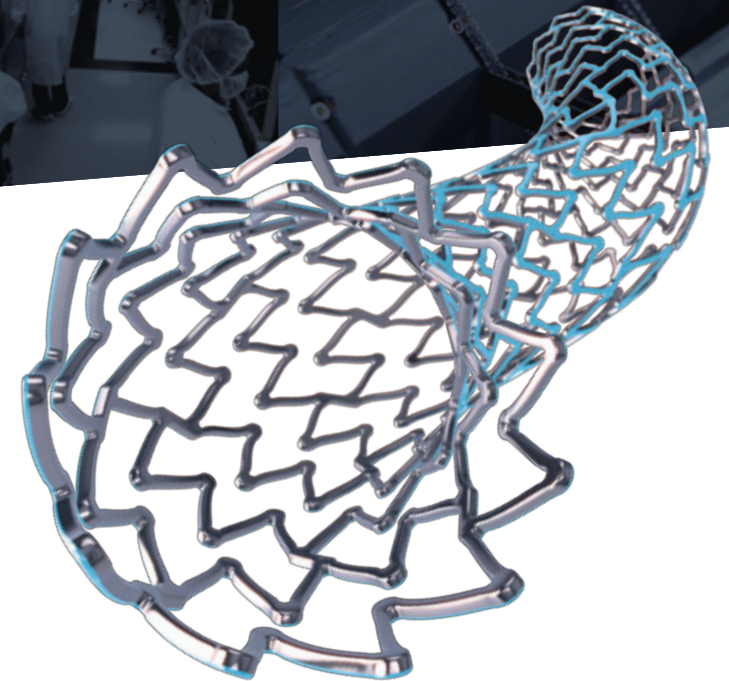




SYNERGY MEGATRON™

Everolimus-Eluting Platinum Chromium Coronary Stent System



**Purpose-built
for Large Vessels**

SYNERGY MEGATRON™ & SYNERGY™ XD LV Model

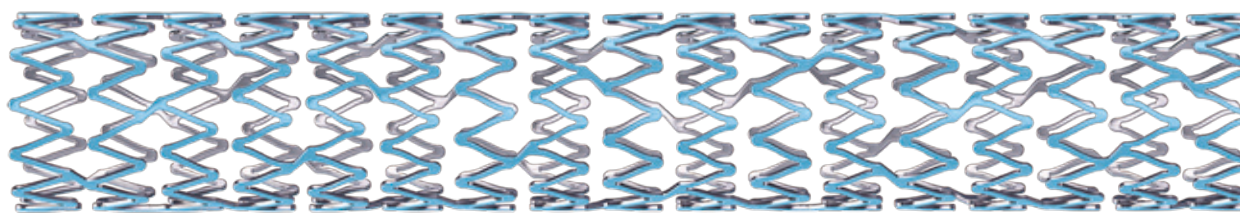
SYNERGY
MEGATRON™
Everolimus-Eluting Platinum Chromium Coronary Stent System

STENT Design

Purpose built stent architecture SYNERGY MEGATRON™

12 Crown Design with Shorter Strut Length

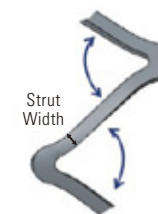
Platinum Chromium(PtCr) Alloy



4 Connectors on Proximal Two Segments

3 Connectors Throughout the Body

Strut Thickness and Width



SYNERGY MEGATRON™
BP Stent



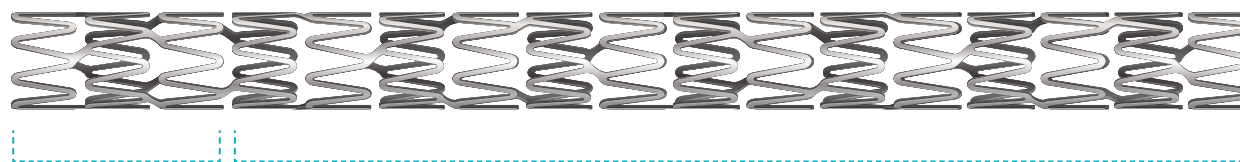
89 μm

92 μm

SYNERGY™ XD : LV Model

10 Crown Design with Shorter Strut Length¹

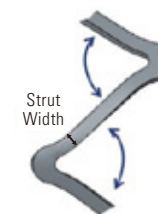
Platinum Chromium(PtCr) Alloy



5 Connectors on Proximal Two Segments¹

2 Connectors Throughout the Body

Strut Thickness and Width



SYNERGY™ XD BP Stent
Large Vessel Sizes



81 μm

94 μm

※SYNERGY™ XD 4.0mm 径

REFERENCE 1. The Small Vessel and Workhorse sizes have 4 connectors on the two most proximal segments. The Large Vessel sizes have 5 connectors on the two most proximal segments.

Purpose Built for Large Proximal Vessels

SYNERGY
MEGATRON™
Percutaneous-Deployable Platinum-Chromium Coronary Stent System

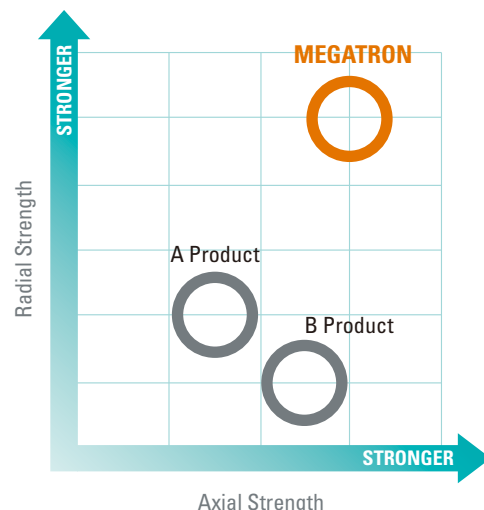
SYNERGY MEGATRON™ Key Features

Designed for

Axial & Radial Strength

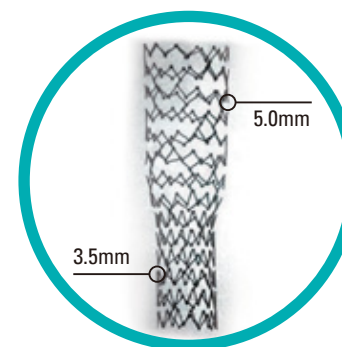
for Proximal Large Vessels

入口部、大径血管のために
血管支持力、縦軸強度を
向上させたステントデザイン



Uniform Lesion

Scaffolding To Reduce tissue prolapse



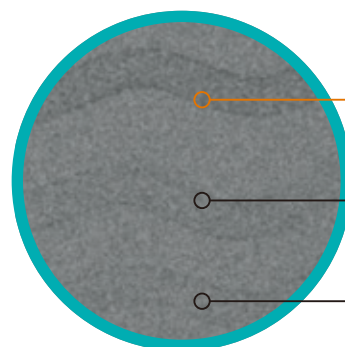
Tissue Prolapse Less

Prolapseを最小限に抑え
内腔径を大きく保つ**12**クラウン デザイン

PtCr for

Visibility to aid accurate stent placement

正確なステントの位置決めを
サポートする高い視認性



SYNERGY MEGATRON™

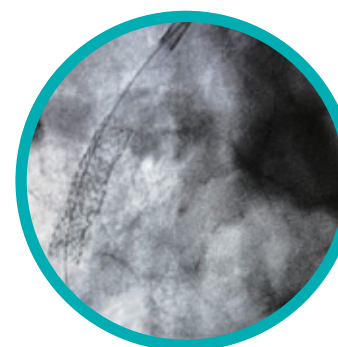
BP Stent

A product

DP Stent

B product

DP Stent



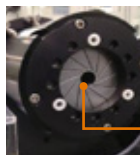
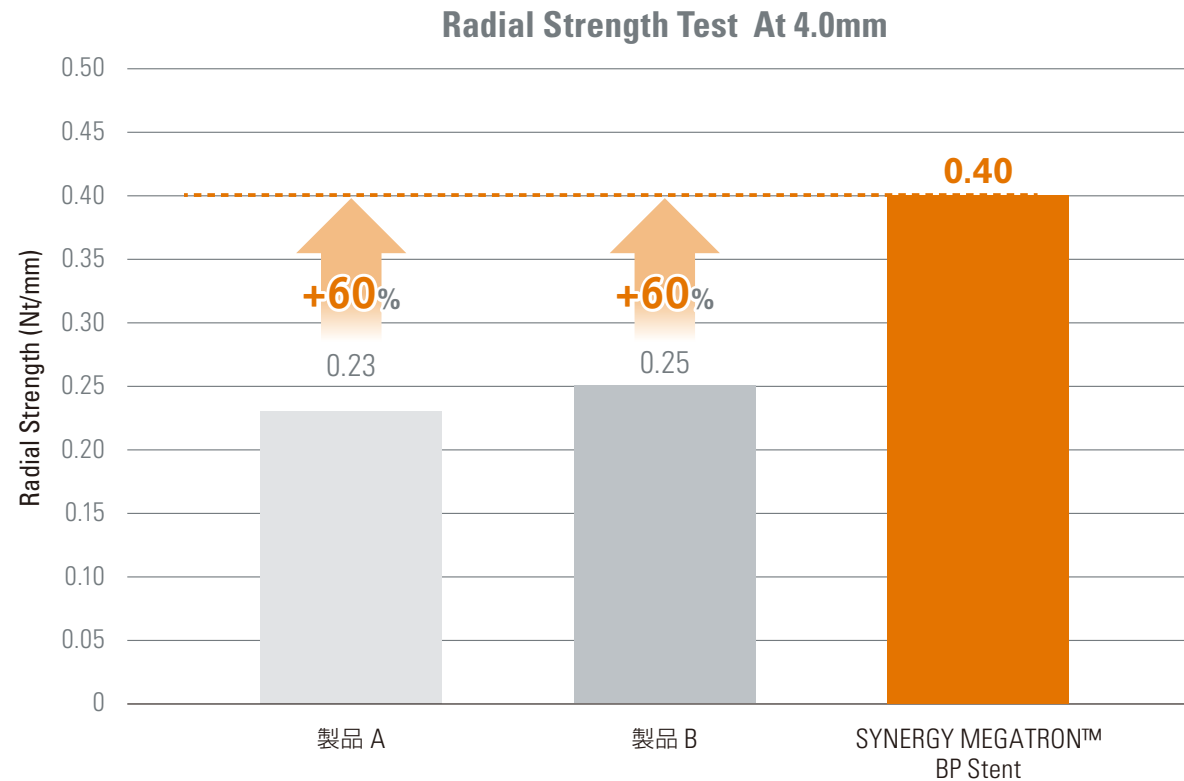
Platinum Chromium (PtCr) Alloy



Radial Strength Bench Test Data



大血管にも対応した高い血管支持力



Radial Compression Resistance Test

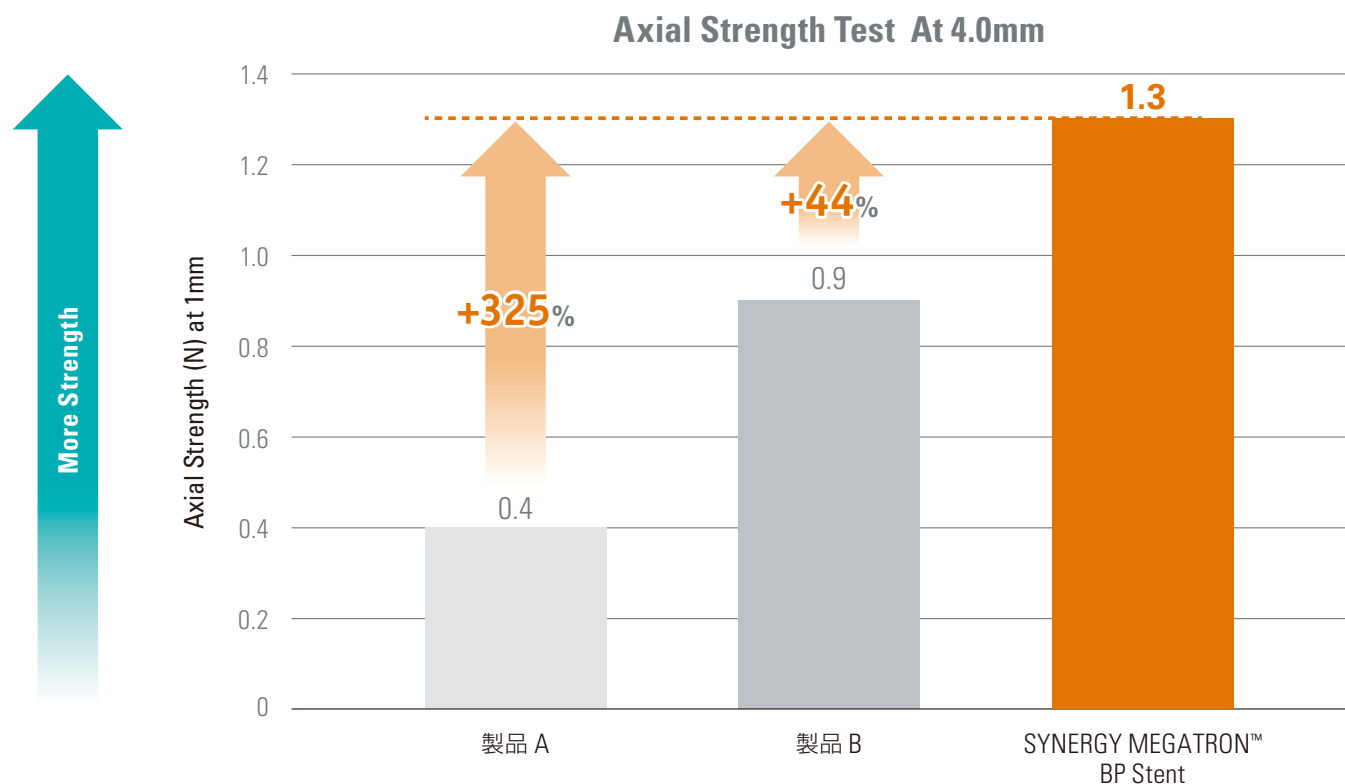
展開したステントの直径を15%縮小するのに必要な半径方向の力量

Stent

REFERENCE 1. Bench tests performed by Boston Scientific Corporation. Data on file. 1. All stents 4.0mm. N=3 minimum. Bench test and computational model results may not necessarily be indicative of clinical performance.

Axial Strength Bench Test Data

入口部留置にも対応した高い縦軸強度



Axial Compression Resistance Test

ステント近位部3mmに1mmの長軸変形を生じさせる力



Uniform Lesion Scaffolding with a 12-Crown Design



プロラプスを最小限に抑え、血管内腔を大きく保つ12クラウンデザイン

拡張後も維持される
ステントデザイン

Prolapseのより少ない
12クラウンデザイン

Prolapseを33%抑制し
内腔径を大きく維持する

SYNERGY MEGATRON™ 12-Crown Design

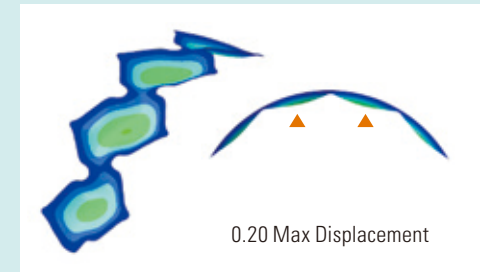


5.0mm

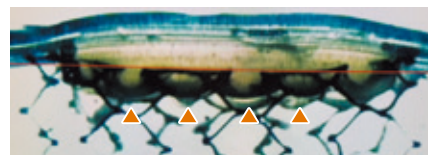
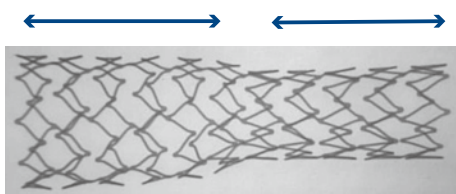
3.5mm



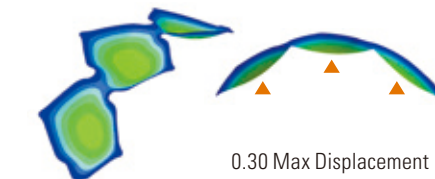
Minimal tissue prolapse (smoother edges)



0.20 Max Displacement



Visible tissue prolapse ("pillowing")



0.30 Max Displacement

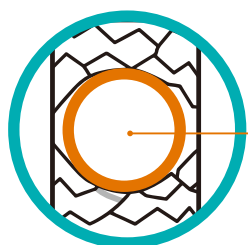
9-Crown Prototype DES

Purpose Built for Large Proximal Vessels

Maximum Expanded Cell Diameter¹

 セル最大拡張径

Side Cell Expansion

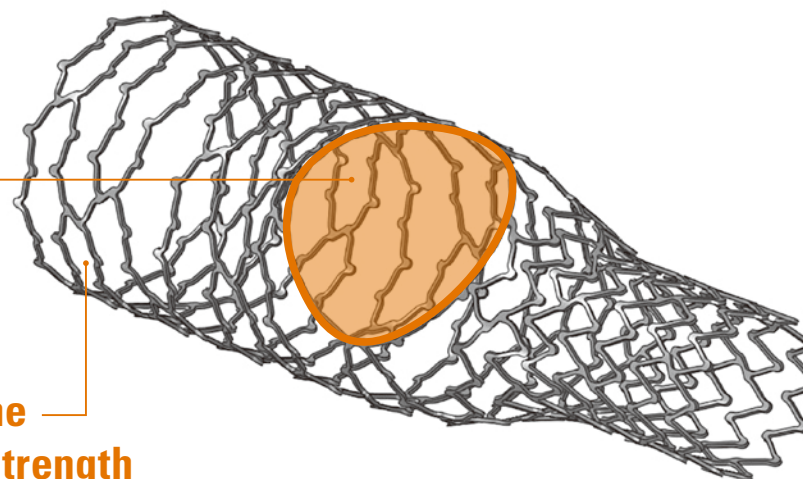


5.0mm

Maximum expanded cell diameter (MECD)¹

Additional connector on the Proximal 2 Segments for Strength

3.8mm MECD in the first two proximal segments¹



MECD

		3.5mm	4.0mm	4.5mm	5.0mm
SYNERGY MEGATRON™		5.0mm (3link) 3.8mm (4link)			
SYNERGY™ XD		5.5mm (2link) 2.7mm (4Link)	7.1mm (2link)	2.9mm (5Link)	

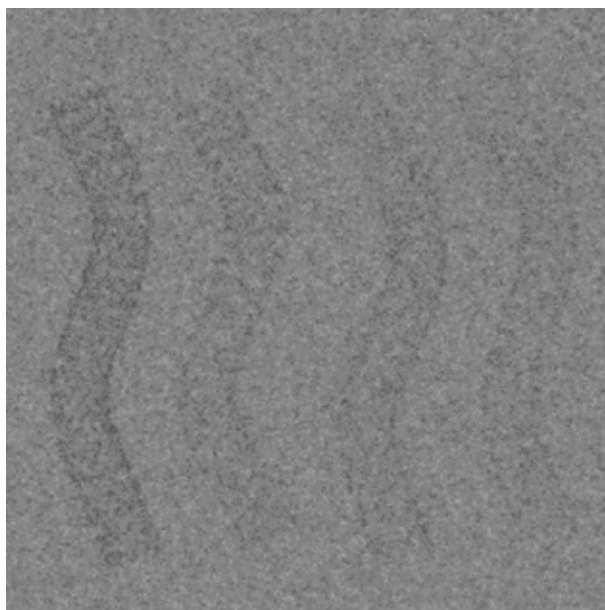
MECDはセルの構造に基づく値であり、正規の検証はされておらず、臨床上安全に拡張できることを担保するものではない。

REFERENCE 1. Based on 5.0mm diameter. Testing Completed by Boston Scientific data on file. Computational model results may not necessarily be indicative of clinical performance.

Visibility

正確な位置決めをサポートする高い視認性

X線透視下におけるステント視認性

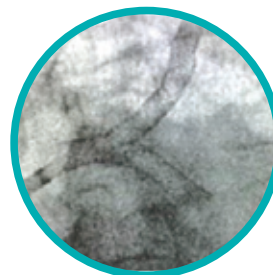
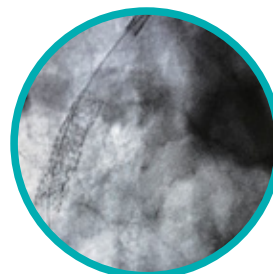


SYNERGY
MEGATRON™
BP-DES

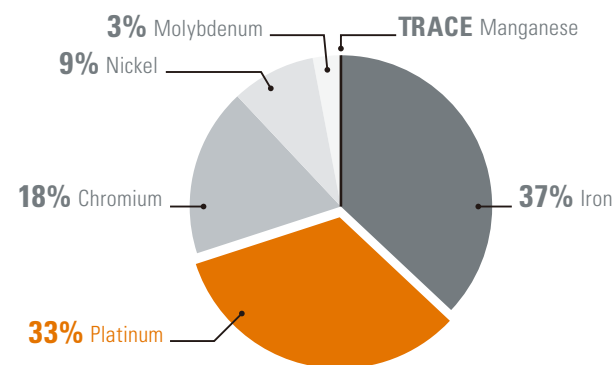
SYNERGY™
XD
BP-DES

A product
DP-DES

B product
DP-DES



プラチナクロム合金組成



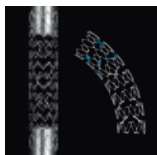
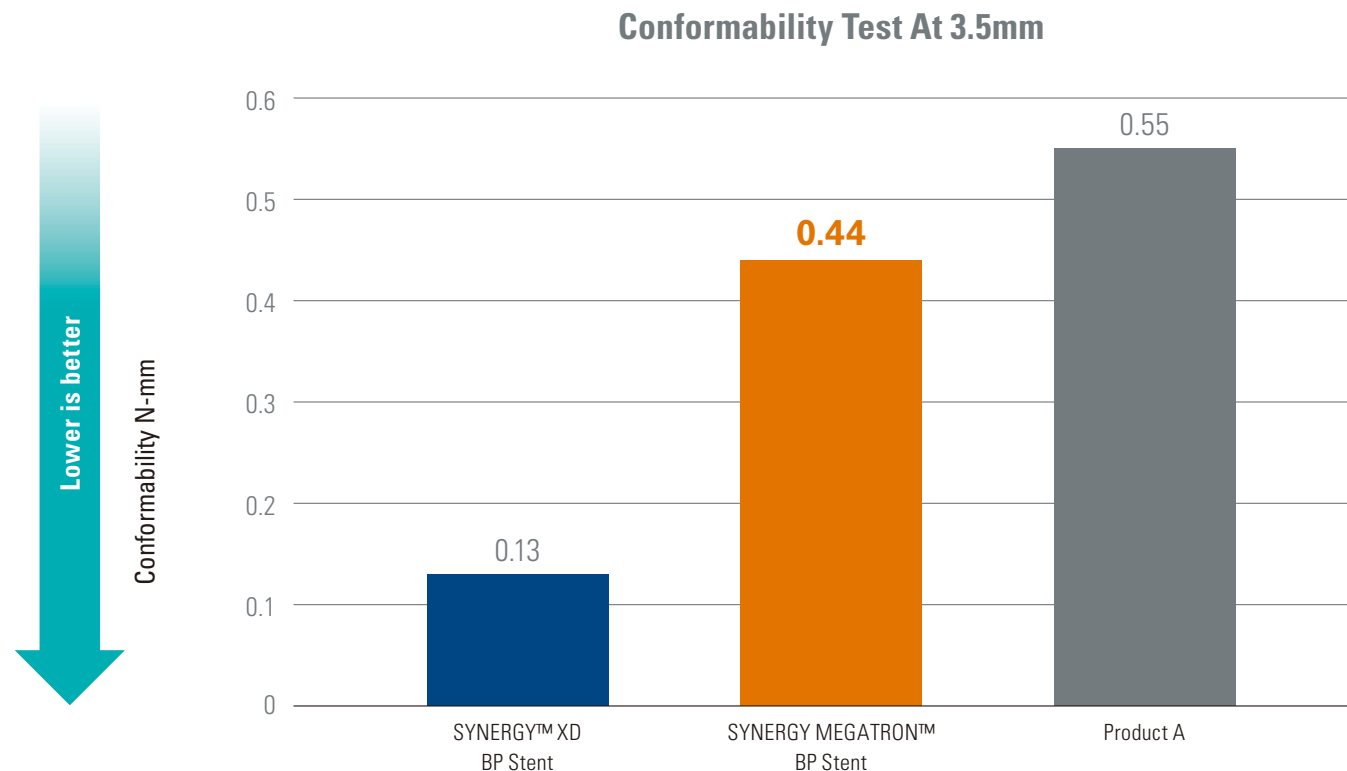
- プラチナは鉄やコバルトに比べ2倍以上の金属密度
- ステンレススチールと合金化することで強度の増加
- 冠動脈ステント用合金として開発

プラチナ合金によるメリット

- よりよい視認性
- ラディアルフォースとコンフォーマビリティ
- リコイルの最小化

Conformability

他社Large Size DESと同等のConformability



Conformability Test

マンドレルに固定したステントの片端をたわませ、目標の曲率半径まで曲げるのに必要なトルク

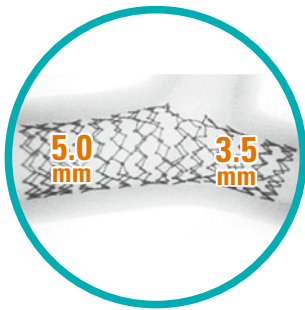
REFERENCE 1. Based on 3.5mm diameter. Testing Completed by Boston Scientific data on file. Bench test and computational model results may not necessarily be indicative of clinical performance.



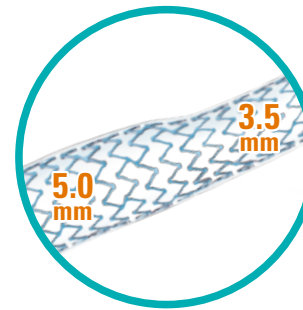
STENT Model



Tapered Vesselや分岐部におけるPOTに対応



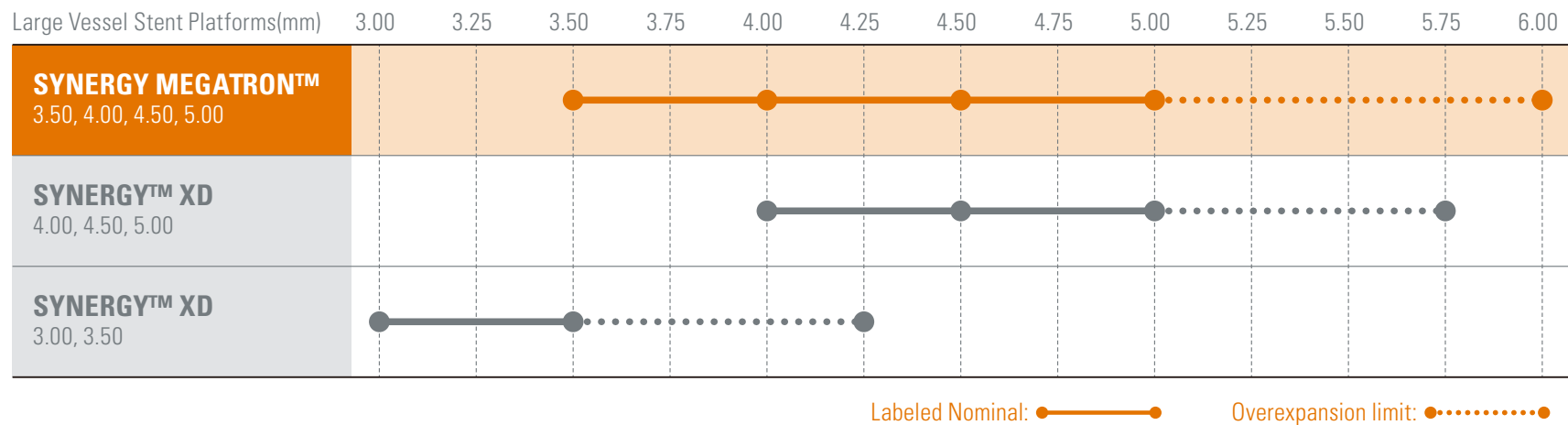
Bifurcation lesion



Tapered lesion



Overexpansion



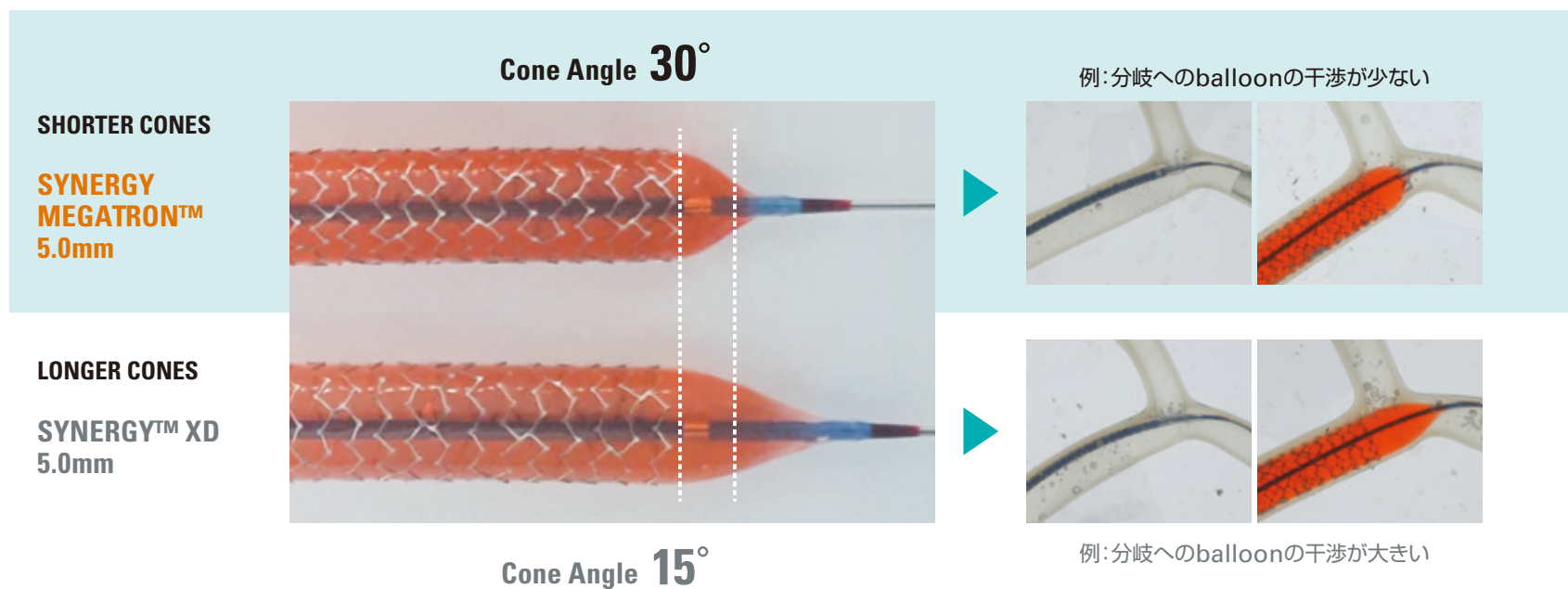
6.0mmは*in vitro*試験において評価したステントの機械的な拡張限界であって、ステント留置部位に与える臨床的影響を考慮した値ではない。ステントのサイジングは適応範囲内（上限5.0mm）で行うこと。

Bench test and computational model results may not necessarily be indicative of clinical performance.

Purpose Built for Large Proximal Vessels

Balloon Cone 4.5mm and 5.0mm diameters

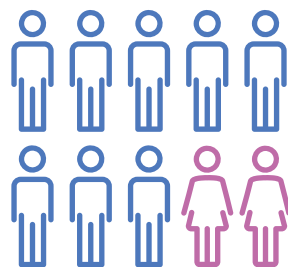
 Coneの角度を変更し、短くなったBalloon Shoulder



Clinical Data | EVOLVE XLV

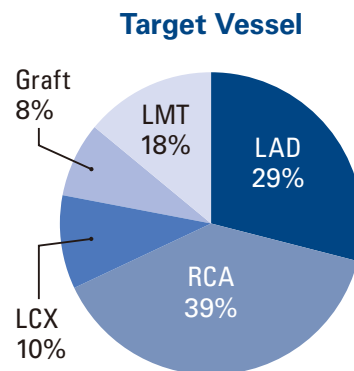
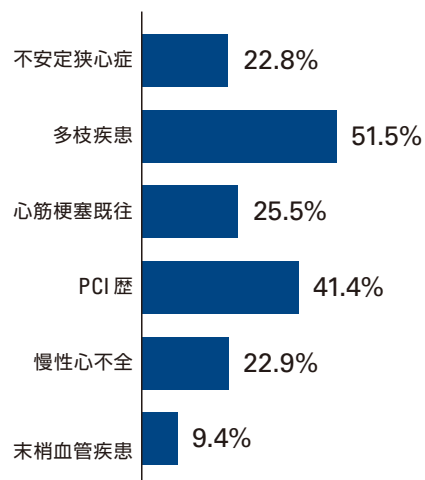
SYNERGY MEGATRON™ 有効性及び安全性評価実臨床試験

Baseline Characteristics



性別: 男性 77% (77)
年齢: 69.7 ± 11.83才
糖尿病: 33% (33)
高脂血症: 80.8% (80)
高血圧: 82% (82)

Cardiac History & Lesion Characteristics



Primary Endpoint : 1 year TLF

10.8% 95% CI [5.3%, 18.9%]

TLF: composite of ischemia-driven TLR, MI related to the target vessel, or cardiac death;
Denominator includes patients with sufficient follow-up or having a TLF event

Cardiac Death and MI at 1 year

Cardiac Death

6.5% 95% CI [2.4%, 13.5%]

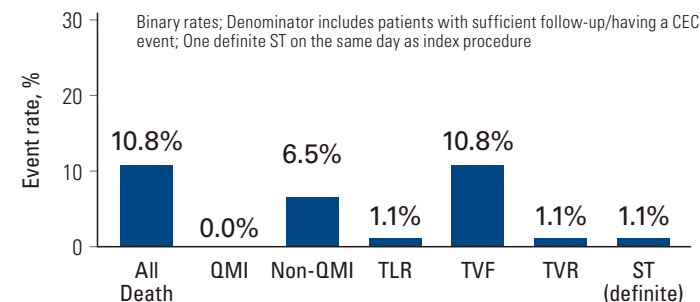
Six cardiac-related deaths unrelated to the study stent;
None of these were related to stent thrombosis

Myocardial Infarction

6.5% 95% CI [2.4%, 13.5%]

Six subjects experienced target vessel related MI,
3 of which were periprocedural MI

Additional Outcomes at 1 year

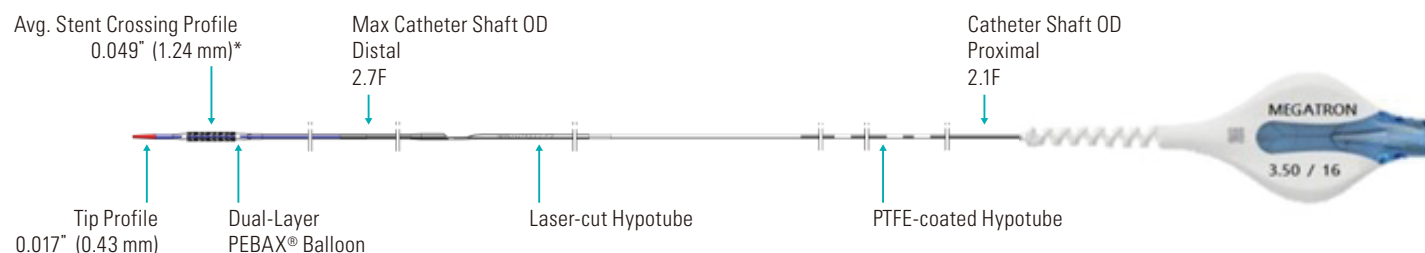


SYNERGY Product Family Specifications

 血管径や血管性状に応じて選択できるSYNERGY スtentファミリー

	SYNERGY MEGATRON™	SYNERGY™ XD		
	ONE Model	SV	WH	LV
Nominal Diameter (mm)	3.50 - 5.00	2.25 - 2.75	3.00 - 3.50	4.00 - 5.00
Length (mm)	8 - 32	2.25mm : 8-38 / 2.50-4.00mm : 8-48 / 4.50-5.00mm : 12-32		
Stent Material	Platinum Chromium (PtCr)			
Coating Material	PLGA / Everolimus			
Coating Thickness (μm)	4 μm Abluminal			
Strut Thickness (μm)	89	74	79	81
Overall Thickness (μm)	93	78	83	85
Number of Crowns	12	8		10
Body Connectors	3	2		
Proximal Connectors	4	4		5

SYNERGY MEGATRON™ Stent System Key SDS Specifications



Lesion entry profile	0.017 in (0.43 mm)
Average stent profile	3.50mm 0.049" (1.24mm), 4.00mm 0.049" (1.24mm), 4.50mm 0.053" (1.34mm), 5.00mm 0.058" (1.47mm)
Total catheter length	144 cm
Distal shaft coating	Bioslide™ hydrophilic coating
Hypotube coating	PTFE
SDS shaft outer diameter (OD)	≤0.70 mm (2.1 F) proximally and 2.6F or 2.7F** (≤ 0.92 mm) distally
Guide catheter compatibility	5F (≥0.056" / 1.42mm) for 3.50 - 4.00 mm sizes
	6F (≥0.070" / 1.78 mm) for 4.50 - 5.00 mm sizes
Delivery system ports	Single access port to inflation lumen.
	Guidewire exit port is located approximately 25 cm from tip.
	Designed for guidewire ≤ 0.014 in (0.36 mm)
Balloon material	PEBAX®
Balloon fold	5 wings
Marker band material	Platinum Iridium
Marker band length	1 mm
Marker band placement	Nominally spaced 0.4 mm away from the end of the stent

*3.50 mm device. **Dependent on diameter and length. Boston Scientific data on file.

PEBAX is registered trademarks of Arkema.

Purpose Built for Large Proximal Vessels

Specifications

カタログ番号 (下段: GS1コード)

ステント長	ステント内径 (ID) (mm)			
	3.50	4.00	4.50	5.00
8mm	H7493942708350	H7493942708400	H7493942708450	—
	8714729985259	8714729985266	8714729985273	
12mm	H7493942712350	H7493942712400	H7493942712450	H7493942712500
	8714729985297	8714729985303	8714729985310	8714729985327
16mm	H7493942716350	H7493942716400	H7493942716450	H7493942716500
	8714729985334	8714729985341	8714729985358	8714729985365
20mm	H7493942720350	H7493942720400	H7493942720450	—
	8714729985372	8714729985389	8714729985396	
24mm	H7493942724350	H7493942724400	H7493942724450	—
	8714729985419	8714729985426	8714729985433	
28mm	H7493942728350	H7493942728400	—	—
	8714729985457	8714729985464		
32mm	H7493942732350	H7493942732400	—	—
	8714729985495	8714729985501		

コンプライアンスチャート

圧力		ステント内径 (mm)			
atm	kPa	3.50	4.00	4.50	5.00
8.0	814	3.18	3.64	4.13	4.59
9.0	910	3.29	3.76	4.26	4.73
10.0	1014	3.38	3.87	4.37	4.86
11.0	1117	3.48	3.98	4.49	4.97
12.0	1213	3.56	4.07	4.59	5.07
13.0	1317	3.63	4.15	4.67	5.16
14.0	1420	3.69	4.21	4.75	5.24
15.0	1517	3.74	4.27	4.80	5.30
16.0	1620	3.78	4.32	4.87	5.36
17.0	1724	3.83	4.37	4.92	5.42
18.0	1827	3.87	4.41	4.97	5.47
19.0	1924	3.93	4.47	5.04	5.52
20.0	2027	3.98	4.53	5.10	5.57

Nominal pressure
Rated Burst pressure*

*この圧を超えて加圧しないでください。

【警告】

1. 適応対象(患者)

- (1) 保護されていない左冠動脈主幹部、冠動脈入口部又は分岐部に病変が認められる患者に対しては、緊急時等を除き、循環器内科医及び心臓外科医らで適用の有無を検討し、患者の背景因子から冠動脈バイパス手術が高リスクと判断され、且つ病変部の解剖学的特徴からステント治療が低リスクと判断された場合に限ること。

添付文書より一部抜粋。詳細は添付文書をご確認ください。

SYNERGY MEGATRON™

Everolimus-Eluting Platinum Chromium Coronary Stent System

※径表示換算目安：1mm=3French=0.0394inches

販売名：シナジー メガトロン ステントシステム
医療機器承認番号：30500BZX00230000

製品の詳細に関しては添付文書等でご確認いただくか、弊社営業担当へご確認ください。
©2023 Boston Scientific Corporation or its affiliates. All rights reserved.
All trademarks are the property of their respective owners.

**Boston
Scientific**
Advancing science for life™

ボストン・サイエンティフィック ジャパン株式会社
本社 東京都中野区中野4-10-2 中野セントラルパークサウス
www.bostonscientific.jp

IC-1716701-AA