

# 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4 The balloon and sheath are then withdrawn leaving the stent apposed to the vessel wall.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

### Lesion Preparation

The target lesion should be prepared in such a way that its **minimum lumen diameter is at least 2.0mm, and residual stenosis should be less than 30%** prior to using the STENTYS-stent. This is particularly important for tight and heavily calcified lesions to minimise withdrawal force.

### Selecting and Preparing the Stent

Use the **distal vessel diameter** to determine the STENTYS-stent diameter. At the stent diameter range boundaries, it is recommended to use the **smaller size**. For example, a vessel diameter of 3.5mm Reference Vessel Diameter (RVD) would receive a 3.0-3.5mm STENTYS-stent, not a 3.5-4.5mm one.

Do not apply negative or positive pressure to the balloon prior to reaching the lesion site.

### Stent Deployment

It is recommended to slowly inflate the balloon to at least the recommended deployment pressure (REC) (12atm). Ensure visually that the **balloon is fully inflated** and increase pressure to Rated Burst Pressure (RBP) (14atm) if necessary.

### Withdrawal

To facilitate un-jailing of the sheath, it is recommended to **withdraw the Guiding Catheter** and constantly adjust its position to **maintain a 2cm gap** between the Guiding Catheter distal tip and the proximal marker of the STENTYS-stent.

### Post dilation

In order to ensure optimal stent expansion, **post dilation of the STENTYS-stent** with a non-compliant balloon is **strongly recommended** with a balloon diameter according to the RVD. Applied pressure should be at nominal value, or higher if needed. No part of the STENTYS-stent may be left under-expanded with respect to the RVD.

## Balloon Characteristics

PRESSURE		2.5-3.0mm	3.0-3.5mm	3.5-4.5mm
<b>8atm (811kPa)</b>	<b>NOM</b> <sup>①</sup>	2.50mm	3.00mm	3.50mm
<b>12atm (1216kPa)</b>	<b>REC</b> <sup>②</sup>	2.70mm	3.15mm	3.65mm
<b>14atm (1419kPa)</b>	<b>RBP</b> <sup>③</sup>	2.80mm	3.26mm	3.74mm

① **NOM** Balloon Nominal Pressure

② **REC** Recommended deployment pressure (also identified as "maximum deployment pressure" **MAX** in previous revision of the IFU)

③ **RBP** Rated Burst Pressure

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

The measurements indicate stent inner diameter. The stent sizing should be confirmed angiographically.

**Do not exceed RBP (Rated Burst Pressure).**

## Ordering Codes

Indicated Reference Vessel Diameter (mm)	Xposition S Sirolimus-Eluting Self-Apposing® Coronary Stent System				Xposition Bare-Metal Self-Apposing® Coronary Stent System				Side-branch diameter (mm) <sup>1</sup>
	Stent nominal length								
	17mm	22mm	27mm	37mm	17mm	22mm	27mm	37mm	
<b>S 2.5 - 3.0mm</b>	BDS02-2530-17	BDS02-2530-22	BDS02-2530-27	BDS02-2530-37	BDS00-2530-17	BDS00-2530-22	BDS00-2530-27	BDS00-2530-37	>2.20
<b>M 3.0 - 3.5mm</b>	BDS02-3035-17	BDS02-3035-22	BDS02-3035-27	BDS02-3035-37	BDS00-3035-17	BDS00-3035-22	BDS00-3035-27	BDS00-3035-37	>2.25
<b>L 3.5 - 4.5mm</b>	BDS02-3545-17	BDS02-3545-22	BDS02-3545-27	BDS02-3545-37	BDS00-3545-17	BDS00-3545-22	BDS00-3545-27	BDS00-3545-37	>2.50

Guidewire compatibility: 0.014" (0.35mm). Compatible with guiding catheters: 6F (2.0mm). Useable catheter length 139cm

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