image	Intended Use	Usage
1.	Guide wire	Straight/J-tip		Guidewires facilitate the delivery of wide variety of Catheters and Stents to a Medical procedure site within the body. In case of Hydrophilic coated, it is to improve the ease of insertion.	Single use
					
		Zebra crossing Nitinol (Straight/J-tip)			
					

**SPECIFICATION:**

- i. Single pigtail Stent/ Double pigtail stent/ Multi Length Stent

STENTS		GUIDEWIRE	POSITIONER
Size(*F)	Specify Length(cm)	Diameter(inches)	Size (*F)
2.5F	6-70CM	0.018"	3F
3F	6-70CM	0.018"	4F
3.5F	6-70CM	0.018"	4F
3.7F	6-70CM	0.018"	4F
3.8F	6-70CM	0.018"	4F
4F	8-70CM	0.025"	4.5F
4.5F	10-70CM	0.028"	5F
4.7F/4.8F	10-70CM	0.032"	5F
5F	10-70CM	0.035"	6F
5.5F	10-70CM	0.038"	6F
6F	10-70CM	0.038"	6.5F



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6.5F	10-70CM	0.038"	7F
7F	10-70CM	0.038"	7F
7.5F	10-70CM	0.038"	7.5F
8F	10-70CM	0.038"	8F
9F	10-70CM	0.038"	9F
10F	10-70CM	0.038"	10F

**F – FRENCH**

**SHELF LIFE:**

The Ureteral Indwelling Pigtail 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
- Stent Migration
- Contamination or Deterioration of product
- Stent fragmentation
- Haematuria
- Toxic to Environment
- Tissue Damage
- Delay in procedure, Inconvenience to the user

**CONTRAINDICATIONS:**

The use of ureteral 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, carefully inspect the stent and packaging for any signs of damage, kinking, or contamination. Do not use if the device is damaged or the packaging is compromised. Regular follow-up is recommended to monitor stent position and function. Extended indwelling



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time beyond the recommended duration increases the risk of encrustation and other complications.

**CAUTIONS:**

- The sale of this device is restricted by or on the order of a Urologist.

**WARNING:**

- All components of the Pigtail Stent / Stent Set are for single use only.
- Stop using the stent if the patient has unusual symptoms like pain, blood in urine, infection signs, or trouble urinating. These could mean the stent is not working properly and may need to be removed or replaced.
- **Duration of Use**
  - Periodic evaluation is advised. The Stent must not remain indwelling more than three 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.
- **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:**

- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Open the package carefully to avoid damaging the stent. Incorrect removal of the stent from the package may lead to contamination or product deterioration.
- Pass the guidewire (included only with the stent set) tip beyond the obstruction using retrograde technique. Use of the antegrade technique is not recommended.
- Estimate the proper stent length using a baseline pyelogram; add 1cm to that estimated ureteral measurement. Accurate measurement enhances drainage efficiency and patient comfort.
- Pass the stent over the guidewire 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.



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- Watch for the distal end of the stent at the ureterovesical junction. At that point halt advancement of the stent.
- As the guidewire is removed hold the stent in position with the positioner.
- The stent pigtail will form spontaneously, carefully remove the positioner.

**POST IMPLANTATION CARE FOR SURGEON/PATIENT:**

Patients should be advised to drink plenty of fluids and avoid physical activity that requires a lot of effort and strength like Heavy lifting, High intensity workouts.

If they experience severe discomfort or concerning symptoms such as pain, discoloration while urinating or blood in the urine, they should consult a healthcare professional.

**MATERIAL USED:**

Polyurethane/Carbothane

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

**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



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SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	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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