Aesculap®
Ergoplant micro bone mill

Legend
1 Handle, 1a Plastic handle, 1b Plunger collar, 1c Plunger
2 Threaded ring
3 Milling chamber
4 Stroke
5 Slide bushing
6 Upper shell
7 Screw
8 Epicor
9 Deposit
10 Lower shell
19 Cleaning instrument (optional); Included with bone mill set D10:008, D10:001R (for fine sleeve), D10:11R (for course sleeve), 11a Pedestal, 11b Spatula

Symbols on product and packages

Applicable to
- For item-specific instructions for use and information on material compatibility, see also the Aesculap Extranet at https://extranet.braun.com

Intended use
The Ergoplant micro bone mill is used for the controlled crushing and processing of autologous bone chips. The application of these bone chips provides a solid basis for bone augmentations.

Safe handling and preparation

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

Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience.
Read, follow, and keep the instructions for use.
Use the product only in accordance with its intended use, as intended use.
Remove the transport packaging and clean the new product, either manually or mechanically, prior to its initial sterilization.
Store any new or unused products in a dry, clean, and safe place.
Prior to each use, inspect the product for flaws, breaks, broken, cracked, worn, or fractured components.
Do not use the product if it is damaged or defective. Set aside the product if it is damaged.
Replace any damaged components immediately with original spare parts.

Safe operation

Filling the bone mill
- Remove handle 1.
- Clamp lower shell 10 and upper shell 6 together with one hand.
- Insert bone fragments into milling chamber 3.
- Insert handle 1 with plunger 1c into milling chamber 3 so that the plunger touches the bone fragments.

Milling the bone material
The size and texture of the milling material can be controlled during the milling process by varying the pressure on handle 1.
- Gently turn handle 1 clockwise, applying appropriate pressure.
- Continue milling until plunger collar 1b touches milling chamber 3.

Removing the milled bone material
- Extract handle 1 from milling chamber 3.
- Hold lower shell 10 and unscrew upper shell 6 counterclockwise.
- To prevent milled bone material from dropping out of deposit 9 in lower shell 10: Hold the bone mill upright.
- Carefully wipe the bone material found on sleeve 7 from sleeve 7 using spatula 11b of cleaning instrument 11, and store it in a suitable container.
- Using a plastic tube of cleaning instrument 11, pull the bone material situated in the nozzles of the sleeve 7 through to the lower shell 10.
- Hold sleeve 7 and remove it by applying mild pressure on ejector 8.
- Remove the prepared, implantable bone material from deposit 9 of lower shell 10, using a suitable instrument.

Disassembling
- Remove handle 1 with plunger 1c from milling chamber 3.
- Unscrew threaded ring 2 counterclockwise from upper shell 6.
- Hold lower shell 10 and unscrew upper shell 6 counterclockwise from lower shell.
- Hold sleeve 7 and remove it by applying mild pressure on ejector 8.

Assembling
- Hold lower shell 10 with one hand and insert, with the other hand, sleeve 7 into the sleeve guide of lower shell 10 as far as it will go.
- Screw upper shell 6 clockwise onto lower shell 10 and tighten hand-tight.
- Lightly lubricate sleeve 4 and slide bushing 5 from the outside, using a sterilizable, steam-permeable and tissue-compatible maintenance oil (e.g. STERILUT® oil spray J0900 or STERILUT® I dip lubricant J0998).
- Insert sleeve 4 and slide bushing 5 into upper shell 6 and screw threaded ring 2 clockwise onto upper shell 6 as far as it will go.
- Insert handle 1 with plunger 1c into milling chamber 3 of the sleeve 4.


Validated reprocessing procedure

General safety instructions
Note: Adhere to national statutory regulations, national and international standards and directives, and local, clinical hygiene instructions for sterile processing.

Note: For patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants of CJD, observe the relevant national regulations concerning the reprocessing of products.

Note: Mechanical reprocessing should be favored over manual cleaning as it gives better and more reliable results.

Note: Successful processing of this medical device can only be assured if the processing method is first validated. The operator/sterilization technician is responsible for this.

Note: The recommended chemistry was used for validation.

Note: If there is no final sterilization, a virucidal disinfectant must be used.

Note: For up-to-date information about reprocessing and material compatibility, see also the Aesculap Extranet at https://extranet.braun.com

The validated steam sterilization procedure was carried out in the Aesculap sterile container system.

General information

Brute or affixed surgical residues can make cleaning more difficult or ineffective and lead to corrosion. Therefore the time interval between application and processing should not exceed 6 h; also, neither filling or de-icing temperatures >+10 °C nor floating disinfecting agents (active ingredient: aldehydes, alcohols) should be used.

Excessive measures of neutralizing agents or basic cleaners may result in a chemical attack and/or fading and the laser marking becoming unreadable visually or by machine for stainless steel.

Residues containing chlorine or chlorides e.g. in surgical residues, medicines, saline solutions and in the service water used for cleaning, disinfection and sterilization will cause corrosion damage (shrinking, stress corrosion) and result in the destruction of stainless steel products. These must be removed by rinsing thoroughly with demineralized water and then drying.

Additional drying, if necessary.

Only process chemicals that have been tested and approved (e.g. VHT or FDA approval or CE mark) and which are compatible with the product's materials according to the chemical manufacturers' recommendations may be used for processing the product. All chemical manufacturer's application specifications must be strictly observed. Failure to do so It can result in the following problems:

- Optical changes of materials, e.g. fading or discoloration of titanium or aluminum. For aluminum, the application process only needs to be of pH >8 to cause visible surface changes.
- Material damage such as corrosion, erosion, fracturing, premature aging or swelling.
- Do not use metal cleaning brushes or other abrasives that would damage the product and cause corrosion.
- Further detailed advice on hygienically safe and material-value-preserving reprocessing can be found at www.a-e-i-k.org, link to Publications, Red Brochure – Proper maintenance of instruments.

Disassembling the product before carrying out the reprocessing procedure
- Disassemble the product immediately after use, as described in the respective instructions for use.

Prepare/soak the product at the place of use
- If applicable, rinse non-visible surfaces preferentially with distilled water, with a disposable syringe for example.
- Remove any visible surgical residues to the extent possible with a damp, lint-free cloth.
- Transport the dry product in a sealed water container for cleaning and disinfection within 6 hours.

Preparation before cleaning
- Disassemble the product prior to cleaning, see Disassembling.

Cleaning/disinfection

Product-specific safety notes on the reprocessing procedure

Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures
- Use cleaning and disinfecting agents according to the manufacturer's instructions which
  - are approved for (e.g. aluminum, plastics, high-grade steel),
  - do not attack softeners (e.g. in silicone).
- Observe specifications regarding concentration, temperature and exposure time.
- Do not exceed the maximum permitted cleaning temperature of 55 °C.

- Clean and disinfect microsurgical products mechanically if they can be placed securely in the machine or on the positioning aids.

<table>
<thead>
<tr>
<th>Validated cleaning and disinfection procedure</th>
<th>Specific requirements</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual cleaning with immersion disinfection</td>
<td>20 ml disposable syringe</td>
<td>Chapter Manual cleaning/disinfection and sub-chapter</td>
</tr>
<tr>
<td>Drying agent: Use a link-free cloth or medical compressed air</td>
<td></td>
<td>Chapter Manual cleaning with immersion disinfection</td>
</tr>
<tr>
<td>Manual pre-cleaning with brush and subsequent mechanical alkaline cleaning and thermal disinfection</td>
<td>20 ml disposable syringe</td>
<td>Chapter Mechanical cleaning/Distillation and sub-chapter:</td>
</tr>
<tr>
<td>Place the instrument in a tray that is suitable for cleaning (shaving trimmer in blue spot).</td>
<td></td>
<td>Chapter Manual pre-cleaning with a brush</td>
</tr>
<tr>
<td>Connect components with lumps and channels directly to the rinsing port of the injector cartridge.</td>
<td></td>
<td>Chapter Mechanical alkaline cleaning and thermal disinfecting</td>
</tr>
<tr>
<td>Keep working ends open for cleaning.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Place instruments in the tray with their hinges open.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Manual cleaning/disinfection
- Prior to manual disinfecting, allow water to drain off for a sufficient length of time to prevent dilution of the disinfectant solution.
- After manual cleaning/disinfection, check visible surfaces visually for residues.
- Repeat the cleaning/disinfection process if necessary.

Manual cleaning with immersion disinfection

<table>
<thead>
<tr>
<th>Phase</th>
<th>Step</th>
<th>T (°C/°F)</th>
<th>t [min]</th>
<th>Conc. [%]</th>
<th>Water quality</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Disinfecting cleaning</td>
<td>RT (cold)</td>
<td>&gt;15</td>
<td>2</td>
<td>D-W</td>
<td>Aldehye-free, phenol-free, and QUAT-free concentrate, pH = 9°</td>
</tr>
<tr>
<td>II</td>
<td>Intermediate rinse</td>
<td>RT (cold)</td>
<td>1</td>
<td>-</td>
<td>D-W</td>
<td>-</td>
</tr>
<tr>
<td>III</td>
<td>Disinfection</td>
<td>RT (cold)</td>
<td>15</td>
<td>2</td>
<td>D-W</td>
<td>Aldehye-free, phenol-free, and QUAT-free concentrate, pH = 9°</td>
</tr>
<tr>
<td>IV</td>
<td>Final rinse</td>
<td>RT (cold)</td>
<td>1</td>
<td>-</td>
<td>FD-W</td>
<td>-</td>
</tr>
<tr>
<td>V</td>
<td>Drying</td>
<td>RT</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

D-W: Drinking water
FD-W: Fully deionized water (demineralized, low microbiological contamination; drinking water at least RT: Room temperature
*Recommended: B.Braun Stabilin

- Note the information on appropriate cleaning brushes and disposable syringes, see Validated cleaning and disinfection procedure.

Phase I
- Fully immerse the product in the cleaning/disinfectant for at least 15 min. Ensure that all accessible surfaces are moistened.
- Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surface.
- If applicable, brush through non-visible surfaces with an appropriate cleaning brush for at least 1 min.
- Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- Thoroughly drain these components with the cleaning disinfectant solution (at least 3 time) using a disposable syringe.

Phase II
- Rinse off the product thoroughly (all accessible surfaces) under running water.
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- Drain any remaining water fully.

Phase III
- Fully immerse the product in the disinfectant solution.
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
- Rinse lumen at least 3 times at the beginning of the exposure time using an appropriate disposable syringe ensuring that all accessible surfaces are moistened.

Phase IV
- Rinse off the product thoroughly (all accessible surfaces).
- Mobilize non-rigid components, such as set screws, joints, etc. during final rinse.
- Rinse lumen with an appropriate disposable syringe at least 5 times.
- Drain any remaining water fully.

Phase V
- Dry the product in the drying phase with suitable equipment (e.g. cloth, compressed air), see Validated cleaning and disinfection procedure.

Mechanical cleaning/disinfection with manual pre-cleaning

- The cleaning and disinfection device must be of tested and approved effectiveness (e.g. FDA approved or CE mark according to DIN EN ISO 11140).

- The cleaning and disinfection device used for processing must be serviced and checked at regular intervals.

Manual pre-cleaning with a brush

<table>
<thead>
<tr>
<th>Phase</th>
<th>Step</th>
<th>T (°C/°F)</th>
<th>t [min]</th>
<th>Conc. [%]</th>
<th>Water quality</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Disinfecting cleaning</td>
<td>RT (cold)</td>
<td>&gt;15</td>
<td>2</td>
<td>D-W</td>
<td>Aldehye-free, phenol-free, and QUAT-free concentrate, pH = 9°</td>
</tr>
<tr>
<td>II</td>
<td>Rinsing</td>
<td>RT (cold)</td>
<td>1</td>
<td>-</td>
<td>D-W</td>
<td>-</td>
</tr>
</tbody>
</table>

D-W: Drinking water
RT: Room temperature
*Recommended: B.Braun Stabilin

- Note the information on appropriate cleaning brushes and disposable syringes, see Validated cleaning and disinfection procedure.

Phase I
- Fully immerse the product in the cleaning/disinfectant for at least 15 min. Ensure that all accessible surfaces are moistened.
- Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surface.
- If applicable, brush through non-visible surfaces with an appropriate cleaning brush for at least 1 min.
- Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- Thoroughly drain these components with the cleaning disinfectant solution (at least 3 time) using a disposable syringe.

Phase II
- Rinse off the product thoroughly (all accessible surfaces) under running water.
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.

Mechanical alkaline cleaning and thermal disinfecting

<table>
<thead>
<tr>
<th>Phase</th>
<th>Step</th>
<th>T (°C/°F)</th>
<th>t [min]</th>
<th>Water quality</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Pre rinse</td>
<td>&lt;25°/77°</td>
<td>3</td>
<td>D-W</td>
<td>-</td>
</tr>
<tr>
<td>II</td>
<td>Cleaning</td>
<td>50°/122°</td>
<td>10</td>
<td>FD-W</td>
<td>-</td>
</tr>
<tr>
<td>III</td>
<td>Intermediate rinse</td>
<td>&gt;10°/50°</td>
<td>1</td>
<td>FD-W</td>
<td>-</td>
</tr>
<tr>
<td>IV</td>
<td>Thermal disinfecting</td>
<td>90°/194°</td>
<td>5</td>
<td>FD-W</td>
<td>-</td>
</tr>
<tr>
<td>V</td>
<td>Drying</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

D-W: Drinking water
FD-W: Fully deionized water (demineralized, low microbiological contamination; drinking water at least RT: Room temperature
*Recommended: B.Braun HeliMail Cleaner alkaline

- Check visible surfaces for residues after mechanical cleaning/disinfecting.

Inspection, maintenance and checks

CAUTION Damage (metal fatigue/fit retention corrosion) to the product caused by insufficient lubrication
- Prior to function checks, lubricate moving parts (e.g. joints, push components and threaded rods) with maintenance oil suitable for the respective sterilization process (e.g. for steam sterilization: Aesculap STERILITI® I all spray J00600 or STERILITI® I dry lubricant J00868).

- Allow the product to cool down to room temperature.
- After each complete cleaning, disinfecting and drying cycle, check that the instrument is dry, clean, operational, and free of damage (e.g. broken instrument or corroded, loose, bent, broken, cracked, worn, or fractured components).
- Dry the product if it is wet or damp.
- Repeated cleaning and disinfection of products that still show impurities or contamination.
- Check that the product functions correctly.
- Immediately put aside damaged or defective products and send them to Aesculap Technical Service, see Technical Service.
- Assemble dismantled products, see Assembling.
- Check for compatibility with associated products.

Packaging
- Place the product in its holder or on a suitable tray. Ensure that all cutting edges are protected.
- Pack tray appropriately for the intended sterilization process (e.g. sterile Aesculap container).
- Ensure that the packaging provides sufficient protection against recontamination of the product during storage.

Steam sterilization

- The product may only be sterilized when dismantled.
- Prior to function checks, lubricate moving parts (e.g. joints, push components and threaded rods) with maintenance oil suitable for the respective sterilization process (e.g. for steam sterilization: Aesculap STERILITI® I all spray J00600 or STERILITI® I dry lubricant J00868).

- Sterilization may be accomplished by a standard preheating cycle in a steam autoclave.
- To achieve a sterility assurance level of 10^-6, Aesculap recommends the following parameters:

<p>| Aesculap Orga Tray/Sterile container (perforated bottom) Minimum cycle parameters* |</p>
<table>
<thead>
<tr>
<th>Sterilization method</th>
<th>Temp.</th>
<th>Time</th>
<th>Minimum drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure</td>
<td>210°F/105°C</td>
<td>4 min</td>
<td>20 min</td>
</tr>
</tbody>
</table>

* Aesculap has validated the above sterilization cycle and has the data on file. The validation was accomplished in an Aesculap sterile container closed by FDA for the sterilization and storage of these products. Other sterilization cycles may also be suitable, however individual or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques. Use an FDA cleared accessory to maintain sterility after processing, such as a wrap, pouch, etc.

Storage
- Store sterile products in germ-proof packaging, protected from dust, in a dry, dark, temperature-controlled area.
WARNING

Risk of injury and/or malfunction!

Do not modify the product.

For service and repairs, please contact your national B. Braun/Aesculap agency.
Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

Service addresses
Aesculap Technischer Service
Am Aesculap-Park
78532 Tutlingen / Germany
Phone: +49 (7461) 95-1902
Fax: +49 (7461) 16-6621
E-Mail: stt@aesculap.de
Or in the US:
Aesculap Inc.
Attn: Aesculap Technical Services
615 Lambert Pointe Drive
Hazelwood
MO 63042
Aesculap Repair Hotline
Phone: +1 (800) 214-3352
Fax: +1 (314) 885-4420
Other service addresses can be obtained from the address indicated above.

Accessories/Spare parts

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>D8002R</td>
<td>Sieve, fine</td>
</tr>
<tr>
<td>D800GR</td>
<td>Sieve, coarse</td>
</tr>
<tr>
<td>D810R</td>
<td>Cleaning instrument set (fine sieve)</td>
</tr>
<tr>
<td>D811R</td>
<td>Cleaning instrument set (coarse sieve)</td>
</tr>
</tbody>
</table>

Disposal

Adhere to national regulations when disposing of or recycling the product, its components and its packaging!

Distributor in the US/Contact in Canada for product information and complaints

Aesculap Inc,
3773 Corporate Parkway
Limerick, PA, USA
USA
TA-No. 011077  02/16  V5  Änd.-Nr. 54187

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