

Technical Data Sheet

Chameleon™ PTA

Balloon Catheter

Product Information

Product code	Diameter (mm)	Balloon length (mm)	Catheter length (cm)	Recommended Sheath size (F)	Nominal Pressure (atm)	Rated Burst Pressure (atm)	Recommended Guidewire (in)	Qty	L x W x D (cm)	Weight (g)
CH05-40-75US	5	40	75	6	14	25	0.035	1	103 x 10 x 1	90
CH06-40-75US	6	40	75	6	14	25	0.035	1	103 x 10 x 1	90
CH07-40-75US	7	40	75	6	14	22	0.035	1	103 x 10 x 1	90
CH08-40-75US	8	40	75	6	14	22	0.035	1	103 x 10 x 1	90
CH09-40-75US	9	40	75	7	12	18	0.035	1	103 x 10 x 1	90
CH10-40-75US	10	40	75	7	12	14	0.035	1	103 x 10 x 1	90
CH12-40-75US	12	40	75	8	12	14	0.035	1	103 x 10 x 1	90

Indication

The Chameleon™ PTA Balloon Catheter is intended for use in Percutaneous Transluminal Angioplasty for the treatment of obstructive lesions of native or synthetic arterio-venous dialysis fistulae and for the treatment of the femoral, iliac, and renal arteries with or without the use of proximal injection of fluids such as contrast media.

Contraindications

DO NOT use the Chameleon™ Device for coronary arteries, cerebral vasculature nor for the delivery and/or expansion of stents.

Warnings and Precautions

Refer to IFU for detailed information

Insertion Technique

Refer to IFU for detailed information

Product Features

- Dedicated opening proximal to the balloon enables the infusion of diagnostics and therapeutic fluids.
- Two radiopaque markers located at both balloon ends.
- Proximal end of the catheter incorporates 3 Luer lock ports dedicated for accessing the balloon inflation lumen, fluid infusion lumen and guide wire loading port.

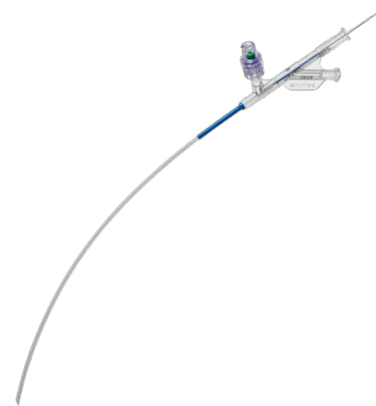


Figure 1. Chameleon™ PTA Balloon Catheter

Device components	Materials of Manufacture
Multi-lumen shaft	Rilsan Aenso
Inner tube	Rilsan Clear G170 med
Infusion plate	Stainless steal 304
Balloon	Pebax & Nylon
Soft tip	Vestamid
Marker bands	90% Platinum / 10% Iridium
Manifold	Makrolon 2458 (Polycarbonate)
Luer activated valve	ABS, PC - Makrolon, Silicone
Strain relief	Pebax 33 series
Rewrap tool/balloon protector	Polyethylene (packaging)
Packaging mandrel	Stainless steal 304
Carrier tube/protective sleeve	Provista copolyester (packaging)

Packaging	Material
Each	Tyvek pouch
Carton	duplex board white 350gr/m ²




Additional Information

Sterilisation Method	Ethylene Oxide
Shelf life	2 years (24 months)
Latex-free	✓
DEHP-free	✓
Single use	✓
Directive Classification	Ila
Country of Manufacture	Ireland
GMDN Code	17184

Standards

ISO 13485:2016
ISO 10555-1:2013/Amd1:2017
ISO 10555-4:2013
ISO 10993-1:2018
ISO 11135:2014/Amd 1:2018
ISO 11607-1:2019
ISO 14971:2019
ISO 15223-1:2016
ISO 80369-7:2016
IEC 62366-1:2015/Amd1:2020

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