



Manufactured by Advanced Bionics

This document details the recommended care, cleaning, sterilization and maintenance processes for the following reusable surgical tools manufactured by Advanced Bionics:

**CI-4509 HiRes Ultra Reusable Surgical Tools Kit**

(includes:)

CI-4331 HiRes Ultra Recess Gauge

CI-4341 HiRes Ultra Coil Gauge

CI-4421 HiRes Ultra BTE Template

**CI-1418 HiRes Ultra Magnet Tool Kit**

(includes:)

CI-4348 HiRes Ultra Magnet Insertion Tool

CI-4349 HiRes Ultra Magnet Pusher Tool

For information on how to use these reusable surgical tools, refer to the surgeon’s manual related to the product/system.

**WARNINGS AND CAUTIONS**

- All tools are supplied unsterilized, therefore, all tools **MUST** be thoroughly cleaned and sterilized prior to use.
- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices, equipment, and cleaning agents.
- Process temperatures should not exceed 145 °C (293 °F) to prevent damage to the tools.

**REPROCESSING GUIDELINES**

**Point of Use:**

- At the point of use and after use, submerge tools in water; this will prevent any contaminate drying on the tools.
- It is recommended that tools be reprocessed as soon as possible after use.

**Preparation for Decontamination**

- Rinse the tools under warm running tap water until visible soil is removed from the tools.

**Cleaning:** *For cleaning, either the manual or automatic method can be used.*

- **Equipment for Cleaning Methods:** soft bristle brush or syringe, ultrasonic unit, washer-disinfector, lint-free cloth, alkaline detergent with pH≥10 - non-abrasive, low-foaming (e.g. Neodisher Mediclean Forte Detergent).

**Manual Processing Steps:**

1. Prepare alkaline detergent per manufacturer’s recommendation using warm tap water.
2. Fully submerge the tools in alkaline detergent solution and soak for three minutes.
3. After three minutes of soaking, brush the tools with the soft bristle brush to remove any debris or soil.
4. Remove the tools from the alkaline detergent solution and rinse under warm running tap water for three minutes.
5. Prepare alkaline detergent per the manufacturer’s recommendation using warm tap water in an ultrasonic unit.
6. Fully submerge the tools in the ultrasonic unit and sonicate for 15 minutes.

**IMPORTANT:** *If using multiple tools, ensure they are not in contact with each other during sonication.*

7. Remove the tools from the ultrasonic unit at the completion of sonication.
8. Rinse the tools with Reverse Osmosis (RO) or Deionization (DI) water for one minute.
9. Dry the tools with lint-free cloth and then visually inspect tools for visual soil. If soil is present, repeat the cleaning process.

**Automatic Processing Steps:**

1. Rinse the tools under warm running tap water until no visible soil is present.
2. A soft bristle brush or syringe maybe used to aid in the rinsing.
3. Place the tools in the washer according to the following parameters:

**Minimum Washer Cycle Parameters**

| Phase    | Recirculation Time (Minutes) | Water Temperature | Detergent          |
|----------|------------------------------|-------------------|--------------------|
| Pre-Wash | 02:00                        | Cold Tap Water    | None               |
| Wash     | 02:00                        | 65.5°C (150°F)    | Alkaline Detergent |
| Rinse    | 01:00                        | 65.5°C (150°F)    | None               |
| Drying   | 15:00                        | 90°C (194°F)      | None               |

4. Dry the tools with a lint-free cloth and then visually inspect the tools for visual soil. If soil is present, repeat the cleaning process.

**Sterilization:**

**Equipment:** Pre-vacuum Sterilizer, Gravity Displacement Sterilizer, CSR wrap

**Processing Steps:**

1. Wrap tools in a double barrier sterilization wrap using the sequential envelope folding technique, and use the following parameters:

Minimum Sterilization Cycle Parameters

| Sterilizer Type      | Temperature   | Dwell Time | Drying     |
|----------------------|---------------|------------|------------|
| Pre-Vacuum           | 132°C (270°F) | 4 minutes  | 15 minutes |
| Gravity Displacement | 134°C (273°F) | 15 minutes | 15 minutes |

**IMPORTANT:** When sterilizing multiple tools, ensure that the sterilizer's maximum load is not exceeded.

**INSPECTION AND MAINTENANCE**

- Carefully examine each instrument(s) to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning process.
- Visually inspect the instrument(s). If any corrosion, discoloration, pitting or cracks are noted during instrument inspection, discard the instrument(s) and contact Advanced Bionics, as the function of the instrument(s) may be compromised.

**STORAGE RECOMMENDATIONS**

It is recommended that you follow the storage process established by the processing facility.

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*The instructions provided above have been validated by Advanced Bionics as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using standard equipment, materials, and personnel in the processing facility to achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. This guide is provided in fulfillment of ANSI/AAMI ST79, ANSI/AAMI ISO 17664 and ANSI/AAMI ISO 15883.*