

# 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.

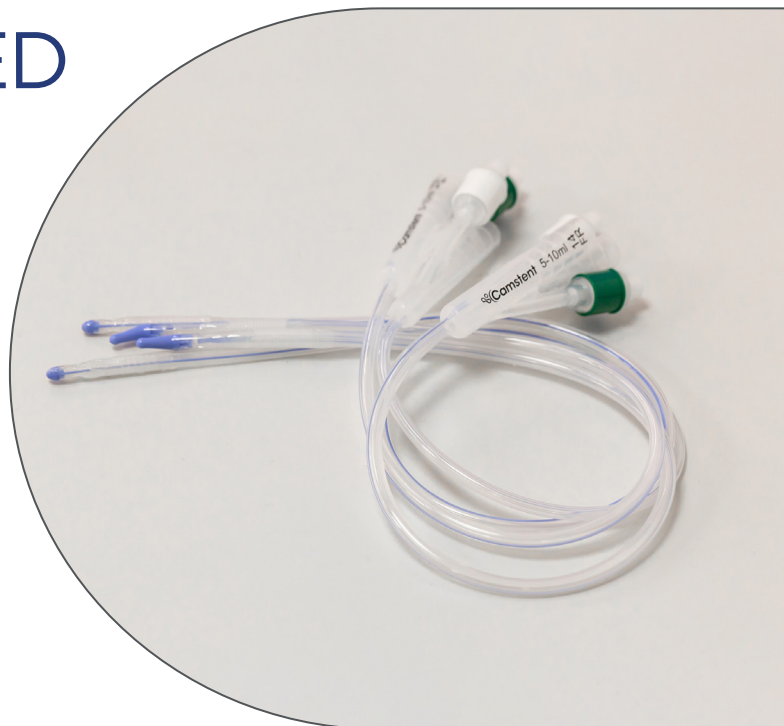
## STORAGE CONDITIONS

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

<b>Device classification (Defined by 93/42/EEC directive)</b>	Class IIa
<b>CE marking</b>	CE 1639
<b>Quality management system certified</b>	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