



Direction for Use **Bi-Manual Irrigation and Aspiration Handles**

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

- The ASICO Bi-Manual Irrigation and Aspiration Handles are supplied UNSTERILE and must be autoclaved before use. To insure patient safety, handle the instrument carefully and protect it from damage. Do not use the instrument if it is damaged in any manner. Do not attempt to alter or repair the instrument. Wash, flush, dry and sterilize prior to initial and each subsequent use.
- Improper or inadequate cleaning may result in particulate matter adhering to the instrument and exfoliation into the surgical field.
- The ASICO Bi-Manual Irrigation and Aspiration Handles are delicate surgical instruments. The user should take special care to make sure that the handle's cannula is not damaged through accidental contact with other instruments. Any impact/hitting of the cannula against a hard surface can permanently damage the instrument.

INTENDED USE :

The Bi-Manual Irrigation and Aspiration Handles are intended to be used under the direction of a physician during cataract surgery. These instruments provide the user with a means to either aspirate material from, or supply irrigation fluid to, the surgical field.

DIRECTIONS FOR USE

Connection to the Phaco System

1. Follow the manufacturer's instructions for priming the system.
2. Connect the female aspiration luer to the gold Bi-Manual Aspiration Handle and the male irrigation luer to the blue Bi-Manual Irrigation Handle.

Checking System Operation

1. Initiate irrigation fluid flow (following the manufacturer's instructions) and verify fluid flow out of the blue Bi-Manual Irrigation Handle.
2. Pinch off the aspiration tubing close to the gold Bi-Manual Aspiration Handle and activate the system's aspiration pump. Make sure the system responds as required.

WARNING: Use caution when performing the following step. The aspiration cannula is extremely delicate and handling may damage the tip.

3. With the system's vacuum set to greater than 400 mmHg, simulate an occlusion of the aspiration port by blocking the port at the tip of the gold Bi-Manual Aspiration Handle with a gloved hand. Activate the vacuum and verify that the vacuum level being sensed climbs to within 50 mmHg of the system setting. Check for leaks or bubbles in the aspiration line while the vacuum is active

WARNING: Do not use the Bi-Manual Irrigation and Aspiration Handles if there are any problems. Proceed to the troubleshooting section or contact ASICO LLC.

Cleaning

The recommended cleaning process for the Bi-Manual Irrigation and Aspiration Handles is as follows:

1. During the Procedure:
 - a. Immediately after use, soak the Bi-Manual Irrigation and Aspiration Handles in distilled water.

2. Post Procedure Cleaning:
 - a. This procedure describes the cleaning of the Bi-Manual Irrigation and Aspiration Handles.
 - b. Part 1
 - i. Fill a 10cc syringe with clean, distilled water.
 - ii. Connect syringe to the blue Bi-Manual Irrigation Handle's luer and expel the water.
 - iii. Disconnect the syringe and repeat steps a and b two more times.
 - iv. Using included with the device, repeat this same process for the gold Bi-Manual Aspiration Handle.
 - c. Part 2
 - i. With the syringe connected to the gold Bi-Manual Aspiration Handle's luer through the female-to-female luer adapter, draw clean, distilled water into the syringe.
 - ii. Disconnect syringe and expel water
 - iii. Repeat steps a and b two more times
 - iv. Repeat this same process for the blue Bi-Manual Irrigation Handle
 - d. Part 3
 - i. Clean the Bi-Manual Irrigation and Aspiration Handles ultrasonically for 5 to 10 minutes after each surgical case.
 - ii. To reduce or avoid endotoxin contamination, it is recommended to change the distilled water from the ultrasound cleaner after each and every use.
 - iii. 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.

NOTE: To avoid damage due to incidental contact, the Bi-Manual Irrigation and Aspiration Handles should be kept apart from other instruments during cleaning and sterilization.

NOTE: When the Bi-Manual Irrigation and Aspiration Handles will not be immediately sterilized, it is important to make sure that the instruments are clean and dry. Using a syringe free of water, force 10cc of air through each handle to ensure that its fluid path is clear. Repeat this step twice to clear and dry the fluid path of each handle.

Sterilization

Sterilize the Bi-Manual Irrigation and Aspiration Handles in a steam autoclave prior to each use.

CAUTION: Do not sterilize prior to performing cleaning procedure described

1. Sterilize to your facility's standard practice or to industry standards such as
 - a. ANSI / AMMI ST46-1993, "Good Hospital Practices: Steam Sterilization and Sterility Assurance."
 - b. EN 554; 1994, "Sterilization of Medical Devices – Validation and routine control of sterilization by moist heat."
 - c. HTM 2010, "sterilization," Part 4.
2. The following techniques, times and temperatures are recommended by ASICO LLC

Gravity Displacement	PreVacuum Cycle
132° to 135° C (270° to 275° F) 10 minutes	132° to 135° C (270° to 275° F) 4 minutes

NOTE: It is normal for coloring of this instrument to change over the instrument life. Contact with BSS, changes in temperature associated with sterilization, contact with body oils as a result of handling, and ultrasonic cleaning are some of the routine processes that affect the color/appearance of the device.

MAINTENANCE

The ASICO Bi-Manual Irrigation and Aspiration Handles require regular cleaning after each use. The Bi-Manual Irrigation and Aspiration Handles should be sterilized before each use. The Bi-Manual Irrigation and Aspiration Handles should be inspected for signs of damage or build up of cortical material in the fluid pathways at least once per day.

TROUBLESHOOTING TIPS

The following list should not be considered to be complete. Contact ASICO if the observed symptom is not listed or if the suggested corrective action does not resolve the problem.

Symptom	Possible Cause	Corrective Action
Leaking or insufficient Irrigation	1. Loose irrigation luer fitting. 2. Clogged Bi-Manual Irrigation Handle	1. Reconnect securely 2. Check Bi-Manual Irrigation Handle
Insufficient aspiration	1. Loose aspiration luer fitting 2. Kinked or damaged aspiration tubing 3. Clogged Bi-Manual Aspiration Handle	1. Reconnect securely 2. Check tubing and replace if necessary 3. Check Bi-Manual Aspiration Handle

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. Federal (U.S.A) law restricts this device to sale by or on the order of a Physician.

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:

ASICO LLC
26 Plaza Drive
Westmont, IL 60559
U.S.A
Tel.: 630-986-8032
Fax: 630-986-0065

Authorized EU

mdi Europa GmbH
Langenhagener Str. 71
30855 Hannover-Langenhagen
Germany
Tel: +49-511-3908 9530
Fax:+49-511-3908 9539