

PRODUCT DATASHEET

100% Silicone Foley Catheter 2-Way Standard w/Prefilled Syringe, 10ml

Brand	: CURAS®
Category	: Incontinence & Urology
Range	: Catheters
Product Group	: 100% Silicone Foley Catheters
REF	: 20020 - 20027



PRODUCT DESCRIPTION

Urology balloon catheter made of 100% silicone material, pre-packed with syringe prefilled with 10% aqueous glycerine solution.

INTENDED USE

The balloon catheter is an indwelling flexible tube retained in the bladder for continuous drainage, for short, medium and long-term use, up to 30 days. The prefilled syringe provides a convenient way to inflate the balloon with the correct fill volume. Single use only.

Type of Foley Catheter

- Siliconized (SIL)
 Silicone Elastomer Coated (SEC)
 100% Silicone

Duration of Use

- Short Term**
 Medium Term
 Long Term

FEATURES & BENEFITS

- Catheter is biocompatible, with encrustation resistant properties.
- 100% medical grade silicone material, DEHP-free and non-pyrogenic.
- Smoothed tip ensures atraumatic introduction.
- X-ray tip and x-ray line provide visualization of positioning.
- Plastic valve for effective inflation and deflation of balloon.
- Colour-coded sleeve allows easy identification of catheter size.
- Symmetrical balloon provides good retention of catheter in the bladder, reducing discomfort.
- Soft funnel for flexible and effective connection, avoiding urinary spills.
- Pre-packed set of catheter and prefilled syringe is a convenient and cost effective solution.
- Ready-to-use set in sterile pack enables aseptic procedure, promotes patient safety and reduces risk of infection.
- Pre-measured volume syringe with 10% aqueous glycerine solution reduces diffusion rate of fill volume in catheter balloon, thus reducing the need for regular checks and re-inflation.

PRODUCT SPECIFICATIONS

REF	Description	Size	Balloon Capacity	Colour Code	Length	Packing
20020	2-Way Std. w/Prefilled Syringe	12 Ch	10 ml	White	40 cm	Sterile Peel Pouch
20021	2-Way Std. w/Prefilled Syringe	14 Ch	10 ml	Green	40 cm	Sterile Peel Pouch
20022	2-Way Std. w/Prefilled Syringe	16 Ch	10 ml	Orange	40 cm	Sterile Peel Pouch
20023	2-Way Std. w/Prefilled Syringe	18 Ch	10 ml	Red	40 cm	Sterile Peel Pouch
20024	2-Way Std. w/Prefilled Syringe	20 Ch	10 ml	Yellow	40 cm	Sterile Peel Pouch

*Set includes Prefilled Syringe, 10ml, 10% Aqueous Glycerine Solution

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Composition

- Catheter made of 100% medical grade silicone material.
- Catheter hard valve made of PVC plastic.
- Syringe prefilled with sterile water + 10% glycerine.
- Syringe barrel and plunger made of homopolymer polypropylene.
- Syringe protective cap made of TPE (styrene block copolymer).
- 100% latex-free, DEHP-free and non-pyrogenic.

Country of Origin

- China

Sterilization

- Catheter sterilized by Ethylene Oxide (EtO).
- Prefilled syringe sterilized by Gamma Irradiation.

Shelf Life

- 5 years for catheter.
- 3 years for prefilled syringe.

Standards & Guidelines

- | | | |
|--|----------------|----------------|
| ■ MDD 93/42/EEC (CE Marking), as amended by Directive 2007/47/EC | ■ EN 980 | ■ EN ISO 11607 |
| ■ EN ISO 13485:2003 | ■ EN 1041 | ■ EN ISO 11135 |
| ■ ISO 14971 | ■ ISO 15223-1 | ■ EN ISO 11137 |
| ■ EN 556-1 | ■ EN 1616 | ■ EN ISO 11138 |
| | ■ EN ISO 10993 | ■ EN ISO 11737 |

Product Storage

- Store at room temperature (10-25°C / 50-77°F) and avoid exposure to elevated temperatures.
- Do not expose product to radiation, sunlight and UV light, as it will change the properties of the product.

Proposed Disposal Method

- Dispose of used catheter and syringe into a clinical waste bag or according to clinical waste protocol, e.g., incineration.

Product Symbols

- Catheter:



- Prefilled Syringe:



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PACKAGING INFO

REF	EAN-13 Barcode	Inner Pouch	Inner Box	Carton	Gross Weight
20020	5051400200205	1 pc catheter + 1 pc prefilled syringe	10 pcs / box	150 pcs / carton	~8.1 kg
20021	5051400200212	1 pc catheter + 1 pc prefilled syringe	10 pcs / box	150 pcs / carton	~8.3 kg
20022	5051400200229	1 pc catheter + 1 pc prefilled syringe	10 pcs / box	150 pcs / carton	~8.4 kg
20023	5051400200236	1 pc catheter + 1 pc prefilled syringe	10 pcs / box	150 pcs / carton	~8.7 kg
20024	5051400200243	1 pc catheter + 1 pc prefilled syringe	10 pcs / box	150 pcs / carton	~8.9 kg

Components / Material Properties			Recommendations on Waste Handling			
Packaging	Material	Contains PVC	Incinerate	Landfill	Recycle	Reuse
Catheter Peel Pouch	PE & Paper	--	√	(√)		
Prefilled Syringe Peel Pouch	PE & Paper	--	√	(√)		
Inner Box	Cardboard Paper	--	(√)	(√)	√	
Outer Carton	Corrugated Paper	--	(√)	(√)	√	
Transport Pallet	Wood	--			(√)	√

√ = Highly recommended

(√) = Recommended

ADDITIONAL INFO

- Catheter bio-compatibility test qualified: cytotoxicity, sensitivity, irritation.
- HS Code: 9018390000
- Documents available upon request.

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