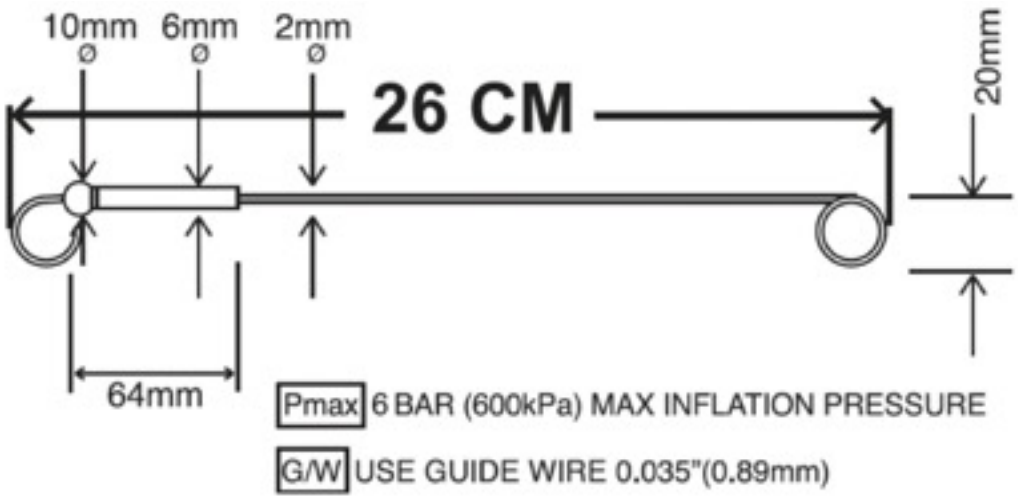
INSTRUCTIONS FOR USE

OVERTOOM
BALLOON CATHETER SYSTEMS®

Catheter Technical Details



Balloon Catheter System®

Device name
The device brand name is the Overtoom Balloon Catheter System®

Device Description
The Overtoom Balloon Catheter System comprises a catheter with a balloon and a non-return valve device and a pusher device with a stylet and two ports.

The sideport of the delivery device is for injecting contrast agent to inflate the balloon, while the straight port is for the guidewire. The catheter has a relatively large-diameter central lumen and a shaft of 2 mm (6 Fr.). The balloon is in two sections: a long narrow shaft section and a larger cranial bulb *.

The balloon is inflated by an injection of contrast agent via the pusher and remains in situ until the expanded urothelium heals. During the healing process urine drains through the wide central lumen. The Overtoom Balloon Catheter may be used in conjunction with a JJ stent for additional drainage. After use the balloon is deflated by snipping the distal end of the catheter. The catheter can then be removed.

**Standard: cranial bulb diameter 10 mm; balloon shaft diameter 6 mm; length 64mm*

How supplied

The pusher, stylet, and grip accessories necessary to operate the device are provided as part of the device.

Intended Use

The Overtoom Balloon Catheter is an inflatable stent intended for the treatment of obstructions (strictures) of the ureter and, in particular, strictures of the ureteropelvic junction after a prior treatment with high pressure balloon dilatation. The device when deployed is intended to remain in situ for up to 30 days to keep the ureter strictures dilated and to allow temporary flow of urine from the pyelum to the bladder through its wide central lumen. It is not intended for use with patient less than 150 cm tall.

Contraindications

It is contraindicated may include but are not limited to the following situations:

- Where a urine infection or infection of the urinary tract is present including pyelonephritis or pyonephrosis
- When kidney or ureter diseases are present
- In patients with presence of stones particularly those that develop very fast kidney stones.
- In patients with bleeding tendency
- In patients that have outsized ureters
- In patients that have crossing lower pole arteries compressing the ureter
- In patients that have ureter-pyeluminvagination
- In patients that have 'high insertion' of the ureter

Materials required not supplied

In addition the device is intended to be used with the following standard accessories that are not provided:

- Guide Wire: This device is intended to be used with a guide wire of 0.035” (0.89 mm). (Recommended guide wire: Terumo® Radifocus® Stiff Type Angled; diameter 0.035. (0.89 mm) length 180 cm)
- Contrast Media: This device is intended to be used with ionic or non-ionic contrast agent to inflate the balloon
- Predilation balloon catheter: This device can be used to predilate the stricture prior to insertion of the Overtoom Device
- Straight catheter: this device can be used to visualise and locate the guidewire
- Inflation device with gauge
- JJ stent: this device can be used in conjunction with the overtoom balloon to provide additional drainage space

Warnings

Do not resterilize or reuse.

The Overtoom Balloon Catheter System is designed for once-only use and must be discarded after the procedure. No attempt should be made to reuse any part of the device. The device cannot be cleaned adequately after exposure to biological materials and attempts to clean it can affect the structural properties of the materials used.

Treatment of a double sided obstruction in one session should not be undertaken.

While the device is in place the patient is not allowed to do sports, exercises or lift heavy things or to do extreme flexions of the hips, to prevent migration of the device.

Ensure the device is removed on or before 30 days

Ensure device is not used in the incorrect part of the body

Ensure device is located correctly before deployment

The following action should be taken to safely remove the system in the unlikely event of failure:

If the balloon will not inflate: Do not detach the catheter. Slowly and gently remove the entire system.

If the stylet (pusher mandrel) fails to remove the catheter with inflated balloon from the pusher:

Deflate the balloon by cutting the distal tip of the catheter 1 cm or more from the distal tip.

Withdraw the detached pusher. Take care to ensure the cut tip section is attached to pusher or remove it from the bladder.

After the balloon is deflated slowly and gently withdraw the catheter.

In the case that the balloon does not deflate after cutting the catheter at the distal tip:

An experienced physician can carry out a needle puncture of the balloon per standard hospital protocol.

The renal system is unpredictable and therefore variation in the interaction between the stents and urinary system are unpredictable.

- Never under any circumstances should resistance be ignored. If resistance is encountered, remove device and determine cause of resistance. Forcing the device may cause perforation or tears.
- Do not inflate with air
- Remove air before filing with fluid
- Do not over-inflate, 2 bar(200kPa) is min, 6 bar is maximum pressure
- Use in primary strictures only

It is not advisable to use the catheter in the following situations:

- Malignancy
- Abnormal sediment
- Glucose or protein in urine
- Strictures longer than 3-4 cm
- Recent myocardial infarction
- Strictures due to prior radiation
- Mono kidney or transplantation kidney
- Pyelocaliceal volume exceeding 100 ml.
- Kidney function of less than 10 to 15 %
- Diseases of the ureter/kidney
- Ensure physician's record and patient's record are completed to avoid a "forgotten" stent
- All JJ catheters including the Overtoom catheter can eventually become blocked by debris and/or sludge in the urine.

General precautions

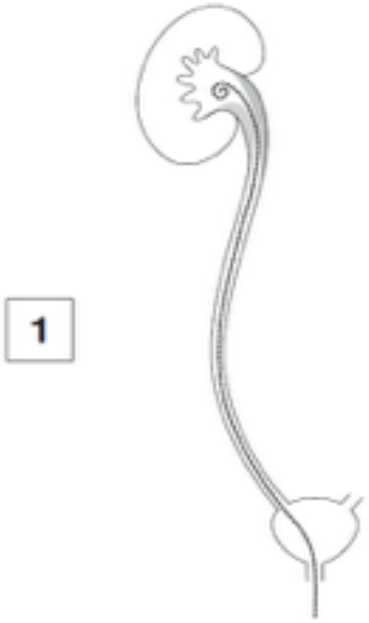
- The Overtoom Balloon Catheter System is intended for use solely by appropriately trained physicians.
- The Overtoom Balloon Catheter System is supplied sterile. Do not use if the packaging is open or damaged.
- Carefully inspect the system prior to use to verify that it has not been damaged during shipment and that it is the right size for the envisaged procedure.
- Store the system in a cool, dark place. Do not expose it to organic solvents or UV radiation.
- Ensure the system is used before the "Use Before Date" date shown on the package label. The polymers used in this product can deteriorate with age.
- The patients are advised to drink a lot of water to prevent concentrated urine.
- All patients must also be aware of, and agree to comply with the follow up requirements
- Patient must be willing and able to have possible surgery in the event of a complication

Specific precautions

- Positioning and dilatation should only be performed under high-resolution fluoroscopy.
- Ensure that the distal and proximal diameters of the balloon do not exceed the diameters of the ureter immediately distal and proximal to the stricture.
- Only inflate the balloon using ionic or nonionic contrast agent. (preferably ionic)
- Do not overinflate the balloon. Overinflation may cause damage or injury.
- The max pressure is 6 bar (600kPa).
- Do not attempt to advance the guide wire or catheter system against significant resistance. The cause of resistance should be determined via fluoroscopy and remedial action taken.
- Never advance the catheter beyond the end of the guide wire.
- It is advisable and highly recommended to place the stent alongside an additional double pigtail stent for additional drainage post operatively.
- Although not required a pre-operative treatment with a double pigtail stent is also advisable to remove from a longtime obstructed pyelum, cellular and other debris to prevent obstruction of the UPJ-balloon-stent and to induce the tone-dependant pyelum volume reduction before treatment.
- It is recommended to flush the pyelum several times after the balloon dilatation to get rid of as much of the debris as possible prior to final placement of the system.

ROCEDURE

A: Predilation procedure where balloon dilation UPJ stenosis is used



STEP 1: Insert Guidewire

Introduce a straight catheter into the ureter and inject ontrast agent.

Pass the guide wire (0.035.) via the straight catheter and the ureter into the renal pelvis (recommended guide wire: Terumo® Radifocus® Stiff Type Angled; diameter 0.035 (0.89 mm), length 180 cm).

When guidewire is correctly in place, retract the straight atheter.

STEP 2: Predilation (if performed)

Pass an appropriately sized high pressure predilation alloon catheter over the guidewire.

CAUTION The urologist must select the correct length and diameter. Typical sizes for the diameter are between 6 and 9 mm. The length depends on the length of the stenosis.

Position the high pressure dilatation balloon catheter in stricture.

Inflate balloon fully until “waist” caused by stricture disappears per the manufacturer’s instructions. Pressure allowed will be per manufacturer’s instructions.

Leave inflated balloon in situ for at least 5 minutes to prevent bleeding.

3

STEP 3 Removal of predilation catheter

Deflate balloon.

Retract balloon over guide wire.

4

B: Overtoom Device Insertion Technique

STEP 4 Insert Overtoom Device

The device as supplied consists of the Overtoom catheter physically connected to the pusher.

Rotate the port assembly (A) to match the recess in the finger grip (B) and push fully home until it clicks.

Pass the Overtoom Balloon Catheter over the guide wire.

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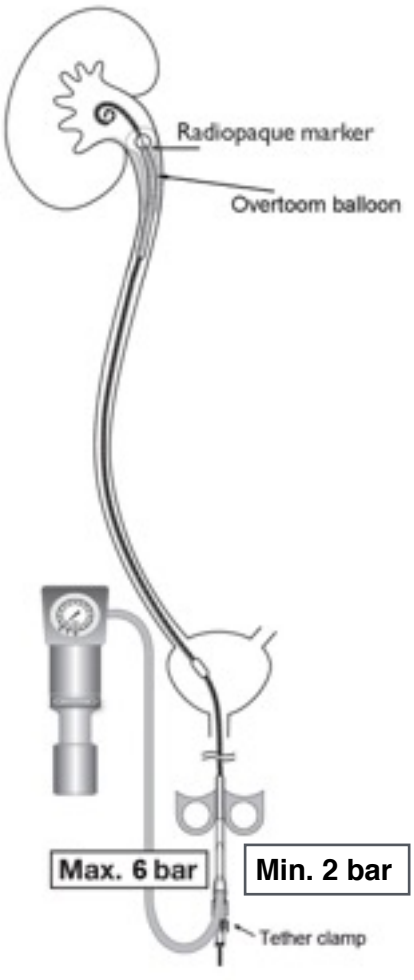
STEP 5 Position the Device

Advance the catheter with the pusher until the radiopaque marker is just above the cranial end of the stenosis.



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STEP 6 Inflate the device

Connect the sideport of the pusher to the inflation device. Remove air by aspiration. Inflate the balloon until it is fully deployed (opening pressure 2 to 3 bar). Inflate to 2 bar and check manometer not dropping. Reinflate to 3 bar if dropping and check again. Repeat until manometer does not drop which indicates balloon fully deployed.
Do not exceed 6 bar (600kPa)

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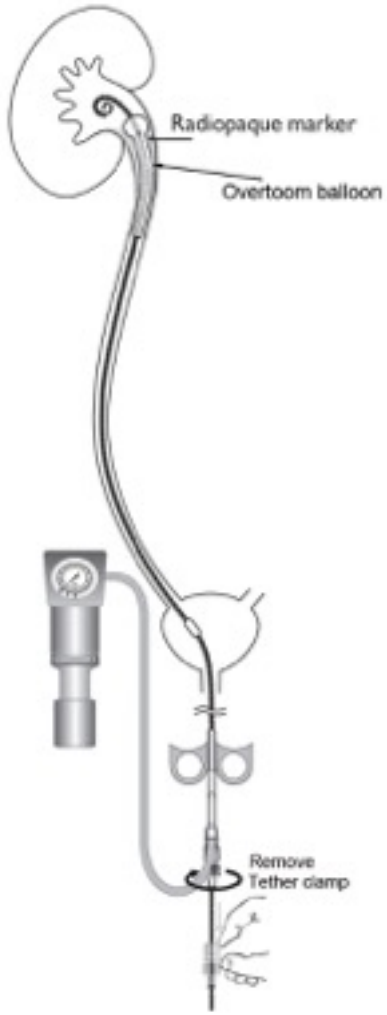
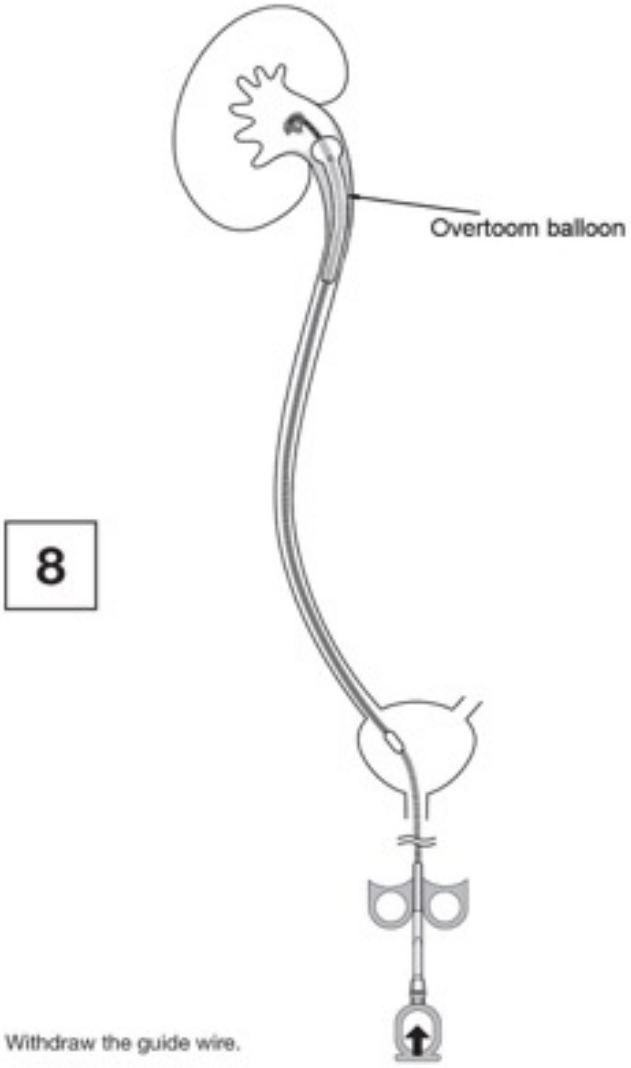


STEP 7 Remove tether clamp

This will remove the tether connected with the inflated balloon catheter to unlock the system.



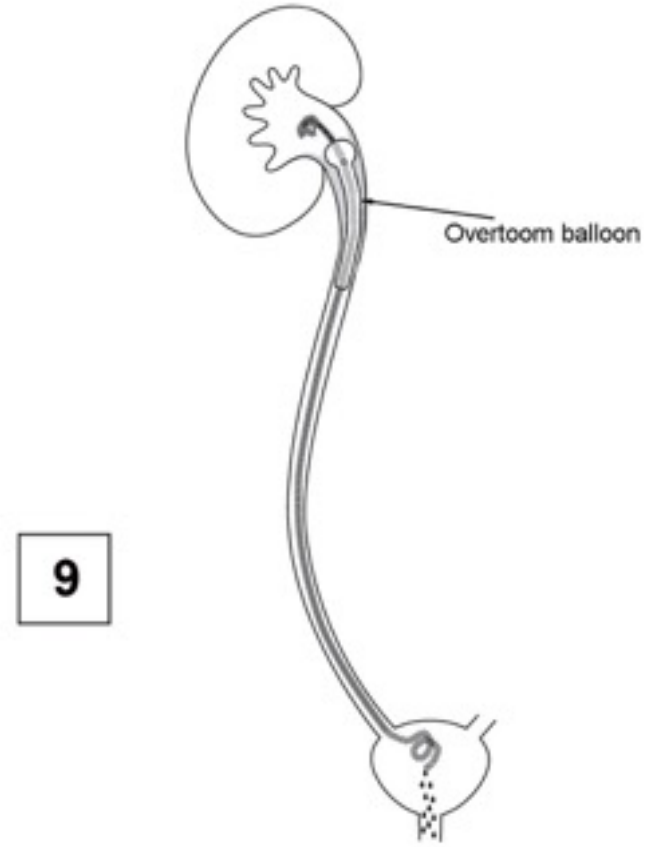
STEP 8 Deploy the device and remove pusher

Withdraw the guide wire. Insert stylet in the pusher *(CAUTION: Do not insert further than the black marker at this time)*.

Push the pusher until the connector section that is located between the device and pusher is in the bladder and ensure that the coils are correctly deployed, free of the bladder wall, to prevent irritation.

Holding the pusher in place with the finger grips, push the stylet fully home until the black marker is no longer visible. This will detach the system, leaving the balloon fully inflated. Note:this can be carried out single handedly by placing finger in the finger grip and thumb in the stylet hoop. Withdraw the pusher, stylet and inflation device.

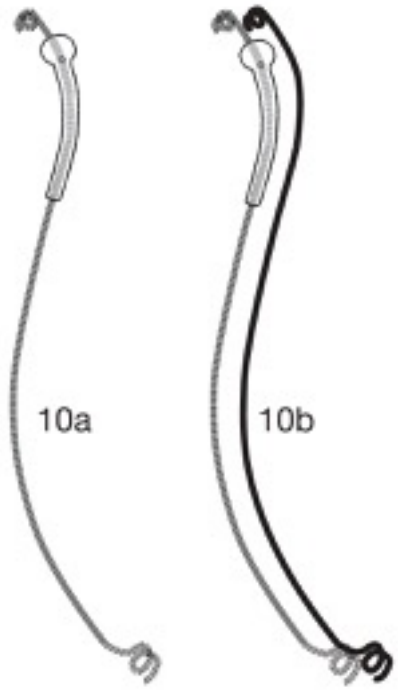
The inflated balloon can be left in situ for up to 30 days allowing drainage and giving time for the expanded urothelium to heal.



Device Removal

In the case of a female patient, the catheter tail can be withdrawn through the urethra during cystoscopy and cut 1 cm or more from the distal tip. This will deflate the balloon.
After the balloon is fully deflated, slowly and gently withdraw the catheter.
In the case of a male patient, the catheter tip can be cut within the bladder during cystoscopy and withdrawn using biopsy forceps.

Combined use:
The Overtoom Balloon Catheter System may be used:



-Alone (fig 10a)
-In conjunction with a JJ stent (fig 10b).
In this case first place back a JJ catheter before inflating the balloon. This option provides additional draining space, reducing the chance of renal colics due to debris or sludge in the catheters(s). However, it is recommended that a JJ stent should be in situ for at least 14 days before the Overtoom Balloon Catheter System is inserted.

Potential adverse events

- pain
- device encrustation
- bladder irritability
- hematuria
- dysuria
- infection
- discomfort
- reduced renal function
- relapse of obstruction after removal
- obstruction of renal flow
- additional cystoscopic procedure to remove the stent
- allergic reaction to contrast media
- faillure to correct UPJ obstruction

Literature reference

AJR Am J Roentgenol. 2009 Apr;192(4):1103-6. Treatment of Ureteropelvic Junction Obstruction Using a Detachable Inflatable Stent: Initial Experience.

Timotheus T. C. Overtoom [1], Peter L. Vijverberg [2], Hendrik W. van Es [1], Sandrine van Selm [2] and Hans P. M. van Heesewijk [1]

[1] *Department of Radiology, St. Antonius Hospital, Koekoekslaan 1, Nieuwegein, Utrecht 3435CM, The Netherlands.*

[2] *Department of Urology, St. Antonius Hospital, Nieuwegein, Utrecht, The Netherlands..*

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