EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 632827**

Issued To: **Abbott Vascular**
3200 Lakeside Drive
Santa Clara
California
95054
USA

In respect of:

XIENCE PRO Everolimus-eluting Coronary Stent Systems

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-04-13** Date: **2021-03-18** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 632827

Issued To:

Abbott Vascular
3200 Lakeside Drive
Santa Clara
California
95054
USA

Device Name: XIENCE PRO 48 Everolimus Eluting Coronary Stent System

Intended purpose per IFU:

Indications:
The XIENCE PRO 48 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 (48 mm) with a reference vessel diameter of ≥ 2.50 mm and ≤ 3.75 mm.

Classification: Class III Implant

Catalog Numbers:

Stent Diameter [mm]	**Stent Length [mm]**
	48
2.50	1017250-48
2.75	1017275-48
3.00	1017300-48
3.50	1017350-48

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Device Name: XIENCE PRO^{X} Everolimus Eluting Coronary Stent System

Intended purpose per IFU:

Indications:
The XIENCE PRO^{X} 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 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, 33mm or 38mm) with a reference vessel diameter of ≥ 2.00 mm and ≤ 4.25 mm.

Classification: Class III Implant

Catalog Numbers:

Stent Diameter [mm]	Stent Length [mm]							
	8	**12**	**15**	**18**	**23**	**28**	**33**	**38**
2.00	1076200-08	1076200-12	1076200-15	1076200-18	1076200-23	1076200-28	--	--
2.25	1076225-08	1076225-12	1076225-15	1076225-18	1076225-23	1076225-28	--	--
2.50	1076250-08	1076250-12	1076250-15	1076250-18	1076250-23	1076250-28	1076250-33	1076250-38
2.75	1076275-08	1076275-12	1076275-15	1076275-18	1076275-23	1076275-28	1076275-33	1076275-38
3.00	1076300-08	1076300-12	1076300-15	1076300-18	1076300-23	1076300-28	1076300-33	1076300-38
3.25	1076325-08	1076325-12	1076325-15	1076325-18	1076325-23	1076325-28	1076325-33	1076325-38
3.50	1076350-08	1076350-12	1076350-15	1076350-18	1076350-23	1076350-28	1076350-33	1076350-38
4.00	1076400-08	1076400-12	1076400-15	1076400-18	1076400-23	1076400-28	1076400-33	1076400-38

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Device Name: XIENCE PRO[A] Everolimus Eluting Coronary Stent System

Intended purpose per IFU:

Indications:
The XIENCE PRO[A] 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, 33mm or 38mm) with a reference vessel diameter of ≥ 2.00 mm and ≤ 4.25 mm.

Classification: Class III Implant

Catalog Numbers:

Stent Diameter [mm]	Stent Length [mm]							
	8	**12**	**15**	**18**	**23**	**28**	**33**	**38**
2.00	1128200-08	1128200-12	1128200-15	1128200-18	1128200-23	1128200-28	--	--
2.25	1128225-08	1128225-12	1128225-15	1128225-18	1128225-23	1128225-28	--	--
2.50	1128250-08	1128250-12	1128250-15	1128250-18	1128250-23	1128250-28	1128250-33	1128250-38
2.75	1128275-08	1128275-12	1128275-15	1128275-18	1128275-23	1128275-28	1128275-33	1128275-38
3.00	1128300-08	1128300-12	1128300-15	1128300-18	1128300-23	1128300-28	1128300-33	1128300-38
3.25	1128325-08	1128325-12	1128325-15	1128325-18	1128325-23	1128325-28	1128325-33	1128325-38
3.50	1128350-08	1128350-12	1128350-15	1128350-18	1128350-23	1128350-28	1128350-33	1128350-38
4.00	1128400-08	1128400-12	1128400-15	1128400-18	1128400-23	1128400-28	1128400-33	1128400-38

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Device Name: XIENCE PRO^S Everolimus Eluting Coronary Stent System

Intended purpose per IFU:

Indications:
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.

Classification: Class III Implant

Catalog Numbers:

Stent Diameter [mm]	**Stent Length [mm]**							
	8	**12**	**15**	**18**	**23**	**28**	**33**	**38**
2.00	1508200-08	1508200-12	1508200-15	1508200-18	1508200-23	1508200-28	1508200-33	1508200-38
2.25	1508225-08	1508225-12	1508225-15	1508225-18	1508225-23	1508225-28	1508225-33	1508225-38
2.50	1508250-08	1508250-12	1508250-15	1508250-18	1508250-23	1508250-28	1508250-33	1508250-38
2.75	1508275-08	1508275-12	1508275-15	1508275-18	1508275-23	1508275-28	1508275-33	1508275-38
3.00	1508300-08	1508300-12	1508300-15	1508300-18	1508300-23	1508300-28	1508300-33	1508300-38
3.25	1508325-08	1508325-12	1508325-15	1508325-18	1508325-23	1508325-28	1508325-33	1508325-38
3.50	1508350-08	1508350-12	1508350-15	1508350-18	1508350-23	1508350-28	1508350-33	1508350-38
4.00	1508400-08	1508400-12	1508400-15	1508400-18	1508400-23	1508400-28	1508400-33	1508400-38

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Certificate History

Date	Reference Number	Action
13 April 2015	10154362	New Issue. Transfer from another Notified Body.
12 January 2016	10159718	DuPont Tyvek Medical Transition Project update.
24 November 2016	10166114	Certificate Renewal.
10 August 2017	8695169	Various IFU updates including revised risk and clinical use information and alignment of structure and general consistency. Update symbols on labels for consistency across project families.
22 December 2017	8868966	Add Synergy Health in Offaly, Ireland as new ETO sterilization site.
05 March 2018	8888512	Addition of product XIENCE PRO^{A} as re-branding of the XIENCE Alpine with no design changes.
27 February 2019	7780598	Traceable to NB 0086.
14 October 2019	9749795	Addition of a new drug manufacturing site including minor adaptions to manufacturing process and update to testing monograph.
20 November 2019	3092491	Change of UPLC column used in the analytical testing for lot release.

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Date	Reference Number	Action
12 January 2021	3079678	Certificate Renewal. Removal of product codes: - 1017225-08/-12/-15/-18/-23/-28 - 1017250-08/-12/-15/-18/-23/-28/-33/-38 - 1017275-08/-12/-15/-18/-23/-28/-33/-38 - 1017300-08/-12/-15/-18/-23/-28/-33/-38 - 1017350-08/-12/-15/-18/-23/-28/-33/-38 - 1017400-08/-12/-15/-18/-23/-28/-33/-38 Addition of product XIENCE PRO^{S} as re-branding of the XIENCE Sierra with no design changes. Update of the supplementary information page to include intended purpose per IFU and device classification as per current BSI template. Reformatting of device models tables. Words "and peripheral" removed from certificate scope.
Current	3329302	Update to IFU dual antiplatelet therapy recommendations for high bleeding risk patients and inclusion in the certificate intended purpose per IFU.

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