

CUSTOMER MAGAZINE FOR  
SURGICAL MICROSCOPY & TECHNOLOGY

# reSOLUTION

**Check Each Product as if it Will be  
Used to Operate on You**

Precise Quality Control of Microsurgical Instruments

EXTRACT

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## Precise Quality Control of Microsurgical Instruments

# Check Each Product as if it Will be Used to Operate on You

Anja Schué, Leica Microsystems

Vitreoretinal surgery demands experienced surgeons and precision technology. The surgeon operates with microscissors and forceps that are less than a millimeter thick. Swiss company Alcon Grieshaber is one of the world's leading specialists in the design and manufacture of hand-held microinstruments for minimally invasive eye surgery. Stereo microscopes from Leica Microsystems are used to support the R&D and manufacturing of these instruments from all stages of development to final inspection.

The retina has 130 million sensory cells for capturing an image of the world around us. If they are damaged and die, our eyes lose their vision. Losing our eyesight is a terrible thought, but for most of us it is just as frightening to imagine an operation on our eyes. There are many causes for retinal damage or detachment or yellow spot (macula), and without an operation there is great danger of going blind. Statistically speaking, one in 10,000 people is affected. Thanks to modern eye surgery, however, the chances of fully restoring the patient's eyesight are excellent if the problem is diagnosed early enough.

### Scissors or forceps – hard to tell with the naked eye

Alcon Grieshaber AG in Schaffhausen, owned by Alcon, Inc., the world's leading eye care company has played a major role in advancing minimally invasive retinal surgery and its handheld precision instruments still lead this market segment today.

**“Our technological lead cannot be seen by the naked eye, it is microscopic.”**

The company has promoted the switchover to single-use instruments worldwide and perfected the instruments for minute dimensions. The tiny tools – scissors, forceps, hooks, knives, fluid handling instruments – fit through an incision smaller than a millimeter wide, the smallest of them measuring a mere 0.5 millimeter when closed. “Our technological lead cannot be seen by the naked eye, it is microscopic,” Jürg Attinger, Manager of Alcon Grieshaber AG, describes his precision instruments.

### Microscopes at all workplaces – from incoming inspection to final cleaning

At Alcon Grieshaber, quality control begins before the products are even made. Even semi-finished goods that are turned, milled and EDMed are measured under the microscope. “We have found an optimal inspection frequency solution that considers time, cost and risk, and luckily, we have an extremely small reject rate”, explains Heinz Etter, Head of Facility Management at Alcon Grieshaber. “All components are checked after two to three production steps at the latest throughout the entire production process. At the end there is always a 100% inspection. No instrument leaves the factory without thorough examination under the microscope.” Almost all the employees work with a microscope – in inspection of incoming material, in production and quality control through to final cleaning and inspection of the finished product in the cleanroom as well as in R&D. There are 118 stereo microscopes and 140 employees – although it is mainly the 65 members of production staff that use them.

The manufacture of microinstruments for eye surgery demands a great deal of precision work – skill, experience, a trained eye and a good portion of perfectionism. Most quality inspection tests are carried out at 20x magnification. Higher magnification would tend to have the effect that even the smallest details that do not impair product quality would be interpreted as defects. In production, higher magnifications are required, mostly 60x.

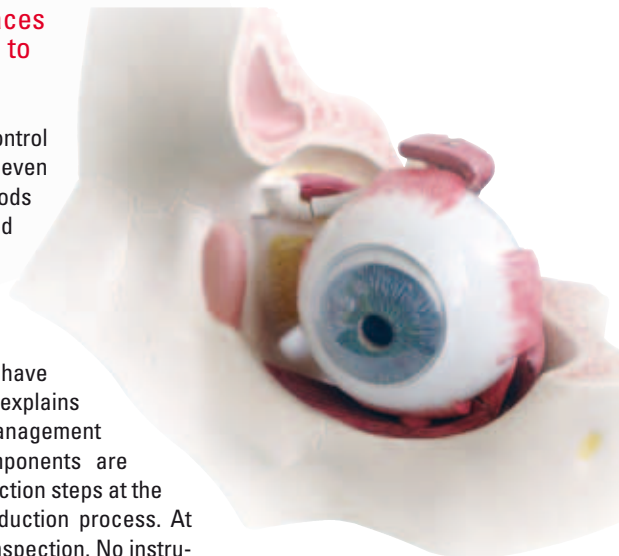


Fig. 1: Surgery in the posterior segment of the eye may be standard practice in ophthalmology today, but it is not easy to perform. It demands sensitivity and experience as well as complex technology – from the surgical microscope to the microinstruments directly applied by the surgeon at the site of the retina or macula requiring treatment. Retina surgery is only possible using a surgical microscope, and three incisions have to be made to access the posterior segment: one for illumination, one for the instrument and one for the infusion to stabilize inner eye pressure. (Copyright Roman Milert - Fotolia)

## The trained eye is unbeatable

Besides the quantitative analysis facilities for 2D measurements offered by the microscope and appropriate software, and traditional mechanical measurements, visual inspection is indispensable. For example, microscissors have three-dimensional free form surfaces with a dimension of only 0.5 millimeter. The part for inspection is compared with a reference sample under the microscope. "For this application, there is no other technique to date that can compete with the eye of an experienced employee – par-

**The quality motto at Alcon Grieshaber: "Check each product as if it were to be used to operate on you."**

ticularly in terms of time and cost, stresses Etter. "Inspecting surface roughness with a 3D scan or profilometry would be far too costly and time-consuming for us. Despite all the potential risks of visual control, experienced employees are unbeatable." One example: One of the instruments is made from a wire 0.14 mm thick with a tolerance of 0.01 mm. The staff are trained to tell whether the tolerance has been adhered to just by holding the thread under the stereo microscope without a comparison sample.

"The true challenges in our quality control begin where the criteria start to soften, where reference samples or photos are called for," says Attinger. "We can and do have a lot of confidence in our staff. We recover the 'discretion' quality we lose by good training. And so far we have been successful – despite the fact that we make our products in expensive Switzerland and even make single-use instruments."

## Optically brilliant and cost-saving stereo microscopes

When it comes to microscopy, Alcon Grieshaber trusts in the stereo microscopes of Leica Microsystems. Besides the optical quality, the Schaffhausen specialists appreciate the LED illumination, the easy and convenient operation, the ergonomic design and the large field of view, especially the 23 mm field of view offered by the new generation of Leica M80 and M50. The Leica M205 with FusionOptics™ additionally provides the excellent depth of field and high resolution that are specifically useful for R&D applications. Nearly all microscopes at Alcon Grieshaber are equipped with LED illumination. 20,000 kWh a year have already been saved with this energy-saving light source. The company also saves because of the much longer lifetimes of LEDs compared with conventional microscope lamps.



Figs. 2: The hand-held precision instruments of Alcon Grieshaber that are used for the various steps of an eye operation have a worldwide reputation of excellence. Depending on the surgical technique employed by the surgeon or the exact reason for surgery, he needs instruments that fit through an incision of 1.15, 0.72 or 0.62 mm to access the inner eye. That is equivalent

to an instrument diameter of 0.9 (20-Gauge), 0.6 (23-Gauge) or 0.5 mm (25-Gauge). The surgeon does not open the scissors or forceps until they have been introduced into the eye. The instruments are freely rotatable. When performing surgery, the surgeon just has to correct the pressure angle. The trend towards smaller incisions has the key advantage that the smallest incisions heal

by themselves without suturing. For the instruments, miniaturization means more and more sophisticated manufacturing techniques and materials and the fact that only single-use instruments can be effectively utilized. Even the smallest damage that is inevitably entailed in a conventional sterilization process renders the microinstruments useless.

Videos and information on surgical techniques in vitrectomy:

<http://www.alconretina.com/surgicalTechniques.asp>

## Ergonomics for all

Many employees at Alcon Grieshaber spend eight hours at the microscope every day. Alcon Grieshaber is one of the pioneers in ergonomics within the Alcon, Inc. Ergonomic chairs, height-adjustable desks, elbowrests to take strain off the shoulders are all automatically provided.

The company also places great value on individually adjusted, ergonomic microscopes and uses Ergo tubes and eyepieces that are matched to different body sizes and physiques.

The fact that Leica Microsystems offers the widest range of ergonomic accessories for stereo microscopes is one of the main reasons for Alcon Grieshaber's long-standing loyalty to Leica Microsystems' products.

Periodically, a specialist from the parent company, Alcon, Inc., comes to Schaffhausen to check site ergonomics and give the staff advice if necessary. But that's not all: "We offer every member of staff a weekly 30-minute shoulder and back massage. The cost is shared by the company and the staff," says Attinger. "If our staff feel good at the workplace and the microscope, they are more efficient, too. And that is ultimately good for our overall result. We carry a great responsibility for our staff, after all we depend on them for our success."

### Contact

Heinz Etter, Head of Facility Management,  
Alcon Grieshaber AG  
[Heinz.Etter@alconlabs.com](mailto:Heinz.Etter@alconlabs.com)  
[www.alconretina.com](http://www.alconretina.com)

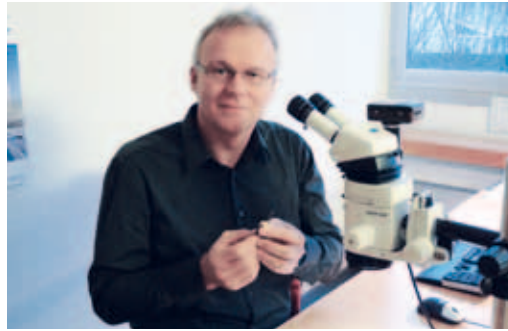


Fig. 3: Like nearly all the employees, Jürg Attinger, Manager of Alcon Grieshaber, has a stereo microscope at his workplace.



Figs. 4 – 5: Alcon Grieshaber attaches great importance to individual ergonomic features of the microscope and the workplace.

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D-35578 Wetzlar (Germany)  
www.leica-microsystems.com

### **Editors in Chief**

Anja Schué,  
Communications & Corporate Identity  
Anja.Schue@leica-microsystems.com

Angel Viosques, European Marketing  
Angel.Viosques@leica-microsystems.com

### **Contributing Editors**

Pam Jandura  
Dr. Petra Kienle  
Kerstin Pingel  
Zsofia Rick  
Janika Wiesner  
Denise Zahnd

### **Layout & Production**

Uwe Neumann,  
Communications & Corporate Identity

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