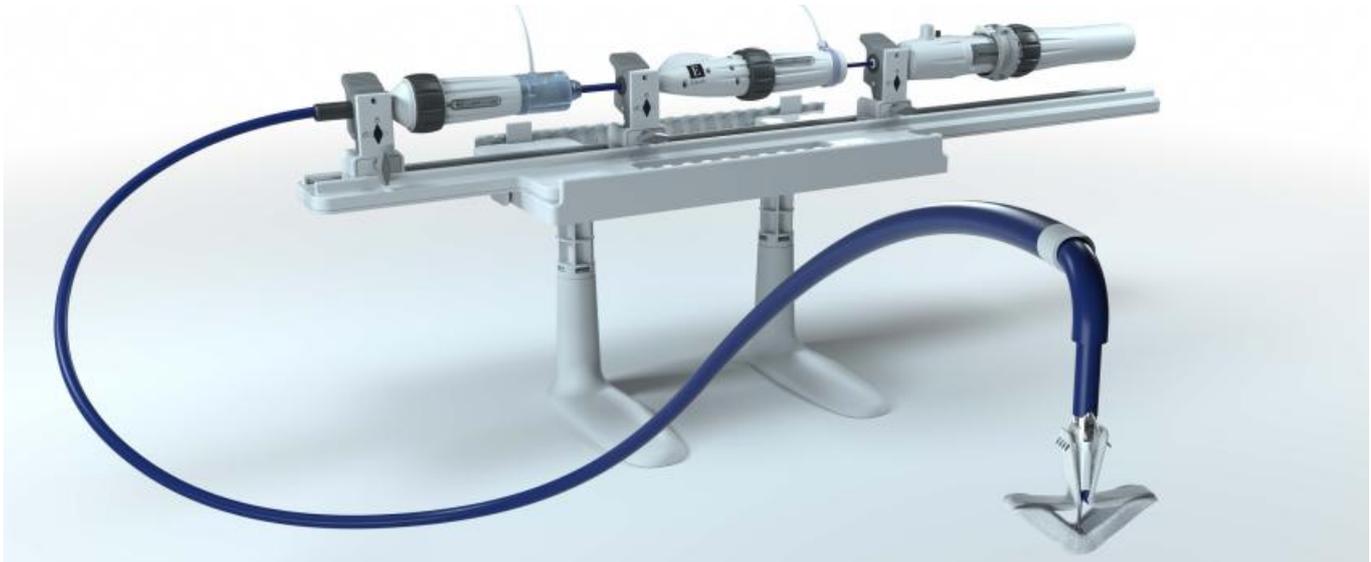


## TCT 2022 - Edwards tries to Clasp an opportunity



[Elizabeth Cairns](#)



### **The Pascal valve repair device boasts a pivotal hit and US approval, but can it compete?**

It is close, but is it close enough? Pivotal data on Edwards Lifesciences' Pascal system, designed to repair faulty mitral valves, showed the device to be non-inferior to Abbott's money-spinning MitraClip - though it was numerically very slightly worse.

The data, presented on Saturday at the TCT meeting in Boston, were pre-empted by the FDA approving Pascal Precision, which consists of the Pascal and Pascal Ace implants and the catheter used to deliver them. But sellside expectations certainly favour Abbott's established product. Edwards will have a job competing with a company three times its size.

The interim data come from 180 patients in the IID part of [the head-to-head Clasp IID/IIF study](#), and concern patients with severe degenerative mitral regurgitation (grade 3+ or 4+) who could not be treated surgically. The IIF part of the trial concerns patients with functional mitral regurgitation. The trial also includes a registry arm.

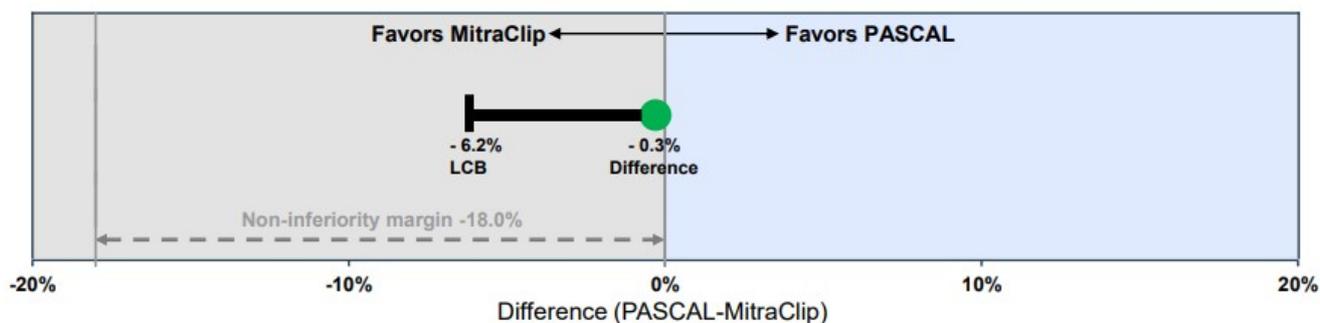
The IID part of the study was intended to prove the noninferiority of Pascal to MitraClip on both major adverse events at 30 days and improving regurgitation severity. It hit the first convincingly, with 3.4% of Pascal-treated patients having an major adverse event versus 4.8% of those given MitraClip.

The hit on the effectiveness endpoint, however, was less emphatic. The severity of the regurgitation was reduced to grade 2+ or lower in 96.5% of Pascal-treated patients at the six-month point. But the same milestone was achieved by even more of the MitraClip-treated patients.

# Primary Effectiveness Endpoint Met

MR ≤2+ at 6 months: 96.5% for PASCAL vs. 96.8% for MitraClip

PASCAL (n=117)	MitraClip (n=63)	Difference	One-sided 95% LCB
96.5% (110/114)	96.8% (60/62)	- 0.3%	- 6.2%




 Confidence intervals based on unpooled Z test with continuity correction. LCB: Lower confidence bound.

Source: TCT.

However, the difference of 0.3% had a one-sided lower confidence boundary of 6.2%, which fell within the prespecified noninferiority margin of 18%, so Edwards is well within its rights to claim a hit here too.

## Niche?

Data from the full 300-patient Clasp IID cohort could come early next year. But the interim cut was good enough for the FDA: last week the agency approved Pascal Precision for mitral degeneration on the strength of the same Clasp IID data that were presented at TCT.

Now it is a matter of getting interventional cardiologists to use Pascal, and here the numerical disadvantage seen on regurgitation severity reduction does not show Edwards' device to best advantage.

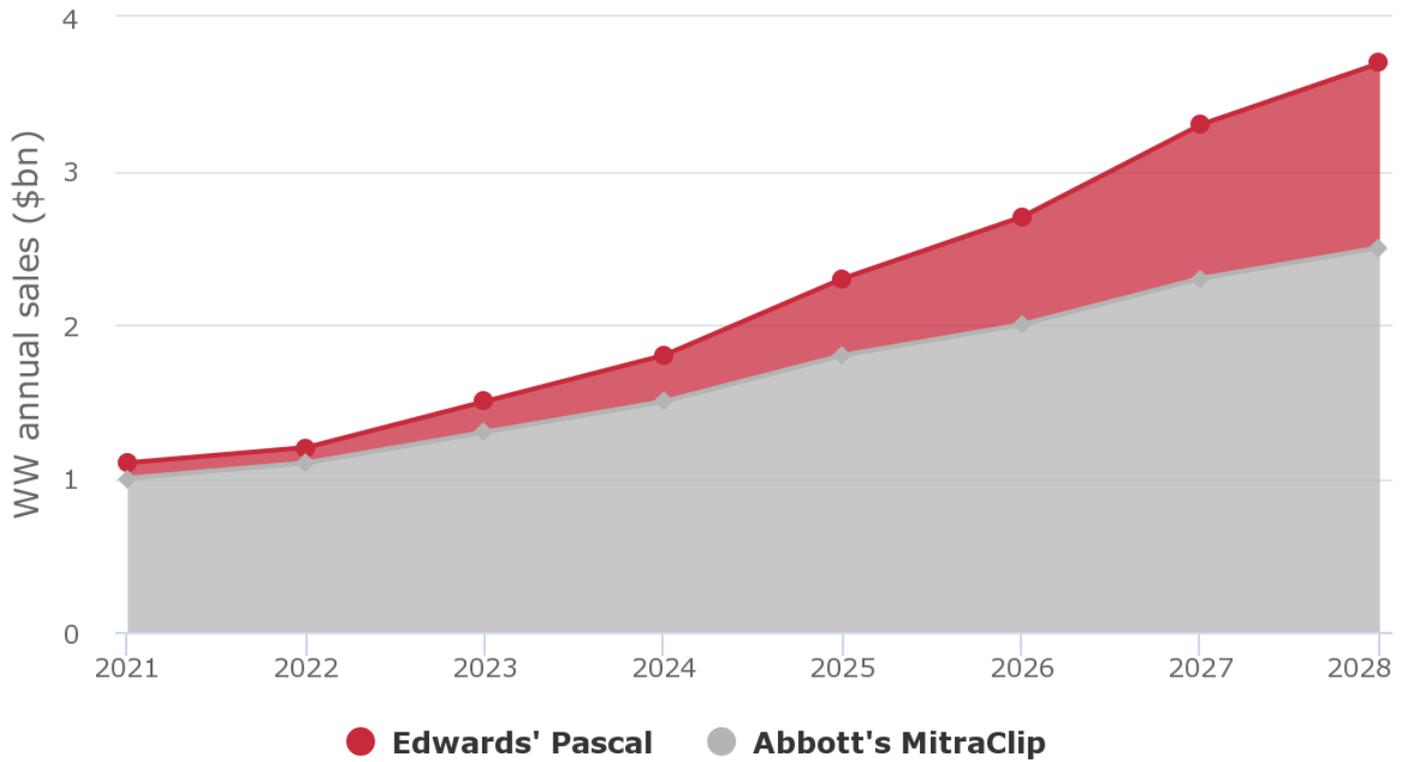
Still, it could find a niche, as some patients might be better treated with Pascal than with MitraClip. Konstantinos Koulogiannis, one of the principal investigators of Clasp IID, said that Pascal may be a good option for patients with more complex anatomy because it can grasp the valve's leaflets independently.

"Our suspicion is that that may allow for a little bit more ease in terms of manoeuvring within the subglobular apparatus where you have high potential for interacting with cords or with leaflets," [he said](#).

The sellside currently sees Pascal making sales of \$1.2bn in 2028, *Evaluate Medtech* consensus shows. MitraClip is forecast to sell more than twice that much. As the smaller company, Edwards will have a tricky time hornning in on Abbott's dominance.

# The mitral repair battle

Forecast sales for two rival devices



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Evaluate HQ  
[44-\(0\)20-7377-0800](tel:44-020-7377-0800)

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[+1-617-573-9450](tel:+1-617-573-9450)

Evaluate APAC  
[+81-\(0\)80-1164-4754](tel:+81-080-1164-4754)

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