

English

Instructions for Use

AndraBalloon® and Andra2Balloon

Important note: The product is supplied in sterile packaging (EO sterilisation), intended for single use and must not be re-sterilised. The product must be stored in a cool, dry place and protected from light. If the product or packaging is damaged, the product must not be used. The product may only be used by a physician familiar with this type of application. The medical device has been designed for single use only. It must not be reprocessed! It must not be cleaned, disinfected or sterilised! Resterilisation, cleaning and/or disinfection may cause changes in the material, impair the performance of this product and increase the risk of an infection or cross contamination. Additional warnings are given throughout these Instructions for Use.

Please note that indications, contraindications and application of the above-named product must always comply with current medical standards. The guidelines and recommendations of the relevant medical professional associations must be observed.

Designation

AndraBalloon® PTA catheter and **Andra2Balloon** Stent-Delivery-Catheter

Description and variants of the AndraBalloon®

The AndraBalloon® PTA catheter is a double-lumen catheter with a balloon that maintains its shape (non-compliant). AndraBalloon® dilatation catheters are used to dilate narrow vessel segments and as Stent-Delivery-Catheter for the AndraStent®.

The **Andra2Balloon** is a Stent-Delivery-Catheter for the AndraStent®. The Andra2Balloon consists of 2 AndraBalloons, to ensure and save an equal opening of the AndraStent®. The two balloons must be inflated separately. The inner Balloons needs to be inflated first and after saving opening the outer balloon should be inflated.

For details of the AndraBalloon® regarding lengths, diameters, operating pressures and recommended introducer sheaths, please refer to table 1 for AndraBalloon® and table 2 for Andra2Balloon.

A Guide wire with maximum 0.035" must be used.

Intended Use Statement

The product group AndraBalloon® PTA catheters is intended as an Stent-Delivery-Catheter.

Indications

The **AndraBalloon®** PTA catheters are applied in the following indications:

- Stent-Delivery-Catheter for the Percutaneous Transluminal Angioplasty (PTA) of stenosis in atherosclerotic disease of peripheral arteries in adult patients treated with the AndraStent® peripheral

The **Andra2Balloon** Stent-Delivery-Catheters apply in the following indications:

- As Stent-Delivery-Catheter for the Percutaneous Transluminal Angioplasty (PTA) of stenosis in atherosclerotic disease of peripheral arteries in adult patients treated with the AndraStent® peripheral

supplied by the respective manufacturer and in accordance with current medical standards.

Medical products may constitute a biological risk after use. Medical devices should be used and disposed of in accordance with statutory provisions and recognised methods.

Technical Details of AndraBalloon® and Andra2Balloon

Table 1: Technical Data AndraBalloon®

Balloon Diameter	Balloon length	Usable length of catheter in mm	Nominal Pressure	Rated Burst Pressure	Recommended Introducer Sheath
10	20 / 30 / 40	800 or 1200	400 kPa (4 bar)	1000 kPa (10 bar)	7 F
12	20 / 30 / 40	800 or 1200	400 kPa (4 bar)	1000 kPa (10 bar)	7 F
14	30 / 40 / 60	800 or 1200	400 kPa (4 bar)	1000 kPa (10 bar)	8 F
16	30 / 40 / 60	800 or 1200	400 kPa (4 bar)	800 kPa (8 bar)	10 F
18	30 / 40 / 60	800 or 1200	400 kPa (4 bar)	700 kPa (7 bar)	10 F
20	30 / 40 / 60	800 or 1200	400 kPa (4 bar)	700 kPa (7 bar)	11 F
22	40 / 60	800 or 1200	400 kPa (4 bar)	700 kPa (7 bar)	11 F
24	40 / 60	800 or 1200	400 kPa (4 bar)	700 kPa (7 bar)	12 F
26	40 / 60	800 or 1200	400 kPa (4 bar)	700 kPa (7 bar)	13 F
28	40 / 60	800 or 1200	400 kPa (4 bar)	700 kPa (7 bar)	13 F
30	40 / 60	800 or 1200	400 kPa (4 bar)	600 kPa (6 bar)	13 F
32	40 / 60	800 or 1200	400 kPa (4 bar)	600 kPa (6 bar)	13 F

Table 2: Technical Data Andra2Balloon

Art.-Nr.	Inner balloon diameter / length	Outer balloon diameter / length	Usable length	Nominal pressure	Rated Burst Pressure	Introducer diameter
	mm	mm	mm	kPa (bar)	kPa (bar)	F