

CAMSTENT COATED FOLEY CATHETER

INTENDED USE

Silicone 2-way, X-ray detectable, urinary catheter for urethral use.

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.

DURATION OF USE

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

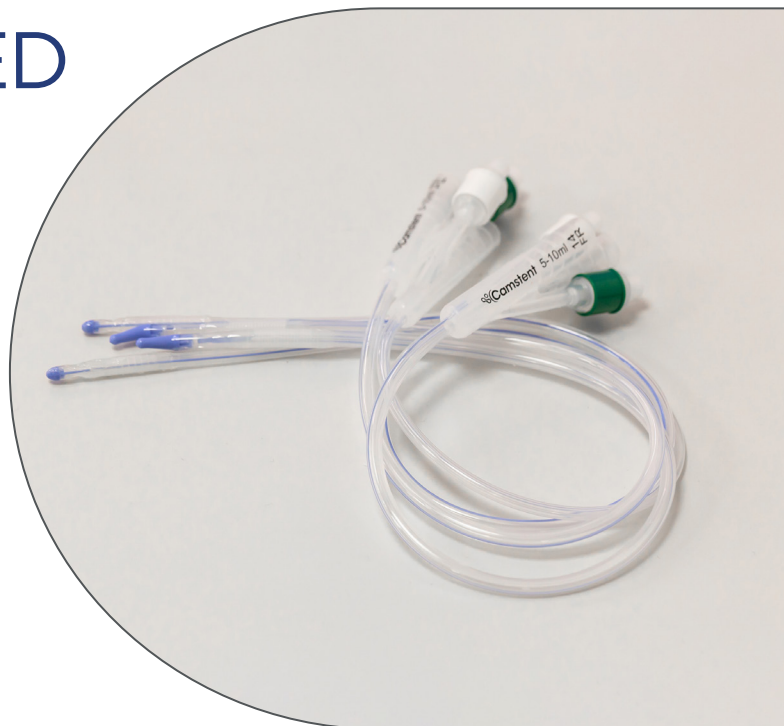
STORAGE CONDITIONS

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 (≥20°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
UKCA marking	 0120
CE marking	 1639
Quality management system certified	ISO 13485:2016

EC REP Medical Device Management Ltd, Block B, The Crescent Building, Northwood, Santry, Dublin 9, D09 C6X8, Ireland. Tel +353 (0) 1893 4143

STERILISATION

Sterile by 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
Coating	Biocompatible acrylic polymer

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
CSF12F10	Female urethral use. 12Fr (4.0mmØ). Effective length 190mm / 5-10ml.
CSF12S10	Male Urethral use. 12Fr (4.0mmØ). Effective length 360mm / 5-10ml.
CSF14F10	Female urethral use. 14Fr (4.7mmØ). Effective length 190mm / 5-10ml.
CSF14S10	Male Urethral use. 14Fr (4.7mmØ). Effective length 360mm / 5-10ml.
CSF16F10	Female urethral use. 16Fr (5.3mmØ). Effective length 190mm / 5-10ml.
CSF16S10	Male Urethral use. 16Fr (5.3mmØ). Effective length 360mm / 5-10ml.
CSF18F10	Female urethral use. 18Fr (6.0mmØ). Effective length 190mm / 5-10ml.
CSF18S10	Male Urethral use. 18Fr (6.0mmØ). Effective length 360mm / 5-10ml.
CSF20F10	Female urethral use. 20Fr (6.7mmØ). Effective length 190mm / 5-10ml.
CSF20S10	Male Urethral use. 20Fr (6.7mmØ). Effective length 360mm / 5-10ml.
CSF12S10T	Male Tiemann tip urethral use. 12Fr (4.0mmØ). Effective length 360mm / 5-10ml.
CSF14S10T	Male Tiemann tip urethral use. 14Fr (4.7mmØ). Effective length 360mm / 5-10ml.
CSF16S10T	Male Tiemann tip urethral use. 16Fr (5.3mmØ). Effective length 360mm / 5-10ml.
CSF18S10T	Male Tiemann tip urethral use. 18Fr (6.0mmØ). Effective length 360mm / 5-10ml.
CSF20S10T	Male Tiemann tip urethral use. 20Fr (6.7mmØ). Effective length 360mm / 5-10ml.

Camstent Ltd.
 The Exchange
 Colworth Science Park
 Sharnbrook, Bedford
 MK44 1LZ United Kingdom

+44(0) 333 987 4050
 info@camstent.com
 www.camstent.com