

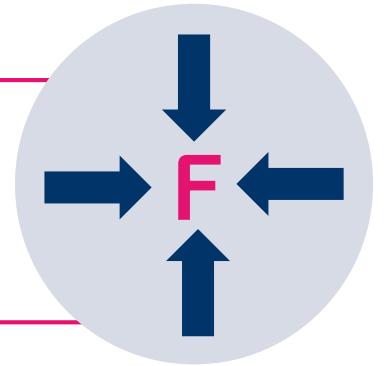
iVolution

The therapy: indication

Treatment of de novo or restenotic atherosclerotic lesions in peripheral arteries located under the aortic arch with a nominal diameter ranging from 4.5 and 9.5 mm

Key features

Use in **exposed arteries**- iliac, superficial femoral artery (SFA) and popliteal artery



FLEXIBILITY

**RADIAL
FORCE**



Stent technology

- ✓ **Open cell** design with **short cell length** to feature:
 - Outstanding flexibility
 - High adaptability to vessel
 - No flaking (no fish scaling effect)
 - Anti-kinking

- ✓ **Closed cell** in both ends for maximum control of stent release (no popping)
- ✓ **4 radiopaque markers** at each end of the stent

► Open short-cell design



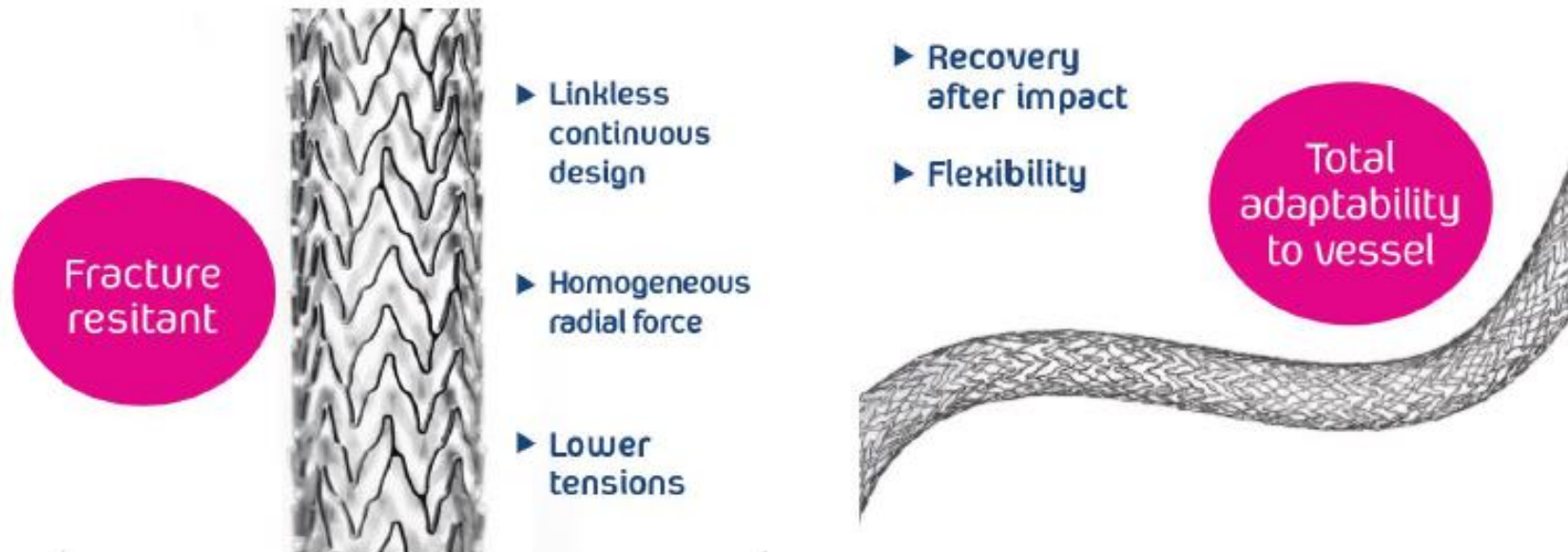
► 4 RO markers in either end of the stent



Stent technology

✓ **Continuous design.** Links are extensions of struts for more homogeneous distribution of stress and less risk of fracture

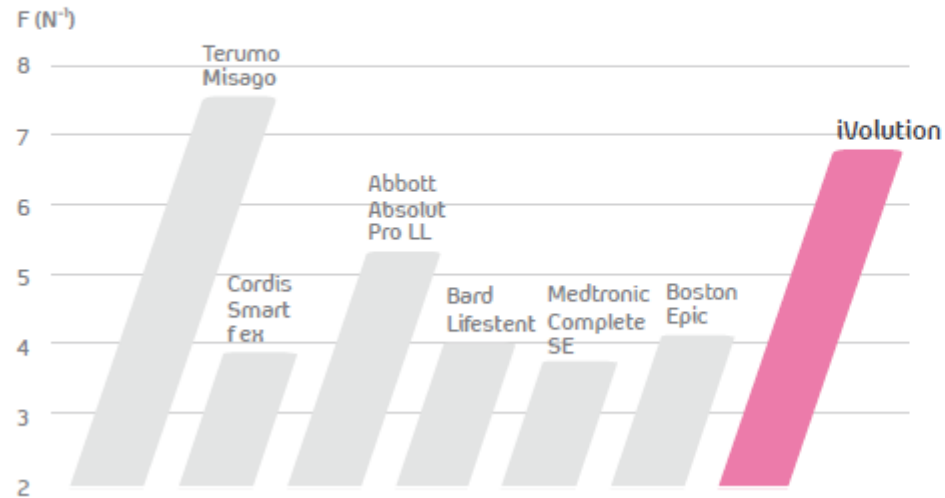
- ✓ High arterial wall **coverage**
- ✓ Perfect **recovery** after impact
- ✓ Best-in-class **radial force**



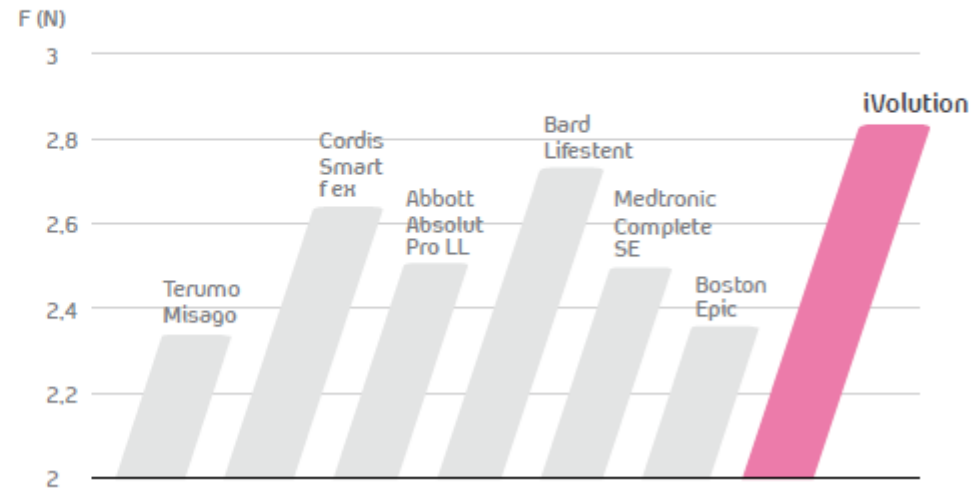
Stent technology

Balance between adaptability and arterial support

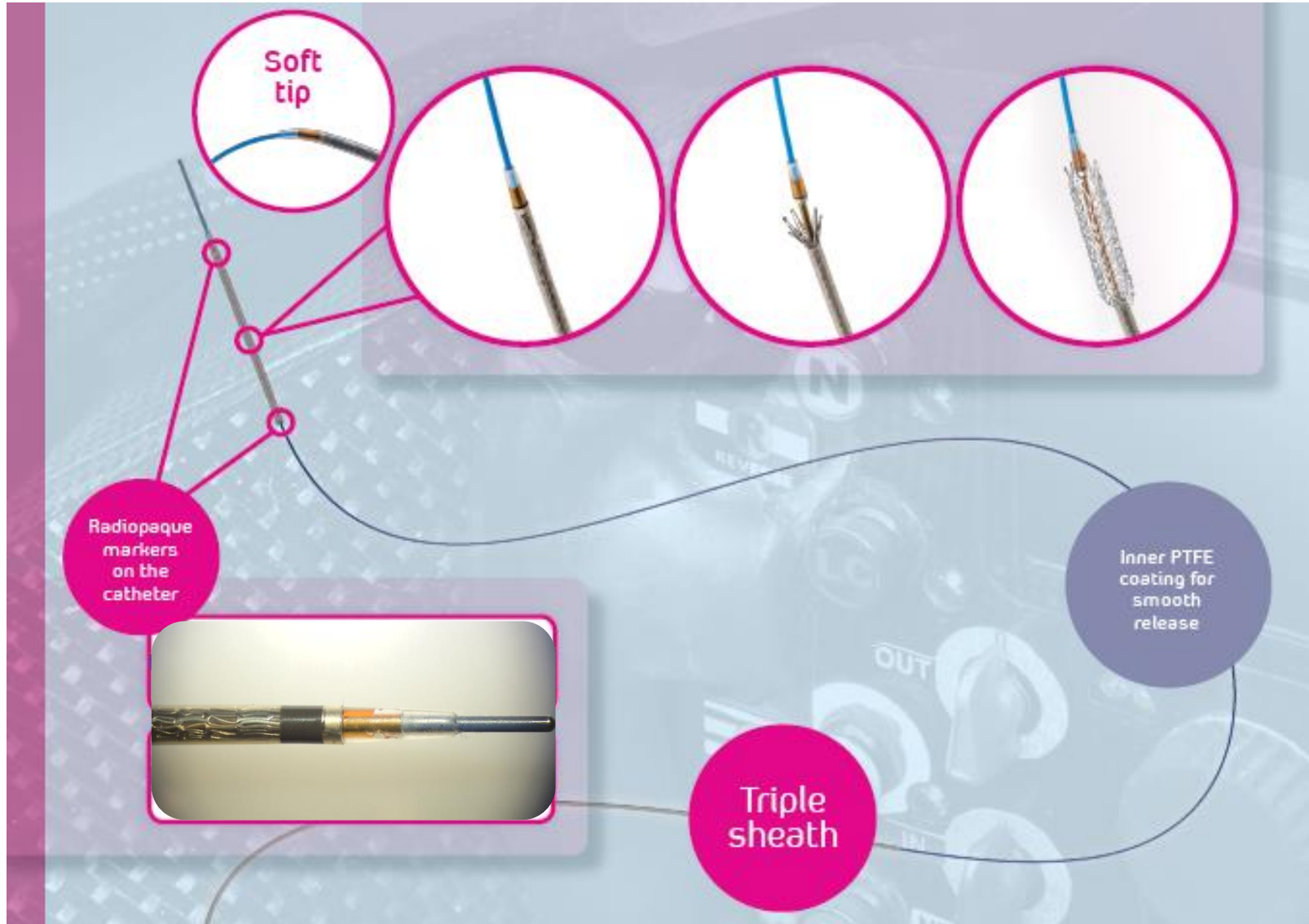
Flexibility



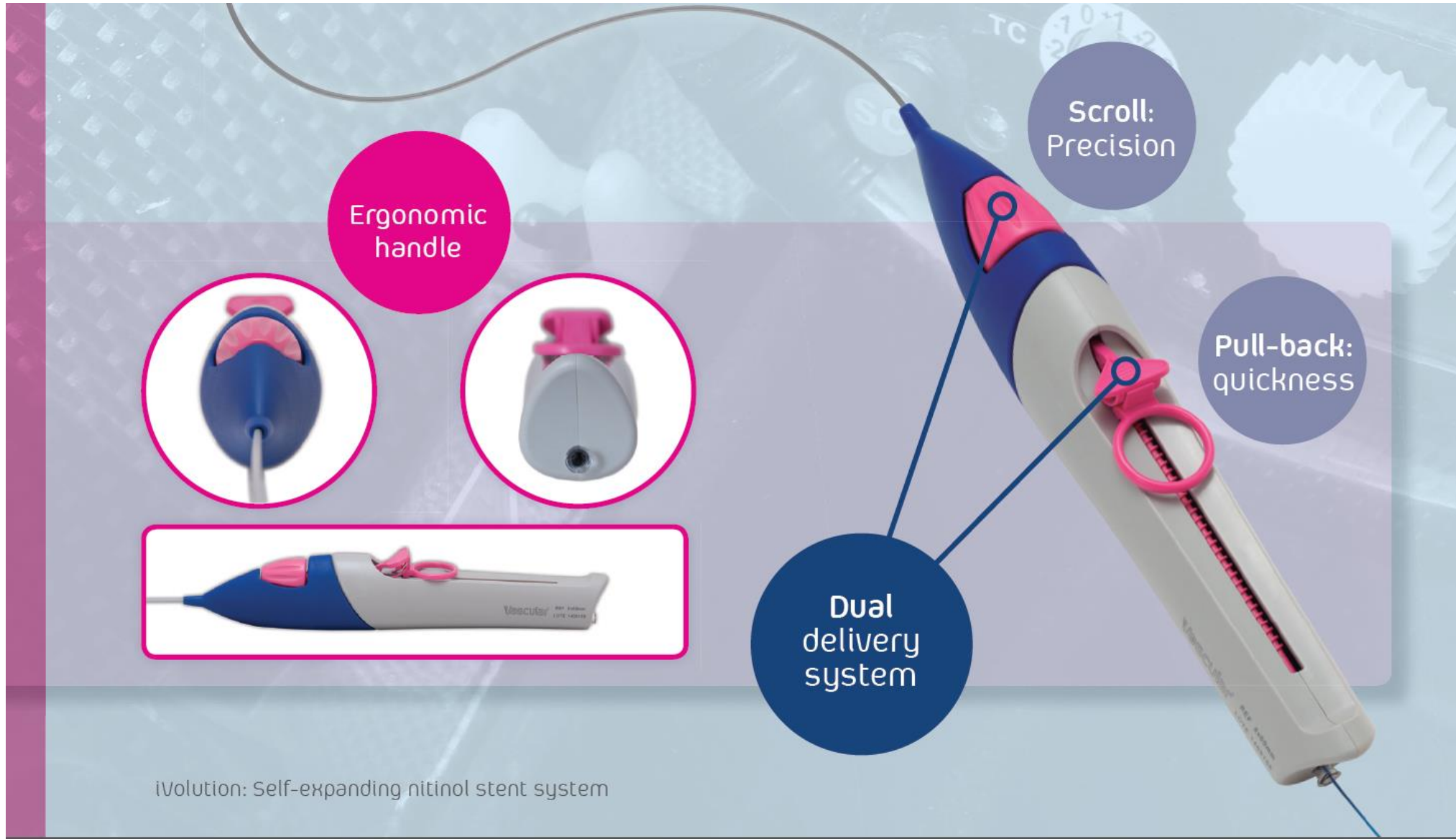
Radial force



Delivery system

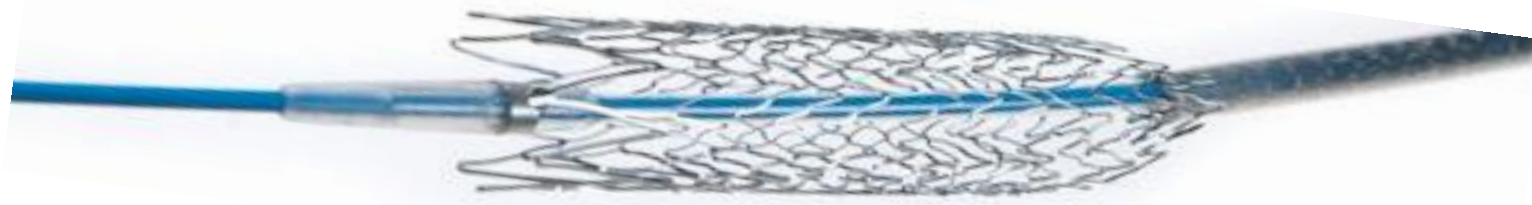


Delivery system



Delivery system

- ✓ Triple sheath design for a comfortable and safer delivery
- ✓ High visibility
 - 2 radiopaque markers on the catheter to limit the stent
 - 1 extra marker on the moving sheath for continuous visibility of the delivery
- ✓ PTFE- coated retrievable sheath for a smooth delivery
- ✓ Non-traumatic soft tip
- ✓ Fully compatible with 6F introducer for all stent sizes



General features

- Nitinol stent
- Triple sheath catheter
- Catheter length: 80 and 140 cm
- Compatible with 6F introducers
- Compatible with 8F guiding catheters
- Compatible with 0.035" guidewires
- 4 RO markers in each end of the stent
- 2 RO markers in the catheter
- 2 handles sizes:
 - Small (L: 40 mm – 100 mm)
 - Large (L: > 100 mm)

Available sizes

0.035					
80, 140 cm	40	60	80	100	150
5.0					
6.0					
7.0					
8.0					
9.0					
10.0					








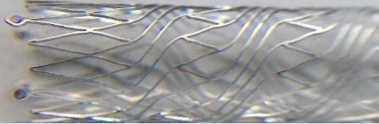
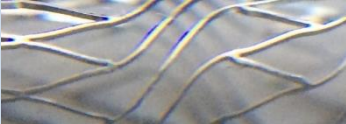

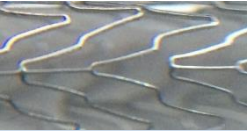

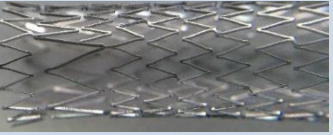





Benchmark analysis

Self-expanding nitinol stent system

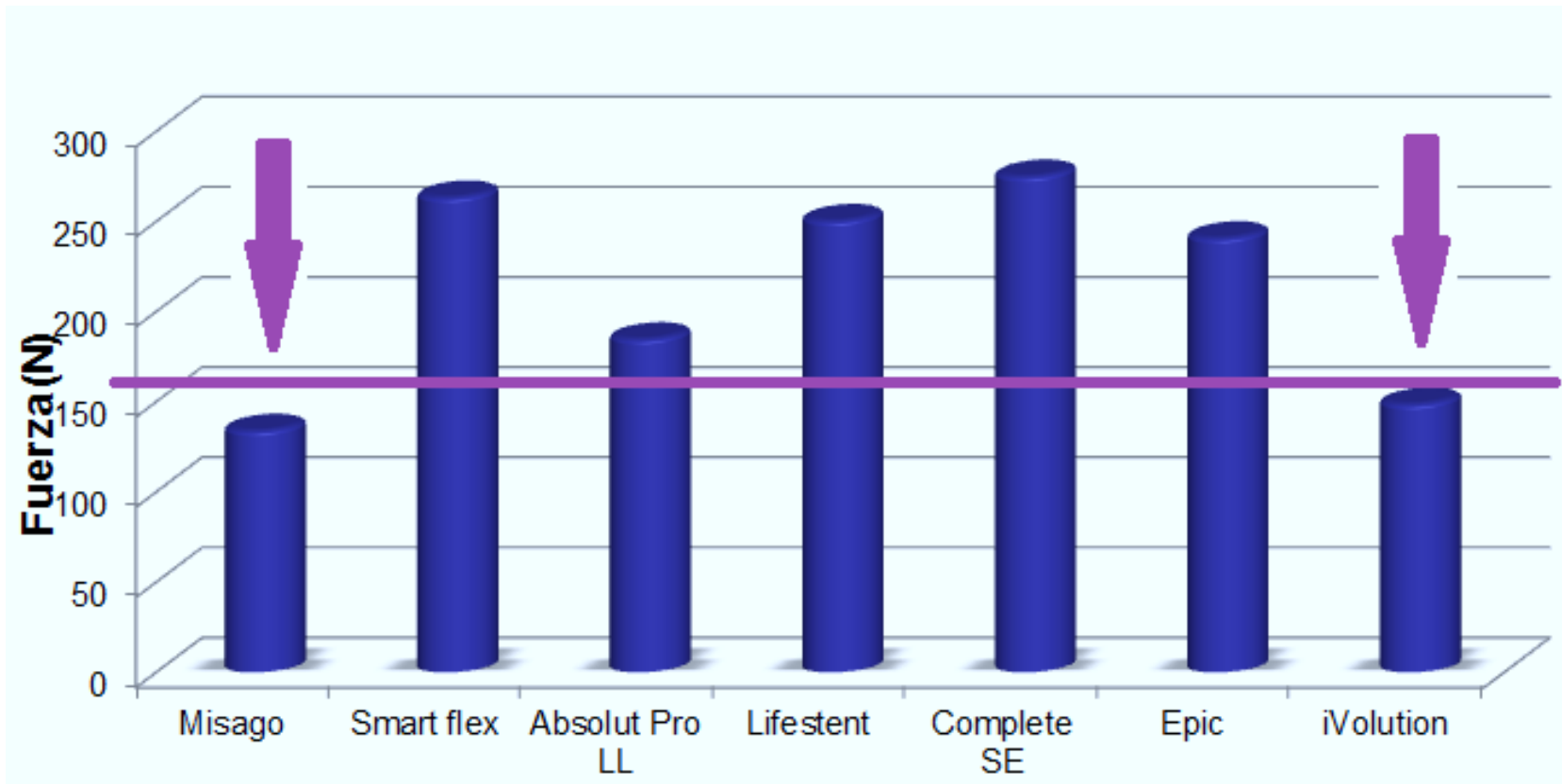
Benchmark analysis

COMPANY	DEVICE NAME	DIMENSION
Terumo	Misago	6*150
Cordis	Smart flex	6*150
Abbott	Absolute Pro LL	6*150
Bard	Lifestent	6*150
Medtronic	Complete SE	6*150
Boston Scientific	Epic	6*120
iVascular	iVolution	6*150

Stent: geometry design

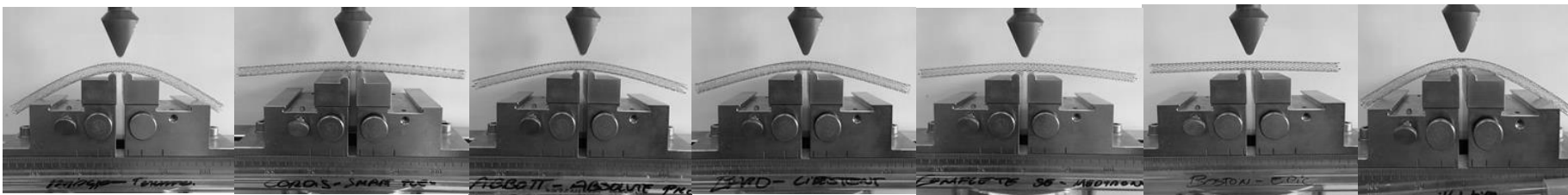
				Cell	Links	Markers	Flexibility	Adaptability to vessel
	iVolution			+ open	No	4	high	high
	Misago			+ open	No	4	high	high
	Smart Flex			closed	long	4	low	low
	Absolute Pro			open	long	4	med	med
	Lifestent			open	short	0	med	med*
	Complete			open	short	4	med	med*
	Epic			open	short	4	med	med*

Stent: flexibility



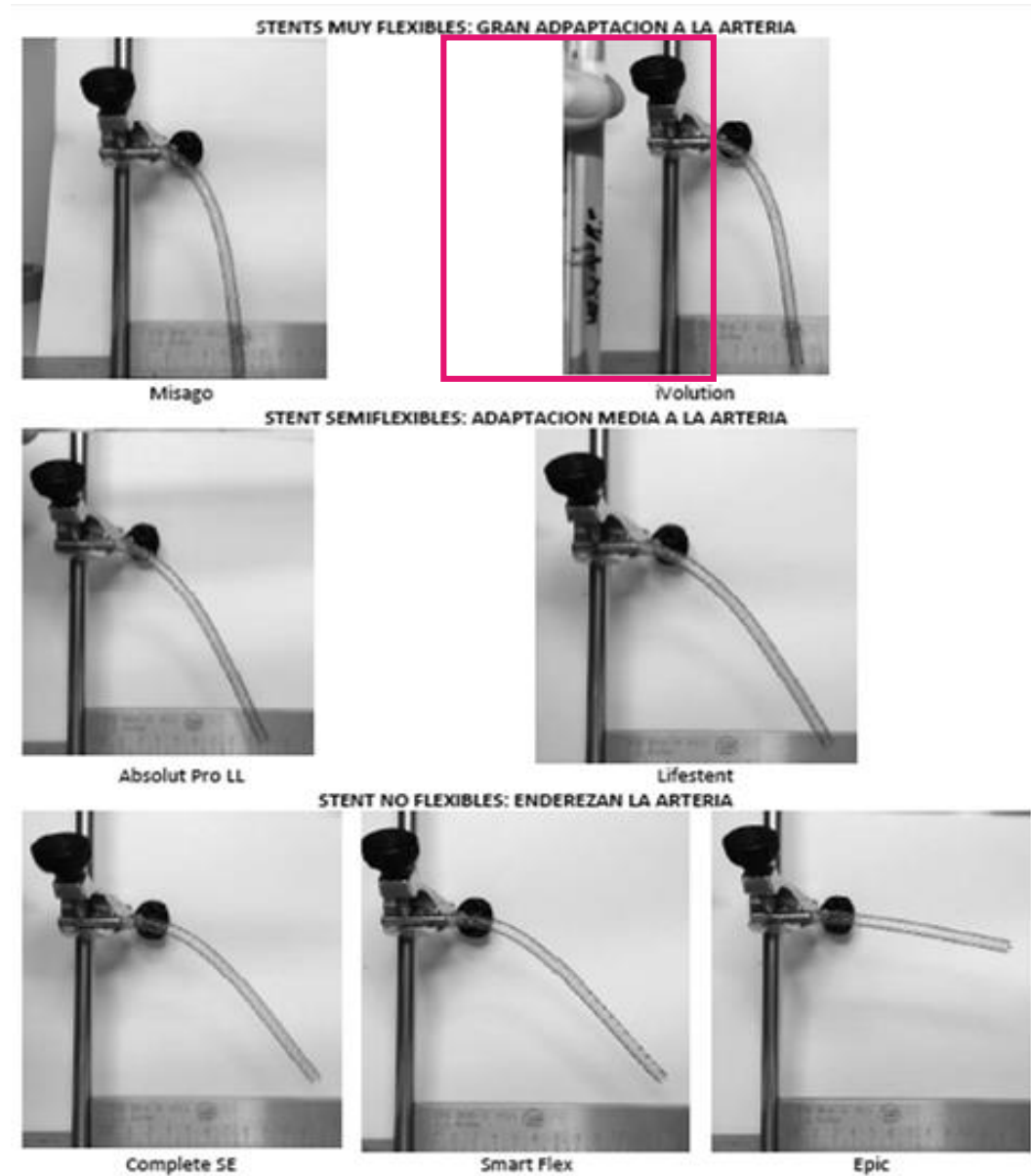
Flexibility is defined as the stent ability to adapt to the anatomy of the treated artery without compromising the function of the implant.

The more flexible, the **more adaptability to the vessel.**



Stent: artery straightening

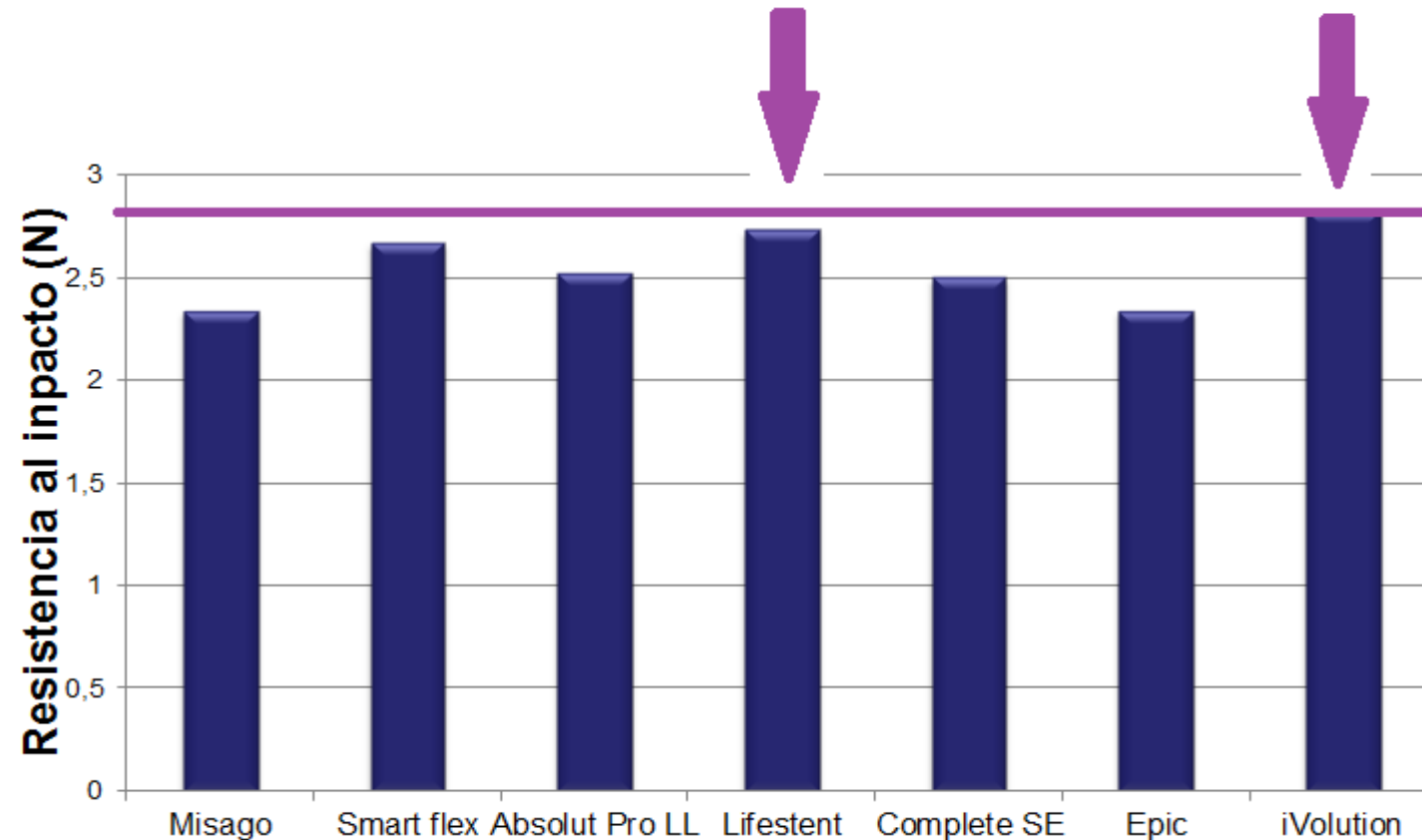
The more flexible is the stent, **the more adaptability and the less straightening**



Stent: **resistance to impact**

The larger the force the stent applies against the impact, the better is the absorption ability without deformation, or alternatively, **absorption ability and following recovery**

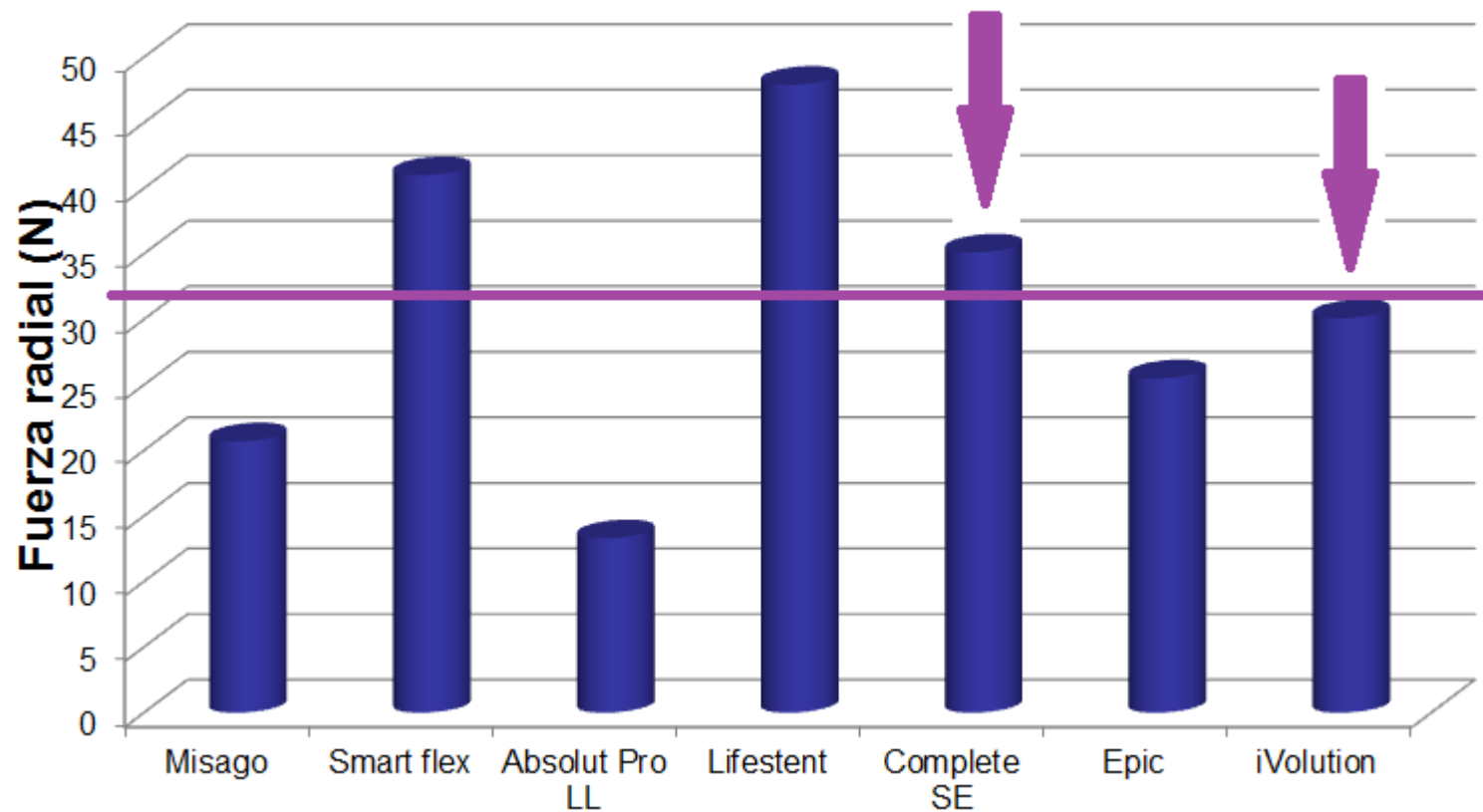
All stents recovery after impact is good though **iVolution have the best data**










Stent: radial force

Stent resistance versus the artery to keep it open















High radial force would permanently damage the artery while a low radial force would not support to hold the artery



Summary

		Flexibility	Resistance to bending	Artery straightening	Resistance to impact	Radial force	Global punctuation
	iVolution	6	6	7	7	7	33
	Misago	7	7	7	1	3	25
	Smart Flex	2	1	3	5	4	15
	Absolute Pro	5	4	5	4	1	19
	Lifestent	3	5	5	6	2	21
	Complete	1	3	3	3	6	16
	Epic	4	2	1	2	5	14

Delivery device comparison

			Handling	Release speed
	iVolution		2-hands	slow: 1-hand fast: 2-hands
	Misago		1-hand	slow
	Smart Flex		2-hands	slow: 1-hand fast: 2-hands
	Absolute Pro		1-hand	slow
	Lifestent		2-hands	slow: 1-hand fast: 2-hands
	Complete		2-hands	slow: 1-hand fast: 2-hands
	Epic		2-hands	slow: 1-hand fast: 2-hands

2 vs:
short/long

iVascular delivery device

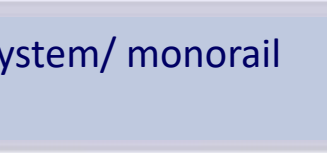
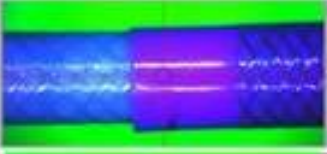
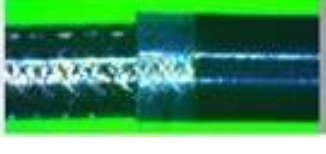
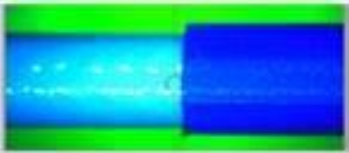
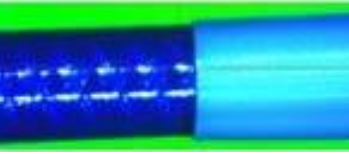
Calibrated release



Sheath comparison

Triple sheath system

The exterior third sheath eases positioning and ensures a safer release.
Softer transition between sheaths.

Terumo - Misago	RX system/ monorail		✓
Cordis - Smart Flex			✗
Abbott - Absolute Pro			✓
LifeStent - Bard			✓
Medtronic - Complete SE			✓
Boston Scientific - Epic			✗
iVascular - iVolution			✓

Clinical Data: **summary**

Clinical Trial	Product	End date	Enrolled patients	Total patients	%enrolled patients	Expected presentations at congresses
EVOLUTION	iVolution	Aug 2017	120	120	100%	<ul style="list-style-type: none"> LINC 2017: interim data 6M/12M presentation- primary and secondary endpoints DEC 2017: Final results 12M

STUDY	PRODUCT	STUDY TYPE	PATIENT/INJURY TYPE	CENTERS	COUNTRIES	PATIENTS	PRIMARY ENDPOINT	SECONDARY ENDPOINT
EVOLUTION	SE STENT iVolution	Multicentric prospective clinical study	Femoropopliteal artery	4	Belgium (Dr. Bosiers)	120	Primary Patency- 12M	Primary patency rate (1M/6M follow-up) Technical success TLR- 1M/6M/12M Clinical success- 1M/6M/12M Serious adverse events

EVOLUTION

6 months – 50 patients (Interim data analysis)

