

PRODUCT DATASHEET

100% Silicone Foley Catheter 2-Way Standard, 30ml

Brand : CURAS®

Category : Incontinence & Urology

Range : Catheters

Product Group : 2-Way Standard, 30ml

REF : 20044 - 20046



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.
- 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.

PRODUCT SPECIFICATIONS

REF	Size	Balloon Capacity	Colour Code	Length
20044	14 Ch	30 ml	Green	40 cm
20045	16 Ch	30 ml	Orange	40 cm
20046	18 Ch	30 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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Asia Pacific

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Type of Foley Catheter ○ Siliconized (SIL) ○ Silicone Elastomer Coated (SEC) ② 100% Silicone Duration of Use ☑ Short Term ☑ Medium Term

✓ Long Term

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 11607-1:2006EN 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



Europe

England

Asia Pacific

Worldwide

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www.curas.com/symbols

PACKAGING INFO

REF	EAN-13 Barcode	Peel Pouch	Inner Box	Carton	Gross Weight
20044	5051400200441	1 pc / pouch	20 pcs / box	300 pcs / carton	~7.8 kg
20045	5051400200458	1 pc / pouch	20 pcs / box	300 pcs / carton	~7.8 kg
20046	5051400200465	1 pc / pouch	20 pcs / box	300 pcs / carton	~7.8 kg

Components / Material Properties Recommendations on Waste Handling Contains Landfill **Packaging** Material Incinerate Recycle Reuse **PVC** Peel Pouch PE & Paper -- $\sqrt{}$ (√) Corrugated Inner Box Corrugated Paper --(√) (√) √ **Outer Carton** Corrugated Paper **1/** (√) (√) Wood Transport Pallet (√)

ADDITIONAL INFO

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

 $^{(\}sqrt{\ })$ = Not highly recommended