

CAMSTENT COATED FOLEY CATHETER

PRODUCT FUNCTION

Drainage of urine from the urinary bladder via the urethra.

PRODUCT DESCRIPTION

The Camstent Coated Foley Catheter is an all-silicone Foley urinary catheter to which a proprietary polymeric coating has been applied.

The catheter is coated with a micro-thin patented polymer coating that reduces friction to aid insertion/withdrawal and for added patient comfort.

The Bacteriophobic™ coating limits attachment of bacteria to the catheter lumen as compared to uncoated surfaces. Fewer bacteria results in less biofilm, which can cause CAUTI.

It is a single use device that is supplied sterile and is available in two lengths, female (190mm) and male (360mm), and in two tip options, standard tip and Tiemann tip.

INTENDED USE

For use in hospitalised adults requiring catheterisation for bladder drainage.

DURATION OF USE

A sterile, single use device for up to 28 days use.

STORAGE CONDITIONS

Store catheters at room temperature, away from sunlight and in dry conditions.

Warning: if catheters are stored below 10°C, they must be maintained at room temperature ($\geq 20^\circ\text{C}$) for a minimum of 24 hours prior to use.

DISPOSAL

After patient use the device is to be immediately disposed of as controlled medical waste.



STANDARDISATION

Device classification (Defined by 93/42/EEC directive)	Class IIa
CE marking	CE 0088
Quality management system certified	ISO 13485:2016

STERILISATION

Gamma irradiation.

SINGLE USE WARNING

These device(s) are designed and sold for single use only. Reprocessing and, or, re-sterilisation after initial use is not permitted.

The effects of any unauthorised reprocessing or re-sterilisation can result in the following complications:

1. cross contamination due to ineffective reprocessing/re-sterilisation;
2. mechanical fatigue, and associated failure, due to the effects of the reprocessing/re-sterilisation method.

PRODUCT MATERIALS

Component/part	Material
Catheter tubing	Silicone elastomer: MSS70-0050
Funnel and tip	Silicone elastomer: MSS50-0030
Tip (X-ray detect media)	Barium sulfate precipitated: blanc fixe
Tip and tube	Colour master batch for silicone: blue
Balloon cuff	Silicone elastomer: MSS25-0010
Sleeve	Acrylonitrile Butadiene Styrene: POLYLAC® ABS 80° Shore D
Check valve materials	Stainless steel spring: grade 302
	Nitrile rubber (NBR): KA5701B
	Polybutylene terephthalate (PBT): Arnite® T06 202/A
	Polypropylene: Eltex® Med 100-MG03

PACKAGING DATA

- Sterile, individual packages, containing one catheter.
 - Pouch packed with coated medical paper (PET/PE film).
- 10 catheters and 10 instructions for use, per box.
 - Box packaging: shipping carton dimensions 555mm x 88mm x 60mm.
 - Gross weight range per box: 0.315kg-0.395kg.
- Syringes and balloon inflation fluid are not provided.



PRODUCT RANGE

Product code	Product description
	All Camstent Coated Foley Catheter for urethral use. Silicone 2-way, X-ray detectable.
CSF12F10	Female urethral use. 12Fr (4.0mmØ). Effective length 190mm / 5-10ml.
CSF12S10	Urethral use. 12Fr (4.0mmØ). Effective length 360mm / 5-10ml.
CSF14S10	Urethral use. 14Fr (4.7mmØ). Effective length 360mm / 5-10ml.
CSF16S10	Urethral use. 16Fr (5.3mmØ). Effective length 360mm / 5-10ml.
CSF18S10	Urethral use. 18Fr (6.0mmØ). Effective length 360mm / 5-10ml.
CSF20S10	Urethral use. 20Fr (6.7mmØ). Effective length 360mm / 5-10ml.
CSF12S10T	Tiemann tip urethral use. 12Fr (4.0mmØ). Effective length 360mm / 5-10ml.
CSF14S10T	Tiemann tip urethral use. 14Fr (4.7mmØ). Effective length 360mm / 5-10ml.
CSF16S10T	Tiemann tip urethral use. 16Fr (5.3mmØ). Effective length 360mm / 5-10ml.
CSF18S10T	Tiemann tip urethral use. 18Fr (6.0mmØ). Effective length 360mm / 5-10ml.
CSF20S10T	Tiemann tip urethral use. 20Fr (6.7mmØ). Effective length 360mm / 5-10ml.

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