

AE-4245N : Faulkner lens holding fcps
AE-2219 : Bahr-Maltzman hook

Caution: Federal (U.S.A) law restricts the sale of this device only to or by the order of a physician.

Description:

These Instruments are autoclavable and reusable.

Operating and maintenance instructions

Handling before and after each use:

The instruments should be ultrasonically cleaned at least once per surgery day. They should also undergo manual cleaning and sterilization immediately after each surgery. Do not use the instrument if it appears to be damaged.

General care items

- The Instruments are provided non sterile and must be ultrasonically cleaned and sterilized prior to initial use.
- To reduce or avoid endotoxin contamination, it is recommended to change the distilled water from the ultrasound cleaner after each and every use.
- Always use de-ionized water for final rinsing.
- Store instrument in a protective tray.

Handling Before Initial Use (Sterilization)

The product must be sterilized by the user prior to initial use. The user must adhere to the applicable sterilization regulations. Sterility assurance is the responsibility of the user. Refer to the recommended sterilization procedure provided in this document.

Handling Before and After Each Use:

The Instruments should be ultrasonically cleaned at least once per surgery day. Immediately after each surgery the Instruments should be cleaned manually and sterilized.

Ultrasonic Cleaning Before Use:

1. Rinse the Instruments vigorously with de-ionized water.
2. Clean the Instruments with a mild soap solution and gently scrub it with a soft bristle brush paying particular attention to the inside and the plunger of the instrument.
3. Thoroughly rinse and flush the Instruments vigorously with de-ionized water for 10 seconds.
4. Ultrasonically clean the Instruments for a minimum of 5 minutes using de-ionized water. For the use of the ultrasonic cleaning bath follow the instructions provided by the manufacturer.
5. After ultrasonic cleaning thoroughly rinse and flush the Instruments under running water and do a final rinsing by using de-ionized water.
6. Dry the Instruments with a lint-free cloth before returning to storage.
7. To reduce or avoid endotoxin contamination, it is recommended to change the distilled water from the ultrasound cleaner after each and every use.
8. The use of ultrasound baths and strong cleaning fluids (alkalis pH > 9 or acids pH < 5) can reduce the life span of products. The manufacturer accepts no liability what so ever in such cases.

Sterilization

1. The Instruments must be sterilized prior to initial use and prior to each use.

Method of Sterilization	Sterilizer Type	Sample Configuration	Temperature	Exposure Time (Minutes)
Steam	Gravity Displacement	Wrapped	132°C (270°F)	34.0
Flash	Gravity Displacement	Unwrapped	132°C (270°F)	10.0
Steam	Prevacuum	Wrapped	132°C (270°F)	4.0
Flash	Prevacuum	Unwrapped	132°C (270°F)	4.0

For steam sterilization, refer to ANSI/AAMI Standards and Recommended Practices Volume 1: Sterilization, Designation ST46-1993, Section 5.8.

For flash sterilization, refer to ANSI/AAMI Standard for Good Hospital Practice: Flash Sterilization – Steam Sterilization of Patient Care Items for Immediate Use. Designation ST37-1996, Section 5.4

Complaints:

Please send reports immediately to ASICO. In case you are in Europe please send the reports to mdi Europa with a copy to ASICO. We will investigate the complaint and respond to you.

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Ordering Information

Contact the ASICO head office by phone 1-630-986-8032, fax 1-630-986-0065, or email info@asico.com.

Customer service

The manufacturer guarantees a repair service and/or a replacement/repair of the original products.

Identification

All products are identified by an article and batch number. All exported products are registered by the supplier, and all repair or inspection work that is carried out by the manufacturer is documented in writing. This system ensures traceability of all repairs or inspections carried out on the products, right back to initial delivery.

Traceability

All products that are exported by ASICO LLC, can be comprehensively traced at any time.

Manufactured by:

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