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Summary essential technical data - *BEROCATH*

<u>Manufacturer:</u>	Beromed GmbH Hospital Products Kronenstrasse 19 10117 Berlin GERMANY
<u>Product:</u>	Urethral Catheters (Foley) (Sterile Latex Foley Balloon Catheters for single use)
<u>Brand:</u>	<i>BEROCATH</i>
<u>GMDN code:</u>	34917
<u>Risk Class:</u>	IIb according to Annex IX, rule 5 of Council Directive 93/42/EEC, as amended by Council Directive 2007/47/EC
<u>Conformity assessment procedure:</u>	according to Annex II.3 of Council Directive 93/42/EEC, amended by Council Directive 2007/47/EC
<u>Notified Body:</u>	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich, Germany Identification no 0123

Brief description of the product:

Latex Foley Balloon Catheters consist of shaft, drainage funnel, inflation funnel, irrigation funnel (if present), balloon and valve. Their smooth tapered tip facilitates insertion, and their silicon-coated surface reduces allergic reactions. They are color-coded for easy identification of the size. Size and balloon capacity are marked both on the package and on the funnel of the catheter. *BEROCATH* Latex Foley Balloon catheters are sterile and non-toxic.

Intended use:

Latex Foley Balloon Catheters are flexible tubes intended to be inserted into the bladder via the urethra for drainage and/or collection of urine, irrigation of the bladder and instillation of fluids. The balloon retains the catheter inside the bladder once inflated. They are disposable items intended for long-term use.

Indications:

Latex Foley Balloon Catheters are passed through the urethra during urinary catheterization and into the urinary bladder for drainage of urine and/or instillation of fluids into the bladder. They are used in departments of urology, internal medicine, surgery, obstetrics and gynecology for drainage of urine and medication. They are also used for patients suffering from moving with difficulty or being completely bed-ridden.

Contraindications:

Not to be used in patients with known hypersensitivity to any of the materials used
Acute urethritis
Acute prostatitis
Acute epididymitis

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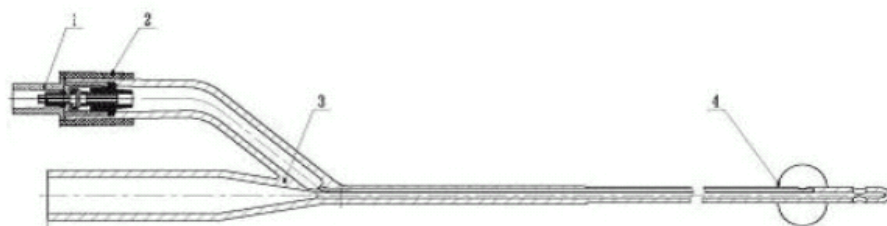
Material specification and drawings:

Latex Foley Balloon Catheters are made from medical grade natural latex. BEROCATH Latex Foley Balloon catheters are silicone-coated.

Component	Material
Shaft	Natural latex
Funnels	Natural latex
Balloon	Natural latex
Sleeve	Natural latex
Hard valve	PVC, PP, ABS, Silicone and stainless steel
Coating	silicone

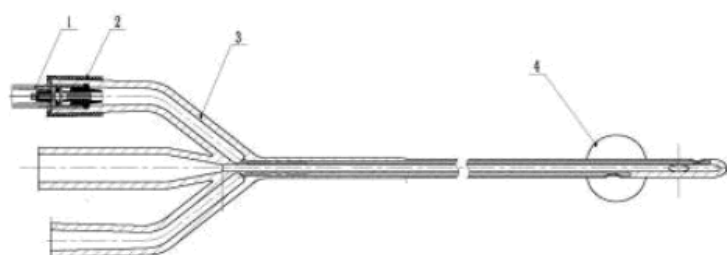
Drawings of the different types:

Latex Foley Catheter, 2-way, with hard valve (paediatric, female, male)



1	Hard valve
2	Sleeve
3	Catheter (Shaft, Inflation funnel, drainage funnel)
4	Balloon

Latex Foley catheter, 3-way, with hard valve



1	Hard valve
2	Sleeve
3	Catheter (Shaft, Inflation funnel, drainage funnel, irrigation funnel)
4	Balloon

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Features:

- Silicone-coated for maximum comfort and protection against urethral irritation
- Colour-coded for visualization of size
- Two lateral eyes for standard Foley catheters
- Catheters with Tiemann tip for facilitated catheterisation of male patients available - see section "variants"
- sterile, non-toxic

Sterilization: sterilized by Ethylene Oxide (EO)

Latex: BERO CATH Latex Foley Balloon Catheters contain latex.

Shelflife: 5 years from the date of manufacture
dates of manufacture and expiry are printed on the individual package

Storage: Store in a clean and dry place. Avoid excessive heat, protect from direct sunlight and moisture. Do not expose to ultraviolet and fluorescent light. Store in a manner preventing crushing.

Disposal: Discard the product after single use in accordance with applicable national regulations for biological hazardous waste.

Precautions for use: Read instructions before use.

Use of this product is restricted to qualified healthcare workers.

The product contains natural rubber latex which may cause allergic reactions.

Visually inspect and check the product and package integrity prior to use and also the expiry date. Improper transport and handling may cause structural and/or functional damage to device or packaging.

Do not use after the expiry date.

The product is sterile and non-toxic if the package is not opened or damaged. Do not use if the individual package is damaged.

Use the product immediately after opening the individual blister packing.

The product is to be used under aseptic conditions.

The balloon is to be tested for leakage and deflation prior to use.

Do not over-inflate the balloon. Refer to the unit package or funnel of the catheter for the balloon capacity.

Inflate the balloon with sterile distilled water.

Do not use a needle to inflate the balloon. Use a Luer syringe without needle.

Do not use ointments or lubricants basing on petroleum. Use medical grade silicone oil or water-soluble lubricants.

Do not clamp or kink the catheter shaft. It may damage the catheter and impede deflation.

The catheter must be removed and replaced after 14 days at the latest.

For single use and for single patient use only. Re-use of single-use devices creates a potential risk of patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

Discard after single use. Do not recycle, reprocess or re-sterilize.

The product should be used according to the instructions for use.

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Packing data:

	Material of packing unit	Pieces per packing unit
Blister (pouch)	65g coated paper + PET12 / PE40 film	1
Inner box	450g whiteboard paper	10
Export carton	Five yellow corrugated kraft paper	200

Variants:

BEROCATH - Sterile Latex Foley Balloon Catheters for single use with hard valve

2-way, paediatric, overall length 270 ± 10 mm				
Article number	Balloon capacity (ml)	Size (CH)	Outer diameter ± 0.3 mm	Flow rate (ml/min)
B261043	3	CH 06	2.0	≥ 10
B260008	3 - 5	CH 08	2.7	≥ 15
B260015	3 - 5	CH 10	3.3	≥ 30
2-way, female, overall length 255 - 270 mm				
Article number	Balloon capacity (ml)	Size (CH)	Outer diameter ± 0.3 mm	Flow rate (ml/min)
B260411	5 - 15	CH 12	4.0	≥ 50
B260428	5 - 15	CH 14	4.7	≥ 70
B260435	5 - 15	CH 16	5.3	≥ 100
B260343	5 - 15	CH 18	6.0	≥ 100
B260350	5 - 15	CH 20	6.7	≥ 100
B260312	5 - 15	CH 22	7.3	≥ 100
B260329	5 - 15	CH 24	8.0	≥ 100
B260336	5 - 15	CH 26	8.7	≥ 100
B260220	5 - 15	CH 28	9.3	≥ 100
B260237	5 - 15	CH 30	10.0	≥ 100
2-way, female, overall length 255 - 270 mm				
Article number	Balloon capacity (ml)	Size (CH)	Outer diameter ± 0.3 mm	Flow rate (ml/min)
B260244	30	CH 12	4.0	≥ 50
B260251	30	CH 14	4.7	≥ 70
B260268	30	CH 16	5.3	≥ 100
B260886	30	CH 18	6.0	≥ 100
B260893	30	CH 20	6.7	≥ 100
B260909	30	CH 22	7.3	≥ 100
B260916	30	CH 24	8.0	≥ 100
B260923	30	CH 26	8.7	≥ 100
B260930	30	CH 28	9.3	≥ 100
B260947	30	CH 30	10.0	≥ 100
2-way, male, overall length 400 ± 10 mm				
Article number	Balloon capacity (ml)	Size (CH)	Outer diameter ± 0.3 mm	Flow rate (ml/min)
B260022	5 - 15	CH 12	4.0	≥ 50
B260039	5 - 15	CH 14	4.7	≥ 70
B260046	5 - 15	CH 16	5.3	≥ 100
B260053	5 - 15	CH 18	6.0	≥ 100
B260060	5 - 15	CH 20	6.7	≥ 100
B260077	5 - 15	CH 22	7.3	≥ 100
B260084	5 - 15	CH 24	8.0	≥ 100
B260091	5 - 15	CH 26	8.7	≥ 100
B260107	5 - 15	CH 28	9.3	≥ 100
B260114	5 - 15	CH 30	10.0	≥ 100

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2-way, male, overall length 400 ± 10 mm				
Article number	Balloon capacity (ml)	Size (CH)	Outer diameter ± 0.3 mm	Flow rate (ml/min)
B260121	30	CH 12	4.0	≥ 50
B260138	30	CH 14	4.7	≥ 70
B260145	30 - 50	CH 16	5.3	≥ 100
B260152	30 - 50	CH 18	6.0	≥ 100
B260169	30 - 50	CH 20	6.7	≥ 100
B260176	30 - 50	CH 22	7.3	≥ 100
B260183	30 - 50	CH 24	8.0	≥ 100
B260190	30 - 50	CH 26	8.7	≥ 100
B260206	30 - 50	CH 28	9.3	≥ 100
B260213	30 - 50	CH 30	10.0	≥ 100
2-way, male, Tiemann, overall length 395 ± 15 mm				
Article number	Balloon capacity (ml)	Size (CH)	Outer diameter ± 0.3 mm	Flow rate (ml/min)
B207737	5 - 15	CH 12	4.0	≥ 50
B207744	5 - 15	CH 14	4.7	≥ 70
B207751	5 - 15	CH 16	5.3	≥ 100
B207768	5 - 15	CH 18	6.0	≥ 100
B207775	5 - 15	CH 20	6.7	≥ 100
B207782	5 - 15	CH 22	7.3	≥ 100
3-way, male, overall length 400 ± 10 mm, flow rate of drainage lumen ≥ 100 ml / min				
Article number	Balloon capacity (ml)	Size (CH)	Outer diameter ± 0.3 mm	Flow rate irrigation lumen (ml/min)
B260275	5 - 15	CH 18	6.0	≥ 25
B260282	5 - 15	CH 20	6.7	≥ 25
B260299	5 - 15	CH 22	7.3	≥ 30
B260305	5 - 15	CH 24	8.0	≥ 30
3-way, male, overall length 400 ± 10 mm, flow rate of drainage lumen ≥ 100 ml / min				
Article number	Balloon capacity (ml)	Size (CH)	Outer diameter ± 0.3 mm	Flow rate irrigation lumen (ml/min)
B260367	30	CH 16	5.3	≥ 25
B260374	30	CH 18	6.0	≥ 25
B260381	30	CH 20	6.7	≥ 25
B260398	30	CH 22	7.3	≥ 30
B260404	30	CH 24	8.0	≥ 30
B261029	30	CH 26	8.7	≥ 30

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