

## PRODUCT DATASHEET

### Latex Foley Catheter, Silicone Coated 2-Way Standard, 30ml

Brand	: CURAS®
Category	: Incontinence & Urology
Range	: Catheters
Product Group	: 2-Way Standard, 30ml
REF	: 20127 - 20131



### PRODUCT DESCRIPTION

Urology catheter / balloon catheter made of natural latex material. Also known as Silicone Elastomer Coated (SEC) catheter. Coated with medical grade silicone fluid on the inner and outer surfaces.

### INTENDED USE

An indwelling flexible tube retained in the bladder for the purpose of continuous drainage. Suitable for medium-term use, up to 14 days. Single use only.

### FEATURES

- Surface-bonded with medical grade silicone fluid on the inner and outer lumen.
- Silicone coating ensures atraumatic introduction and protects against urethral irritation.
- 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.

### PRODUCT SPECIFICATIONS

REF	Size	Balloon Capacity	Colour Code	Length
20127	14 Ch	30 ml	Green	40 cm
20128	16 Ch	30 ml	Orange	40 cm
20129	18 Ch	30 ml	Red	40 cm
20130	20 Ch	30 ml	Yellow	40 cm
20131	22 Ch	30 ml	Purple	40 cm

### Composition

- Made of natural latex material.
- Coated with medical grade silicone fluid.
- Hard valve made of ABS (acrylonitrile butadiene styrene).

### Country of Origin

- China

### Sterilization

- Ethylene Oxide (EtO)

Type of Foley Catheter
<input type="radio"/> Siliconized (SIL) <input checked="" type="radio"/> <b>Silicone Elastomer Coated (SEC)</b> <input type="radio"/> 100% Silicone
Duration of Use
<input checked="" type="checkbox"/> <b>Short Term</b> <input checked="" type="checkbox"/> <b>Medium Term</b> <input type="checkbox"/> Long Term

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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 1618:1997
- 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
20127	5051400201271	1 pc / pouch	20 pcs / box	400 pcs / carton	~9 kg
20128	5051400201288	1 pc / pouch	20 pcs / box	400 pcs / carton	~10 kg
20129	5051400201295	1 pc / pouch	20 pcs / box	400 pcs / carton	~10 kg
20130	5051400201301	1 pc / pouch	20 pcs / box	400 pcs / carton	~12 kg
20131	5051400201318	1 pc / pouch	20 pcs / box	400 pcs / carton	~13 kg

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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

- Product contains natural rubber latex which may cause allergic reactions.
- Bio-compatibility test qualified: cellular toxicity, inner skin stimulus, allergy and pyrogen.
- H.S. Code: 9018390000
- Documents can be made available upon request.