Integra® CUSA® Clarity – Ultrasonic Surgical Aspirator System
Disassembling, Cleaning, and Sterilizing the System

PREFACE

Intended Audience
This cleaning instruction guide and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for cleaning the CUSA® Clarity Ultrasonic Surgical Aspirator System only.

CAUTION Federal (USA) law restricts this device to sale by or on the order of a physician.

Overview
This section describes how to disassemble the system and clean the console, handpiece, and components.

Disassembling the System

Disassembling the Handpiece

1. Remove the irrigation tubing from the clip at the base of the handpiece.
2. Remove the handpiece cable from the aspiration tubing clips.
3. Remove the aspiration tubing from the aspiration port at the base of the handpiece.
4. Remove the irrigation tubing from the Luer fitting on the handpiece flare.

Disassembling the System

CUSA® Clarity Items to Keep and Discard After a Surgical Procedure

<table>
<thead>
<tr>
<th>Keep</th>
<th>Discard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handpiece</td>
<td>Nosecone</td>
</tr>
<tr>
<td>Contamination Guard Flue</td>
<td>Flue</td>
</tr>
<tr>
<td>EUTs (with less than 5 uses)</td>
<td>EUTs (after 5 uses)</td>
</tr>
<tr>
<td>Torque Base</td>
<td>Tip Stylet</td>
</tr>
<tr>
<td>Footswitch</td>
<td>Torque Wrench</td>
</tr>
<tr>
<td>CUSA Quick Connect™ Cartridge and Tubing Set</td>
<td>Torque Canister</td>
</tr>
<tr>
<td>Sterilization Tray</td>
<td>Irrigation Supply</td>
</tr>
<tr>
<td>Specimen Trap (if used)</td>
<td>Single Use Tip</td>
</tr>
</tbody>
</table>

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5. Slide the flue off of the nosecone base along the tip.
6. Twist off the nosecone counter-clockwise until it unlocks.
7. Slide the nosecone off the tip.
8. Place the handpiece on the torque base as shown and make sure that the 2 flat metal sides fit snugly in the metal slot at the end of the base.
9. Hold the handpiece in the base and place the torque wrench (color side towards handpiece) over the tip.
10. Rotate the torque wrench counter-clockwise.
11. Unthread the tip from the handpiece connecting body by turning the tip counter-clockwise by hand.
12. Discard the items (listed in the table in “CUSA® Clarity Items to Keep and Discard After a Surgical Procedure” on page 2) in compliance with hospital policy for contaminated waste.

Disassembling the Console

1. Detach the aspiration tubing from the patient port on the canister.
2. Disconnect the contamination guard tubing from the vacuum port of the canister.
3. Open cartridge door, if necessary press the pinch valve button, and remove the cartridge from the console by sliding it up.
4. Detach the handpiece cable from the console by gently pulling on the handpiece cable connector in the handpiece port on the front of the console.
5. Unplug the power cord from the wall receptacle and the console.
6. Disconnect the footswitch cable connector from the back of the console.
7. Discard the used/contaminated items in compliance with hospital policy for contaminated waste.

NOTE
The contamination guard should not be removed from the console unless it is time to replace it (every six months or when the color changes).

CAUTION
To avoid product damage, always use the torque base to hold the handpiece while using the torque wrench to tighten or loosen the tip. Avoid over torqueing the tip.
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Detaching the Contamination Guard

NOTE  The contamination guard should not be removed from the console unless it is time to replace it (every six months or when the color changes).

1. Detach the handpiece cable from the console by gently pulling on the handpiece cable connector in the handpiece port on the front of the console.
2. Discard the contamination guard in compliance with hospital policy for contaminated waste.

Powering Down the System

Press the Power button on the front of the console. The touchscreen will go dark. Do not unplug power cord until system has powered down.

Cleaning the System

Cleaning the Touchscreen

Make sure the console is unplugged before cleaning it. Clean the touch screen with a lint-free wipe and a cleaner, such as window/glass cleaner, eyeglass cleaner, or a quaternary ammonia disinfectant.

NOTE  Do not wipe the touch screen with a sponge because it may scratch the surface.

NOTE  Never apply cleaner directly to the touch screen.

Cleaning the Console and Cart

1. Unplug the power cord from the wall receptacle and the console.
2. Clean the surface with a lint-free wipe soaked with one of the following:
   • 70% IPA
   • Super Sani-Cloth®
   • Sani-Cloth® Bleach
3. Make sure the surfaces remain visibly wet for a minimum of two (2) minutes, then air dry.
4. Clean the wheels at the base of the system cart to ensure that the four anti-static wheels function correctly.

WARNING  Do not allow fluids to enter the console.

NOTE  Make sure that the surface of the wheels is free from dirt and dust. Make sure that the surface is completely dry before using the system again.

Cleaning the Handpiece, EUT, and Torque Base

The handpiece, extended use tips, and torque base may be cleaned by either the manual cleaning or autowash cycle process prior to sterilization. For Sterilization Parameter, see “Sterilizing the System” on page 8.

Manual Cleaning

1. Use the provided cleaning brush to clean out the internal channels of both the handpiece and tip. Continue to pass the brush through the tip and handpiece until it comes out clean.

NOTE  Make sure to keep the handpiece cable connector dry.

2. Clean the exterior of the handpiece and tip with a lint free cloth soaked with warm water and a non-alkaline detergent.
3. Use the cloth to manually clean the junction where the tip attaches.
4. Rinse the entire handpiece and tip thoroughly with water and dry with a soft cloth.

Autowash Cycle:

Before auto washing, use the provided cleaning brush to thoroughly clean the internal channels of the handpiece and tip. Continue to pass the brush through the tip and handpiece until it comes out clean.

In a Steamco DS50 DRS or equivalent washer/disinfector, perform a prewash cycle of 5 minutes, then clean using a 1% solution of alkaline detergent (Neodisher® MediClean forte or equivalent, final pH between 10.0-11.5) for 10 minutes at 60°C (140°F), disinfect for 10 minutes at 93°C (199.4°F), and dry for 20 minutes.

Cleaning the Footswitch

1. Disconnect the footswitch from the console.
2. Wipe it clean.
3. If the footswitch is contaminated with blood or fluid:
   a. Immerse the footswitch in warm water containing detergent or disinfectant.
   b. Rinse the footswitch with clean water.

NOTE  Make sure to keep the connector dry.

4. Allow the footswitch to drain after rinsing.

Sterilization Tray Cleaning

Use a neutral detergent to clean the tray.

NOTE  Do not clean the sterilizer tray with abrasives. Product damage will result.

NOTE  Product damage may result if you do not follow the instructions described in the cleaning section.

WARNING  Electric Shock Hazard - Always unplug the CUSA Clarity System before cleaning it.

NOTE  The contamination guard should not be removed from the console unless it is time to replace it (every six months or when the color changes).

WARNING  Do not wipe the touch screen with a sponge because it may scratch the surface.

NOTE  Never apply cleaner directly to the touch screen.

CAUTION  Product damage may result if you do not follow the instructions described in the cleaning section.

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WARNING  Do not apply cleaner directly to the touch screen.
Sterilizing the System

Packaging the Handpiece and Components for Sterilization

The handpiece and components need to be packaged for sterilization.

Integra provides a sterilization tray for steam sterilization of the CUSA Clarity handpiece. This tray protects the handpiece during sterilization and during transfer to the sterile field. The handpiece and components must be cleaned prior to sterilization, see “Cleaning the Handpiece, EUT, and Torque Base” on page 6.

Sterilization Tray Layout

1. Handpiece
2. Handpiece Cable Posts
3. Handpiece Connector
4. Nosecone
5. Flue and Stylet
6. Torque Base
7. EUT Slots (3)
8. Lid (Not shown)

Most Common Sterilization Tray Configuration

1. Place the handpiece in the appropriate slot ➀ and align it with the outline on the bottom of the tray.
2. Wrap the handpiece cable around the posts ➋.
3. Place the handpiece connector in the appropriate slot ➂ and align it with the outline on the bottom of the tray.
4. Optional. Place the nosecone in the appropriate slot ➃ and align it with the outline on the bottom of the tray.
5. Optional. Place the flue anywhere on the bottom of the tray.
6. Place the torque base in the appropriate slot ➅ and align it with the outline on the bottom of the tray.
7. Optional. Place the Extended Use Tips (up to 3) in the appropriate slots ➆ and align them with the outline on the bottom of the tray.
8. Put on the lid ➇ on the sterilizer tray.
9. Close and latch the lid.

Sterilization Parameters

The CUSA Clarity handpiece and components must be sterilized with steam.

Sterilization Tray Packaging

The handpiece and components can be packaged in the sterilization tray either:

- Wrapped—Sterilization tray double wrapped in hospital CSR material
- Flash (Unwrapped)—Sterilization tray unwrapped

The cycles below are acceptable for sterilizing the CUSA Clarity handpiece and components:

<table>
<thead>
<tr>
<th>Packaging</th>
<th>Temperature</th>
<th>Type</th>
<th>Time</th>
<th>Dry Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped</td>
<td>132°C (269.6°F)</td>
<td>Prevac</td>
<td>4 min</td>
<td>30 min</td>
</tr>
<tr>
<td></td>
<td>134°C (273.2°F)</td>
<td>Prevac</td>
<td>3 min</td>
<td>30 min</td>
</tr>
<tr>
<td></td>
<td>134°C (273.2°F)</td>
<td>Prevac</td>
<td>18 min</td>
<td>30 min</td>
</tr>
<tr>
<td>Flash (Unwrapped)</td>
<td>Prevac</td>
<td></td>
<td>4 min</td>
<td>None</td>
</tr>
</tbody>
</table>

Sterilizing the Handpiece and Components with Steam

Sterilizing the handpiece with steam depends on the following factors:

- Temperature
- Exposure time
- Population and resistance of resident bioburden
- Method of air removal from the autoclave

Use the validated steam sterilization cycle parameters in these instructions. If you deviate from this recommended method of sterilizing, it is your Health Care Facility’s responsibility to validate the deviation. For sterilizing the handpiece with steam, do not exceed 134°C (273.2°F).

CAUTION Do not use sterilization methods involving temperatures in excess of 134°C (273.2°F) as this may damage the handpiece.
Sterilization of Handpieces and Accessories

You must sterilize the CUSA Clarity handpiece with steam before use. Some of the CUSA Clarity system accessories are sterile, single-use items. Other accessories are reusable. You must sterilize all reusable accessories with steam before use.

The table below describes the sterilization requirements for the handpiece and accessories. For information on the sterilization parameters and sterilization procedure for the handpieces and accessories, see “Assembling the System Prior to Use” on page 6-1.

<table>
<thead>
<tr>
<th>Item</th>
<th>Initially Sterile</th>
<th>Reusable/Requires Sterilization by the User</th>
<th>Validated Number of Sterilizations Cycle</th>
<th>Sterilization Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handpiece</td>
<td>No</td>
<td>Yes</td>
<td>200</td>
<td>Steam</td>
</tr>
<tr>
<td>Torque Base</td>
<td>No</td>
<td>Yes</td>
<td>200</td>
<td>Steam</td>
</tr>
<tr>
<td>Torque Wrench</td>
<td>Yes</td>
<td>No</td>
<td>Single Use</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>CUSA Quick Connect Cartridge and Tubing Set</td>
<td>Yes</td>
<td>No</td>
<td>Single Use</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Single Use Tip Pack (all items)</td>
<td>Yes</td>
<td>No</td>
<td>Single Use - One time prior to use</td>
<td>Steam</td>
</tr>
<tr>
<td>EUT Tip Pack (all items)</td>
<td>No</td>
<td>Tip: Yes</td>
<td>5 (EUT tip only)</td>
<td>Steam</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All other items: No (not reusable; but require sterilization prior to use)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ไหล, สตีท และ นิวเกน - one time prior to use</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**WARNING** Single-use devices are for single patient use only. Do not reprocess or re-use.