

Elana receives FDA approval for lifesaving bypass device

Dutch medical device manufacturer, Elana bv, announced today that it has received approval from the U.S. Food and Drug Administration (FDA) for a humanitarian device exemption (HDE), enabling a lifesaving cerebral bypass. Elana bv is a corporate spin-off from the University Medical Centre Utrecht, the Netherlands.

Bypass

“The Elana Surgical Kit may help those with a rare condition for whom there previously was no treatment option”, said Jeffrey Shuren, M.D., director of the FDA’s Center for Devices and Radiological Health. The company expects that annually a thousand patients worldwide are eligible to be treated with the device.

The patented Elana Surgical Kit_{HUD} is currently used in neurosurgery in numerous European countries as well as in Canada. In the United States the device has been used under a clinical study in St. Luke’s Roosevelt Hospital in New York, University of Illinois at Chicago, University of Texas Southwestern Medical School and the University of Arkansas for Medical Sciences.

Elana produces a disposable laser catheter and an implant, through which blood vessels can be connected and subsequently opened. Surgeons are able to use the Elana Surgical Kit_{HUD} for constructing a vascular bypass without any interruption of the blood flow on patients of 13 years and older who have an aneurysm or tumor at the skull base. “It changes the concept of bypassing fundamentally, making it more safe for patients”, states Prof C.A.F. Tulleken, Emeritus Professor and former Chairman of Neurosurgery UMC Utrecht, The Netherlands, and, with his team, inventor of this concept.

Future plans

Currently, R&D efforts are ongoing to apply the technique in other surgical fields with substantially bigger market potential. David Langer MD, Associate Professor of Neurological Surgery at Hofstra University School of Medicine, and the first neurosurgeon to use the device in the US, believes that this technology holds promise not just in neurosurgery but in the area of coronary bypass, transplant and peripheral vascular surgery as well.

Elana has concluded a pre-clinical study agreement for applications in cardiac bypass with the UMC Utrecht, The Netherlands, departments Experimental Cardiology and Cardiothoracic Surgery. Chairman of the department, Prof.dr. L. A. van Herwerden: “We feel privileged to cooperate with Elana on this promising technology for applications in cardiac surgery.

In order to facilitate market introduction in the US and further research and development activities, Elana recently raised additional capital. Felix von Coerper, CEO of the privately owned company, is optimistic: “With approval from the FDA and with the potential to leverage our technique and intellectual property for other vascular applications we are looking forward to build a sustainable and fast growing business”.

Market

Elana has a strong patent portfolio; its first patent dates from 1994. The Elana Surgical Kit_{HUD} is being used in neurosurgery since 2005 in nine European countries and in Canada since 2008. The device has been used in an investigational setting in the US since 2007. Eventually, cardiac surgery has a much bigger potential for Elana, since annually over 500.000 cardiac bypass surgeries take place worldwide.

Elana bv

Elana bv is an international, young and dynamic medical device company in Utrecht, with a subsidiary in the USA. Our goal is to improve quality of life for people with vascular diseases by maintaining a leading edge in bypass research and through the development of unique solutions for bypass surgery. The medical centers, scientists and surgeons that are involved are internationally renowned and are regarded as top class. Our company is based on the campus of the UMC Utrecht in proximity of the clinic and laboratories.

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University Medical Center Utrecht

The University Medical Center Utrecht is one of the largest public health care institutions of the Netherlands. With almost 10.000 people we build continuously on good healthcare with knowledge and people as foundation. The UMC Utrecht wants to be an internationally renowned academic medical center in which knowledge about health, illness and care is being made, tested and applied. UMC Utrecht is part of the Dutch Federation of University Medical Centers (NFU). The NFU is a collaboration of the eight university medical centers in the Netherlands. See www.nfu.nl for more information about the NFU.