



AMERICAN OPTISURGICAL INC.

26902 Vista Terrace, Lake Forest, CA 92630

Tel: 800.576.1266 / 949.580.1266 Fax: 949.580.1270



Phaco Handpiece

EC Rep:
Donawa LifeScience Consulting
Piazza Albania, 10
00153 Rome, Italy
(+39/06) 578-2665

Instructions for Cleaning, Sterilization and Preparation for Use

Follow this procedure before the initial and each subsequent use of your Phacoemulsification handpiece.



WARNINGS AND PRECAUTIONS



- When you receive your Phaco handpiece from AOI, remove the tie wrap and nose cone protector.
- Clean your Phaco handpiece immediately after each surgical procedure.
- Never use wire cleaning instruments or steel brushes to clean your Phaco handpiece.
- Never use enzymatic or ultrasonic cleaners to clean your Phaco handpiece.
- Never use chemical cleansers or sterilizing agents on your Phaco handpiece.
- You must thoroughly clean your Phaco handpiece before sterilization.
- Sterility assurance is the responsibility of the institution performing the sterilization.

INSTRUCTIONS

CLEANING

1. Disconnect tubing from Phaco handpiece. Remove the silicone sleeve and Phaco tip (if applicable) for separate cleaning and sterilization.
2. Rinse the exterior of the Phaco handpiece under warm tap water (72°-110°F/22°C-43°C) for 15 seconds. If necessary, remove all visible soil from the outside of the Phaco handpiece and cable using a soft cloth moistened with water and mild soap. Remove all traces of the solution with another soft cloth moistened with distilled water.
3. **AUTOMATED** Prepare the QuickRinse™ manufactured by American Optisurgical Inc. for use as described in the Operator's Manual. Connect the Nose Cone Flush Attachment accessory to the Phaco handpiece nose cone and press the *Cycle* button to begin the automated flush/dry cycle. After 30 seconds both amber lights will turn off, indicating that the cycle is complete. Press the *Cycle* button again to run a second cycle.

Note: Each QuickRinse™ automated cycle delivers >150cc of fluid through the connected instrument.

4. **MANUAL** Flush each lumen of the Phaco handpiece with at least 150cc of ambient distilled or de-ionized water followed by air using a syringe and appropriate attachment. AOI recommends flushing from the nose cone out the back of the handpiece using an appropriate adapter.
5. Check the cable and strain relief for cuts and tears. Check the connector for bent pins. Do not use if damage is found.

STERILIZATION

1. Double wrap the Phaco handpiece in muslin, i.e. CSR blue hospital wrap, and sterilize using steam following your institution's validated procedures and cycle parameters. AOI recommends the following temperatures and times:

Recommended Steam Sterilization Parameters

Type of Sterilizer	Temperature	Exposure Time	Dry Time
Gravity	270°F (132°C)	15 minutes	30 minutes
Pre-vacuum	270°F (132°C)	4 minutes	20 minutes

PREPARATION FOR USE

1. Thread a clean, sterile Phaco tip into the Phaco handpiece using a clean, sterile tip wrench. **DO NOT OVER-TIGHTEN.**
2. Thread a clean, sterile silicone sleeve over the tip until the desired amount of tip is exposed and the holes are lined up perpendicular to the tip bevel, if applicable.
3. Attach the irrigation line to the irrigation fitting and attach the aspiration line to the aspiration fitting.

Your Phaco handpiece is a delicate surgical instrument. Proper care and handling is required to ensure reliability and optimum performance.

WARNING

Do not rapidly cool the Phaco handpiece after autoclaving by immersing in a cold bath or a cold wrap. Failure to observe this warning can thermally stress the internal crystals and void your warranty.

WARNING

Do not bypass the drying step of your autoclave and be sure to allow the Phaco handpiece to cool to room temperature before use. Failure to observe this warning can thermally stress the internal crystals and void your warranty.

Conditions not covered under warranty

• External Damage	The Phaco handpiece has been dropped causing thread damage, nose cone damage, scratches, bent irrigation luer, or any other damage.
• Strain Relief Damage	The Phaco handpiece has been disconnected from the Phacoemulsifier by pulling the silicone strain relief at the electrical connector. Always connect or disconnect the Phaco handpiece by holding the connector.
• Bent Pins	Plugging the connector in without properly lining up the red dot on the connector with the red dot on the Phaco console panel mount receptacle.
• Corrosion	The Phaco handpiece and/or connector has come in contact with or been allowed to soak in a corrosive solution.
• Cuts on Cord	Surgical instruments can damage the Phaco handpiece cord. Please use caution when near the cord.
• Thread Damage	Over-tightening the Phaco tip can cause thread damage. Pliers are never to be used when removing Phaco tips.
• Wet Connector	Plugging the connector in before it is completely dry may cause an electrical short. (Arced Connector)