Instruments For Use In Open Magnetic Resonance Imaging (MRI) Systems

Instructions for use /Technical description
CE marking according to directive 93/42/EEC

These AESCULAP instruments are high-quality products. The following is a description of their proper handling and use. In order to maintain the utility value of these instruments, please read the instructions carefully and keep in a safe place.

1. GENERAL
These instruments are designed for the use in open MRI systems of magnetic field strength < 1.5 Tesla. These instruments may be used without any risk to patients or to theatre staff in or in close proximity to a MRI. Non-ferromagnetic materials have been used as a basic material. In principle, artefacts may occur during MRI scanning due to the use of these materials. It is recommended to remove the instruments from the scanning level prior to scanning. Should this not be feasible, the maximum distance between the instruments and any region to be diagnosed should be ensured. Furthermore the severity of events may be reduced by selection of the different sequences. This should be optimized in individual cases together with the operating (neuro) radiologists and be additionally adapted to your specific surgical environment (i.e. additional monitoring and/or therapeutic devices, etc.).

Warning:
The use of these AESCULAP MRI instruments for any other purposes than scheduled may cause damage to or destruction of the instruments.
The MRI instruments may not be used in a magnetic field strength exceeding 1.5 Tesla.

2. NOTES ON USE
These instructions comprise special guidelines for the application of AESCULAP MRI instruments, yet do not refer to the surgical technique or the use of open MRI systems.

Prior to using the instrument, ensure compliance with appropriate literature relating to techniques, complications and risks.

In order to avoid confusion with other ferromagnetic standard instruments, AESCULAP MRI instruments are marked with \textit{mr-safe, < 1.5 Tesla} or are purple in color for ease of identification, if marking is not possible.

Before each use, examine instrument for correct function and for bent, cracked or worn parts and/or surface defects.

Damaged or defective instruments must not be used!

The materials used are softer than those normally found in surgical instruments for non-magnetic environments. Consequently, instruments may wear faster (i.e. blunting cutting edges or bend) than conventional AESCULAP instruments. Please treat your instruments with care and do not exert excessive force in order to avoid damage to the instruments.

When not in use, store instruments in a dry, clean, protected place.

3. CARE AND HANDLING
The procedures outlined below should be followed to ensure safe handling of biologically contaminated surgical instruments. All instruments must be sterilized before use.
Pre-Cleaning

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments.

Remove gross contaminants with a steady stream of lukewarm/cool water (below 110°F/43°C). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions.

Open jaws of hinged instruments for cleaning. Give special attention to joints and serrations. Instruments having more than one part or piece must be disassembled to expose all surfaces to the cleaning process. Retain all parts to facilitate reassembly.

Separate sharps and delicate surgical instruments. Avoid processing instruments of different metallic composition together.

Keep ebonized instruments separate from other stainless steel instruments to avoid scratches to and removal of the ebonized coating.

Cleaning

Cleaning Precautions

- If appropriate, disassemble surgical instruments prior to cleaning and sterilization.

- Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed two hours soaking in any solution.

- Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

- Microsurgical, plated and delicate instruments should be cleaned chemically or manually and should not be processed in an ultrasonic cleaner. Carefully protect the tips of delicate microsurgical instruments throughout the entire cleaning and sterilization process.

- To preserve the surface coating of ebonized instruments, keep ebonized instruments separate from other instruments and avoid mechanical cleaning and abrasive cleaners as these processes can scratch the surface and remove the surface coating.

- Color anodized aluminum instruments may lose their color through the use of conventional, mechanical treatment processes.
  A. Manual Cleaning
    - Hand wash using a low-sudsing protein dissolving detergent. Follow manufacturers’ directions regarding concentration, temperature, contact time and reuse.
    - Totally immerse instruments during cleaning to prevent aerosolization
    - Use a large syringe or pulsating water jet to thoroughly flush all channels and lumens with cleaning solution to remove debris.
    - Use appropriate-sized, soft nylon brushes to clean the instruments and their parts.

  B. Ultrasonic and Mechanical Cleaning
    - For ultrasonic cleaning, follow manufacturer’s specifications for water level, concentration levels of cleaning agent and temperature.
• When using mechanical washer, make sure all instruments stay properly in place and do not touch or overlap each other. Do not allow ebonized instruments to come in contact with each other or other instruments.

• Always follow the manufacturer's specifications for automatic washer-sterilizers and use a free-rinsing, low-sudsing detergent with a neutral pH (6.0 -8.5). Due to variations in water quality, the type of detergent and its concentration may require adjustment for optimal disinfection and cleaning.

C. Rinsing
• Rinse all instruments thoroughly with tap water, deionized or distilled water to remove all traces of debris and cleansing agents. Make sure all internal lumens and ratchets are thoroughly rinsed.

Decontamination

*Note: The decontamination procedure does not sterilize the instruments. Refer to and process the instruments as outlined in the STERILIZATION section.*

Select a proper product for high-level disinfection such as the glutaraldehyde-family of disinfectant products. Follow the cleaning agent’s recommended directions regarding concentration, temperature, contact time and solution re-use.

Do not use high acid (pH 4 or lower) or high alkaline (pH 10 or higher) products for disinfection, such as bleach and bi-chloride of mercury.

Completely immerse instruments in the disinfecting solution, including all lumens and shafts. Force solution into all areas and cavities.

Thoroughly rinse with distilled water to remove all traces of disinfecting solution.

**USE STERILE WATER ON THE FINAL RINSE.**

Drying

Instruments must be thoroughly dried and all residual moisture must be removed before they are stored. Use a soft, absorbent towel/cloth to dry external surfaces. Compressed air or a 70% alcohol rinse may be used to aid the drying process.

Lubrication / Assembly

Lubrication is essential every time instruments are processed. Special attention should be given to lubrication of joints, box locks, and movable parts. Only lubricate dry instruments.

Do not use mineral oil, petroleum, or silicone-based products. To lubricate box locks and joints, use a non-silicone, water-soluble lubricant prior to sterilization such as Aesculap Instrument Oil, JG598.

Reassemble instruments, as necessary, before assembly into baskets or trays. Inspect instruments for bent tips, pits, cracks, misalignment and corrosion. Remove stained, discolored or damaged instruments. Mechanically test the working parts to verify that each instrument performs correctly. Close instruments with a ratchet lock in the first ratchet position before sterilization to avoid temperature-induced stress cracks in the joints.

4. STERILIZATION

Instruments may be packaged in rigid containers, woven or non-woven materials. Packaging should ensure sterility of instruments until opened for use at the sterile field and permit removal of contents without contamination.
Sterilization of instruments may be accomplished by steam or ethylene oxide (EtO) gas.

Flash sterilization should only be used in special circumstances as determined by the facility's infection control members. Flash sterilization is not recommended for complex, multi-part or lumened instruments.

Surgical instruments may also be placed within an Aesculap rigid sterilization container (STERILCONTAINER™) for processing under generally accepted hospital in-use conditions.

The recommended sterilization parameters are as follows:

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Temperature</th>
<th>Wrapped</th>
<th>STERILCONTAINER™ System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Vacuum</td>
<td>270° -275° F / 132° -135° C</td>
<td>4 minutes</td>
<td>4 minutes (solid or perforated bottom)</td>
</tr>
<tr>
<td>GRAVITY</td>
<td>250° -254° F / 121° -123° C</td>
<td>15 -30 minutes</td>
<td>40 minutes (perforated bottom only)</td>
</tr>
<tr>
<td></td>
<td>270° -275° F / 132° -135° C</td>
<td>10 -25 minutes</td>
<td>30 minutes (perforated bottom only)</td>
</tr>
<tr>
<td>FLASH Pre-vacuum</td>
<td>270° F / 132° C</td>
<td>3 minutes (non-porous items)</td>
<td>Not Recommended</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 minutes (non-porous &amp; porous items)</td>
<td></td>
</tr>
<tr>
<td>Gravity</td>
<td>270° F / 132° C</td>
<td>3 minutes (non-porous items)</td>
<td>Not Recommended</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 minutes (non-porous &amp; porous items)</td>
<td></td>
</tr>
<tr>
<td>Ethylene Oxide (EtO)</td>
<td>127° -135° F / 53° -57° C</td>
<td>Relative Humidity: 70 ± 5%</td>
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<td></td>
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<td>Pressure Set Point: 8.12 psia</td>
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<tr>
<td></td>
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<td>EO Concentration: 725 ± 25 mg/L</td>
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<td>Gas Exposure Time: 105 minutes</td>
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<td></td>
<td></td>
<td>Drying Time: 12 hours at 131° ± 2° F (55° ± 2° C)</td>
<td></td>
</tr>
</tbody>
</table>

The cycle times for wrapped product are based on the recommendations of the AAMI Guidelines ST46 for steam sterilization and ST37 for Flash sterilization. Instruments have also been validated for sterility in a STERILCONTAINER™ System at the above recommended cycle parameters.

WARRANTY
Every product bearing the Aesculap name is guaranteed to be free of defects in workmanship and materials when used normally for its intended surgical purpose. Any Aesculap product delivered from Aesculap, Inc., proving to be defective, will be replaced or repaired, at Aesculap's discretion, at no charge to the customer.

These warranties shall not apply to conditions or defects resulting from, but not limited to: negligence, improper use, improper cleaning and handling, improper opening techniques, unauthorized repair work, caustic or abrasive cleaners, or items modified or customized by the customer at the customer's request.

5. MAINTENANCE AND REPAIR
The blackened surface of ebonized instruments will deteriorate over time; in some instances, ebonized instruments may stain slightly during use and the coating may rub off. These instruments should be returned to the Aesculap
Repair Department for re-ebonization. Allow two to four weeks for processing (or you may schedule your repair order in advance).

If your Aesculap instruments require repair or maintenance, return the instruments in the Aesculap Instrument Repair (A.I.R.) box or other sturdy box with adequate foam, bubbles or other packaging material to protect the instruments. Send the packaged instruments to:

Aesculap, Inc.
615 Lambert Pointe Dr.
Hazelwood, MO 63042
Attn.: Aesculap Technical Services

Instruments returned to Aesculap for repair must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

Products repaired by Aesculap are guaranteed for 90 days to be free of defects in workmanship and parts when used normally for their intended surgical purpose. Any workmanship or parts proving to be defective will be replaced or repaired, at Aesculap's discretion, at no charge to the customer.

Contact your local Aesculap, Inc. representative if you have any questions.

References:

ANSI/AAMI ST46-1993; Good Hospital Practice: Steam sterilization and sterility assurance.
ANSI/AAMI ST41-1992; Good Hospital Practice: Ethylene oxide sterilization and sterility assurance.
ANSI/AAMI ST37-1996; Flash Sterilization: Steam sterilization of patient care items for immediate use.

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