Aesculap Spine

$S^4$ Spondylolisthesis Reduction Instrument (SRI)

Instructions for use

$S^4$ Spondylolisthesis Reduction Instrument (SRI)
Legend
1 Cylinder piece
2 Polyaxial screw body
3 Mounting post
4 Outer T-handle
5 Inner T-handle
6 Distraction spindle
7 Articular head of mounting post
8 Distraction spindle nut
9 Tightening keys
10 Reduction lever
11 Positioning screws

Symbols on product

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Explanation</th>
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<tbody>
<tr>
<td>!</td>
<td>Attention, see instructions for use</td>
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</table>

Intended use
The S4 Spondylolisthesis Reduction Instrument (SRI) is used for reduction of spondylolisthesis or dislocated vertebrae in the region of the lumbar spine.

Safe handling and preparation

CAUTION
Federal law restricts this device to sale by or on order of a physician!
The S4 reduction instrument requires the surgeon to have practical experience with spine stabilization systems and a good biomechanical knowledge of the unstable spine. The decision as to whether, and to what extent, reduction is required is dependent on the indication and is the responsibility of the surgeon.
The key to a safe reduction is to utilize carefully controlled force and to limit distraction to no more than physiological disc space height.

The S4 Spondylolisthesis Reduction Instrument should be used exclusively with implants of the Aesculap S4 Spinal System. For specific information about S4 implants and instruments, please contact your Aesculap Sales Representative or Aesculap Inc, Center Valley, directly.

- Read, follow and keep the instructions for use.
- Use the product only in accordance with its intended use, see Intended use.
- Clean the new product 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: loose, bent, broken, cracked, worn or fractured components.
- Do not use the product if it is damaged or defective. Immediately set aside the product if it is found damaged.
- Replace any damaged components immediately with original spare parts.

CAUTION
Trauma to the spinal columns and nerve roots due to incorrect application!
- Monitor under image intensifier control and/or monitor spinal cord!
- Avoid over-distraction or over-reduction!
- Avoid over-tightening the repositioning device to the pedicle screw!
Safe operation

Screw Placement

Note
Screw placement is critical. It is recommended to place the screws parallel in the sagittal plane and to make sure the screws are not too laterally deviated.

- Within the limits of the patient's anatomy, place the screws in the cephalad vertebral body parallel to its superior endplate and as parallel to each other as possible.
- Place the caudal vertebra screws so that they are parallel to the cephalad vertebra screws in both planes (as compared to the standard convergent manner).
- Placement of screws in this way allows for optimal operation of the reduction instrument and provides for easier rod placement.

Preparation

- Remove the break-off tabs from the pedicle screws and assemble the jig.
- Insert the cylinder piece 1 into the tulip of the screw 2 and screw the thread on the mounting post 3 into the thread in the tulip head of the pedicular screw of the vertebra to be repositioned using the outer T-handle 4.
- Insert the inner T-handle 5 to apply counter torque during tightening, see Fig. 1. Do not turn the inner T-handle 5. It is used just to apply counter torque when tightening the outer T-handle 4.
- Position the mounting post 3 on the pedicle screw of the other vertebra as described above.
- Insert the distraction spindles 6 into the articular head 7 of the mounting post. Make sure that the articular heads of the traction spindles are positioned inferiorly, see Fig. 2.

Note
Using the component marked "R" on the patient's right and the component marked "L" on the patient's left will result in placement of the SRI threaded distraction rod lateral to the pedicle screws.
For larger patients this orientation may result in soft tissue impingement on the SRI device.
An alternative technique is to reverse the system by placing the component marked "R" on the left and the component marked "L" on the right.
This will place the threaded distraction rod medial to the pedicle screws and will result in less soft tissue impingement.

Distraction

- Use any standard distracting instrument, such as a cervical lamina spreader, and place it between the screw attachments.
- Slowly spread the SRI device to achieve the desired distraction and then lock the distraction in place with the distraction nut on the threaded distraction spindle.
- Distract the bodies only enough to separate the vertebral bodies as minimally as needed.
- For distraction turn the distraction spindle nuts 8 on both sides in the direction of the articular head, if necessary with the aid of the tightening key 9.

Reduction

- Carry out the reduction (lordosis, kyphosis) by placing both T-handles 4 on the two caudal SRI positioning screws 11 and carefully reduce the spondylolisthesis simultaneously on both sides.
- Monitor the cephalad root tension as the reduction occurs.
- Best results are usually achieved by one or two turns of the positioning screw 11 on alternating sides.
A marked decrease in the root tension will be observed as the spondylolisthesis is being reduced.
**S4 Spondylolisthesis Reduction Instrument (SRI)**

**Fixing the reduction**
- Use an interbody spacer or suitable distractor to hold the position achieved.

**Removing the reduction instrument and final assembly**
- In case of distraction, first release the distraction screw to allow an easy removal of the jig.
- Remove one side of the instrument by unscrewing with the outer T-handle whilst at the same time applying counter torque with the inner T-handle. Do not turn the inner T-handle. It is used just to apply counter torque when tightening the outer T-handle.
- Insert an S4 rod.
- Load the set screw in the screw head and tighten to the specified torque, using the designated instrumentation and as described in the S4 instructions for use TA011187.
- For removing the other side of the device proceed as described above.

**Care and handling**

**Note**
Observe all relevant national regulations and standards concerning reprocessing.

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

**Note**
Up-to-date information on reprocessing can be found on the Aesculap Extranet at www.aesculap-extra.net

**Preparation**
The S4 reduction instrument is delivered unsterile. After removal of packaging, sterilization should be carried out in accordance with the standard clinical specifications.
- Pre-clean product, if necessary.
- Reprocess the product immediately after use.
- Prior to mechanical cleaning and disinfecting, rinse the product thoroughly with running water.
- Completely disassemble the instrument, i.e. remove reduction levers and set screws.
- Carry out non-fixating/NaCl-free pre-cleaning immediately after use.

**Note**
We recommend using ultrasound treatment to clean the jig mounting posts, see Cleaning/Disinfecting.

**Cleaning/Disinfecting**
- Use cleaning/disinfecting agents that are suitable for the product. Always follow the manufacturer’s instructions regarding concentration, temperature and exposure time.
- Avoid encrustation of residues/proteins (e.g. caused by aldehyde/alcohol).
- Only use bactericidal, fungicidal and virucidal disinfecting agents.
- Carry out ultrasound cleaning:
  - as an effective mechanical supplement to manual cleaning/disinfection.
  - to prepare products with encrusted debris for mechanical cleaning/disinfection.
  - as an integrated mechanical support measure for mechanical cleaning/disinfection.
  - as an aftertreatment for products that are still dirty after mechanical cleaning/disinfection.
- Preferably apply thermal disinfecting processes.
- After chemical disinfection, rinse the product thoroughly under running water. Always adhere to the manufacturers’ instructions.
Mechanical cleaning/disinfecting

Pre-cleaning
- Thoroughly pre-rinse under running water.
- Carry out ultrasound treatment.
- Use cleaning brush.
- Carry out the final rinse under running water.

Cleaning
- Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots).
- Ensure that water can flow out of openings.
- Process the product in a cleaning/disinfecting machine. Follow the instructions provided by the manufacturer of the machine.
- Run the processing cycle
  - Use a suitable cleaning/disinfecting agent according to the manufacturer's instructions.
  - Do not exceed the maximum allowable washing temperature of 55 °C.
  - Wash the product for at least 10 min.
  - Neutralize, if necessary.
  - Carry out intermediate rinse for at least 1 min.
  - Carry out intensive final rinse with distilled, demineralized or fully desalinated water.
  - Carry out thermal disinfection: Rinse with distilled, demineralized or fully desalinated water for 10 min at 93 °C.
  - Conclude the program with a drying period of at least 40 min at a temperature not exceeding 110 °C.
- After completion of the mechanical cleaning/disinfecting cycle, inspect surfaces, cavities, lumens and openings for visible debris.
- Carry out additional manual cleaning, if necessary.

Manual cleaning/disinfecting

- Use a suitable cleaning/disinfecting agent according to the manufacturer’s instructions.
- Immerse the product in the cleaning/disinfecting agent in such a way that all surfaces, cavities, lumens and openings are covered.
- After the end of the disinfection period, thoroughly rinse the product under running water. Ensure that water flows through every lumen and channel and all blind holes are repeatedly filled and drained.
- Clean hinged or jointed products in open and closed positions.
- Remove encrusted debris with a soft nylon brush. Do not use harsh cleaning agents or metal brushes.
- Clean lumens, channels and blind holes with soft round plastic brushes of fitting diameter.
- Carry out intensive final rinse with distilled, demineralized or fully desalinated water.
- Inspect surfaces, cavities, lumens and openings for visible debris. If necessary, repeat the cleaning/disinfection process.
- Use a lint-free cloth or a compressed-air gun for drying the product.
- Make certain that lumens, channels and blind holes are dried, too.
Control, care and inspection

**Note**

*Intensive use of the product may lead to normal signs of wear.*

- Allow the product to cool down to room temperature.
- Lightly lubricate moving parts such as hinges and joints with a sterilizable, steam-permeable and tissue-compatible maintenance oil (e.g. Aesculap SERILIT® spray JG600 or maintenance oil JG598).
- After assembly of the individual components, check the instrument for correct functioning, in particular for easy adjustment of the reduction levers.
- After each cleaning and disinfecting cycle, inspect the product to make sure it is: clean, functioning properly, and not damaged (e.g. insulation), and does not have any loose, bent, broken, cracked, worn, or fractured components.
- Check for compatibility with associated products.
- Immediately set aside the product if it is found damaged.

Packaging

- Sort the product into its appropriate storage device or put it on a suitable tray. Make certain that any existing sharp edges are protected. Observe the weight limit for each tray/container.
- Pack wire baskets appropriately for the sterilization process (e.g. in Aesculap sterile containers).
- Pack the product in such a way that the packaging will prevent recontamination of the product in the period between reprocessing and reuse.

Sterilization method and parameters

- Check to make certain that the sterilizing agent will be in contact with all external and internal surfaces (e.g. by opening any valves and faucets).
- Sterilize with steam, observing the following rules: Sterilization must be carried out through a validated steam sterilization process (e.g. in a sterilizer according to EN 285/ANSI/AAMI/ISO 11134–1993, ANSI/AAMI ST46–1993, and validated according to EN ISO 17665 or EN 554/ISO 13683). For the fractionated vacuum process, sterilization has to be carried out with the 134 °C/2 bar program for a minimum holding time of 5 min.
- When sterilizing several products at the same time in one steam sterilizer: Make certain that the maximum load capacity of the steam sterilizer, as specified by the manufacturer, is not exceeded.
Sterilization for the US market

- The product is suitable for steam sterilization.
- 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</th>
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<tbody>
<tr>
<td></td>
<td>Wrapped</td>
<td>In a sterile container</td>
</tr>
<tr>
<td>Pre-vacuum*</td>
<td>270–275 °F</td>
<td>4 min</td>
</tr>
</tbody>
</table>

*Dry time: 20 min

WARNING for the US market

If this device is/was used in a patient with, or suspected of having Creutzfeld-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 cross-contamination!

Storage

- Store processed products under conditions as germ-free as possible, in a dry, dark, cool and dust-protected room.

Technical Service

For service, maintenance or 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

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

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

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CE marking according to directive 93/42/EEC