OPTILUME®

URETHRAL DRUG COATED BALLOON CATHETER

URETHRAL DRUG COATED BALLOON DILATION CATHETER

Instructions for Use

1.0 DEVICE DESCRIPTION

1.1 Balloon Catheter

The Urethral Drug Coated Balloon (DCB) Dilation Catheter is a 0.038" (0.97 mm) over-the-wire (OTW) guidewire compatible catheter with a dual lumen design and a tapered atraumatic tip. Balloon diameters of 6mm-10mm (18Fr-30Fr) are flexible cystoscope compatible. The Optilume DCB is used to exert radial force to dilate narrow urethral segments (strictures). The distal end of the catheter has a semi-compliant inflatable balloon that is coated with a proprietary coating containing the active pharmaceutical paclitaxel. The drug coating covers the working length of the balloon body. The device has two radiopaque marker bands that indicate the working length of the balloon.

The device is sterilized using ethylene oxide in a Tyvek pouch. Post sterilization the pouched catheter is sealed in a foil pouch with desiccant and contained within a single unit carton. Each DCB is supplied with a protective sheath that covers the drug-coated balloon portion of the catheter. A balloon compliance chart is located on the Tyvek pouch label.

1.2 Drug Coating

The drug coating consists of the active pharmaceutical ingredient paclitaxel and excipients. The drug coating covers the working length of the balloon component of the catheter. The drug coating is evenly distributed across the balloon surface at a concentration of 3.5 µg/mm2. The key functional characteristic of the drug coating is to allow for release of the paclitaxel to the urothelium during balloon inflation.

DCB Dosing Matrix

Catalog Number	Diameter (Fr/mm)	Length (mm)	Paclitaxel Dose (mg)
1110-06030E	18.0/6.0	30	2.0
1110-06050E	18.0/6.0	50	3.3
1110-08030E	24.0/8.0	30	2.6
1110-08050E	24.0/8.0	50	4.4
1110-10030E	30.0/10.0	30	3.3
1110-10050E	30.0/10.0	50	5.5
1110-12030E	36.0/12.0	30	4.0
1110-12050E	36.0/12.0	50	6.6
1110-14030E	42.0/14.0	30	4.6
1110-14050E	42.0/14.0	50	7.7

2.0 INTENDED USE

Optilume Drug Coated Balloon (DCB) Catheter is intended for the treatment of strictures in the anterior urethra in adult males.

3.0 INDICATIONS FOR USE

Optilume DCB Catheter is used to treat patients with bothersome urinary symptoms associated with de novo or recurrent anterior urethral stricture. It is de signed to be used in adult males as a standalone dilation balloon for a single ure thral stricture of ≤3 cm in length or used as an adjunctive therapy with other dilation devices and/or procedure.

4.0 CONTRAINDICATIONS

The Urethral Drug Coated Balloon (DCB) Dilation Catheter is contraindicated for use in:

- Patients with known hypersensitivity to paclitaxel or structurally related compounds.

5.0 WARNINGS

- The urethral DCB is supplied STERILE for single use only. Do not reprocess or resterilize. Reprocessing and resterilizing could increase the risk of patient infec tion and risk of compromised device performance.
- The foil pouch and the outer surface of the inner pouch are NON-STERILE. The CONTENTS of the inner pouch are STERILE. Use Immediately once the foil pouch has been opened.
- Do not use this device if there is infection in the Urethra (UTI) or Bladder. Infec tion must be cleared before treating the stricture with the Optilume DCB.
- The DCB should be used only by physicians who are experienced and knowledge able of the clinical and technical aspects of urethral balloon dilatation.
- Prior to use of the DCB, physicians should read and understand the instructions for use. Failure to follow the indications, contraindications, restrictions, warnings and precautions may result in complications.
- Do not use after the “Use By” date.
- The DCB contains paclitaxel, a known genotoxin. Do not use the DCB in women

who are breastfeeding, pregnant or intending to become pregnant. Men should have protected sex (wear a condom) for 30 days post treatment.
- Monitor for signs of anaphylaxis or hypersensitivity to Paclitaxel
- Never use air or any gaseous medium to inflate the DCB.
- When in use the DCB should be manipulated under direct visualization via cystos copy or high quality fluoroscopic observation.
- Do not manipulate the DCB in an inflated state.
- If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to device or lumen. Carefully with draw the catheter.
- Men with sexual partners of childbearing potential should use condom for at least 90 days post-treatment.

6.0 PRECAUTIONS

- Always inflate with a sterile liquid (Sterile Saline or 50% contrast mixture). Never inflate with air, carbon dioxide or any other gas. The DCB should not be inflated beyond the rated burst pressure (RBP). Do not overinflate the balloon.
- Balloon catheters are intended for use by physicians trained and experienced in techniques for balloon catheter dilation.
- To ensure proper regulation of balloon pressure, use of a balloon inflation device with pressure gauge is recommended.
- Aspirate the balloon completely before gently removing the device from the urethra. Using excessive force to withdraw the balloon can inflict trauma to tissue.
- Carefully inspect the DCB and package prior to use. Do not use the catheter if it is damaged or if the size, shape or condition is unsuitable for the intended procedure.
- Do not immerse or wipe the balloon section of the DCB with any fluid as the integrity of the drug coating may be damaged or compromised. Replace any DCB where the balloon has come in contact with fluids prior to use.
- Use dry sterile gloves or dry gauze pads to handle the DCB prior to use. Care should be taken to minimize contact with the coated balloon portion of the device.
- Never inflate the DCB outside the body or prior to reaching the target stricture as it may disrupt the coating integrity.
- Do not attempt to pass the DCB through a smaller French size cystoscope than indicated on the label.
- The DCB working length must cover the entire target stricture length.
- For proper drug delivery to the target stricture, allow the coating to hydrate in the urethra for a minimum of 60 seconds prior to inflation and maintain inflation of the DCB for a minimum of 5 minutes. To optimize stricture dilatation, longer inflation times > 5 minutes may be performed at the discretion of the operator.
- If the product has a failure prior to, or during inflation replace DCB and inflate per procedure. If failure is after inflation to RBP do not repeat DCB procedure.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local regulations.

- Healthcare practitioners should avoid using latex gloves to prevent possible allergic reactions by patients who are allergic to latex.
- Urethral lumen preparation of the target lesion, using the appropriate lumen preparation method as determined by the treating physician, is required prior to the use of the Optilume DCB.
- Lumen preparation using only pre-dilatation with an uncoated balloon catheter or DVIU was studied in the Robust I clinical study.
- Safety and effectiveness data has not been established during the clinical study to support the treatment of strictures in patients with:
    - o BPH
    - o Radical prostatectomy
    - o Pelvic radiation
    - o Botox treatment
    - o More than 1 stricture
    - o Previous urethroplasty within the anterior urethra
    - o Bacterial urethritis or gonorrhea
    - o Presence of a penile implant artificial sphincter or urethra/prostatic stent
    - o Known neurogenic bladder, sphincter abnormalities, or poor detrusor muscle function.
    - o Diagnosed with Lichen Sclerosis, or previous hypospadias repair.
    - o History within the last 5 years of carcinoma of the bladder or prostate
    - o Stricture due to balanitis xerotica obliterans (BXO
    - o Urethral tumors or penile cancer

7.0 USE IN SPECIAL POPULATIONS

The safety and effectiveness of the Urethral DCB has not been established in pediatric patients (< 18 years of age) or in women. Use of the Urethral DCB in patients ≥ 18 years of age and older is at the discretion of the physician.

8.0 POSSIBLE COMPLICATIONS

Possible complications associated with the use of the Optilume DCB Catheter are similar to the ones associated with standard urethra dilation procedures. Possible complications may include, but are not limited to:

- Pain and tenderness
- Bladder spasm from Foley catheter placement
- Tissue Trauma in surrounding structures, including urethral damage
- Hematuria
- Drug reactions, allergic reaction to contrast medium used during diagnostic urethrogram
- Urinary Tract Infection
- Tissue perforation
- Stricture recurrence requiring further surgery
- Incontinence
- Dysuria
- Fever
- Urinary retention

9.0 DRUG INFORMATION

o MECHANISM OF ACTION

The Urethral DCB coating contains paclitaxel, an anti-mitotic pharmaceutical agent that specifically binds to and stabilizes microtubules. Paclitaxel has been reported to inhibit smooth muscle cell and fibroblast proliferation and migration as well as secretion of extracellular matrix. The combination of these effects may result in the inhibition of urothelium hyperplasia and therefore stricture recurrence.

o DRUG INTERACTIONS

Formal drug interaction studies have not been conducted for the Urethral DCB. The respective instructions for use for all drugs used in conjunction with the DCB should be consulted for interactions with paclitaxel.

Consideration should be given to the potential for systemic and local drug inter actions in the urethra in a patient who is taking a drug with known interactions to paclitaxel or when deciding to initiate drug therapy in a patient who has been treated with the DCB.

The metabolism of paclitaxel is catalyzed by cytochrome P450 isoenzymes CYP2C8 and CYP3A4 and it is a substrate of P-glycoprotein. Potential drug interactions may occur with any drug that affects these isoenzymes. In the absence of formal drug interaction studies, caution should be exercised when administering paclitaxel.

o CARCINOGENICITY, GENOTOXICITY AND REPRODUCTIVE TOXICOLOGY

No long-term studies have been performed to evaluate the carcinogenic potential of the drug paclitaxel or of the Optilume DCB, and there are no adequate and well-controlled studies published in pregnant women or in men intending to father children. Paclitaxel inhibits cell proliferation by interacting with microtubules, and one consequence is the loss of whole chromosomes during cell division. This indirect action is consistent with positive responses in vitro and in vivo micronucleus genotoxicity assays, which detect DNA fragments. Positive results have also been reported for chromosomal aberrations in primary human lymphocytes. It is not known whether paclitaxel has a separate direct action on DNA in the generation of DNA strand breaks or fragments. It is negative in assays for gene mutation, including salmonella and CHO/HPRT.

Studies performed in rats and rabbits receiving IV paclitaxel during organogenesis revealed evidence of maternal toxicity, embryotoxicity, and fetotoxicity at dosages of 1 and 3 mg/kg, respectively (approximately 13 and 39 times the dose provided by the Optilume DCB coated with 5.5 mg paclitaxel (10mm x 50mm balloon) ad justed for body weight). No teratogenicity was observed in gravid rats receiving daily IV paclitaxel doses of 1 mg/kg (a daily dose of approximately 13 times the dose of the Optilume DCB (10mm x 50mm), adjusted for bodyweight).

The treating physician should balance the potential medical benefits of the Optilume DCB Catheter against these genotoxic and reproductive risks. WARNING: The Urethral DCB contains paclitaxel, a known genotoxin. Do not use the DCB in women who are breastfeeding, pregnant or intending to become pregnant. Men should have protected sex (wear a condom) for 30 days' post treatment.

10.0 HOW SUPPLIED

The Optilume DCB catheter is supplied STERILE for single use only (ethylene oxide sterilization). The DCB is in a double pouch packaging system (foil and Tyvek pouches) contained within a single unit box.

11.0 STORAGE

The Urethral DCB should be stored at room temperature in a dry location in its original packaging. The device should be used prior to the "Use by" date on the packaging.

12.0 RECOMMENDED ITEMS

Prepare the following items using sterile technique:

- 0.038" guidewire or smaller with flexible tip (refer to product labeling)
- Cystoscope (flexible preferred)
- Sterile saline
- 10 cc syringe
- Two-way stopcock
- Inflation device with attached manometer or pressure gage
- Contrast media – Note: Optional for use with fluoroscopic guided procedures

13.0 DIRECTIONS FOR USE

13.1 PRIOR TO USE

Peri Procedural Medication

It is recommended that physicians follow guidelines for pre-procedure medications and preparation for an endoscopic procedure, including the administration of a pre-procedure antibiotic as appropriate. Oral NSAIDs are also recommended to be given prior to the procedure.

If a urinary tract infection (UTI) is present at the time of treatment, the patient must be treated until the infection is cured before the treatment procedure can take place.

13.2 TARGET STRICTURE PREPARATION

Urethral preparation of the target stricture, using the appropriate preparation method as determined by the treating physician, is recommended for highly stenosed and difficult to cross strictures (less than 2.1mm diameter) prior to the use of the Optilume DCB.

13.3 DEVICE SIZING

Verify the selected DCB balloon diameter at nominal pressure is the same or slightly greater than the diameter as the healthy urethra adjacent to the distal edge of the stricture.

Select a DCB balloon length that is slightly longer than the stricture length to be treated. The balloon length must extend approximately 0.5-1 cm beyond the stricture on both sides. For example, if the stricture length is 3 cm, choose a DCB balloon that is 5 cm

13.3 BALLOON CATHETER PREPARATION

Evacuate Air from the DCB Catheter. The balloon lumen of the catheter contains air and the air must be displaced to make certain that only liquid fills the balloon while the catheter is in the urethra.

1. Attach stopcock in the open position to the balloon inflation connector.
2. Attach half saline filled syringe to the stopcock.
3. With syringe down draw back plunger to full volume of syringe (this creates maximum negative pressure) and hold until no air bubbles can be seen coming out of the saline in the syringe. Repeat as needed to purge the air from the catheter. Keep plunger back, release vacuum, and remove syringe. Half fill an inflation device with normal saline or 1:1 contrast: saline if using fluoroscopy, and purge air from the line.
4. Attach inflation device to the stopcock on the balloon catheter, pull vacuum on the inflation device.

13.4 OPTILUME DCB INSERTION

1. Position a 0.038” guidewire with the flexible tip coiled in the bladder with the aid of a cystoscope.
2. Remove the balloon protector from the tip of the DCB catheter.

Caution: *Care should be exercised when passing a balloon coated with paclitaxel through any cystoscope system. Minimize excessive handling and do not touch the balloon. Do not wipe the balloon with dry, wet or lubricated gauze, or any solvent which could damage the integrity of the drug coated balloon.*

3. For 18-30Fr (6-10mm) sizes advance the DCB catheter within the working channel of the cystoscope. Alternately, all DCB sizes may be placed by positioning the guidewire and DCB side by side with the cystoscope.

   Warning: *Side by side positioning must be used for the 36 and 42 Fr DCBs as they are not compatible with the working channel of a flexible cystoscope.*

4. Use the cystoscope to guide the placement of the DCB. Alternatively position the DCB with fluoroscopy by using the radiopaque markers located under the balloon body/cone transition.

Caution: *Do not advance the guidewire or the balloon dilation catheter if resistance is met without first determining the cause of resistance and taking remedial action.*

13.5 OPTILUME DCB INFLATION

Caution: *Inflation devices are capable of attaining very high pressures with minimal effort. The use of an inflation device with a high-pressure gauge is strongly recommended to optimize dilatation force to yield the urethral stricture and allow drug penetration into the yielded urothelium.*

1. Ensure that the urethra is flushed with saline.
2. Position the DCB across the stricture with the cystoscope distal to the balloon (away from the bladder) to visualize the proper placement of the balloon across the stricture. Leave the balloon in position uninflated for a minimum of 1 minute prior to inflation. Check that the balloon radiopaque markers are in the correct position using fluoroscopy.
3. Inflate the balloon to the rated burst pressure using the inflation device. Do not exceed rated burst pressure (RBP) of the balloon. Maintain pressure for a minimum of 5 minutes, or until desired dilation is achieved.
4. Deflate balloon by applying aspiration to the balloon with the inflation device. When the balloon is completely deflated, withdraw guidewire and DCB slowly. If slight resistance is felt when the balloon is being removed gently rotate the catheter to help the balloon fold around the catheter shaft and facilitate withdrawal.

Caution: *If resistance is encountered when removing a guidewire through a catheter through a cystoscope, STOP and remove them together at the same time as a complete unit to prevent damage to the guidewire, catheter or patient anatomy.*

5. If the product has a failure prior to, or during inflation (but less than RBP) replace DCB and inflate per procedure. If failure is after inflation to RBP do not repeat DCB procedure
6. Insert a 12-14 Fr lubricious Foley catheter and leave in place for a minimum of 2 days or per standard of care, whichever is greater

13.6 COMPLIANCE CHART

18Fr (6mm) x 30mm (Flexible cystoscope compatible)

(ATM) Pressure	kPa		(mm) Balloon
6.0	600	**Nominal**	6.11 (18Fr)
8.0	800		6.23
10.0	1000		6.34
12.0	1200	**RBP**	6.45

18Fr (6mm) x 50mm (Flexible cystoscope compatible)

(ATM) Pressure	kPa		(mm) Balloon
6.0	600	**Nominal**	5.87 (18Fr)
8.0	800		6.03
10.0	1000		6.16
12.0	1200	**RBP**	6.25

24Fr (8mm) x 30mm (Flexible cystoscope compatible)

(ATM) Pressure	kPa		(mm) Balloon
6.0	600	**Nominal**	7.98 (24Fr)
8.0	800		8.16
10.0	1000		8.32
12.0	1200	**RBP**	8.46

24Fr (8mm) x 50mm (Flexible cystoscope compatible)

(ATM) Pressure	kPa		(mm) Balloon
6.0	600	**Nominal**	8.00 (24Fr)
8.0	800		8.20
10.0	1000		8.37
12.0	1200	**RBP**	8.54

30Fr (10mm) x 30mm (Flexible cystoscope compatible)

(ATM) Pressure	kPa		(mm) Balloon
6.0	600	**Nominal**	9.83 (30 Fr)
8.0	800		10.09
10.0	1000	**RBP**	10.29

30Fr (10mm) x 50mm (Flexible cystoscope compatible)

(ATM) Pressure	kPa		(mm) Balloon
6.0	600	**Nominal**	9.98 (30 Fr)
8.0	800		10.23
10.0	1000	**RBP**	10.44

36Fr (12mm) x 30mm (Incompatible with flexible cystoscopes)

(ATM) Pressure	kPa		(mm) Balloon
6.0	600	**Nominal**	11.71 (36Fr)
7.0	800		11.89
8.0	1000	**RBP**	12.04

36Fr (12mm) x 50mm (Incompatible with flexible cystoscopes)

(ATM) Pressure	kPa		(mm) Balloon
6.0	600	**Nominal**	11.69 (36Fr)
7.0	700		11.88
8.0	800	**RBP**	12.03

42Fr (14mm) x 30mm (Incompatible with flexible cystoscopes)

(ATM) Pressure	kPa		(mm) Balloon
6.0	600	**Nominal**	14.00 (42Fr)
7.0	700		14.27
8.0	800	**RBP**	14.51

42Fr (14mm) x 50mm (Incompatible with flexible cystoscopes)

(ATM) Pressure	kPa		(mm) Balloon
6.0	600	**Nominal**	13.68 (42Fr)
7.0	700		13.97
8.0	800	**RBP**	14.25

Caution: *The rated burst pressure should not be exceeded. Refer to product label for rated burst pressures. Inflation beyond the rated burst pressure may cause the balloon to rupture. If loss of pressure within the balloon occurs during inflation or if balloon ruptures during dilation, immediately discontinue the procedure. Deflate the balloon carefully and remove from urethra. Do not re-inflate.*

14.0 WARRANTY

Urotronic warrants that reasonable care has been used in the design and manufacture of this product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties for a particular purpose. Handling, storage, cleaning and sterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Urotronic's control directly affect the device and the results ob tained from its use. Urotronic's obligation under this warranty is limited to the repair or replacement of this device and Urotronic shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. Urotronic assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, express or implied, including but not limited for a particular purpose, with respect to such devices.

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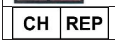
15.0 SYMBOLS USED IN THE DEVICE LABELS

	Quantity of 1 per box
	Caution: Federal law restricts this device to sale by or on the order of a physician.
	Indicates the date when the medical device was manufactured.
	Do not resterilize
	Do not re-use
	Do not use if package is damaged
	Fragile
	Use-by date
	Keep away from sunlight
	Keep Dry
	Manufacturer
	Does not contain latex
	Temperature limit 15°C - 30°C
	Caution: Consult instructions for use
	Sterilized using ethylene oxide
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside
	Catalog number
	Lot number
	Medical Device
	Unique Device Identifier
	Contains a medicinal substance
	CE Marked per the Medical Device Directive 93/42/EEC of the European Union (Notified Body #1434)
	European Union Authorized Representative
	Swiss Authorised Representative