GB  Instructions for use
USA  Hip endoprosthetics instrument set
Symbols on product

<table>
<thead>
<tr>
<th>LEFT</th>
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<td>RIGHT</td>
<td>Right</td>
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<tr>
<td>ANT or Anterior</td>
<td>Anterior</td>
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<tr>
<td>POST or Posterior</td>
<td>Posterior</td>
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<tr>
<td>MED or Medial</td>
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<tr>
<td>LAT or Lateral</td>
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<tr>
<td>TOP</td>
<td>Top</td>
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<td>F or FEM</td>
<td>Femur</td>
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<tr>
<td>SZ or SIZE</td>
<td>Size</td>
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<tr>
<td>S or SMALL</td>
<td>Small</td>
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<tr>
<td>M or MEDIUM</td>
<td>Medium</td>
</tr>
<tr>
<td>L or LARGE</td>
<td>Large</td>
</tr>
<tr>
<td>RESECT</td>
<td>Resection</td>
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</table>

Intended use

This instrument set was specially developed for the initial and revisionary implantation of Aesculap hip endoprostheses. It comprises all the instruments necessary to work, given the indication, on the osseous and soft parts of the hip joint in such a way that an Aesculap hip implant can be inserted.

Safe handling and preparation

CAUTION

Federal law restricts this device to sale by or on order of a physician!

- Use the instrument set with Aesculap implants only.
- Read and follow the instructions for use and keep them in a safe place.
- Use the product only in accordance with professional standards and practices, see intended use.

- Prior to its first sterilization, remove the wedging elements from the new product.
- Prior to its first sterilization, remove the individual packaging from the new product.
- Clean the new product either manually or mechanically prior to the initial sterilization.
- Store any new or unused products in a dry, clean and safe place.
- Inspect the product after each cleaning and disinfecting cycle to be sure it is clean, functioning properly, not damaged, has intact insulation and does not have any loose, bent, 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.
- Prior to each use, inspect the product for: loose, bent, broken, cracked, worn, or fractured components.
- Apply appropriate care when assembling or disassembling instruments.
- Read the operation room manual before using the instrument set, follow the instructions and keep the manual.
- Check the instrument set for completeness and working condition.
- Follow the instruction for use of the hip endoprostheses.

Safe operation

- Read, observe and keep product-specific instructions for use of the individual instruments, if such instructions are provided for the respective product.
- Follow the instructions in the appropriate operation room manual when using the instruments in an operation.
Care and handling

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

➢ Observe specifications with regard to cleaning, disinfecting and sterilizing of instruments with product-specific instructions for use under all circumstances.

After each use
The products can be cleared away in either dry or wet condition.

➢ Whenever possible, clear the products away in dry condition.

➢ Reprocess the contaminated products as soon as possible.

➢ If not cleaned sufficiently in mechanical cleaning, the products should undergo non-fixating pre-wash immediately after use.

➢ Carry out ultrasound cleaning if necessary, provided such treatment is not excluded in the product-specific instructions for use.

➢ Use $\text{H}_2\text{O}_2$ as a cleaning medium, if applicable (procedure, see Manual cleaning, disinfecting).

Manual cleaning, disinfecting

➢ Place the products in a suitable active cleaning disinfectant in such a way that all surfaces, interior surfaces, lumens, and openings are covered. Follow the disinfectant manufacturer’s instructions.

➢ Open the products with hinge.

➢ Disassemble separable products.

➢ After disinfecting chemically, rinse the product thoroughly in plenty of clear running water. Follow the disinfectant manufacturer’s instructions.

➢ Use clear water to rinse off surface contaminations.

➢ Remove encrusted materials with a soft nylon brush and a suitable cleaning agent. Do not use scouring cleaning agents or metal brushes.

➢ Clean lumen, channels and blind holes with soft round plastic brushes of fitting diameter. Use $\text{H}_2\text{O}_2$ as a cleaning medium, if applicable.

➢ Clean jointed instruments in both opened and closed condition.

➢ Move non-demountable adjusting or clamping screws during cleaning, or clean each of them in different positions.

➢ As an alternative to manual cleaning, ultrasound cleaning can be applied if necessary, provided such treatment is not excluded in the product-specific instructions for use.

➢ Use $\text{H}_2\text{O}_2$ as a cleaning medium, if applicable.

➢ Rinse products thoroughly under running water. In doing this make certain that the water flows through every lumen, link and canal and that all blind holes are repeatedly filled and emptied.

➢ Make certain that no tissue and bone residues remain in the cavities.

➢ Carry out intensive final rinse with demineralized water.

➢ Use absorbent, lint-free cloth for manual drying.

➢ Dry lumen and channels with compressed air.

Mechanical cleaning, disinfecting

➢ Reprocess the products using cleaning-optimized, validated processes. Follow the instructions provided by the respective device manufacturer.

➢ For mechanical cleaning, place products on wire baskets appropriate for cleaning (to prevent rinsing blind spots).

➢ Position the products in the basket in such a way that water can flow out of cavities, lumens and openings.

➢ Carry out a final rinse with demineralized water.

➢ Make certain the products are dried sufficiently.

Control

➢ Let products cool down to room temperature.

➢ After the cleaning cycle, inspect surfaces, links, cavities, lumens and openings for visible soiling.

➢ Repeat the cleaning process if there is any residual soiling.

➢ Spray moving parts (e.g. links and other metallic sliding surfaces) with a sterilizable, steam-permeable maintenance oil (e.g. Aesculap Steril oil JG 600 or maintenance oil JG 588).

➢ Check the product after each cleaning and disinfecting cycle to make certain it is: clean, functioning properly, not damaged, has intact insulation and does not have any loose, bent, broken, cracked, worn, or fractured components.

➢ Immediately set aside any damaged products.
Storage
➢ Arrange products in their appropriate baskets, or place them on suitable universal basket trays.
➢ Pack baskets in a way that is appropriate for the sterilization process (e.g., in Aesculap sterile containers).
➢ Make certain the packaging will prevent recontamination of the products reprocessing and reuse.

Sterilization method and parameters
➢ Sterilize with steam, taking note of the following:
  • Sterilization has to be performed in a validated steam sterilization process (e.g., in a sterilizer according to EN 285/ANSI/AAMI/ISO 11134-1993, ANSI/AAMI ST46-1993, validated according to EN 554/ISO 13863).
  • When using a steam sterilizer, make certain that the maximum allowable load according to manufacturers' specifications is not exceeded.
  • Make certain the products are dried sufficiently.

Sterilization for the US market
• Sterilization of the device may be accomplished by steam.
• Aesculap does not recommend the device be sterilized by “Flash” or chemical sterilization.
• Surgical instruments may also be placed within an Aesculap rigid sterilization container (sterile container) for processing under generally accepted hospital in-use conditions.

The recommended sterilization parameters are as follows:

<table>
<thead>
<tr>
<th>sterilization method</th>
<th>Temp.</th>
<th>minimum exposure time (wrapped)</th>
<th>minimum exposure time (in a sterile container system)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum</td>
<td>270–275 °F</td>
<td>4 min</td>
<td>4 min</td>
</tr>
</tbody>
</table>

WARNING for the US market
If this device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of crosscontamination.

Repairs
Service work, repairs or modifications to the product have to be carried out only by persons authorized by Aesculap. Only in this way will warranties and guarantees remain valid.
➢ If any repairs are needed, please send the product to:
  Aesculap Technischer Service
  Am Aesculap-Platz
  78532 Tuttlingen / Germany
  Phone: +49 7461 95-2700
  Fax: +49 7461 16-2887
  E-mail: ats@aesculap.de

Or in the US:
Aesculap Inc.
Attn. Aesculap Technical Services
615 Lambert Pointe Drive
Hazelwood
MO, 63042
Aesculap Repair Hotline
Phone: +1 800 214-3392
Fax: +1 314 895-4420

Other service addresses can be obtained from the address indicated above.

Distributor in the US/Contact in Canada for product information and complaints
Aesculap Inc.
3773 Corporate Parkway
Center Valley, PA 18034
USA
CE-Kennzeichnung gemäß Richtlinie 93/42/EWG
CE marking according to directive 93/42/EEC
Marquage CE conforme à la directive 93/42/CEE
Identificación CE en conformidad con la directiva 93/42/CEE
Marchio CE conforme alla direttiva 93/42/CEE
Simbolo CE, em conformidade com a Directiva 93/42/CEE
CE-certifiers conform richtlijn 93/42/EEG
CE-markering iht. reëlanlegging 93/42/EEC
CE-märkning i enlihet med direktiv 93/42/EEG
93/42/EEC-standardin mukainen CE-hyväksyntä
Ενδεικτής CE σύμφωνα με την Οδηγία 93/42/ΕΕC
CE-označení podle směrnice 93/42/EEHS

Technische Änderungen vorbehalten
Technical alterations reserved
Sous réserve de modifications techniques
Sujeto a modificaciones técnicas
Con riserva di modifiche tecniche
Salvo alteraciones técnicas
Technische wijzigingen voorbehouden
Retten til tekniske ændringer forbeholdes
Vi har forbehold om eventuelle tekniske endringer
Med reservation för eventuella tekniska ändringar
Oikeustekniikasta syntyvät muutokset pidätetään
Επιμελούμαστηκε για τεχνικές αλλαγές
Technické změny vyhrozeny

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Phone +49 7461 95-0
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