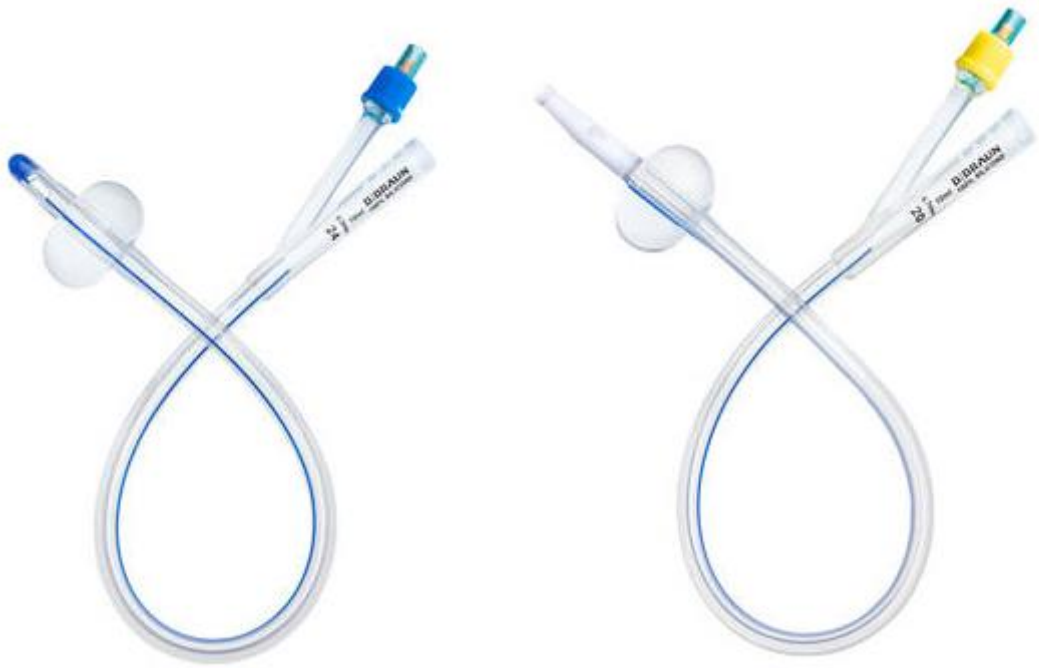
Urimed® Cath foley catheters

TECHNICAL DATA SHEET



ADMINISTRATIVE INFORMATION	
Importer	B. Braun Melsungen Ag.
Legal Manufacturer	Well Lead Medical Co., Ltd.
SBA	Urinary care
Last update	08/04/2025
CERTIFICATION	
Medical device classification	IIb, Rule 8
EU regulation	2017/745
Notified Body	BSI Group The Netherlands B.V.
Certificate	MDR 801167 R000

DESCRIPTION AND COMPOSITION OF THE DEVICE

Trade name

Urimed® Cath

References

Urimed® Cath Foley Nelaton	Useful length	CH	Ø	Balloon capacity (ml)	10 units		Individual packaging	
					Units/box	Ref.	Units/box	Ref.
	234 mm	08	2.7	3	10	4563308	5	4563308-01
		10	3.3	3	10	4563310	5	4563310-01
	334 mm	12	4.0	10	10	4563312	5	4563312-01
		14	4.7	10	10	4563314	5	4563314-01
		16	5.3	10	10	4563316	5	4563316-01
		18	6.0	10	10	4563318	5	4563318-01
		20	6.7	10	10	4563320	5	4563320-01
		22	7.3	10	10	4563322	5	4563322-01
		24	8.0	10	10	4563324	5	4563324-01
Urimed® Cath Foley Tiemann	350 mm	12	4.0	10	10	4563412	5	4563412-01
		14	4.7	10	10	4563414	5	4563414-01
		16	5.3	10	10	4563416	5	4563416-01
		18	6.0	10	10	4563418	5	4563418-01
		20	6.7	10	10	4563420	5	4563420-01

GMDN code

34917

Indication

Urimed® Cath, 2 ways Silicone Foley catheters are indicated for

- Patient has acute urinary retention or bladder outlet obstruction
- Need for accurate urine output measurements
- Use for selected surgical procedures
- To assist in healing of open sacral or perineal wounds
- Patient requires prolonged immobilization
- To improve comfort for end-of-life care
- Patient with prostatic hypertrophy and urethral strictures

The Tiemann tip is designed to deal with the prostatic curve in male patients.

Product description

The product is made from silicone. It consists of shaft, drainage funnel, inflation funnel, pre-loaded stylet (for CH8 and CH10), balloon and valve. Spigot and syringe are op tional. The product can be used on perioperative patient, patient have urinary retention or bladder outlet obstruction, patient who need to measure the urine volume accurately.

Technical characteristics and composition of the device

	Technical characteristics		Composition
Tip	Nelaton Closed tip	Tiemann Closed tip	Silicone
X Ray tip and line			Silicone
Color sleeve			PP
Inflation valve			PVC

Balloon	Volume to inflate the balloon indicated on the connector: • 10 mL: for CH 12, CH 14, CH 16, CH 18, CH 20, CH 22, CH 24 • 3 mL: for CH 08 and CH 10: (pediatric)		Silicone
Eyes	2 drainage eyes	1 drainage eye	
Catheter	*Available in CH08 – CH24*	*Available in CH12 – CH20*	Silicone
	Universal catheter length		
Packaging	• Double sterile packaging • 2 opening of the packaging: lateral and longitudinal		Primary packaging: EVA
			Peel-pack: Paper / Laminate
IFU			Paper

Dimension

	Length with connector (L2)
Nelaton tip	31cm for CH08 – CH10 40cm for CH12, CH14, CH16, CH18, CH20, CH22, CH24
Tiemann tip	42cm for CH12, CH14, CH16, CH18, CH20

STERILIZATION PROCESS: REPORT °

Sterile MD: Yes/No — Sterile - ISO standard 20696

Sterilization method — Ethylene Oxide

CONSERVATION AND STORAGE CONDITIONS

Storage conditions

- Store in a cool and dry place, keep away from sunlight.
- Protect product from moisture and excessive heat.
- Avoid prolonged exposure to ultraviolet, sunlight and fluorescent light.
- Store in manner preventing crushing.

Transport conditions — No restrictions.

Shelf life	5 years from date of manufacture.
Packaging	The packaging includes a primary and a secondary packaging: • The product is individually packed in primary packaging that ensures the sterility of the product. • The secondary packaging must protect the product from transport and storage conditions. Packaging in 5 units boxes with individual packaging or 10 units boxes.

ENVIRONMENT

Waste management: Discard the catheter according to the current local regulations.

SAFETY IN USE

Technical: MRI, X-ray detectable	N/A
Organic:	Urimed® Cath catheter is made of silicone.
Biocompatibility:	Standard EN ISO 10993-1: 2020 Biological evaluation of medical devices
Hazardous substances:	This product is DEHP free, Latex free.

Standards & requirements

EU regulation 2017/745
NF EN ISO 20696 : 2018
EN ISO 13485 : 2016

RECOMMENDED USE

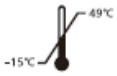
IFU: Yes/No	Yes, one per box.
Precaution of use Contraindication	Self-catheterization should only be carried out under medical advice and only in accordance with the instructions given.

ADDITIONAL PRODUCT INFORMATION

Reusable/single use device	Single use device – Not reusable

PICTURES & PICTOGRAM

Meanings of symbols on package

	Date of manufacture		Use-by date		Batch code
	Do not re-use		Consult instructions for use		Do not use if package is damaged
	Sterilized using ethylene oxide		Do not resterilize		Single sterile barrier system with protective packaging inside
	Medical Device		Manufacturer		Authorized representative in the European Community
	CE Marked Product		Keep dry		Keep away from sunlight
	Importer		This way up		Fragile, handle with care
	Catalogue number		Temperature limits: -15°C~49°C		UKCA Marked Product
	UK Responsible Person		Authorized representative in Switzerland		Unique device identifier

IFU

EN Instructions for use
Urimed® Cath All Silicone Foley Catheter

MODEL

- All Silicone Foley Catheter
- All Silicone Foley catheter with integrated balloon
- Nelaton Tip, Tiemann tip

DESCRIPTION

The product is made from silicone. It consists of shaft, drainage funnel, inflation funnel, irrigation funnel (if present), pre-loaded stylet (if present), cap (if present), balloon and valve. Spigot and syringe are optional. The product can be used on perioperative patient, patient have urinary retention or bladder outlet obstruction, patient who need to measure the urine volume accurately.

FEATURES

- Made from 100% silicone
- Color coding for size identification
- With plastic valve
- With X-ray opaque line
- Different tip type available

INTENDED USE

It is intended to be used by trained person or trained medical staff for drainage and/or irrigation of the patient bladder by inserting the catheter into the vesical cavity of the bladder through the urethra.

CLINICAL BENEFITS

- Drain urine from patients with urinary retention, in order to alleviate discomfort.
- Assist in clinical diagnosis, such as obtaining uncontaminated urine samples for bacterial culture, measuring bladder capacity and pressure, and examining residual urine. It can also be used for urethrography or cystography.

PATIENT TARGET GROUP

Infant, child, adult

INTENDED USER

Must be operated by trained professionals

INDICATIONS

- Patient has acute urinary retention or bladder outlet obstruction
- Need for accurate urine output measurements
- Use for selected surgical procedures
- To assist in healing of open sacral or perineal wounds
- Patient requires prolonged immobilization
- To improve comfort for end of life care
- Patient with prostatic hypertrophy and urethral strictures

CONTRAINDICATIONS

- Acute urethritis
- Acute prostatitis
- Acute epididymitis

ADVERSE REACTIONS

- Reported adverse reactions associated with Foley Catheter are: Septicemia, Urethritis, Urinary tract infection and encrustations, bladder spasms, abdominal discomfort, etc.
- If difficulty is encountered aspirating the balloon with a syringe, a rare and infrequently reported event, and the leg of the catheter with the valve should be cut with a sharp scissors at the bifurcation or the balloon ruptured according to established procedures reported in medical literature. Should it be necessary to rupture the balloon, care must be taken to remove all fragments from the patient's bladder.
- Incorrectly positioned catheters can cause urethral damage if the balloon is inflated contrary to instructions within the urethra.
- Irritation of the urethral mucosa, blockage of the catheter due to encrustation and catheter induced infections are documented complications with some catheter materials and patients. The patient should be routinely monitored in accordance with accepted procedures and the catheter shall be removed after a suitable interval as determined by a physician or other suitably qualified personnel.
- Long term use of catheter has the risk of urinary tract infection, sphincter relaxation and urethral relaxation.

DESCRIPTION FOR USE

Preparation:

- The following additional items are required for catheterization:

✓ Sterile field, Sterile gloves, Items required for cleaning the patient meatus (sterile, based on established techniques), Luer syringe with sterile water or sterile glycerin solution for balloon inflation (if not included), Empty syringe for balloon deflate(if not included), Sterile dressings

✓ Urine drainage device

- Before use, visually inspect the catheter to detect mechanical damages and check that no leakage occurs.
- Place male patients in supine position, female patients in lithotomy position.
- Wash and dry hands thoroughly.
- Using aseptic technique, remove the catheter from its pouch and place it on a sterile field.
- Put on sterile gloves and remove the catheter sleeve.
- Lubricate the tip and the shaft of the catheter with a water-based lubricant.
- Clean the opening of the urethra and the surrounding area, using established techniques.
- It is recommended that patients with conditions such as prostatic hyperplasia or urethrostenosis give preference to tipped catheters.

Catheterization:

- With the uncontaminated hand, pick up the catheter from the sterile field.
- (Tiemann tip, Couvelaire tip, Dufour tip, Mercier tip application)The tip should be facing towards the ceiling or patients' face, assuming the patient is supine.
- Carefully insert catheter tip into the bladder (normally indicated by urine flow), and then a further 5~7 cm to ensure balloon is also inside the bladder.
- Advance the catheter further to ensure that the balloon is located beyond the bladder neck, within the bladder.
- Inflate the catheter balloon with sterile water or sterile aqueous glycerin solution, at the discretion of the physician.
- Use the syringe or sterile glycerin solution to inflate the balloon with the required fluid volume (marked on the catheter funnel).
- Slowly retract the catheter until some resistance is felt to ensure that the balloon is correctly located within the bladder, before the bladder neck.
- Connect the catheter to a urine drainage device.
- Observe urine flow.

Catheter removal

- For removal of the catheter, deflate the balloon by inserting a Luer syringe into the valve. Release the syringe plunger and allow the balloon to deflate. Only use gentle aspiration, if necessary, to deflate the balloon. The balloon should spontaneously deflate.
- Discard the catheter according to hospital protocol.

CATHETER CARE

- Ensure local cleaning and hygiene protocols are followed to keep the catheter and meatus as clean as possible.
- Conduct hand hygiene immediately before and after any manipulation of the catheter and the urine drainage system. Wear disposable gloves when handling the system.
- Maintain unobstructed urine flow.
- Ensure that the catheter and collection tube do not kink.

LONG-TERM USING CARE

- The patient should wash his hands before and after any catheter operation.
- The area around the catheter is rinsed with a mild soap box at least twice a day.
- The patient taking 2 to 3 liters of water a day can help wash the catheter and keep the urine clear.
- The patient should regularly drain urine bags.
- The patient should always keep the drainage system closed.

WARNINGS / PRECAUTIONS

- Read all warnings and instructions before use. Improper use can result in serious or fatal illness or injury.
- Do not use if the sterile packaging is damaged or unintentionally opened before use.
- Do not use if it's damaged or irregularly shaped.
- Do not use after the expiry date.
- For single use only.
- Not compatible with MRI.
- Do not over inflate the balloon. Refer to outer unit pack or funnel of catheter for balloon capacity.
- Inflate catheter balloon only with sterile water or sterile glycerine solution.
- The pre-filled syringe with sterile water or sterile aqueous glycerine solution (if included) is for inflation of the balloon only. Not for injection.
- The empty syringe (if included) is for deflation of the balloon before the removal of the catheter.
- The product is intended for use by physicians trained and aseptic technique must be practiced.
- Do not use ointment and lubricants having petroleum base. Use water soluble lubricants.
- Do not clamp catheter shaft. It may damage catheter and prevent deflation.
- Do not use needle syringe to inflate balloon. Use a Luer syringe (Luer slip or Luer lock).
- Patients should be regularly monitored as determined by a physician.

- Ensure local cleaning and hygiene protocols are followed to keep the catheter and meatus as clean as possible.
- During long-term use, the balloon inflation volume should be regularly monitored in case any clinical signs of deflation occur, such as bypassing of urine or urethral pain. If necessary, the balloon volume should be adjusted.
- The balloon must be completely deflated before catheter removal.
- The retention time of Silicone Foley Catheter should be decided by the medical care professionals according to the actual situation of using. Suggest to use less than 90 days.
- Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in injury, illness or death of the patient. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Precautions shall be taken when discarding device and disposal of the device shall be mad in accordance with applicable national regulations for biological hazardous waste.
- Dispose of product and packaging in accordance with hospital administrative and/or local government policy.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the local competent authority of the user's place.

STORAGE CONDITIONS

- Store in a cool and dry place, keep away from sunlight.
- Protect product from moisture and excessive heat.
- Avoid prolonged exposure to ultraviolet, sunlight and fluorescent light.
- Store in manner preventing crushing.

The Key Performance Characteristics of All Silicone Foley Catheter

- Flow rate

The flow shall meet the requirements of Table 1:

Table 1

Specifications (Fr)	6	8	10	12	14	16	18	20	22	24	26
Drainage Flow, ≥mL/min	10	15	30	50	70	100	100	100	100	100	100
Irrigation Flow, ≥mL/min	/	/	/	/	/	25	25	25	30	30	30

- Balloon Safety: the balloon shall not leak and shall not occlude the lateral drainage holes.

For healthcare Professional use only
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