

Gebrauchsanweisung

Einsatzgebiet

Die chirurgischen Augen-Instrumente werden in der Augen Chirurgie eingesetzt. Sie sind speziell für enge räumliche Verhältnisse geeignet. Sie dienen zum Schneiden, Fassen, Präparieren, Dilatieren, Spülen, Säugen etc. von Gefäßen und Gewebe.

Lieferbare Modelle und Größen

Das aktuelle Produktprogramm ist im Albert Heiss Katalog beschrieben.

Sichere Handhabung und Bereitstellung

- Gebrauchsanweisung lesen und aufbewahren.
- Instrument nur bestimmungsgemäß verwenden, siehe Einsatzgebiet.
- Fabrikneues Instrument vor der ersten Sterilisation unbedingt gründlich reinigen (manuell oder maschinell).
- Fabrikneues oder unbenutztes Instrument an einem trockenen, sauberen und geschützten Platz aufbewahren.
- Instrument nach jeder Reinigung und Desinfektion und vor jeder Verwendung prüfen auf: Sauberkeit, Funktion und Beschädigungen, z. B. lose, verbogene, zerbrochene, rissige, abgenutzte und abgebrochene Teile.
- Kein beschädigtes oder defektes Instrument verwenden.
- Beschädigte Einzelteile sofort durch Originalersatzteile ersetzen.
- Beschädigtes Instrument sofort aussortieren.

Reinigung, Desinfektion, Sterilisation

Nach jedem Gebrauch

- Kontaminiertes Instrument schnellstmöglich aufbereiten.
- Gelenkinstrument in einem 90°-Winkel öffnen.
- Bei maschineller Reinigung Instrumente auf reinigungsgerechte Stabkröbe legen (Spülschatten vermeiden).
- Wenn möglich, Instrument in Einzelteile zerlegen.
- Vorzugsweise trocken entsorgen.
- Bei Nassentsorgung/reinigungsaktive Desinfektionsmittel verwenden. Vor maschineller Reinigung und Desinfektion Instrument gründlich mit klarem, fließendem Wasser spülen.

Falls nötig, Ultraschallbehandlung nach den Anweisungen des Geräteherstellers durchführen:

- als effektive mechanische Unterstützung bei manueller Reinigung.
- zur Vorbehandlung von Instrumenten mit angetrockneten Verschmutzungen vor der maschinellen Reinigung.

Manuelle Reinigung/Desinfektion

- Instrument in ein geeignetes reinigungsaktives Desinfektionsmittel legen, so dass alle Oberflächen, Hohlräume, Lumen und Öffnungen bedeckt sind. Anweisungen des Desinfektionsmittelherstellers beachten.
- Nach der chemischen Desinfektion immer ausreichend und intensiv mit klarem und fließendem Wasser abspülen. Anweisungen des Desinfektionsmittelherstellers beachten.

- Anhaftende Verschmutzungen sollten mit einer weichen Kunststoffbürste entfernen. Niemals schneuernden Reinigungsmittel oder Metallbürsten verwenden.
- Lumen und Kanäle mit weichen Kunststoff-Rundbürsten aus reinigen. Die Durchmesser von Lumen und Bürsten müssen einander entsprechen.
- Schüsselpulung mit destilliertem oder vollentsalztem Wasser durchführen.
- Instrument anschließend mit einem saugfähigem, weichem und fusselfreiem Tuch trocknen.
- Lumen und Kanäle mit Druckluft trocknen.

Maschinelle Reinigung/Desinfektion

- Bei der Programmwahl das Material (z. B. nichtrostender Instrumentenstahl, Aluminium) des zu reinigenden Instruments berücksichtigen. Anweisungen des Geräteherstellers beachten.
- Schüsselpulung mit vollentsalztem Wasser durchführen.
- Ausreichende Trocknungsphase einhalten.
- Instrument sofort nach Beendigung des Programms aus der Maschine nehmen.

Pflege, Prüfung

- Instrument auf Raumtemperatur abkühlen lassen.
- Bewegliche Teile (z. B. Gelenke und Schlüssel) mit sterilisierbarem, dampfdurchlässigem Pflegeöl leicht ölen
- Nach jeder Reinigung und Desinfektion Instrument prüfen auf: Sauberkeit, Funktion und Beschädigung, z. B. lose, verbogene, zerbrochene, rissige, abgenutzte und abgebrochene Teile.
- Beschädigtes und defektes Instrument aussortieren und ersetzen.

Packen

- Instrument mit feinem Arbeitssende und/oder mikrochirurgisches Instrument in geeigneten Lagerungshilfen lagern.

Sterilisieren

- Sterilisieren mit Dampf, dabei Folgendes beachten:
 - Die Sterilisation hat nach einem validierten Dampfsterilisationsverfahren (z. B. in einem Sterilisator gemäß EN 285/ANSI/AAMI/ISO 11134-1:1993, ANSI/AAMI ST46-1:1993 und validiert gemäß EN 554/ISO 13683) zu erfolgen. Bei der Anwendung des fraktionierten Vakuumverfahrens ist die Sterilisation mit dem 134 °C/2 bar-Programm bei einer Mindesthaltezeit von 5 Minuten durchzuführen.

Weitere Informationen entnehmen Sie bitte von der Internetseite des Arbeitskreises Instrumentenaufbereitung: <http://www.a-k-1.org>.

Reparatur

Reparaturen dürfen nur von Personen durchgeführt werden, die von Albert Heiss hierzu ermächtigt wurden. Nur so bleiben Garantie und Gewährleistungsansprüche erhalten. Instrumente die an Albert Heiss zurückgeschickt werden, können nur akzeptiert werden, wenn diese Instrumente nachweislich gereinigt und sterilisiert wurden.

Reparaturen einschicken an:

Albert Heiss GmbH & Co. KG
Stoekacher Str. 138
D-78532 Tuttlingen
Germany

Instructions for Use

Product Description

Ophthalmic Surgical Instruments are designed to perform specific functions such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating, suturing, or ligating. The use of an instrument for tasks other than those for which they are indicated may result in damaged or broken instruments. Proper cleaning, handling and sterilization and standard routine maintenance (such as sharpening, if applicable) will ensure that the Ophthalmic Surgical Instruments perform as intended and will extend their useful life.

How Supplied

Albert Heiss' Ophthalmic Surgical Instruments are supplied non-sterile and must be cleaned and sterilized prior to each use according to the procedures outlined in this document.

Inspection

Before use, inspect the instruments for possible damage, wear or non-functioning parts. Carefully inspect the critical, inaccessible areas, joints and all movable parts. Damaged or defective instruments should not be used or processed.

Precautions

Delicate Ophthalmic Surgical Instruments require special handling to prevent damaging the tips. Use caution during cleaning and sterilization. A non-fibrous sponge should be used to wipe off all blood and debris. Do not apply excessive stress or strain at joints; misuse will result in misalignment or cracks at the box locks or jaws.

Rongeurs and bone cutting forceps should only be used to cut bone, never wire or pin. Do not twist or apply excessive stress during use.

Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated instruments. Instruments manufactured from different metals should be processed separately to avoid electrolytic action between the different metals.

WARNING

If this device is/was used in a patient with, or suspected of having Creutzfeldt Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination.

Care and Handling

The procedures outlined below should be followed to ensure safe handling of biologically contaminated Ophthalmic Surgical Instruments. All instruments must be sterilized before use.

Pre-Cleaning

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments.

Remove gross contaminants with a steady stream of lukewarm/cool water (below 110°F/43°C). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions.

Open jaws of hinged instruments for cleaning. Give special attention to joints and serrations. Instruments having more than one part or piece must be disassembled to expose all surfaces to the cleaning process. Retain all parts to facilitate reassembly. Separate sharps and delicate Ophthalmic Surgical Instruments. Avoid processing instruments of different metallic composition together.

Cleaning

Cleaning Precautions

If appropriate, disassemble Ophthalmic Surgical Instruments prior to cleaning and sterilization. Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed two hours soaking in any solution. Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents. Microsurgically, plated and delicate instruments should be cleaned chemically or manually and should be processed in an ultrasonic cleaner. Carefully protect the tips of delicate micro-surgical instruments throughout the entire cleaning and sterilization process.

Manual Cleaning

Hand wash using a low-sudsing protein dissolving detergent. Follow manufacturers' directions regarding concentration, temperature, contact time and reuse. Totally immerse instruments during cleaning to prevent aerosolization. Use a large syringe or pulsating water jet to thoroughly flush all channels and lumens with cleaning solution to remove debris. Use appropriate-sized, soft nylon brushes to clean the instruments and their parts.

Ultrasonic and Mechanical Cleaning

For ultrasonic cleaning, follow manufacturer's specifications for water level, concentration levels of cleaning agent and temperature. When using mechanical washer, make sure all instruments stay properly in place and do not touch or overlap each other. Always follow the manufacturer's specifications for automatic washer-sterilizers and use a free-rinsing, low-sudsing detergent with a neutral pH (6.0 - 8.5). Due to variations in water quality, the type of detergent and its concentration may require adjustment for optimal disinfection and cleaning.

Rinsing

Rinse all instruments thoroughly with tap water, deionized or distilled water to remove all traces of debris and cleansing agents. Make sure all internal lumens and ratchets are thoroughly rinsed.

Decontamination

Note: The decontamination procedure does not sterilize the instruments. Refer to and process the instruments as outlined in the STERILIZATION section. Select a proper product for high-level disinfection such as the glutaraldehyde-family of disinfectant products. Follow the cleaning agent's recommended directions regarding concentration, temperature, contact time and solution re-use. Do not use high acid (pH 4 or lower) or high alkaline (pH 10 or higher) products for disinfection, such as bleach and bi-chloride of mercury. Completely immerse instruments in the disinfecting solution, including all lumens and shafts. Force solution into all areas and cavities. Thoroughly rinse with distilled water to remove all

traces of disinfecting solution. USE STERILE WATER ON THE FINAL RINSE.

Drying

Instruments must be thoroughly dried and all residual moisture must be removed before they are stored. Use a soft, absorbent towel/cloth to dry external surfaces. Compressed air or a 70% alcohol rinse may be used to aid the drying process.

Lubrication / Assembly

Lubrication is essential every time instruments are processed. Special attention should be given to lubrication of joints, box locks, and movable parts. Only lubricate dry instruments. Do not use mineral oil, petroleum, or silicone-based products. To lubricate box locks and joints, use a non-silicone, water-soluble lubricant prior to sterilization. Reassemble instruments, as necessary, before assembly into baskets or trays. Inspect instruments for bent tips, pits, cracks, misalignment and corrosion. Remove stained, discolored or damaged instruments. Mechanically test the working parts to verify that each instrument performs correctly. Close instruments with a ratchet lock in the first ratchet position before sterilization to avoid temperature-induced stress cracks in the joints.

Sterilization

Sterilization method and parameters

Sterilize with steam, taking note of the following:

The sterilization has to be done according to a validated steam sterilization procedure (e.g. in a sterilizer in conformance with EN 285/ANSI/AAMI/ISO 11134-1:993, ANSI/AAMI ST46-1:993, and validated in conformance with EN 554/ISO 13683). In case of application of the fractionated vacuum procedure the sterilization has to be carried out for a minimum of 5 minutes at 134 °C and at 2 bar pressure.

Sterilization for the US market:

Sterilization of the device may be accomplished by steam or ethylene oxide (EtO) gas. Albert Heiss does not recommend the device be sterilized by "Flash" or chemical sterilization.

Surgical instruments may also be placed within an rigid sterilization container for processing under generally accepted hospital in-use conditions.

The recommended sterilization parameters are as follows:

Sterilization Method	Temperature	Wrapped	Rigid sterilization container
Pre-Vacuum	270°-275°F 132°-135°C	4 minutes	(solid or perforated bottom)
Gravity	250°-254°F 121°-123°C 270°-275°F 132°-135°C	15 - 30 minutes 40 minutes 10 – 25 minutes 30 minutes	(perforated bottom only) (perforated bottom only)
FLASH	270°F/132°C	3 minutes	
Pre- Vacuum		(non-porous items) 4 minutes (non-porous & porous items)	Not Recommended

Sterilization Method	Temperature	Wrapped	Rigid sterilization container
Gravity	270°F/132°C	3 minutes (non-porous items) 10 minutes (non-porous & porous items)	Not Recommended

Ethylene Oxide (EtO)	127°-135°F 53°-57°C	Relative Humidity: 70 ± 5% Pressure Set Point: 8.12 psia EO Concentration: 725 ± 25 mg/L Gas Exposure Time: 105 minutes Drying Time: 12 hours at 131° ± 2° F (55° ± 2°C)	
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Further information are available on the homepage of the Arbeitskreis Instrumentenaubereitung: <http://www.a-k-1.org>.

Warranty

Every product bearing the Albert Heiss name is guaranteed to be free of defects in workmanship and materials when used normally for its intended surgical purpose. Any Albert Heiss product delivered from Albert Heiss GmbH & Co. KG, proving to be defective, will be replaced or repaired, at Albert Heiss' discretion, at no charge to the customer. These warranties shall not apply to conditions or defects resulting from, but not limited to: negligence, improper use, improper cleaning and handling, improper opening techniques, unauthorized repair work, caustic or abrasive cleaners, or items modified or customized by the customer at the customer's request.

Maintenance and Repair

If your Albert Heiss instruments require repair or maintenance, return the instruments in the sturdy box with adequate foam, bubbles or other packaging material to protect the instruments. Send the packaged instruments to:

Albert Heiss GmbH & Co. KG
Stockacher Str. 138
D-78532 Tuttlingen
Germany

Instruments returned to Albert Heiss for repair must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair. Contact your local Albert Heiss representative if you have any questions.

Tuttlingen, January 2005

Albert Heiss GmbH & Co. KG

Stockacher Str. 138
D-78532 Tuttlingen
Germany
Tel: +49 (0) 74 61 - 25 27
Fax: +49 (0) 74 61 - 1 22 29
Email: info@albert-heiss.de
www.albert-heiss.de

