

CLEANING AND STERILIZATION GUIDE

TruClear™ System Handpiece



REPROCESSING INSTRUCTIONS

Reprocessing Instructions for the Handpiece

Caution

The handpiece is provided nonsterile and must be cleaned and sterilized prior to use.

Detergent solutions used shall be between pH neutral and mild alkaline (7.0 to 10.8) to ensure material compatibility.

Limitations and restrictions on processing: Repeated processing at the listed parameters has minimal effect on Covidien™ reusable devices. Wear and damage due to use normally determine the end of instrument life.

Initial treatment at the point of use:

1. Remove contamination

- Remove excess soil on the handpiece with disposable wipes.

CAUTION: Disposable wipes containing bleach shall not be used.

- Flush the channels of the handpiece with warm tap/sterile water or with an enzymatic solution per the detergent label instructions.

2. Prepare for transportation

- The handpiece should be cleaned thoroughly after every use to remove all traces of blood and surgical debris. Reprocess as soon as possible following use. If reprocessing of the handpiece cannot be performed immediately, cover the device with a moist towel or spray with an enzymatic solution per the detergent label instructions.
- Transport per hospital procedures.

Preparation before cleaning:

1. Dispose of the tissue removal device(s) used during the procedure.
2. Disconnect the handpiece cable from the front panel by pulling back the locking collar on the connector to disengage it from the control unit. Do not disconnect the cable from the handpiece.
3. Place the protective cap on the connector end of the cable.
4. Set the suction control lever to the fully open position.



CLEANING INSTRUCTIONS

NOTE: Perform the following manual or automatic cleaning instructions.

Manual cleaning

1. Set the suction control lever to the fully open position.
Ensure the suction control lever remains open throughout the cleaning process.
2. Under 32-40°C (90-104°F) running tap water, rinse the handpiece to remove all blood and surgical debris. Ensure the water flows out through the device lumen/port when rinsing the open end of the handpiece.

3. Immerse the handpiece in a 32-40°C (90-104°F) pH neutral enzymatic bath diluted per the label instructions and soak for a minimum of 5 minutes up to 10 minutes.
 - Steris Prolystica™™ 2x Concentrate Enzymatic or an equivalent detergent may be used in accordance with its label instructions.
4. While the handpiece is immersed, prime the lumen/port with 30ml of detergent solution to ensure all air is removed.
5. While the handpiece is immersed, scrub the device.
 - With the suction control lever in the open position, insert the brush through the port and scrub the lumen for 30-60 seconds using a 5 mm soft nylon bristle brush.
 - Scrub the opening of the handpiece and inner lumen with a 5 mm brush soft nylon bristle brush for 30-60 seconds. Ensure the brush reaches in-between the inner and outer lumen.
 - Scrub the exterior of the handpiece, including the cable, with a soft nylon bristle general instrument brush for 1-2 minutes.
6. Under 32-40°C (90-104°F) running tap water, rinse the handpiece for 1-2 minutes. Ensure the water flows out through the lumen/port when rinsing the open end of the handpiece.
7. Rinse the handpiece under purified water for 30-60 seconds.
8. Dry the handpiece with medical grade compressed air (20-30 PSI).
9. Inspect the handpiece. If not visually clean, repeat the cleaning process from Step 3.

Automatic Cleaning

1. Set the suction control lever to the fully open position. Ensure the suction control lever remains open throughout the cleaning process.
2. Under 32-40°C (90-104°F) running tap water, rinse the handpiece to remove all blood and surgical debris. Ensure the water flows out through the device lumen/port when rinsing the open end of the handpiece.
3. Under 32-40°C (90-104°F) running tap water, scrub the handpiece:
 - With the suction control lever in the open position, insert the brush through the port and scrub the lumen for 30-60 seconds using a 5 mm soft nylon bristle brush.
 - Scrub the opening of the handpiece and inner lumen with a 5 mm brush soft nylon bristle brush for 30-60 seconds. Ensure the brush reaches in-between the inner and outer lumen.

- Scrub the exterior of the handpiece, including the cable, with a soft nylon bristle general instrument brush for 1-2 minutes.

4. Perform the automatic cleaning cycles, following the recommendations in the table (right):

Note: Attach the handpiece to the washer-disinfector MIS rack or equivalent, if available.

Note: Place the handpiece into the washer-disinfector in a manner that will protect them from unwanted motion or potential mechanical damage during the automatic wash cycle.

Treatment	Time (MM:SS)	Temperature	Chemical
Pre-Wash	01:00	Cold Tap Water	N/A
Wash	03:00	Hot Tap Water [150°F / 66°C]	Mild alkaline detergent diluted per the label instructions
Rinse	00:15	Hot Tap Water [110°F / 43°C]	N/A
Wash	02:00	Hot Tap Water [150°F / 66°C]	Mild alkaline detergent diluted per the label instructions
Rinse	00:15	Hot Tap Water [110°F / 43°C]	N/A
Thermal Rinse	01:00	Hot Purified Water heated to 180° F (82° C)	N/A
Dry	06:00	High Setting [heated to 194°F/ 90°C]	N/A

Note: neodisher MediClean forte™™ or an equivalent detergent may be used in accordance with its label instructions.

5. Dry the handpiece with medical grade compressed air (20-30 PSI).
6. Inspect the handpiece. If not visually clean, repeat the cleaning process from Step 3.

Pre-sterilization disinfection

(optional)

In facilities that require disinfection before sterilization, the thermal rinse cycle during the automatic cleaning process should be programmed for 1 minute at 90°C / 194°F.

FOR FURTHER INFORMATION

If further information on this product is needed, contact Customer Service at + 877.664.8926, or an authorized representative.