

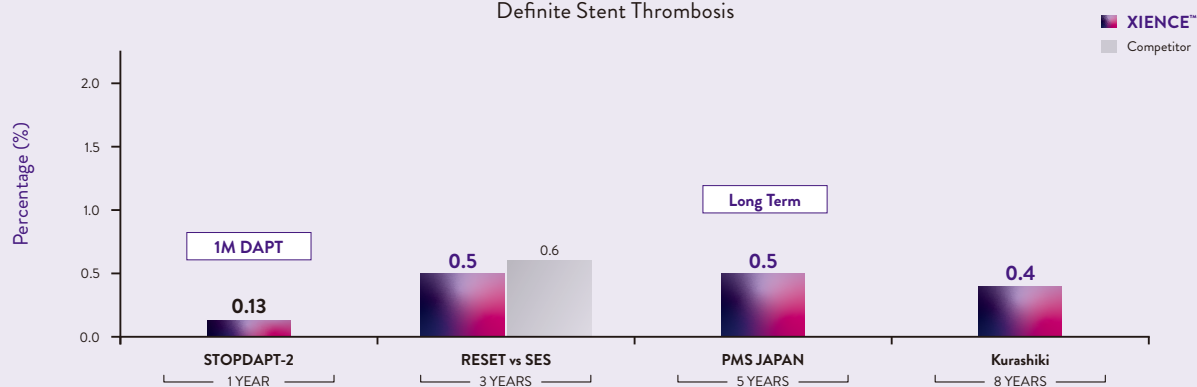
Reach for **XIENCE**TM

患者様と共に、その後の人生を歩むステントに安心を。

CLINICAL EVIDENCE OVERVIEW

Real World Evidence in JAPAN

Definite Stent Thrombosis



JAPAN

カテゴリ	トライアル名	Number of patients	First Publication	F/U year	Primary EP	Primary EP Result	P-Value	Source
All Comers	RESET	3200	2012	1Y, 3Y	1 Year Any TLR	XIENCE:4.3% / SES:5.0%	P NI=<0.0001	1, 2
	NEXT	3235	2013	1Y, 3Y, 5Y	1 Year Any TLR	XIENCE:4.2% / BES:4.2%	P NI=<0.0001	3, 4, 5
	XIENCE V / PROMUS PMS JAPAN	2010	2016	3Y, 5Y	No Primary Endpoint	No Primary Endpoint	-	6, 7
	Kurashiki	1193	2019	8Y	No Primary Endpoint	No Primary Endpoint	-	8
STEMI / ACS	Yano et al.(STEMI)	380	2015	2Y	2 Years MACE	XIENCE:3.0% / BMS:9.9%	P=0.008	9
DAPT	STOPDAPT	1525	2016	1Y	1 Year MACCE	3M DAPT 2.8% / 12M DAPT 4.0% (RESET trial)	P=0.06	10
	STOPDAPT-2	3045	2019	1Y	1 Year MACCE	1M DAPT 2.36% 12M DAPT 3.70%	P=0.04	11
	STOPDAPT-2 HBR	1054	2020	1Y	1 Year MACCE	1M DAPT 3.48% 12M DAPT 5.98%	P=0.06	12
	STOPDAPT-2 CYP2C19	750	2020	1Y	1 Year MACCE	PM 3.91% / IM 3.58% / EM 2.41%	-	13
Hemodialysis	EES vs SES HD	100	2012	8M	8 Months Binary Restenosis	XIENCE:8.72% / SES:21%	P=0.041	14
	XIENCE V / PROMUS PMS JAPAN Calcification	1546	2018	3Y	3 Years ID-TLR	Non-HD Ca(+):5.8% / Non-HD Ca(-):3.1% HD Ca(+):14.3% / HD Ca(-):17.9%	Non-HD:P=0.025 HD:P=0.85	15
	Sato et al. (DP-EES vs BP-EES)	104	2018	1Y	1 Year TLR and MACE	TLR:XIENCE:8.8% / PtCr-EES:9.6% / BP-EES:22.7% MACE:XIENCE:25% / PtCr-EES:27.7% / BP-EES:33%	TLR:P= 0.07 MACE:P=0.76	16
OCT	EES STEMI OCT	102	2014	10M	No Primary Endpoint	No Primary Endpoint	-	17
	MECHANISM pilot	24	2015	2W	No Primary Endpoint	No Primary Endpoint	-	18
	MECHANISM AMI	52	2019	2W	% Uncovered Strut	21±14%	P<0.001 *post vs. 2weeks	19
	MECHANISM ELECTIVE	50	2019	12M	3 Months %Uncovered Strut	2.0±2.5%	P<0.001 *post vs. 3months	20

*1 All-cause death, any recurrent myocardial infarction, and any revascularization

*2 Death, myocardial infarction, and target vessel revascularization

*3 Cardiac death, myocardial infarction not clearly related to a non-target vessel, and target lesion revascularization

*4 Death, myocardial infarction, and target lesion revascularization

*5 Death, stroke, or myocardial infarction

*6 Death, myocardial infarction, cerebrovascular accident, target vessel failure, stent thrombosis and binary angiographic restenosis

*7 Cardiac death, target vessel-related myocardial infarction, or target lesion revascularization

*8 All death, myocardial infarction, and target vessel revascularization

*9 Death, myocardial infarction, and target vessel revascularization

*10 Safety (cardiac death and non-fatal myocardial infarction) and efficacy (clinically indicated target vessel revascularization)

*11 Cardiac death, target vessel myocardial infarction, and target lesion revascularization

*12 Cardiac death, target vessel myocardial infarction, and target lesion revascularization

*13 Safety (cardiac death and myocardial infarction, definite stent thrombosis) and efficacy (target vessel revascularization)

*14 All-cause mortality, non-fatal myocardial infarction, and target vessel revascularization

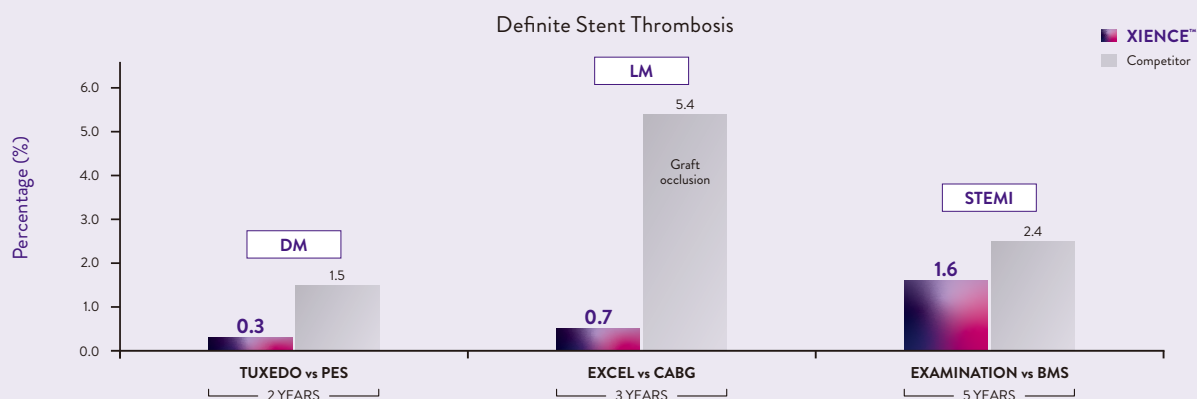
*15 Death, myocardial infarction, urgent target vessel revascularization, stroke and major bleeding

*16 Death, myocardial infarction, and target vessel revascularization

Reach for **XIENCE™**

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Evidence in Complex Patient



COMPLEX

カテゴリ	トライアル名	Number of patients	First Publication	F/U year	Primary EP	Primary EP Result	P-Value	Source
STEMI / ACS	EXAMINATION	1498	2012	1Y, 2Y, 5Y	1 Year Patient-Oriented Composite* ¹	XIENCE:11.9% / VISION:14.2%	P=0.19	21, 22, 23
	LESSON-ACS	1746	2012	3Y	3 Years Composite* ²	XIENCE:13.8% / SES:17.7%	P=0.02	24
	XAMI	625	2012	1Y, 3Y	1 Year MACE	XIENCE:4.0% / SES:7.7%	P=0.048	25, 26
	Long term STEMI EES vs ZES	931	2012	3Y	3 Years Device-Oriented Endpoint* ³	XIENCE:9.7% / ZES:13.7%	P=0.049	27
	HOST-REDUCE-POLYTECH-ACS	3413	2021	1Y	1 Year POCO	DP-DES 5.2% / BP-DES 6.4%	P=0.146 P NI<0.001	28
Diabetes	ESSENCE DIABETES	300	2011	8M	8 Months In-Segment LL	XIENCE:0.23±0.27 / SES:0.37±0.52	P=0.02	29
	TUXEDO	1830	2015	1Y, 2Y	1 Year TVF	XIENCE 2.9% / PES 5.6%	P=0.005	30, 31
	BP-SES vs CoCr-EES in Diabetes	510	2020	1Y	1 Year TLR	BP-SES 11.4% / XIENCE 2.0%	P=0.003	32
CTO	EXPERT CTO	250	2015	1Y	1 Year MACE	XIENCE:8.2% * per protocol解析による	-	33
	PRISON IV	330	2017	9M, 3Y	9 Months In-Segment LL	XIENCE:0.02±0.47mm / SES:0.13±0.63mm	P=0.08 P NI=0.11	34, 35
LM	ISAR LEFT MAIN 2	650	2013	1Y	1 Year Composite* ⁴	XIENCE:14.3% / ZES:17.5%	P=0.25	36
	EXCEL	1905	2016	3Y, 5Y	3 Years Composite* ⁵	XIENCE:15.4% / CABG:14.7%	P NI=0.02	37, 38
Bifurcation	CELTIC Bifurcation	170	2018	9M	9 Months Composite* ⁶	XIENCE:19% / CoCr-EES:16%	P NI=0.003	39
All Comers	BASKET PROVE	2314	2010	2Y	2 Years Cardiac death or Non-fatal MI	XIENCE:3.2% / SES:2.6% / BMS:4.8%	XIENCE vs SES P=0.78 XIENCE vs BMS P=0.37	40
	XIENCE USA	5054	2011	1Y, 2Y	1 Year ARC Def / Prob ST	XIENCE:0.84%	-	41, 42
	ISAR TEST 4 sub	1304	2011	3Y	3 Years Composite* ⁷	XIENCE:19.6% / SES 22.3%	P=0.26	43, 44
	SPIRIT V	2700 RCT 300	2011	1Y	30 Days Composite* ⁸	XIENCE:2.7%	-	45
	LESSON 1	1342	2011	3Y	3 Years Composite* ⁹	XIENCE:14.9% / SES:18.0%	P=0.056	46
	TWENTE	1391	2012	1Y, 2Y, 3Y	1 Year TVF	XIENCE:8.1% / ZES:8.2%	P NI=0.01	47, 48, 49
	COMPARE II	2707	2013	1Y, 3Y, 5Y	1 Year Composite* ¹⁰	XIENCE:4.8% / BES:5.2%	P NI=<0.0001	50, 51, 52
	CoCr-EES vs BMS on Cardiovascular events	4896	2014	2Y	2 Years Cardiac Mortality	XIENCE:2.7% / BMS:4.0%	P=0.01	53
	BIOSCIENCE	2119	2014	1Y, 2Y, 5Y	1 Year TLF	XIENCE:6.7% / BP SES:6.7%	P=0.950	54, 55, 56
	CARDIOBASE Bern PCI Registry	7042	2019	1Y	1 Year Device-Oriented Endpoint* ¹¹	XIENCE:7.8% / BP EES:7.1%	P=0.49	57
Long Lesion (48mm)	Tan et al.	123	2018	1Y	1 Year MACE	XIENCE:3.3%	-	58
	FREIUS	218	2018	1Y	1 Year Device-Oriented Endpoint* ¹²	XIENCE:48mm:7% / Controls:10.5%	P=0.1	59

WORLD

カテゴリ	トライアル名	Number of patients	First Publication	F/U year	Primary EP	Primary EP Result	P-Value	Source
FIM	SPIRIT First	60	2005	1Y, 5Y	6 Months In-Stent LL	XIENCE:0.10±0.21 / VISION:0.87±0.37	P<0.001	60, 61
Pivotal	SPIRIT II	300	2006	6M, 3Y, 4Y, 5Y	6 Months In-Stent LL	XIENCE:0.11±0.27 / PES:0.36±0.39	P NI=<0.0001 P Sup<0.001	62, 63, 64, 65
	SPIRIT III	1002	2008	1Y, 2Y, 3Y, 5Y	8 Months In-Segment LL	XIENCE:0.14±0.39 / PES:0.28±0.46	P=0.003	66, 67, 68, 69
	SPIRIT IV	3690	2010	1Y, 2Y, 3Y	1 Year TLF	XIENCE:4.2% / PES:6.8%	P=0.001	70, 71, 72
	PLATINUM	1530	2011	1Y, 3Y, 5Y	1 Year TLF	XIENCE:2.9% / PtCr-EES:3.4%	P NI=0.001	73, 74, 75
	CENTURY II	1123	2014	9M	9 Months Freedom From TLF	XIENCE:95.1% / BP-SES:95.6%	P NI=<0.0001	76
	BIOFLOW V	1334	2017	1Y	1 Year TLF	XIENCE:10% / BP-SES:6%	P=0.04	77
Longterm	COMPARE	1800	2010	1Y, 2Y, 5Y	1 Year Composite*13	XIENCE:6% / PES:9%	P=0.02	78, 79, 80
	RESOLUTE AC	2292	2010	1Y, 2Y, 4Y, 5Y	1 Year TLF	XIENCE:8.3% / ZES:8.2%	P=0.94	81, 82, 83, 84
	SORT OUT IV	2774	2012	1Y, 2Y, 3Y, 5Y	9 Months Composite*14 of safety and efficacy	Safety: XIENCE:4.9% / SES:5.2% Efficacy: XIENCE:2.8% / SES:3.5%	P NI=0.02 P=0.32	85, 86, 87, 88
	Bern Rotterdam	12339	2012	4Y	4 Years Definite ST	XIENCE:1.4% / SES:2.9% / PES:4.4%	XIENCE vs SES P<0.0001 XIENCE vs PES P<0.0001	89
	NYS Cardiac Registry	13663	2019	10Y	6 Years All-cause Mortality	HR1.10, 95%CI1.04-1.17	P=0.003	90
	University of Milan	6893	2017	6Y	MACE	3Y:5.9% 5Y:9.6% 5Y-10Y:8.6%	-	91
DAPT	ITALIC	2031	2015	1Y, 2Y	1 Year Composite*15	6M DAPT 1.5% / 24M DAPT:1.6%	P=0.85	92, 93
	IVUS-XPL	1400	2016	1Y, 5Y	1 Year MACCE	6M DAPT 2.2% / 12M DAPT 2.1%	P=0.854	94, 95
Overlap	Overlapping 2nd Gen EES vs 1st Gen DES	350	2013	1Y	1 Year MACE	XIENCE: 6.5% / SES:16.8%; PES:10.1%	2nd vs 1st. P=0.026 XIENCE vs SES P=0.014 XIENCE vs PES P=0.458	96
	Long term Overlapping	1601* EESのみ	2014	3Y	3 Years Composite*16	Overlap 22.3% / Non-Overlap 18.5%	P=0.32	97
Restenosis	RIBS V	189	2014	8M, 3Y	9 Months Minimal Lumen Diameter	XIENCE:2.36±0.6mm / DEB:2.01±0.6mm	P<0.001	98, 99
	RIBS IV	309	2016	1Y, 3Y	6-9 Months Minimal Lumen Diameter	XIENCE:2.03±0.7mm / DEB:1.80±0.6mm	P<0.01	100, 101
OCT	HEAL-EES	36	2016	6, 9, 12M	No Primary Endpoint	No Primary Endpoint	-	102

Source:

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XIENCE™ Stent 10年の信頼

2020年、XIENCE™ Stentは日本において
発売10周年を迎えました。

XIENCE™ Stentの臨床的有用性は、日本における
市販後調査、STOPDAPT-2試験をはじめとする
120以上の臨床試験、12万人以上の患者様のデータ
をもって証明されています。



1500万本以上

使用実績

125000人以上

臨床試験登録

120以上






臨床試験

10年以上

臨床成績

Data on file at Abbott. 15,000,000 implants number is based on data of DES implants through Q1, 2020.

一貫した継続的な改良

	2010 Feb	2012 May	2013 Aug	2015 Apr	2018 May	2020 Nov
	XIENCE V™	XIENCE PRIME™	XIENCE Xpedition™	XIENCE Alpine™	XIENCE Sierra™	XIENCE Skypoint™
Catheter technology 	MULTI-LINK VISION™ Catheter	XIENCE PRIME™ Catheter	XIENCE XPEDITION™ Catheter	XIENCE ALPINE™ Catheter	XIENCE SIERRA™ Catheter Improved pushability ¹	Excellent Deliverability
Balloon 	Single Layer balloon	Single Layer balloon	Thin, multilayer balloon	→	Ultra thin single layer balloon Reduced profile ¹	継承
Stent design and material 	MULTI-LINK VISION™ CoCr	MULTI-LINK 8™ CoCr	→	→	Enhanced stent design Smaller crimped profile & larger post-dil expansion ¹	3.5/4.0mm径 → 5.75mm
Drug/ Dosage ² 	Everolimus 100 µg/cm ²	→	→	→	→	継承
Coating 	PVDF Fluoropolymer	→	→	→	→	継承

1: Test performed by and data on file at Abbott.
2: Data on file at Abbott.

Now Available!

販売名：XIENCE Skypoint 48 薬剤溶出ステント
販売名：XIENCE Skypoint 薬剤溶出ステント
販売名：XIENCE Sierra 薬剤溶出ステント
販売名：XIENCE Xpedition 薬剤溶出ステント
販売名：XIENCE Alpine 薬剤溶出ステント

医療機器承認番号：30200BZX00330000 分類：高度管理医療機器
医療機器承認番号：30200BZX00320000 分類：高度管理医療機器
医療機器承認番号：23000BZX00091000 分類：高度管理医療機器
医療機器承認番号：22500BZX00309000 分類：高度管理医療機器
医療機器承認番号：22600BZX00529000 分類：高度管理医療機器

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