HARPOON Beating Heart Mitral Valve Repair System

Welcome to the future of surgical mitral valve repair



Elegant simplicity and reliable repair



Least-invasive surgical procedure



Real-time confirmation of results

Edwards continues its legacy of elevating surgical care in meaningful and lasting ways with the HARPOON Beating Heart Mitral Valve Repair System.

For more information about HARPOON Beating Heart Mitral Valve Repair System, please contact your Edwards representative.

Reference

1. Gammie JS, et al. Safety and performance of a novel transventricular beating heart mitral valve repair system: 1-year outcomes. *European Journal of Cardio-Thoracic Surgery*. 2021;59(1):199-206.

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Envision a new way forward in surgical mitral valve repair







In the treatment of severe degenerative mitral regurgitation (DMR)

The challenges are known. The future is clear.

Surgeons are consistently seeking to improve the outcomes of DMR repair with simplicity, reproducibility, and reliable results.

Patients are looking for a less disruptive, low-risk option that can get them back to their lives more quickly.

Edwards Lifesciences brings decades of innovation and experience to the challenges of mitral valve repair

We are focused on redefining the surgical experience for patients and surgeons – turning procedural challenges into new opportunities for better outcomes.

Introducing reproducible, beating-heart, off-pump surgical mitral repair

A new procedure designed to improve outcomes in DMR repair

Elegant simplicity in the least-invasive surgical procedure



Performed off pump on a beating heart – no cardiopulmonary bypass required, significantly reducing patient impact



Based on familiar surgical principles – enables multiple chords to be deployed in mitral valve repair



Options preserved – preserves the ability to perform future mitral valve repair

Reliable reproducibility with real-time confirmation of results



Guided by echocardiography – enables real-time chordal adjustment and confirmation of results

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It all comes together with HARPOON **Beating Heart Mitral Valve Repair System**

Re-envisioning the surgical experience

Simplified delivery. Surgical flexibility. Standardised experience.

Small-footprint ePTFE chords with proprietary self-forming anchors are easily deployed and securely anchored using the preloaded HARPOON delivery system.



Three procedure-defining system components



Dedicated hemostatic introducer minimises blood loss



Low-profile (9 Fr) delivery system minimises apical incision size



Proprietary, self-forming double-helix ePTFE knot preserves the option for future mitral valve repair

Improving the patient experience

Least-invasive surgical procedure for mitral repair – facilitates excellent safety and rapid patient recovery¹

Baseline Status

Mean Age: 61.0 years (n = 62)	N
YHA Class: 40.7% Class I (n = 59)	N





* Procedural outcomes defined as new onset complications from procedure through discharge

Aean LVEF: 69.2% (n = 53)

Aean STS Risk Score (PROM): 0.6% (n = 56)

No cardiopulmonary bypass or

- sternotomy required;
- <5 cm left thoracotomy incision.

Ability to perform procedure through a non-rib-spreading technique in a 2-hour time frame, enabling faster return to normal activity.

Average procedure introducer time 0.7 ± 0.3 +10

Average number of implanted ePTFE chords

Additional 1 Year Outcomes Mortality Endocarditis N=1 (2%) Reoperation N=8 (13%) Stroke

N=2(3%)N=1 (2%)

Putting reproducible success in your hands

Real-time confirmation of results¹

Immediate reduction of MR – restored mitral valve function



of patients had MR reduced to \leq mild at discharge (n = 58)

Significant improvement in functional class compared to baseline



of patients reported in NYHA Functional Class I at 1 year (n = 52)

Reduction of MR*



Favourable echocardiographic reverse remodeling

Significant decrease in mitral annular diameter and LVEDV at 1 year



Sustained low gradients of 1.4 ± 0.7 mmHg at 1 year follow up

For reliable repair, seeing is achieving

Know before you close

Collaborative echo guidance allows real-time chordal adjustment on the beating heart, ensuring optimal leaflet coaptation and reduction of MR.







Place

- Accurate placement of knot anchors
- Placement of multiple chords

Adjust

• Titration of chordal length and tensioning

Confirm

• Confirmation of results prior to closure