Welcome to the future of surgical mitral valve repair

Elegant simplicity and reliable repair

Least-invasive surgical procedure

Real-time confirmation of results

Envision a new way forward in surgical mitral valve repair

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.
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

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 recovery

Baseline Status

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age</td>
<td>61.0 years (n = 62)</td>
</tr>
<tr>
<td>Mean LVEF</td>
<td>69.2% (n = 53)</td>
</tr>
<tr>
<td>NYHA Class</td>
<td>40.7% Class I (n = 59)</td>
</tr>
<tr>
<td>Mean STS Risk Score (PROM)</td>
<td>0.6% (n = 56)</td>
</tr>
</tbody>
</table>

No cardiopulmonary bypass or sternotomy required; <5 cm left thoracotomy incision.

Ability to perform procedure through a non–rib-spreading technique in a 1- to 2-hour time frame, enabling faster return to normal activity.

Average procedure time (hours)

- **Introducer time** $0.7 \pm 0.3$

Average number of implanted ePTFE chords

- **2.1 ± 0.6**
- **4.0 ± 1.1**

**Procedural Safety Outcomes**

- **0%** Mortality
- **0%** Stroke
- **0%** Renal failure
- **0%** Transfusion

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>N=2 (3%)</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>N=1 (2%)</td>
</tr>
<tr>
<td>Reoperation</td>
<td>N=8 (13%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>N=1 (2%)</td>
</tr>
</tbody>
</table>

Additional 1 Year Outcomes

*Procedural outcomes defined as new onset complications from procedure through discharge*
Putting reproducible success in your hands

Real-time confirmation of results

**Immediate reduction of MR—restored mitral valve function**

95% of patients had MR reduced to ≤ mild at discharge (n = 58)

**Significant improvement in functional class**

92% of patients reported in NYHA Functional Class I at 1 year (n = 52)

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