

# 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 UTI.

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 30 days use.

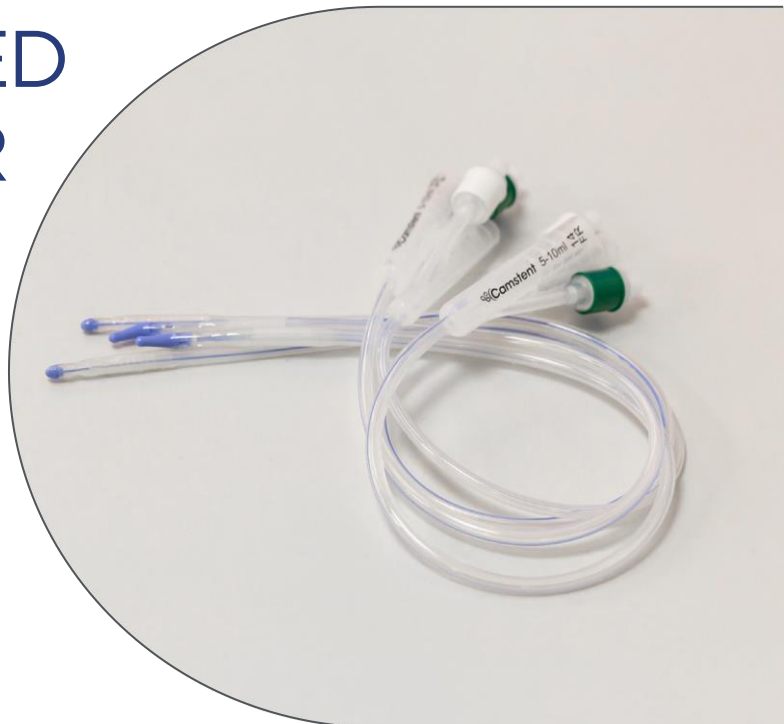
## STORAGE CONDITIONS

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<br>(Defined by 93/42/EEC directive) | Class IIa  |
| UKCA marking  |  0120 |
| CE marking  |  1639 |
| Quality management system certified                       | ISO 13485:2016   |

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## 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 RANGE**

| Product code   | Product description   |
|----------------|---|
| <b>FST952</b>  | Camstent BACTERIA-PHOBIC® Coated Foley Catheter<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Female Urethral use. 12Fr (4.0mmØ) Effective Length 190mm / 5-10ml            |
| <b>FST953</b>  | Camstent BACTERIA-PHOBIC® Coated Foley Catheter<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 12Fr (4.0mmØ) Effective Length 360mm / 5-10ml              |
| <b>FST1045</b> | Camstent BACTERIA-PHOBIC® Coated Foley Catheter<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Female Urethral use. 14Fr (4.7mmØ) Effective Length 190mm / 5-10ml            |
| <b>FST954</b>  | Camstent BACTERIA-PHOBIC® Coated Foley Catheter<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 14Fr (4.7mmØ) Effective Length 360mm / 5-10ml              |
| <b>FST1048</b> | Camstent BACTERIA-PHOBIC® Coated Foley Catheter<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Female Urethral use. 16Fr (5.3mmØ) Effective Length 190mm / 5-10ml            |
| <b>FST955</b>  | Camstent BACTERIA-PHOBIC® Coated Foley Catheter<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 16Fr (5.3mmØ) Effective Length 360mm / 5-10ml              |
| <b>FST1047</b> | Camstent BACTERIA-PHOBIC® Coated Foley Catheter<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Female Urethral use. 18Fr (6.0mmØ) Effective Length 190mm / 5-10ml            |
| <b>FST960</b>  | Camstent BACTERIA-PHOBIC® Coated Foley Catheter<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 18Fr (6.0mmØ) Effective Length 360mm / 5-10ml              |
| <b>FST1046</b> | Camstent BACTERIA-PHOBIC® Coated Foley Catheter<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Female Urethral use. 20Fr (6.7mmØ) Effective Length 190mm / 5-10ml            |
| <b>FST962</b>  | Camstent BACTERIA-PHOBIC® Coated Foley Catheter<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 20Fr (6.7mmØ) Effective Length 360mm / 5-10ml              |
| <b>FST963</b>  | Camstent BACTERIA-PHOBIC® Coated Foley Catheter, Tiemann Tip<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 12Fr (4.0mmØ) Effective Length 360mm / 5-10ml |
| <b>FST964</b>  | Camstent BACTERIA-PHOBIC® Coated Foley Catheter, Tiemann Tip<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 14Fr (4.7mmØ) Effective Length 360mm / 5-10ml |
| <b>FST965</b>  | Camstent BACTERIA-PHOBIC® Coated Foley Catheter, Tiemann Tip<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 16Fr (5.3mmØ) Effective Length 360mm / 5-10ml |
| <b>FST966</b>  | Camstent BACTERIA-PHOBIC® Coated Foley Catheter, Tiemann Tip<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 18Fr (6.0mmØ) Effective Length 360mm / 5-10ml |
| <b>FST967</b>  | Camstent BACTERIA-PHOBIC® Coated Foley Catheter, Tiemann Tip<br>Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 20Fr (6.7mmØ) Effective Length 360mm / 5-10ml |

## 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.



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