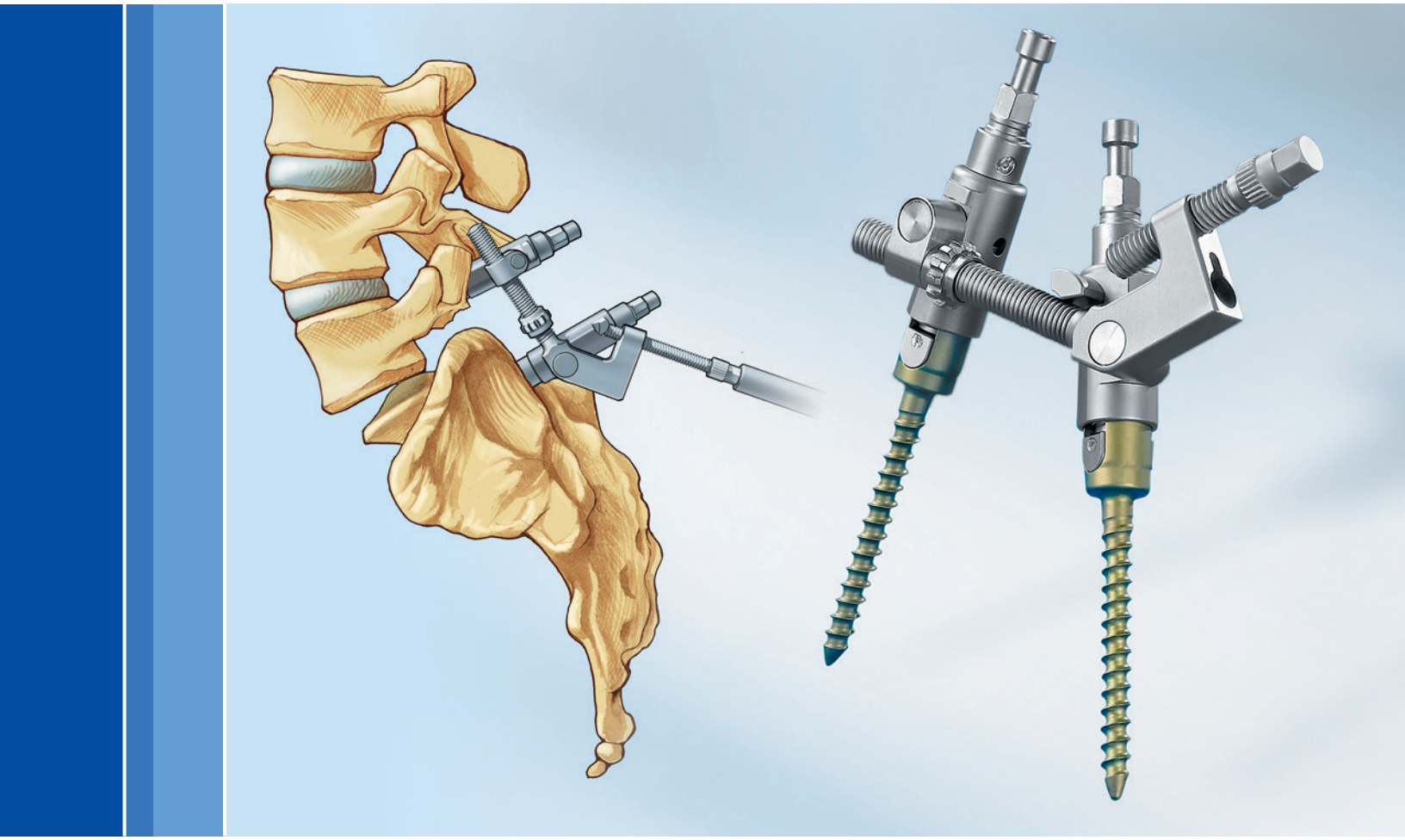
S4® SRI

Spondylolisthesis Reduction Instrument Surgical Technique



Aesculap Spine

AESCULAP®
Implant Systems

S4® SRI

Spondylolisthesis Reduction Instrument Surgical Technique

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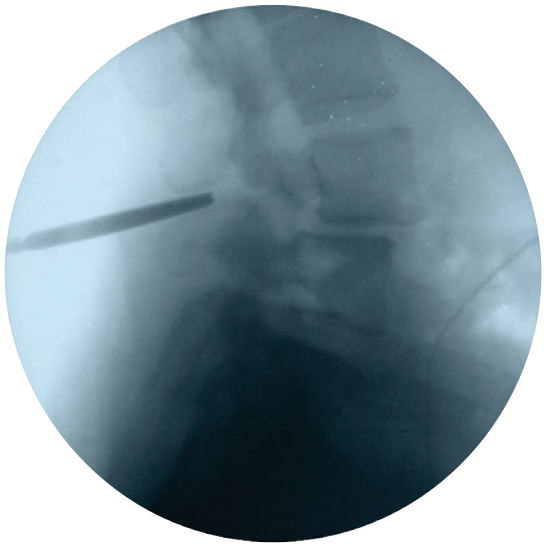
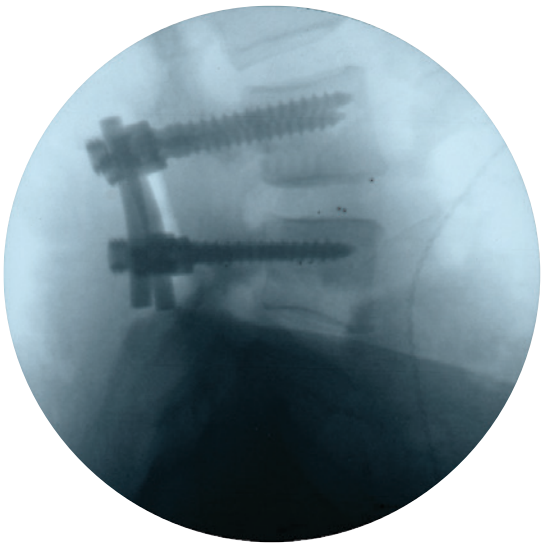
I. Product Overview





A safe reduction utilizing Aesculap's spondylolisthesis reduction instrument and the S⁴ Spinal System with TLIF.

Fig. 1

Main Advantages of the S⁴® Spondylolisthesis Reduction Instrument:

- The unique design of the S⁴ SRI facilitates simultaneous correction of translation and slip angle
- Allows reduction with single-level fusion, sparing adjacent healthy vertebra
- Reduces the listhetic vertebral body along the same curved displacement route, minimizing interference with anatomical structures and eliminating neurologic deficits that typically result from initial over-distraction of an already stretched nerve root
- Enables simultaneous reduction and distraction making it easier to use while reducing overall procedure time
- Reduction maneuver is precise and controlled, reducing risk of inadvertent (unwanted and potentially damaging) movements

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II. Indications for Use, and Cautions

Intications for 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.

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 overreduction!
- ➢ Avoid over-tightening the repositioning device to the pedicle screw!

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.

Safe Operation

Screw Placement

> **Note**
> *Screw placement is critical. It is recommended to place the screws parallel in the saggital 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. 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 patients'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.

II. Indications for Use and Cautions *(continued)*

- 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.

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 5. It is used just to apply counter torque when tightening the outer Thandle 4.
- 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.

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II. Indications for Use and Cautions *(continued)*

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

II. Indications for Use and Cautions *(continued)*

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:

		Minimum Exposure Time	
Sterilization Method	Temp.	Wrapped	In a Sterile Container System
Pre-vacuum	270–275°F	4 min	4 min

*Dry time: 20 min

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 cross-contamination!

Storage

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

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III. Surgical Technique

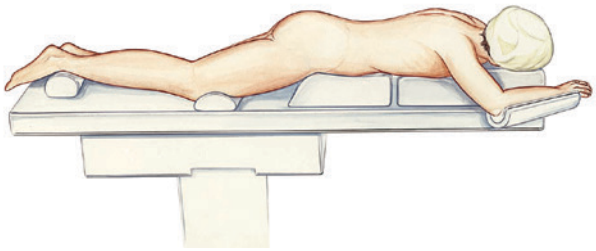

Fig. 2

1. Patient Position and Monitoring

- Position the patient on a radiolucent table for a posterior / dorsal surgical approach (Fig. 2).
- Use of a C-Arm is mandatory to track and monitor vertebral position change and manipulation.

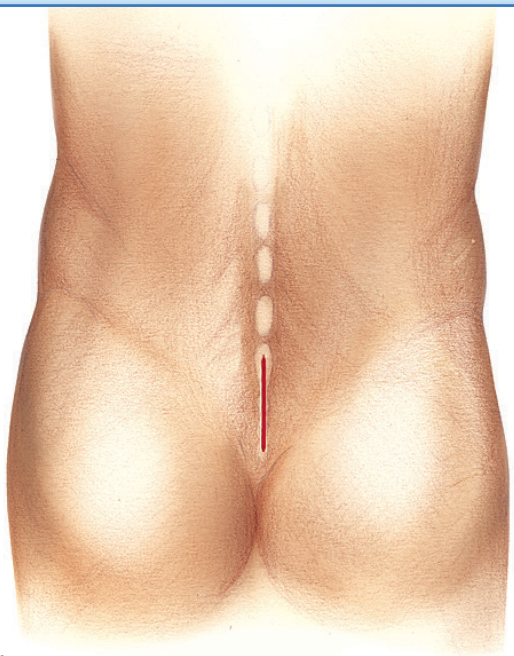

Fig. 3

2. Incision

- The intended skin incision is marked midline (Fig. 3).
- A longitudinal skin incision is made over the spinous processes of the appropriate vertebrae and the fascia and ligaments are incised (Fig. 4).
- Strip muscles away from the spine using standard dissection instruments to reveal boney surface.

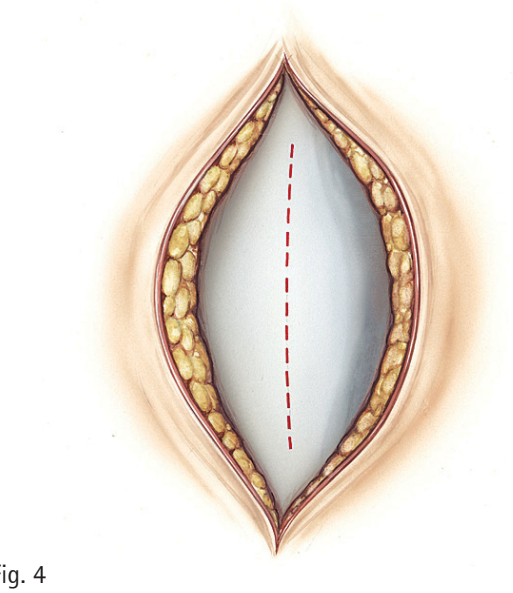

Fig. 4

III. Surgical Technique *(continued)*

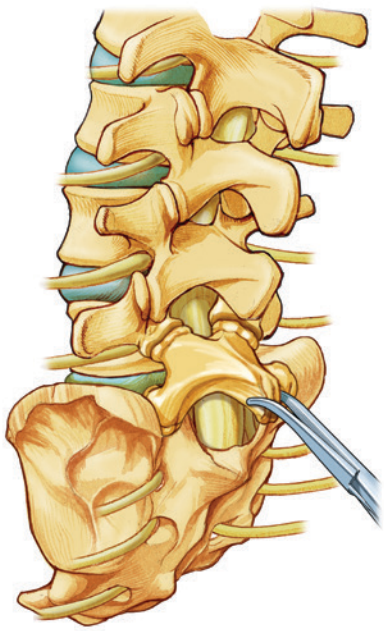

Fig. 5

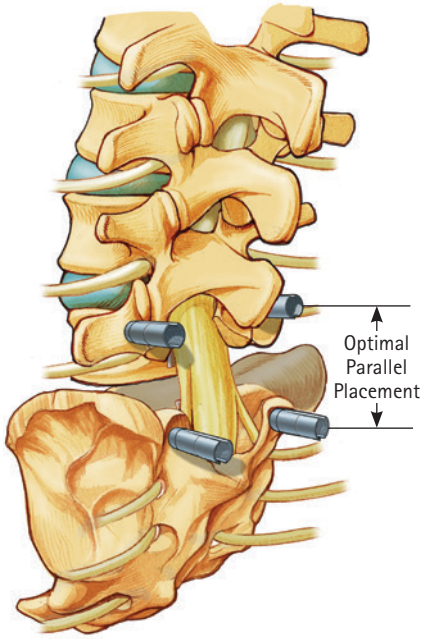

Fig. 6

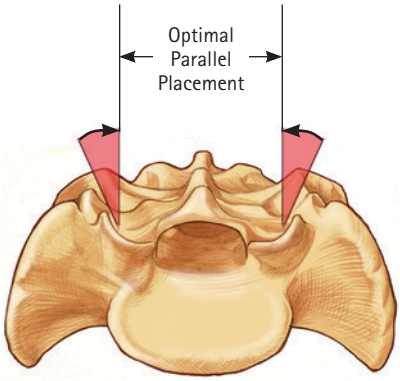

Fig. 7

3. Decompression

- Perform a standard Gill Procedure (Fig. 5). During the decompression, perform a complete resection of the pars interarticularis defects to fully decompress the exiting nerve roots. Also, perform a complete resection of the residual superior articular processes in preparation for the TLIF or PLIF.

4. Screw Placement and Selection

- Within the limits of the patient's anatomy, the screws in the cephalad vertebral body are best placed parallel to its superior endplate and as parallel to each other as possible (Fig. 6 & 7). 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) (Fig. 6 & 7). Placement of screws in this way allows for optimal operation of the reduction instrument and provides for easier rod placement.
- Polyaxial screws should be used in the cephalad vertebra to be repositioned and monoaxial screws should be used in the caudal vertebral body. In the case of an L5/S1 reduction, the chosen length at S1 should achieve bi-cortical purchase.

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III. Surgical Technique *(continued)*

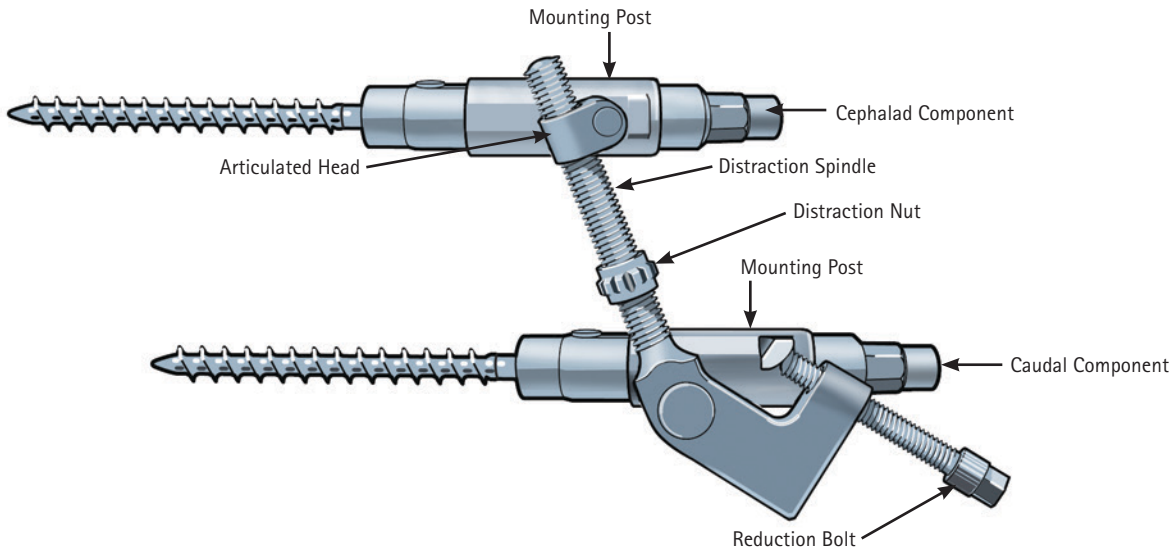

Fig. 8

5. S4® SRI – Application and Use

The instrument (Fig. 8) has two components: a right and a left. Each has two pedicle screw attachments: one attaches to the cephalad vertebral screw that will be repositioned, and the other to the caudal vertebral screw.

Tips & Tricks: *When attaching the S4 SRI, it is not necessary to over-tighten the connection of the instrument to the pedicle screw.*

6. Prior to attaching the instrument

- On the caudal components, make sure the distraction nuts are at a point of minimal distraction (toward the most caudal position of the S4 SRI).
- Also, on the caudal components, make sure the reduction bolts are backed out to the point of minimal reduction.

III. Surgical Technique *(continued)*

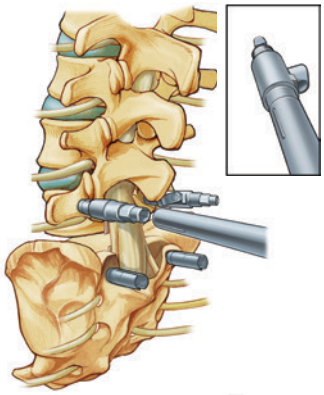

Fig. 9

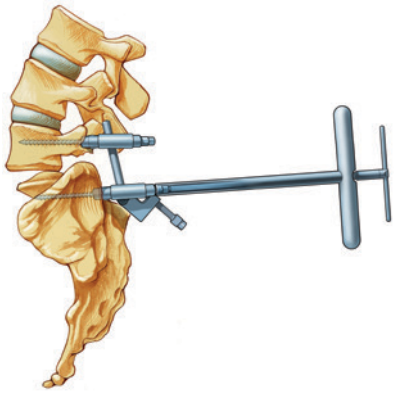

Fig. 10

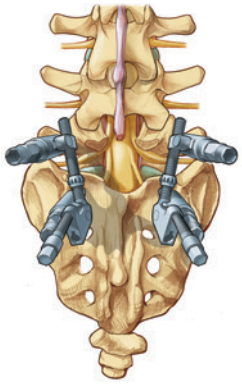

Fig. 11

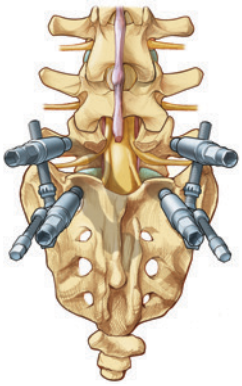

Fig. 11A

7. Attaching the instrument to the pedicle screws

- The caudal components are labeled "R" for right and "L" for left. Following this labeling leads to lateral placement of the reduction instruments (Fig. 11A). Alternatively, the devices can be placed medially to the pedicle screws by putting the right on the left and the left on the right (Fig. 11).
- Attach the cephalad component first (Fig. 8). Insert the mounting post into the tulip of the screw and tighten (Fig. 9) enough to engage *only* 2-3 threads into the screw body. Final tightening will be completed once all four components are in place.
- Ensure that the articulated head (Fig. 8) is positioned inferiorly and insert the distraction spindle (caudal component) into the articulated head of the cephalad component. At the same time, insert the mounting post into the tulip of the pedicle screw of the caudal vertebra and tighten enough to engage *only* 2-3 threads into the screw body.
- Once the instrument is attached and positioned properly, use the t-handles (Fig. 10) to advance the caudal and cephalad components together in an alternating fashion. For final tightening, hold the smaller inner t-handle (FW232R) and use it to apply counter torque while tightening with the larger outer t-handle (FW231R). The mounting post on polyaxial screws should be tightened enough to lock the polyaxial head. The mounting post on monoaxial screws need only be tightened enough to provide a snug fit.

Tips & Tricks: *Medial placement of the reduction instrument is the preferred method because it usually allows for easier reduction and less soft tissue impingement from the device itself. Lateral placement sometimes allows an easier interbody placement, but can make the reduction maneuver more difficult.*

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III. Surgical Technique *(continued)*

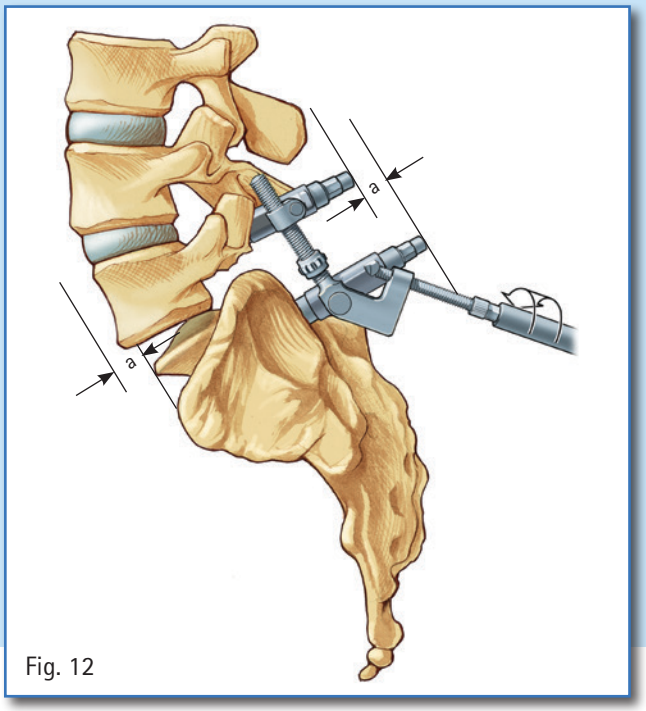

Fig. 12

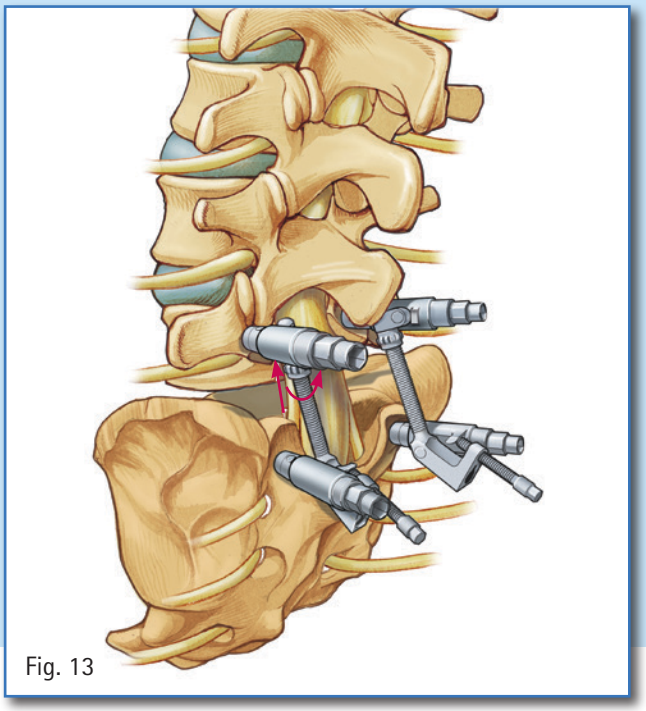

Fig. 13

8. The Reduction process

- Using the large outer t-handle (FW231R) on the reduction bolt, turn clockwise to carefully reduce the spondylolisthesis under C-arm control (Fig. 12).
- Best results are usually achieved by one or two turns of the reduction bolt on alternating sides.
- Monitor the nerve root tension during reduction – typically, a decrease in the nerve root tension will be observed.

9. Distraction

- Using the S4® distractor (FW181R – located in the S4 Spinal System set) slowly spread the S4 SRI device to achieve the desired distraction and then lock the distraction in place with the distraction nut on the threaded distraction spindle (Fig. 13).

Tips & Tricks: *Screw depth should be adjusted to achieve a distance at least equal to the translation of the slip (Fig. 12 Distance a)*

III. Surgical Technique *(continued)*

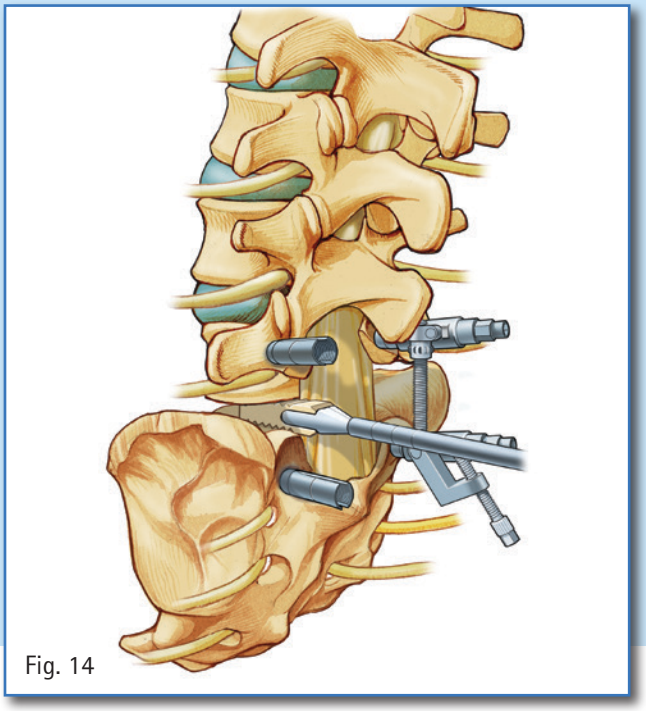

Fig. 14

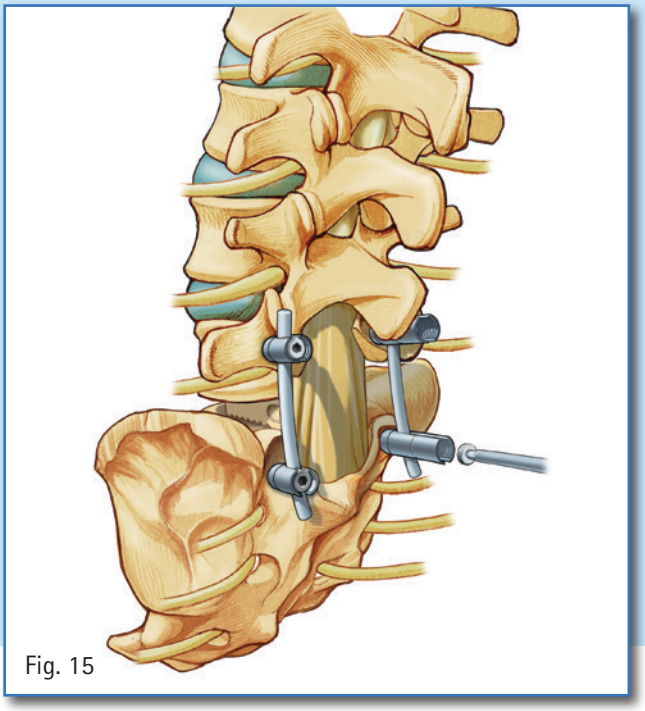

Fig. 15

10. Interbody and Rod Placement

- Using the t-handles and applying counter torque as described in the tightening procedure on page 7, remove the S⁴ SRI from one side (if required to provide room to work) and perform a routine TLIF or PLIF (Fig. 14) with the Aesculap PROSPACE allograft system as outlined in Aesculap DOC478 (TLIF) or DOC414 (PLIF).
- If the S⁴ SRI was not removed from one side during the previous step, remove one side.
- Place the S⁴ rod, and then lock in place with the set screws (Fig. 15) as described in the S⁴ Surgical Technique DOC528.
- Repeat on the contralateral side.

Tips & Tricks: *Overreduction by 2-3 mm allows for the minimal loss of reduction that occurs with graft placement.*

S4® SRI

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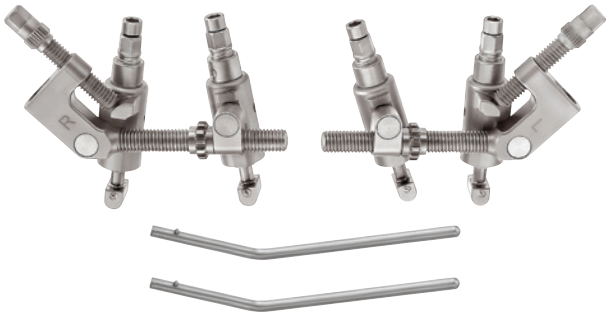
IV. Instrumentation Overview

Item No.	Description	Set Qty.	
FW225R	S4® SRI Spondylolisthesis Reduction Instrument	1	
FW231R	S4 SRI T-Wrench	2	
FW232R	S4 T-Wrench with Hexagonal Chuck	2	
FG322R	Quick-Act Tightening Key/Socon SRI	1	

Note: S4 Implants and Instruments must be used with S4 SRI.

Aesculap Implant Systems, LLC | 3773 Corporate Parkway | Center Valley, PA | 18034
Phone 866-229-3002 | Fax 610-984-9096 | www.aesculapimplantsystems.com

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DOC593 Rev. C 9/17