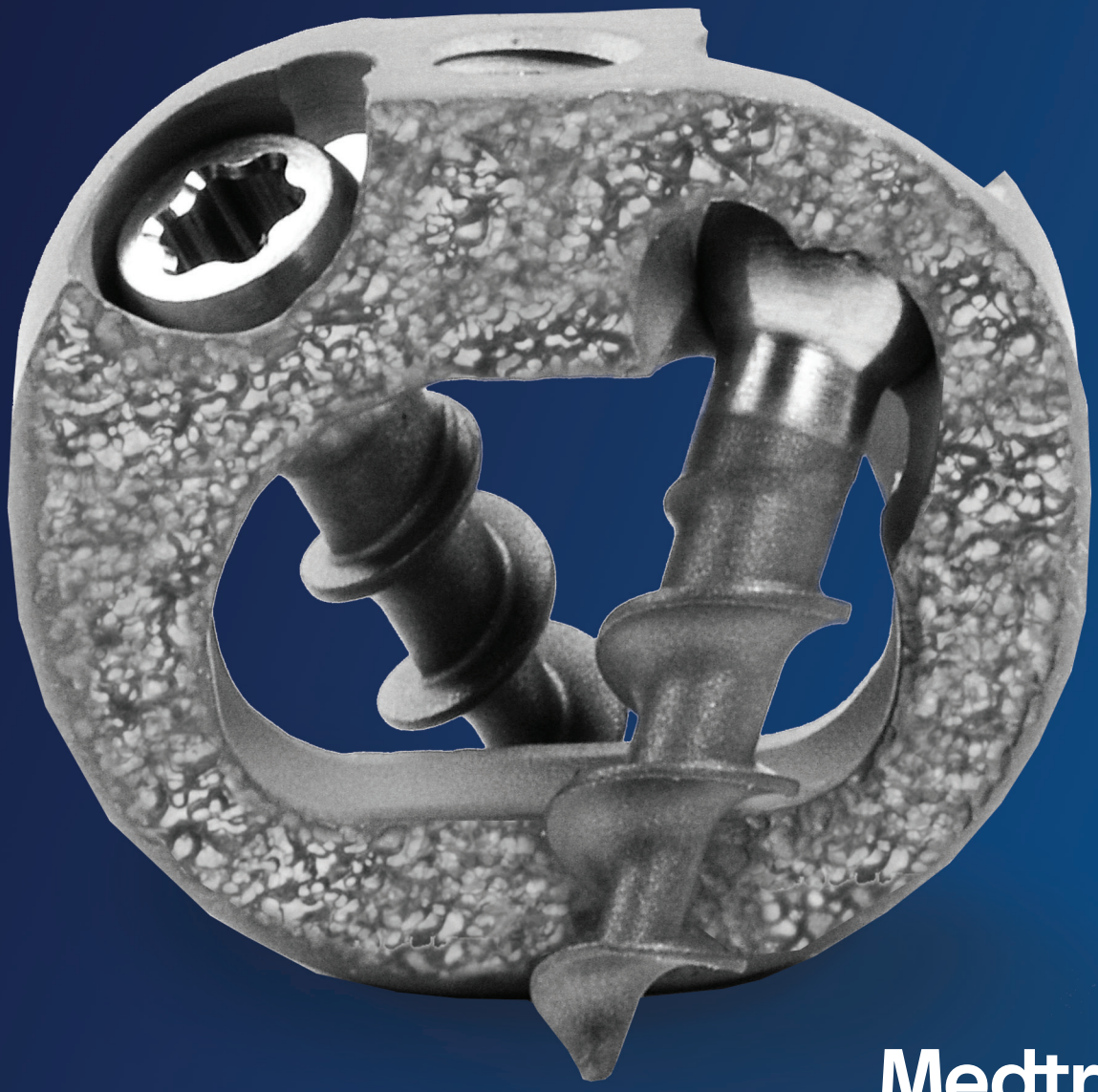
SURGICAL
TECHNIQUE

Endoskeleton™ TCS Interbody System



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DIRECTIONS **FOR USE**

The Endoskeleton TCS 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. Refer to the Endoskeleton TCS Interbody Fusion Device Surgical Technique in the following section.

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 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 TCS 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, 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.

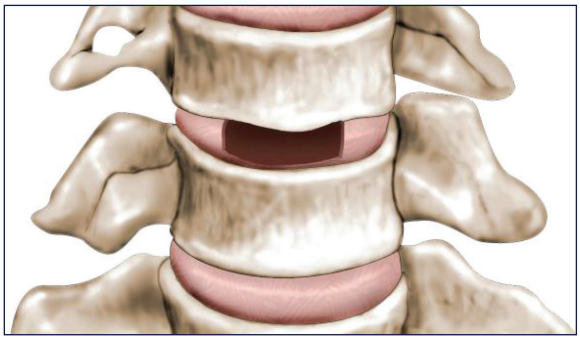

Figure 1

TRIALING

Using the implant trials, establish the correct height and footprint of the implant to be used. 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 x-ray or fluoroscopic view (Figure 2). The selected width and depth should allow positioning of the device on the apophyseal rim of the vertebral endplate with the anterior edge of the implant barely countersunk past the anterior edge of the vertebral bodies. The implant chosen is recommended to be the same height as the last trial used.

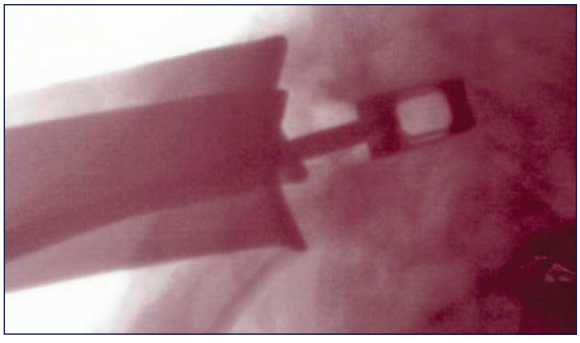

Figure 2

IMPLANT **GRAFT PACKING**

Fill the implant with autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination (Figure 3).

Figure 3

IMPLANT-INSERTER **ASSEMBLY**

Assemble the implant to the implant inserter by rotating the inserter in a clockwise direction (Figure 4).

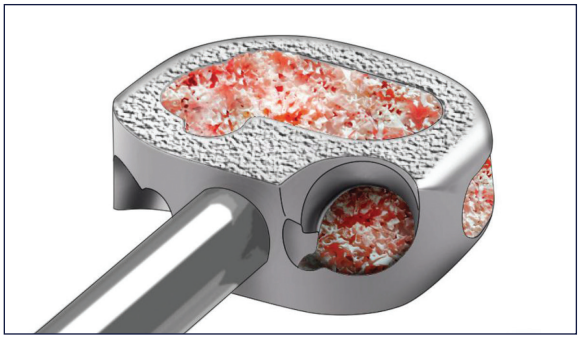

Figure 4

IMPLANTATION

Place the implant loaded with autograft bone into the disc space. Detach the implant once the trailing edge of the implant is inside the disc space by rotating the inserter in a counterclockwise direction. There is no "up" or "down" orientation of the implant. If necessary, adjust the position of the implant using the tamp 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 (Figure 5).

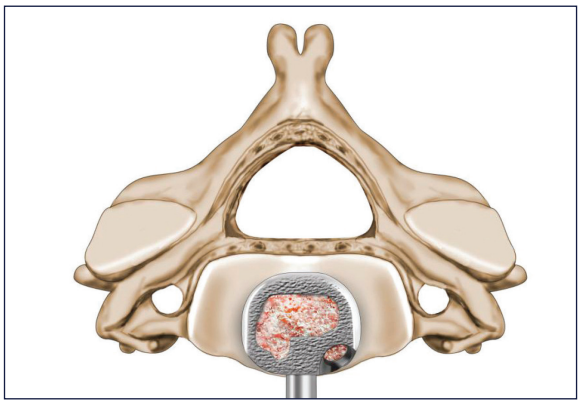

Figure 5

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

ADDITIONAL **BONE GRAFT**

Additional autograft bone, allograft bone comprised of cancellous and/or coritcocancellous bone, demineralized allograft with bone marrow aspirate, or a combination should be placed in and around the cage.

PLACEMENT OF **IMPLANT SCREWS**

Create pilot holes for the screws using the appropriate length awl (relative to anticipated screw length usage) under A/P and lateral fluoroscopy. When determining the appropriate sized awl, the 2 mm awl may be used for creating pilot holes in osteoporotic bone. The awl guide must be used to help facilitate the desired pilot hole trajectory and position. Confirm desired awl trajectory prior to awl advancement using fluoroscopy. The torque limiting handle must be used during screw tightening to prevent damage to the driver and/or screw. Assemble the screws to one of the screwdrivers (Figure 6) and seat the screws fully into the implant body.

Note: Use caution to only place hand on the silicone portion of the Torque Limiting Handle while driving Bone Screws.

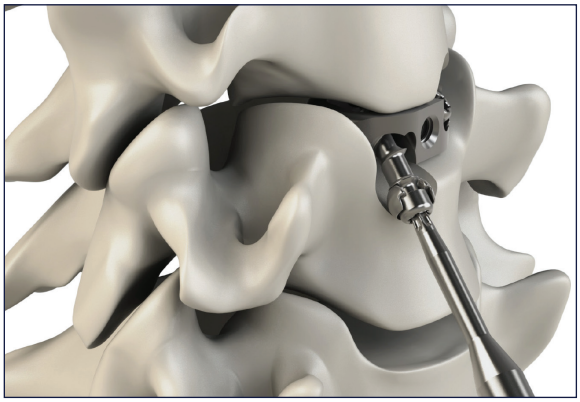

Figure 6

Figure 7

Figure 8

Figure 9

Figure 10

SUPPLEMENTAL **FIXATION**

In order to stabilize the construct if the integrated screws are not used, the Endoskeleton TCS is indicated to be used with supplemental fixation cleared for the cervical spine.

CLOSURE

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

REMOVAL **AND REVISION**

If the implant needs to be repositioned or removed during the index procedure prior to screw placement, the implant inserter may be re-attached to the implant. A slap hammer is provided and can be used to remove or reposition the implant anteriorly. 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 instrumentation described above. If the screws must be removed, the following technique is recommended. Locking screws may be reverse spun by one of the screwdrivers to disengage the anti-backout mechanism. For a stripped thread condition, use the screw rescue extractor. Assemble the extractor to the handle and then insert the extractor into the screw drive feature on the screw head and rotate counter-clockwise while applying forward pressure. Once the extractor is firmly engaged within the screw, reverse spin the screw while pulling away from the implant to explant the screw (Figure 16). If necessary, remove the implant using the procedure stated above.

Figure 16

ENDOSKELETON TCS
ORDERING INFORMATION

Endoskeleton TCS Instrument Set

PART NUMBER	DESCRIPTION	QTY
5046-1205	Endoskeleton TCS 6 Deg Lordotic, Trial, Small, 5 mm	1
5046-1207	Endoskeleton TCS 6 Deg Lordotic, Trial, Small, 7 mm	1
5046-1209	Endoskeleton TCS 6 Deg Lordotic, Trial, Small, 9 mm	1
5046-1211	Endoskeleton TCS 6 Deg Lordotic, Trial, Small, 11 mm	1
5066-1405	Endoskeleton TCS 6 Deg Lordotic, Trial, Medium, 5 mm	1
5066-1407	Endoskeleton TCS 6 Deg Lordotic, Trial, Medium, 7 mm	1
5066-1409	Endoskeleton TCS 6 Deg Lordotic, Trial, Medium, 9 mm	1
5066-1411	Endoskeleton TCS 6 Deg Lordotic, Trial, Medium, 11 mm	1
5086-1605	Endoskeleton TCS 6 Deg Lordotic, Trial, Large, 5 mm	1
5086-1607	Endoskeleton TCS 6 Deg Lordotic, Trial, Large, 7 mm	1
5086-1609	Endoskeleton TCS 6 Deg Lordotic, Trial, Large, 9 mm	1
5086-1611	Endoskeleton TCS 6 Deg Lordotic, Trial, Large, 11 mm	1
5210-1036	Endoskeleton TCS Slap Hammer	1
5210-1015	Endoskeleton TCS Rongeur	1
5210-1048	Endoskeleton TCS Bone Screw Extractor	2
5210-1024	Endoskeleton TCS No 8 Hexalobe, Fillet Spring, U-Joint Driver	1
5210-1004	Endoskeleton TCS No 8 Hexalobe, Fillet Spring, Straight Driver	2
5210-1067-15	Endoskeleton TCS Fixed Angle Driver, Driver Shaft Assembly	2
5210-1067-25	Endoskeleton TCS Fixed Angle Driver, Outer Body	2
5210-1067-90	Endoskeleton TCS No 8 Hexalobe, Fillet Spring, Fixed Angle Driver Bit	1
5210-1067-100	Endoskeleton TCS Fixed Angle Driver, 2.5 mm Drill Tip	1
5210-1068	Endoskeleton TCS Fixed Angle Driver, Ancillary Handle	1
5210-1022	Endoskeleton TCS Straight, Retractable Awl	1
5210-1016	Endoskeleton TCS Ratcheting Handle	1
5210-1003	Endoskeleton TCS Mallet	1
5210-1062	Endoskeleton TCS Straight, Fixed Awl, 2 mm	1
5210-1063	Endoskeleton TCS Curved, Fixed Awl, 2 mm	1
5210-1064	Endoskeleton TCS Bayoneted Awl Guide, 2.0 mm	1
5210-1066	Endoskeleton TCS 45 Deg, Curved, Retractable Awl	1
5210-1073	Endoskeleton TCS 15 Deg Bayoneted Awl Guide, 2.0 mm	1
5210-1075	Endoskeleton TCS 45 Deg, Curved Retractable Awl	1
5280-1705	Endoskeleton TC 6 Deg Lordotic, Rasp, Small, 5 mm	1
5200-1003	Endoskeleton TC Tamp	1
5210-1021	Endoskeleton TCS Inserter	2
5210-1046	Endoskeleton TCS Torque Limiting Handle	1

ENDOSKELETON TCS
ORDERING INFORMATION (cont.)

Endoskeleton TCS Implant Set

PART NUMBER	DESCRIPTION	QTY
5301-3514	Endoskeleton TCS 3.5 mm Dia, Standard, Bone Screw, 14 mm	4
5301-3516	Endoskeleton TCS 3.5 mm Dia, Standard, Bone Screw, 16 mm	4
5301-3518	Endoskeleton TCS 3.5 mm Dia, Standard, Bone Screw, 18 mm	4
5301-3814	Endoskeleton TCS 3.8 mm Dia, Standard, Bone Screw, 14 mm	4
5301-3816	Endoskeleton TCS 3.8 mm Dia, Standard, Bone Screw, 16 mm	4
5301-3818	Endoskeleton TCS 3.8 mm Dia, Standard, Bone Screw, 18 mm	4
5346-1205	Endoskeleton TCS 6 Deg Lordotic, Implant, Small, 5 mm	2
5346-1206	Endoskeleton TCS 6 Deg Lordotic, Implant, Small, 6 mm	2
5346-1207	Endoskeleton TCS 6 Deg Lordotic, Implant, Small, 7 mm	2
5346-1208	Endoskeleton TCS 6 Deg Lordotic, Implant, Small, 8 mm	2
5346-1209	Endoskeleton TCS 6 Deg Lordotic, Implant, Small, 9 mm	2
5346-1210	Endoskeleton TCS 6 Deg Lordotic, Implant, Small, 10 mm	2
5346-1211	Endoskeleton TCS 6 Deg Lordotic, Implant, Small, 11 mm	2
5346-1212	Endoskeleton TCS 6 Deg Lordotic, Implant, Small, 12 mm	2
5366-1405	Endoskeleton TCS 6 Deg Lordotic, Implant, Medium, 5 mm	2
5366-1406	Endoskeleton TCS 6 Deg Lordotic, Implant, Medium, 6 mm	2
5366-1407	Endoskeleton TCS 6 Deg Lordotic, Implant, Medium, 7 mm	2
5366-1408	Endoskeleton TCS 6 Deg Lordotic, Implant, Medium, 8 mm	2
5366-1409	Endoskeleton TCS 6 Deg Lordotic, Implant, Medium, 9 mm	2
5366-1410	Endoskeleton TCS 6 Deg Lordotic, Implant, Medium, 10 mm	2
5366-1411	Endoskeleton TCS 6 Deg Lordotic, Implant, Medium, 11 mm	2
5366-1412	Endoskeleton TCS 6 Deg Lordotic, Implant, Medium, 12 mm	2
5386-1605	Endoskeleton TCS 6 Deg Lordotic, Implant, Large, 5 mm	2
5386-1606	Endoskeleton TCS 6 Deg Lordotic, Implant, Large, 6 mm	2
5386-1607	Endoskeleton TCS 6 Deg Lordotic, Implant, Large, 7 mm	2
5386-1608	Endoskeleton TCS 6 Deg Lordotic, Implant, Large, 8 mm	2
5386-1609	Endoskeleton TCS 6 Deg Lordotic, Implant, Large, 9 mm	2
5386-1610	Endoskeleton TCS 6 Deg Lordotic, Implant, Large, 10 mm	2
5386-1611	Endoskeleton TCS 6 Deg Lordotic, Implant, Large, 11 mm	2
5386-1612	Endoskeleton TCS 6 Deg Lordotic, Implant, Large, 12 mm	2
5302-3514	Endoskeleton TCS 3.5 mm Dia, Locking, Bone Screw, 14 mm	6
5302-3516	Endoskeleton TCS 3.5 mm Dia, Locking, Bone Screw, 16 mm	6
5302-3518	Endoskeleton TCS 3.5 mm Dia, Locking, Bone Screw, 18 mm	6
5301-3513	Endoskeleton TCS 3.5 mm Dia, Standard, Bone Screw, 13 mm	4
5302-3513	Endoskeleton TCS 3.5 mm Dia, Locking, Bone Screw, 13 mm	6

ENDOSKELETON TCS
ORDERING INFORMATION (cont.)

Endoskeleton TCS Implant Set (cont.)

PART NUMBER	DESCRIPTION	QTY
5301-3514	Endoskeleton TCS 3.5 mm Dia, Standard, Bone Screw, 14 mm	4
5301-3516	Endoskeleton TCS 3.5 mm Dia, Standard, Bone Screw, 16 mm	4
5301-3518	Endoskeleton TCS 3.5 mm Dia, Standard, Bone Screw, 18 mm	4
5301-3814	Endoskeleton TCS 3.8 mm Dia, Standard, Bone Screw, 14 mm	4
5301-3816	Endoskeleton TCS 3.8 mm Dia, Standard, Bone Screw, 16 mm	4
5301-3818	Endoskeleton TCS 3.8 mm Dia, Standard, Bone Screw, 18 mm	4
5302-3514	Endoskeleton TCS 3.5 mm Dia, Locking, Bone Screw, 14 mm	6
5302-3516	Endoskeleton TCS 3.5 mm Dia, Locking, Bone Screw, 16 mm	6
5302-3518	Endoskeleton TCS 3.5 mm Dia, Locking, Bone Screw, 18 mm	6
5302-3814	Endoskeleton TCS 3.8 mm Dia, Locking, Bone Screw, 14 mm	6
5302-3816	Endoskeleton TCS 3.8 mm Dia, Locking, Bone Screw, 16 mm	6
5302-3818	Endoskeleton TCS 3.8 mm Dia, Locking, Bone Screw, 18 mm	6

Endoskeleton TCS nanoLOCK Implant Set

PART NUMBER	DESCRIPTION	QTY
5346-1205-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Small, 5 mm	1
5346-1206-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Small, 6 mm	2
5346-1207-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Small, 7 mm	1
5346-1208-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Small, 8 mm	1
5346-1209-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Small, 9 mm	1
5346-1210-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Small, 10 mm	1
5346-1211-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Small, 11 mm	1
5346-1212-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Small, 12 mm	1
5366-1405-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Medium, 5 mm	1
5366-1406-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Medium, 6 mm	2
5366-1407-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Medium, 7 mm	2
5366-1408-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Medium, 8 mm	2
5366-1409-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Medium, 9 mm	1
5366-1410-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Medium, 10 mm	1
5366-1411-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Medium, 11 mm	1
5366-1412-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Medium, 12 mm	1
5386-1605-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Large, 5 mm	1
5386-1606-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Large, 6 mm	2
5386-1607-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Large, 7 mm	2
5386-1608-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Large, 8 mm	1
5386-1609-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Large, 9 mm	1
5386-1610-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Large, 10 mm	1
5386-1611-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Large, 11 mm	1
5386-1612-N	Endoskeleton TCS nanoLOCK Surface Technology, 6 Deg Lordotic, Implant, Large, 12 mm	1

GRAFT VOLUME INFORMATION

Endoskeleton TCS

SMALL CONFIGURATIONS				MEDIUM CONFIGURATIONS				LARGE CONFIGURATIONS			
M/L X A/P 14 x 12 mm	Anterior Height (mm)	Graft Volume (cc)	Posterior Height (mm)	M/L X A/P 16 x 14 mm	Anterior Height (mm)	Graft Volume (cc)	Posterior Height (mm)	M/L X A/P 18 x 16 mm	Anterior Height (mm)	Graft Volume (cc)	Posterior Height (mm)
5346-1205	14 X 12 X 5	0.24	4.0	5366-1405	16 X 14 X 5	0.34	3.8	5386-1605	18 X 16 X 5	0.48	3.6
5346-1206	14 X 12 X 6	0.30	5.0	5366-1406	16 X 14 X 6	0.43	4.8	5386-1606	18 X 16 X 6	0.61	4.6
5346-1207	14 X 12 X 7	0.37	6.0	5366-1407	16 X 14 X 7	0.53	5.8	5386-1607	18 X 16 X 7	0.75	5.6
5346-1208	14 X 12 X 8	0.43	7.0	5366-1408	16 X 14 X 8	0.62	6.8	5386-1608	18 X 16 X 8	0.87	6.6
5346-1209	14 X 12 X 9	0.49	8.0	5366-1409	16 X 14 X 9	0.72	7.8	5386-1609	18 X 16 X 9	1.01	7.6
5346-1210	14 X 12 X 10	0.55	9.0	5366-1410	16 X 14 X 10	0.82	8.8	5386-1610	18 X 16 X 10	1.15	8.6
5346-1211	14 X 12 X 11	0.62	10.0	5366-1411	16 X 14 X 11	0.88	9.8	5386-1611	18 X 16 X 11	1.27	9.6
5346-1212	14 X 12 X 12	0.69	11.0	5366-1412	16 X 14 X 12	0.89	10.8	5386-1612	18 X 16 X 12	1.41	10.6

Endoskeleton TCS with nanoLOCK

SMALL CONFIGURATIONS				MEDIUM CONFIGURATIONS				LARGE CONFIGURATIONS			
M/L X A/P 14 x 12 mm	Anterior Height (mm)	Graft Volume (cc)	Posterior Height (mm)	M/L X A/P 16 x 14 mm	Anterior Height (mm)	Graft Volume (cc)	Posterior Height (mm)	M/L X A/P 18 x 16 mm	Anterior Height (mm)	Graft Volume (cc)	Posterior Height (mm)
5346-1205-N	14 X 12 X 5	0.24	4.0	5366-1405-N	16 X 14 X 5	0.34	3.8	5386-1605-N	18 X 16 X 5	0.48	3.6
5346-1206-N	14 X 12 X 6	0.30	5.0	5366-1406-N	16 X 14 X 6	0.43	4.8	5386-1606-N	18 X 16 X 6	0.61	4.6
5346-1207-N	14 X 12 X 7	0.37	6.0	5366-1407-N	16 X 14 X 7	0.53	5.8	5386-1607-N	18 X 16 X 7	0.75	5.6
5346-1208-N	14 X 12 X 8	0.43	7.0	5366-1408-N	16 X 14 X 8	0.62	6.8	5386-1608-N	18 X 16 X 8	0.87	6.6
5346-1209-N	14 X 12 X 9	0.49	8.0	5366-1409-N	16 X 14 X 9	0.72	7.8	5386-1609-N	18 X 16 X 9	1.01	7.6
5346-1210-N	14 X 12 X 10	0.55	9.0	5366-1410-N	16 X 14 X 10	0.82	8.8	5386-1610-N	18 X 16 X 10	1.15	8.6
5346-1211-N	14 X 12 X 11	0.62	10.0	5366-1411-N	16 X 14 X 11	0.88	9.8	5386-1611-N	18 X 16 X 11	1.27	9.6
5346-1212-N	14 X 12 X 12	0.69	11.0	5366-1412-N	16 X 14 X 12	0.89	10.8	5386-1612-N	18 X 16 X 12	1.41	10.6

IMPORTANT INFORMATION **FOR ENDOSKELETON TCS**

DESCRIPTION

The Endoskeleton TCS Interbody Fusion Device is available in a variety of sizes and is designed with a large hollow region in the center to house autograft bone, allograft bone comprised of cancellous and/or corticocancellous bone, demineralized allograft with bone marrow aspirate, or a combination thereof. 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 Chemtex® surface treatment or nanoLOCK surface treatment (MMN) designed to improve fixation to the adjacent bone. The nanoLOCK surface technology (MMN) provides a microscopic roughened surface with nano-scale features. The new bone formation through the implant is intended to provide long-term structural support and fusion at the implanted disc space. The Endoskeleton TCS Interbody Fusion Device system includes integrated fixation screws for stabilizing the implants when placed in the interbody space. The implants and screws are composed of ASTM F136 Ti 6Al-4V ELI titanium alloy and are provided either sterile or non-sterile.

An implant holding feature has been incorporated into the trailing surface of the implant to mate with the implant inserter, and to facilitate placement of the implant into the interbody space. Screws include internal hexalobular drive features matched to instrumentation for installation.

INDICATIONS FOR USE

The Endoskeleton TCS Interbody Fusion Device is an anterior cervical intervertebral body fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) (defined as pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) at one disc level from C2 to T1. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The device is indicated to be used with autograft bone and/or allograft bone comprised of cancellous and/or corticocancellous bone and/or demineralized allograft bone with bone marrow aspirate. The device is a stand-alone system when used with Endoskeleton TCS Interbody Fusion Device integrated screws and when used without the integrated screws it requires additional supplemental fixation cleared for the cervical spine.

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 TCS Interbody Fusion Device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Endoskeleton TCS Interbody Fusion Device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CONTRAINDICATIONS

1. As with all orthopedic implants, the Endoskeleton TCS 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 TCS Interbody Fusion Device should never be implanted in patients with a systemic or local infection.
3. The Endoskeleton TCS Interbody Fusion Device should not be used with components of any other interbody systems.
4. The Endoskeleton TCS Interbody Fusion 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 TCS Interbody Fusion device.
6. The Endoskeleton TCS 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 TCS 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 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.

IMPORTANT INFORMATION **FOR ENDOSKELETON TCS**

PRECAUTIONS (continued)

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. Either autograft, cancellous and/or corticocancellous allograft, demineralized allograft with bone marrow aspirate or a combination thereof 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 of implant(s) 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 ensure 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 TCS Interbody Fusion Devices 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.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser.
For best results, use Adobe Acrobat® Reader with the browser.

Medtronic
Spinal and Biologics Business
Worldwide Headquarters
2600 Sofamor Danek Drive
Memphis, TN 38132

medtronic.com

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