

# GIZA<sup>®</sup>

## Surgical Technique

• Vertebral Body Replacement System



**Titanium alloy material provides mechanical integrity during insertion and distraction, x-ray visibility, and biocompatibility\***

**Rotatable superior endplate with variable lordotic angles**

**Optional *in-situ* insertion of bone graft**

**One step locking of the distraction mechanism**

**Fenestration to promote vascularization during the fusion process**

**Holder/Distractor connection**

**Fixed Inferior Endplate**



\*Data on file

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## Introduction

The following technique describes an open thoracolumbar corpectomy procedure. This technique may be used in anterior or anterolateral approaches in the thoracolumbar spine (T1-L5) based on the pathology being addressed and surgeon preference.

The GIZA Vertebral Body Replacement System is indicated for use in the cervical and thoracolumbar spine in OUS (Outside United States) markets.

## Description

The GIZA Vertebral Body Replacement System consists of a titanium alloy (TA6V ELI) Distractible In Situ implant, which enables the surgeon to customize the height of the implant after implantation. Adjustments of the implant height are achieved *in situ* as a result of the locking mechanism which maintains distraction.

A 14mm diameter footprint is available in three height ranges, including 18 - 22mm, 23 - 32mm and 33 - 54mm. Each implant comes fully assembled with the option of a rotatable superior endplate in 2, 5, 7, 8 and 10 degrees of lordosis.

## Exposure

### ANTERIOR APPROACH

#### Patient Positioning

Patient positioning on the operating table is dependent on the level(s) to be operated. For the anterior approach, the patient is typically placed in the supine position with or without a small intrascapular bump to gently extend the neck. Wrist straps may be applied to help facilitate gentle caudal distraction of the shoulders to help improve radiographic visualization of the spine, see Figure 1.



**Figure 1: Example of patient placed in the supine position**

#### Surgical Approach

Through an anterior approach, the anterior aspect of the spinal column is exposed. Intraoperative x-ray or fluoroscopy is used to help confirm the operative level. A partial or full corpectomy or vertebrectomy is performed. The bony endplates are prepared for implant insertion using standard surgical procedures and instrumentation, see Figures 2a and 2b.



**Figure 2a: Example of a corpectomy of a thoracic vertebral body**



**Figure 2b: Example of a vertebrectomy of a thoracic vertebra**

### ANTEROLATERAL APPROACH

#### Patient Positioning

Patient positioning on the operating table is dependent on the level(s) to be operated. For the anterolateral approach, the patient is typically placed in the lateral decubitus position, see Figure 3. Patient will be placed on either the left side or right side depending on level being operated.



**Figure 3: Example of patient placed in the lateral decubitus position**

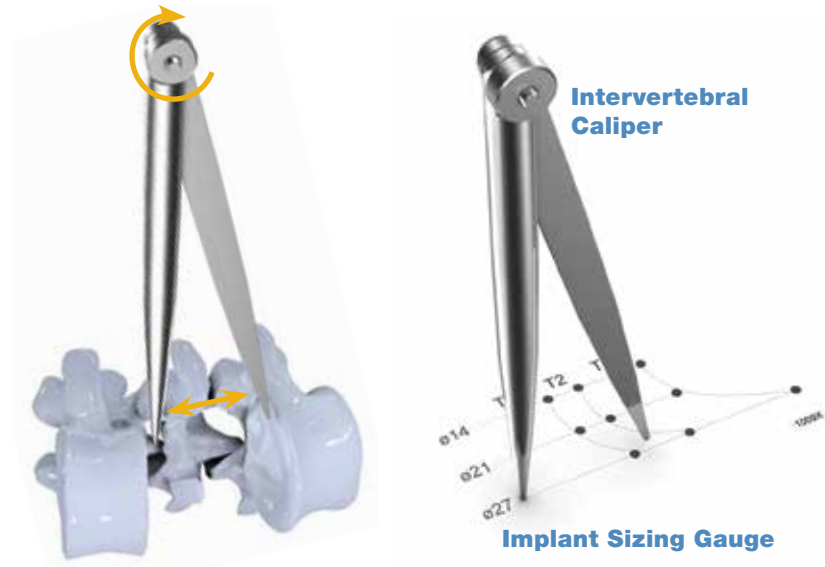
#### Surgical Approach

Through an anterolateral incision the thoracolumbar spine is exposed. Intraoperative x-ray or fluoroscopy is used to help confirm the operative level. A partial or full corpectomy or vertebrectomy is performed. The bony endplates are prepared for implant insertion using standard surgical procedures and instrumentation, see Figures 2a and 2b.

## Implant Measurement

The appropriate size implant can be determined preoperatively, by measuring the defect from the patient's films or CT scans. However, the measurement should be confirmed *in situ* with an **Intervertebral Caliper** or ruler. It is recommended to measure *in situ* from the posterior aspect of the inferior endplate of the vertebral body above the affected level to the posterior aspect of the superior endplate of the vertebral body below the affected level, see Figure 4.

**Note:** Implant height should be confirmed via fluoroscopy.



**Figure 4: Example of determining implant sizing using the Intervertebral Caliper in conjunction with the Implant Sizing Gauge**

## Implant Selection

The GIZA Vertebral Body Replacement System consists of a titanium alloy (TA6V ELI) Distractible In Situ implant, which enables the surgeon to customize the height of the implant after implantation. Adjustments of the implant height are achieved *in situ* as a result of the locking mechanism which maintains distraction.

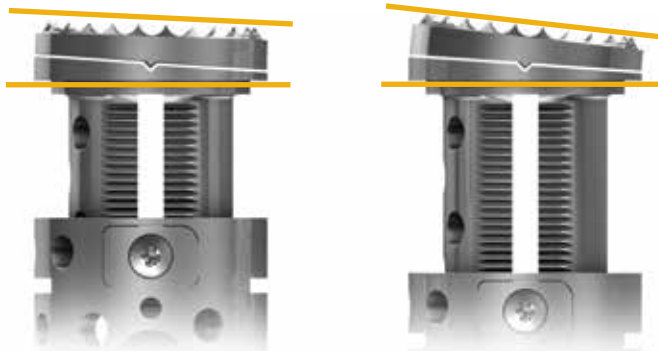
A 14mm diameter footprint is available in three height ranges, including 18 - 22mm, 23- 32mm and 33 - 54mm. Each implant comes fully assembled with the option of a rotatable superior endplate. Please refer to the chart for all possible combinations.

Ø14mm Implant	Distraction Range	Lordotic Angle Options
	<b>18 - 22mm</b>	<b>2°, 5°</b>
		<b>5°, 8°</b>
	<b>23 - 32mm</b>	<b>2°, 5°</b>
		<b>7°, 10°</b>
	<b>33 - 54mm</b>	<b>2°, 5°</b>
		<b>7°, 10°</b>

## Endplate Assembly

The GIZA VBR Implant comes fully assembled and sterile packaged. The 14mm diameter implants have the option of a rotatable superior endplate for those cases in which lordosis is desired to provide sagittal alignment and increased stabilization of the implant construct, see Figure 5. The inferior endplate is fixed in a neutral position and does not allow for rotation.

**Note:** The implant comes preassembled and the endplates are not meant to be removable. If rotated more than 180 degrees, there is potential for the endplates to detach from the implant.



**Figure 5:** Example of varying degrees of implant lordosis achievable by rotating the superior endplate of the implant

## Endplate Adjustment

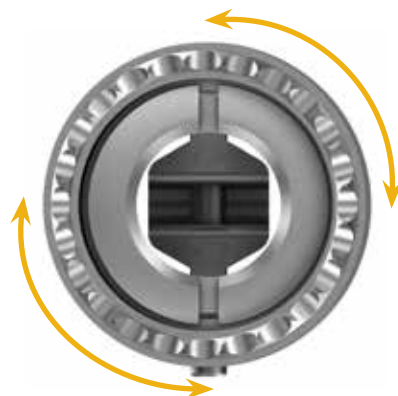
Adjustment of the superior endplate is done pre-operatively by using the **Endplate Holder**. The surgeon can increase or decrease the angulation by rotating the superior endplate with the Endplate Holder. To obtain the highest degree of lordosis, rotate the endplate 180 degrees.

**Step 1:** Use the Endplate Holder to disengage the locking nut to allow for rotation of the superior endplate, see Figure 6a.

**Step 2:** Turn the Endplate Holder to adjust lordosis. Turning 180 degrees will reach maximum lordotic angle for each height, see Figure 6b.

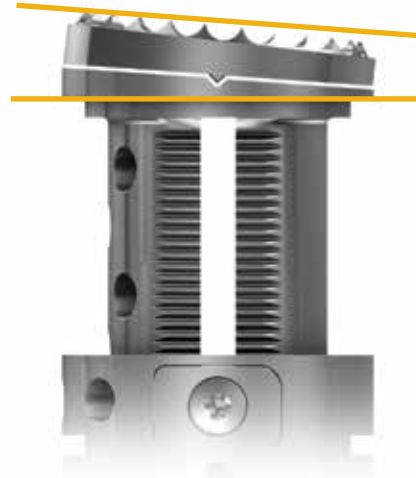


**Figure 6a**



**Figure 6b**

**Step 3:** Lock the endplate locking nut to secure implant lordosis, see Figure 6c.



**Figure 6c**

## Bone Graft Placement (Optional)

The GIZA VBR System can be packed with bone graft. The use of bone graft with this system is optional. It is recommended that the bone graft be packed into the implant after construct assembly and confirmation of the implant construct with sagittal alignment *in situ*.

The GIZA VBR System includes a **Bone Graft Compactor** which can be used in conjunction with the **Implant Holding Block** to help pack bone graft into the implant. The Bone Graft Compactor has knurled tips designed for more precise packing of the bone graft, see Figure 7. Prior to implantation, it is recommended to pack bone graft into the opening of the superior endplate. A modest amount of excess bone graft will help eliminate any voids between the implant and the adjacent bony endplates that may appear after implant distraction.

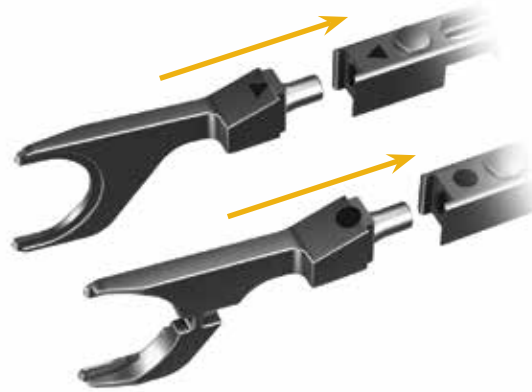
**Note:** Surgeon must ensure that all bone graft is secured within the cage prior to insertion.



**Figure 7**

## Implant Attachment

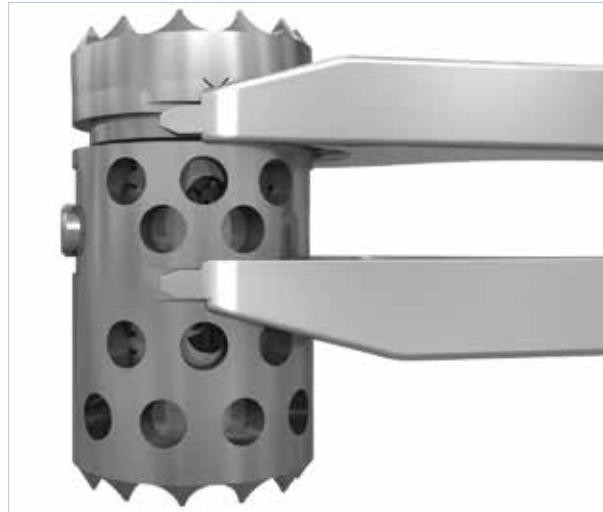
**Step 1:** Push the button on the **Holder/Distractor** and introduce the removable tip into the Holder/Distractor. Maintain force on the button and ensure that the circles and triangles are aligned with each other, see Figure 8a.



**Figure 8a**

**Note:** The **Holder/Distractor** is available in 320mm and 220mm lengths.

**Step 2:** Attach the implant to the Holder/Distractor and ensure that the tangs are fully seated, see Figure 8b.

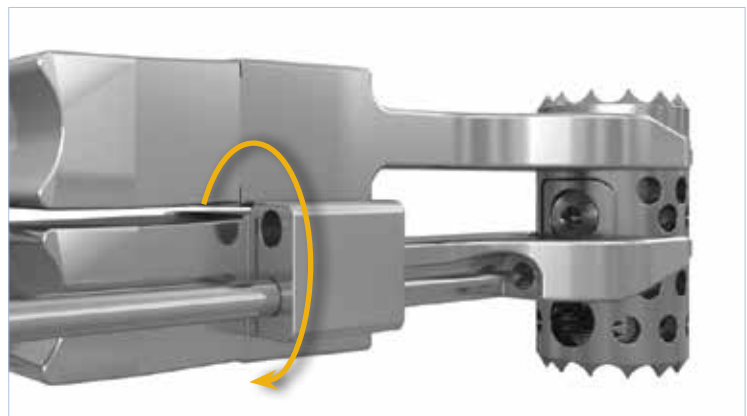


**Figure 8b**

**Step 3:** Connect the 320mm **Screwdriver** to the **Torque Limiting Handle**.

**Note:** The **Screwdriver** is also available in a 250mm length.

**Step 4:** Engage the locking screw with the 320mm **Screwdriver** and turn clockwise to secure the implant to the Holder/Distractor, see Figure 8c.



**Figure 8c**



## Implant Insertion

**Step 1:** Insert the implant into the disc space taking care to protect the integrity of the surgical site. The Holder/Distractor ratchets in 1mm increments. Carefully monitor for overdistraction, especially in cases of spondylectomy and trauma. Once desired height is achieved, temporarily lock the proximal end of the Holder/Distractor to maintain distraction, see Figure 9a.



Figure 9a

**Step 2:** Next, secure desired distraction level by engaging the locking screw and turn the 320mm Screwdriver clockwise until fully tightened to 1.1 Nm, see Figure 9b.

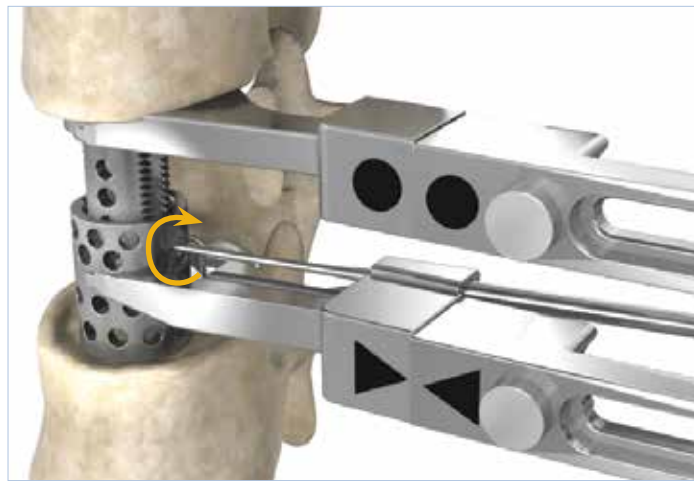


Figure 9b

**Note:** The locking screw should be firmly hand tightened.

**Note:** If adjustment is needed, the implant locking mechanism must be unscrewed 3.5 to 4 rotations from the tightened position, to free the superior cylinder from the inferior one. No more than 4 counterclockwise rotations should be applied to the locking screw, as doing so could potentially lead to disassembly of the implant's locking mechanism.

**Step 3:** To disengage the implant from the Holder/Distractor, engage the screw and turn the 320mm Screwdriver counterclockwise until the Holder/Distractor can be released from the implant, see Figure 9c. Gently remove the Holder/Distractor from the disc space.

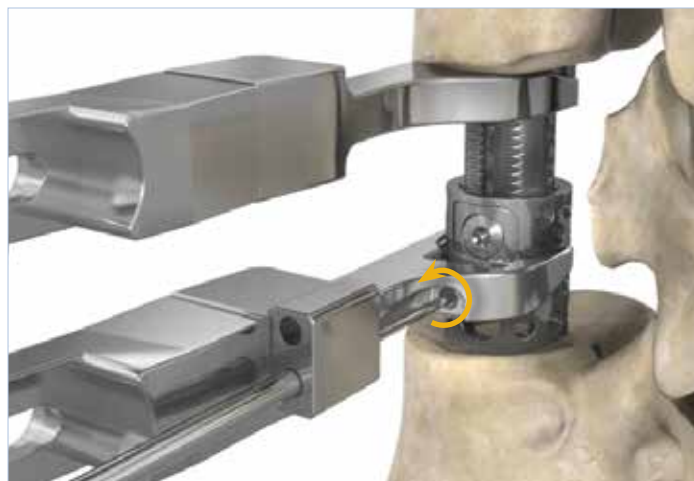


Figure 9c

**Note:** Fluoroscopy may be useful in determining the appropriate final positioning.

## Implant Removal

If fusion or bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the GIZA system is not intended for removal unless the management of a complication or adverse event requires removal. Standard instruments may be used to hold and disengage the device from the vertebrae. Any decision by a physician to remove the device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. The following steps can be used if the GIZA device must be removed:

**Step 1:** Insert the Holder/Distractor and engage the locking screw. Turn the 320mm Screwdriver clockwise to tighten the implant to the inserter, see Figure 10a.

**Step 2:** Slightly distract the implant to allow the locking mechanism to be unscrewed.

**Step 3:** Rotate the locking screw counterclockwise to reduce the height of the implant until it is possible to remove the implant from the defect, see Figure 10b.

**Note:** No more than 4 counterclockwise rotations should be applied to the locking screw, as doing so could potentially lead to disassembly of the implant's locking mechanism.

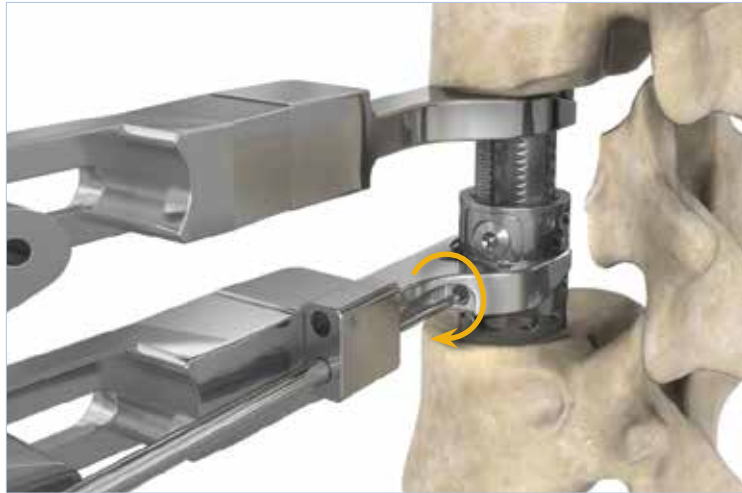


Figure 10a

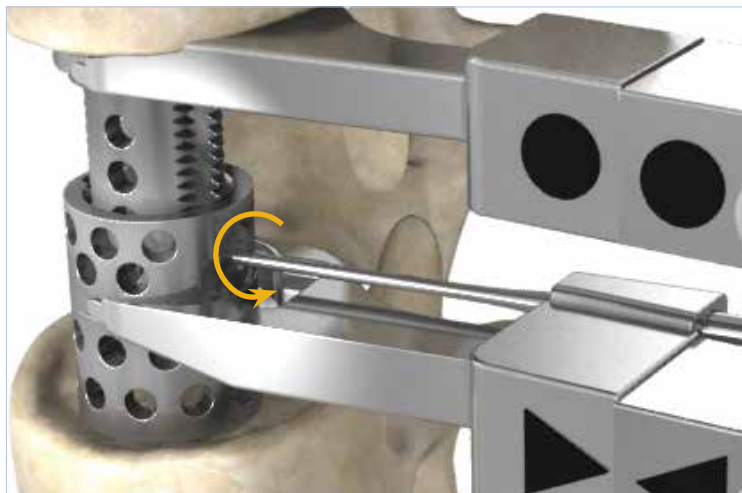


Figure 10b

## Bone Graft Placement *In Situ*

Autogenous bone grafting material may be placed lateral, ventral, and/or dorsal to the implanted GIZA VBR Implant.

## Supplemental Fixation

If supplemental fixation was not applied prior to the insertion of the GIZA implant, it must be applied once the implant is in place. The supplemental internal fixation systems that may be used with GIZA include, but are not limited to, Stryker Spine plate or rod systems (Xia Spinal System, Radius Spinal System, Trio+ Spinal System, Mantis Spinal System, or Thor Plating System).














GIZA pictured with the Xia 3 Spinal System



GIZA pictured with the Xia Anterior Spinal System

## Instruments

	Reference Number	Description	Quantity/ Set
	48293320	Holder/Distractor Lg 320mm	1
	48293220	Holder/Distractor Lg 220mm	1
	48293014	Distractor Tips for 14mm Implant	1
	48293114	Endplate Holder for 14mm Implant	1
	48293132	Screwdriver Lg 320mm	1
	48293125	Screwdriver Lg 250mm	1
	48293402	Torque Limiting Handle	1
	48293403	Bone Graft Compactor	1
	48293404	Implant Holding Block	1
	48293405	Intervertebral Caliper	1
	48293406	Implant Sizing Gauge	1
	48293400	Instruments Tray with Silicone Inserts	1
	48293401	Instruments Tray Lid	1

## Implants



Reference Number	Diameter	Distraction Range	Lordotic Angle	Quantity/ Set
48291482S	Ø14mm	18-22mm	2, 5 Degrees	2
48291485S	Ø14mm	18-22mm	5, 8 Degrees	1
48291422S	Ø14mm	23-32mm	2, 5 Degrees	2
48291427S	Ø14mm	23-32mm	7, 10 Degrees	1
48291432S	Ø14mm	33-54mm	2, 5 Degrees	2
48291437S	Ø14mm	33-54mm	7, 10 Degrees	1

## DESCRIPTION OF THE DEVICE

The corpectomy implant is in the form of an assembly of two cylindrical elements, one sliding over the other. An integrated locking system allows locking the implant once the distraction is finished. The vertebral plates positioned at each end adjust the angulation of the device to the intervertebral angulation. The upper plate and the lower plate have a notched surface to help anchor it with the vertebrae involved.

The device, which is expandable *in situ*, permits the vertebral segment involved to be distracted during the surgery. The implant can be distracted by a specific instrument that simultaneously grips and distracts it.

## DEVICE MATERIALS

The corpectomy implant is made up of titanium alloy TA6V ELI parts that can be implanted according to standards ISO 5832-3 or ASTM-F 136. This material is not compatible with stainless steel or other metals.

## INDICATIONS FOR USE (USA)

The GIZA Vertebral Body Replacement is intended for use during open surgical procedures in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (e.g. fracture). The GIZA Vertebral Body Replacement System is intended to be used with supplemental internal spinal fixation systems that have been labeled for use in the thoracic and lumbar spine (i.e. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems) The use of allograft or autograft with the GIZA Vertebral Body Replacement device is optional.

## INDICATIONS FOR USE (OUTSIDE THE USA)

The corpectomy implant is a surgical implant that allows reconstructing of the intervertebral space in the cervical and thoracolumbar spine. This device is mainly intended to be used in tumoral and traumatic spinal surgery. The indications include:

- Vertebral body tumor
- Anterior column fracture
- Cervical stenosis requiring single or multisegment reconstruction

## CONTRAINDICATIONS

The corpectomy implant should not be used in patients in the following conditions:

- Local infection or inflammation
- Vertebral osteoporosis
- Pregnancy
- Allergy or intolerance to titanium or its alloys
- Incompatible age and physical condition of the patient
- Any case not included in the indications

The corpectomy implant is not designed, intended or sold for uses other than those indicated.

## WARNINGS

- Never reuse a GIZA implant.
- Only surgeons familiar with the GIZA surgical technique should perform this surgery.
- Instruments are supplied non-sterile and must be sterilized prior to use.

## POSSIBLE SIDE EFFECTS

The following potential side effects (separate or in combination), although not observed, could occur and result from the implantation of the corpectomy implantation:

- Infection,
- Intolerance to the material,
- Disassembly, deformation and/or breakage of elements,
- Damage of the dura mater and/or nerve roots.

**Note:** An additional surgical procedure may be necessary to correct a side effect.

**Warning:** A completely satisfactory result is not systematically obtained with each surgical procedure. This is particularly true in spinal surgery, where numerous external elements can compromise the results.

## SURGICAL PRECAUTIONS

The surgeon should be completely familiar with the device, the method of application, the instruments, and the surgical technique. The corpectomy implant should be implanted according to the recommended surgical technique. The corpectomy implant should be chosen as a function of the height to be restored and the inclination of the vertebral plates should be adjusted to conform to the vertebral segment; an unsuitable height may compromise the clinical result. Before implanting the device, the vertebral endplates should be carefully curetted and

debrided without being weakened in order to prevent subsidence of the corpectomy implant. The entire surface of the implant plates should be in contact with the adjacent vertebral body endplates. However, it is important to keep the vertebral body endplates intact. The proper positioning of the implant with regard to the vertebrae can be confirmed by x-ray. The locking screw should be firmly hand tightened. After implantation, the lot number and the reference of the GIZA corpectomy implant should systematically be recorded in the patient's surgical record.

## PRECAUTIONS

The corpectomy implant should be implanted only by experienced spinal surgeons who specialize in the spinal column, and who have been specifically trained in the use of this device and instrumentation.

Knowledge of the preoperative and intraoperative procedures, the surgical technique, the choice of implant size and its placement are essential for surgeons to optimally use the device. All these considerations will considerably affect the clinical results for the patient.

Patients should be advised of the pre-, intra- and postoperative procedures.

Be in an aseptic environment when opening the device packaging.

Handle the device with care so it does not contact other objects that could damage it. Damaged implants will not function reliably.

The device should not be used with components from other manufacturers. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions which may impact on the performance of the system.

The GIZA device has not been evaluated for safety and compatibility in the MR environment. The GIZA device has not been tested for heating or migration in the MR environment

## CAUTION (USA only)

Sale of the GIZA VBR is restricted to use by or on the order of a physician.







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