

Directions for Use
InterTip™ and InterTip-T™ System Instructions

CAUTION: This instrument is packaged in a non-sterile condition. To ensure patient safety, handle instrument carefully and protect it from damage. Do not use this instrument if it appears damaged in any manner. Do not attempt to alter or repair the instrument. Prior to initial and each subsequent use, wash, flush, rinse dry & sterilize the instrument.

CAUTION: Improper or inadequate cleaning may result in particulate matter adhering to the instrument and exfoliation into the surgical field. In addition, the function and life expectancy may become compromised.

WARNING
DO NOT attach InterTip™ tips to any other handle other than the InterTip™ handle or InterTip-T™ tips to any other than the InterTip-T™ handle. Use of handles not intended to be used with the InterTip™ or InterTip-T™ systems will result in non-functioning systems and may present patient safety issues.

NOTE: MicroSurgical I/A handles are sold under a variety of different names. Call us at 888-279-3323 (USA) or 425-861-4002 with questions about compatibility.

INTENDED USE

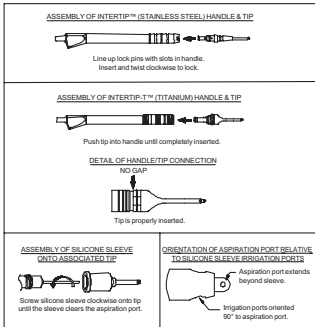
The InterTip™ and InterTip-T™ systems provide the user with a means to aspirate material from, and supply irrigation fluid to the crystalline lens during cataract surgery.

DIRECTIONS FOR USE

The MicroSurgical InterTip™ and InterTip-T™ handle and tip must be sterilized in a steam autoclave prior to each use. The handle and tip should not be assembled during autoclaving.

• Connection to the Phaco System

- Follow the manufacturer's instructions for priming the system.
- Connect the female luer to the aspiration port and the male luer to the irrigation port of the I/A handle.



- Insert the sterilized tip into the handle making sure that it is correctly engaged, as shown in the figure.
- If the selected I/A tip requires a silicone infusion sleeve, screw the infusion sleeve onto the tip until the desired exposure of the aspiration tip is achieved. When setting the exposure of the tip, the orientation of the irrigation port holes on the sleeve should be at a right angle to the aspiration port on the tip as shown.
- Initiate irrigation fluid flow (following the manufacturer's instructions) and verify fluid flow out of the irrigation ports.

• Checking System Operation

- Fill a test chamber with balanced salt solution (BSS) and slide the test chamber onto the I/A tip.
- Place or hold the I/A handle horizontally at the level of the cassette.
- Pinch off the aspiration tubing close to the I/A handle's aspiration luer and activate the system's aspiration pump. Make sure the system responds as required.
- With the aspiration pump still activated, release the pinch of the aspiration line while watching the test chamber. The chamber should maintain its shape or dimple only slightly. After verifying chamber stability the vacuum may be released.

WARNING

Use caution when performing the following step. The aspiration cannula of some tips are extremely delicate and handling may damage the tip.

- With the system's vacuum set to greater than 400mmHg, simulate an occlusion of the aspiration port by blocking the port at the tip 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 handle if there are any problems. Proceed to the troubleshooting section or contact MicroSurgical Technology.

• Cleaning

The recommended cleaning process for the InterTip™ and InterTip-T™ systems are as follows:

- DURING THE PROCEDURE**
Immediately after use, soak I/A tips and handles in distilled water.
- POST PROCEDURE CLEANING**

This procedure describes the cleaning of the InterTip™ or InterTip-T™ system with the tip attached to the handle.

Part I:

- Fill a 10cc syringe with distilled water.
- Connect syringe to the handle's irrigation port and expel the water.
- Disconnect the syringe and repeat steps a and b two more times.
- Repeat this same process for the handle's aspiration port.

Part II:

- With the syringe connected to the handle's aspiration port, draw distilled water into the syringe through the aspiration port.
- Disconnect syringe and expel water.
- Repeat steps a and b two more times.
- Repeat this same process for the irrigation port.

Part III:

- Periodic ultrasonic cleaning of the I/A tip and handle is recommended. Follow the instructions provided by the manufacturer of the ultrasonic cleaner for cleaning times and cleaning solution removal.

NOTE: To avoid damage due to incidental contact, the InterTip™ and InterTip-T™ components should be kept apart from other instruments during cleaning and sterilization.

NOTE: When the InterTip™ and InterTip-T™ parts 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 the irrigation line to ensure the line is clear. Repeat this step twice to clear and dry the irrigation path. This same procedure should be followed for the aspiration path.

• Sterilization

CAUTION: Do not sterilize prior to performing cleaning procedure described above.

- Sterilize to your facility's standard practice or to industry standards such as
 - ANSI/AMMI ST-46-1993, "Good Hospital Practices: Steam Sterilization and Sterility Assurance".
 - EN 554-1994 "Sterilization of Medical devices – Validation and routine control of sterilization by moist heat".
 - HTM 2010, "Sterilization", Part 4.
- The following techniques, times and temperatures are recommended by MicroSurgical Technology:

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

MAINTENANCE

The MicroSurgical Technology InterTip™ and InterTip-T™ system requires regular cleaning after each use. The InterTip™ and InterTip-T™ system parts should be sterilized before each use.

The InterTip™ and InterTip-T™ handle and tips should be inspected for signs of damage or build up of cortical material in the fluid pathways at least once per day of use.

O-rings on the InterTip™ and InterTip-T™ handle and tips should be inspected for signs of damage and wear prior to each use.

O-rings should be replaced at least once per year (up to 4000 uses).

TROUBLESHOOTING TIPS

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

Symptom	Possible Cause	Corrective Action
Test chamber shape is not maintained.	<ol style="list-style-type: none"> Restriction in the irrigation tubing or pathway. Clogged I/A handle or tip. 	<ol style="list-style-type: none"> Check for kinks in irrigation line. Check I/A handle and tips. Check other areas of the system for possible fault.
Test chamber collapses – does not refill.	<ol style="list-style-type: none"> Clogged Irrigation path in handle or tip. 	<ol style="list-style-type: none"> Check Irrigation path in handle and tips. Check other areas of the system for possible fault.
Fluidics balance test fails.	<ol style="list-style-type: none"> Clogged I/A handle or tip. 	<ol style="list-style-type: none"> Check I/A handle and tips.
InterTip™ Handle leaking at tip or handle connection.	<ol style="list-style-type: none"> Loose tip. Damaged O-ring. 	<ol style="list-style-type: none"> Make sure that the tip is fully inserted into the handle. Replaces the O-rings on the tip with new ones.
Insufficient aspiration.	<ol style="list-style-type: none"> Loose aspiration (blue) luer fitting. Kinked or damaged tubing. Clogged Aspiration path in handle or tip. Damaged O-ring. 	<ol style="list-style-type: none"> Reconnect securely. Check tubing and replace if necessary. Check Aspiration path in handle and tips. Replace the O-rings on the tip with new ones.

ACCESSORIES

The following items are compatible with the InterTip™ and InterTip-T™ systems and are available from MicroSurgical Technology and your local distributor.

Tip(s) _____	MicroSurgical Technology offers a variety of InterTip™ and InterTip-T™ tips.
Test Chamber (5/bag) _____	IH-90339
Silicone Sleeve, Non Sterile (5/bag) _____	IH-90337
O-rings _____	
InterTip™ _____	IH-90330
InterTip-T™ _____	TA-93331
MST Silicone I/A Tip Adaptor _____	
InterTip™ _____	SA-01340
InterTip-T™ _____	TA-01332

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