Abbott

COMPETITIVE INSIGHTS

AMPLATZER™ TALISMAN™ PFO OCCLUDER VS. GORE‡ CARDIOFORM SEPTAL OCCLUDER

MAT-2309661 v1.0 | Item approved for OUS use only.

AMPLATZER™ TALISMAN™ PFO OCCLUDER

OFTEN IMITATED
NEVER MATCHED [1,2]

STRUCTURAL HEART | STRUCTURAL INTERVENTIONS

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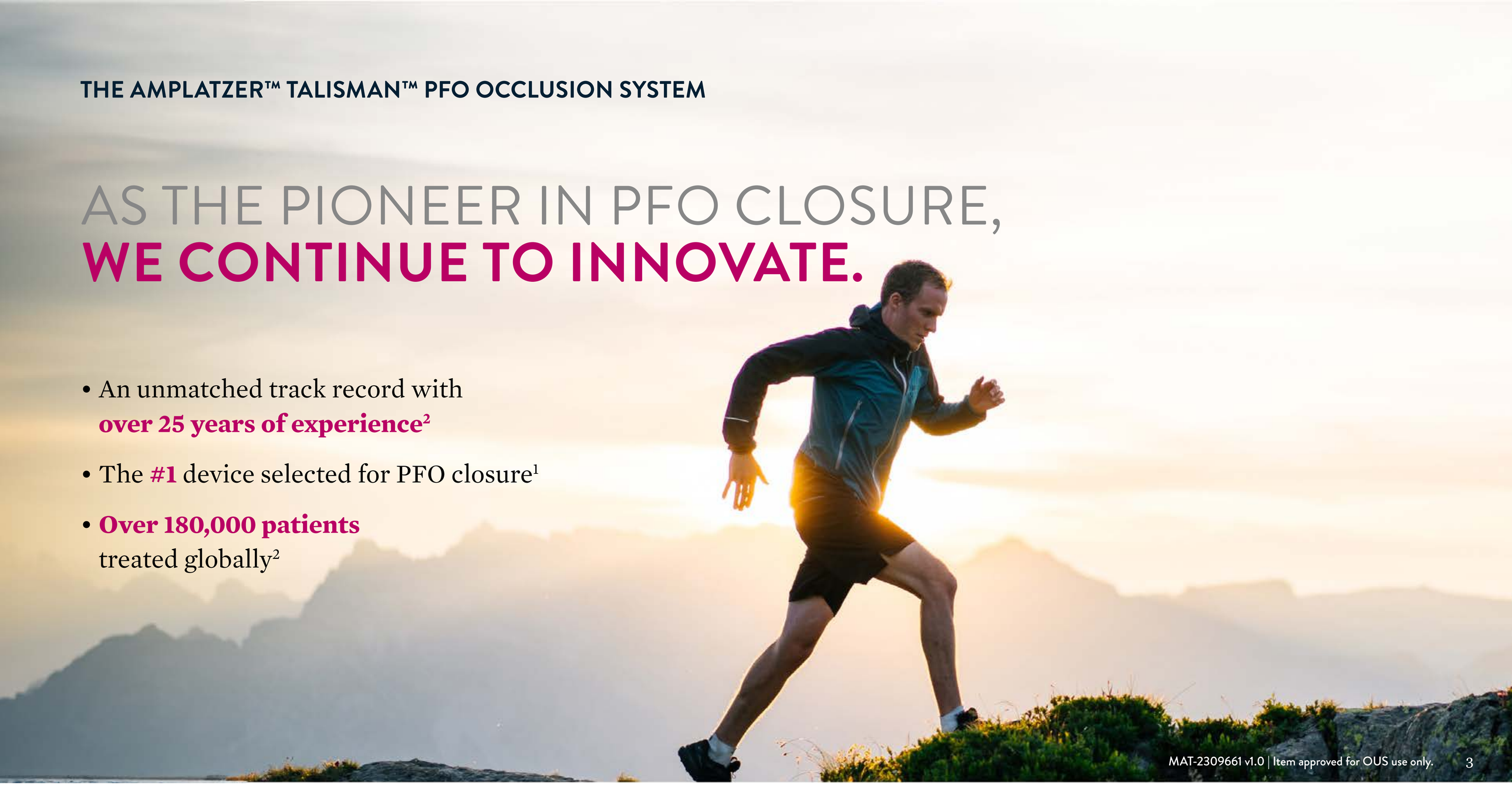
AS THE PIONEER IN PFO CLOSURE, **WE CONTINUE TO INNOVATE.**

- An unmatched track record with **over 25 years of experience**[2]
- The **#1** device selected for PFO closure[1]
- **Over 180,000 patients** treated globally[2]



WE RAISED THE BAR WITH THE LANDMARK RESPECT TRIAL

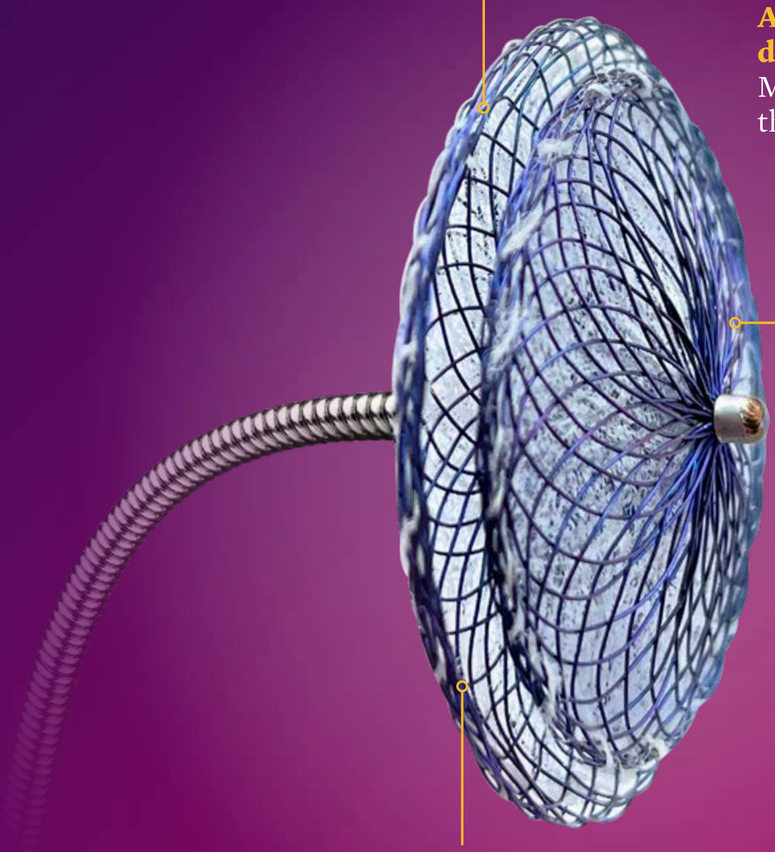
- RESPECT[3] is the largest long-term trial for PFO closure with 5,810 patient-years of data — **almost 2x more** than other PFO trials
- RESPECT is the only trial to include patients on either antiplatelet or anticoagulation therapy — **a real-world cross-section** of patients[3]

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 at 6 months)

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.



Durable nitinol wire mesh with polyester fabric thread
Excellent visibility under fluoro

Asymmetric double disc design*
Minimizes material in the left atrium

Intaglio™ wire treatment
Reduces nickel leaching by more than 97%[4]

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

DEMONSTRATED EXCELLENCE IN SAFETY AND EFFICACY

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

> 94%
CLOSURE RATE†
AT 6 MONTHS IN RESPECT TRIAL[3]

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

ZERO

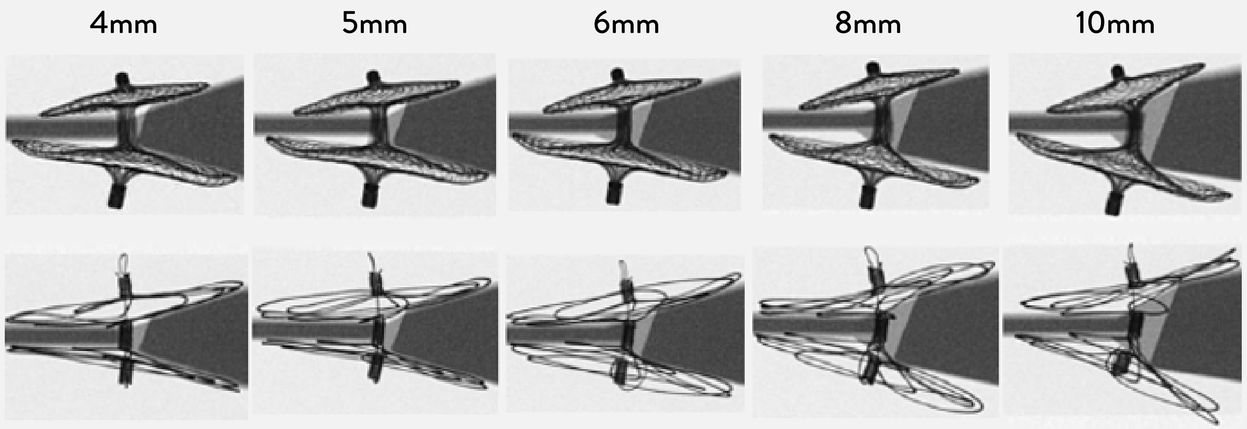
- DEVICE EROSIONS
- DEVICE THROMBUS
- DEVICE EMBOLIZATION EVENTS
- WIRE FRAME FRACTURES

† 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.

TALISMAN MAINTAINS STRUCTURAL INTEGRITY

Bench testing was performed to understand how the offered size ranges of Amplatzer Talisman PFO occluder and GORE CARDIOFORM Septal Occluder perform in varying simulated PFO septum thicknesses, looking at structural integrity.

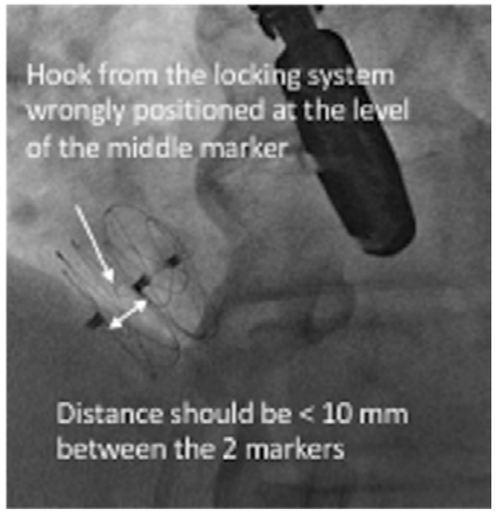
With wider septum separation, GORE experiences deformation with wires being pulled away from the disc structure.
In contrast, Talisman maintains structural integrity across a wide range of septum thicknesses to support reliable closure.

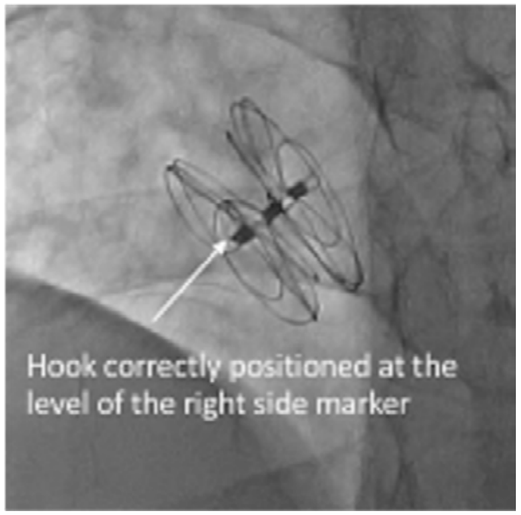


Data on file.

WHAT ARE THE CHALLENGES OF A LOCK-LOOP DESIGN?

GORE's implant procedure requires a visual confirmation of successful deployment by verifying that the lock loop is engaged. GORE's lock loop can fail, costing valuable time for a second attempt with a new device.





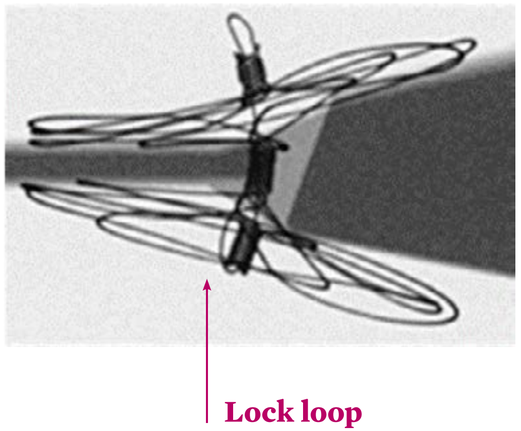


Image source: Noble et al. Fluoroscopic and echocardiographic illustrations of an unsuccessful locking of the GORE CARDIOFORM septal occluder device. Canadian Cardiovascular Society 2020, 2(6): 743–744
GORE Instructions for Use

WIRE FRAME FRACTURE

Kumar et al. published on a case of pericardial tamponade secondary to atrial perforation caused by a nitinol wire fracture of a GORE CARDIOFORM Septal occluder used for PFO closure.[13]

Wire fractures are reported to occur with the GORE CARDIOFORM Septal Occluder.[14] While mostly asymptomatic, some cases have been documented to have caused serious clinical conditions, including atrial perforation, pericardial effusion and cardiac tamponade.[13]

The risk of atrial perforation from a wire frame fracture should be shared with patients considering percutaneous PFO closure with a GORE CARDIOFORM Septal Occluder.[13]

Wire frame fracture has never been reported with the Amplatzer Talisman PFO occluder or Amplatzer™ PFO occluder.*

* MAUDE Database search as of September 7, 2023

LESS AF = LESS RISK

What's the risk?

- In RESPECT, Amplatzer™ PFO device patients were ~2.4 X more likely than medical management patients to experience AF. (AF was detected in 4.4% of patients in the Amplatzer PFO closure arm vs. 1.9% in Medical Management arm)[15]

- Meanwhile in REDUCE, GORE device patients were ~14.7 X more likely than medical management patients to experience AF. (AF was detected in 6.6% of patients in the Gore PFO closure arm vs. 0.4% in Medical Management arm)[15]

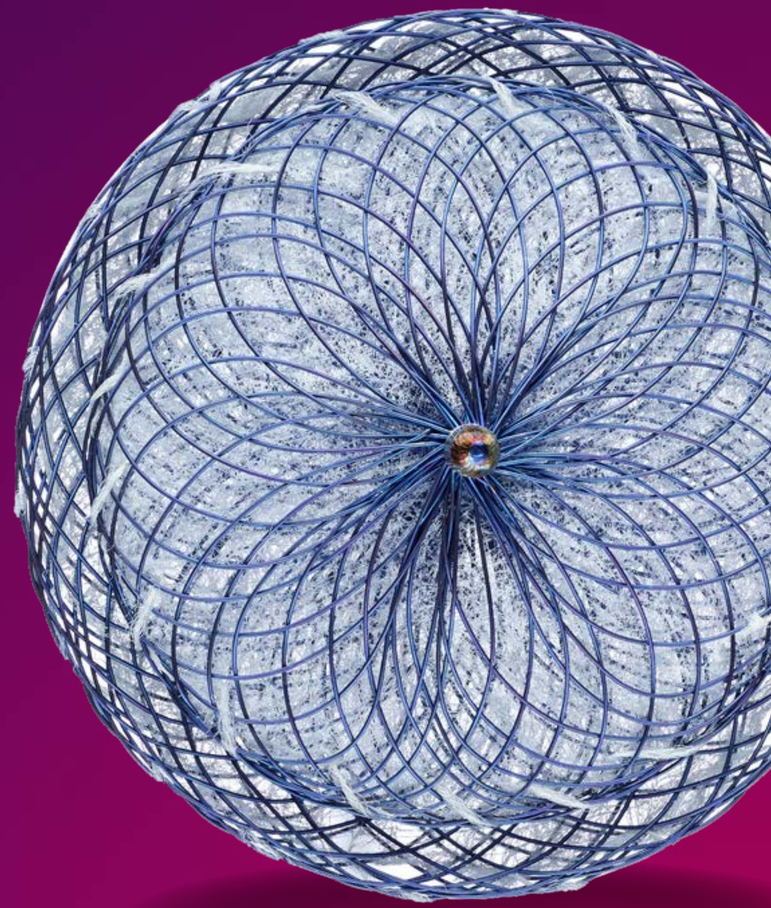
New-onset AF could result in need for OACs, thereby increasing bleeding risk[15]

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 and ease of use, zero wire frame fractures, and showed a lower increased risk of AF in RESPECT compared to GORE devices in the REDUCE trial.

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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