



COMPETITIVE INSIGHTS

AMPLATZER™ TALISMAN™ PFO OCCLUDER VS. OCCLUTECH‡ FIGULLA FLEX II PFO OCCLUDER

AMPLATZER™ TALISMAN™ PFO OCCLUDER

OFTEN IMITATED
NEVER MATCHED^{1,2}



STRUCTURAL HEART | STRUCTURAL INTERVENTIONS

Information contained herein for **PRESENTATION** outside of the **U.S. ONLY**.
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THE AMPLATZER™ TALISMAN™ PFO OCCLUSION SYSTEM

AS THE PIONEER IN PFO CLOSURE,
WE CONTINUE TO INNOVATE.

- An unmatched track record with **over 25 years of experience²**
- The **#1** device selected for PFO closure¹
- **Over 180,000 patients** treated globally²



UNMATCHED CLINICAL EVIDENCE

WE RAISED THE BAR WITH THE LANDMARK RESPECT TRIAL

- RESPECT³ is the largest long-term trial for PFO closure with 5,810 patient-years of data — **almost 2x more** than other PFO trials
- RESPECT is the only trial to include patients on either antiplatelet or anticoagulation therapy — **a real-world cross-section** of patients³

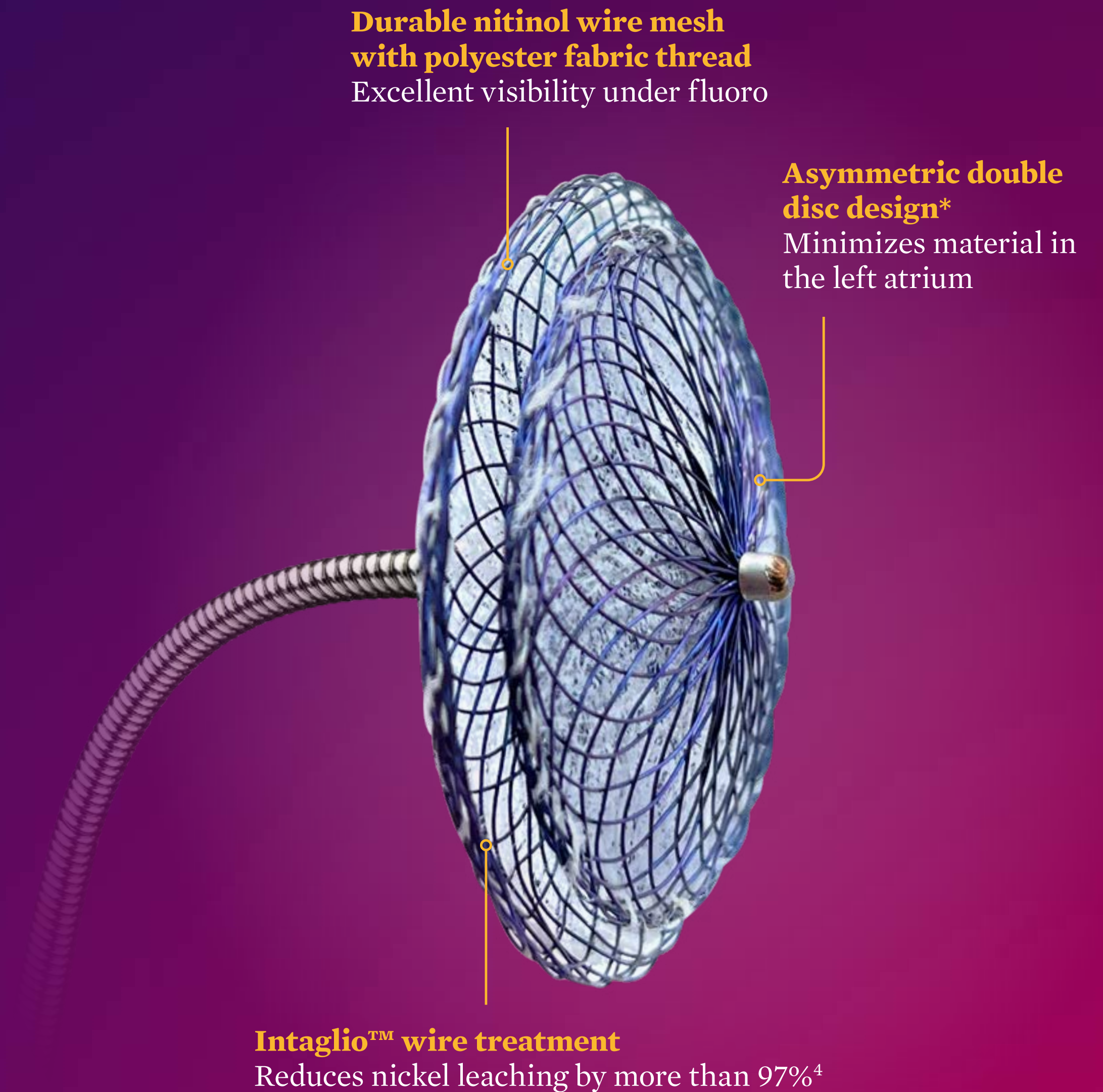
THE RESPECT TRIAL ³	
Devices Used	100% Amplatzer™ PFO Occluder
Patients	980
Follow-Up-Patient Years	5,810 (median 5.9yrs per patient)
Anticoagulant Allowed in Control Group?	Yes
Relative risk reduction for recurrent stroke compared to medical management	45%
Effective Closure	94.2% Freedom from >9 bubbles (Evaluated after 6 months)

A photograph of two surgeons in an operating room. They are wearing blue scrubs, surgical masks, and hairnets. One surgeon is pointing at a large monitor on the left side of the frame. The background is dark and out of focus, showing other people in the room.

OVER 25 YEARS AGO, WE PIONEERED
PFO CLOSURE WITH THE AMPLATZER™
PFO OCCLUDER **TO REDUCE THE RISK OF
RECURRENT PFO-ASSOCIATED STROKE.**^{1,2}

OFTEN IMITATED NEVER MATCHED^{1,2}

Unique design features set the Amplatzer™
Talisman™ PFO Occluder apart from the rest.



* Note: Only the 18mm size is not asymmetric.

UNMATCHED CLINICAL EVIDENCE

DEMONSTRATED EXCELLENCE IN **SAFETY** **AND EFFICACY**

Trusted and relied upon by thousands
of physicians around the world.



† Effective closure

* Patients in device group of each trial implanted with the Amplatzer™ PFO Occluder:
RESPECT = 465, PREMIUM = 119, PC = 191, CLOSE = 121, DEFENSE = 53, PRIMA = 41.

In **6 published trials**^{3, 5-9} with 990* patients,
the Amplatzer™ PFO Occluder showed:



DEVICE EROSIONS
DEVICE THROMBUS
DEVICE EMBOLIZATION EVENTS
WIRE FRAME FRACTURES

AMPLATZER™ TALISMAN™ PFO OCCLUDER VS. OCCLUTECH‡ FIGULLA FLEX II PFO OCCLUDER

BENCH TESTING

Bench testing was performed to understand how the Amplatzer Talisman PFO Occluder and Occlutech Figulla Flex II PFO Occluder perform in varying simulated PFO septum thicknesses, looking at structural integrity.

Testing was also conducted on the delivery systems, which consist of the device cable and delivery sheath, focusing on cable bias on device placement and delivery sheath visibility under fluoroscopy.

Device sizes and delivery systems across the full range of each line were assessed as a part of this testing.

AMPLATZER™ TALISMAN™ PFO OCCLUDER VS. OCCLUTECH‡ FIGULLA FLEX II PFO OCCLUDER

TALISMAN MAINTAINS STRUCTURAL INTEGRITY

With wider septum separation, there is a gap between the septum and the Occlutech device.

In contrast, Talisman maintains structural integrity across a wide range of septum thicknesses to support reliable closure.

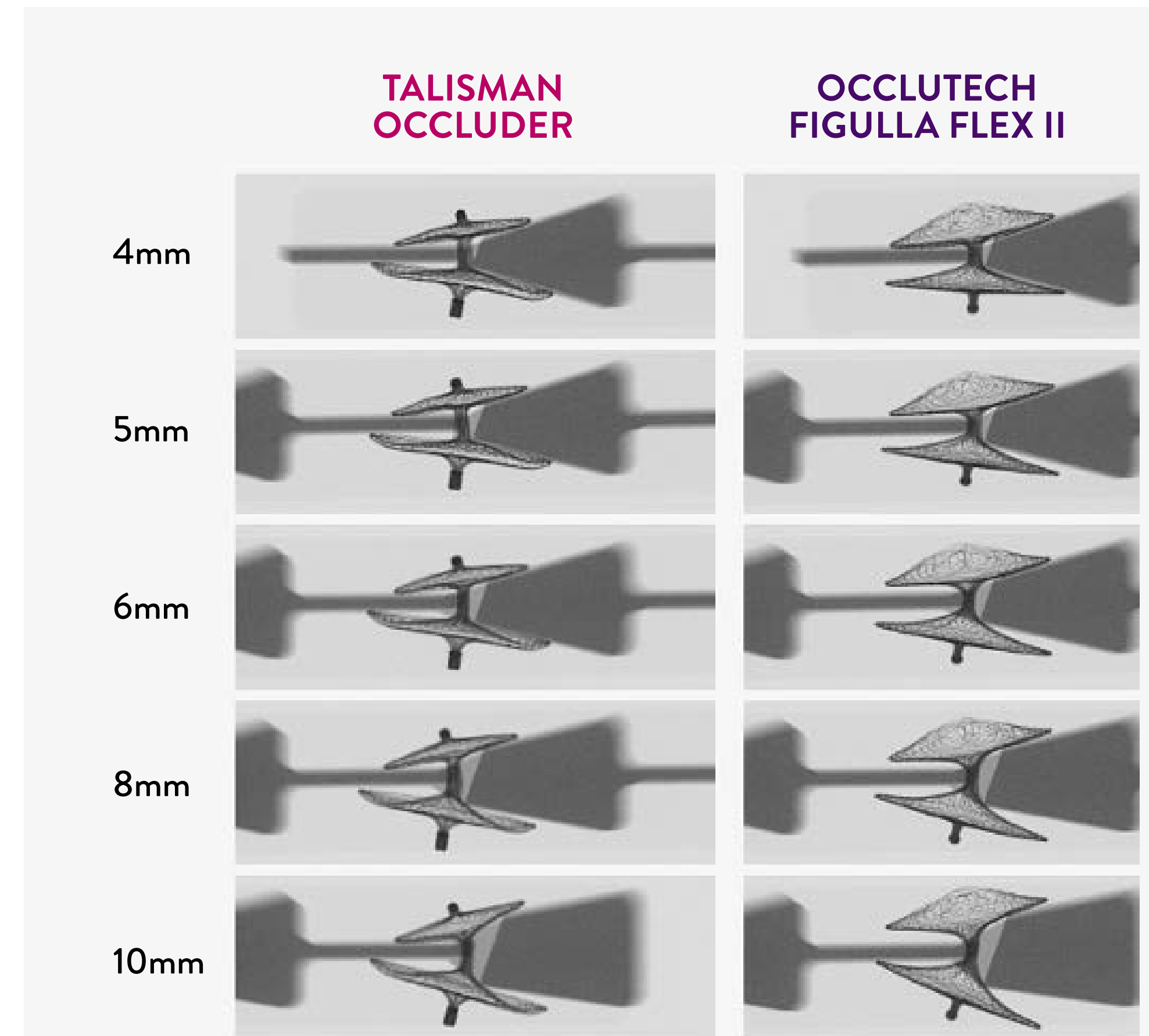


Figure 1. Amplatzer Talisman PFO Occluder vs. Occlutech Figulla Flex II PFO Occluder in stimulated PFO septums 4-10mm.

Abbott data on file

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AMPLATZER™ TALISMAN™ PFO OCCLUDER VS. OCCLUTECH‡ FIGULLA FLEX II PFO OCCLUDER

TALISMAN OFFERS GREATER FLEXIBILITY

Occlutech's stiffer delivery cable limits the angle of approach, creating tension that makes it unclear where final device placement will be. In contrast, the Talisman delivery cable offers flexibility for easy and reliable final device placement visualization.

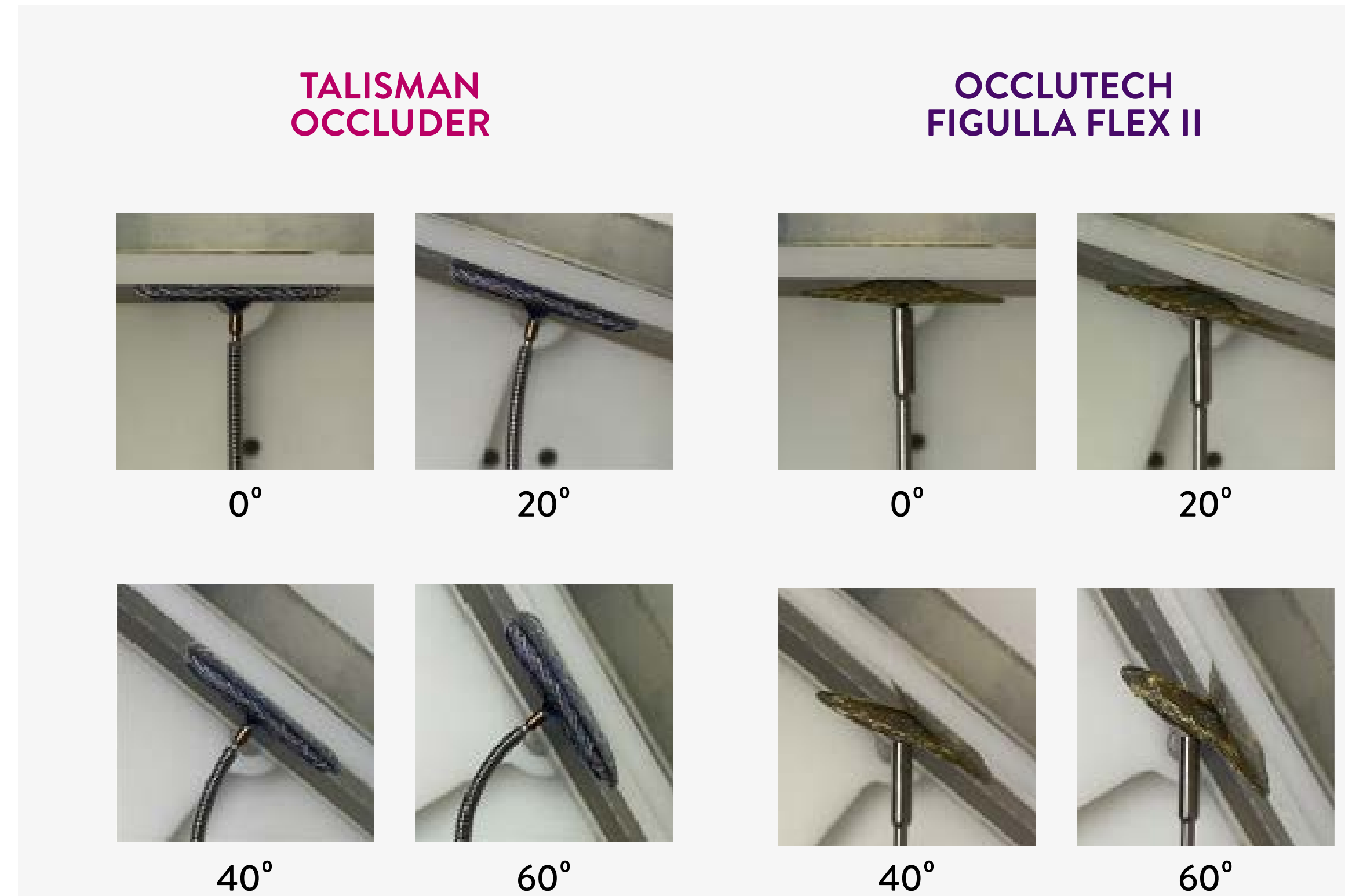


Figure 2. Amplatzer Talisman delivery cable (left) vs. Occlutech Figulla Flex II delivery cable (right) at angles of 0-60 degrees.

Abbott data on file

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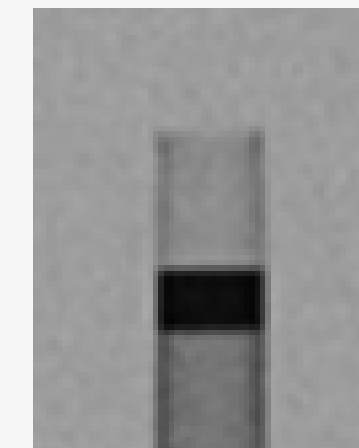
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TALISMAN PROVIDES EASIER VISUAL VERIFICATION

VERIFY AT A GLANCE.

Occlutech does not have a marker band on the delivery sheath. In contrast, Talisman has a marker band at the distal end of the delivery sheath providing reliable information for device placement.

TALISMAN
OCCLUDER



OCCLUTECH
FIGULLA FLEX II

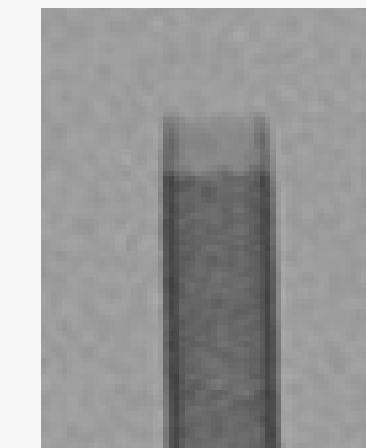


Figure 3. Amplatzer delivery sheath (left) vs. Occlutech Figulla Flex II delivery sheath (right).

OCCLUTECH LACKS ROBUST CLINICAL EVIDENCE

Occlutech has no published multi-center, prospective, randomized controlled trials to support design differences or clinical outcomes.

In comparison, Amplatzer™ has the largest trial for PFO closure, 5,810 patient years of data, and is the only trial to include patients on anticoagulation therapy, a real-world cross-section of patients.³

KEY FINDINGS

- 45% relative risk reduction for recurrent stroke compared to medical management³
- 94.2% effective closure rate at 6 months³

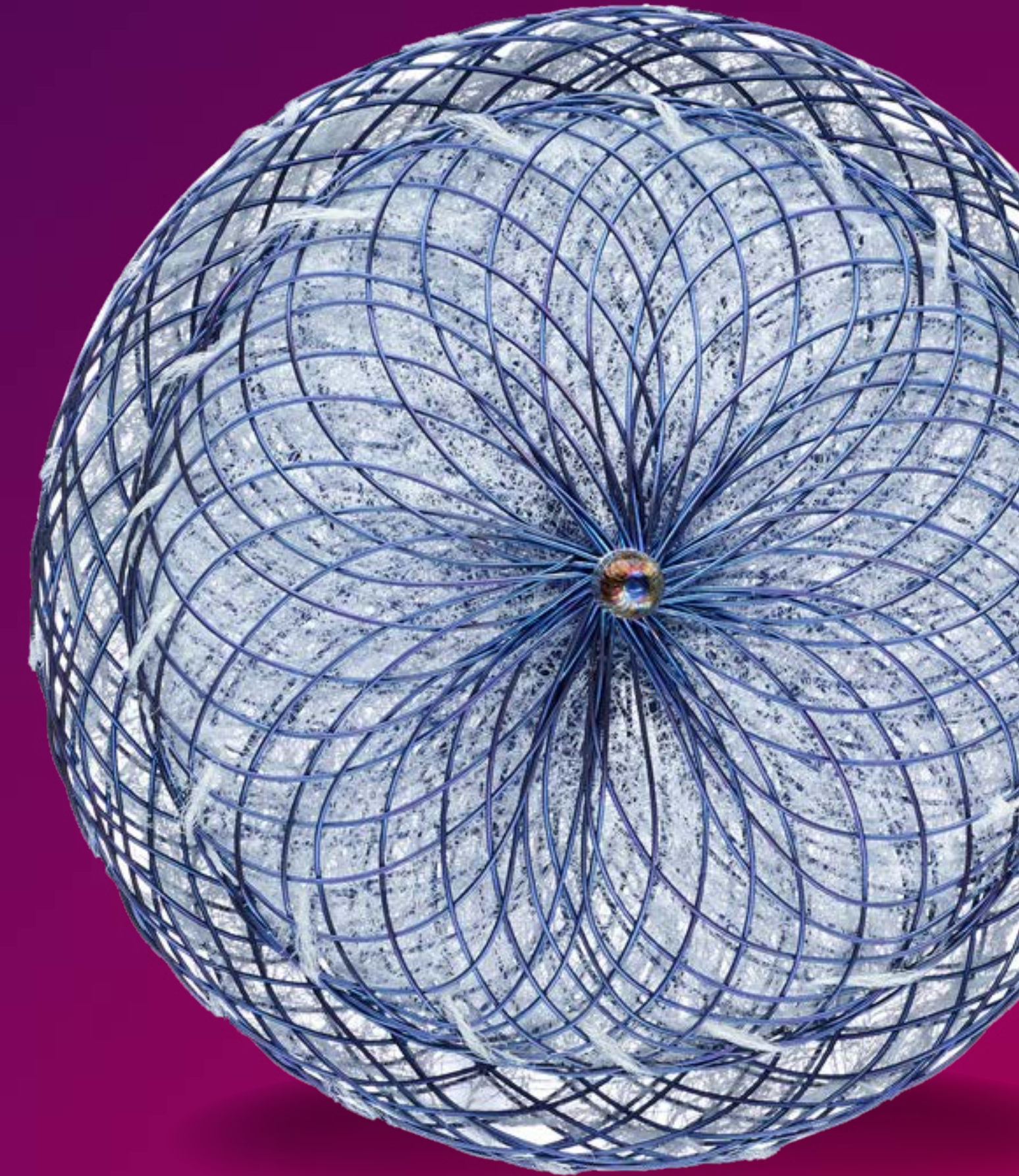
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WHY TALISMAN?

Talisman is the #1 PFO device worldwide with a trusted, proven design and legacy of over 25 years of excellence.^{1,2}

Talisman demonstrates excellent structural integrity with a delivery system that allows for flexibility at a range of angles for reliable device assessment and clear placement verification for precise delivery and deployment.

The Talisman system offers robust clinical evidence, with demonstrated excellence in safety and effectiveness and a low risk of device-related events.



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Indications, Contraindications, Warnings, Precautions, and Adverse Events. Information contained herein for **PRESENTATION** outside of the **U.S. ONLY**. Always check the regulatory status of the device in your region.

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