

REDEFINING SELF-APPOSITION WITH A NEW BALLOON DELIVERY SYSTEM



1 Stent is mounted on a semi-compliant balloon and is restrained by a splittable sheath.



2 Balloon inflation splits the sheath and releases the Self-Apposing® stent.



3 The balloon is then deflated leaving the 0.0032" sheath between the stent and the vessel wall.



4 The balloon and sheath are then withdrawn leaving the stent apposed to the vessel wall. The two radiopaque stent markers are located at the edges of the stent.

Key Procedural Points

- DO NOT apply negative or positive pressure to the balloon prior to reaching the lesion site.
- The target lesion should be prepared in such a way that its minimum lumen diameter is at least 2.0mm. This is particularly applicable for tight and heavily calcified lesions.
- It is recommended to always slowly inflate the balloon to maximum deployment pressure (12atm). Avoid fast inflation.
- Ensure that the balloon is fully deflated before attempting to remove the STENTYS Delivery System.
- Some resistance will be felt initially during removal. This is inherent to the procedure. Attention should be brought to the possible forward movement of the Guiding Catheter.
- Post-dilation is strongly recommended using a non-compliant balloon of the same size as RVD. Applied pressure should be at nominal value or higher if needed. No part of the STENTYS-Stent should be left under-expanded with respect to the reference vessel diameter.

Balloon Characteristics



PRESSURE		2.5-3.0mm	3.0-3.5mm	3.5-4.5mm
8atm (811kPa)	Nominal	2.50mm	3.00mm	3.15mm
12atm (1216kPa)	MAX*	2.70mm	3.26mm	3.50mm
14atm (1419kPa)	RBP	2.80mm	3.65mm	3.74mm

* MAX: Maximum deployment pressure (Recommended Implantation Pressure).

The nominal in-vitro device specifications do not take into account any lesion resistance.

Do not exceed RBP (Rated Burst Pressure).

Ordering Codes

Recommended Reference Vessel Diameter	 Sirolimus-Eluting Self-Apposing® Coronary Stent System			 Bare-Metal Self-Apposing® Coronary Stent System			Maximum Vessel Diameter for Vessels with Diameter Variations	Minimum Side Branch Diameter
	Stent Nominal Length			Stent Nominal Length				
∅ (mm)	17mm	22mm	27mm	17mm	22mm	27mm	∅ (mm) ◊	∅ (mm) ▲
2.5 - 3.0mm	BDS02-2530-17	BDS02-2530-22	BDS02-2530-27	BDS00-2530-17	BDS00-2530-22	BDS00-2530-27	4	≥2.2
3.0 - 3.5mm	BDS02-3035-17	BDS02-3035-22	BDS02-3035-27	BDS00-3035-17	BDS00-3035-22	BDS00-3035-27	5	≥2.25
3.5 - 4.5mm	BDS02-3545-17	BDS02-3545-22	BDS02-3545-27	BDS00-3545-17	BDS00-3545-22	BDS00-3545-27	6	≥2.5

Guiding Catheter Compatibility ∅: 6F (2.0mm) Note the use of buddy wire may require the use of guiding catheter larger than 6F.

◊ Maximum Vessel Diameter For Vessels with Diameter variations (e.g. tapered, ectactic).

Foreshortening can be over 10% outside the Recommended Reference Vessel Diameter Range.

▲ For lesions in vessels involving a Side Branch (bifurcation); Side Branch & Main Branch having 30-70° Angle.