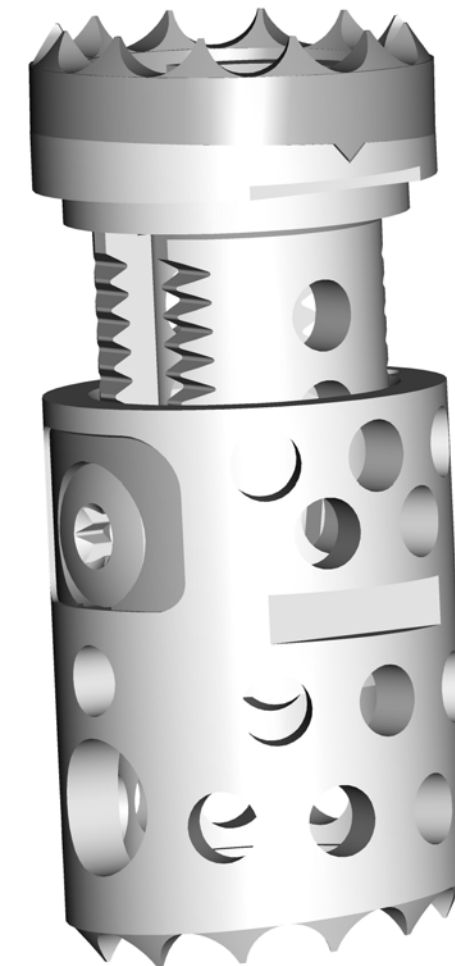


GIZA™

VERTEBRAL BODY REPLACEMENT Surgical Technique Guide



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Introduction

The GIZA™ is the latest generation of titanium expandable Vertebral Body Replacement Systems. It allows surgeons to perform cervical, lumbar or thoracic Corpectomy procedures, and has been specifically developed to improve patient care by saving valuable O.R. time and by decreasing the risk of subsidence.

A Corpectomy is a surgical procedure performed to fuse the vertebrae together after a portion of the bone and disc has been removed. To safely achieve this goal, the GIZA™ also features an open architecture designed to allow bone growth.

The GIZA™ is designed to work with the anatomy in a modular fashion. Each implant comes fully assembled, inclusive of multiple angulation options available by simple rotation of the implants endplates. Adjustment of the implant height is securely achieved in-situ with a simple and reliable locking mechanism that maintains the implant in distraction and avoids compression

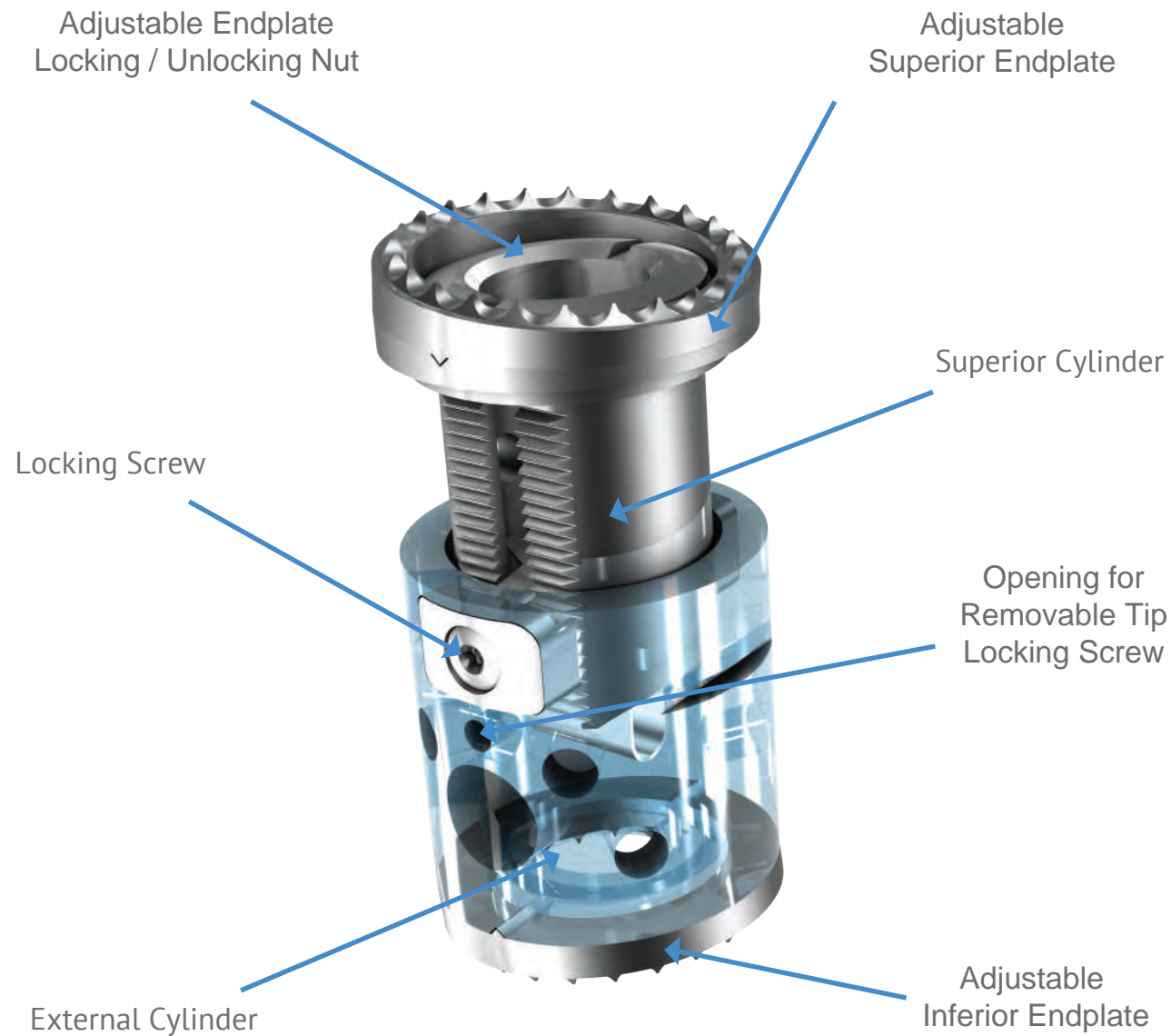
Clinical Indications:

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

Contra-indications:

- Local infection or inflammation
- Vertebral osteoporosis
- Pregnancy
- Allergy or intolerance to titanium or its alloys
- Incompatible age and physical condition of the patient

Any other case not included in the indications.



SAFETY - RELIABILITY - ADAPTABILITY

The GIZA™ is intended for use in the cervical, thoracic and lumbar area of the spine to replace and fuse a collapsed, damaged, or unstable vertebral body due to tumor or fracture.

1. POSITIONING THE PATIENT

Cervical Area

The patient is positioned on the operating table horizontally with the head held by an adjustable piece. The head is placed facing away from the surgical approach. A horizontal incision is made in order to expose the concerned cervical segment.

Thoracic Area

The patient is positioned on the operating table in a lateral decubitus position. A thoracotomy is performed to access the thoracic spine.

Lumbar Area

The patient is placed either in a prone position, or in a knee-chest position, avoiding vascular compression. A median or lateral retroperitoneal incision is performed to access the site.

2. SURGICAL SITE PREPARATION

Discectomy & Corpectomy

Following standard surgical technique, both discs adjacent to the affected vertebral body are completely excised and the affected vertebral body is removed. A proper decompression of the vertebral canal should be done.

Preparation of the Vertebral Endplates

Before implanting the device, the vertebral endplates should be carefully curetted 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. However, it is important to keep the vertebral body endplates intact.

3. IMPLANT SELECTION & POSITIONING

A. Determining the Intervertebral Distance.

The GIZA™ provides surgeons with the capability to reconstruct most defects by offering a variety of implant heights and diameters to choose from.



The use of the caliper, included in the instruments set, is recommended to determine the length of the implant required.




An implant sizing gauge is also provided to allow surgeons to precisely measure the implant size needed for each patient

After measuring the space in the patient's spine, the caliper must be carefully placed on the implant sizing gauge to select the right implant size (T1, T2 and T3).



B. Implant Selection: A Modular System with Multiple Implant Sizes.

A wide variety of options are provided for all areas of the spine as described here-under:

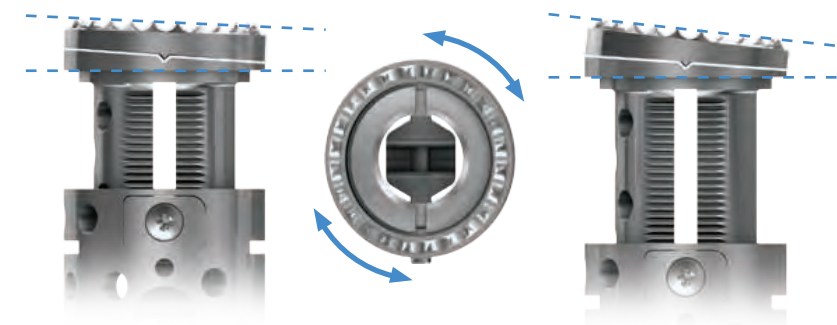
	Height		Endplates Angles	
	Ø14 mm	18 - 22 mm	2° - 5°	
		23 - 32 mm	5° - 8°	
		33-54 mm	2° - 5° 7° - 10°	
	Height		Endplates Angles	
	Ø21 mm	22 - 26 mm	4° - 8° - 12°	
		27 - 36 mm		
37 - 56 mm				
	Height		Endplates Angles	
	Ø27 mm	28 - 36 mm	4° - 8° - 12°	
		37 - 54 mm		
55 - 90 mm				

C. Adjusting Implant Angulation.

The GIZA™ VBR provides surgeons with multiple angulations options by simple endplate rotation. The adjustment of the angulations is done pre-operatively with the "Endplate Holder."

CERVICAL IMPLANTS: The inferior endplate is fixed. Only the superior endplate is adjustable. In its sterile packaging, the implant is in neutral position with the smallest angulation. The surgeon can increase the angulation of the superior endplate by simply rotating the endplate with the "Endplate Holder." To obtain the highest degree of lordosis, the adjustable endplate can be rotated 180°.

THORACIC & LUMBAR IMPLANTS: Both superior and inferior endplates are adjustable. The surgeon can increase the angulations of the superior and inferior endplates by simply rotating the endplates with the "Endplate Holder," until he obtains exactly the implant lordosis or kyphosis that he desires for his patient.



To modify implant angulation:

- 1) Unlock the endplate locking/unlocking nut
- 2) Make a 180 degree rotation of the endplate
- 3) Lock the endplate locking/unlocking screw again

4. FOUR STEPS TO IMPLANT POSITIONING

Step 1: Implant & Angulation Selection.

After selecting the right implant, in terms of diameter and height, the surgeon must (1) use the “Endplate Holder” to position the modular endplates onto the implant itself (2) then turn the “Endplate Holder” to rotate the endplates until the desired angulation is obtained, as described on page 5.

Step 2: Attach the Implant to the Holder-Distractor.

The holder-distractor comes with 3 pairs of removal tips. One for each implant diameter (i.e. 3 regions of the spine).

The surgeon must select the pair of removable tips that corresponds to the selected implant. Then, he must align them correctly on the holder-distractor using the engraved markers (i.e. circles & triangles). He must click them onto the holder-distractor.



The screwdriver fits perfectly in the screw head thanks to its guiding hole.

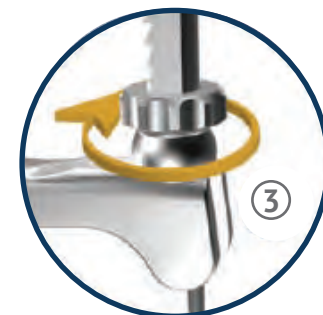
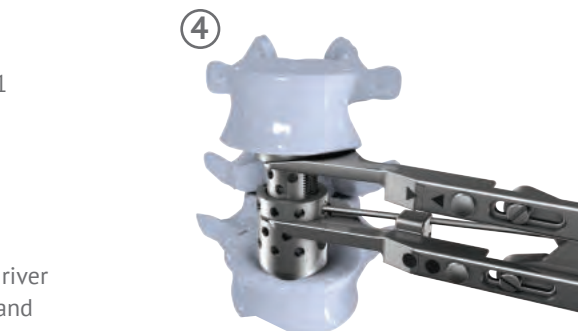
Step 3: Distract the Implant and Lock-it into Position.

First, insert the implant into the disc space in a non-distracted position.

Second, distracting the implant until the desired height. The holder-Distractor ratchets in 1 mm increments.

Third, once desired height is achieved, temporarily lock the proximal end of the Holder-Distractor to maintain distraction.

Fourth, secure desired distraction level by engaging the locking screw and turn the screwdriver clockwise until fully tightened to 1.1 Nm. Thanks to the the guiding hole, the screwdriver and implant locking screw perfectly align.



Step 4: Detach the Implant from the Holder-Distractor.

To disengage the implant from the Holder-Distractor, engage the screw and turn the screwdriver clockwise until the Holder-Distractor can be released from the implant.

The Giza is now fully implanted.



Closing the Approach

Standard closure procedures with suction drainage ought to be followed.



The GIZA™ Corpectomy device is designed to maintain the distraction between vertebrae. It is IMPERATIVE to associate the GIZA™ with a stabilization osteosynthesis device to be chosen by the surgeon.

Implant Removal

- 1- The holder-distractor must be re-attached to the implant;
- 2- 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;
- 3- The implant must be slightly compressed, to allow the superior cylinder to slide back into the inferior cylinder;
- 4- The implant can be safely removed with the holder-distractor.

