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ENDOSKELETON® TAS

TAS

SURGICAL TECHNIQUE GUIDE

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Instrument Overview	4
Description	8
Indication for Use	8

ENDOSKELETON® TAS INTERBODY FUSION DEVICE SURGICAL TECHNIQUE

Patient Positioning	12
Surgical Approach	12
Disc Space Preparation	13
Determine the Size of the Required Implant	13
Implant Graft Packing	14
Implant-Insertion Assembly	14
Placement of the Implant	15
Additional Autograft Bone	17
Closing Procedure	17
Removal and Revision	17

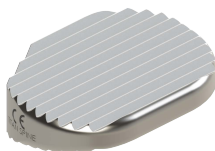
INSTRUMENT OVERVIEW



Threaded Holder
2106-1003



Rasp
7° - 2106-7XXX
12° - 2X12-7XXX



Rasp
16° - 2316-7XXX
20° - 2320-7XXX
24° - 2324-7XXX



Distractor
7° - 2106-9XXX
12° - 2X12-9XXX



Slap Hammer
2106-1002



Implant Holder Locking
2300-1015

INSTRUMENT OVERVIEW



TAS Hyperlordotic Two-Up
Anterolateral Inserter
2300-1310



TAS Hyperlordotic One-Up
Anterolateral Inserter
2300-1311



TAS Fixed Handle Awl,
Straight 2300-1110



TAS Fixed Handle Awl, Curved
2300-1120

INSTRUMENT OVERVIEW



Screwdriver T-Handle Non-ratchet
Square Drive 1/4"
2300-1039



Screwdriver Handle Non-ratchet
Square Drive 1/4"
2300-1038



TAS Square Drive Ratcheting
2300-1046



Awl Guide Assembly
2300-1036



Bone Awl, Universal Joint Assembly
2300-1035



Hex Driver Universal Joint Assembly
2300-1034



Swivel Hex Driver with Lead
2300-1302



TAS 40 Deg. Fixed Angle Driver
2300-1313



TAS Fixed Angled Driver, Ancillary Handle
2300-1314



Impactor
2106-1000



Implant Remover
2300-1012

DESCRIPTION

The ENDOSKELETON® TAS and ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Device implants are available in a variety of Anterior Lumbar Interbody Fusion (ALIF) sizes with a variety of lordotic angles, to accommodate patient anatomy; Hyperlordotic implants are those defined by a lordotic angle $\geq 16^\circ$. Implants are designed with a large hollow region in the center to house autograft bone material. 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 superior and inferior surfaces include either the previously cleared Chemtex® surface treatment or previously cleared nanoLOCK® surface treatment to improve fixation to the adjacent bone. The nanoLOCK® surface technology provides a microscopic roughened surface with nano-scale features. The implant system includes integrated fixation (screws) for stabilizing the implants when placed in the interbody space.

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. Screws include internal hex drive features matched to instrumentation for implantation. All implantable components are manufactured from medical grade titanium alloy (Ti6A14V-ELI).

INDICATIONS FOR USE

The ENDOSKELETON® TAS Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is a standalone system that is intended to be used with the bone screws provided and requires no additional supplementary fixation. The device is indicated to be used with autograft bone.

HYPERLORDIC DEVICES $\geq 16^\circ$

The Endoskeleton® TAS Hyperlordotic Interbody Fusion Device ($\geq 16^\circ$) is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device is indicated to be used with autograft bone. The Endoskeleton® TAS Hyperlordotic Interbody Fusion Device must be used with a posterior supplemental internal spinal fixation that has been cleared by the FDA for use in the lumbar spine.

WARNINGS

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 larger and smaller than those expected to be used.
3. The correct handling of the implants is extremely important. Contouring of the implants is to be avoided.
4. The Titan Spine ENDOSKELETON® TAS or ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Systems have 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® TAS or ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Devices 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® TAS or ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Device should never be implanted in patients with a systemic or local infection.
3. The ENDOSKELETON® TAS or ENDOSKELETON® TAS Hyperlordotic system should not be used with components of any other interbody systems.
4. The ENDOSKELETON® or TAS ENDOSKELETON® TAS Hyperlordotic device should not be implanted in patients with an allergy to titanium or titanium alloys.
5. All patients should have at least 6 months of non-operative care prior to spinal fusion with the ENDOSKELETON® TAS or ENDOSKELETON® TAS Hyperlordotic device.
6. The ENDOSKELETON® TAS or ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Device should not be implanted in patients with a prior fusion at the level(s) to be treated.

PRECAUTIONS

Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.
2. Based on fatigue testing results, when using the ENDOSKELETON® TAS or ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Devices, 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 implants 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 implants 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 they should be returned to Titan Spine for further evaluation.
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(s) and should be cautioned regarding weight bearing and body stress on the appliance 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(s) 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(s) 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(s). 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(s) loosen, bend and /or break, the implant(s) 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(s).

By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the implant(s). 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® TAS or ENDOSKELETON® TAS Hyperlordotic 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® TAS or ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Device implants are provided either sterile or non-sterile, see package labeling for identification. Implants provided sterile are sterilized with gamma irradiation. Implants removed from sterile packaging but never used in surgery, as well as implants found in damaged packaging must be returned to Titan Spine for proper disposition. Refer to Titan Spine Recommended Cleaning and Sterilization Instruction 70-0015 for detailed instruction.

ENDOSKELETON® TAS or ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Device non-sterile implants, screws and instruments are provided non-sterile in either a non-rigid reusable container system or a rigid reusable sterilization container system. The rigid reusable sterilization container system has been validated for use with the single use paper filter (US751) only. ENDOSKELETON® TAS or ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Devices 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
Rigid Sterilization	Steam	Pre-vacuum	273°F (134°C)	3 minutes	Minimum of 30 minutes

DIRECTIONS FOR USE

The ENDOSKELETON® TAS or ENDOSKELETON® TAS Hyperlordotic Interbody Fusion Devices should only be implanted by surgeons who are experienced in the use of such implants and the required specialized spinal surgery techniques. Refer to the ENDOSKELETON® TAS Interbody Fusion Device Surgical Technique in the following section:

A copy of the surgical technique manual/IFU can be obtained by contacting Titan Spine at 262-242-7801 or tsinfo@titanspine.com.

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 the ENDOSKELETON® TAS or ENDOSKELETON® TAS Hyperlordotic 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. A pad is placed under the lumbar spine to maintain lordosis. Arms are crossed over the chest to facilitate fluoroscopy. The surgical area is then cleaned and sterilely prepped and draped.

SURGICAL APPROACH

A vascular or general surgeon begins the procedure through a low transverse or paramedian 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 confirm the position of the midline.

DISC SPACE PREPARATION

The annulus is identified and a rectangular portion of annulus is incised and removed. Perform a discectomy and expose bleeding punctate bone of the superior endplate of the inferior vertebra and the inferior endplate of the superior vertebra (Figure 1). Care should be taken to remove only cartilaginous endplate, and to leave the bony endplate intact. A rasp is available that is designed to match the footprint of the implant (Figure 2). Hyperlordotic implants (i.e., $\geq 16^\circ$) will utilize rasps for sizing.



FIGURE 1

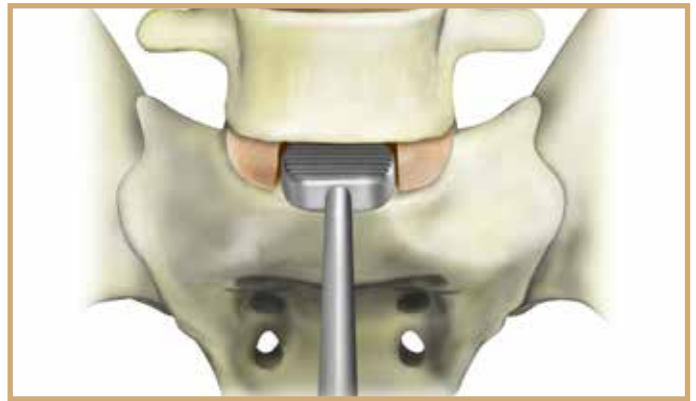


FIGURE 2

DETERMINE THE SIZE OF THE REQUIRED IMPLANT

Using the implant trials, establish the correct height and footprint of the implant to be used such that the final position of the implant should ideally rest on the apophyseal ring and the anterior edge of the implant should barely be countersunk past the anterior edge of the vertebral bodies.. The implant chosen is recommended to be 1mm taller than the last trial used. Hyperlordotic implants (i.e., $\geq 16^\circ$) will utilize rasps for sizing.

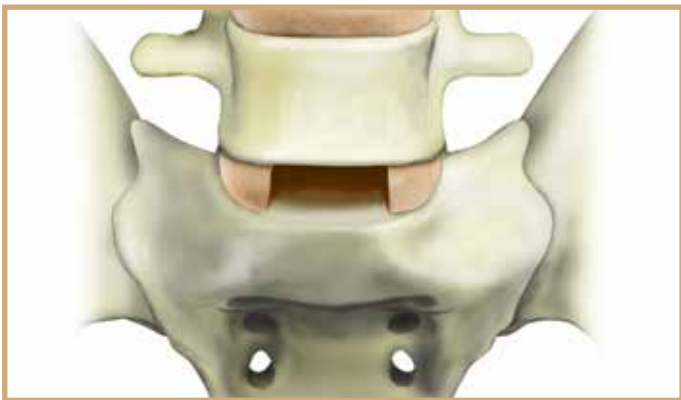


FIGURE 1

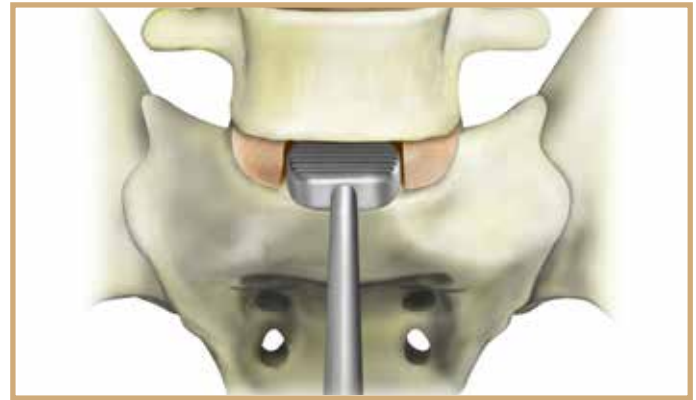


FIGURE 2

IMPLANT GRAFT PACKING

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



FIGURE 3

IMPLANT-INSERTER ASSEMBLY

To assemble the implant to the implant holder, match the male end of the holder to the female portion of the implant while connecting the latch to the corresponding slot on the inside of the implant (Figures 4 & 5).



FIGURE 4



FIGURE 5

Note: Care should be taken not to attach the inserter to the implant with the latch on the implant's surface.

PLACEMENT OF IMPLANT

Place the implant loaded with bone graft into the disc space (Figure 6). Detach the holder once the trailing edge of the implant is inside the disc space. Implant/screw orientation is at the discretion of the physician in that the implant has no “up” or “down” orientation.

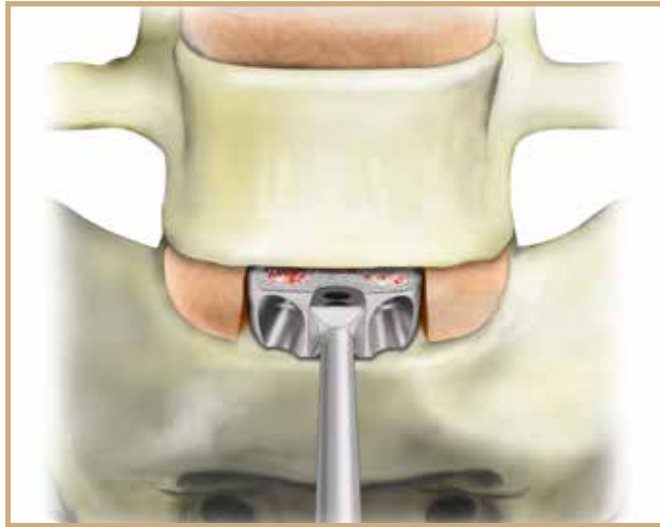


FIGURE 6

If necessary, adjust the position of the implant using the impactor instrument. The final position of the implant should ideally rest on the apophyseal ring and the anterior edge of the implant should barely be countersunk past the anterior edge of the vertebral bodies as shown in Figure 7.

Note: It is important to verify proper positioning of the implant via fluoroscopy prior to screw placement in case any adjustments needs to be made.

Note: Attempting to pivot the implant with the implant inserter within the disc space may damage the instrument.



FIGURE 7

PLACEMENT OF IMPLANT SCREWS

Remove a small portion of the anterior vertebral body in order to gain full access to the implant screw sockets (Figure 8). Retain removed bone fragments for replacement after the screws are seated if desired.

Perforate the endplate using the awl instrument of choice for correct subsequent screw alignment. The alignment guide should be used to aid in selecting the appropriate trajectory and to center the perforation within the implant body's screw holes. A/P and lateral x-rays should be used to confirm desired trajectories (Figure 9). Assemble screws to the driver instrument of choice and insert screws into the perforated sites (Figure 10). Seat screws fully into implant body and verify proper position using fluoroscopy (Figure 11). Replacement of bone segments harvested for screw access can be replaced at this time if desired.

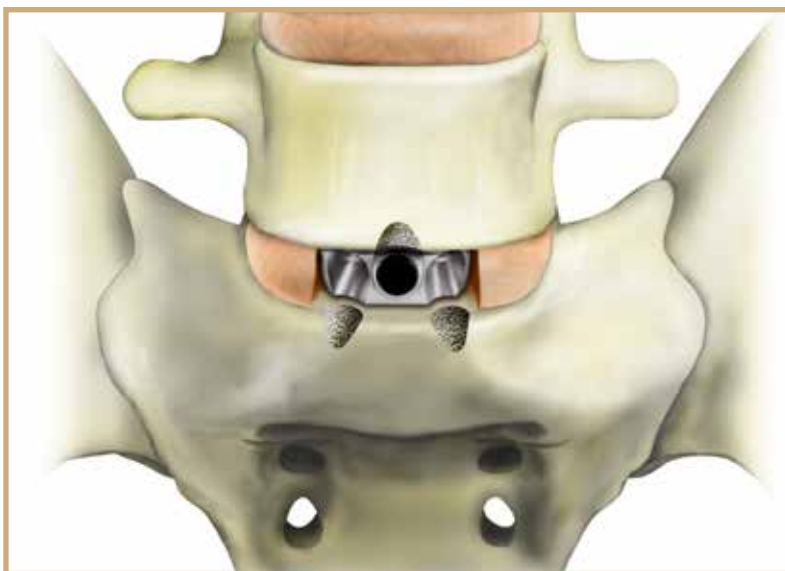


FIGURE 8

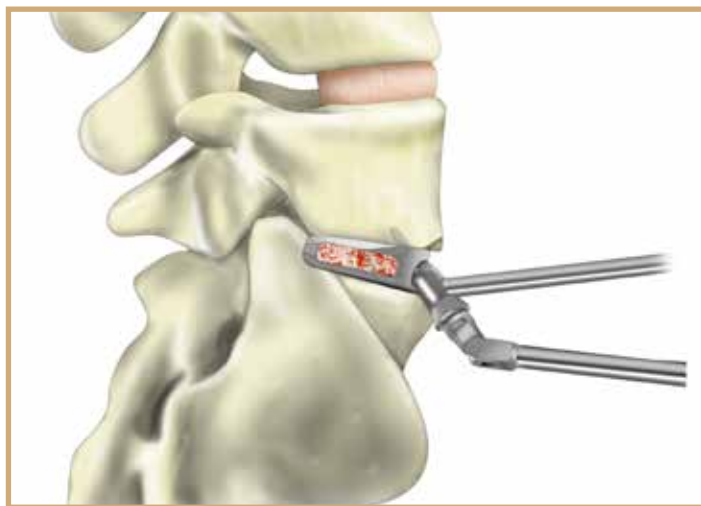


FIGURE 9

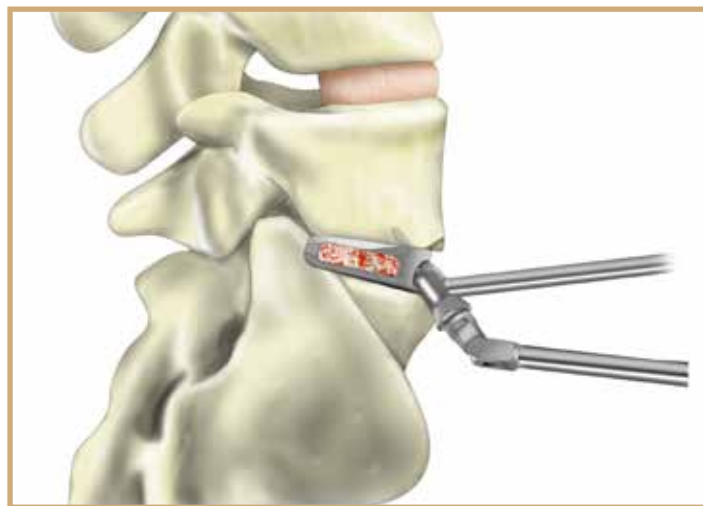


FIGURE 10

PLACEMENT OF IMPLANT SCREWS CONT.

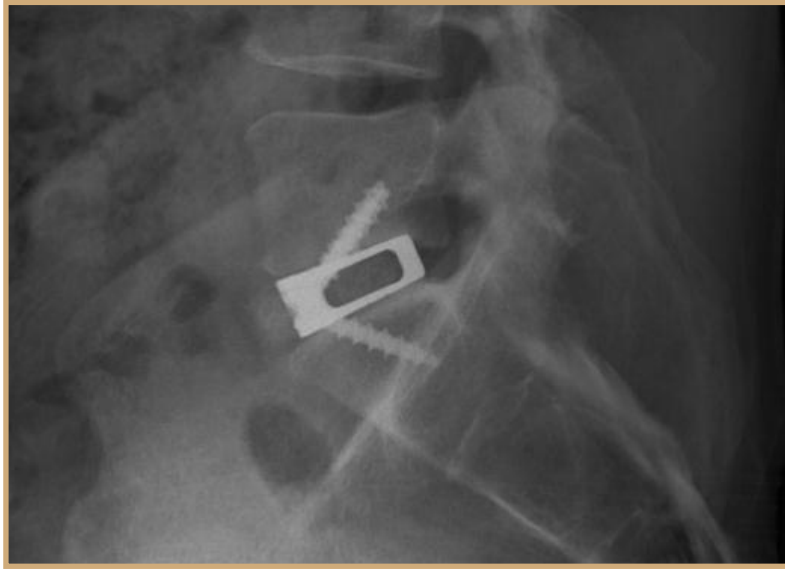


FIGURE 11

ADDITIONAL AUTOGRAFT BONE

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

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 required to correct the size or position of the implant after reviewing the construct via fluoroscopy. If the implant needs to be adjusted or removed during the index procedure prior to screw placement, gently distract the disc space to disengage the implant from the endplates. To adjust the position of the implant more posteriorly, use the impactor tool. To adjust the position of the implant more anteriorly or remove it entirely, attach the implant inserter to the implant and then attach the slap hammer to the inserter to move the implant in an anterior direction. If necessary, screw removal can be facilitated using one of the screwdrivers. If the implant is removed, follow the directions listed above to reinsert the implant.

NOTES

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Notice: One or more products are covered by patents.
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Printed in USA. Literature Part Number 60-0039, Rev 03.



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