

PRODUCT DATASHEET

100% Silicone Foley Catheter 2-Way Tiemann, 10ml

Brand	: CURAS®
Category	: Incontinence & Urology
Range	: Catheters
Product Group	: 2-Way Tiemann, 10ml
REF	: 20033 - 20035



PRODUCT DESCRIPTION

Urology catheter / balloon catheter made of 100% silicone material.

INTENDED USE

An indwelling flexible tube retained in the bladder for the purpose of continuous drainage. Suitable for short, medium and long-term use, up to 30 days. Single use only.

FEATURES

- Biocompatible, with encrustation resistant properties.
- 100% medical grade silicone material, DEHP-free and non-pyrogenic.
- Angled tip eases navigation of the male urethra, especially when a stricture is present.
- 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 for easy identification of size.
- Symmetrical balloon for good retention of catheter in the bladder, reducing discomfort.
- Soft funnel for flexible and effective connection, avoiding urinary spills.
- Perforated inner sleeve for aseptic handling.

Type of Foley Catheter

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

Duration of Use

- Short Term**
- Medium Term**
- Long Term**

PRODUCT SPECIFICATIONS

REF	Size	Balloon Capacity	Colour Code	Length
20033	14 Ch	10 ml	Green	40 cm
20034	16 Ch	10 ml	Orange	40 cm
20035	18 Ch	10 ml	Red	40 cm

Composition

- Made of 100% medical grade silicone material.
- Hard valve made of PVC plastic.

Country of Origin

- China

Sterilization

- Ethylene Oxide (EtO)

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Shelf Life

- 5 years

Standards & Guidelines

- MDD 93/42/EEC (CE Marking), amended by Directive 2007/47/EEC
- EN 980:2008
- EN 1616:1997
- EN ISO 13485:2003
- EN ISO 14971:2007
- EN ISO 10993-1:2003
- EN ISO 11135-1:2007
- EN ISO 11607-1:2006
- EN ISO 11737-1:2006

Product Storage

- Store at room temperature (15-25°C / 60-80°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 into clinical waste bag or according to clinical waste protocol, e.g., incineration.

Product Symbols



PACKAGING INFO

REF	EAN-13 Barcode	Peel Pouch	Inner Box	Carton	Gross Weight
20033	5051400200335	1 pc / pouch	20 pcs / box	300 pcs / carton	~7.8 kg
20034	5051400200342	1 pc / pouch	20 pcs / box	300 pcs / carton	~7.8 kg
20035	5051400200359	1 pc / pouch	20 pcs / box	300 pcs / carton	~7.8 kg

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

(√) = Not highly recommended

ADDITIONAL INFO

- Bio-compatibility test qualified: cytotoxicity, sensitivity, irritation.
- H.S. Code: 9018390000
- Documents can be made available upon request.

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