Instruction for Use

Hydro Affinity Stent

Device Description

The Hydro Affinity coating enhances the ease of inserting the stent. The surface of the stent is exceptionally smooth, allowing it to pass through the delicate ureter with minimal friction. When exposed to fluids, the surface of the stent becomes hydrophilic, creating a cushion-like effect between the stent and the surrounding tissue, ensuring a smooth and frictionless insertion process. Additionally, the tapered tip of the Hydro Affinity stent facilitates easier maneuverability around ureteral obstructions. The configurations available include:

Family	Accessories	Size (x 0.1 Fr.)	Length (cm)	Type	Variants
Hydro Affinity Stent	Pusher	2.5	6	OEO (One End Open), BEO (Both Ends Open), BEC (Both Ends Closed), BESL (Both Ends Single Loop), OEML (One End Multi Loop), BEML (Both Ends Multi Loop)	Hydro Affinity Blue Stent, Hydro Affinity Green Stent, Hydro Affinity White Stent, Hydro Affinity Black Stent, Hydro Affinity Yellow Stent
	Guide Wire	3.0	8		
	Suture	3.5	10		
	Clamp	3.8	12		
	Steerable Pusher	4.0	14		
		4.5	16		
		4.7	18		
		4.8	20		
		5.0	22		
		5.5	24		
		6.0	26		
	NOTE: The accessories mentioned above are provided based on the device requirement.	6.5	28		
		7.0	30		
		8.0	32		
		9.0	34		
		10.0	36		
			38		
			40		

Intended Purpose

The Hydro Affinity Stents are indicated for use in Urology procedures to ensure the patency of a Ureter. It is used to drain the urine from the kidney into the bladder in the case of a blockage.

Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Medical Conditions to Be Treated

- Ureteral obstruction
- Kidney stones causing urinary blockage
- Post-surgical ureter stabilization
- Leaking or dysfunctional ureter
- Ureteral stricture

Performance Characteristics of the Device

The Urological Catheters or Double-J refers to the shape of the stent ends (“J-Shaped” Curled ends) where one is anchored in the renal pelvis and the other inside the bladder in order to prevent its displacement. The DJ Stent is placed in the ureter, which functions as a low pressure, stretchy tube with its own peristalsis. Ureteric stents may be placed from an antegrade approach by an interventional radiologist or a retrograde approach by a urologist. Stent placement may replace a percutaneous nephrostomy that has been performed in the acute setting. This method is widely used as it internalizes the methos of obstruction bypass without the negatives of a nephrostomy.

Indications

- Stabilization of Ureter after Surgery.
- To provide drainage through a ureter that is obstructed, leaking, dysfunctional or structured in patients with Urinary Obstruction or Kidney Stone.

Contraindications

- Patients with Urinary Bladder Outlet Obstruction.
- Bladder Fistulas
- Spastic/ noncompliant bladder
- Uncorrectable Coagulopathy
- Uncooperative Patient

Precautions & Warnings

Carefully read all instructions for use. Do not use this product without reading and understanding the complete instructions enclosed herein.
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.

Precautions:

- The intended user of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures authorized by the Competent Authority of the country in which the Physician is practicing.
- Each physician is responsible for using the appropriate technique and deciding on the indication for use of this device.
- Monitor the stent as required. It is recommended that indwelling time should not exceed THIRTY (30) days to avoid cord encrustation.
- 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.
- Device is not recommended for use in patients with the above-mentioned contraindicated conditions.
- A pregnant patient must be more closely monitored for possible stent encrustation due to calcium supplements. Individual variations of interaction between stents and the urinary system are unpredictable.
- Store the Hydro Affinity Stent at a temperature between 12-35^0 C and a Humidity range of 30-75%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

Warnings:

- All components of the “Hydro Affinity Stent” are for single use only.
- The product must not be re-used. Reusing of single-use devices can lead to potentially serious consequences for the patient such as: Bio-contamination due to release of infectious agents from device into the body which further may result in Urinary Infection.
- Do not use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.

- Do not reprocess or re-sterilize, reprocessing or re-sterilization may compromise the structural integrity of the device and /or lead to failure which, in turn, may result in patient injury.

Intended Patient Population

- The intended patient population for the device is patients of age 18 years and above.
- Recommended for use in both Male and Female patients.

Shelf-life

The shelf life of the Hydro Affinity Stent is 3 years (Indicated on product label with the following use-by symbol).

Sterility – This product is Sterile unless the package has been opened or damaged

- The Hydro Affinity Stent have been sterilized by exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage of Urinary System.
- The "Hydro Affinity Stent" are packed single. Product in each pack must be utilized immediately when opened.

Directions for Use

Open the package from the Chevron Side ('V' Notch) of the pouch.

Placement method from the bladder (retrograde)

- Placement of stent to be done after treating the patient with general anesthesia.
- Insert a cystoscope through the urethra and into the bladder, visualizing the opening to the ureter.
- A suitable guidewire is then guided through the cystoscope, up the ureter, and onto the kidney.
- The Hydro Affinity Stent is inserted over the wire.
- Withdraw the guidewire slowly to allow distal coil to form in the renal pelvis.
- A Fluoroscope (a kind of x-ray machine) or x-ray may be used to confirm the position of the stent.
- Once the stent is firmly in place, remove the cystoscope.

Placement method from renal pelvis (antegrade)

- Insert an Indwelling needle from the surface of the kidney to the renal pelvis and insert the dilator tube to the distal side of the ureter while handling the tip of the outer tube.
- Insert the guidewire into the dilator tube and insert to the bladder.
- Pull out the dilator tube and insert the stent tube along the guidewire.
- Insert the dilator tube again along the guidewire, push one side of the stent tube into the bladder, then remove the dilator tube.
- Place the stent tube in place. Confirm that a loop has formed in the bladder and renal pelvis.
- Withdraw the guidewire slowly
- The incision on the ventral side of the bladder is sutured and closed.

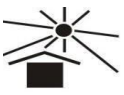
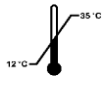
Removal Instructions

- Removal of the stent to be done after treating the patient with a local anesthetic.
- Insert a cystoscope through the urethra into the bladder of the patient.
- The stent is grasped using a stent remover and removed.
- In cases where suture has been left attached to the end of the stent, the suture is allowed to come out of patient's urethra since the time of insertion of the stent. The stent can be removed by gently pulling the suture.
- If resistance is encountered during removal of the Stent, stop and determine cause of resistance before proceeding.

Disposal Instructions

Dispose of all equipment, in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
REF	Catalogue Number	UDI	Unique Device Identifier	2 STERILIZE	Do not re sterilize	CC	Country of Manufacture	MD	Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
LOT	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use	75% % 30%	Humidity Limit
STERILE EO	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		

Bibliography

- Contraindications:https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3312172/#:~:text=of%20the%20ureter.,CONTRAINDICATIONS,Uncorrectable%20coagulopathy%20is%20a%20contraindication.
- Single use medical device: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices- Information to be supplied by the manufacturer.