TITAN SPINE

ENDOSKELETON® TC

TC

SURGICAL TECHNIQUE GUIDE

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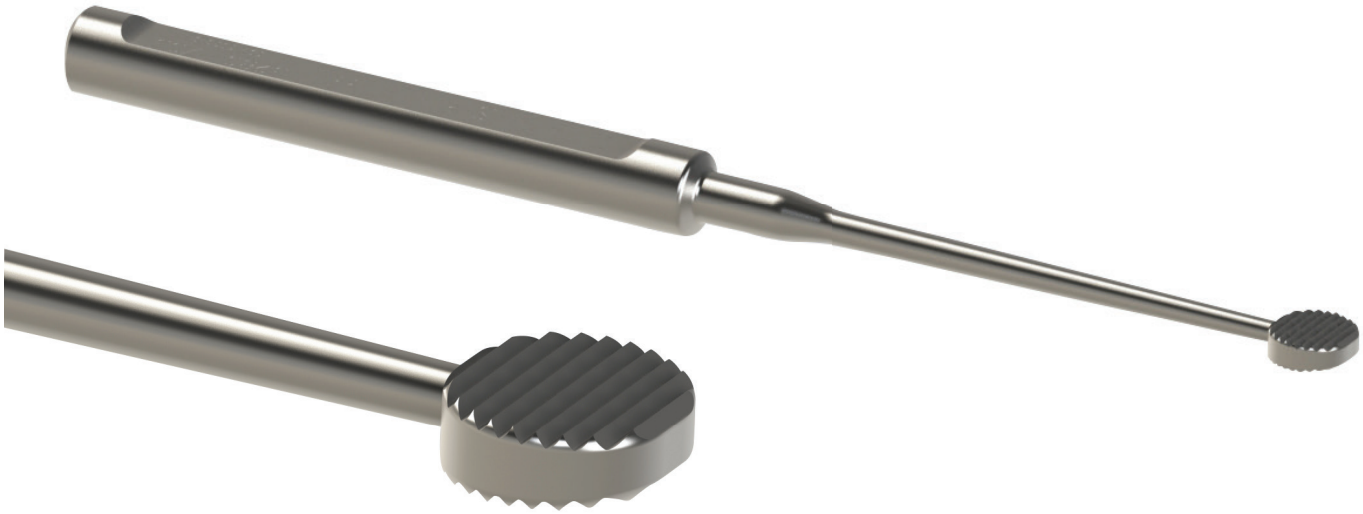
INSTRUMENT OVERVIEW



TC Lordotic Rasp 5mm
5280 – 1705

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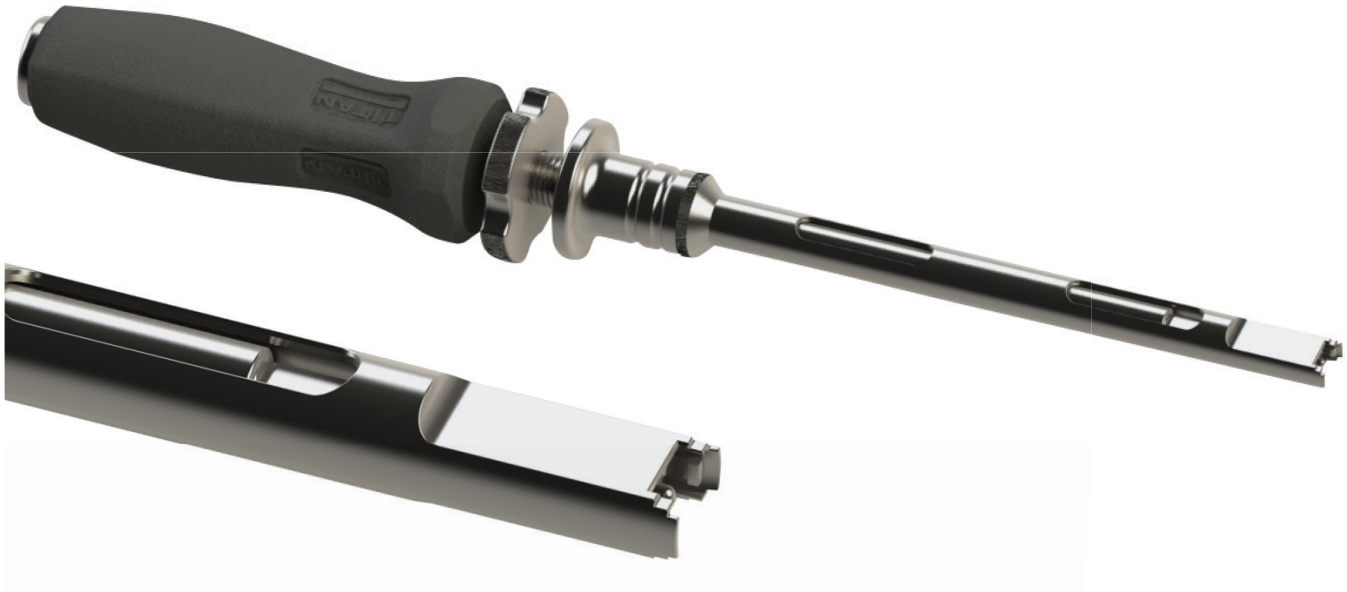
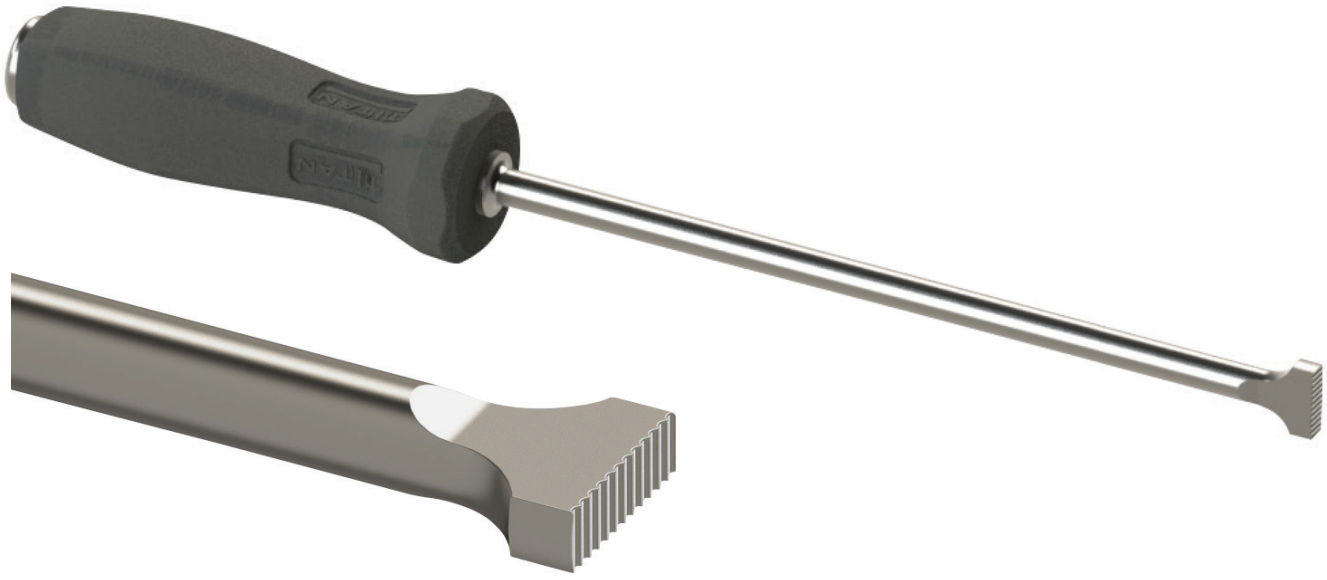
52X6-2XXX

INSTRUMENT OVERVIEW



TC Implant Holder
5200-1001



TC Tamp
5200-1003

DESCRIPTION

The ENDOSKELETON® TC Interbody Fusion implants are designed with a large hollow region in the center to house autograft bone. The new bone formation through the implant is intended to provide long-term structural support and fusion at the implanted disc space. The design incorporates “windows” through the implant to permit visualization of the graft material and over time formation of new bone. The implants are composed of ASTM F136 Ti 6Al-4V ELI titanium alloy and are provided non-sterile.

An implant holding feature has been incorporated into the trailing surface of the implant to mate with the implant holder, and to facilitate placement of the implant into the interbody space.

INDICATION FOR USE

The ENDOSKELETON® TC Interbody Fusion Device is indicated for use in anterior cervical interbody spinal fusion procedures in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine at one disc level from C-3 to C-7. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The ENDOSKELETON® TC device is indicated for use with supplemental fixation systems cleared for use in the cervical spine. It is indicated to be used with autograft bone.

WARNINGS

In using metallic implants, the surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape, and design of the implant.
2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes that are larger and smaller than those expected to be used.
3. The correct handling of the implant is extremely important. Contouring of the implant is to be avoided.
4. The ENDOSKELETON® TC Interbody Fusion System has not been evaluated for safety and compatibility in the MR environment. Potential risks in the MR environment may include; heating, migration, and image artifact.

CONTRAINDICATIONS

1. As with all orthopedic implants, the ENDOSKELETON® TC Interbody Fusion Device should never be reused under any circumstances. Reuse may result in, but is not limited to the following; infection or bending, loosening or breakage due to impairment of implant integrity.
2. The Endoskeleton® TC Interbody Fusion Device should never be implanted in patients with a systemic or local infection.
3. The Endoskeleton® TC system should not be used with components of any other interbody systems. Supplemental fixation must be used.
4. The Endoskeleton® TC device should not be implanted in patients with an allergy to titanium or titanium alloys.
5. All patients should have at least 6 weeks of non-operative care prior to spinal fusion with the Endoskeleton® TC device.
6. The Endoskeleton® TC Interbody Fusion Device should not be implanted in patients with a prior fusion to the level to be treated.

PRECAUTIONS

Preoperative:

1. Only patients that meet the criteria described in the indication should be selected.
2. Based on fatigue testing results, when using the Endoskeleton® TC Interbody Fusion Device, 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 this system.
3. Safety and effectiveness has not been established in patients with the following conditions: morbid obesity; symptomatic cardiac disease; pregnancy; signs of local inflammation; fever or leukocytosis; metal sensitivity/allergy to the implant materials; any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count; grossly distorted anatomy due to congenital abnormalities; osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the obtainable correction, the amount of mechanical fixation, and /or the quality of the bone graft); long term systemic corticosteroid use; active drug abuse; any case requiring the mixing of metals from different components; any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition; any patient unwilling to cooperate with the postoperative instructions; any time implant utilization would interfere with anatomical structures or expected physiological performance. Patient conditions and/or predispositions such as these should be avoided. Other conditions may exist where safety and effectiveness have not been established.
4. Care should be used in handling and storage of the implants and instruments. The implant should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments. Devices should be routinely inspected; if they exhibit wear, damage, corrosion, or discoloration
5. The type of construct to be assembled for the case should be determined prior to beginning the surgery.
6. Because mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the implants to verify that all parts and necessary instruments are present before the surgery begins.
7. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
8. Postoperative care is important. The patient should be instructed in the limitations of his/her metallic implant and should be cautioned regarding weight bearing and body stress on the appliances prior to secure bone healing.

PRECAUTIONS

Intraoperative:

1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in loss of neurological functions.
3. The implant surfaces should not be scratched or notched since such actions may reduce the functional strength of the construct.
4. Autograft bone must be placed in the area to be fused and the graft must be in contact with viable bone.
5. Internal and external threads on instruments can be damaged by cross-threading. Inspect internal and external threads for damage prior to assembly. If threads are damaged, set the product aside and do not use. When threading components together, keep to the thread axis. Screw in the component as far as it will go and make sure that the product is flush with the insertion instrument. On all threaded connections, finger tighten only.

Postoperative:

1. The physician's postoperative directions and warnings to the patient and corresponding patient compliance are extremely important.
2. Detailed instructions on the use and limitations of the implant should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening, or breakage of the implant are complications which can occur as a result of excessive or early weight bearing or excessive muscular activity. The risk of bending, loosening, or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active or if the patient is debilitated, demented, or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. To allow maximum chances for a successful surgical result, the patient should not be exposed to mechanical vibrations that may loosen the implant. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions, and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
4. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction on body motion.
5. If a nonunion develops or if the implant loosens, bends, and/or breaks, the implant should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual bending, loosening or breakage of the implant. It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
6. Any retrieved implants should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the ENDOSKELETON® TC Interbody Fusion implants should ever be reused under any circumstances. Reuse may result in, but is not limited to the following: infection or bending, loosening or breakage due to impairment of implant integrity

ADVERSE EVENTS

Possible adverse effects include, but are not limited to, bending, loosening, or fracture of the implants or instruments; loss of fixation; sensitivity to a metallic foreign body, including possible tumor formation; skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications; nonunion or delayed union; infection; nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis, and cerebral fluid leakage; gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency, and/or loss of consortium; pain or discomfort; bone loss due to resorption or stress shielding, or bone fracture at, above, or below the level of surgery (fracture of the vertebra); hemorrhage of blood vessels and/or hematomas; malalignment of anatomical structures, including loss of proper spine curvature, correction, reduction, and/or height; bursitis; bone graft donor site pain; inability to resume activities of normal daily living; reoperation or death.

CLEANING & STERILIZATION

ENDOSKELETON® TC Interbody Fusion Device implants are provided non-sterile. Implants must be sterilized using a validated sterilization method prior to use. Refer to Titan Spine Recommended Cleaning and Sterilization Instruction 70-0015 for detailed instruction.
ENDOSKELETON® TC instrumentation is provided non-sterile and must be cleaned and sterilized prior to use. Refer to Titan Spine Recommended Cleaning and Sterilization Instruction 70-0015 for detailed instruction.
The following sterilization cycle should be used:

Surgical Case	Method	Cycle	Temperature	Exposure Time	Dry Time
Wrapped	Steam	Pre-vacuum	273° F (134° C)	3 minutes	Minimum of 10 minutes

DIRECTIONS FOR USE

The ENDOSKELETON® TC Interbody Fusion Device should only be implanted by surgeons who are experienced in the use of such implants and the required specialized spinal surgery techniques.

PREOPERATIVE PLANNING

Prior to surgery, the operating room staff must inspect the surgical trays to be sure there is an adequate supply of each of the implant sizes and each of the instruments. The surgical trays containing the non-sterile implants, trial spacers and instruments must be cleaned and sterilized prior to use. All components must be inspected to verify there are no defects or flaws in any of the components.
A/P and lateral x-rays must be reviewed by the implanting surgeon to verify that the patient's vertebral body dimensions are of sufficient size to accommodate one of the ENDOSKELETON® TC implant sizes.

PATIENT POSITIONING

The patient is brought to the operating room, transferred to the surgical table in the supine position and put to sleep under general anesthesia. An endotracheal tube is placed to facilitate breathing during surgery. The surgical area is then cleaned and sterilely prepped and draped.

SURGICAL APPROACH

The surgeon begins the procedure through an anterior transverse incision. Access to the appropriate disc space is performed in the surgeon's usual manner. A pin is placed in the disc space and fluoroscopy is taken to confirm access of the correct level and to confirm the position of the midline.

DISC SPACE PREPARATION

The annulus is identified and a rectangular portion of annulus is incised and removed (Figure 1). A discectomy is performed in the surgeon's preferred manner until bleeding bone is exposed on the superior and inferior vertebral endplates. Care should be taken to remove only cartilaginous endplate and to leave the boney endplate intact.

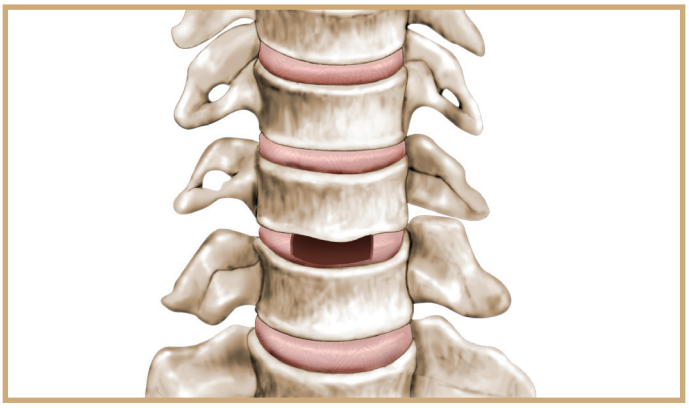


FIGURE 1

DETERMINE THE SIZE OF THE REQUIRED IMPLANT

Using the implant trials, establish the correct height and footprint of the implant to be used. The ENDOSKELETON® TC is designed to rest upon the strong outer rim of the vertebral endplate. The footprint width is identified using the trial and may be viewed directly. Footprint depth is identified using the trial in conjunction with a lateral fluoroscopic view (Figure 2). The selected width and depth should allow positioning of the device on the apophyseal rim of the vertebral endplate. The implant chosen is recommended to be the same height as the last trial used.

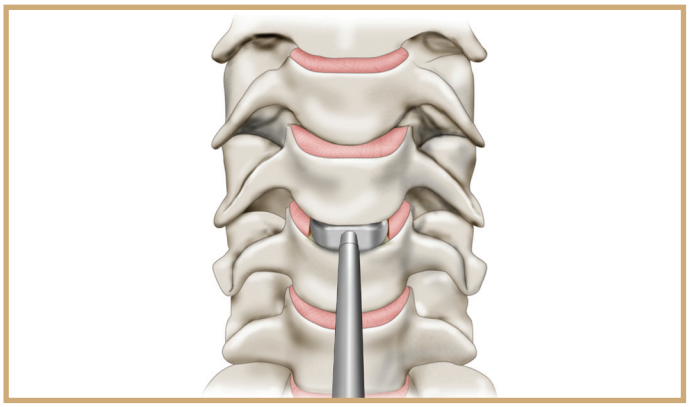


FIGURE 2

IMPLANT GRAFT PACKING

Fill the implant with autograft bone material (Figure 3).

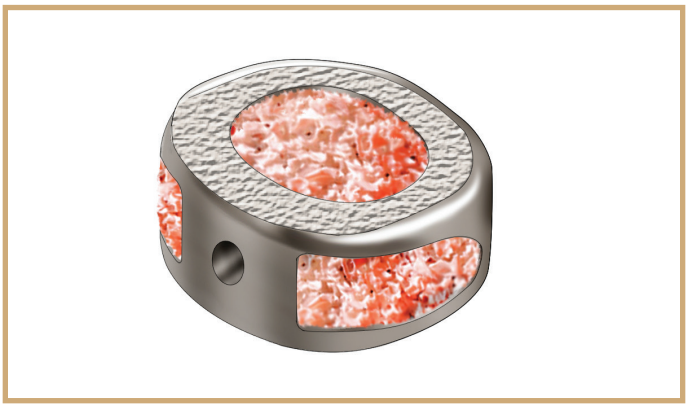


FIGURE 3

IMPLANT-INSERTER ASSEMBLY

Assemble the implant to the implant holder (Figure 4).

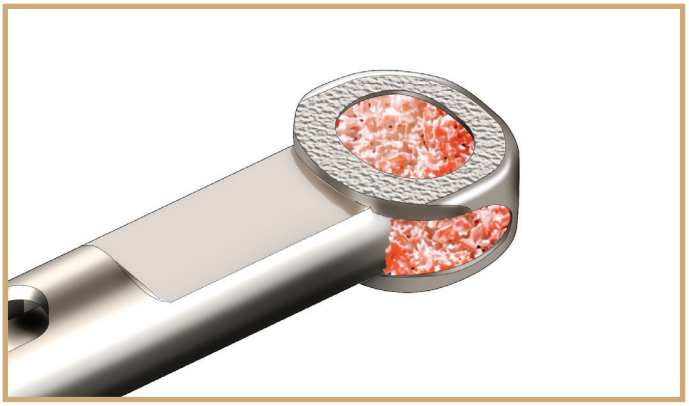


FIGURE 4

Note: Caution should be taken to only finger tighten the knob and avoid applying excessive force.

PLACEMENT OF THE IMPLANT

Place the implant loaded with autograft bone into the disc space (Figure 5). Detach the holder once the trailing edge of the implant is inside the disc space.

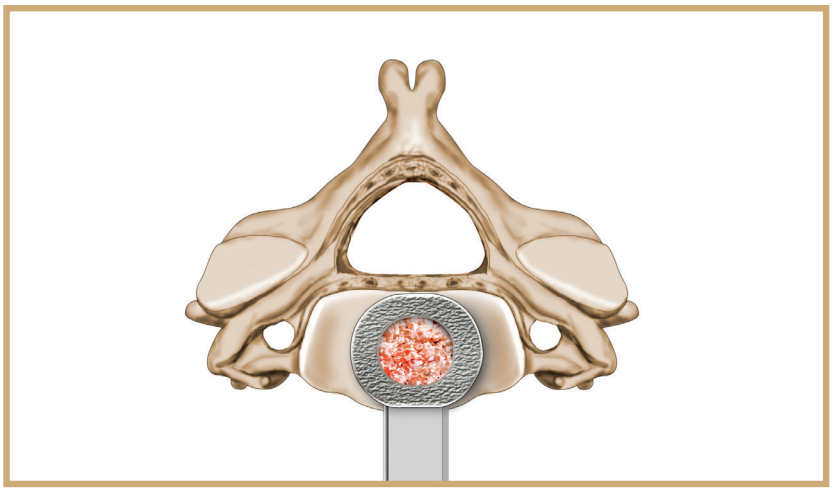


FIGURE 5

Maneuver the implant into its final position using the impactor if necessary. The final position of the implant should ideally rest on the posterior apophyseal ring of the vertebral endplate as shown in (Figure 6).

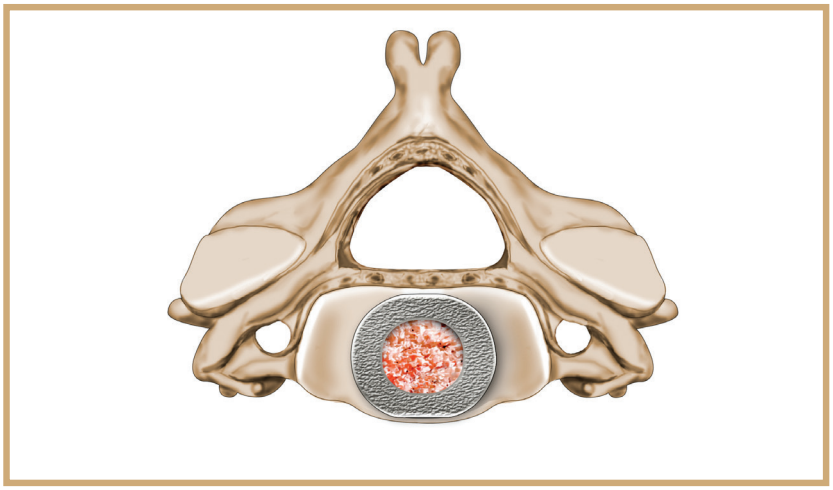


FIGURE 6

Note: Attempting to pivot the implant with the implant holder may damage the instrument.

ADDITIONAL AUTOGRAFT BONE

Additional autograft bone may be placed in and around the implant.

SUPPLEMENTAL FIXATION

In order to stabilize the construct, the ENDOSKELETON® TC is indicated to be used with supplemental fixation.

CLOSING PROCEDURE

Remove the retractors to allow the vessels and muscles to relax toward their normal position and close in the usual manner.

REMOVAL AND REVISION

Removal or revision of the implant during the index procedure may be deemed necessary by the surgeon. If the implant needs to be repositioned or removed during the index procedure, the implant holder may be re-attached to the implant. Removal of the implant at a later time may require an alternative access approach to the spine to be determined by the surgeon based on individual patient requirements. If removal or revision of the implant through the original access approach is required at a time after the index procedure, the surgeon may utilize the instruments described above.

NOTES

TITAN SPINE

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