

Heart valve invented in Minnesota allows new kind of heart treatment

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Inaugurating a potential blockbuster medical device category, a wire-and-mesh medical device invented in Roseville, Minn., has become the first catheter-delivered implant to get European approval to replace the

heart's mitral valve without open-chest surgery.

European approval of Abbott Laboratories' Tendyne Transcatheter Mitral Valve is "a very important first step" toward gaining U.S. approval, which would open a device category potentially worth billions in annual sales, analysts and company officials say.

The Tendyne [valve](#) is a minimally invasive treatment for the world's most common heart-valve disease, [mitral regurgitation](#), in which blood leaks backward through a leaky mitral valve.

The foldable heart valve is snaked into place using a skinny catheter inserted through a small chest incision, and then unfurled while the heart is still beating. It was invented at a Roseville startup called Tendyne, and acquired by Abbott in 2015 for about \$250 million.

The design bears hallmarks of the familiar TAVR valves made by Medtronic and Edwards Lifesciences to treat stenosis of the aortic valve. The mitral device replacement includes a porcine tissue valve stretched over a stent-like chassis of nitinol memory wire, making it "self-expanding."

Receiving CE Mark approval to treat [high-risk patients](#) in European countries creates "a new choice in how we approach correcting a leaking mitral valve," cardiac surgeon Dr. Hendrik Treede of the University Hospital Bonn, Germany, said in Abbott's announcement.

A post-approval study of the device is underway. To date, Abbott said, global trial results show that 98.9% of Tendyne patients had their MR eliminated at discharge from their clinical site, and the results were sustained through one year.

"For the first time outside of clinical trial settings, heart teams now have

a minimally invasive valve replacement therapy that is backed by an excellent safety profile and designed to help physicians reposition the device as needed for improved patient outcomes," Treede said.

Abbott already sells the leading mitral-valve treatment in the U.S., the catheter-delivered MitraClip device, which retains the native valve tissue instead of replacing it like the Tendyne [device](#).

The Tendyne replacement valve is an option for MR patients at high risk for problems with traditional surgery and those whose native mitral tissue is too damaged to be repaired with a clip.

The [mitral valve](#) market could be larger than the TAVR market someday, because MR is more prevalent than aortic stenosis, analysts say.

Last year, TAVR procedures to replace aortic valve accounted for more than \$5 billion in sales, and kept thousands of patients from being hospitalized for valve surgery.

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