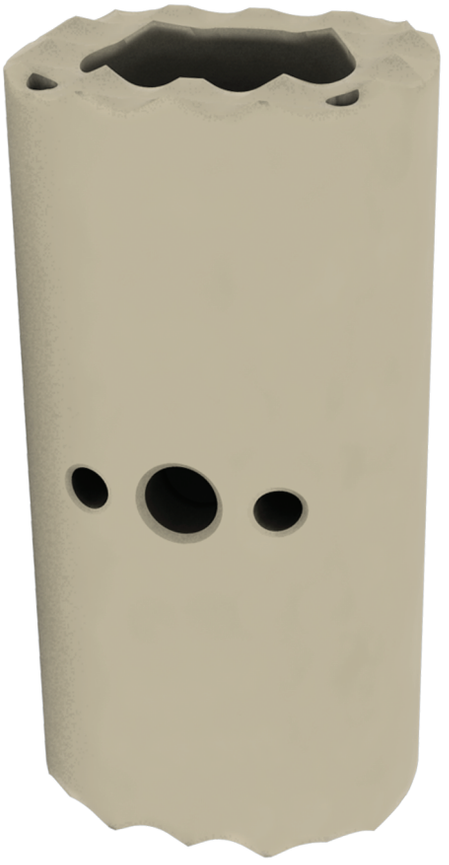
ChoiceSpine™
Propelling Spinal Surgery



HAWKEYE™

Vertebral Body Replacement (VBR)

Surgical Technique

Introduction

The ChoiceSpine HAWKEYE™ Vertebral Body Replacement (VBR) System is intended for use in the thoracolumbar spine (T1 - L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The HAWKEYE™ VBR System is intended for use with supplemental fixation and is to be used with autogenous and/or allogeneic bone graft comprised of cancellous, cortical, and/or corticocancellous bone graft to facilitate fusion.

The implant device is made from radiolucent PEEK and comes in a variety of lengths, widths, heights, and lordotic angles to accommodate most patient anatomies.

The ChoiceSpine HAWKEYE™ VBR System comes with effective instrumentation and a variety of implant options to treat numerous patient conditions.

System Features

- Choice of endplate lordosis: 0° and 6°
- Two footprint options: small and medium to treat various patient anatomies
- Implant sizes: 10-50mm in 1mm increments
- Large center opening for packing bone graft material
- Radiographic markers for implant positioning, verification, and confirmation of the fusion process over time
- Surgeon friendly instrumentation to simplify the procedure

Step 1 Perform Corpectomy

Perform a partial or complete corpectomy at the indicated level (Fig. 1). Remove disc material and decorticate the endplates. A rasp may be used to prepare the endplates if desired.

CAUTION: Avoid excessive preparation of the endplates that may remove cortical bone and weaken them.

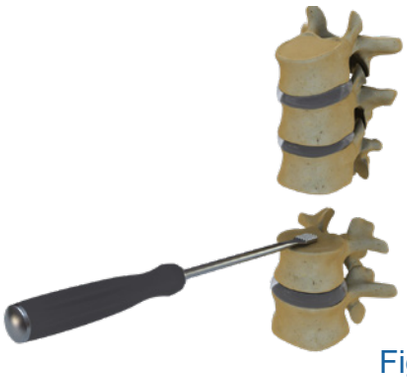


Fig. 1

Step 2 Sizing the Implant Device

The size of the empty space is measured using the caliper (Fig. 2). The height of the defect should be measured from the anterior aspect of the inferior endplate to the anterior aspect of the superior endplate. The surgeon may increase the traction on the back to ensure the proper sizing. Select the appropriate size implant based off the measured distance between the endplates.

Fig. 2

Step 3 Bone Grafting

Before insertion, load the implant with autograft or allograft (Fig. 3).

Bone tamps are provided to assist the surgeon in packing the material. The implant must be fully impacted before insertion so that there are no ridges of bone in the implant. The bone graft acts as a supportive column to the implant.

Fig. 3

Step 4 Sizing the Implant Device

Load the selected implant onto the insertion tool (Fig. 4). Prepare the inserter by seating the center rod inside the outer shaft (Fig. 5). Care must be taken so that the implant is properly connected. The tips of the insertion device correspond with the holes of the implant. If these holes are not engaged the implant is not connected to the instrument. When properly connected, the inserter will thread easily into the implant by rotating the knob clockwise (right) until the implant is snug on the tip (Fig. 6). Then the surgeon is ready to insert the implant into the depth in the space. Care should also be taken not to loosen any bone graft material while inserting the implant. If this occurs, the surgeon will be forced to remove the implant and begin this step again.

The surgeon uses tamps to ensure that the implant is completely full of bone graft material and properly packed inside the space. Once the surgeon puts the implant at the desired depth, the insertion instrument is unseated by rotating the knob counter clockwise (left) to remove the instrument from the joint cavity.

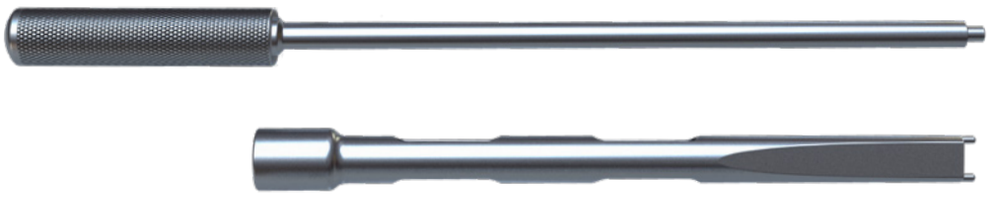


Fig. 4

Fig. 5

Fig. 6

Step 5 Implant Confirmation

Proper insertion of the implant is verified via AP and lateral fluoroscopy (Fig. 7). These images should be reviewed before the surgery is concluded. If the height of the implant needs to be adjusted in the space, the insertion instrument can be used again, as can the tamp. Additional bone can be packed anteriorly to ensure fusion.

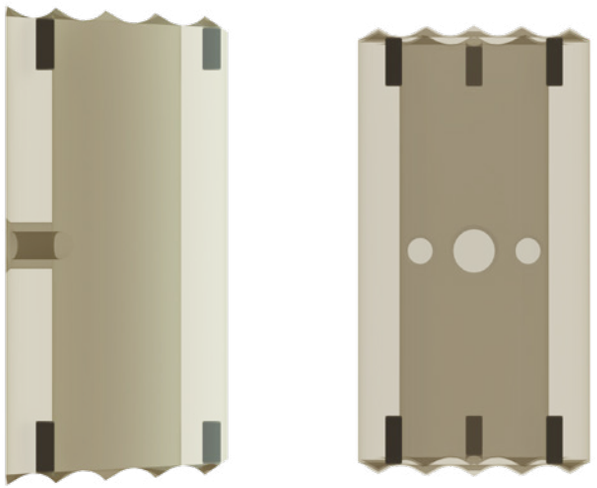


Fig. 7

Step 6 Supplemental Fixation

The ChoiceSpine HAWKEYE™ VBR System is to be used with supplemental fixation such as the ChoiceSpine LANCER™ or THUNDERBOLT™ systems.

Removal

In the event removal is required, attach the insertion tool to the VBR by the tips of the insertion device. Care must be taken so that the implant is properly connected. When properly connected, the inserter will thread easily into the implant by rotating the knob clockwise (right) until the implant is seated on the tip. At this time the surgeon can begin removal of the implant.

HAWKEYE™ Instruments

Inserter

Straight Rasp

Straight Tamp

VBR Ramp

Dual Trial

Caliper

HAWKEYE™ Standard Set Configuration

Catalog Number	Description	Quantity
Implants 12x14 6° (Small)		
DP30-1214610	VBR Spacer 12x14x10, 6°	1
DP30-1214612	VBR Spacer 12x14x12, 6°	1
DP30-1214614	VBR Spacer 12x14x14, 6°	1
DP30-1214616	VBR Spacer 12x14x16, 6°	1
DP30-1214618	VBR Spacer 12x14x18, 6°	1
DP30-1214620	VBR Spacer 12x14x20, 6°	1
DP30-1214622	VBR Spacer 12x14x22, 6°	1
DP30-1214624	VBR Spacer 12x14x24, 6°	1
DP30-1214626	VBR Spacer 12x14x26, 6°	1
DP30-1214628	VBR Spacer 12x14x28, 6°	1
DP30-1214630	VBR Spacer 12x14x30, 6°	1
DP30-1214632	VBR Spacer 12x14x32, 6°	1
DP30-1214634	VBR Spacer 12x14x34, 6°	1
DP30-1214636	VBR Spacer 12x14x36, 6°	1
DP30-1214638	VBR Spacer 12x14x38, 6°	1
DP30-1214640	VBR Spacer 12x14x40, 6°	1
DP30-1214642	VBR Spacer 12x14x42, 6°	1
DP30-1214644	VBR Spacer 12x14x44, 6°	1
DP30-1214646	VBR Spacer 12x14x46, 6°	1
DP30-1214648	VBR Spacer 12x14x48 6°	1
DP30-1214650	VBR Spacer 12x14x50 6°	1

Catalog Number	Description	Quantity
Implants 14x16 6° (Medium)		
DP40-1416610	VBR Spacer 14x16x10, 6°	1
DP40-1416612	VBR Spacer 14x16x12, 6°	1
DP40-1416614	VBR Spacer 14x16x14, 6°	1
DP40-1416616	VBR Spacer 14x16x16, 6°	1
DP40-1416618	VBR Spacer 14x16x18, 6°	1
DP40-1416620	VBR Spacer 14x16x20, 6°	1
DP40-1416622	VBR Spacer 14x16x22, 6°	1
DP40-1416624	VBR Spacer 14x16x24, 6°	1
DP40-1416626	VBR Spacer 14x16x26, 6°	1
DP40-1416628	VBR Spacer 14x16x28, 6°	1
DP40-1416630	VBR Spacer 14x16x30, 6°	1
DP40-1416632	VBR Spacer 14x16x32, 6°	1
DP40-1416634	VBR Spacer 14x16x34, 6°	1
DP40-1416636	VBR Spacer 14x16x36, 6°	1
DP40-1416638	VBR Spacer 14x16x38, 6°	1
DP40-1416640	VBR Spacer 14x16x40, 6°	1
DP40-1416642	VBR Spacer 14x16x42, 6°	1
DP40-1416644	VBR Spacer 14x16x44, 6°	1
DP40-1416646	VBR Spacer 14x16x46, 6°	1
DP40-1416648	VBR Spacer 14x16x48 6°	1
DP40-1416650	VBR Spacer 14x16x 50 6°	1

Catalog Number	Description	Quantity
Instruments		
D070-0001	Inserter	2
D070-0002	Straight Rasp	1
D070-0003	Straight Tamp	1
D070-0008	Ramp	1
D070-0009	Trial	1
D070-0010	Caliper	1

Optional

Catalog Number	Description	Quantity
Implants 12x14 0° (Small)		
DP30-1214010	VBR Spacer 12x14x10, 0°	1
DP30-1214012	VBR Spacer 12x14x12, 0°	1
DP30-1214014	VBR Spacer 12x14x14, 0°	1
DP30-1214016	VBR Spacer 12x14x16, 0°	1
DP30-1214018	VBR Spacer 12x14x18, 0°	1
DP30-1214020	VBR Spacer 12x14x20, 0°	1
DP30-1214022	VBR Spacer 12x14x22, 0°	1
DP30-1214024	VBR Spacer 12x14x24, 0°	1
DP30-1214026	VBR Spacer 12x14x26, 0°	1
DP30-1214028	VBR Spacer 12x14x28, 0°	1
DP30-1214030	VBR Spacer 12x14x30, 0°	1
DP30-1214032	VBR Spacer 12x14x32, 0°	1
DP30-1214034	VBR Spacer 12x14x34, 0°	1
DP30-1214036	VBR Spacer 12x14x36, 0°	1
DP30-1214038	VBR Spacer 12x14x38, 0°	1
DP30-1214040	VBR Spacer 12x14x40, 0°	1
DP30-1214042	VBR Spacer 12x14x42, 0°	1
DP30-1214044	VBR Spacer 12x14x44, 0°	1
DP30-1214046	VBR Spacer 12x14x46, 0°	1
DP30-1214048	VBR Spacer 12x14x48 0°	1
DP30-1214050	VBR Spacer 12x14x50 0°	1

Catalog Number	Description	Quantity
Implants 14x16 0° (Medium)		
DP40-1416010	VBR Spacer 14x16x10, 0°	1
DP40-1416012	VBR Spacer 14x16x12, 0°	1
DP40-1416014	VBR Spacer 14x16x14, 0°	1
DP40-1416016	VBR Spacer 14x16x16, 0°	1
DP40-1416018	VBR Spacer 14x16x18, 0°	1
DP40-1416020	VBR Spacer 14x16x20, 0°	1
DP40-1416022	VBR Spacer 14x16x22, 0°	1
DP40-1416024	VBR Spacer 14x16x24, 0°	1
DP40-1416026	VBR Spacer 14x16x26, 0°	1
DP40-1416028	VBR Spacer 14x16x28, 0°	1
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DP40-1416044	VBR Spacer 14x16x44, 0°	1
DP40-1416046	VBR Spacer 14x16x46, 0°	1
DP40-1416048	VBR Spacer 14x16x48 0°	1
DP40-1416050	VBR Spacer 14x16x50 0°	1

General Description:
The Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) System is intended for use in the thoracolumbar spine (T1-L5) and cervical spine (C2-T1) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The Choice Spine HAWKEYE™Ti VBR System is intended for use with supplemental fixation & is to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The Choice Spine HAWKEYE™ Ti VBR System consists of spacers comprised of Ti6AL-4V ELI (ASTM F136 or ASTM F3001).

The spacers have a basic oval/trapezoidal shape, a hollow center for placement of bone graft, and angled ridges or "teeth" on both the superior & inferior surfaces for resisting migration. They are available in an assortment of heights & in multiple angles of lordosis to accommodate different anatomic requirements.

Indications for Use:
The Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) Spacers are vertebral body replacement devices intended for use in the thoracolumbar spine (T1-L5). Hawkeye™ Ti (VBR) Spacers are also intended for use in the cervical spine (C2-T1).
When used in the cervical spine (C2-T1), the HAWKEYE™ Ti VBR devices are intended for use in the skeletally mature patients to replace a diseased or damaged vertebral body caused by tumor, fracture, or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. These spacers are 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 spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.
When used in the thoracolumbar spine (T1-L5), the HAWKEYE™ Ti VBR Spacers are intended for use to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). These spacers are designed to provide anterior spinal column support even in the absence of fusion for a prolonged period.
The interior of the spacers can be packed with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft as an adjunct to fusion.
These devices are intended to be used with FDA-cleared supplemental spinal fixation systems that have been labeled for use in the cervical, thoracic, and/or lumbar spine (i.e.,posterior screw and rod systems, anterior plate systems, and anterior screw and rod systems). When used at more than two levels, supplemental fixation should include posterior fixation.

Contraindications:
Contraindications for the Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) System are similar to those of other systems of similar design, & include, but are not limited to:
1. Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
2. Conditions, such as morbid obesity, which may put excessive stress on the bone & implants
3. Severe osteopenia or osteoporosis may prevent adequate fixation.
4. Suspected or documented metal allergy
5. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow postoperative instructions
6. Pregnancy
7. Patients who are unwilling to restrict activities or follow medical advice
8. Use with components of other systems.
9. Patients with physical or medical conditions that would prohibit beneficial surgical outcome

Warnings:
1. Mixing of dissimilar metals in the supplemental fixation to be used with this VBR System can accelerate the corrosion process. Stainless steel & titanium implants must NOT be used together in building a construct.
2. A satisfactory outcome is enhanced by the selection of the appropriate spacer size & angle.

MRI Safety Information
3. The Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) System has not been evaluated for safety & compatibility in the MR environment. The Choice Spine HAWKEYE™ Ti VBR System has not been tested for heating, migration, or image artifact in the MR environment.

Precautions:
1. The Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) System should be implanted only by surgeons who are fully experienced in the use of such implants & the required specialized spinal surgery techniques as this is a technically demanding procedure.
2. The spacers should not be reused, even if they appear in a perfect state. Any spacer that has been used, twisted, bent, implanted & then removed, even if it appears intact, must be discarded.
3. The Choice Spine HAWKEYE™ Ti Vertebral Body Replacement (VBR) System is not intended to be the sole means of spinal support – supplemental internal fixation must be used. Bone grafting must be part of the spinal fusion procedure. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e. scratches, notches) & loads from weight bearing & activity will affect the implant's longevity.
4. Refrain from handling the spacers as much as possible before implantation, & always handle it with the utmost care. The devices (in their original packaging) must be stored with care in a clean & dry place away from radiation or extreme temperatures. Should these requirements not be followed, reduced mechanical properties may occur which could lead to implant failure in some cases.
5. Metal sensitivity has been reported following exposure to orthopedic implants and instruments. The most common sensitivities (nickel, cobalt, and chromium) are present in medical grade stainless steel and cobalt-chrome alloys.

Notes

Notes

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