Camstent

CAMSTENT 'BACTERIA-PHOBIC®' COATED FOLEY CATHETER

CE 1639 UKCA 0120

Product Code REF	Description Narrative
CSF12F10	CAMSTENT 'BACTERIA-PHOBIC®' COATED FOLEY CATHETER Silicone 2-way, X-ray detectable, Urinary Catheter for Female Urethral use. 12Fr (4.0mmØ) Effective Length 190mm / 5-10ml
CSF12S10	CAMSTENT 'BACTERIA-PHOBIC®' COATED FOLEY CATHETER Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 12Fr (4.0mmØ) Effective Length 360mm / 5-10ml
CSF14F10	CAMSTENT 'BACTERIA-PHOBIC®' COATED FOLEY CATHETER Silicone 2-way, X-ray detectable, Urinary Catheter for Female Urethral use. 14Fr (4.7mmØ) Effective Length 190mm / 5-10ml
CSF14S10	CAMSTENT 'BACTERIA-PHOBIC®' COATED FOLEY CATHETER Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 14Fr (4.7mmØ) Effective Length 360mm / 5-10ml
CSF16F10	CAMSTENT 'BACTERIA-PHOBIC®' COATED FOLEY CATHETER Silicone 2-way, X-ray detectable, Urinary Catheter for Female Urethral use. 16Fr (5.3mmØ) Effective Length 190mm / 5-10ml
CSF16S10	CAMSTENT 'BACTERIA-PHOBIC®' COATED FOLEY CATHETER Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 16Fr (5.3mmØ) Effective Length 360mm / 5-10ml
CSF18F10	CAMSTENT 'BACTERIA-PHOBIC®' COATED FOLEY CATHETER Silicone 2-way, X-ray detectable, Urinary Catheter for Female Urethral use. 18Fr (6.0mmØ) Effective Length 190mm / 5-10ml
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CSF20F10	CAMSTENT 'BACTERIA-PHOBIC®' COATED FOLEY CATHETER Silicone 2-way, X-ray detectable, Urinary Catheter for Female Urethral use. 20Fr (6.7mmØ) Effective Length 190mm / 5-10ml
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CSF12S10T	CAMSTENT 'BACTERIA-PHOBIC®' COATED FOLEY CATHETER, TIEMANN TIP Silicone 2-way, X-ray detectable, Urinary Catheter for Male Urethral use. 12Fr (4.0mmØ) Effective Length 360mm / 5-10ml
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en - Camstent Coated Foley Catheter

IMPORTANT NOTES
This document is designed to provide instructions on how this product/s is used. It is not a reference to clinical techniques, and does not replace local, or national, guidance or protocols.

INTENDED USER
This product should only be used by a suitably trained healthcare professional, in a healthcare establishment.

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

INDICATIONS FOR USE
The Camstent Coated Foley Catheter is indicated at the clinician's discretion for adults requiring urinary catheterisation.

The catheters are sterile, single use devices, and are biocompatibility qualified for up to a maximum of 30 days continuous* use. *(*Immediate replacement of the devices shall be considered as continuous use.)*

PRODUCT CHARACTERISTICS
The catheter is coated.

The 'BACTERIA-PHOBIC®' coating limits attachment of bacteria to the catheter lumen as compared to uncoated surfaces. Fewer bacteria results in less biofilm which can cause CAUTI.

The coating applied is a silky smooth micro-thin patented polymer coating that also reduces friction to aid insertion/withdrawal and added patient comfort.

HOW SUPPLIED
Supplied sterile, ready for single patient use.

Pack Contents:
10 Camstent Coated Foley Catheters, together with 10 copies of the Instructions For Use.
Note: Syringes and balloon inflation fluid are not provided.

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.

CONTRAINDICATIONS
(1) Urethral injury or stricture
(2) Significant urinary obstruction, fistula or false passage

PRECAUTIONS / WARNINGS

(1) Ensure catheters have been stored at room temperature for >24hrs prior to use to ensure their flexibility.
(2) Do not use if the package is received open or damaged.
(3) Procedures should be performed only by clinicians with adequate training and knowledge. Medical literature should be consulted for techniques, hazards, contraindications, and complications prior to the procedure.
(4) The standard procedural precautionary measures used in all catheter insertion and withdrawals must be followed.
(5) The user should review compatibility of, and the instructions for use for, all devices being used in conjunction with these product/s so as to ensure safe and effective application'
(6) Do not use petroleum-based lubricants with the catheter as these may degrade catheter performance
(7) Do not use the female length catheters options for male patients
(8) Do not inflate the balloon without firstly ensuring the catheter is in the correct position.
(9) Continuous indwelling time shall not to exceed 30 days.
(10) In the event that the balloon does not deflate, and the user is not trained to deal with the situation, request assistance as directed by the local healthcare policy and protocol
(11) MRI Safety Information:

Non-clinical testing demonstrated that the Silicone Foley Balloon Catheter is MR Conditional.
A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 2,000-Gauss/cm (20-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Under the scan conditions defined, the Silicone Foley Balloon Catheter is expected to produce a maximum temperature rise of 1.5°C after 15-minutes of continuous scanning (i.e., per pulse sequence). In non-clinical testing, the image artefact caused by the Silicone Foley Balloon Catheter extends approximately 30-mm

POSSIBLE ADVERSE REACTIONS

As with all urinary catheters, possible adverse reactions for catheterised patients include:

(1) Urinary tract infection
(2) Injury to skin or urethra
(3) Haematuria
(4) Bladder stones
(5) Allergic reactions

SINGLE USE PRECAUTION

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

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

(1) Cross contamination due to ineffective re-processing/re-sterilisation.
(2) Mechanical fatigue, and associated failure, due to the effects of the re-processing / re-sterilisation method.

DIRECTIONS FOR USE

Catheter Insertion:

(1) Insert the catheter according to local and national policies, using aseptic non-touch technique (ANTT):
(2) Apply sterile gloves to clean hands and create a sterile procedure field.
(3) Visually inspect the sterile barrier system pouch immediately prior to use, in order to determine if breaches in the integrity of the sterile barrier system are evident. If a sterile barrier integrity breach is found the item shall be considered non-sterile and the product shall not be used.
(4) Open the packaging and hold the catheter using the innermost sleeve.
(5) Flex, and then visually inspect, the catheter surfaces for absence of coating defects such as surface cracking. If defects are noted the product shall not be used
(6) Apply lubricant according to standard local practice. Note: do not use petroleum-based lubricants.
(7) Insert the catheter tip and advance the catheter into the bladder via the urethra up to the Y-junction.
(8) Inflate the balloon using a prefilled syringe (not provided) containing 5-10ml of sterile water. Note: Ensure that urine is seen to drain freely before the balloon is inflated and monitor patient response for pain. If there is any uncertainty regarding the correct position of the catheter in bladder, or catheter tip resistance is felt at insertion, do not inflate the balloon and abandon the procedure.
(9) Attach a suitable urine collection system to the catheter.
(10) To minimise bladder neck and meatal pressure, secure the catheter and/or the collection device according to local procedures.
(11) Include the provided patient sticky label with the patient notes.
(12) Dispose of all used equipment according to local policy.
(13) Monitor the catheter and urine drainage according to local patient care practice.

Catheter Withdrawal:

(1) Apply gloves to clean hands.
(2) Deflate the balloon using a 10ml syringe (not supplied). This may need to be repeated to ensure the balloon is completely empty.
(3) Gently withdraw the catheter.
(4) Wipe the meatus according to local practice.
(5) Dispose of the used catheter and equipment according to local policy. Refer to 'Disposal' guidance below:

DISPOSAL

Discard after single use, DO NOT re-sterilise.

This product/s is to be disposed of as controlled medical waste according to national guidelines.

CATHETER REPLACEMENT SCHEDULE

The schedule for replacing the catheter is based on the individual patients' clinical needs, as judged by the healthcare professional

SERIOUS INCIDENT REPORTING

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

en: LABELLING SYMBOLOGY - EN ISO 15223-1, unless otherwise stated			
			
en: Manufacturer	**en:** Keep dry	**en:** Keep away from sunlight	**en:** Do not reuse
			
en: Use-by date	**en:** Sterilised using irradiation	**en:** Consult instructions for use	**en:** Batch code
			
en: Catalogue number	**en:** Do not use if package is damaged	**en:** European Conformity mark	**en:** Caution
			
en: Do not re-sterilise	**en:** Lower limit of temperature 10°C (Do Not use below)	**en:** Does not contain Latex.	**en:** Manufactured date
			
en: Medical device	**en:** Unique Device Identifier	**en:** Single sterile barrier system with protective packaging inside	**en:** MR Conditional *From labelling standards IEC 62570:2014 / ASTM F2503-13*
			
en: Authorized representative in the European Community	Non-Harmonised symbol raised for identifying “Quantity” of products contained	En: UK Conformity Assessed mark	

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