Aesculap Implant Systems®
SecureSpan™ Laminoplasty System
Implants and Instruments

PRODUCT DESCRIPTION
The Aesculap SecureSpan™ Laminoplasty Plating System consists of the following implants and instruments:
- Plates Single Bend for 4, 6, 8, 10 and 12mm gap
- Ø2.0mm self drilling / self tapping Screws 4, 6, 8, 10 and 12mm length
- Ø2.4mm Emergency Screws 5, 7, 9, 11 and 13mm length
- Ø2.0mm Allograft Screw – round tip
- Allografts 4, 6, 8, 10 and 12mm length
- Screwdriver
- Graftholder
- Lamina Lifter
- Plateholder
- Plate Bender
- Trial Implants 4, 6, 8, 10 and 12mm
- Drills Ø1.1mm 4, 6, 8, 10 and 12mm length
- Depth Gauge
- Assembling Device
- AWl
- Angled Plate holder
- Drill Guide
- Drill for Drill Guide
- Other general instruments (e.g. curettes etc.)

SYMBOLS ON PRODUCT PACKAGES

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<thead>
<tr>
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<th>Caution, General Warning Symbol</th>
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<td>See documentation supplied with the product</td>
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SYSTEM PRECAUTIONS

The testing and regulatory approval of the Aesculap SecureSpan™ Laminoplasty Plating System results from using only Aesculap Implants together with Aesculap instruments. Aesculap Implant Systems cannot be held liable for problems encountered where implants or instruments from other manufacturers is used in combination with the Aesculap products.

PRECAUTION: The SecureSpan™ Laminoplasty Plating System has not been evaluated for safety and compatibility in the MR environment. The Laminoplasty Plating System has not been tested for heating or migration in the MR environment.

Indications
The Aesculap SecureSpan™ Laminoplasty Plating System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Aesculap SecureSpan™ Laminoplasty Plating System holds or buttresses the allograft in place in order to prevent expulsion of the allograft, or impinging on the spinal cord.

Contraindications
The Aesculap SecureSpan™ Laminoplasty System is not to be used:
- For screw attachment or fixation to the posterior elements of the lumbar spine
- For single or two-level spondylosis without developmental spinal canal stenosis.
- Under any direct load bearing conditions.

The Aesculap SecureSpan™ Laminoplasty System is not to be used when the indication is:
- Focal anterior compression
- Isolated radiculopathy
- Loss of anterior column support resulting from tumor, trauma, or infection

The Aesculap SecureSpan™ Laminoplasty System must always be used with:
- Structural allograft

HOW SUPPLIED
All Aesculap SecureSpan™ Laminoplasty Plating System Allograft implants are supplied sterile.
All Aesculap SecureSpan™ Laminoplasty Plating System metal Implants and Instruments are supplied non-sterile and must be cleaned and sterilized prior to each use according to the procedures outlined in this document.

INSPECTION

Before use, inspect the instrument components for possible damage, wear or non-functioning parts. Carefully inspect the critical components (e.g. thread on screwdriver, graft holder clamping jaws, bent drills etc.), inaccessible areas, joints and all movable parts.

Damaged or defective instruments should not be used or processed. Contact your local sales representative or Aesculap Implant Systems, LLC for repair or replacement.

Use caution during cleaning and sterilization. A non-fibrous sponge should be used to wipe off all blood and debris.

Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated instruments.

SAFE HANDLING & PRECAUTIONS

CAUTION

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

- Keep the screwdriver on the screw axis when picking up and inserting the screws – Don’t bend!
- Implants are intended for single use only. After bending the plates, do not bend back.
- Take extreme care not to damage soft tissue / neural structures during implantation.
- To avoid tearing out the screws from the bone or damaging the screws or plates never over tighten.
Ensure that all products and accessories are operated and used only by persons with the requisite training, knowledge, or experience.

Read, follow, and keep the instructions for use.

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 any products if they are damaged or defective. Set aside any damaged products.

Replace any damaged instrument components immediately with original spare parts if available.

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 eliminate the risk of cross-contamination through reprocessing or sterilization.

CLEANING AND DISINFECTION
The procedures outlined below should be followed to ensure safe handling of biologically contaminated surgical instruments. All instruments must be sterilized before use.

1. 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.

Disassemble components to expose all surfaces and clean separately. Disassemble the component parts for the screwdriver, depth gauge and allograft holder and any other instrument with component parts. Give special attention to joints and all parts to facilitate reassembly.

2. CLEANING

Cleaning Precautions

- Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other bodily fluids. Do not exceed two hours soaking in any solution.
- Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

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 cavities with cleaning solution to remove debris.

Use appropriate-sized, soft nylon brushes to clean the instruments and their parts.

Disassembly

Single Drill Guide FG868R

Fig. 1

- Remove guide sleeve 1 by turning it clockwise. Be aware that it is a left-hand thread. You will hear and feel the guide sleeve clicking into position every half turn.

Depth gauge FG866R

Fig. 2

- Loosen knurled nut 7.
- Extract caliper 8 in the direction of the arrow.
- Unscrew and remove knurled nut 7.

Screwdriver FG848R

Fig. 3

- Unscrew locking nut 9 of locking screwdriver C clockwise.
- Slide outer shaft 10 of the distal tip of locking screwdriver C.

Assembly

Single drill guide FG868R

- Insert guide sleeve 1 by turning it counterclockwise.
- Be aware that it is a left-hand thread.
- You will hear and feel the guide sleeve clicking into position every half turn.
- Refer to Fig. 1 above.

Depth gauge FG866R

- Slide knurled nut 7 over the tip of caliper 8.
- Place caliper 8 and knurled nut 7 assembly in outer shaft 6.
- Tighten knurled nut 7.
- Refer to Fig. 2 above.

Screwdriver FG848R

- Slide the out shaft 10 over the distal tip of the inner shaft.
- Tighten locking nut 9.
- Refer to Fig. 3 above.
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.

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, de-ionized or distilled water to remove all traces of debris and cleansing agents. Make sure all internal cavities and ratchets are thoroughly rinsed.

3. 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. 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.

4. 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.

5. LUBRICATION / ASSEMBLY

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

Do not use mineral oil, petroleum, or silicone-based products. To lubricate 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 instrument components for mechanical damage, pits, cracks, misalignment and corrosion.

Remove stained, discolored or damaged instruments. Mechanically test the working parts to verify that each instrument performs correctly.

STERILIZATION

Sterilization of instruments is to be accomplished by steam. Instruments are to be sterilized within their trays, with the implant caddies and the caddy contents sterilized in the separate caddy tray.

The recommended sterilization parameters are as follows:

Preconditioning Pulses: 3

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<th>Sterilization Method</th>
<th>Temperature</th>
<th>Full Cycle Time</th>
<th>Minimum Dry Time</th>
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<tr>
<td>Pre-Vacuum</td>
<td>270°F 132°C</td>
<td>4 minutes</td>
<td>20 minutes</td>
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MAINTENANCE AND REPAIR

Aesculap Repair Hotline
Phone: +1 (800) 214-3392
Fax: +1 (314) 895-4420

If any Aesculap SecureSpan™ Laminoplasty Plating System instrument or its components require repair or maintenance, return the entire instrument set in a sturdy box with adequate foam, bubble wrap or other packaging material to protect it. Send the packaged instrument to:

Aesculap Technical Services
615 Lambert Point
Hazelwood, St. Louis MO 63042

Instruments returned to Aesculap Implant Systems 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.

Aesculap Implant Systems, LLC
3773 Corporate Parkway
Center Valley, PA 18034

SOP-AIS-5000664 Rev. 05 01/18