

Instructions for Use AESCULAP Modulift VBR System

CARE AND HANDLING OF IMPLANTS AND INSTRUMENTS

PRODUCT DESCRIPTION

The Modulift VBR System is an adjustable vertebral body replacement device that is implanted into the vertebral body space to improve stability of the spine during fusion. The system is comprised of spacers and foot plates of various heights and sizes to fit the anatomical needs of a wide variety of patients. The device can be adjusted to the required height after implantation. Once it is adjusted to the desired height the column is mechanically locked in place by means of both caudal and cranial locking screws. Each VBR has an axial hole to allow grafting material to be packed inside the device. Spikes on the end of the foot plates improve the anchoring of the implant to the vertebral body. The foot plates of the device are available in various curvature correction angles. Instrumentation is also included in the system.

INDICATIONS

The Modulift VBR System is indicated for use in the cervical spine (C3-C7 vertebral bodies for the small VBR implant) and thoracolumbar spine (T1-L5 vertebral bodies for the small/medium/large VBR implant) in skeletally mature patients for partial or total replacement of a diseased, collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The Modulift VBR System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion. The Modulift VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

The Modulift VBR System is intended to be used with supplemental fixation systems that have been cleared by the FDA. When used in the thoracolumbar spine, the Modulift VBR System is intended for use with supplemental spinal fixation systems such as the Aesculap MACS TL or S4 Systems. When used in the Cervical Spine at one or two levels, the Modulift Vertebral Body Replacement (VBR) System is intended to be used with supplemental fixation systems (i.e., ABC Anterior Cervical System or the Quintex Cervical System). When used at more than two levels in the cervical spine, supplemental fixation should include posterior fixation that has been cleared by FDA (i.e., Aesculap S4 Cervical System).

MATERIALS

The VBR is manufactured from titanium alloy (Ti6Al4V) per ASTM F136 and Cobalt Chrome (CoCr) per ASTM 1537.

WARNINGS

- The potential for success is increased by the proper selection of implant size, shape and design. The VBR should not be expected to withstand the unsupported stresses of full load bearing.

- Ensure that all necessary implants and instruments are on hand and inspected prior to use.
- For implants and instruments that are supplied non-sterile, they must be sterilized prior to use.
- For implants provided in sterile packages, the sterile barrier must be visually assured.
- The Modulift VBR should not be re-used under any circumstances.
- Patients should be advised of the possible limitations of their implant(s), including postoperative mobility and load bearing stress.
- Patient behavior can greatly affect surgical outcomes. Smokers and non-compliant patients should be advised of this fact and warned of the increased risk of potential complications.
- The Modulift VBR is not to be used for interbody fusion.
- Bone grafting material that has been compromised (disease, infection, or used prior to implantation) may not provide adequate support and/or fixation to the device.
- A mal-positioned footplate or implant can lead to dislodgement from the disc space leading to severe patient injury.
- The regulatory approval of the Modulift VBR implants is predicated upon test results using system implants together with system instruments. Aesculap Implant Systems cannot be held liable for problems encountered where implants or instruments from other manufacturers are used in combination with Aesculap products.
- To prevent the risk of collapse, the Modulift VBR must be tightened using both cranial and caudal axial clamping grub screws to the specified tightening torque with instrumentation provided.

PRECAUTIONS

- The Modulift VBR System has not been evaluated for safety and compatibility in the MR environment, nor has it been tested for heating or migration in the MR environment.
- Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
- Mixing of stainless steel implants with unalloyed titanium, titanium alloy, and other cobalt alloy implants should be avoided for implants that are in contact with each other.

CONTRAINDICATIONS

Do not apply in the presence of:

- Fever
- Infection
 - Systemic
 - In the spine
 - Local
- Pregnancy
- Acute osteopenia
- Medical or surgical conditions that could negatively affect the success of the implantation
- Foreign body sensitivity to the implant materials
- Inadequate patient compliance
- Severe osteoporosis or similar loss of bone density
- Severe damage to bone structures that would prevent the stable implantation of system components
- Bone tumor in the region of implant fixation
- Anticipated excessive load on the implant
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism
- System or metabolic diseases
- General poor condition of patient
- Wound healing disorders
- Neuromuscular diseases or disorders

- Mental illness
- Cases not listed under indications

SIDE-EFFECTS AND ADVERSE INTERACTIONS

Implant failure caused by excessive load:

- Warping or bending
- Loosening
- Breakage
- Inadequate fixation
- Dislocation and migration
- Failed or delayed fusion
- Infection
- Vertebral body fracture

Injuries to

- nerve roots
- spinal cord
- blood vessels
- organs

SAFETY NOTES

- It is the operating surgeon's responsibility to ensure that the operative procedure is performed properly.
- General risks associated with surgical procedures are not described in this document.
- 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 the bone anatomy and the pathways of nerves, blood vessels, muscles and tendons.
- The instructions for use of the individual Aesculap implant components must be observed.
- Only combine Aesculap modular implant components with each other.
- Do not use damaged or surgically excised components under any circumstances.
- Implants that have already been used must not be reused.
- To avoid internal stresses and weakening of the implant: avoid scoring or scratching of the implant components.
- Do not bend metal implants.
- The spikes on the footplates are sharp and can cause injury to the patient and / or operative personnel.
- Delayed healing can cause implant components to fracture as a result of metal fatigue.
- Damage to the load-bearing structures of the implant may cause loosening of components, their dislocation and migration, and other severe complications.
- The physician in charge decides whether an implant component implanted should be removed.
- The implant components used in a patient, along with their article numbers, the name of the implant, and 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.

Discectomy and preparation of the vertebral body end plate

- Use standard instruments to remove just enough of the disk so that the trial implant can be inserted into the disk compartment.
- Remove all cartilage from the vertebral body end plates.
- Partial or complete corpectomy of the damaged vertebral body.
- Excessive endplate removal will lead to implant subsidence and migration.
- Inadequate cartilage removal and endplate preparation may delay or prevent fusion.

Verification of implant size

- Select appropriate Modulift VBR implants according to indication, preoperative planning and bone situation found intra-operatively.
- When selecting the Modulift VBR components, consider the size of the vertebral body endplates, the resected space between the vertebral body endplates and the intended distraction distance.
- Use trial implants for implant endplates and bodies to select the Modulift VBR components.
- The height of the trial implants for implant endplates corresponds to the height of the implant endplate with spikes.
- The length of the trial implants for the implant body corresponds to the minimal length of the Modulift VBR with spikes.
- Always use the largest possible trial implant for selecting the implant body.
- Ensure central positioning of the trial implants by applying x-ray monitoring.

Assembling

- Remove the selected implant body and footplates from their packaging or storage tray.
- Install implant body in the correct orientation in its respective hole in the supplied bench block. Note: the markings on the bench block correspond with the desired anatomical orientation of the implant.
- Be careful to assemble the required footplate components onto the VBR body in their correct positions using the footplate assembly tools provided.
- A mal-positioned footplate or implant can lead to dislodgement from the disc space leading to severe patient injury.
- Completely slide together the components until the implant foot-plate snaps into place and fits flush with the implant body.
- Incorrect seating of the implant foot-plate on the VBR body could result in post-operative footplate dislodgement.

Packing with Grafting Material

- The central hole of the implant can be packed with grafting material using the funnel and bone impactors provided.

Implantation

- Couple the insertion instrument to the implant body for positioning the Modulift VBR. Note the position of the end plates relative to the insertion instrument. The bench block markings can be used to assist correct set-up.

Distraction

- Distract the implant body by turning the bevel gear drive in a clockwise direction. The distraction limit is indicated by a line marking on the implant body.
- Note: Attempting to over-distract beyond the limit puts excessive force on the bevel gear, drive instrument and travel limiting pins and can cause serious damage to the implant as well as the instruments.

Locking the implant

- Lock using both cranial and caudal axial clamping grub screws.
- To avoid moments being applied to the spine during locking use the inserter to apply counter torque while tightening both screws to the specified tightening torque.

Refer to the system's Surgical Technique for detailed implantation/explantation information. To obtain a Surgical Technique Guide, please contact Aesculap Implant Systems Customer Service Department at (866) 229-3002 or your Sales Representative.

HOW SUPPLIED - INSTRUMENTS

Instruments are provided non sterile. The instruments must be cleaned and sterilized prior to each use according to the procedures outlined in this document.

INSPECTION

Before use, visually inspect the instrument components for possible damage, wear/tear or non-functioning parts. Carefully inspect the critical components (i.e. tip of set screwdriver, implant inserter etc.), inaccessible areas, joints and all movable parts. Mechanically test the working parts to verify that each instrument functions correctly. Inspect for corrosion, pitting, discoloration, and cracked seals, etc. Remove stained, discolored or damaged instruments.

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

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

Wear appropriate personal protective equipment when handling biologically contaminated instruments.

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 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 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.

HOW SUPPLIED - IMPLANTS

The Modulift VBR system implants are supplied either **non-sterile or sterile**. Non sterile implants must be sterilized prior to each use according to the procedures outlined in this document.

STERILIZATION

Sterile Packed Implants

- The sterile packed implant components come individually packed in protective packaging that is labeled according to its contents.
- The implant components have been sterilized by irradiation (min. dose 25 kGy).
- Store implant components 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 implant components that are past their expiry dates or whose packaging is damaged.

Sterilization of non-sterile implants and Instruments

The VBR implants are for single use only. Sterilization of implants and instruments is to be accomplished by steam autoclave in a standard prevacuum cycle. To achieve a sterility assurance level of 10⁻⁶, Aesculap recommends the following parameters:

Preconditioning Pulses: 3

Sterilization Method	Temperature	MINIMUM EXPOSURE TIME	
		Full Cycle Time SterilContainer™ System	Minimum Dry Time
Pre-Vacuum	270°F	4-minutes	20-30minutes

*The above parameters have been validated for sterility in an Aesculap STERILCONTAINER™ System. The cycle times for wrapped product are based on recommendations of the AAMI guidelines ST79 for steam sterilization.

*Aesculap has validated the above sterilization cycles and has the data on file. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended methods are advised to validate any alternative method using proper laboratory techniques.

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.

If implant becomes contaminated, do not resterilize, reprocess, or reuse.

STORAGE

Once the product is sterilized, it can be stored in the SterilContainer™.

MAINTENANCE AND REPAIR

If any Modulift VBR 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.

AESCLAP
Implant Systems

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