

AMADEUS. II

ziemer

The «three-in-one» Microkeratome for traditional LASIK, EPI-LASIK, and anterior and posterior Lamellar Keratoplasty





AMADEUS II

In a world of rapidly changing technologies and applications in refractive and corneal surgery, AMADEUS is and remains a proven value, offering surgeons a platform that serves all their needs and allows them to stay abreast of evolving technologies while protecting their investment. AMADEUS remains a viable and dependable alternative to femtosecond laser technology for many types of refractive and corneal surgery.

Ziemer Group

We develop and produce diagnostic and surgical products for the ophthalmic market that distinguish themselves from established standards in terms of usability, precision, quality, and productivity.



The AMADEUS platform supports a wide range of applications:

- Traditional LASIK.
- Surface ablation (epi-LASIK).
- Therapeutic Lamellar Keratoplasty.
- Superficial Anterior Lamellar Keratoplasty (SALK)
- Deep Anterior Lamellar Keratoplasty (DALK).
- Endokeratoplasty and Lap-Joint Keratoplasty.
- Descemet Stripping and Endothelial Keratoplasty (DSEK / DSAEK).

Intelligent Design for Performance and Quality

Titanium Strength: lightweight and sturdy

All components vital to structural integrity, cutting precision and vacuum tightness are machined from one single block of medical grade titanium. Smoothness of surfaces and resistance to mechanical damage or bacterial contamination are far superior than what can be achieved with other materials.

Handling and assembly: safe and easy

Quick and easy two-snap assembly of blade and Blade Holder eliminates assembly errors and system malfunction. Before each procedure, a comprehensive, 20-step self-test is performed by system firmware. To minimize suction time, patient inconvenience, and trauma to the eye, all assembly and test steps are completed before engaging the patient's eye. The perfectly balanced, lightweight handpiece, designed for single-handed operation, is easy to control and stabilize on the eye during movement and virtually eliminates vibration at any blade oscillation speed up to 20'000 rpm.

User Interface and Procedure Control: intuitive and flexible

The large color touch-screen and a well-structured, highly intuitive graphic user interface make it easy to set up standard procedures while allowing for a wide range of customization options. By selecting the appropriate Suction Unit from a wide selection of available geometries, and by adjusting suction level, translation speed, and oscillation rate, the surgeon may customize the procedure to any individual situation. Any chosen combination of cutting parameters is checked by the program logic for consistency and safety.

Blade Quality: no compromise

Exclusive SurePass™ LASIK Blades and Surface Separators are made from surgical grade materials and are sterilized to the same standards as implantable surgical devices. Each individual blade is manually inspected before packaging.



Suction Units, precision-milled from a single piece of titanium. They can be used for all surgical applications (LASIK, Epi-LASIK, and Lamellar Keratoplasty). Suctions Units are symmetrical and can therefore be used for both left and right eye procedures. Suction Units are available with Suction Units of different inner and outer dimensions, to accommodate a wide range of flap dimensions and anatomical situations.



The AMADEUS microkeratome is assembled prior to the surgical procedure, by fitting the Motor Unit with the Blade Holder, Blade, and Suction Unit chosen for the intended surgical procedure. The four components snap into place in an unequivocal way and lock into each other, making assembly errors virtually impossible. The entire assembly is completed before the patient's eye is touched.



All relevant AMADEUS procedure parameters are computer-controlled and may be programmed using the system's graphical user interface (GUI). Parameters are entered using the control unit's touch screen. Setting up a procedure is supported by voice prompts to avoid erroneous parameter entry. All settings, including suction, are electronically monitored and regulated during the procedure. For documentation purposes, an optional printer interface allows printing detailed procedure reports on any attached printer.

LASIK

Versatile choice of flap dimensions

To cover the wide range of LASIK parameters required to customize the procedure to your patient's specific situation, AMADEUS gives you 11 different types of Suction Units for flap diameters from 8.5 to 10 mm, and for three outer diameters suitable for any anatomy. And with a choice from four types of Blade Holders, flap thicknesses from 110 microns to 160 microns may be created. Hinge dimensions are controlled by software and are operator-selectable.

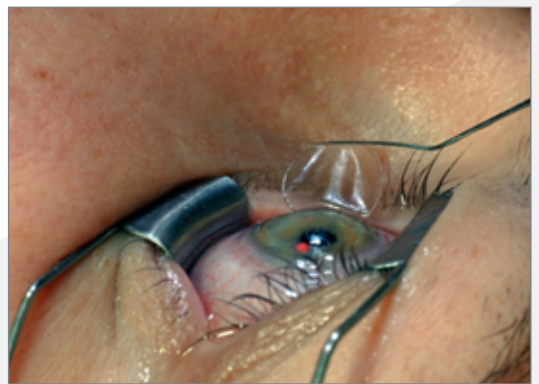
Full Control

Blade and flap are visible at all times during the procedure for continuous visual control.

All important procedure parameters are programmable, allowing the surgeon to customize the microkeratome to his/her specific needs and preferences.



The AMADEUS handpiece is lightweight and easily controlled single-handedly. It gives the surgeon excellent visibility of the cornea during the procedure.



LASIK flaps created with AMADEUS II are characterized by excellent uniformity, consistent thickness, perfect, smooth edges and a uniform, smooth stromal bed surface.

Surface Ablation and epi-LASIK

Epithelial flaps or free cap

For surface ablation procedures, AMADEUS employs the same Motor Unit and Suction Units proven in hundreds of thousands of LASIK procedures. The Surface Separator used for separating the epithelium layer from Bowman's membrane is made from a surgical grade synthetic material.

Standard parameters optimized for epi-LASIK are provided by system software. Optionally they may be customized according to surgeon preference.



A SurePass Separator is being fitted into an epi-LASIK Blade Holder, to prepare the AMADEUS for an epi-LASIK procedure.

Lamellar Keratoplasty

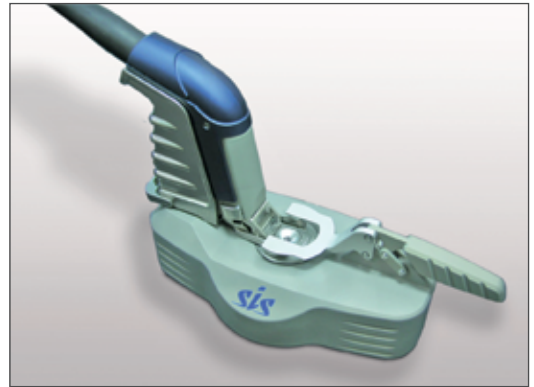
With the aid of the optional Lamellar Keratoplasty Module, deep lamellar resections from recipient eyes and donor buttons from a donor cornea may be prepared. The module includes an Artificial Anterior Chamber Module for donor corneas, and an Eye Holder for preparing donor flaps.

The system is perfectly suitable for performing Descemet Stripping Automated Endothelial Keratoplasty (DSAEK), as well as Anterior Lamellar Keratoplasty.

Graft creation and handling made easy with the Artificial Chamber

The desired thickness of the corneal lamella and the corresponding graft may be chosen by selecting the appropriate Blade Holder (available for 200, 250, 350, and 400 microns).

The diameter of the flap and of the graft is chosen by using the appropriate Suction Unit, available for 8.5, 9.0, 9.5, and 10 millimeters.



Preparing a lamellar graft.



Preparation of a lamellar graft from a donor cornea.

AMADEUS II, the Universal Microkeratome Platform.

The preferred choice on all counts:

- **Flexibility:** One unit for all applications: LASIK, surface ablation, and Lamellar Keratoplasty.
- **Versatility:** 11 different Suction Units and 8 Blade Holders — the right combination for every anatomy and every surgical situation.
- **Innovation:** Personalized LASIK with customizable speed, oscillation and suction parameters. Customized suction reduction on reverse pass.
- **Reliability:** Independence from environmental factors with built-in backup battery and automatic adjustment to current barometric pressure.
- **Simplicity:** Handpiece assembly involves only 4 parts that snap together in an unequivocal way. Special assembly guides safeguard against improper assembly.
- **Comfort:** Single-handed, lightweight handpiece avoids operator fatigue. Short eye contact and suction time maximizes patient comfort.
- **Safety:** Extensive self-test before each procedure; continuous monitoring and adjustment of suction during the pass.
- **Control:** Fully computer controlled procedure; continuous monitoring of motors and suction. Flap and blade are visible at all times during the procedure. Voice feedback and voice prompts give the surgeon maximum control with minimum distraction. Full printed report of procedure data (with optional printer interface).
- **Quality:** All-Titanium housing and components. Individually inspected blades.
- **Superior results:** Consistent Flaps, smooth and uniform stromal bed.

Technical Data

System Dimensions	
Dimensions (DxWxH) of Control Unit	245 x 200 x 360 mm (9.7 x 9.0 x 14.2")
Dimensions of assembled handpiece	102 x 27 x 94 mm (4 x 1 x 3.7")
System Weight	15 kgs (33 lbs)
Weight of assembled handpiece	135 g (5oz)
Voltage; Power requirement	110-240 VAC, 50-60 Hz, max. 80 VA

System Characteristics	
Oscillation rate	4'000 to 20'000 rpm
Advance Feed Rate	1.5 to 4 mm/sec
Flap diameter	8.5, 9.0, 9.5, 10.0 mm (for each diameter, a specific Suction Unit is required)
Flap thickness	LASIK: 120, 140, 160 µm LK: 200, 250, 300, 350, 400, 450, 500 µm (for each thickness, a specific Blade Holder is required)
Hinge depth / width	0.4 to 2.0 mm / 3.6 to 8.0 mm
Vacuum; minimum setting for suction	600 mbar = 450 mmHg = 8.7 PSI = 17.7 inchHg
Vacuum; maximum setting	up to 920 mbar (depends on atmospheric pressure)

Product Information

- Manufacturer: SIS Surgical Instrument Systems AG, CH-2562 Port, Switzerland (a Ziemer Group Company)
- Sales & Service: Ziemer Ophthalmic Systems AG, CH-2562 Port (Switzerland) and its network of established ophthalmic equipment distributors. Visit www.ziemergroup.com for details.
- Availability: Europe: CE-marked Class IIa device. USA: FDA approved Class I device. For other countries, availability may be restricted due to local regulatory requirements; please contact Ziemer Ophthalmics for details.
- Configuration: self-contained system includes: Control Unit with integrated control processor, touch screen, backup battery, and vacuum reservoir; Handpiece consisting of Motor Unit and Blade Holder; two foot pedals.
- Required Accessories: a selection from the available range of Suction Units and Blade Holders.
- Required single use components: SurePass™ LASIK Blades; epi-LASIK Separators, vacuum tubing.
- Service: Regular Maintenance and Repair Service is available from the manufacturer and from local certified Service Centers (please contact your local distributor or consult the Ziemer Group website for address information). Regular performance checks are recommended every 2 years and are performed by Service Centers and distributors.
- System components must be carefully cleaned and sterilized after each use, according to manufacturer's instructions in the User Manual. Convenient Maintenance and Service Contracts are available.
- Warranty: Ziemer's AMADEUS II system comes with a 12-month limited warranty on parts and workmanship. Please consult Ziemer Ophthalmic Systems' Warranty Terms for details.
- Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.



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Actual product characteristics, specifications, and prices are subject to change. 102202 / 0702

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