Xposition S

Sirolimus-eluting Self-Apposing® Coronary Stent System

Xposition

Bare-metal Self-Apposing® Coronary Stent System

REDEFINING SELF-APPOSITION
WITH A NEW BALLOON DELIVERY SYSTEM

1 Stent is mounted on a semi-compliant balloon and is restrained by a splitable 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4 The balloon and sheath are then withdrawn leaving the stent apposed to the vessel wall.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.

STENTYS

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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
8atm (811kPa)	NOM ①	2.50mm	3.00mm	3.50mm
12atm (1216kPa)	REC ②	2.70mm	3.15mm	3.65mm
14atm (1419kPa)	RBP ③	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 — Stent nominal length				Xposition Bare-Metal Self-Apposing® Coronary Stent System — Stent nominal length				Side-branch diameter (mm)[1]
		17mm	22mm	27mm	37mm	17mm	22mm	27mm	37mm	
S	2.5 - 3.0mm	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
M	3.0 - 3.5mm	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
L	3.5 - 4.5mm	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

 BDS-Tech-20160512 Rev 1