Edwards PASCAL Transcatheter Valve Repair System

This is what innovation in tricuspid repair looks like.

A differentiated technology that makes leaflet repair a reality for patients with tricuspid regurgitation.
Tricuspid regurgitation is largely undertreated.

Up to **18.4%** reported prevalence for mild or greater TR\(^1\)

Fewer than **1%** are treated surgically\(^2\)

Patient mortality is significant.
- Moderate or greater TR is associated with worse prognosis.\(^3\)

### Survival\(^3\)

The Kaplan-Meier survival curves of all patients according to TR grade

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Survival Probability</th>
<th>Cumulative proportion of survival, % (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None/Trace</td>
<td>0.100</td>
<td>77 (0.01)</td>
</tr>
<tr>
<td>Mild</td>
<td>0.853</td>
<td>53 (0.01)</td>
</tr>
<tr>
<td>Moderate</td>
<td>0.674</td>
<td>35 (0.02)</td>
</tr>
<tr>
<td>Severe</td>
<td>0.420</td>
<td>30 (0.04)</td>
</tr>
</tbody>
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\(^{1}\) Reference 1
\(^{2}\) Reference 2
\(^{3}\) Reference 3
PASCAL repair system is designed to address the complexity of tricuspid repair.

Demonstrating a significant impact on TR reduction\textsuperscript{4}

\begin{itemize}
\item Improved patient quality of life at six months\textsuperscript{5}
\begin{itemize}
\item 89\% patients sustained NYHA I or II
\item Six-minute walk distance improved by 87 m (p<0.001)
\end{itemize}
\end{itemize}
Approach complex tricuspid anatomy with a system designed to help overcome coaptation and imaging challenges.

Independent grasping is essential in tricuspid procedures having been utilized in 90% of cases during early compassionate use experiences.4

Independent grasping provides opportunities to bridge large coaptation gaps and optimise the images.

- Central spacer increases the span width without applying excessive tension to the leaflets.
- Two implant designs (PASCAL and PASCAL Ace) allow for the tailored treatment.
- Continuous atrial pressure monitoring provides procedural guidance.
Tricuspid anatomy is highly variable. The PASCAL repair system’s atraumatic design preserves fragile leaflets.\textsuperscript{6,7}

Tricuspid leaflets are thin, translucent, and more delicate.\textsuperscript{8,9}

The tricuspid valve often has more than three leaflets, and can be variable with deep clefts and folds.\textsuperscript{8}

- Distinct clasp design with a single row of retention elements reduces stress on fragile tricuspid leaflets.
- Super-elastic nitinol construction allows tension to be distributed on leaflets to minimise risk of injury.
Safe subvalvular maneuvering helps to overcome challenges of dense chordae and limited landing zones.\textsuperscript{6,7}

- Device elongation feature facilitates safe repositioning within dense chordae and the subvalvular apparatus.
- The PASCAL Ace implant system has a narrower paddle width with improved visualization.
- One dedicated delivery system for both tricuspid and mitral procedures designed to shorten learning curves.

“Flexibility is great, and it has the ability to steer wherever you want. PASCAL can be elongated and maneuvered – this is helpful as it allows you to get out of the valve in case you are entangled with chords, without chance of injury.”

*Interventional Cardiologist, Germany*
Edwards PASCAL Transcatheter Valve Repair System

Purposeful design. Purposeful partnership.

Edwards Lifesciences believes that the key to tricuspid therapies starts with partnership. From screening to procedural planning and imaging support, our dedicated tricuspid team will collaborate with your heart team every step of the way. Together, we are making a meaningful mark on the lives of patients.

Personalised Solutions
by Edwards Lifesciences

Personalised Touch
by you, the physician

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

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