

From Eye to Insight

*Leica*  
MICROSYSTEMS

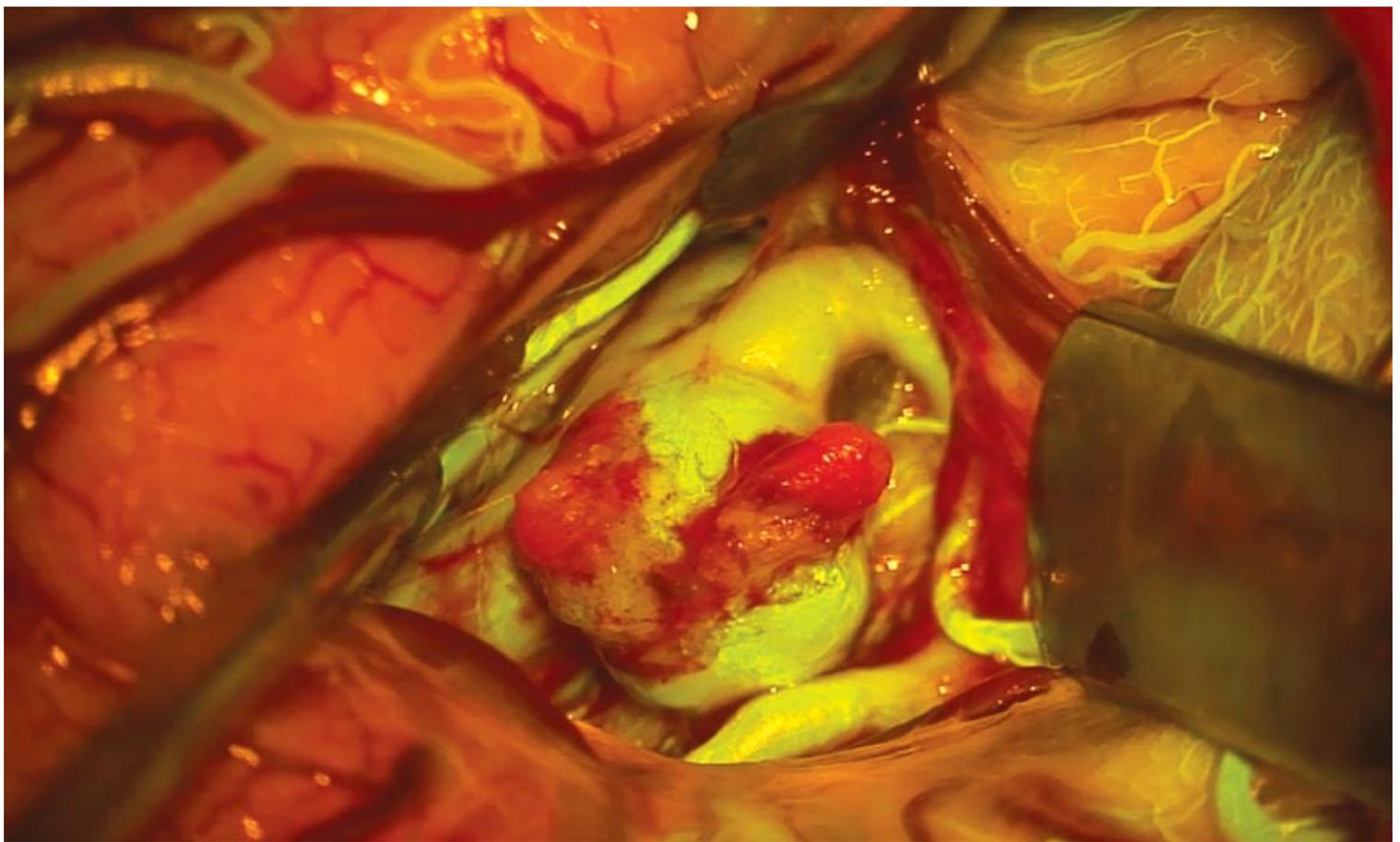


Fluorescence filter for M530 OH6 microscopes

## FL560 FLUORESCENCE IMAGING

First FDA 510(k)-cleared filter  
for cerebrovascular fluorescence  
with fluorescein





## Real-time, simultaneous visualization of cerebral anatomy and cerebrovascular blood flow with fluorescein supports your surgical decisions.

Assessing cerebral anatomy and vascular flow, particularly in small vessels and the areas they perfuse, can be challenging under white light or near-infrared ICG fluorescence. The FL560 fluorescence module, used with fluorescein, allows you to simultaneously view anatomical structures and real-time cerebrovascular blood flow, clearly differentiated and with high contrast.



### **First FDA 510(k) clearance**

FL560 fluorescence is the first FDA 510(k)-cleared microscope filter for viewing cerebrovascular fluorescence in conjunction with fluorescein. A fluorescein procedure kit and instructions are available from Leica Microsystems, giving you confidence that your formulation, dosage and administration are correctly optimized for the FL560 filter.

### **One simultaneous view**

The FL560 filter was designed to effectively separate fluorescence excitation light and the observation spectrum. This is then combined with the premium optics and illumination of the M530 OH6 microscope. The result is one complete, high-resolution, and high-contrast image for crisp anatomical view and clearly delineated vascular flow even in tiny vessels.

### **Simplify your workflow**

With a simultaneous view of anatomy and real-time fluorescence you no longer need to switch back and forth between views. Simply activate FL560 mode with a touch of the handgrip or foot-switch thanks to full integration with your M530 OH6 microscope. And, as fluorescein is visible for up to 1 hour, you may only need one bolus, further streamlining your procedure.



### A decade of pioneering fluorescence from Leica Microsystems

- > **First** surgical microscope filter with FDA 510(k) clearance for FL800 vascular fluorescence with ICG
- > **First** surgical microscope with TriFluoro – three integrated modes of fluorescence in a single microscope
- > **First** surgical microscope with Augmented Reality (AR) fluorescence, GLOW800\*
- > **First** surgical microscope filter with FDA 510(k) clearance for FL560 vascular fluorescence with fluorescein

A DECADE OF  
PIONEERING  
FLUORESCENCE



### Full integration today or tomorrow

The FL560 module can be seamlessly integrated into your M530 OH6 microscope at any time, thanks to Leica's OpenArchitecture design. The M530 OH6 was also the first surgical microscope to be offered with TriFluoro. This gives you the flexibility to have up to three modes of fluorescence (FL560, FL400\*\*, FL800) in a single microscope.

### Recording and display made easy

Share the view with your team in the OR via HD or 3D monitor and record in HD or 3D for later presentation and teaching. Start recording with the touch of a button. Mode Control technology from Leica Microsystems automatically activates the correct video display and recording settings that have been optimized for fluorescence and white light modes.

\* Not available for sale in the United States  
\*\*Investigational use only in the United States

## MICROSCOPE COMPATIBILITY

New and existing	M530 OH6
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## TECHNICAL DATA

Fluorescence excitation	Peak of ~460 – ~500 nm (blue light)
Fluorescence signal	Emission observation comprising green, yellow and red spectral band $\geq$ 510 nm
Recommended fluorophore	AK-FLUOR 10% Fluorescein Injection, USP, 100 mg/ml, 5 mL sterile vial, NDC 17478-253-10, provided in FL560 Procedure Kit

Contact your local Leica representative for availability information.

Images courtesy of Prof. Dr. Cleopatra Charalampaki, Department of Neurosurgery, Cologne Medical Center, Germany

## REGULATIONS AND STANDARDS

- > Council Directive 93/42/EEC on Medical Devices (MDD) and its amendments.
- > IEC 60601-1 / EN 60601-1 Medical Electrical Equipment, Part 1: General requirements – 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 13485, and ISO 14001 relating to quality management, quality assurance and environmental management



CONNECT  
WITH US!

Leica Microsystems (Schweiz) AG · Max Schmidheiny Strasse 201 · CH-9435 Heerbrugg  
T +41 71 726 3333 · F +41 71 726 3399

[www.leica-microsystems.com](http://www.leica-microsystems.com)

