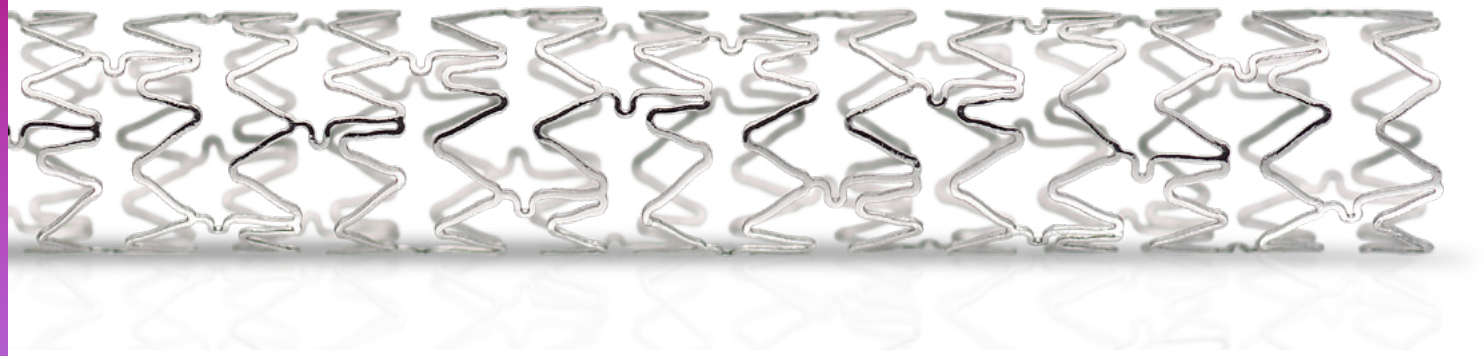
Abbott

XIENCE Pro™ S

Everolimus Eluting Coronary Stent System

REDEFINING DELIVERABILITY IN COMPLEX LESIONS



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Information contained herein for DISTRIBUTION outside the U.S. ONLY. Check the regulatory status of the device before distribution in areas where CE marking is not the regulation in force.

TABLES

FIGURES

XIENCE Pro™ S
Everolimus Eluting Coronary Stent System

PRODUCT DESCRIPTION[1]

The XIENCE Pro™ S Everolimus Eluting Coronary Stent System (EECSS) includes:

- A pre-mounted L-605 cobalt chromium (CoCr) alloy XIENCE Pro™ S Stent with a coating that consists of a blend of the anti-proliferative drug everolimus and polymers. The product family consists of:

Table 1: Product Name and Sizes[1]

PRODUCT NAME	STENT DIAMETER (mm)	STENT LENGTH (mm)
XIENCE Pro™ S Stent	2.0, 2.25, 2.5, 2.75, 3.0, 3.25, 3.5, 4.0	8, 12, 15, 18, 23, 28, 33, 38

PRODUCT CHARACTERISTICS

XIENCE Pro™ S Stent is specifically designed for best-in-class deliverability*, expanded treatment options^ and unparalleled safety[1] in complex anatomy.

- XIENCE Pro™ S Stent offers ultra-low crimped stent crossing profile of 0.039 inch.*
- XIENCE Pro™ S Stent offers increased post dilatation capabilities up to 3.75 mm for diameters 2.0 – 3.25 mm and 5.5 mm for diameters 3.5 – 4.0 mm.[2]
- XIENCE Pro™ S Stent offers exceptional deliverability from the re-engineered stent delivery system featuring a single-piece outer member for added pushability and trackability.

Figure 1: XIENCE Pro™ S Stent 3.0 x 18 mm Crimped Image

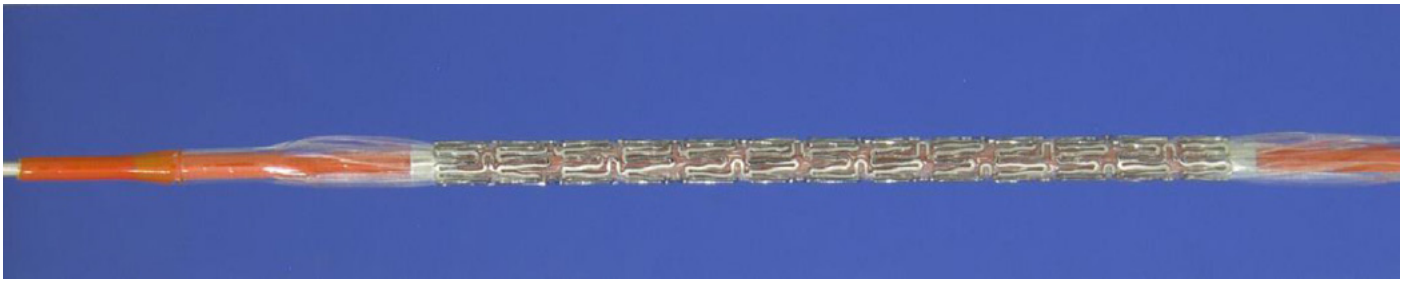

Photo on file at Abbott.

Data on file at Abbott, unless otherwise noted.

* XIENCE Pro™ S Everolimus Eluting Coronary Stent System (3.0 x 18 mm) n=5, SYNERGY‡ Stent System (3.0 x 20 mm) n=5, Resolute Onyx‡ Stent System (3.0 x 18 mm) n=5.

^ Increased maximum expansion compared to other XIENCE™ Everolimus Eluting Coronary Stent System.

1. Zanchin C, et al. *JACC Cardiovasc Interv*. 2019;12(17):1665-1675. Serruys P, et al. *N Engl J Med*. 2010;363:136-146. Shiomi H, et al. *JACC Cardiovasc Interv*. 2019;12:637-647. Kufner S, et al. *Circulation*. 2019:139(3):325-333. Palmerini T, et al. *Lancet*. 2013;379:1393-1402. Bangalore S, et al. *Circulation*. 2012;125:2873-2891. Bangalore S, et al. *Circ Cardiovasc Interv*. 2013;6(6):378-390. Pilgrim T, et al. *Lancet*. 2014;384:2111-2122. Pilgrim T, et al. *Lancet*. 2018;392:737-746.
2. XIENCE Pro™ S Stent Instructions for use (IFU). Refer to IFU for additional information.

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INDICATIONS PER IFU

The XIENCE Pro™ S Everolimus Eluting Coronary Stent System is indicated for improving coronary luminal diameter in the following:

- Patients with symptomatic ischemic heart disease due to discrete de novo native coronary artery lesions.
- For restoring coronary flow in patients experiencing acute myocardial infarction who present within 12 hours of symptom onset.
- For the treatment of patients with concomitant diabetes, acute coronary syndrome, dual vessel lesions (two lesions in two different epicardial vessels), lesions residing within small coronary vessels; lesions where treatment results in the jailing of side branches (lesions with a side branch < 2 mm in diameter or an ostial stenosis < 50%); for the treatment of elderly patients (age ≥ 65), and for treatment of both men and women.
- For treatment of patients with high bleeding risk (HBR) under dual anti-platelet therapy (DAPT) as short as 28 days.
- For the treatment of patients presenting with in-stent restenosis in coronary artery lesions; chronic total occluded coronary artery lesions (defined as coronary artery lesions with TIMI flow 0 and lasting longer than 3 months); and coronary artery bifurcation lesions. In all cases, the treated lesion length should be less than the nominal stent length (8 mm, 12 mm, 15 mm, 18 mm, 23 mm, 28 mm, 33 mm, or 38 mm) with a reference vessel diameter of ≥ 2.00 mm and ≤ 4.25 mm.

ONE-MONTH (AS SHORT AS 28 DAYS) DAPT INDICATION

The safety of the XIENCE™ Stent in high bleeding risk (HBR) patients treated with 1-month (as short as 28 days) dual antiplatelet therapy (DAPT) post-PCI was established in the XIENCE 28 trial.

The XIENCE 28 trial is a prospective, single arm, multicenter, open label, nonrandomized trial to evaluate the safety of 1-month (as short as 28 days) dual antiplatelet therapy (DAPT) in high bleeding risk (HBR) patients undergoing PCI with the XIENCE™ Stent.

Patients were eligible for inclusion in XIENCE 28 if they fulfilled clinical criteria indicative of HBR and, if in the opinion of the referring physician, the risk of major bleeding with more than 1-month DAPT outweighed the antithrombotic benefit.

The objective of the trial was to show noninferiority of the primary endpoint of all death or all myocardial infarction (MI; modified ARC) from 1 to 6 months following XIENCE™ Stent implantation in HBR patients treated with 1-month DAPT compared to a historical control, treated with up to 12-month DAPT, after propensity score (PS) stratification.

The primary endpoint was met demonstrating that the XIENCE™ Stent is safe in HBR patients treated with 1-month (as short as 28 days) DAPT post-PCI.

XIENCE Pro™ S Stent Instructions for use (IFU). Refer to IFU for additional information.

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Table 2: Primary and Powered Secondary Endpoints Results – All Death / All MI and BARC 2-5 Bleeding from 1-6 Months in 1-Month Clear Patients[1]

	XIENCE 28 1-MONTH CLEAR PATIENTS (N = 1392)	XIENCE V™ STENT USA 1-MONTH CLEAR PATIENTS (N = 1411)	P-VALUE
All death / All MI	3.5%	4.3%	0.0005*
BARC 2–5 bleeding	4.9%	5.9%	0.1888**

* Noninferiority p-value; noninferiority margin and one-sided significant level are 2.5% and 0.025, respectively.
** Superiority p-value; superiority significance level is 0.025.

LONGITUDINAL STRENGTH[2]

Background Information

- Longitudinal strength is the ability of a stent to resist forces applied in a longitudinal direction post deployment of the stent. This force can come from IVUS pullback during post-deployment inspection, crossing with the stent delivery system or balloon dilatation catheter, guide catheter deep seating, and withdrawal of a jailed guidewire.
- Lack of longitudinal strength results in longitudinal stent compression or elongation (Longitudinal Stent Deformation: LSD), which could happen at any location of a stent.

Figure 2: Longitudinal Strength and Longitudinal Compression Angiographic Images

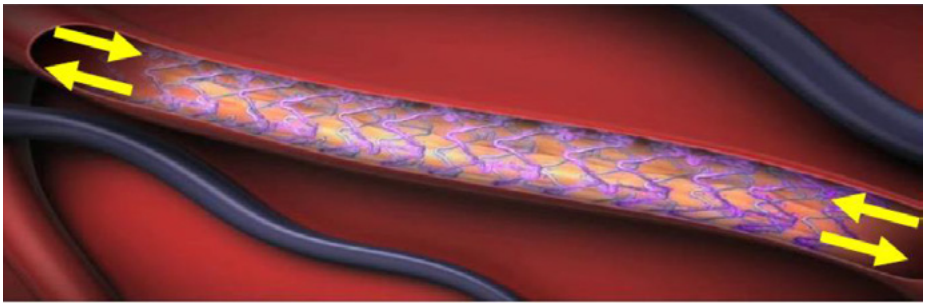
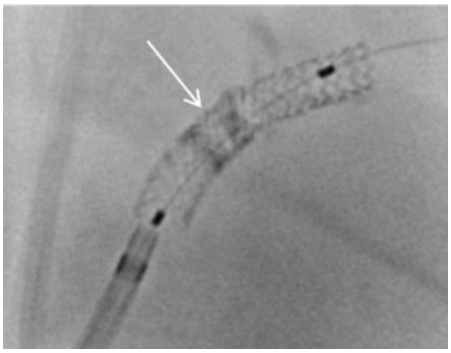


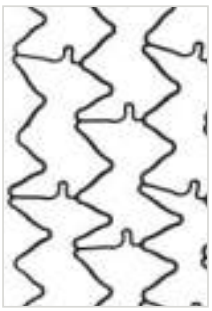
Photo on file at Abbott.



Mid-stent longitudinal compression
Fleig, PCR 2012

1. XIENCE Pro™ S Stent Instructions for use (IFU). Refer to IFU for additional information.
2. Data on file at Abbott.

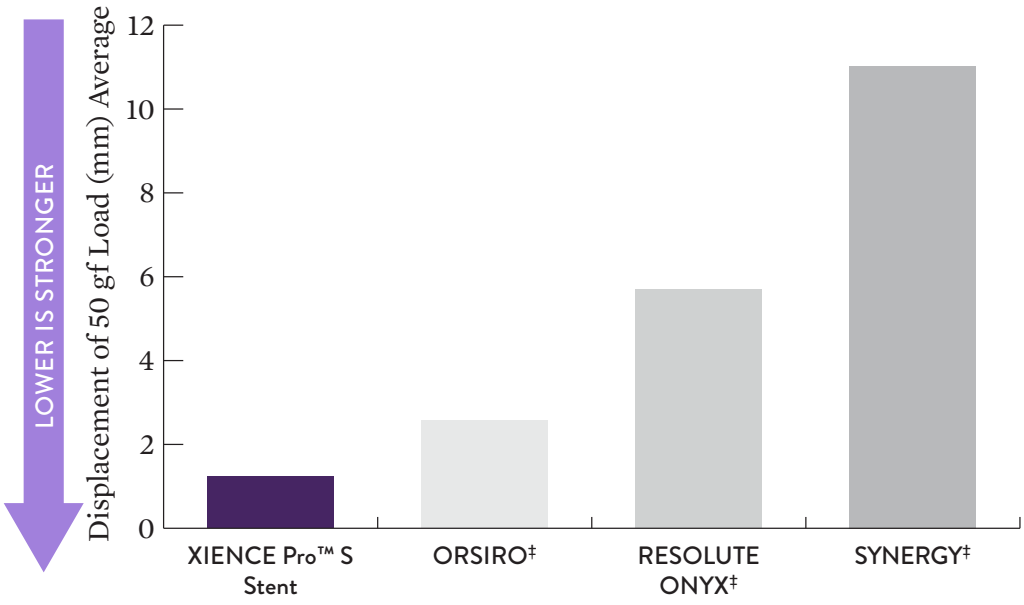
XIENCE™ Stents Have Superb Longitudinal Strength



- XIENCE Pro™ S Stent, XIENCE Pro™ A Stent, XIENCE Xpedition™ Stent, XIENCE PRIME™ Stent, and XIENCE V™ Stent are much less prone to longitudinal deformation.
- The XIENCE™ Family of Stents is based on the MULTI-LINK stent platform, which has 3 links per ring that connect peaks of one ring to the valleys of the adjacent ring.

The design prevents struts from compressing together and stretching apart (elongating).

Figure 3: XIENCE Pro™ S Stent Demonstrates Excellent Longitudinal Strength. Amount of Longitudinal Compression Caused by 50 gram Applied Load*



Data on file at Abbott.
* XIENCE Pro™ S Everolimus Eluting Coronary Stent System (3.0 x 18 mm) n=5, SYNERGY‡ Stent System (3.0 x 20 mm) n=5, Resolute Onyx‡ Stent System (3.0 x 18 mm) n=5, Orsiro‡ Sirolimus Eluting Coronary Stent System (3.0 x 18 mm) n=5.

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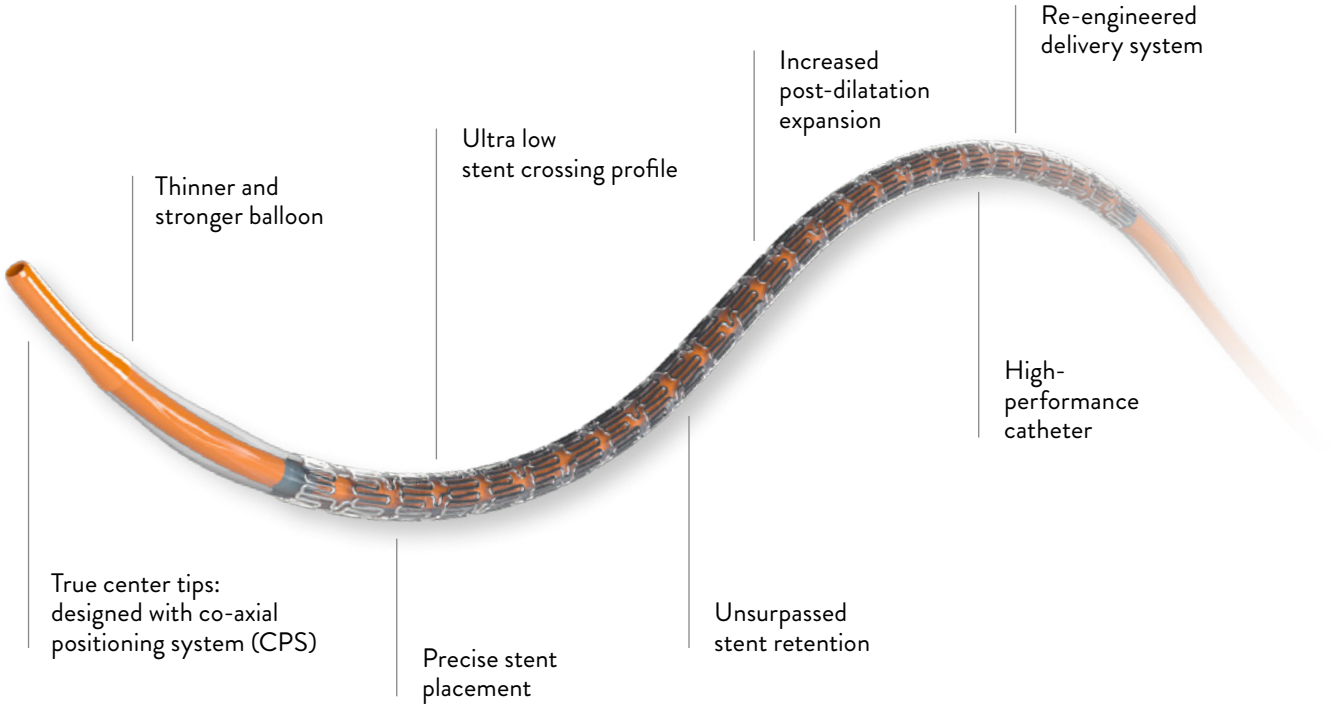
XIENCE PRO™ S STENT FEATURES

XIENCE Pro™ S Stent is specifically designed to provide best-in-class deliverability*, expanded treatment options^, and unparalleled safety[1] in increasingly complex lesions featuring a thinner and stronger balloon, ultra-low stent crossing profile*, increased post-dilatation expansion[2], and re-engineered delivery system, while maintaining the same key features of XIENCE Pro™ A Stent: True Center Tips, precision stent placement, unsurpassed stent retention, and high performance catheter.

Figure 4: XIENCE Pro™ S Stent Features



KEY FEATURES:

- Ultra-low stent crimped profile: Ultra low stent crimped profile of 0.039" for crossing tight lesions enabled by the new stent design and balloon technology.*

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* XIENCE Pro™ S Everolimus Eluting Coronary Stent System (3.0 x 18 mm) n=5, SYNERGY‡ Stent System (3.0 x 20 mm) n=5, Resolute Onyx‡ Stent System (3.0 x 18 mm) n=5.
^ Increased maximum expansion compared to other XIENCE™ Everolimus Eluting Coronary Stent System.

1. Zanchin C, et al. *JACC Cardiovasc Interv*. 2019;12(17):1665-1675. Serruys P, et al. *N Engl J Med*. 2010;363:136-146. Shiomi H, et al. *JACC Cardiovasc Interv*. 2019;12:637-647. Kufner S, et al. *Circulation*. 2019:139(3):325-333. Palmerini T, et al. *Lancet*. 2013;379:1393-1402. Bangalore S, et al. *Circulation*. 2012;125:2873-2891. Bangalore S, et al. *Circ Cardiovasc Interv*. 2013;6(6):378-390. Pilgrim T, et al. *Lancet*. 2014;384:2111-2122. Pilgrim T, et al. *Lancet*. 2018;392:737-746.
2. XIENCE Pro™ S Stent Instructions for use (IFU). Refer to IFU for additional information.

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Figure 5: XIENCE Pro™ S Stent Offers Ultra Low Stent Crimped Profile (3.0 x 18 mm)*

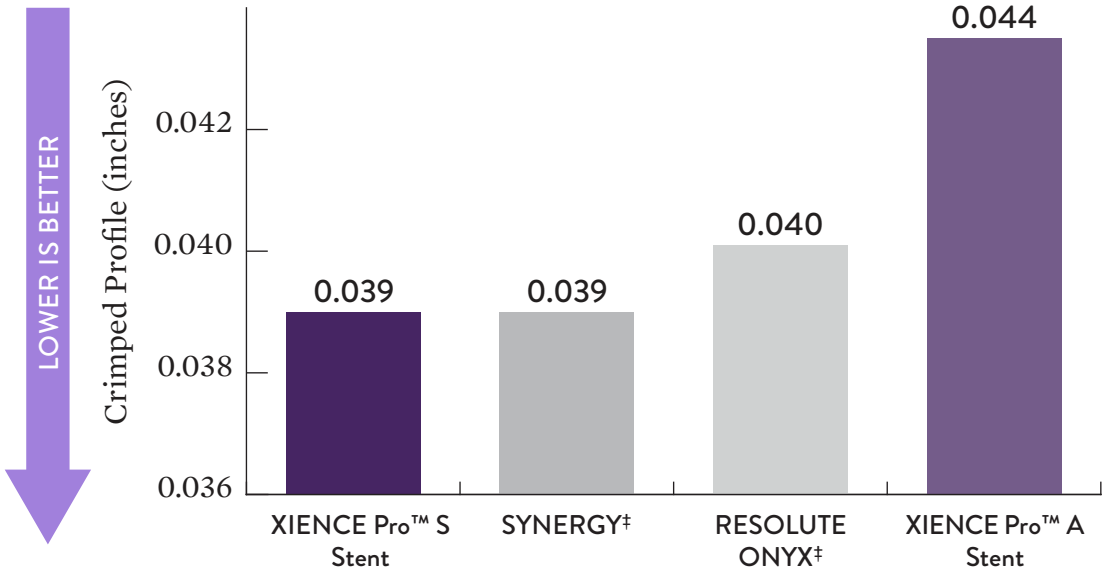
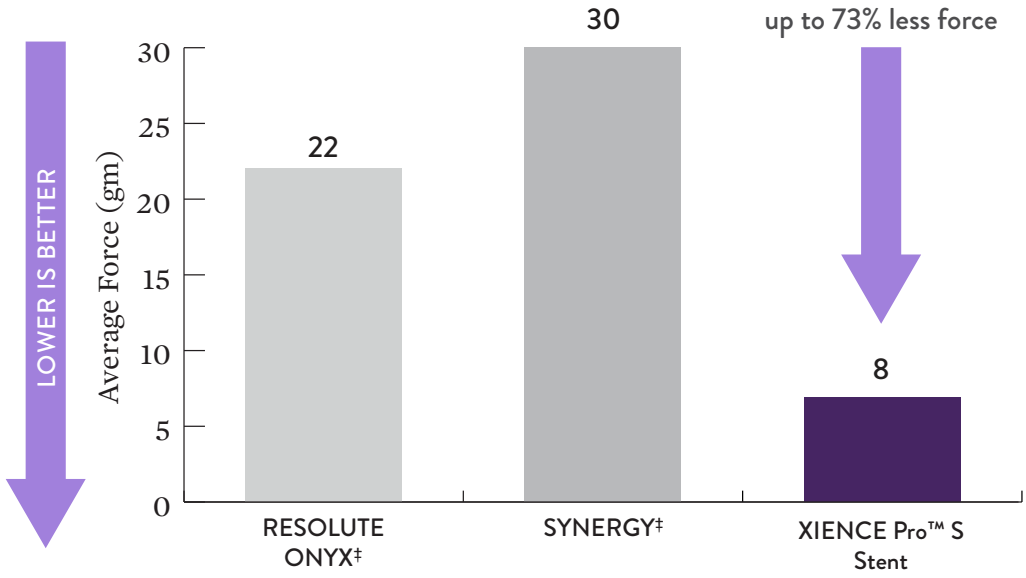


Figure 6: XIENCE Pro™ S Stent Requires 73% and 64% Less Force Than SYNERGY‡ and Resolute Onyx‡ Respectively to Cross the Same Lesion^



- Increased post–dilatation expansion: XIENCE Pro™ S Stent offers increased post dilatation capabilities up to 3.75 mm for diameters 2.0 – 3.25 mm and 5.5 mm for diameters 3.5 – 4.0 mm.

Data on file at Abbott.
* XIENCE Pro™ S Everolimus Eluting Coronary Stent System (3.0 x 18 mm) n=5, XIENCE Pro™ A (3.0 x 18 mm) n=5, SYNERGY‡ Stent System (3.0 x 20 mm) n=5, Resolute Onyx‡ Stent System (3.0 x 18 mm) n=5.
^ XIENCE Pro™ S Everolimus Eluting Coronary Stent System (3.0 x 18 mm) n=5, SYNERGY‡ Stent System (3.0 x 20 mm) n=5, Resolute Onyx‡ Stent System (3.0 x 18mm) n=5.

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Figure 7: Unsurpassed Precision in Placement with ZERO Shortening Even at Max Expansion*

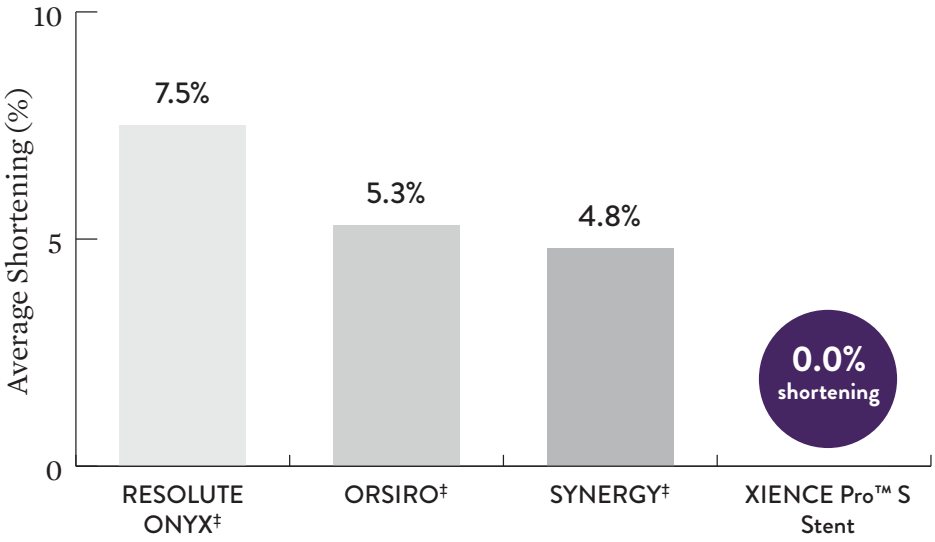
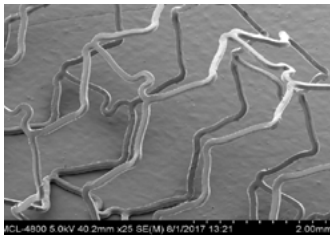
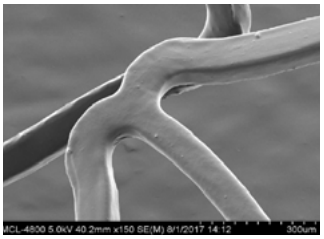


Figure 8: XIENCE Pro™ S Stent Displays Superior Coating Integrity Even at Max Expansion[2]

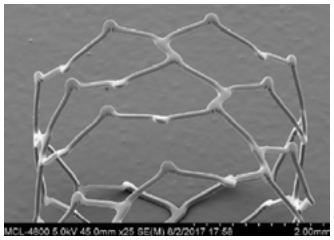
XIENCE Pro™ S Stent
(3.5 x 18 mm) 25x magnification at max expansion of 5.5 mm



XIENCE Pro™ S Stent
(3.5 x 18 mm) 150x magnification at max expansion of 5.5 mm

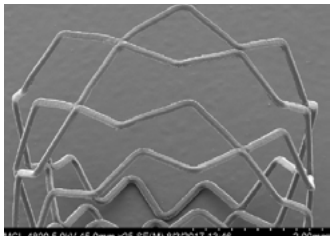


Synergy‡
(3.5 x 20 mm) 25x magnification at max expansion of 4.25 mm

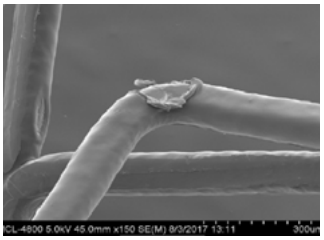


Synergy‡
(3.5 x 20 mm) 150x magnification at max expansion of 4.25 mm

Resolute Onyx‡
(3.5 x 18 mm) 25x magnification at max expansion of 4.75 mm



Resolute Onyx‡
(3.5 x 18 mm) 150x magnification at max expansion of 4.75 mm



Data on file at Abbott.
* XIENCE Pro™ S Everolimus Eluting Coronary Stent System (4.0 x 18 mm) n=5, SYNERGY‡ Stent System (4.0 x 20 mm) n=5, Resolute Onyx‡ Stent System (4.5 x 18 mm) n=5.

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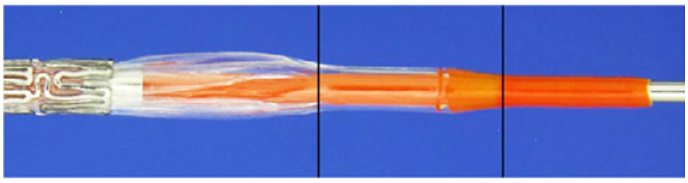
RE-ENGINEERED DELIVERY SYSTEM: Exceptional deliverability from the enhanced stent delivery system featuring a single-piece outer member[1] for added pushability and trackability.*

DURABLE BALLOON WITH FLEXIBILITY AND FLAT COMPLIANCE: Thin, single-layer balloon enables high pressure deployment while maintaining flexibility and strength.

TRUE CENTER TIP: Flexible tip design with co-axial positioning system (CPS) for peak performance in complex lesions.

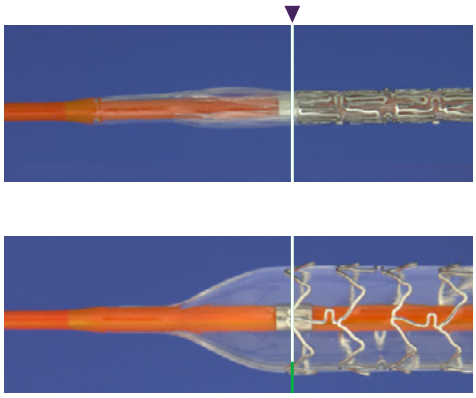
- Flexible distal tip: provides superb maneuverability to traverse tortuous anatomy. Navigate to the lesion.
- Co-axial Positioning System (CPS): reinforced proximal tip that re-centers the wire to eliminate bias and maintain stent positioning through complex, calcified lesions. Navigate through the lesion.

Figure 9: Image of True Center Tip of XIENCE Pro™ S Stent (3.0 x 18 mm)



CPS Flexible Distal Tip

Figure 10: Images of Crimped and Expanded XIENCE Pro™ S Stent (3.0 x 18 mm)



XIENCE Pro™ S Stent 3.0 x 18 mm

HIGH PERFORMANCE CATHETER: engineered to optimize strength, flexibility, and pushability

- Zero-transition distal shaft: Inner member extends to become the tip for flexibility, direct force transfer, and uncompromising control.
- Proprietary skive design: seamless hypotube with proprietary skive design for exceptional push force transmission
- Robust hypotube with ideal inner and outer diameter proportions: kink-resistant and smooth force transfer
- Specially formulated outer member: engineered for strength and endurance with flexibility in navigating complex anatomy

PRECISE PLACEMENT STENT DESIGN: market-leading MULTI-LINK design with accurate mid-marker to mid-marker stent placement for precise deployment.

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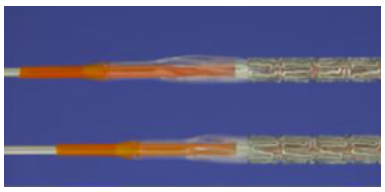
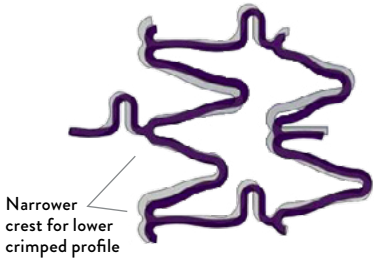
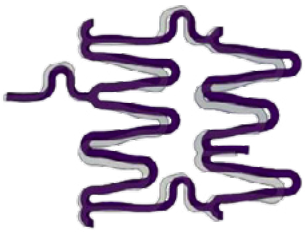
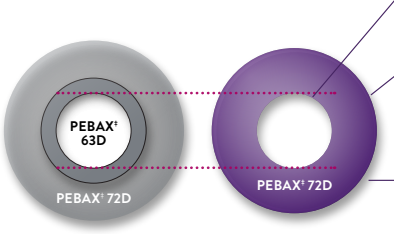
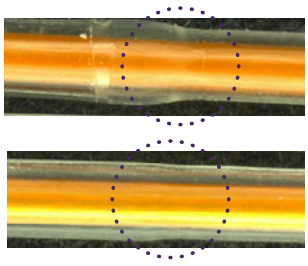
XIENCE Pro™ S
Everolimus Eluting Coronary Stent System

COMPARISON BETWEEN XIENCE PRO™ S STENT AND XIENCE PRO™ A STENT

	XIENCE Pro™ S Stent	XIENCE Pro™ A Stent	Photo/Drawing
Crimped Stent Profile	Lower crimped stent profile than XIENCE Pro™ A Stent 0.039 inch*	0.044 inch	 XIENCE Pro™ S Stent 3.0 x 18 mm XIENCE Pro™ A Stent 3.0 x 18 mm
Small Stent Platform (2.0-3.25mm) 6 Crest – 3 Link	Narrower crest, slimmer and more flexible links	MULTI-LINK stent Cobalt Chromium 3 non-linear links Peak-to-Valley design	 XIENCE Pro™ S Stent XIENCE Pro™ A Stent Narrower crest for lower crimped profile
Medium Design (3.5-4.0mm) 9 Crest – 3 Link	Extended bar arm for greater post dilatation to 5.5 mm	MULTI-LINK stent Cobalt Chromium 3 non-linear links Peak-to-Valley design	 Elongated bar arms for greater post-dilation to 5.5mm XIENCE Pro™ S Stent XIENCE Pro™ A Stent
Balloon	Thin, single-layer balloon enables high pressure deployment while maintaining flexibility and strength. Pebax‡ 72D	Durable Multi-Layer Balloon Inner layer: Pebax‡ 63D Outer layer: Pebax‡ 72D	 XIENCE Pro™ A Balloon XIENCE Pro™ S Balloon PEBAX‡ 63D PEBAX‡ 72D PEBAX‡ 72D **REMOVED SOFT PEBAX‡ 63D** resulting in a thinner, single-layer balloon **THINNER WALL** allows for maximum flexibility and lower crimped profile **STRONGER PEBAX‡ 72D** balloon material optimized for controlled balloon growth with thinner profile
Outer Member	A single-piece outer member for added pushability and trackability	Two-piece outer member	 **XIENCE PRO™ A STENT** Two-piece outer member **XIENCE PRO™ S STENT** Seamless outer member uniquely engineered to deliver consistent force transmission

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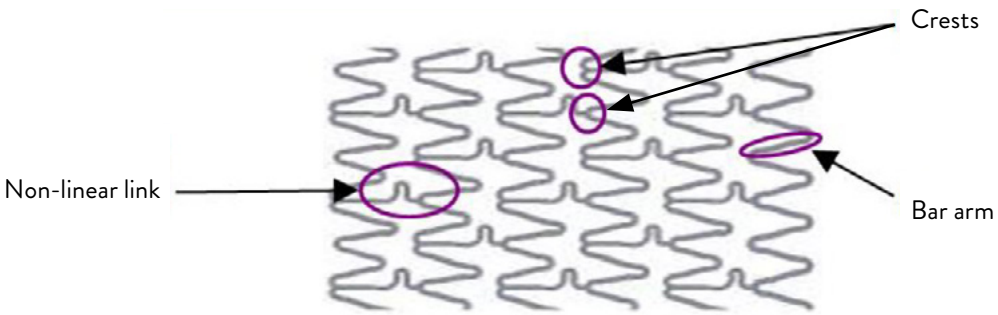
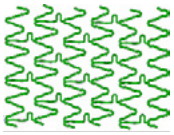
STENT TECHNICAL SPECIFICATIONS

Stent Terminology



Technical Parameter

Material Composition	L-605 Cobalt Chromium Chromium
Available Stent Diameters (mm)	2.0, 2.25, 2.5, 2.75, 3.0, 3.25, 3.50, 4.00
Available Stent Lengths (mm)	8, 12, 15, 18, 23, 28, 33, 38
Stent Design	Slotted tube stent, based on the MULTI-LINK stent design. There are two stent designs to maximize the flexibility, conformability, and expansion range of the various diameters. The 2.0 – 3.25 mm diameter stent design has 6 crests, connected by non-linear links.  The 3.50 and 4.0 mm diameter stent design has 9 crests, connected by non-linear links.  Both stent designs have a proximal end ring with symmetric crests and bar arms for improved pullback into the guide catheter.

Data on file at Abbott.

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Technical Parameter (continued)

Strut Design and Thickness	The struts are rounded and are 0.0032 inches (0.081 mm) thick for minimal vessel injury.[1]
Maximum Stent Expansion with Post-Dilatation	2.0 – 3.25 mm diameters: 3.75 mm 3.50 – 4.00 mm diameters: 5.50 mm
Metallic Surface Area when Stent is Expanded	13.3% Metal-to-Artery ratio at 3.0 mm (8 mm-28 mm in length) 13.2% Metal-to-Artery ratio at 3.0 mm (33 mm,38 mm in length) 13.9% Metal-to-Artery ratio at 4.0 mm (all length)
Percentage of Shortening on Expansion (not longitudinal stent compression)	0% for 4.00 x 18 mm delpoyed to 5.5 mm
Degree of Recoil of Stent Diameter	4.1% for 3.0 x18 mm at nominal.
Radial Strength	High. 1195 mmHg Above peak arterial pressure of 175 mmHg[2]
Longitudinal Stability /Deformation	Not prone to longitudinal deformation when an external force is applied to the stent.
Maximum Circular Unsupported Area (MCUSA)	1.14 mm^2 for 3.0 x 18 mm
Maximum Circular Access Diameter (MCAD) Largest diameter that can fit through struts	1.20 mm for 3.0 x 18 mm
Degree of Radiopacity	Comparable to XIENCE V™ Stent, XIENCE PRIME™ Stent, XIENCE Xpedition™ Stent, XIENCE Pro™ A Stent, MULTI-LINK VISION™ Stent, MULTI-LINK 8™ Stent

Data on file at Abbott, unless otherwise noted.

1. Intracoronary Stent and Angiographic Results: Strut Thickness Effect on Restenosis Outcome (ISAR-STEREO) Trial. A. Kastrati, et al, *Circulation* 2011; 103:2816-2821.
2. C.M. Agrawal, et al, Evaluation of poly (L-lactic acid) as a material for intravascular polymeric stents, Biomaterials, 1992.

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Technical Parameter (continued)

MRI Compatibility[1]	Non-clinical testing has demonstrated that the XIENCE Pro™ S Stent, in single and in overlapped configurations up to 71 mm in length, is MR Conditional. A patient with this device can be scanned in an MR system under the following conditions: • Static magnetic field of 1.5 or 3 Tesla • Maximum Spatial gradient field of 3000 Gauss/cm • Maximum MR System reported whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode) Under the scan conditions defined above, the XIENCE Pro™ S Stents are expected to produce a maximum temperature rise of less than 4.5°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device extends approximately 6 mm from the stents when imaged with a gradient echo or spin echo pulse sequence and a 3T MRI system. 1Certican‡ UK label 2017, Afinitor‡ EU authorization SPC 2014, Votubia‡ EU SPC 2017, Afinitor‡ US label 2010 & 2014, and Zortress‡ US label 2018. Refer to www.MHRA.gov.uk, www.ema.europa.eu, and www.fda.gov for the most recent versions of these SPC/labels. The effects of MRI on overlapped stents greater than 71 mm in length or stents with fractured struts are unknown. As demonstrated in non-clinical testing, an image artifact can be present when scanning the XIENCE Pro™ S Stent. MR image quality may be compromised if the area of interest is in the exact same area as, or relatively close to, the position of the XIENCE Pro™ S Stent. Therefore, it may be necessary to optimize the MR imaging parameters for the presence of XIENCE Pro™ S Stents.

1. XIENCE Pro™ S Stent Instructions for use (IFU). Refer to IFU for additional information.

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DRUG + COATING TECHNICAL SPECIFICATIONS

Technical Parameter

Drug	Everolimus
Drug Content	2.0 – 3.25 mm x 08: 39 µg 2.0 – 3.25 mm x 12: 58 µg 2.0 – 3.25 mm x 15: 72 µg 2.0 – 3.25 mm x 18: 85 µg 2.0 – 3.25 mm x 23: 111 µg 2.0 – 3.25 mm x 28: 131 µg 2.50 – 3.25 mm x 33: 157 µg 2.50 – 3.25 mm x 38: 177 µg 3.50 – 4.00 mm x 08: 53 µg 3.50 – 4.00 mm x 12: 72 µg 3.50 – 4.00 mm x 15: 99 µg 3.50 – 4.00 mm x 18: 117 µg 3.50 – 4.00 mm x 23: 145 µg 3.50 – 4.00 mm x 28: 181 µg 3.50 – 4.00 mm x 33: 209 µg 3.50 – 4.00 mm x 38: 236 µg
Drug Dose Density	100 µg/cm²
Coating	Coating technology: Functional mechanical integrity • Fluorinated copolymer/primer combination applied by a multi-layer process • Flexible/elastic with known durability over time[1] • Controlled drug release throughout the restenosis cascade[2] Enhanced biocompatibility to improve outcomes, including reduction of thrombus formation Fluorinated surfaces have long been recommended for cardiovascular implants Fluorinated surfaces minimize platelet activation and optimize protein absorption and retention[3,4] which contributes to: • Faster re-endothelialization[2,5,6] • Decreased inflammation[7] • Low thrombogenicity[8]

Data on file at Abbott, unless otherwise noted.

1. Palmerini T et al. *JACC* Nov 2013 doi: 10.1016/j.jacc.2013.09.061.
2. Perkins, Laura E. L., et al. XIENCE V™ Everolimus-Eluting Coronary Stent System: A Preclinical Assessment. *Journal of Interventional Cardiology*, vol. 22, 2009, S28-S40.
3. Garfinkle A, Hoffman A, Ratner B, et al. Effects of a tetrafluoroethylene glow discharge on patency of small diameter Dacron vascular grafts. *T Am Soc Art Int Org.* 1984;30:432-439.
4. Kiaei D, Hoffman A, Horbett T. Tight binding of albumin to glow discharge treated polymers. *J Biomat Sci-Polym E.* 1993;4(1):35-44.
5. Joner, Michael, et al. Endothelial Cell Recovery Between Comparator Polymer-Based Drug-Eluting Stents. *Journal of the American College of Cardiology*, vol. 52, no. 5, 2008, pp. 333–342.
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7. Otsuka, Fumiyuki. Acute Thrombogenicity of a Durable Polymer Everolimus-Eluting Stent Relative to Contemporary Drug-Eluting Stents With Biodegradable Polymer Coatings Assessed Ex Vivo in a Swine Shunt Model. *JACC: Cardiovascular Interventions*, vol. 8, no. 9, 2015, pp. 1248–1260.
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STENT DELIVERY SYSTEMS TECHNICAL SPECIFICATIONS

Technical Parameter

Catheter	XIENCE Pro™ S Stent Rapid Exchange / Monorail
0.014 inch Compatability	Yes
Tip Entry Profile (Average)	0.017 inches (3.00 x 18 mm)
Tip Length	3-4 mm for stent with diameter of 2.0 – 3.25 mm 4-5 mm for stent with diameter of 3.5 - 4.0 mm
Tip construction (laser bonded, tapered etc.)	Tapered, integrated with distal shaft
Crimped Stent Profile (Average)	0.039 inches (3.00 x 18 mm)
Balloon Material	Single-layer Pebax‡
Folding of Balloon	Five folds to ensure uniform stent deployment (2.75 – 4.0 mm). Three folds for small diameters (2.0 - 2.5 mm).
Balloon Taper Lengths	2.0 - 3.25 mm: 3 mm 3.50 mm: 4 mm 4.00 mm: 5 mm
Stent-to-Balloon Shoulder Length	Distal Stent to Shoulder (DSTD) + Proximal Stent to Shoulder (PSTD) < 2.8 mm
Nominal Pressure	2.0 – 2.5 mm balloon diameter: 9 ATM 2.75 – 4.0 mm balloon diameter: 12 ATM
Rated Burst Pressure (RBP)	16 ATM
Number of Balloon Markers	All diameters have 2 markers
Position of Radiopaque Markers	Proximal and distal markers clearly indicate both the position of the expanded stent and balloon working length
Placement of Stent on Markers	The stent edges are crimped on the markers for stent placement accuracy

Data on file at Abbott.

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Technical Parameter (continued)

Width of Marker	1.0 mm (for 8 mm – 28 mm lengths) 1.5 mm (for 33 and 38 mm lengths)
Distance of Marker from Balloon Shoulder	Markers located within shoulders
Delivery System Shaft Markers	95 cm and 105 cm proximal to the distal tip
Mechanism of Deployment	Balloon Expandable
Pre-mounted on Delivery Catheter	Yes
Balloon Marker Material	Platinum Iridium
Recommended Deployment Pressure	In vitro nominal pressure is 9 atm for 2.0-2.5 mm balloon diameters, 12 atm for 2.75-4.0 balloon diameters in saline. Clinically, recommended deployment pressure is between nominal and 16 atm according to lesion characteristics.
Distal Shaft Coating (not including working length of balloon)	Hydrophilic
Working Catheter Length	145 cm
Distal Catheter Length	25.5 cm
Diameter of Distal Shaft	Min 0.033" (0.84 mm) Max 0.037" (0.94 mm)
Diameter of Mid Shaft	Min 0.035" (0.89 mm) Max 0.039" (0.99 mm)
Diameter of Proximal Shaft (Hypotube)	0.029" (0.74 mm)
Minimum Guiding Catheter	2.0-4.0 mm: Minimum ID guiding catheter 5Fr
Kissing Stent Compatible	7 French (0.070 inch)
Maximum Guidewire Diameter	0.014" (0.36 mm)
Sterilization Method	EtO (Ethylene Oxide Gas) sterilized

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Technical Parameter (continued)[1]

Storage Recommendation	Store in a dry, dark, cool place. Protect from light. Do not remove from carton until ready for use. Store at 25°C (77°F); excursions permitted to 15 – 30°C (59 – 86°F).
Single use and sterile product	

COMPLIANCE CHART[2]

PRESSURE		STENT ID BY SYSTEM DIAMETER							
atm	kPa	2.0 mm	2.25 mm	2.5 mm	2.75 mm	3.0 mm	3.25 mm	3.5 mm	4.0 mm
8	811	2.05	2.27	2.53	2.6	2.79	2.98	3.36	3.74
9	912	2.09	2.31	2.58	2.66	2.86	3.05	3.42	3.82
10	1,013	2.13	2.35	2.63	2.71	2.91	3.11	3.47	3.89
11	1,115	2.16	2.39	2.67	2.75	2.96	3.17	3.52	3.95
12	1,216	2.19	2.42	2.71	2.79	3.00	3.22	3.56	4.01
13	1,317	2.22	2.45	2.74	2.82	3.04	3.26	3.59	4.05
14	1,419	2.24	2.48	2.77	2.86	3.07	3.30	3.63	4.10
15	1,520	2.27	2.51	2.80	2.88	3.10	3.33	3.66	4.14
16	1,621	2.29	2.53	2.83	2.91	3.13	3.37	3.70	4.18
17	1,723	2.31	2.56	2.85	2.94	3.16	3.40	3.73	4.22
18	1,824	2.33	2.58	2.88	2.97	3.19	3.43	3.77	4.26
19	1,925	2.35	2.60	2.91	3.00	3.21	3.46	3.81	4.29
20	2,027	2.38	2.63	2.94	3.03	3.24	3.50	3.84	4.34

Nominal RBP

1. XIENCE Pro™ S Stent Instructions for use (IFU). Refer to IFU for additional information.
2. Data on file at Abbott.

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ORDERING INFORMATION

STENT DIAMETER	LENGTH								POST-DILATATION LIMIT
	8 mm	12 mm	15 mm	18 mm	23 mm	28 mm	33 mm	38 mm	
2.0 mm	1508200-08	1508200-12	1508200-15	1508200-18	1508200-23	1508200-28	1508200-33	1508200-38	3.75 mm
2.25 mm	1508225-08	1508225-12	1508225-15	1508225-18	1508225-23	1508225-28	1508225-33	1508225-38	3.75 mm
2.5 mm	1508250-08	1508250-12	1508250-15	1508250-18	1508250-23	1508250-28	1508250-33	1508250-38	3.75 mm
2.75 mm	1508275-08	1508275-12	1508275-15	1508275-18	1508275-23	1508275-28	1508275-33	1508275-38	3.75 mm
3.0 mm	1508300-08	1508300-12	1508300-15	1508300-18	1508300-23	1508300-28	1508300-33	1508300-38	3.75 mm
3.25 mm	1508325-08	1508325-12	1508325-15	1508325-18	1508325-23	1508325-28	1508325-33	1508325-38	3.75 mm
3.5 mm	1508350-08	1508350-12	1508350-15	1508350-18	1508350-23	1508350-28	1508350-33	1508350-38	5.50 mm
4.0 mm	1508400-08	1508400-12	1508400-15	1508400-18	1508400-23	1508400-28	1508400-33	1508400-38	5.50 mm

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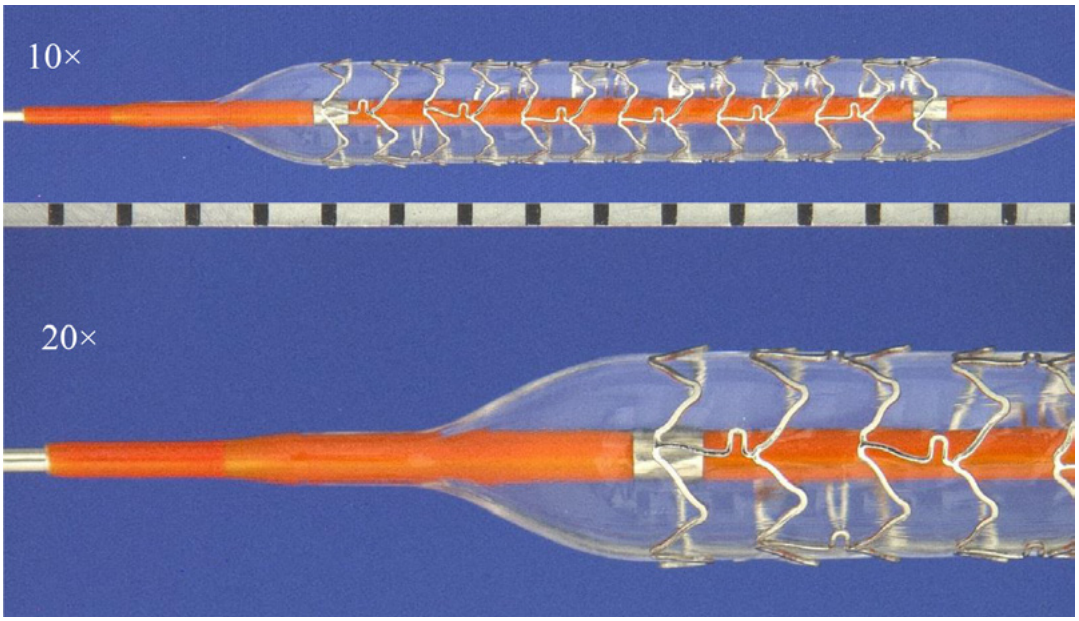
STENT EXPANDED IMAGES

Figure 11: Expansion Images of 10x and 20x for XIENCE Pro™ S Stent (3.0 mm x 18 mm)



SPIRIT and XIENCE Family of Clinical Trials[1]

The XIENCE Pro™ S EECSS is based on the predicate devices XIENCE V™ EECSS, XIENCE PRIME™ EECSS, XIENCE Xpedition™ EECSS, and XIENCE Alpine™ EECSS.

The XIENCE Pro™ S EECSS uses a similar stent platform, identical drug coating formulation, identical drug primer, similar nominal total drug content, and the identical stent contacting balloon materials as the XIENCE PRIME™ EECSS, XIENCE Xpedition™ EECSS, and XIENCE Alpine™ EECSS.

The XIENCE Pro™ S EECSS differs from the XIENCE Alpine™ EECSS in the stent delivery system. The XIENCE Pro™ S Stent delivery system utilizes the same principle of operation and materials as other Abbott Vascular RX stent systems and coronary dilatation catheters.

Compared to the XIENCE V™ EECSS and to the XIENCE PRIME™ EECSS, the XIENCE Pro™ S EECSS has the same stent security specification, same stent placement on the balloon between the balloon markers, a similar tip entry profile, and a similar taper length for XIENCE Pro™ S Stent sizes up to 28 mm in length. Based on the similar nature of the XIENCE Pro™ S Stent to the XIENCE PRIME™ Stents and XIENCE V™ Stents, performance of the XIENCE Pro™ S EECSS can be predicted to be similar to the performance of XIENCE V™ Stent and XIENCE PRIME™ Stent. Therefore, clinical trial data for XIENCE V™ Stent and XIENCE PRIME™ Stent are summarized in this section.

Note: XIENCE Pro™ S Stent 3.0 mm x 18 mm was used for image-taking at 10 x and 20 x magnification. The stent was expanded at nominal pressure of 12 atm. Images were captured using the Keyence VHX Series digital microscope camera system.

Data on file at Abbott.

1. XIENCE Pro™ S Stent Instructions for Use (IFU). Refer to IFU for additional information.

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Table 3: SPIRIT Family of XIENCE V Stents Clinical Trial Designs (Pre-market)[1]

Angiographic Results	SPIRIT III RCT	SPIRIT IV	SPIRIT Small Vessel Registry	SPIRIT PRIME Clinical Trial	
				Core Size Registry	Long Lesion Registry
Study Type / Design	• Multi-center • Randomized • Single-blinded • Active-control	• Multi-center • Randomized • Single-blinded • Active-control	• Multi-center • Open-label • Single-arm	• Multi-center • Open-label • Single-arm	• Multi-center • Open-label • Single-arm
Number Of Subjects Enrolled	N=1,002 XIENCE V™ Stent (668): TAXUS‡ Express Control (334)	N=3,690 XIENCE V™ Stent (2,460): TAXUS‡ Express Control (1,230)*	N=150 2.25 mm XIENCE V™ Stent	N=400 XIENCE PRIME™ Stent	N=100 XIENCE PRIME™ Stent
Treatment	Up to two *de novo* lesions in different epicardial vessels	Up to three *de novo* lesions, maximum of two lesions per epicardial vessels	Up to two *de novo* lesions in different epicardial vessels	Up to two *de novo* lesions in different epicardial vessels	Up to two *de novo* lesions in different epicardial vessels
Lesion Size	RVD: ≥ 2.5 ≤ 3.75 mm Length: ≤ 28 mm	RVD: ≥ 2.5 ≤ 4.25 mm** Length: ≤ 28 mm	RVD: ≥ 2.5 < 2.5 mm Length: ≤ 28 mm	RVD: ≥ 2.25 ≤ 4.25 mm Length: ≤ 22 mm	XIENCE PRIME™ Stent CS: RVD: ≥ 2.25 ≤ 4.25 mm Length: ≤ 22 mm XIENCE PRIME™ Stent LL: RVD: ≥ 2.25 ≤ 4.25 mm Length: > 22 mm and ≤ 32 mm
Primary Endpoint	In-segment late loss at 240 days	Ischemia-driven target lesion failure at 1 year (composite of cardiac death, target vessel MI or ischemia-driven TLR)	TLF (target lesion failure) at 1 year	TLF (target lesion failure) at 1 year	TLF (target lesion failure) at 1 year
Co-Primary Endpoint	TVF at 270 days	None	None	None	None
Clinical Follow-up	30, 180, 240, 270 days, 1 to 5 years	30, 180, 270 days, 1 to 3 years	30 days, 240 days, 1 to 3 years	30, 180 days, 1 to 3 years	30, 180 days, 1 to 3 years
Angiographic Follow-up	240 days (N=564)	None	240 days (N=69)	None	None

1. XIENCE Pro™ S Stent Instructions for Use (IFU). Refer to IFU for additional information.

* In the TAXUS‡ stent arm, there was 1 subject who received 1 TAXUS Liberté‡ stent.

** RVD ≥ 2.5 mm to ≤ 3.75 mm and stent sizes up to 3.5 mm until 4.0 mm TAXUS‡ is commercially available.

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Table 4: SPIRIT Family of Clinical Trials Angiographic Results (Pre-market)[1]

Angiographic Results	SPIRIT III RCT 240 days		SPIRIT Small Vessel 240 Days
	XIENCE V™ Stent (N=376) (M=427)	TAXUS‡ (N=188) (M=220)	2.25 mm XIENCE V™ Stent (N=69) (M=69)
In-Stent Late Loss (mm)	0.16 ± 0.41 (342)	0.30 ± 0.53 (158)	0.20 ± 0.40 (52)
In-Segment Late Loss (mm)	0.14 ± 0.39 (343)	0.26 ± 0.46 (158)	0.16 ± 0.41 (52)
In-Stent Binary Restenosis	2.3% (8/343)	5.7% (9/158)	3.8% (2/52)
In-Segment Binary Restenosis	4.7% (16/344)	8.9% (14/158)	9.6% (5/52)

Note:
Data are mean (mm) ± SD or % (n/N). N is the total number of patients; M is total number of lesions.
SPIRIT III and SV 240-day include follow-up window (240 + 28 days).

1. XIENCE Pro™ S Stent Instructions for Use (IFU). Refer to IFU for additional information.

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Table 5: SPIRIT Family of Clinical Trials 1-Year Clinical Outcomes (Pre-market)[1]

	SPIRIT IV		SPIRIT III RCT		SPIRIT Small Vessel	SPIRIT PRIME Clinical Trial	
	XIENCE V™ Stent (N=2458)	TAXUS‡ (N=1229)	XIENCE V™ Stent (N=669)	TAXUS‡ (N=333)	2.25 mm XIENCE V™ Stent (N=144)	Core Size Registry (N=401)	Long Lesion Registry (N=104)
TLF	4% (97/2416)	6.8% (81/1195)	5.3% (35/655)	9.7% (31/319)	8.1% (11/136)	4.5% (18/399)	7.7% (8/104)
TVF	5.5% (134/2416)	7.7% (92/1195)	8.5% (56/655)	11.6% (37/319)	11.0% (15/136)	N/A	N/A
MACE	4.1% (98/2416)	6.9% (82/1195)	6.0% (39/655)	10.3% (33/319)	8.1% (11/136)	4.5% (18/399)	7.7% (8/104)
All Death	1.0% (25/2416)	1.3% (15/1195)	1.2% (8/657)	1.3% (4/320)	1.5% (2/136)	0.8% (3/399)	1.0% (1/104)
Cardiac Death	0.4% (10/2416)	0.4% (5/1195)	0.8% (5/657)	0.9% (3/320)	1.5% (2/136)	0.3% (1/399)	0.0% (0/104)
MI	1.9% (45/2416)	3.1% (37/1195)	2.7% (18/655)	4.1% (13/319)	1.5% (2/136)	1.8% (7/399)	4.8% (5/104)
Cardiac Death or MI	2.2% (54/2416)	3.3% (39/1195)	3.4% (22/655)	4.7% (15/319)	2.9% (4/136)	2.0% (8/399)	4.8% (5/104)
Ischemia-Driven TLR	2.3% (56/2416)	4.6% (55/1195)	3.4% (22/655)	5.6% (18/319)	5.1% (7/136)	2.5% (10/399)	2.9% (3/104)
Ischemia-Driven TVR, Non-TL	2.2% (54/2416)	2.4% (29/1195)	3.2% (21/655)	4.7% (15/319)	5.9% (8/136)	2.8% (11/399)	2.9% (3/104)
Stent Thrombosis							
ARC (Def/Pro)	0.29% (7/2391)	1.10% (13/1181)	0.9% (6/650)	0.6% (2/316)	1.5% (2/136)	0.5% (2/399)	0.0% (0/104)
ARC (Def)	0.3% (6/2385)	0.8% (10/1183)	0.8% (5/650)	0.3% (1/317)	0.7% (1/138)	0.5% (2/399)	0.0% (0/104)

Notes:

All counts presented in the table are subject counts. Subjects are counted only once for each event for each time period. 1-year includes the follow-up window (365 + 28 days) for all trials. TLF includes cardiac death, MI attributed to target vessel and ischemia-driven TLR. SPIRIT SV and PRIME used clinically indicated TLR definition rather than ischemia-driven TLR. TVF includes cardiac death, MI, ischemia-driven TLR and TVR, non-target lesion. SPIRIT SV and RPIME used clinically indicated TLR and TVR definition rather than ischemia-driven TLR and TVR definition, which were used for SPIRIT II, SPIRIT III and SPIRIT IV. MACE includes cardiac death, MI and ischemia-driven TLR.

1. XIENCE Pro™ S Stent Instructions for Use (IFU). Refer to IFU for additional information.

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Table 6: SPIRIT Family of Clinical Trials. Principal Clinical Outcomes from Latest Follow-up (Pre-market)[1]

	SPIRIT IV 3 Years		SPIRIT III RCT 5 Years		SPIRIT Small Vessel 2 Years	SPIRIT PRIME Clinical Trial 1 Year	
	XIENCE V™ Stent (N=2458)	TAXUS‡ (N=1229)	XIENCE V™ Stent (N=669)	TAXUS‡ (N=333)	2.25 mm XIENCE V™ Stent (N=144)	Core Size Registry (N=401)	Long Lesion Registry (N=104)
TLF	9.5% (223/2348)	11.9% (138/1158)	13.4% (81/605)	20.6% (59/286)	8.3% (11/133)	4.5% (18/399)	7.7% (8/104)
TVF	13.3% (312/2348)	14.5% (168/1158)	20.3% (123/605)	26.6% (76/286)	12.0% (16/133)	N/A	N/A
MACE	9.8% (231/2348)	12.3% (142/1158)	14.4% (87/605)	22.0% (63/286)	8.3% (11/133)	4.5% (18/399)	7.7% (8/104)
All Death	3.4% (81/2348)	5.2% (60/1158)	6.0% (37/621)	10.3% (31/300)	1.5% (2/133)	0.8% (3/399)	1.0% (1/104)
Cardiac Death	1.4% (34/2348)	1.9% (22/1158)	2.7% (17/621)	4.3% (13/300)	1.5% (2/133)	0.3% (1/399)	0.0% (0/104)
MI	3.1% (73/2348)	4.7% (55/1158)	4.6% (28/605)	7.0% (20/286)	1.5% (2/133)	1.8% (7/399)	4.8% (5/104)
Cardiac Death or MI	4.5% (105/2348)	6.0% (70/1158)	7.1% (43/605)	11.2% (32/286)	3.0% (4/133)	2.0% (8/399)	4.8% (5/104)
Ischemia-Driven TLR	6.3% (148/2348)	7.9% (92/1158)	8.9% (54/605)	12.9% (37/286)	5.3% (7/133)	2.5% (10/399)	2.9% (3/104)
Ischemia-Driven TVR, Non-TL	5.6% (132/2348)	5.4% (63/1158)	8.8% (53/605)	11.9% (34/286)	6.8% (9/133)	2.8% (11/399)	2.9% (3/104)
Stent Thrombosis							
ARC (Def/Pro)	0.62% (14/2263)	1.73% (19/1098)	1.5% (9/582)	1.9% (5/268)	1.5% (2/132)	0.5% (2/399)	0.0% (0/104)
ARC (Def)	0.49% (11/2263)	1.28% (14/1098)	1.2% (7/582)	0.7% (2/268)	0.8% (1/132)	0.5% (2/399)	0.0% (0/104)

Notes:

All counts presented in the table are subject counts. Subjects are counted only once for each event for each time period. Data includes the follow-up window of + 28 days for all trials. TLF includes cardiac death, MI attributed to target vessel and ischemia-driven TLR. SPIRIT SV and PRIME used clinically indicated TLR definition rather than ischemia-driven TLR. TVF includes cardiac death, MI, ischemia-driven TLR and TVR, non-target lesion. MACE includes cardiac death, MI and ischemia-driven TLR.

1. XIENCE Pro™ S Stent Instructions for Use (IFU). Refer to IFU for additional information.

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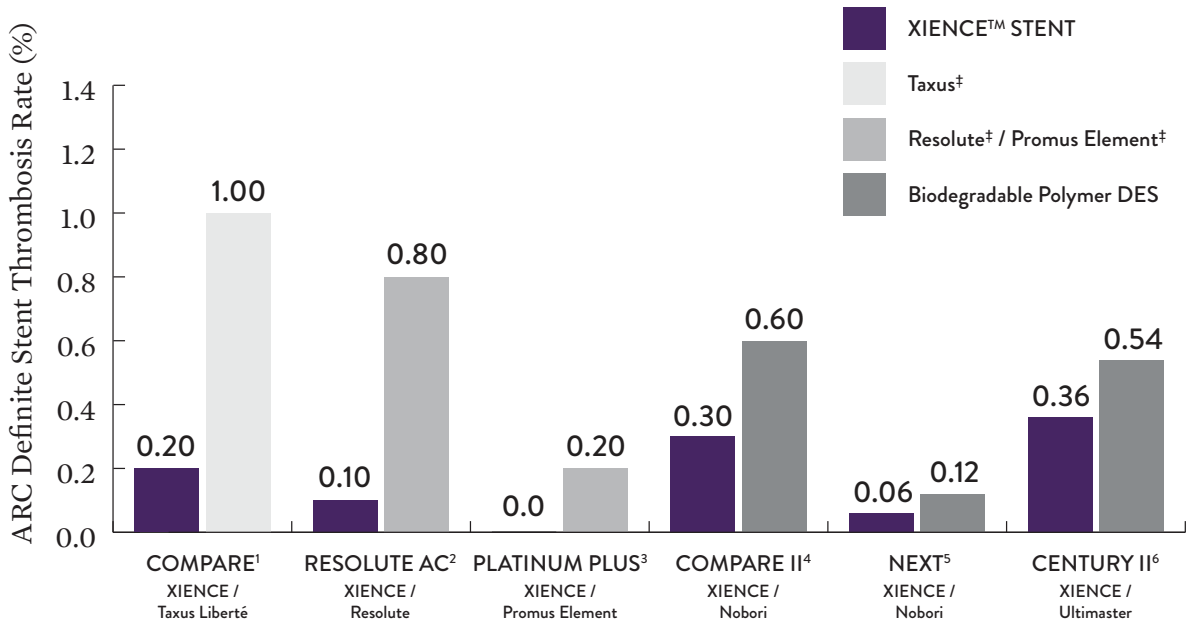
Figure 12: Early Definite Stent Thrombosis Rates (0-30 Days) Comparing XIENCE™ Stent vs. Competitors' Stents



Note: Data from different trials presented for educational purposes and are not directly comparable.

1. Kedhi, E. et al. 2nd Gen EES and PES in real-life practice (COMPARE): a randomized trial. *The Lancet,* Jan 2010. DOI:10.1016/S0140-6736(09)62127-9.
2. Serruys, PW et al. RESOLUTE All Comers Trial, 1-Yr Results Presentation, EuroPCR 2010.
3. Fajadet, PLATINUM PLUS, TCT 2012.
4. Smits P, et al. Abluminal biodegradable polymer BES vs. durable polymer EES (COMPARE II): a randomized, controlled, non-inferiority trial, *The Lancet,* dx.doi.org/10.1016/S0140-6736(12)61852-2, Jan 2013.
5. Natsuaki M, NEXT 1-Year Results, Presentation ACC 2013.
6. Saito, S et. al. A randomized, prospective, intercontinental evaluation of a bioresorbable polymer sirolimuseluting coronary stent system: the CENTURY II (Clinical Evaluation of New Terumo Drug-Eluting Coronary Stent System in the Treatment of Patients with Coronary Artery Disease) trial, *European Heart Journal,* May 2014.

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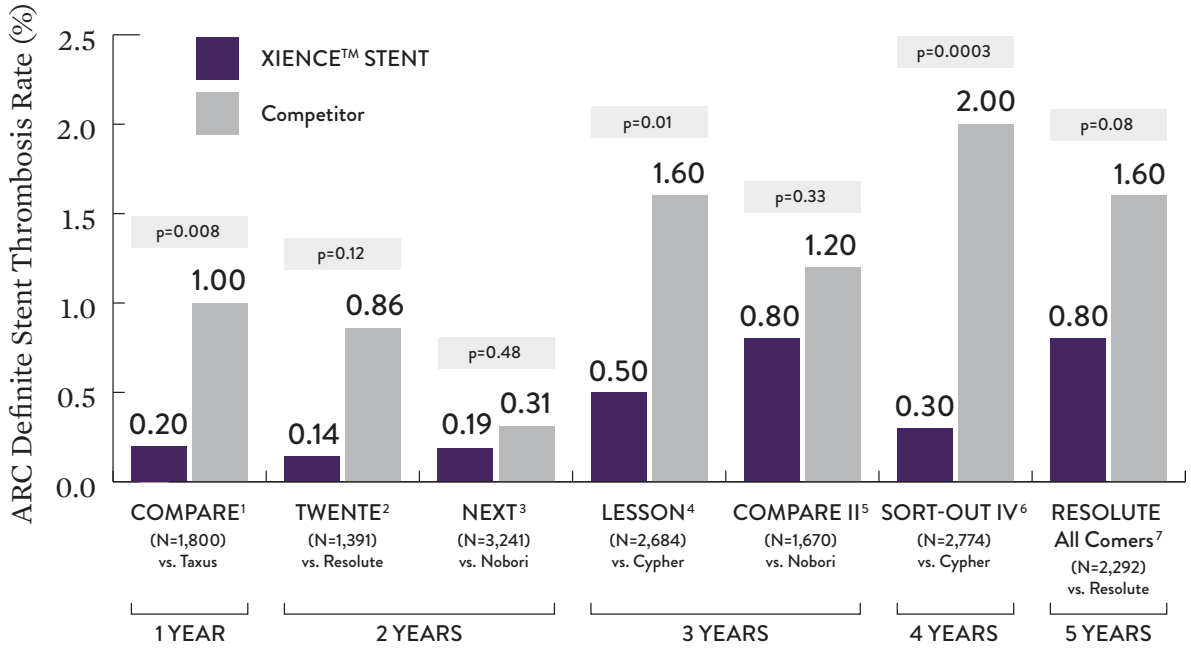
Figure 13: Stents Thrombosis Rates (ARC and Definite) Comparing XIENCE™ Stent vs. Competitors' Stents out to 5 years



1. Kedhi, E. et al. 2nd Gen EES and PES in real-life practice (COMPARE): a randomized trial. *The Lancet,* Jan 2010. DOI:10.1016/S0140-6736(09) 62127-9.
2. von Birgelen, C, TWENTE 2 Year Presentation, TCT 2012.
3. Natsuaki M, NEXT 2-Year Presentation, ACC 2014.
4. Raber L, LESSON I 3-Year Presentation, ESC 2010.
5. Smits P, COMPARE II 3-Year Presentation, EuroPCR 2014.
6. Okkels Jensen L, SORT OUT IV 4-Year Presentation, TCT 2013.
7. Windecker S, RESOLUTE All-Comers 5-Year Presentation, EuroPCR 2014.

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PACKAGING AND STORAGE[1]

The inner header bag (pouch) within the foil pouch is the sterile barrier. Only the contents of the inner pouch should be considered sterile. The outside surface of the inner pouch is NOT sterile.

Store in a dry, dark, cool place. Protect from light. Do not remove from carton until ready for use. Store at 25˚C (77˚F); excursions permitted to 15 – 30˚C (59 – 86˚F).

MANUFACTURER

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US Phone Number: 1-800-227-9902

1. XIENCE Pro™ S Stent Instructions for Use (IFU). Refer to IFU for additional information.

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CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at vascular.eifu.abbott or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

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Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

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