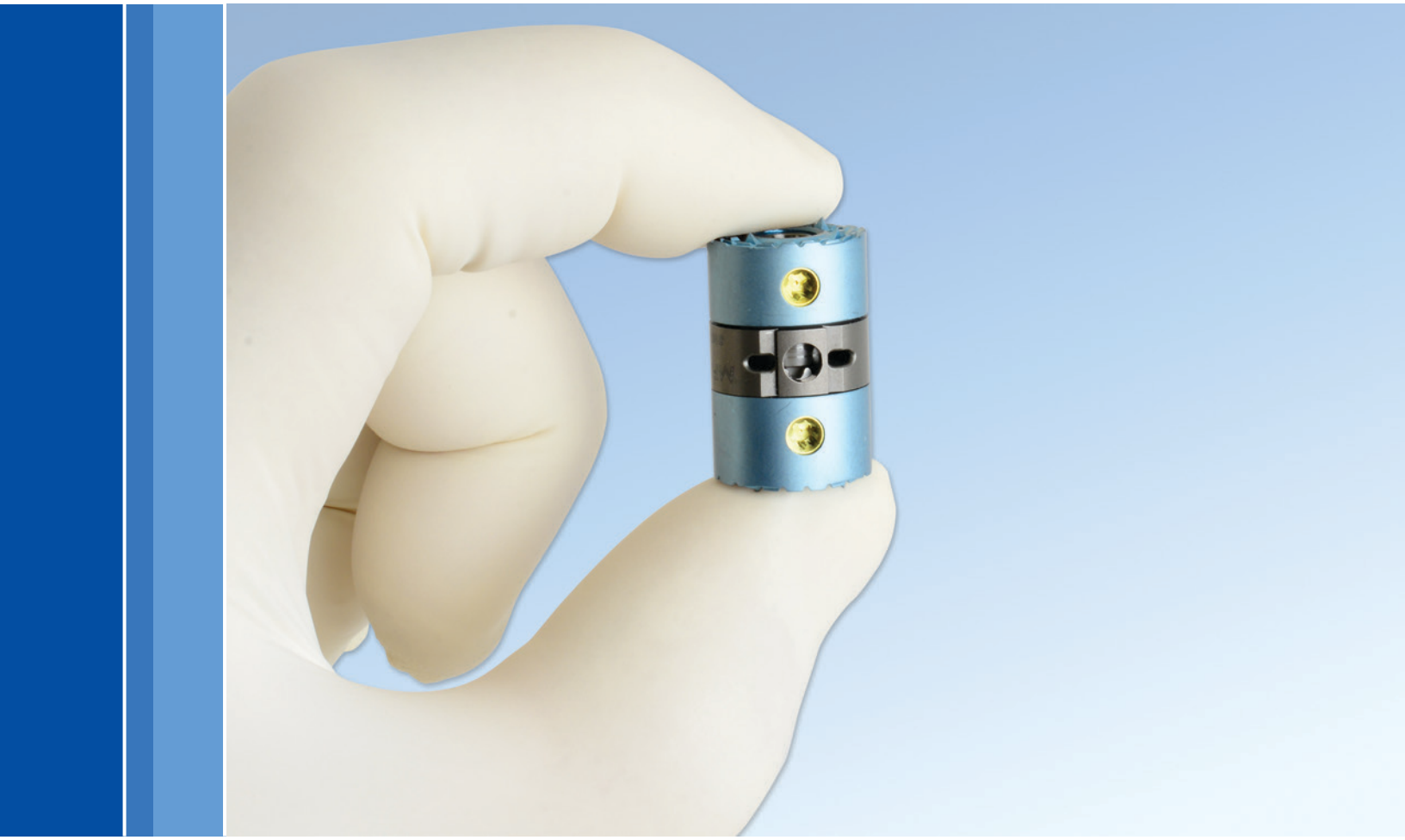
Modulift™ Small Vertebral Body Replacement System

Surgical Technique



Aesculap Spine

AESCULAP®
Implant Systems

Modulift™ Small Vertebral Body Replacement System

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I. Product Overview

Aesculap Implant Systems, LLC is proud to introduce the Modulift™ Small Vertebral Body Replacement System. The Modulift Small VBR is a one-piece device provided sterile. The device expands in both directions by turning the expansion driver clockwise. This engineering breakthrough optimizes tactile feedback and biomechanical restoration to accentuate conditions for a positive bone modeling response.

Our advanced technology includes:

- Aesculap Spines state-of-the–art bevel gear mechanism and patented dual geometry drive handle which provides variability in mechanical advantage and accommodates visualization of both endplates during the critical distraction phase of the corpectomy surgery.
- A one-piece design with built-in set screws and a state-of-the-art instrumentation system that simplifies the Modulift VBR insertion, distraction and locking process
- Initial stability is optimized with spikes and an aggressive waffle pattern. Remodeling occurs into the central hole and fenestrations on the footplate. These important features, combined with the ability to correct sagittal balance, optimize conditions for a positive bone modeling response and stable fusion.
- A one-piece device with 0, 5 and 10 degrees of curvature correction individually packaged sterile for uncompromised patient safety

II. Indications and Contraindications

Indications for Use

The Aesculap Modulift VBR System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e. fracture). The Aesculap Modulift VBR System is intended for use with supplemental spinal fixation systems such as the Aesculap MACS TL® or S4® Systems. The Aesculap Modulift VBR System may be used with bone graft.

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

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III. Precautions and Warnings

Precautions

- The Aesculap 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 on 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.

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 full load bearing - adjunct stabilization is indicated.
- Ensure that all necessary implants and instruments are on hand and inspected prior to use. The Modulift VBR Implants are wrapped sterile.
- For instruments that are supplied non sterile, they must be sterilized prior to use.
- For implants provided in sterile packaging, the sterile barrier must be visually assured.
- The Aesculap 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 Aesculap 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 Aesculap 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 Aesculap Modulift VBR must be tightened using both cranial and caudal axial clamping set screws to the specified tightening torque with instrumentation provided.

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

IV. Component Overview

VBR Components and Terminology

The Modulift™ VBR represents the next generation in expandable cage technology.

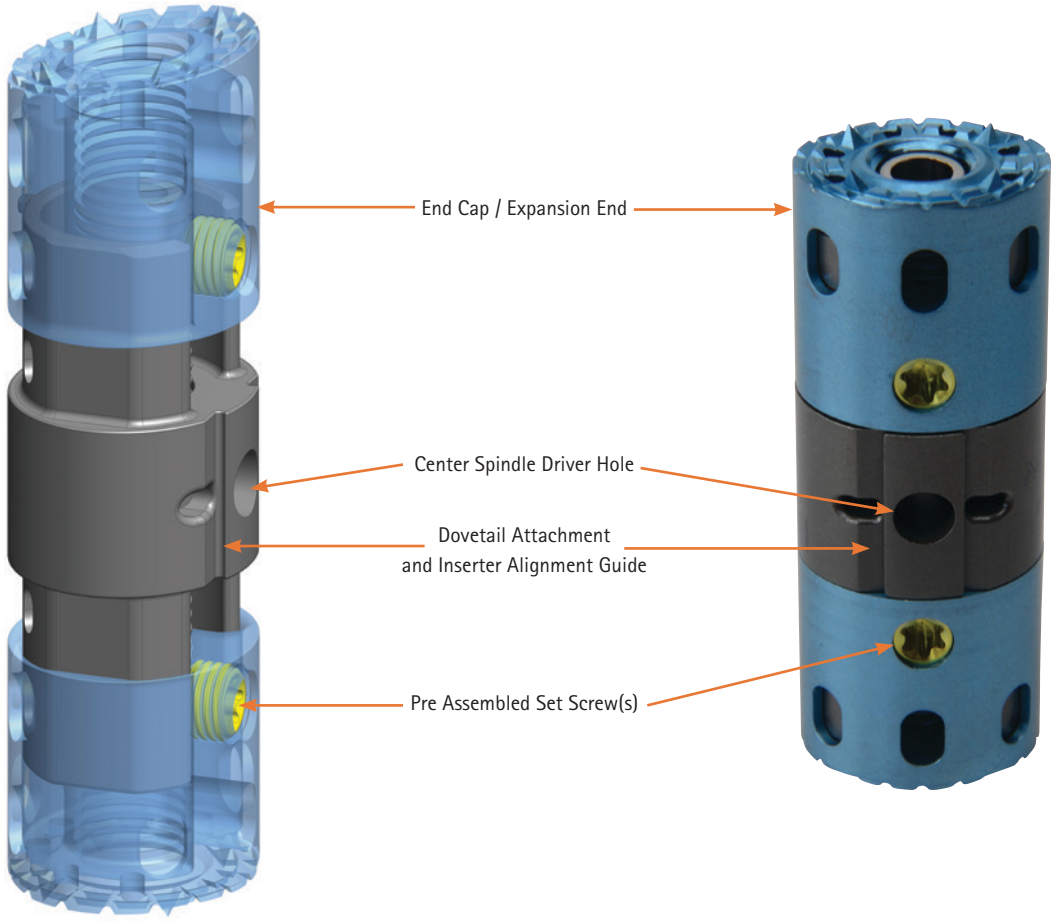

Fig. 1

Modulift™ Small Vertebral Body Replacement System

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V. Surgical Technique

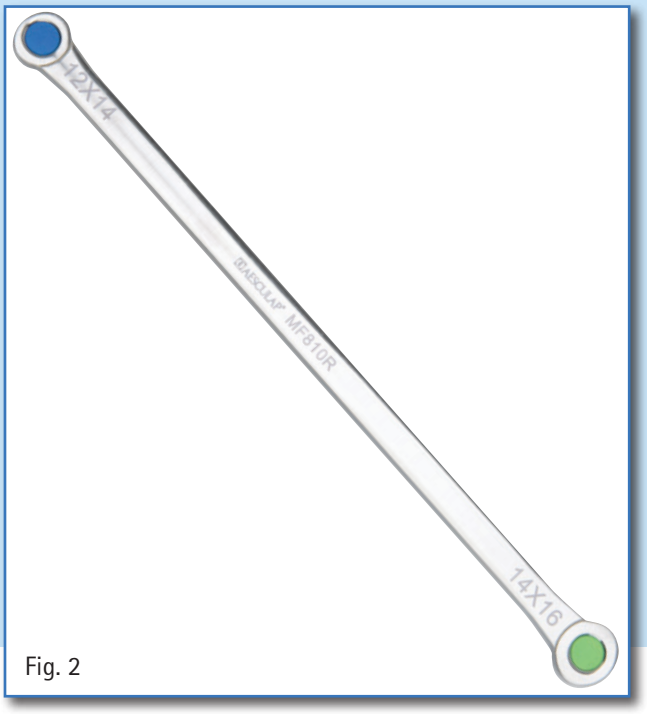


Fig. 2

1. Pre-Operative Planning

Use the appropriate imaging techniques to determine the patient's osseous anatomy, proper size and type of the instrumentation to be used.

Anticipate your needs with pre-operative planning to identify the implant components to be used for the assembly (implant expansion range, footplates). Changes in implant configuration may become necessary based on intra-operative findings and conditions.

2. Patient Positioning & Exposure

- For levels T1 to T3, L5 – Anterior Supine Position

For levels T4 to L4 – Lateral Decubitus Position or Posterior Approach

2a. Perform Corpectomy

To perform the partial corpectomy, mark the edges of the implant bed with a long osteotome. Remove the bone using a rongeur or rasp.

The endplate of both adjacent vertebral bodies should be cleaned with a curette to help ensure a secure bony connection to the implant.

3. Footplate Sizing

Utilize the trial endplate sizer to determine the appropriate implant endplate size, cranially and caudally. Ensure adequate coverage of the vertebral body endplate.

Each Trial Endplate sizer is color coded to match the dimensions of the footplate.

Fig. 3

Note: *Orientation of the footplates to the VBR is provided by matching alignment lines on the endplate and VBR trials.*

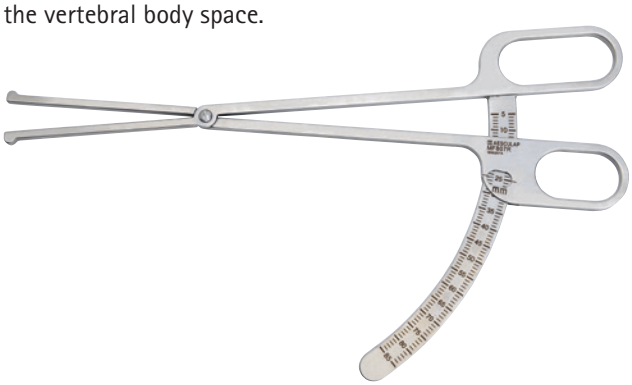
4. Expansion Range Sizing

The trial sizer replicates the collapsed height of the VBR with footplates. Lordotic curvature correction can be determined by using the modular trial footplate attachments.

Assemble the footplates to the body trial sizer by lightly squeezing the body spring mechanism. Use of imaging is recommended at this time to evaluate the anatomy.

The Modulift™ VBR size range incorporates overlap in expansion range capability. It is recommended to avoid selecting a VBR at the end of its expansion range.

Alternatively - a caliper MF807R can be used to measure the vertebral body space.



Item No.	Description
MF810R	Modulift VBR Size Small Foot Plate Sizer
MF811T	Modulift VBR Size Small Trial Implant 19-23 mm
MF812T	Modulift VBR Size Small Trial Implant 21-27 mm
MF813T	Modulift VBR Size Small Trial Implant 25-35 mm
MF814T	Modulift VBR Size Small Trial Implant 30-45 mm
MF815T	Modulift VBR Size Small Trial Implant 38-57 mm
MF816T	Modulift VBR Size Small Trial Implant 48-74 mm
MF808T	Modulift VBR Size Small Trial Implant 34-49 mm

Item No.	Description
MF795T	Modulift VBR Size Small Foot Plate Trial 0°
MF796T	Modulift VBR Size Small Foot Plate Trial 5°
MF797T	Modulift VBR Size Small Foot Plate Trial 10°

Item No.	Description
MF817R	Modulift VBR Size Small Handle for Trial Implant
MF807R	Modulift VBR Size Small/Medium Caliper

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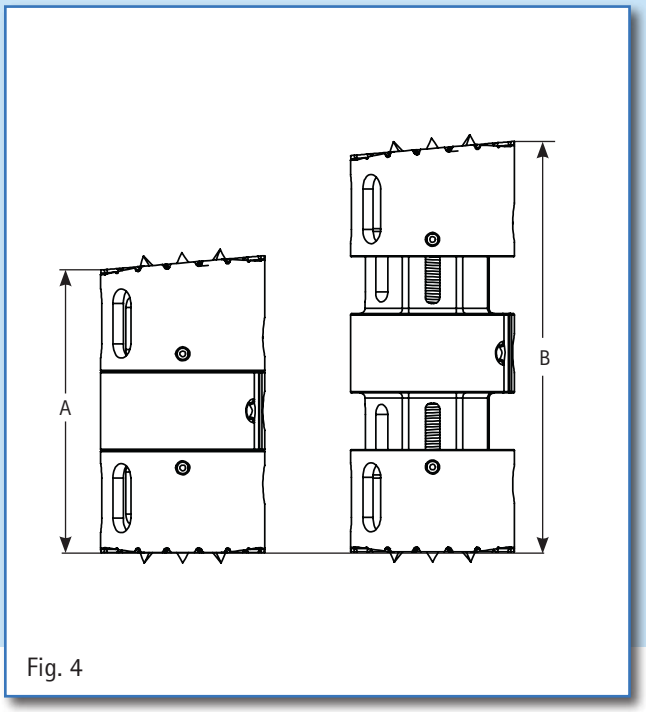

Fig. 4

Based on the preoperative plan and / or endplate size, curvature correction and expansion range needed, select the appropriate VBR.

Curvature Correction footplates add to the vertical dimension of the VBR. See charts below for complete critical dimension information.

Small VBR Critical Dimensions

Small VBR Critical Dimension Information

				Collapsed		Expanded	
Item No.	Description	Item No.	Description	A(mm)	B(mm)	A(mm)	B(mm)
MF617T	Modulift VBR, S, 12x14, 19-23 mm, 0°	MF633T	Modulift VBR, S, 14x16, 19-23 mm, 0°	19		23	
MF618T	Modulift VBR, S, 12x14, 21-27 mm, 0°	MF634T	Modulift VBR, S, 14x16, 21-27 mm, 0°	21		27	
MF619T	Modulift VBR, S, 12x14, 25-35 mm, 0°	MF635T	Modulift VBR, S, 14x16, 25-35 mm, 0°	25		35	
MF620T	Modulift VBR, S, 12x14, 30-45 mm, 0°	MF636T	Modulift VBR, S, 14x16, 30-45 mm, 0°	30		45	
MF622T	Modulift VBR, S, 12x14, 19-23 mm, 5°	MF638T	Modulift VBR, S, 14x16, 19-23 mm, 5°	19	20.1	23	24.1
MF623T	Modulift VBR, S, 12x14, 21-27 mm, 5°	MF639T	Modulift VBR, S, 14x16, 21-27 mm, 5°	21	22.1	27	27.1
MF624T	Modulift VBR, S, 12x14, 25-35 mm, 5°	MF640T	Modulift VBR, S, 14x16, 25-35 mm, 5°	25	26.1	35	36.1
MF625T	Modulift VBR, S, 12x14, 30-45 mm, 5°	MF641T	Modulift VBR, S, 14x16, 30-45 mm, 5°	30	31.1	45	46.1
MF626T	Modulift VBR, S, 12x14, 38-57 mm, 5°	MF642T	Modulift VBR, S, 14x16, 38-57 mm, 5°	38	39.1	57	58.1
MF627T	Modulift VBR, S, 12x14, 48-74 mm, 5°	MF643T	Modulift VBR, S, 14x16, 48-74 mm, 5°	48	49.1	74	75.1
MF629T	Modulift VBR, S, 12x14, 25-35 mm, 10°	MF645T	Modulift VBR, S, 14x16, 25-35 mm, 10°	25	27.2	35	37.2
MF630T	Modulift VBR, S, 12x14, 34-49 mm, 10°	MF646T	Modulift VBR, S, 14x16, 34-49 mm, 10°	34	36.2	49	51.2
MF631T	Modulift VBR, S, 12x14, 48-74 mm, 10°	MF647T	Modulift VBR, S, 14x16, 48-74 mm, 10°	48	50.2	74	76.2

Spike Length (superior to waffle pattern)	1 mm

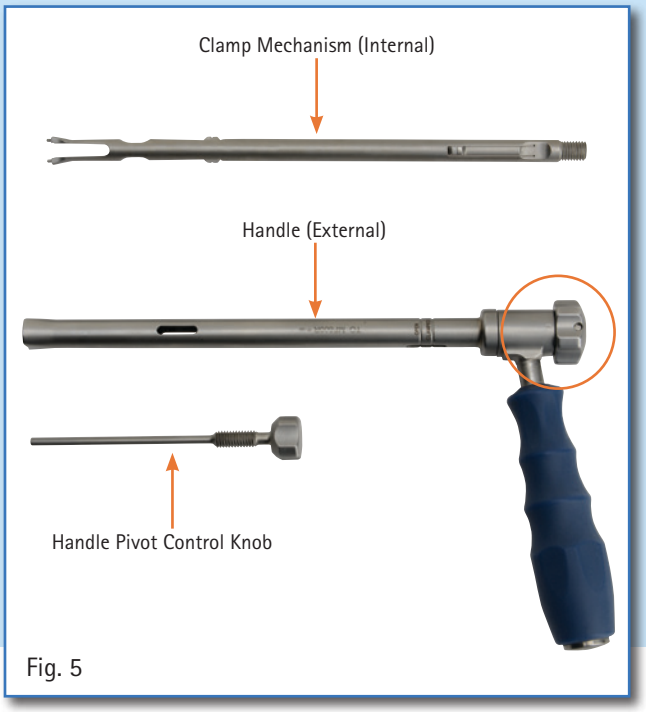

Fig. 5

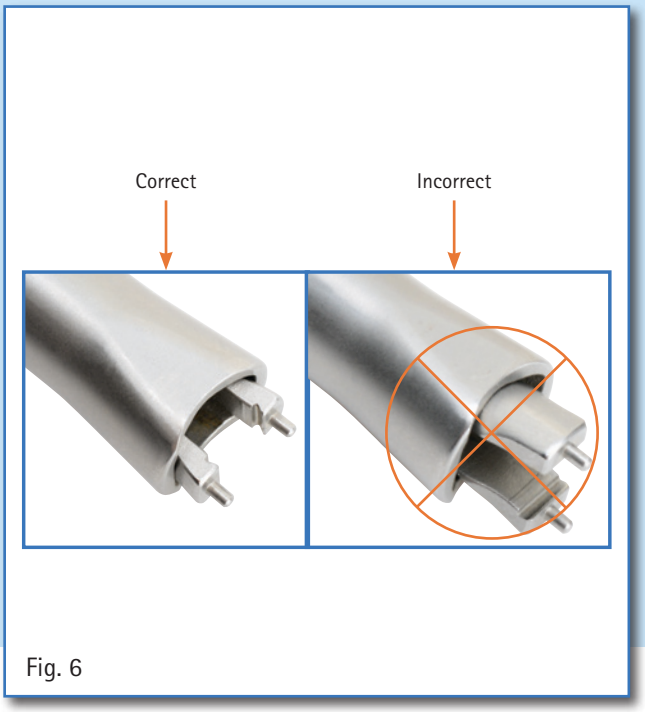

Fig. 6

5. Inserter Assembly

Assemble the three inserter components by inserting the clamp mechanism through the barrel of the handle. Engage the threads of the clamp by turning the thumb (circled above) knob clockwise one or two turns.

The handle pivot control knob allows the handle to rotate 360 degrees around the barrel of the inserter for optimized ergonomics and x-ray image capability.

Note: *The Flat surfaces of the clamp mechanism and barrel of the handle assembly (Fig. 6) must be on the same plane.*

Item No.	Description
MF800R	Modulift™ VBR SZ. S Implant Inserter Handle - Primary (Blue Handle) Clamp Mechanism Handle Pivot Control

Item No.	Description
MF801R	Modulift VBR Size Small Expansion Driver

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Fig. 7

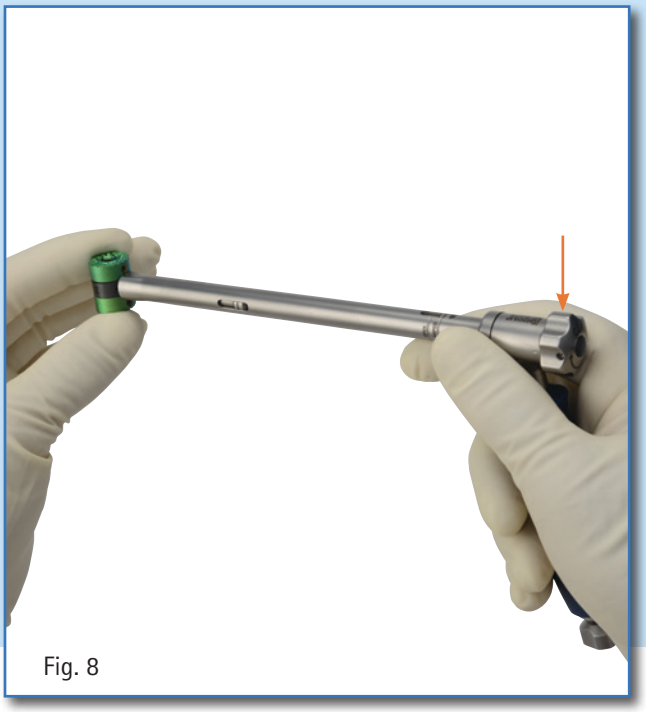

Fig. 8

Attach the insertion handle to the VBR
For proper alignment and expansion function, ensure that the two male ends on the inserter match the female VBR alignment holes.

The clamp mechanism on the inserter should be open enough to grasp the dove tail attachment of the VBR. This will ensure the VBR is in the correct position relative to the clamp and expansion driver function.

Rotate the thumb knob clockwise to close the jaws. Check the security of the attachment. Use the thumb screw and rotate counterclockwise to loosen the jaws.

Caution: *Do not overtighten the clamp mechanism. Finger tighten the thumb knob by turning in clockwise direction to secure the Modulift VBR implant to the insertion handle.*

Fig. 9

By loosening the index knob (circled) you can optimize the ergonomics and image technique by rotating the handle around the barrel of the inserter. Be sure to re-tighten once the optimal handle position is selected.

Fig. 10

6. Bone Packing

Use the graft funnel and graft tamp (MF708R,709R) to add bone substitute to the VBR prior to expansion.

Item No.	Description
MF708R	Modulift™ VBR Size S/M Bone Tamp
MF709R	Modulift VBR Size S/M Graft Funnel
MF809P	Modulift VBR Size S Bench Block

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Note: *A broken line on the expansion body represents 50% expansion. A solid line on the VBR body represents a fully expanded VBR.*

Fig. 11

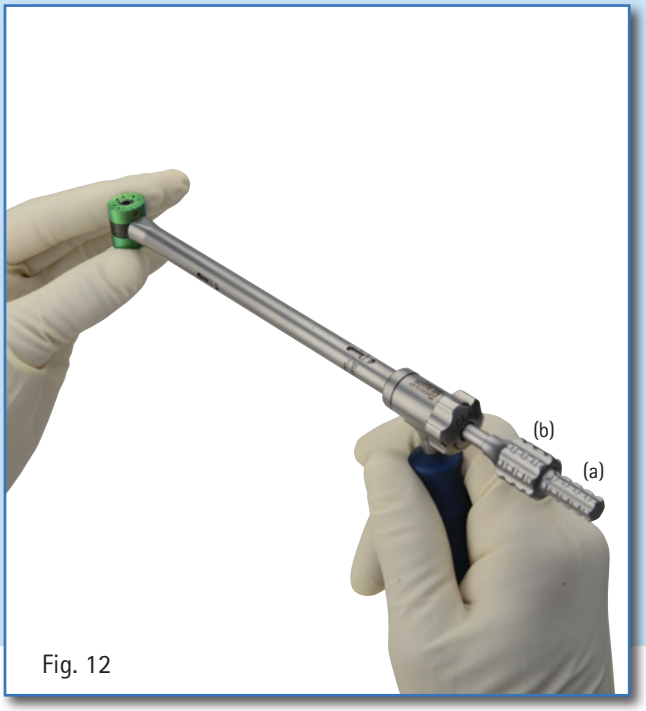

Fig. 12

7. Insertion and Expansion

Carefully slide the expansion driver instrument (MF801R) into the inserter to engage the expansion gear drive located on the internal assembly of the VBR.

There will be an audible click when the expansion driver is properly engaged.

Once the expansion driver is properly engaged with the VBR, rotate the expansion knob **clockwise.** This will ensure the VBR expands as desired. Return the VBR to the collapsed height prior to insertion.

Note: *One full rotation of the expansion driver yields a change in vertical height of 0.4 mm*

Insert the VBR and insure your position is appropriate relative to the patient's anatomic situation, overall stability and bone quality.

Expand the VBR to fit the prepared space.

The dual geometry expansion driver provides a smaller handle (a) for quicker expansion and a larger handle (b) for greater mechanical advantage. Both options provide optional tactile feedback of the spinal anatomy.

Item No.	Description
MF801R	Modulift VBR Size S Expansion Driver

Fig. 13

Once a satisfactory position has been found - commence final expansion under fluoroscopic conditions.

If a less than satisfactory result is achieved, rotate the expansion knob counterclockwise to collapse the VBR in a controlled manner, reposition and re-expand.

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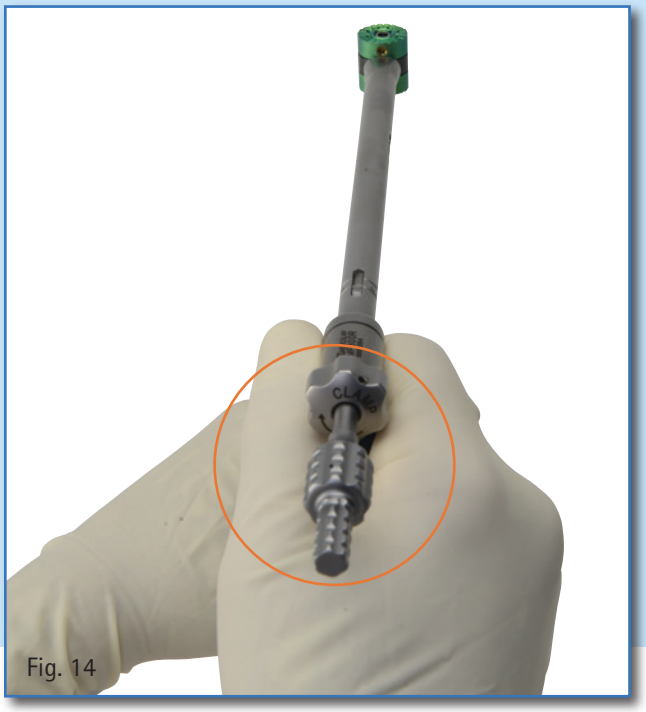

Fig. 14

Fig. 15

8. Final Implant Verification

Once final seating and positioning is confirmed, remove only the expansion driver (circled). The inserter will remain and function as your counter torque.

Lock both set screws utilizing the appropriate torque limited driver. Because of the patented dual-expansion mechanism, two locking screws are provided for added security. The pre-positioned locking screw is already a part of the VBR construct. Use the set screw torque driver to lock the set screws by turning clockwise until the torque limit is reached and the handle clicks. Use the insertion handle for maintaining stability and counter torque.

Item No.	Description
MF802R	Modulift VBR SZ. S Set Screw Driver
MF828R	Modulift VBR SZ.S Torque Limit HDL 1.2NM

Fig. 16

9. Implant Removal

Clear all soft tissue and bony in-growth around the VBR.

For counter torque attach the inserter if possible, then insert the expansion driver.

Unscrew both lock mechanisms with the appropriate set screw removal driver (MF827R).

Rotate the driver counterclockwise to retract the VBR.

Continue removal of all soft tissue and bony in-growth until the VBR is loose and able to be removed with minimal force.

Caution: *Do not remove the VBR by force. Patient injury will occur.*

Item No.	Description
MF827R	Modulift™ VBR SZ. S Set Screw Removal DRV.

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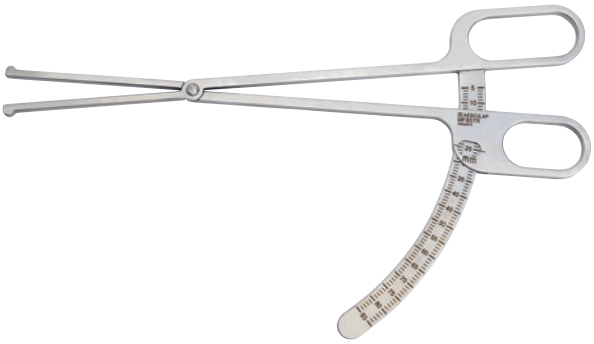
VI. Instrument Overview

Calipers



Item No.	Description	Qty.
MF807R	Modulift VBR Size Small/Medium Caliper	1

Footplate Sizer

Item No.	Description	Qty.
MF810R	Modulift VBR Size Small Footplate Sizer	1

Trial Implants

Modulift Size Small

Item No.	Description	Qty.
MF811T	Modulift VBR Size S Trial Implant 19-23 mm	1
MF812T	Modulift VBR Size S Trial Implant 21-27 mm	1
MF813T	Modulift VBR Size S Trial Implant 25-35 mm	1
MF814T	Modulift VBR Size S Trial Implant 30-45 mm	1
MF815T	Modulift VBR Size S Trial Implant 38-57 mm	1
MF816T	Modulift VBR Size S Trial Implant 48-74 mm	1
MF808T	Modulift VBR Size S Trial Implant 34-49 mm	1

Trial Footplates

Modulift Size Small

Item No.	Description	Qty.
MF795T	Modulift VBR Size S Footplate Trial 0°	1
MF796T	Modulift VBR Size S Footplate Trial 5°	1
MF797T	Modulift VBR Size S Footplate Trial 10°	1

Trial Implant Inserter Handle

Item No.	Description	Qty.
MF817R	Modulift, Small,Trial Handle	2

Implant Inserter

Item No.	Description	Qty.
MF800R	Modulift™ VBR Size Small Implant Inserter	1

Expansion Driver

Item No.	Description	Qty.
MF801R	Modulift VBR Size S Expansion Driver	2

Bench Block

Item No.	Description	Qty.
MF809P	Modulift VBR Size Small Bench Block	1

Bone Tamp

Item No.	Description	Qty.
MF708R	Modulift VBR Size Small/Medium Bone Tamp	1

Graft Funnel

Item No.	Description	Qty.
MF709R	Modulift VBR Size Small/Medium Graft Funnel	1

Set Screw Driver

Item No.	Description	Qty.
MF802R	Modulift VBR Size Small Set Screw Driver	2

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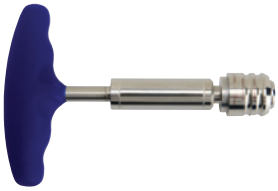
Set Screw Removal Driver

Item No.	Description	Qty.
MF827R	Modulift VBR Size Small Set Screw Removal Driver	1

Torque Limiting Handle



Item No.	Description	Qty.
MF828R	Modulift VBR Size Small Torque Limit Handle 1.2 NM	1

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