



University Heart Center
Hamburg

GERMAN
AORTIC CENTER
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How Does the Advanta V12 Make a Difference and Leads the Way

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The LINC logo features the letters 'L', 'I', 'N', and 'C' in a white, sans-serif font, set against a background of colorful, abstract brushstrokes in shades of blue, red, and yellow.

L I N C

25–29 January 2021



Disclosures



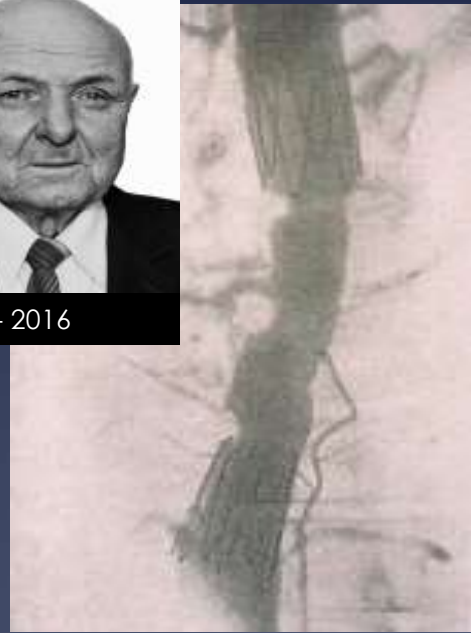
- * Research-grants, travelling, proctoring speaking-fees, IP, royalties with Cook Medical.
- * Consultant with Philips
- * Consultant, Speaking fees with Getinge
- * IP, Consultant with Terumo Aortic
- * Shareholder Mokita-Medical GmbH

Advanta V12 Covered Stent is indicated for restoring and improving the patency of the iliac and renal arteries. Renal approval includes 5, 6 and 7mm diameter Advanta V12.

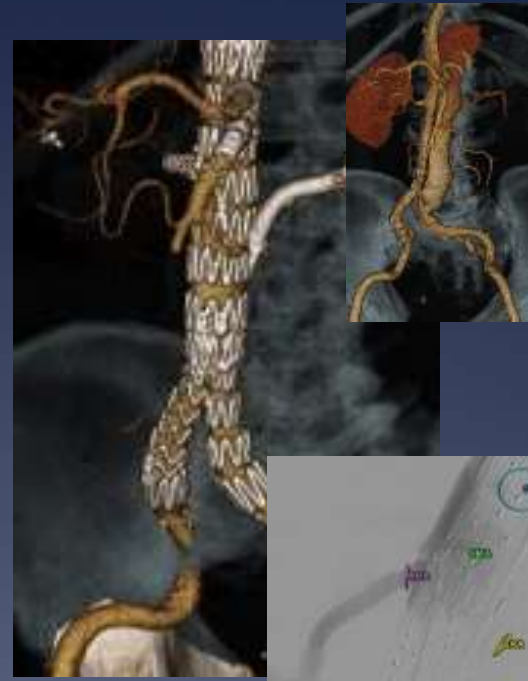
Endovascular Interventions



1934 - 2016



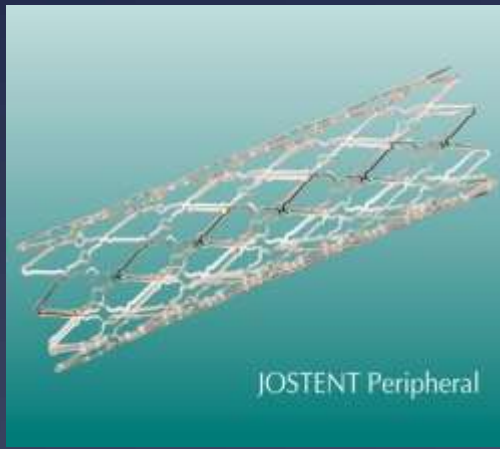
1987



2016



Device Maturation



Ballon Expandable Covered Stent



Advanta V12



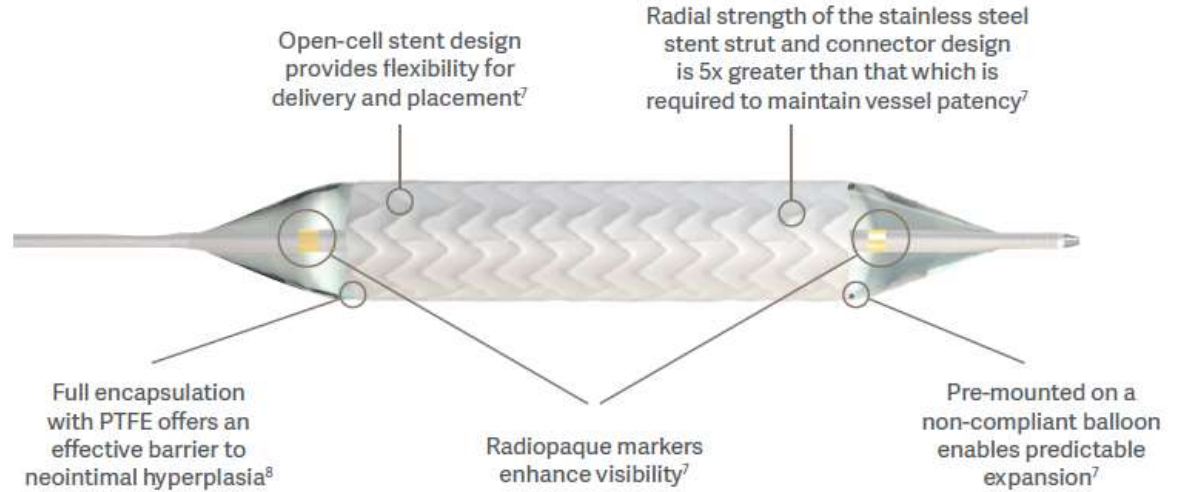
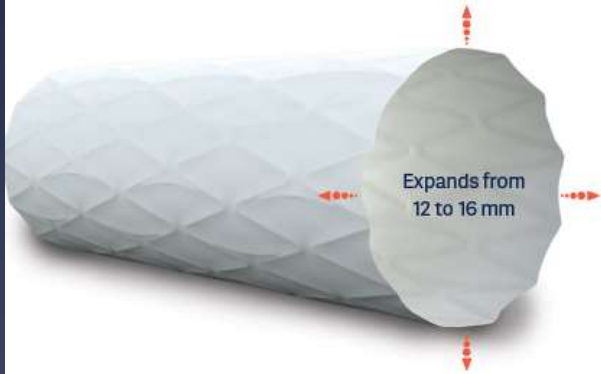
Requirements:

- * Profile: 7F
- * Safe flaring
- * Accessible for re-intervention
- * Patency & Long-term durability
- * Tear-resistant
- * High retention force
- * Predictable diameter
- * Limited foreshortening
- * Real world data

Advanta V12



Advanta V12 Large Diameter





Advanta V12 Indication



The **Advanta V12** balloon expandable covered stent is **CE marked** and indicated for **restoring and improving the patency of iliac and renal arteries**. Renal indication is for 5-7mm diameter arteries.

Advanta V12 has Canadian Health Ministry license for restoring the patency of iliac lesions. In Canada, the Advanta V12 indication excludes renal arteries.

The Advanta V12 Stent is not available in the U.S.





Methodology of bench testing



Competitive testing was performed at Atrium Medical Corp (a subsidiary of Getinge AB) to assess how the Advanta V12 balloon expandable covered stent compares to its competition. Testing included the Atrium* **Advanta V12*** stent, **Bentley* BeGraft*¹** and **Bard* LifeStream*** stent.

All testing was performed internally by Atrium in the engineering lab by experienced engineers and technicians. Clinical use testing was performed in a simulated environment, in fluid and at body temperature.

Except as otherwise noted, all of the Advanta V12 data provided in this report came from each Advanta V12 device being tested side by side with the competitive product at the same time. All samples were stored, together, in a cool, dry location.

The data included in this report was derived from limited sample sizes, therefore, the conclusions provided herein are directional only and do not provide statistical significance.

All data is on file at Atrium.



Context of bench testing



1- Insertion Force & Stent Retention

2- PTFE Cover Integrity

3- Water Entry Pressure

4- Stent Flexibility

5- Stent Diameter (Recoil & Predictability)

6- Stent Length (Foreshortening & Predictability)

Retention Force



Advanta V12 was designed with a high safety factor and stent delivery system to minimize risk of stent dislodgement.

Advanta V12	Sheath Size	Peak Insertion Force (N)	Stent Retention Force (N)
5x16mm	6 Fr	5.8	7.6
5x32mm	7 Fr	5.4	11.1*
6x32mm	7 Fr	5.3	12.6
7x16mm	7 Fr	Not tested	14.2*
9x32mm	7 Fr	Not tested	15.1*
10x59mm	7 Fr	9.2	19.5

Stent retention force was significantly higher than insertion force, indicating **low potential for stent dislodgement.**

Retention Force



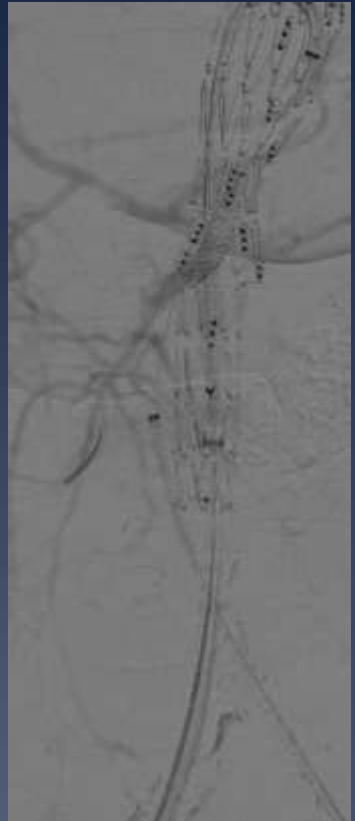
BeGraft Peripheral	Sheath Size	Peak Insertion Force (N)	Stent Retention Force (N)
5x18mm	6 Fr	Not tested	4.4
6x58mm	6 Fr	6.4	Not tested
7x18mm	6 Fr	Not tested	6.7
8x57mm	6 Fr	6.6	Not tested
10x27mm	7 Fr	Not tested	4.2
10x57mm	7 Fr	6.2	Not tested

Lower stent retention force compared to Advanta V12.

LifeStream	Sheath Size	Peak Insertion Force (N)	Stent Retention Force (N)
6x37mm	6 Fr	11.4	9.1
6x58mm	7 Fr	6.9	Not tested
7x37mm	7 Fr	7.0	9.3
8x37mm	7 Fr	Not tested	6.2
9x38mm	7 Fr	7.1	Not tested
9x58mm	7 Fr	Not tested	Not tested

Stent retention force was lower than insertion force, indicating potential for stent dislodgement

Stent-Dislodgement

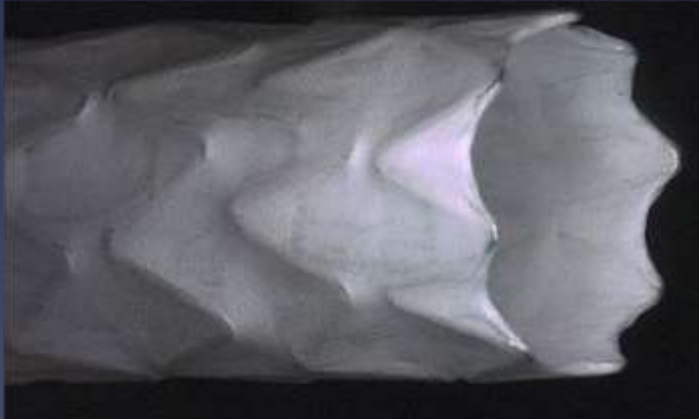


Competitors device

PTFE Covering Integrity



Advanta V12 has a sophisticated one-piece covering construction that passes rigorous internal quality standards, ensuring optimum integrity.

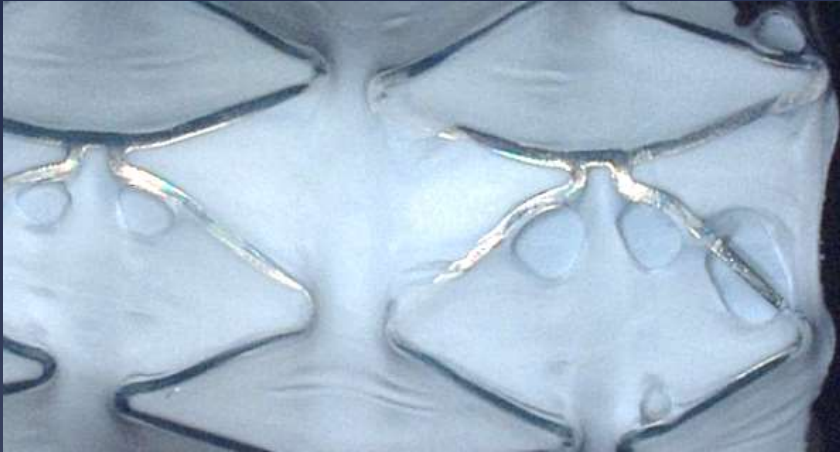


- Double layer, one-piece of PTFE wrapped around ends and cuff overlapped in center.
- No cover integrity issues were observed (n=8/8)*.

PTFE Covering Integrity



LifeStream



Relatively thin outer PTFE layer with noticeable holes (n=11/14)* – no full breaches in two layer cover were observed.

BeGraft Peripheral



PTFE thinning (n=15/15)* and holes (n=4/15)* in single layer cover were observed.

PTFE Covering Integrity



Competitors device



Fabric Damage



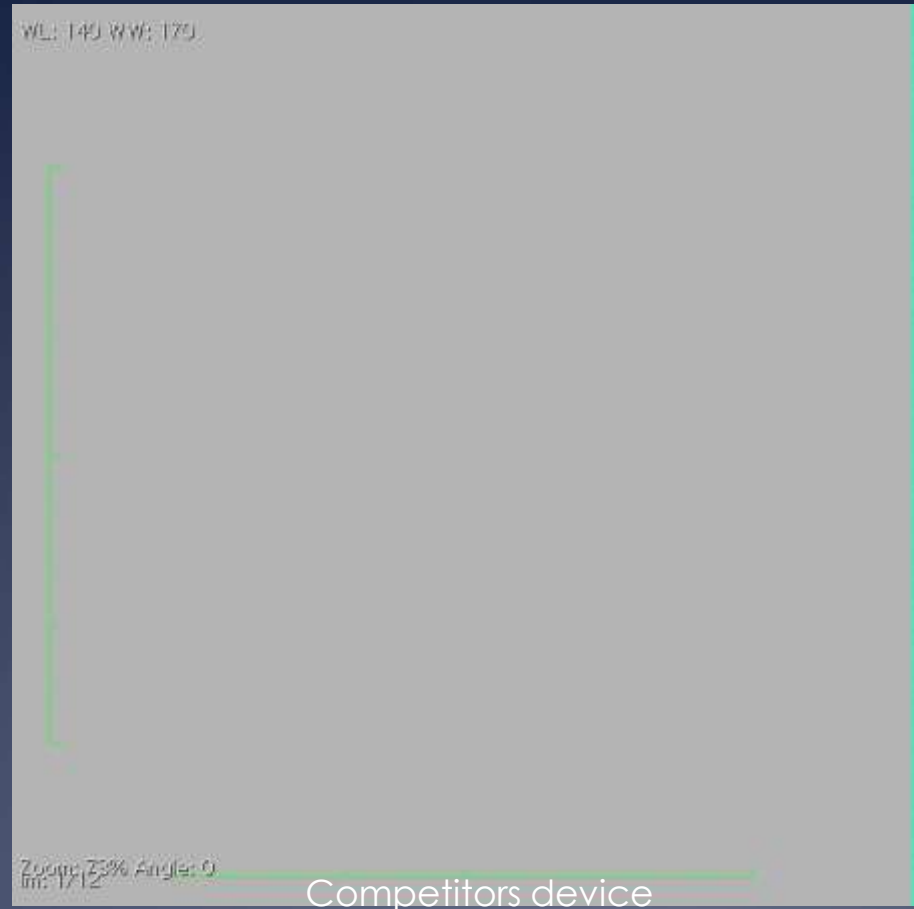
Competitors device

Fabric Damage

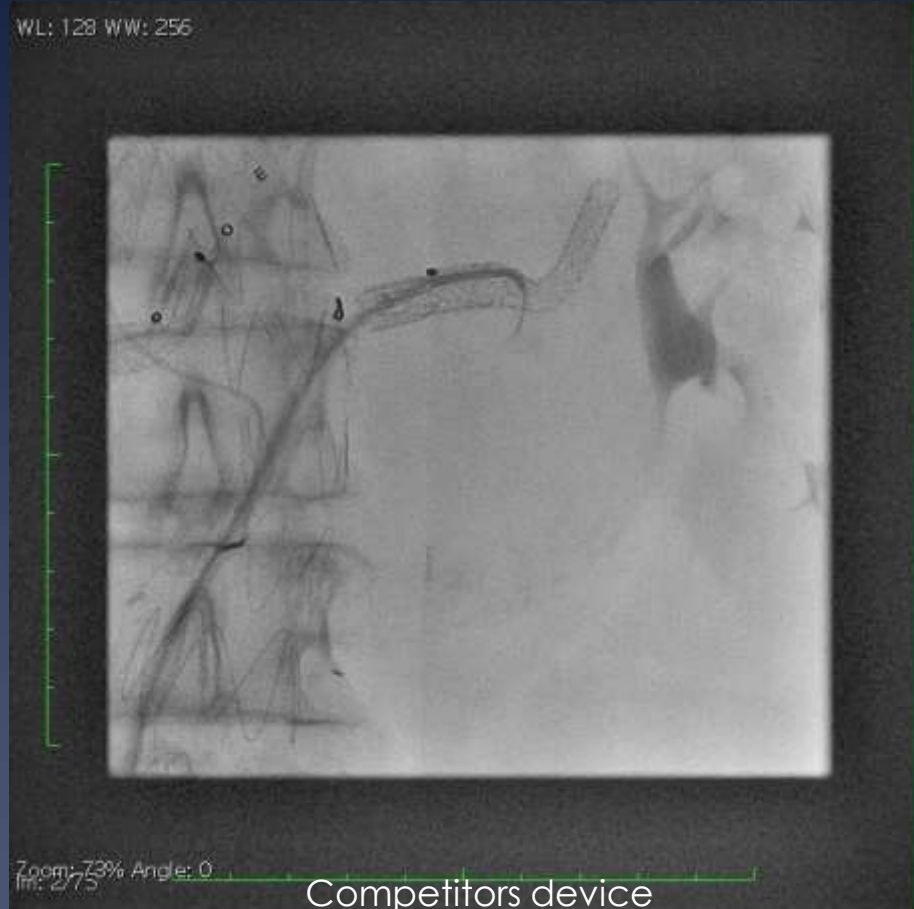




Fabric Damage



Fabric Damage



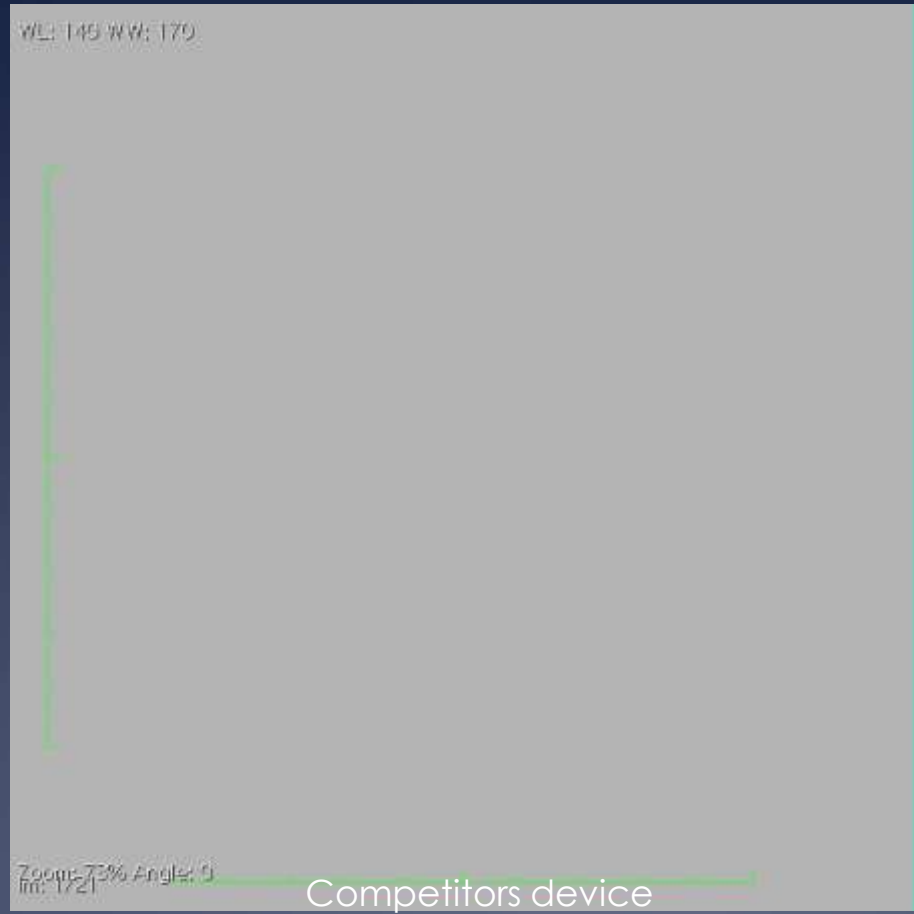
Fabric Damage



Competitors device



Fabric Damage



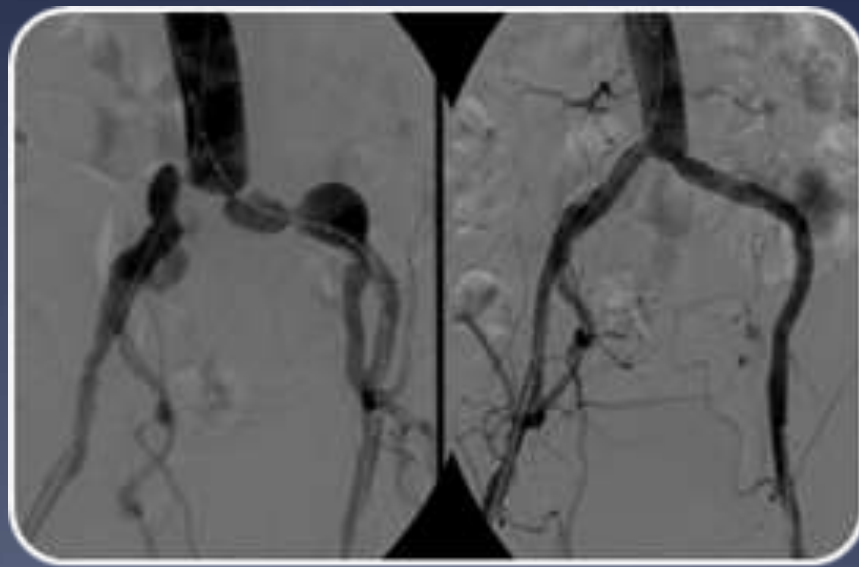
Stent Flexibility



Advanta V12 was designed to conform to the vessel structure, flexible enough to be navigated to the iliac anatomy and to accommodate a 90-degree bend*.



Advanta V12
8x59mm
at ~90 degree
bend.



Advanta V12 conforming to tortuous anatomy

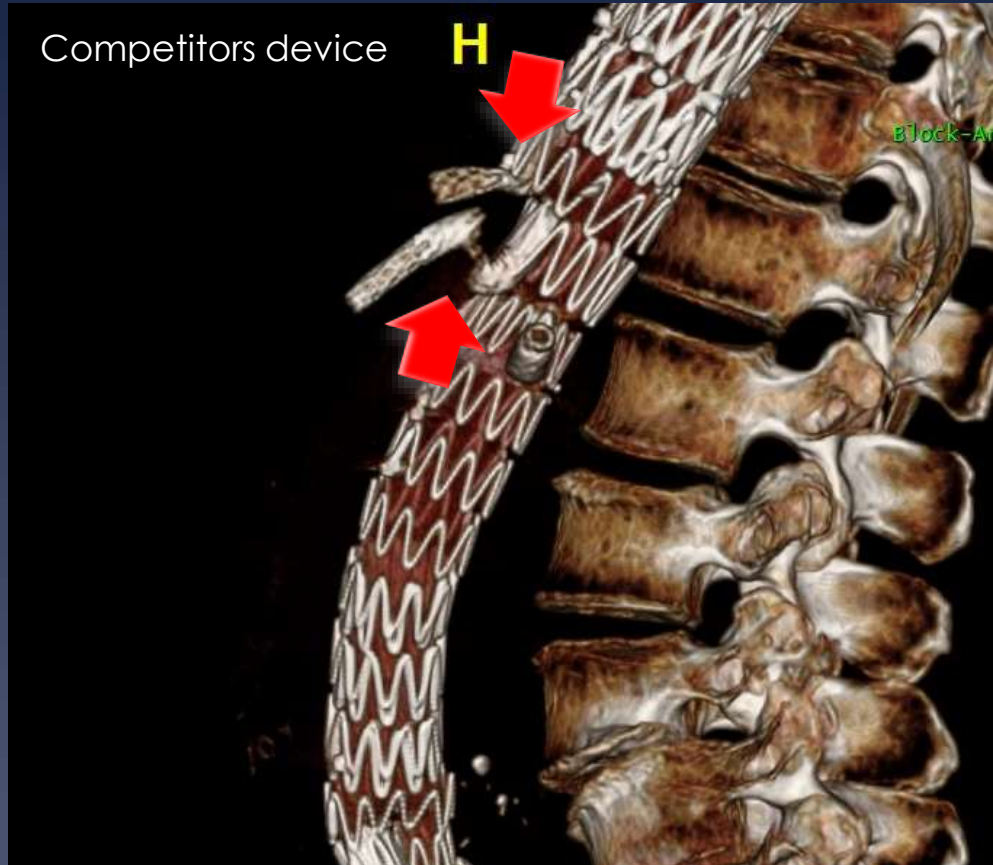
*8-10mm diameters only.

Stent-Fracture



Competitors device

H



Stent-Fracture



Competitors device

Latest Clinical Evidence



A systematic review of covered balloon-expandable stents for treating aortoiliac occlusive disease

B. Patrice Mwapatayi, MD, MMed, MClEd, FCS, FRACS,^{AB} Kenneth Ouriel, MD, MBA,^C

	iCast/Advanta V12	Viabahn VBX	Lifestream	BeGraft	Jostent
No. of studies	9	2	1	1	1
Clinical trials	3	2	1	1	1
Real-world studies ^D	6	0	0	0	0
No. of patients	611	164	155	70	12
Follow-up range, months	8.3-60.0	9-12	9	12	6
Primary patency, months, range					
6	87.2%-97.0%	100%	NR	NR	92%
9	96.4%	96.7%	89.1%	NR	NA
12	83.6%-96.4%	96.6%	NA	94.4%	NA
18	77.0%-87.3%	NA	NA	NA	NA
24	68.0%-92.0%	NA	NA	NA	NA
36	72.0%	NA	NA	NA	NA
48	63.4%-79.9%	NA	NA	NA	NA
60	74.7%	NA	NA	NA	NA
Freedom from TLR, months, range					
6	92.4%-99.3%	100.0%	98.1%	NA	NA
9	97.2%	97.4%	96.1%	NA	NA
12	88.2%-94.3%	96.6%	NA	96.7%	NA
24	85.6%-88.3%	NA	NA	NA	NA
36	86.6%	NA	NA	NA	NA
48	67.4%	NA	NA	NA	NA

Conclusion



- * Endovascular repair of AIOD offers valid alternative to open surgery.
- * Technical specifications of covered balloon expandable stents are different and one cannot be used as a reference to another. Each stent should be proven with its own trial.
- * **Advanta V12** is the preferred covered stent which offers high precision, reliability, and the only proven device with long-term patency and real world data.