

Instructions for Aesculap® Implant Systems A-Space SIBD Spinal System



Indications

The A-Space SIBD Spinal System is a stand-alone device intended to be used with the four supplied bone screws if no supplemental fixation is used.

As an intervertebral body fusion device designed for use with autograft, the A-Space SIBD Spinal System is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s).

Patients should be skeletally mature and have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Aesculap® Implant Systems device.

Materials

The materials used in the A-Space SIBD components are listed on the package. The A-Space SIBD spacers are made of PEEK-OPTIMA®. They contain marker pins made of tantalum to ensure radiological visibility for inspecting the implant position. The A-Space SIBD screws are made of titanium alloy (Ti6Al4V).

PEEK-OPTIMA® is a registered trademark of Invibio Ltd, Lancashire, FY5 4QD, UK.

General Surgical Indications

Surgically installed implants serve to support normal healing processes. They should neither replace normal structures of the body nor permanently bear the loads occurring in the case of incomplete healing.

Contraindications

The operation should not be carried out against the following contraindications:

- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the A-Space SIBD devices
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient
- All cases that are not listed under indications

Risks

The surgical intervention involves the following potential risks:

- Neurological complications caused by overdistraction or trauma of the nerve roots or dura
- Loss of intervertebral disk height due to removal of healthy bone material

Complications that can generally occur in connection with intervertebral surgery:

- Pseudarthrosis
- Incorrect implant position
- Spondylolisthesis
- Loss of fixation; dislocation or migration

Side-Effects and Adverse Interactions

None known

Safety Notes

- It is the operating surgeon's responsibility to ensure that the surgical procedure is performed properly.
- General risk factors associated with surgical procedures are not described in the present documentation.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- The operating surgeon must be thoroughly familiar with bone anatomy, including the pathways of nerves, blood vessels, muscles and tendons.
- Aesculap Implant Systems is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- The instructions for use of the individual Aesculap Implant Systems A-Space SIBD components must be observed.
- Do not use damaged or surgically excised components under any circumstances.
- Implants that have already been used must not be reused.
- Delayed healing can cause bone screws to fracture as a result of metal fatigue.
- The implant components applied, along with their article numbers, the name of the implant, as well as the batch number and serial number (if available) must be documented in all patient records.
- During the postoperative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed.

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.

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 implant inserter, trial inserter 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 body 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 medical grade, low-sudsing, protein dissolving detergent. Follow the 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.

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 water, 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, lint-free, 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.

STERILITY

- The PEEK spacers are provided **sterile**. They come individually packed in protective packaging that is labeled according to its contents.
- The PEEK spacers have been sterilized by irradiation (min. dose 25 kGy).
- Store PEEK spacers in their original packaging. Remove them from their original protective packaging only just prior to application.
- Prior to use, check the product expiry date and verify the integrity of the sterile packaging. Do not use PEEK spacers that are past their expiry date or whose packaging is damaged.

STERILIZATION

The A-Space SIBD bone screws and supporting instruments are provided **non sterile** and may be sterilized using the chart below.

Sterilization Method	MINIMUM EXPOSURE TIME		
	Temperature	Full Cycle Time	STERILCONTAINER™ System Minimum Dry Time
Pre-Vacuum	270° - 275° F 132° - 135° C	10 minutes	20 minutes

Note: Time and temperature parameters required for steam sterilization may vary according to the type of sterilizer, cycle design, and packaging/ containerization. The manufacturer's instructions must be followed for each sterilization chamber.

To obtain a Surgical Technique Guide please contact Aesculap Implant Systems Customer Service department at 866-229-3002 or your Sales representative.

Application

The operating surgeon draws up an operating plan that specifies and appropriately documents the following steps:

- Selection of the implant components and their dimensions
- Positioning of the implant components in the bone
- Location of intraoperative landmarks
- The following conditions must be fulfilled prior to application:
 - All requisite implant components are ready to hand
 - Operating conditions are highly aseptic
 - The implantation instruments, including the special Aesculap implant system instruments, are complete and in working condition.
- The operating surgeon and operating team are aware of information concerning the operating technique and the range of implants and associated instruments; this information is complete and ready to hand.
- The operating surgeon is familiar with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant scientific publications by medical authors.
- The manufacturer has been consulted if the preoperative situation was unclear and if implants were found in the area operated on.

- The intervention has been explained to the patient, whose consent concerning the following information has been documented:
- In the case of delayed or incomplete fusion, the implants can break and loosen due to high loads.
- The life-span of the implant may depend on the patient's body weight.
- Corrective surgery may become necessary if the implant loosens.
- The patient must undergo regular check-ups of the implant components, performed by a physician.

Implanting the A-Space SIBD devices

- Select the appropriate A-Space SIBD spacer size and shape according to the indication, the preoperative planning, and the bone situation found intraoperatively.
- Correctly apply the preparation instruments (rasps, curettes and chisels)
- for preparing the implant bed, as well as the implantation instrument.
- Apply appropriate care when inserting the implant.
- Check spacer height and/or angle using the trial spacers.

Further information on B. Braun/Aesculap Implant Systems is always available from B. Braun/Aesculap or the relevant B. Braun/Aesculap agency.

WARNING

Implants supplied in sterile condition must not be resterilized or reused under any circumstances. Danger to the patient and possible loss of implant functionality due to resterilization!

WARNING

If the physician chooses to use fewer than four screws then an additional supplemental spinal fixation system such as the Aesculap® Implant Systems S4 System should be used to augment stability.

WARNING

If less than four screws are used then there is an increased risk of migration due to over-preparation of the vertebral body endplates!

When preparing the implant bed, make certain that the base and cover plates of the adjacent vertebral bodies are not weakened.

WARNING

Prior to screw placement, prepare a pilot hole with a bone awl or drill. Refer to surgical technique for instructions on pilot hole preparation.

WARNING

Risk of tearing glove or injuring surgeon or patient.

- Tip of bone screw is sharp.

WARNING

Risk of compression screw removal failure if revision instrument is not used.

- Locate compression screw, which is to be revised, and engage revision instrument (ME078R).
- Retract the bone screw from the vertebral body by applying an axial distraction force while turning the screw in a counterclockwise motion.
- Repeat the compression bone screw removal process with the remaining compression bone screws in the PEEK cage.

PRECAUTION

The A-Space SIBD Spinal System has not been evaluated for safety and compatibility in the MR environment. The A-Space SIBD Spinal System has not been tested for heating or migration in the MR environment.

PRECAUTION

Based upon fatigue testing results physicians should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

PRECAUTION

Components of the A-Space SIBD Spinal System should not be used with components of any other system or manufacturer.

MAINTENANCE AND REPAIR

If any A-Space SIBD Spinal 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.

**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE
TO SALE BY OR ON THE ORDER OF A PHYSICIAN.****Distributed in the U.S. by:**

Aesculap Implant Systems, LLC.
3773 Corporate Parkway
Center Valley, PA 18034
www.aesculapimplantsystems.com

Phone: 866-229-3002

SOP-AIS-5000643 Rev. 03 05/16