

[MUSIC PLAYING]

**NICHOLAS AMOROSO:** The JenaValve or JenaValve, depending on what part of the world you're coming from, is a TAVR device, and it's really a new heart valve that is designed to treat both aortic regurgitation and aortic stenosis, which is novel, because previously, TAVR was really only designed to treat patients with aortic stenosis. This procedure with JenaValve is offering a treatment opportunity for a whole group of patients who we've only been able to treat with open heart surgery in a safe manner. While TAVR for aortic regurgitation has been done, we all know, those of us who do TAVR routinely, know that that's a much higher risk procedure than performing TAVR for aortic stenosis, with the devices we currently have in the US. So the JenaValve really offers us a safer alternative for treating patients with aortic regurgitation but through minimally-invasive technique that helps patients recover more quickly.

We have what we call a heart team. The heart team includes a cardiac surgeon, interventional cardiologist, cardiac anesthesiologist, sometimes some of our other clinical providers, like heart failure specialist, and we put our heads together to help determine what's the best way to treat these special types of heart problems. In doing so, then, it makes sure we're offering patients the broad range of options that's going to give them the best results, both the safest, the easiest recovery, and the most effective.

As TAVR is typically done, it's a percutaneous procedure, where we gain access in the femoral artery. A needle hole goes in the femoral artery, and a sheath goes from the femoral artery up to the aorta. The JenaValve specifically is a 24-French design, and it has a long sheath that goes reaching all the way from the femoral artery up to the ascending aorta. This allows for safe passage of the JenaValve and allows us to then expose the locators, which are the specialized clipping mechanism of the JenaValve.

From that position, then, we're able to make rotations to get them properly aligned to the patient's anatomy, make sure that we grasp the leaflets, and confirm that we have a good grasp. Once we've confirmed that both by fluoroscopy and transesophageal echocardiogram, then we release the valve. Afterwards, we assess that we have eliminated aortic regurgitation, and we're able to remove our delivery equipment. Percutaneous closure is completed, as we would typically do for TAVR, and patient generally goes to recovery and to a floor service, where they're monitored overnight.

Most patients are able to go home the following day. There's still a small percentage of patients that suffer from stroke during TAVR or require permanent pacemaker implants afterwards. Otherwise, thankfully, issues of emergency open heart surgery, death, or vascular complications are relatively low risk, much like the contemporary TAVR experience with other commercial valves.

The patients that we've treated so far have had successful procedures, thankfully, and we know that other patients across the country have also been seeing good results. The JenaValve is also already commercially approved in Europe, just this past year, and so it's being used a little bit more widely with excellent results, as we anticipated. So in the future, I think that there is opportunity for this valve to become a standard of care. Right now, they are working through clinical trial in hopes of gaining FDA approval and showing that they get the excellent results that they anticipate.