

Leica FL800 has received FDA 510(k) approval for the viewing of intra-operative blood flow in the cerebral vascular area

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Brain vessels with ICG fluorescence marker, photographed with a Leica M207 CHS FL800. Left: Two seconds after the ICG injection, arteries become visible. Center: After five seconds, the ICG reaches the first capillaries. Right: After nine seconds, the ICG marked blood flows through the veins as well.

Leica Microsystems has received, first in surgical microscopy, the FDA 510(k) approval for the Leica FL800, an intra-operative video angiogram device for the viewing of intra-operative blood flow in the cerebral vascular area.

Leica Microsystems has received an FDA 510(k) approval for the Leica FL800, an intra-operative video angiography device for the viewing of blood flow in the cerebral vascular area using Akorn ICG. This is the only FDA (U.S. Food and Drug Administration) approval for video angiography in the cerebral vascular area using ICG (IndoCyanine Green) as a fluorescent agent.

Surgeons with experience in vascular fluorescence have commented that the goal of ICG fluorescence lies in the quick and easy visualization of blood flow, which subsequently enables the surgeon to determine the permeability of vessels and effects of their surgery while they are operating through the Leica surgical microscope. Surgeons at a recent Congress of Neurosurgery in Chicago commented that real time vascular fluorescence is the biggest advance in intra-operative vascular neurosurgery in years.

The Leica FL800 fluorescence system is designed as a combination of an excitation light system, an ICG fluorescent agent, and a near infra-red camera to achieve the result. The FDA 510(k) approval for the Leica FL800 was limited to the Akorn ICG, Leica surgical microscopes, and to the cerebral vascular area. Leica Microsystems may consider additional application extensions to its FDA approval in the future.

The Leica FL800 vascular fluorescence procedure is quite simple for the surgeon to perform. The ICG agent is injected intravenously and the surgeon presses one button. The special NIR camera then picks up the fluorescent signal and displays it to the surgeon in real time. In addition the Leica FL800 records the imaging as a special loop so the surgeon can repeat the image later in surgery. This procedure can be repeated six times in a single surgery so the surgeon can track the effects of his surgical procedure on blood flow in the brain.

for more information on Leica Microsystems visit:

www.leica-microsystems.com/Surgical_Microscopes

for more information on Akorn ICG visit:

www.akorn.com

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Leica Microsystems is a leading global designer and producer of innovative, high-tech, precision optical systems for the analysis of microstructures. It is one of the market leaders in each of its business areas: Microscopy, Confocal Laser Scanning Microscopy, Imaging Systems, Specimen Preparation and Medical Equipment. The company manufactures a broad range of products for numerous applications requiring microscopic imaging, measurement, and analysis. It also offers system solutions for life science including biotechnology and medicine, research and development of raw materials, and industrial quality assurance. The company is represented in over 100 countries with 8 manufacturing facilities in 6 countries, sales and service organizations in 19 countries and an international network of dealers. With its workforce of about 3,200 employees it made turnover of US\$ 597m in 2005. The international management is headquartered in Wetzlar, Germany.

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