

Vscan

COMPANY	GE Healthcare
PHONE	(888) 202-5528
WEB	www.gehealthcare.com

KEY FEATURES

- Intuitive user interface that is controlled with the thumb
- Voice annotation
- PC linking for organization and export of data
- Battery charger station and battery life of one hour of scanning
- Online portal provides users with training tools for the product and basic clinical applications

Roughly the size of a smart phone, Vscan (GE Healthcare, Wauwatosa, WI) houses ultrasound technology that provides clinicians with an immediate, noninvasive method to secure visual information



about their patients. Vscan is portable and can easily be taken from room to room and used in many clinical, hospital, and primary care settings.

Although palpation and sense of touch are critical during a physical examination, having a tool at the clinician's fingertips to take a quick look inside a patient has the potential to help redefine the physical examination. According to the company, Vscan may help clinicians detect disease earlier, accelerate the time to treatment, and reduce patient wait times while helping to avoid unnecessary additional testing and improving physician workflow.

The Vscan imaging device received 510(k) clearance from the US Food and Drug Administration, CE Mark approval by the European Union, and the Medical Device License from Health Canada and is now commercially available in the United States, Europe, India, and Canada.

Engage and Engage TR Introducers

COMPANY	St. Jude Medical, Inc.
PHONE	(800) 544-1664
WEB	www.sjmprofessional.com
	www.sjm.com

KEY FEATURES

- The Engage includes 22 model configurations of varying sizes to accommodate a wide variety of procedures
- The Engage TR includes 18 model configurations
- Offers physicians more control and minimizes risks during access and throughout the procedure

St. Jude Medical, Inc. (St. Paul, MN) recently announced US Food and Drug Administration clearance and European CE Mark approval for the Engage and Engage TR introducers for use in diagnostic and interventional cardiac catheterization procedures. The Engage family of introducers incorporates features that offer more control and minimize risks both during access and throughout the procedure, the company stated.

According to St. Jude Medical, the Engage introducers are designed to provide femoral access to the vasculature, minimize trauma to the artery, and set the stage for the use of closure devices.

"The new Engage family of introducers help to set the stage for a successful procedure by reducing the number of potential variables that can affect patient outcomes," Dr. Javier Goicolea from Hospital Puerta de Hierro in Majadahonda, Spain, said.



Edwards Sapien XT Transcatheter Heart Valve

COMPANY	Edwards Lifesciences
PHONE	41-21-787-4300
WEB	www.edwards.com/eu
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KEY FEATURES

- Advanced leaflet design and manufacturing based on Edwards clinically proven aortic tissue valves
- Optimized frame height for noninterference with surrounding anatomy
- High radial strength for proper hemodynamics and valve durability

Edwards Lifesciences (Irvine, CA) announced CE Mark approval of its Edwards Sapien XT transcatheter heart valve. Heart teams can now deliver a transcatheter aortic valve with the proven design

er a transcatheter aortic valve with the proven design benefits of the world's most widely implanted tissue valves. The advanced design of the new valve restores proper hemodynamics and maintains valve performance while respecting the anatomical structure of the heart.

The Edwards Sapien XT valve features the company's technologically advanced leaflet design and manufacturing, optimized frame height for proper placement and noninterference with the surrounding anatomy, and high radial strength for improved hemodynamics and valve durability.

The Edwards Sapien XT valve is the second commercially available transcatheter valve in the Edwards Sapien product portfolio. Edwards is the only company to commercialize both transfemoral and transapical transcatheter aortic valve systems, which have been available in Europe since 2007. In the United States, the Edwards Sapien transcatheter valve is an investigational device being studied as part of the world's only randomized, pivotal clinical trial of a transcatheter aortic valve and is not yet available commercially.

NovaFlex Transfemoral Delivery System

COMPANY	Edwards Lifesciences
PHONE	41-21-787-4300
WEB	www.edwards.com/eu

KEY FEATURES

- Steerable catheter enables controlled navigation in challenging anatomies
- Innovative catheter tip enhances ability to smoothly cross the native valve
- Delivery balloon catheter engineered for reliable valve placement
- 18-F profile improves ease of access

Edwards Lifesciences (Irvine, CA) announced CE Mark approval of its NovaFlex transfemoral delivery system that provides easy, precise, balloon-expandable delivery of the advanced Edwards Sapien XT transcatheter heart valve. This low-profile delivery system offers controlled navigation, smooth crossing of the native valve, and reliable valve placement.

The NovaFlex system features a steerable catheter for controlled navigation in challenging anatomies, an innovative catheter tip for smooth native valve crossing, and a delivery balloon catheter engineered for predictably accurate valve placement. Furthermore, the 18-F profile of this new delivery system improves ease of access.

The NovaFlex system is the latest generation of the Edwards transfemoral delivery system product line. Edwards is the only company to commercialize both transfemoral and transapical transcatheter aortic valve systems, which have been available in Europe since 2007.