

TempSure Cleaning & Disinfecting Manual

Cleaning

Always keep the operative area, Generator, and accessories clean. Good hygiene and cleanliness help inhibit the spread of disease. Refer to instructions for specific handpieces for cleaning.



CAUTION: You must turn the Generator OFF before cleaning it to prevent damage to the system.

Cleaning the Generator

The generator and all cords must be wiped down using 70% IPA solution, repeatedly until soil is no longer visible, and then dried with a dry lint-free cloth.

The console display should be gently wiped down with a water dampened lint free wipe.



CAUTION: Allow for flammable agents used for cleaning or disinfecting, or as solvents of adhesives, to completely evaporate before the application of RF surgery.

Do not use any organic solvent, acid or alkali solution on the display or it may become damaged.

Only non-flammable agents should be used for cleaning and disinfection wherever possible.

Cleaning Envi 10mm, 15mm, 20mm, 25mm, 30mm, and Vitalia 18mm Handpieces

Before cleaning, unplug the handpiece from the generator.

Handpieces should be cleaned post use following the instructions provided with the device. Inspect the cord to ensure no damage has occurred during use and that it can be effectively cleaned according to the procedure.

NOTE: To ensure proper cleaning of the handpiece, never reuse a wipe.

NOTE: The Vitalia 18mm Handpiece includes a reusable smart handpiece in addition to the single-use disposable probe. The smart handpiece should always be draped with a disposable sleeve during use, however cleaning the smart handpiece post use is recommended.



CAUTION:

DO NOT IMMERSE HANDPIECE IN WATER. Immersing the handpiece will result in damage rendering the handpiece unusable. When cleaning the handpiece, only clean client contacting surfaces with cleaning solution.



IMPORTANT!

For each cleaning step, hold the handpiece at a downward angle to allow the cleaning solutions to flow off the electrode without contacting the handle. This will prevent water damage to the handpiece.



Clean

To clean the handpiece, complete the following steps:

1. Remove massage head or sleeve prior to cleaning.
2. Remove gel and debris from all client contacting surfaces of the handpiece by wiping it clean with a warm water dampened paper towel and repeat as necessary, using fresh paper towels, until the surface is free of all visible debris.
3. Dispose of used paper towels in accordance with local regulations.
4. Prepare a solution of warm water and mild detergent. Refer to detergent's instruction for mixing parts.
5. Obtain soft-bristled nonmetallic cleaning brush.
6. Dip brush head into solution.
7. Using a circular motion scrub the client contacting electrode and edge for a minimum of 60 seconds. Brush directly on the perimeter seam and thermistor.

 **CAUTION:** Hold the handpiece at a downward angle (as shown) to prevent water or solution from getting into the handpiece.

8. Obtain foam tip swab or cotton-tipped applicator.
9. Wet swab with solution, then clean using a clockwise motion around the thermistor sensor set in the client contact electrode. Clean thermistor sensor for a minimum of 60 seconds. Use a circular motion around the thermistor sensor getting into the seam as much as possible.
10. Rinse tip under warm water for a minimum of ten seconds. Only rinse client contacting surfaces.
IMPORTANT! Ensure that the handpiece tip is pointing down to allow the water to freely flow off the device.



11. Submerge client contacting surface in 70% Isopropyl alcohol (IPA) for 30 seconds.

 **CAUTION:** Only immerse client contacting surface of the handpiece in IPA.



12. Allow the device to air dry (with tip pointing downward) before storing.

 **WARNING:** If water accidentally gets into the handpiece dam area, clear the dam area of water and do not plug the handpiece into the Generator or use the handpiece to treat a client, until the water has completely evaporated (at least 24 hours) and the handpiece has been effectively tested.

Cleaning 25mm and 30mm Massage Heads and Sleeve

Visually inspect the Massage Heads and Sleeve before and after each procedure. Clean the massage head and sleeve after each use.

NOTE: Do not autoclave. Do not ETO sterilize.

1. Remove the massage head and sleeve from handpiece.
2. Prepare a solution of water and mild detergent. Refer to detergent's instruction for mixing parts.
3. Using a solution dampened lint-free wipe, wipe down the Massage Head and sleeve until visibly clean.
4. Obtain a soft-bristled, nonmetallic cleaning brush.
5. Dip brush head into solution.
6. Brush debris from Massage Head and sleeve until visually clean.
7. Rinse for a minimum of two minutes under warm running potable tap water to remove cleaning residue.
8. Dry Massage Head and sleeve using a soft, absorbent lint-free cloth.

Disinfecting Envi 10mm, 15mm, 20mm, 25mm, and 30mm Handpieces

 **IMPORTANT!** Before disinfecting the handpiece, you must complete the cleaning procedure.

To disinfect client-contacting surfaces, complete the following steps:

1. Wipe down all client contacting surfaces with 70% IPA.
2. With the handpiece held horizontally, spray the client-contacting surface and brush head with 70% IPA.
3. Using the brush and circular motions, scrub all seams of the client-contacting surface and edges, with particular attention around the probe-collar interface and the thermistor-probe interface and while keeping the surfaces wet with the 70% IPA solution.
4. Flush the client contacting area with 70% IPA to wash away any debris.
5. Using a fresh 70% IPA wipe, wrap the client-contacting surfaces in the wipe and let them sit wet for a minimum of three minutes.
6. Using another fresh 70% IPA wipe, vigorously wipe the client-contacting surfaces again.
7. Dispose of the used wipes in accordance with local regulations.
8. Allow the client-contacting surfaces and handpieces to air-dry.

Cleaning 60mm Handpiece

Before cleaning, unplug the handpiece from the generator.

Handpieces should be cleaned post use following the instructions provided with the device. Inspect the handpiece and cord to ensure no damage has occurred during use and that they can be effectively cleaned according to the procedure.

NOTE: To ensure proper cleaning of the handpiece, never reuse a wipe.

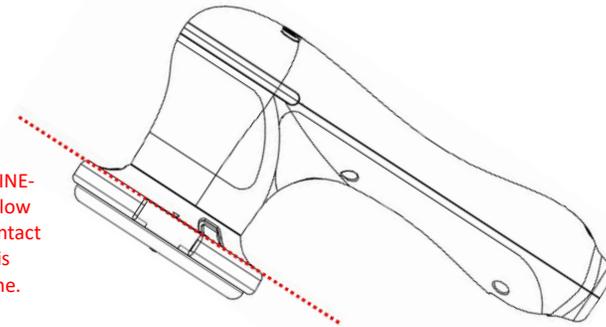


CAUTION: DO NOT IMMERSE HANDPIECE IN WATER. Immersing the handpiece will result in damage rendering the handpiece unusable. When cleaning the handpiece, only clean client contacting surfaces with cleaning solution.



IMPORTANT! For each cleaning step, hold the handpiece such that the cleaning solutions may flow off the electrode without contacting the handle. This will prevent water damage to the handpiece.

WATER LINE-
Do not allow
water contact
above this
dotted line.



To clean the handpiece, complete the following steps:

1. Remove massage head prior to cleaning.
2. Remove gel and debris from all client contacting surfaces of the handpiece by wiping it clean with a warm water dampened paper towel and repeat as necessary, using fresh paper towels, until the surface is free of all visible debris.

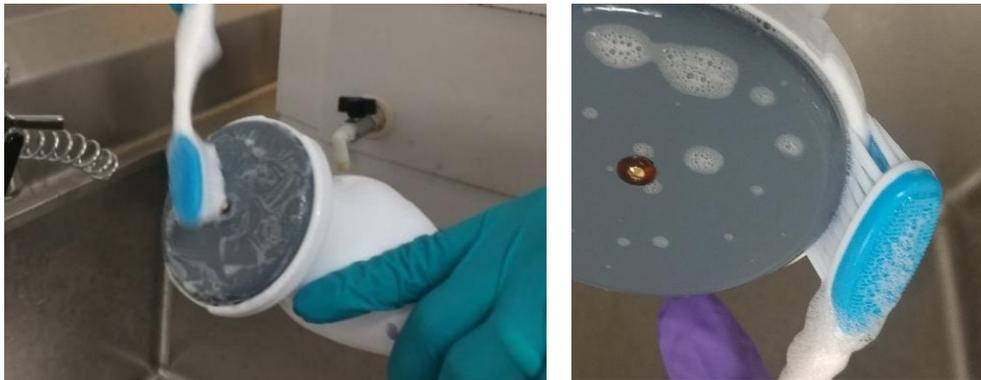


3. Dispose of used paper towels in accordance with local regulations.

4. Prepare a solution of warm water and mild detergent. Refer to detergent's instruction for mixing parts.
5. Obtain soft-bristled nonmetallic cleaning brush, such as a toothbrush.
6. Dip brush head into solution.
7. Using a circular motion scrub the client contacting electrode and edge for a minimum of 60 seconds. Brush directly on the thermistor (at the center of the patient contact surface) and in the gap between the tip and the plastic housing. The brush bristles should be in the full depth of the gap. Make sure to scrub the gap around the entire circumference between the electrode (patient contact surface) and the plastic housing.



IMPORTANT! Hold the handpiece to allow water to run off the end, to prevent water or solution from getting into the handpiece.



8. Obtain foam tipped swab or cotton swab.
9. Wet swab with solution, then clean using a clockwise motion around the thermistor sensor set in the client contact electrode. Clean thermistor sensor for a minimum of 60 seconds. Use a circular motion around the thermistor sensor getting into the seam as much as possible.



- Using a squirt bottle, rinse tip surface with warm water for a minimum of 30 (thirty) seconds. DO NOT hold handpiece under running water.

IMPORTANT! Ensure that the handpiece tip is positioned to allow the water to freely flow off the device.



After rinsing the surface, place tip of bottle against the gap and rinse thoroughly around the entire circumference between the electrode and the housing. Do not hold handpiece under running water. Only rinse client contacting surfaces.

INCORRECT:



CORRECT:



- Repeat steps 6 through 10.
- Submerge client contacting surface in 70% Isopropyl alcohol (IPA) for 30 seconds. Do not submerge beyond the top edge of the circular electrode housing. Do not submerge far enough to cover the LEDs on top of the electrode housing.

IMPORTANT! Only immerse client contacting surface of the handpiece in IPA.

13. Allow the device to air dry on its side as shown before storing.

NOTE: If water accidentally gets into handpiece, do not plug the handpiece into the Generator or use the handpiece to treat a client until the water has completely evaporated (at least 24 hours) and the handpiece has been effectively tested.



Cleaning 60mm Handpiece Massage Head

Visually inspect the Massage Head before and after each procedure. Clean the massage head after each use.

NOTE: Do not autoclave. Do not ETO sterilize.

1. Remove the massage head from handpiece.
2. Prepare a solution of water and mild detergent. Refer to detergent's instruction for mixing parts.
3. Using a solution dampened lint-free wipe, wipe down the Massage Head and sleeve until visibly clean.
4. Obtain a soft-bristled, nonmetallic cleaning brush.
5. Dip brush head into solution.
6. Brush debris from Massage Head until visually clean. Brush directly in the seam on the top of each foot of the massage head.



7. Rinse for a minimum of two minutes under warm running potable tap water to remove cleaning residue. Make sure to rinse each foot of the massage head, directing water into the seams.



8. Repeat steps 5 – 7.
9. Dry Massage Head and sleeve using a soft, absorbent lint-free cloth.
10. Submerge Massage Head in 70% Isopropyl alcohol (IPA) for 30 seconds.
11. Allow to air dry before storing.

Disinfecting 60mm Handpiece



IMPORTANT! Before disinfecting the handpiece, you must complete the cleaning procedure.

To disinfect client-contacting surfaces, complete the following steps:

1. Wipe down all client contacting surfaces with 70% IPA (Isopropyl Alcohol).
2. With the handpiece held so that fluid may run off, spray or squirt the client-contacting surface and brush head with 70% IPA.
3. Using the brush and circular motions, scrub the client-contacting surface and edges, with particular attention to the seam around the thermistor and to the gap between the electrode and plastic housing, as shown in the cleaning procedure, while keeping the surfaces wet with the 70% IPA solution.
4. Flush the client contacting area with 70% IPA to wash away any debris. A squirt bottle is recommended.
5. Using a 70% IPA wipe, wipe inside the gap between the electrode and the plastic housing.
6. Submerge the client-contacting surface in 70% IPA for 3 minutes. Do not submerge far enough to cover the LEDs on top of the electrode housing. Do not let the handle drop into the IPA.



IMPORTANT! Only immerse client contacting surface of the handpiece in IPA.

7. Using another fresh 70% IPA wipe, vigorously wipe the client-contacting surfaces again.
8. Dispose of the used wipes in accordance with local regulations.
9. Allow the client-contacting surfaces and handpieces to air-dry.

Disinfecting 60mm Massage Head



IMPORTANT! Before disinfecting the massage head, you must complete the cleaning procedure.

To disinfect client-contacting surfaces, complete the following steps:

1. Wipe down all surfaces of the massage head with 70% IPA, with particular attention to the seam around the gray top of each foot of the massage head.
2. Submerge the entire massage head in 70% IPA for 3 minutes.
3. Dispose of the used wipes in accordance with local regulations.
4. Allow the massage head to air-dry.

Cleaning Surgical Electrodes

Please follow the below recommendations for handling and cleaning the surgical electrodes. This will prolong the life of the reusable electrodes.

- Inspect electrodes prior to each use for any sign of damage.
- Immediately replace any electrode which has visible damage or is not functioning properly.
- Electrodes have a limited life span which may be prolonged by careful handling during procedures and sterilization.
- We recommend using a different electrode for each client during the day. Keep a supply of spare, sterile electrodes individually wrapped. Electrodes will then last longer, provide more trouble-free service and be more economical.

 **CAUTION:** Damaged electrodes, or those whose shafts have not been thoroughly rinsed and dried, may cause electrical burns to the client or doctor.

This procedure does not apply to microrincipional handpieces.

1. Engage the TempSure System COAG waveform, the normal power setting.
2. Place four gauze pads together and fold in half.
3. Saturate the gauze with tap water.
4. With the electrode in handpiece, place it between the folds of the gauze.
5. Activate the unit for 1-2 seconds while moving the electrode back and forth within the gauze with little or no finger pressure. Repeat procedure (you should hear "sizzling" sound). This volatilizes the water molecules and "steam cleans" your electrodes.

NOTE: OSHA requires that gloves be worn during all clinical procedures and during cleaning, disinfecting, and sterilizing of instruments including electrodes.

Sterilizing Electrodes

Sterilization instructions are included with each electrode. Please refer to package insert instructions.

Reusable Electrodes Care

Electrodes are made of surgical grade wire and will eventually volatilize and break. If misused, they will carbonize and rapidly wear out. To increase their efficiency and prolong their life follow these recommendations:

- Plug handpieces into the correct port.
- Electrodes should only be handled by the insulated shafts. The surgical grade wires have thin diameters and are very fragile.
- When using bendable electrodes, bend only at the insulated shaft portion of the electrode.
- Tissue should be moist.
- Always activate the TempSure handpiece before making contact with the tissue.
- Never apply pressure. Always remember that the RF is doing the cutting.
- If there is resistance, drag, or tissue sticking to the electrode, the power setting is too low. This will cause bending and breakage. Adjust accordingly by raising power gradually.
- If there is sparking (which causes carbonization), the power setting is too high. Adjust accordingly by lowering power gradually.
- Electrode loops need slightly higher power than straight wires (adjust up gradually) and are more fragile.
- If electrode becomes stuck on tissue, do not force the electrode. Deactivate the TempSure™ System and carefully remove the electrode from the tissue.