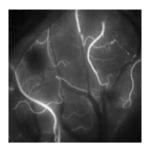
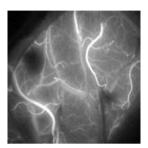




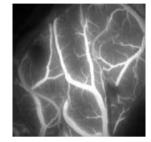
Representational pictures of the Leica FL800 ULT



ICG injection after 2 seconds:



ICG injection after 5 seconds: Capillary view



ICG injection after 9 seconds: Venous view

Please check the status of the FL800 ULT regulatory approval with your local Leica Microsystems representative.



Pioneering Fluorescence Innovation

The development of fluorescence microscopy has a long tradition at Leica Microsystems, dating back to the beginning of the 20th century. Today, the successful integration of Leica Microsystems' high-resolution surgical optics with the science of fluorescence provides brand new possibilities in vascular procedures. Thanks to this progress even small arteries and veins can be visualized in real time through the optics of a surgical microscope.

This ability to view blood flow in tissue and vessels intra-operatively during surgery can benefit surgical outcomes. The FL800 ULT's integration with the surgical microscope makes vascular fluorescence a seamless part of surgery.

Visualize Blood Flow

The Leica FL800 ULT is used in conjunction with the fluorescent agent IndoCyanineGreen (ICG) to view vascular blood flow directly through the surgical microscope eyepieces or on a video monitor. Obtaining this ICG-fluorescence information at the near infrared (NIR) is a fast, easy procedure. To change from white light to NIR mode, the surgeon simply pushes a button found on the pistol grip of the surgical microscope.

The ICG Process

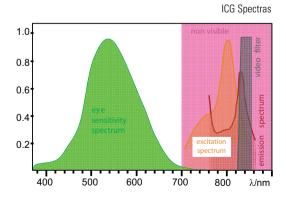
ICG perfusion is detectable because it excites at 800nm light and then emits fluorescence at 835nm. The 835nm light is filtered away from the normal white light and is detected by a special NIR CCD-camera. The CCD-camera converts the 835nm light (invisible to the human eye) to white light and projects it to a standard video monitor and/or recording device.



Easy Set-up and Use

Surgeons with experience in vascular fluorescence have commented that the main purpose of ICG fluorescence lies in the visualization of blood flow. Subsequently, this enables the surgeon to determine the patency of vessels during surgery.

The smooth set-up and use of the FL800 ULT perfectly integrates into the efficient flow of a vascular procedure. The press of a single button on the surgical microscope activates the FL800 ULT ICG process. The fluorescence is then filtered through Leica Microsystems' superior surgical optics with maximum brightness and high contrast. The system is designed to make this process easy for surgical staff and to increase their comfort level as all filtering is built into the system and is available whenever the surgeon chooses to use ICG.





REGULATIONS AND STANDARDS

Class IIa FL800 ULT

C€₁₂₅₀

- > Council Directive 93/42/EEC onMedical Devices (MDD) and its amendments.
- > IEC 60601-1 / EN 60601-1 Medical Electronical Equipment, Part 1: General requirments including national differences of EU, CA, US.
- > IEC 60601-1-2 / EN 60601-1-2 Electromagnetic Compatibility.

The Medical Division, within Leica Microsystems (Schweiz) AG, holds the management system certificates for the international standards ISO 9001, ISO 13485, and ISO 14001 relating to quality management, quality assurance and environmental management.

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