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 (USA)

The Giza® Vertebral Body Replacement is intended for use during open surgical procedures in the thoraco and lumbar 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 is intended to be used with supplemental internal spinal fixation systems that have been labeled for use in thoracic and lumbar spine (i.e. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).
The use of the allograft or autograft with the Giza Vertebral Body Replacement is optional.

INDICATIONS (outside the USA)

The corpectomy implant is a surgical implant that allows reconstructing the intervertebral cervical, thoracolumbar spine space. 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.

PRECAUTIONS (USA ONLY)

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

PACKAGING, LABELING AND STORAGE

The GIZA implant is provided sterile in individual packages.
The storage conditions must maintain the integrity of the implants and their respective packaging. The storage conditions must meet the following requirements:
Protect from humidity and light and store at ambient temperature.
If the sterile packaging, label or implants are damaged or expired, the devices concerned should not be used and should be returned to Eden Spine LLC (For US use) and Eden Spine Europe (For out of US use).

DECONTAMINATION, CLEANING AND STERILIZATION OF THE INSTRUMENTS

> > For instruments provided non-sterile:
All the instruments of the Giza® instrumentation (holder distractor, tips, screwdriver, measuring device, compactor) are made of stainless steel in accordance with standard EN ISO 7153-1 and supplied non-sterile. They must be decontaminated, cleaned and sterilized before use. Decontamination reduces the population of microorganisms and facilitates subsequent cleaning. Furthermore, sterilization will be efficient only if the material is clean.

CLEANING (USA ONLY)
At the point of use: Use clean flowing water and disposable wipes to remove excess soil. Reprocess instruments as soon as possible to prevent body fluid and tissue from drying on instruments prior to cleaning.

Preparation for cleaning: Disassemble the inserter/holder to provide maximum exposure for cleaning per instructions provided below.

Cleaning –Automated: Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated system may be used as a follow-up method to manual cleaning.

Cleaning-Manual:

1. Disassemble inserter/holder before cleaning. See pictures 1&2.
2. Prepare the cleaning solution using 1 oz. of Enzol (or equivalent) per gallon of water
3. Completely submerge instruments in enzyme solution and allow to soak for a minimum of 1 minute. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, and appropriately sized soft-bristled brush (e.g. pipe cleaner brush).
4. Remove the devices from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.
5. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas. Use de-ionized water for final rinse of all components.
6. Repeat the cleaning and rinse steps above until all visible contamination has been removed.

Thoroughly and promptly, remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe. Allow the tray and components to dry for a minimum of 15 minutes. The tray and components must be thoroughly dry prior to sterilization cycle.

Decontamination: Decontamination is only acceptable as an adjunct to full sterilization for reusable surgical instruments.

Maintenance, inspection, and testing: Carefully inspect each device to ensure that all visible blood and soil have been removed. Inspect lumens to confirm that all foreign material has been removed.
Visually inspect for damage and/or wear.
Note: If any damage or wear is noted that impairs the function of the instrument, contact your company representative for a replacement.

CLEANING (outside of the USA)
Decontamination: Immerse instruments in bactericide and fungicide solution. If necessary remove the debris (cement) from the instruments
Soaking time: 20 minutes. Rinse with deionizer water.
Cleaning: Wash instruments in an ultrasonic machine with appropriate cleaning products, rinse and dry. Avoid using products that can alter the material, such as sodium hydroxide, formaldehyde, etc. The conditions for use of the decontamination and cleaning products must be scrupulously respected, especially the concentration and usage time. The instruments must be carefully rinsed with water after decontamination and cleaning.

PACKAGING (USA and outside of the USA)
The set of instruments must be loaded into a dedicated tray, supplied by the manufacturer, for sterilization.

STERILIZATION (USA and outside of the USA)
Visually inspect all instruments for any remaining debris prior to sterilization.
The instruments are provided non-sterile and should be autoclave sterilized using the sterilizer manufacturer's instructions and the institution's procedures for ensuring sterility. The sterilization cycle should occur in a validated steam sterilizer.

The instruments must be sterilized by the steam process using the following parameters:
Method: **Saturated steam sterilization**
Duration: 18 min
Temperature: 134°C (273°)
Drying time: 20 min back to room temperature

For USA use ONLY: The 18 minute, 273°F pre-vacuum steam sterilization cycle is not considered by the US Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the US Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Drying times may vary according to load size and should be increased for large loads.
Dry, thoroughly and promptly, after both cleaning and sterilization.

Comment 1: Sterilization does not replace pre-disinfection or cleaning. Only clean equipment can be sterilized properly.

The implants are provided sterile; they should not be resterilized or reused.

PRECAUTION (USA ONLY): Use only FDA-cleared wrap for sterilization.

STORAGE
Store components in a clean, dry, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and extremes in humidity and temperature.

COMPLAINTS

Any health professional (for example, a surgeon using the products) who has a claim or who is unsatisfied with the quality, identification, reliability, safety, efficacy and/or performance of the device should inform Eden Spine LLC or the distributor, if applicable. In the case of a serious incident or risk of serious incident that could lead to or has led to death or serious deterioration of the patient's or user's health status, the health professional should follow the vigilance directives of his or her healthcare establishment and should alert Eden Spine LLC as soon as possible.

ADDITIONAL INFORMATION

Caution (USA ONLY)
Sale of the Giza® VBR is restricted to use by or on the order of a physician.

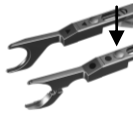
To obtain a Surgical Technique Manual, contact your local Eden Spine sales representative, or the company office.
For further information, contact Eden Spine US office or Eden Spine Europe SA office at:

Eden Spine US office	Eden Spine Europe office
377 Maitland Ave.	41, rue du 31 Décembre
Suite 1015	1207 Genève
Altamonte Springs, FL 32701 Switzerland	
+ 1 407-900-9986	+41 22 310 29 1

A. Disassembling procedure of the Inserter/Holder tips:

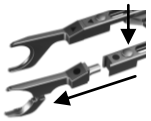
Step 1: Press the button on the inserter/holder

Picture 1



Step 2: Continue pressing the button on the inserter/holder & pull the tip from the inserter/holder, thereby detaching the tip.

Picture 2



Step 3: Same procedure should be applied for the second tip.

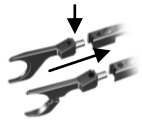
B. Re-assembling procedure of the Inserter/Holder tips:

On the lateral side of the tip, a laser marking (or) is applied to facilitate connection with the inserter/holder.
Similar markings appear on the holder distractor. Correct positioning is achieved by aligning the markers.

Picture 3

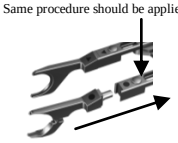
Step 1:
Press the button on the inserter/holder & introduce the tip into the inserter/holder, maintaining force on the button, ensuring that the 2 triangles are aligned and for the second tip that the two circles are aligned.

Picture 4



Step 2: Same procedure should be applied for the second tip.

Picture 5



Eden Spine LLC
377 Maitland Ave - Suite 1015
Altamonte Springs, FL 32701
Phone: +1 407 900 9986
Fax: +1 407 264 8303

Eden Spine Europe
41, rue du 31 Décembre
1207 Genève – Switzerland
Phone : +41 22 310 29 11

Distributor information: Distributed by **:**

OUS Distribution	US Distribution
STRYKER Spine	STRYKER Spine SA
Le Cret-du-Locle 10a	2 Pearl Ct., Allendale
2300 La Chaux-de-Fonds	NJ 07401-1077, USA
Switzerland	
t: +41 32 924 6000	t: 1 201 760 8000
f: +41 32 926 2410	

Refer to instructions for use

Single use

STERILE — Device delivered sterile (sterilization method – moist heat)

CE 1253

Manufacturing date: xxxx

mm/yyyy (Exp. Date)

Note: The present instructions apply to the entire range of Giza® implants delivered sterile