



Serrated Radial Ribs

Table of Contents

1	Introduction
2	Patient Positioning
3	Operative Technique
4	Interbody Space Insertion
6	Hole Preparation for Screw Placement
9	Cover Plate
10	Implant Removal
11	Part Numbers

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the Instructions For Use for the complete list of indications, warnings, precautions, and other important medical information.



INTRODUCTION / DEVICE DESCRIPTION

LONESTAR[®] is a stand-alone cervical interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy. The implant is composed of a Titanium Alloy cover plate, screws, and interbody spacer. LONESTAR interbody spacers are available in heights ranging from 6mm to 14mm, and widths of 15mm and 17mm. The available depths of the implant are 13mm and 15mm, offered in 0° and 7° of lordosis. The implants are available with standard and enhanced stability features. LONESTAR is manufactured with a PEEK posterior portion and a titanium anterior portion used in conjunction with screws that allow intradiscal fixation to the vertebral body and titanium cover plates to prevent screw back out.



LONESTAR for Standard Stability during Implantation



LONESTAR, Serrated Radial Ribs for Enhanced Stability during Implantation

1. PATIENT POSITIONING

Carefully place the patient in the supine position on the operating table ensuring all bony prominences are padded and the cervical spine in neutral to a slightly extended position following the induction of anesthesia (**Fig. 1**). When treating C6-7 it is important to ensure that the shoulders do not limit x-ray visualization. For all cases both the cephalad and caudal vertebrae being treated should be completely visible.



Fig. 1

2. EXPOSURE / DISCECTOMY

A standard anterior approach is utilized and the operative level is confirmed with intraoperative fluoroscopy or x-ray. Complete discectomy, neuro-decompression and endplate preparation are then completed (**Fig. 2**).

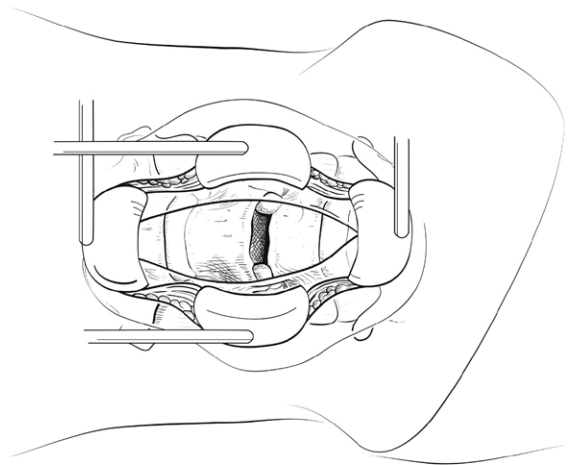


Fig. 2

Standard Interbody Spacer Sizing		
Implant sizes		
Footprint	Height	Sagittal Profile
15mm W x 13mm L	6-9mm	7°
17mm W x 15mm L	6-9mm	7°
Note: Additional footprints available as special order only.		

A **Universal Rasp (83-9040)** may be used to prepare the end plates. Move the universal rasp anterior/posterior and medial/lateral around the vertebral endplates until desired preparation is achieved (**Fig. 3**). Selection of the proper Interbody Spacer is essential. Insert the trials, in sequential order, into the disc space to determine the proper interbody spacer size (height, footprint, and lordosis). With the segment fully distracted, the trial spacer should fit tightly between the endplates in footprint, height, depth and lordotic angle. The use of lateral fluoroscopy will assist in determining proper implant depth.

NOTE: Rasps may also be used to determine the appropriate size of interbody.

NOTE: The Rasps and trials mirror the interbody footprint.

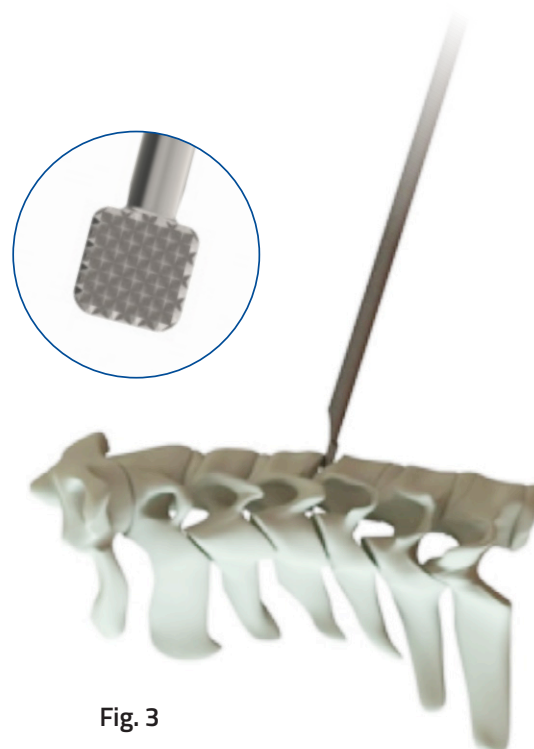


Fig. 3

3. INTERBODY SPACER INSERTION

Once the size has been determined, attach the **Interbody Spacer** to the **Implant Inserter (83-9003)**. To attach the interbody spacer, engage the implant inserter into the threaded hole of interbody spacer and turn the knob clockwise until finger tight (**Fig. 4**).

It is recommended to pack autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft into the window of the interbody spacer to help promote fusion. An optional **Graft Block (83-9030)** and **Graft Tamp (83-9037)** are available for use with the standard interbody spacers but not with the Lonestar, Serrated Radial Ribs spacers as they will not seat in the graft block correctly.

CAUTION: There is no depth limiting stop on the Inserter, Trials, or Rasps. Instruments should be impacted only as deep as intended for interbody spacer placement. Lateral fluoroscopy is recommended to confirm desired position of the interbody.

NOTE: The distance from the center of the tantalum marker to the posterior edge of the implant is 2.0mm.

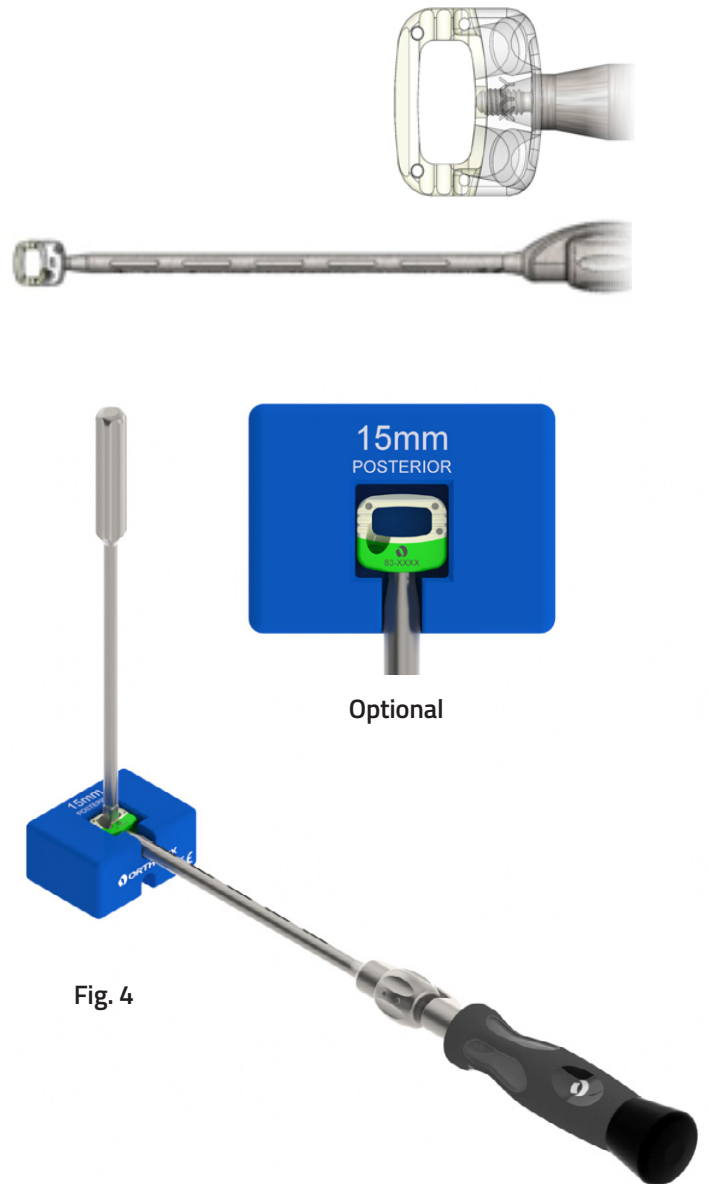


Fig. 4

Insert the **Interbody Spacer** into the disc space using the **Inserter (83-9003)**. The depth of the interbody spacer can be assessed by visualizing the tantalum markers on the posterior aspect of the implant which are 2mm from the edge of the implant under the guidance of fluoroscopy. The Inserter may remain attached to the Interbody Spacer during Awl, Drill and Screw insertion if more control over interbody position is desired during these steps. To release the Interbody Spacer, turn the knob on the implant inserter counterclockwise (**Fig. 5**).

If repositioning is needed, use the **Tamp (83-9005)** to adjust the interbody spacer position (**Fig. 6**). The use of fluoroscopy is recommended to reduce the risk of unintentionally damaging neural structures.

NOTE: The Tamp should be seated in cover plate recess during impaction.

NOTE: The serrated portion of the Lonestar Serrated Radial Ribs interbody is intended to rest on the anterior portion of the vertebral body and not be inserted fully into the disk space (**Fig 7**).

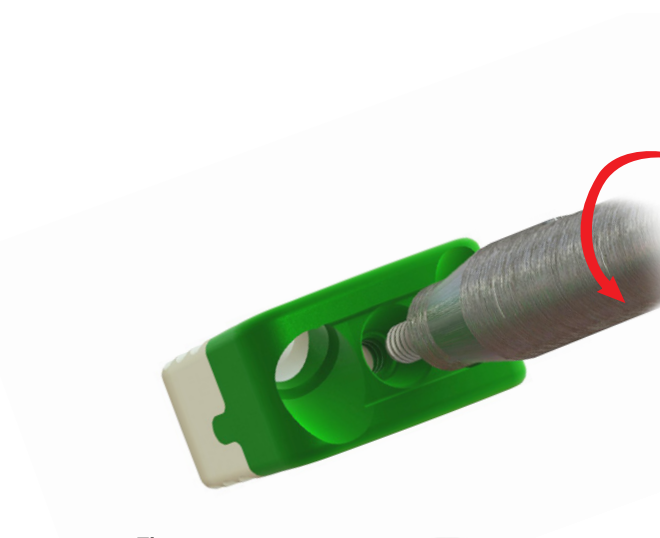


Fig. 5

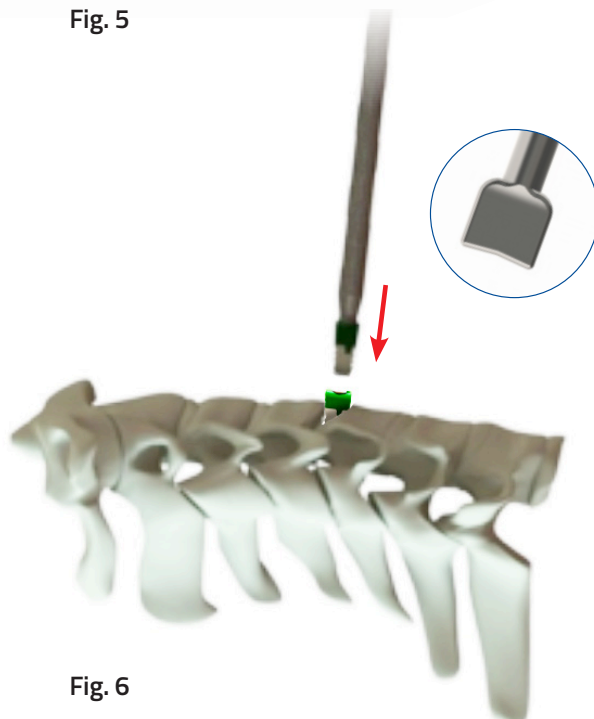


Fig. 6

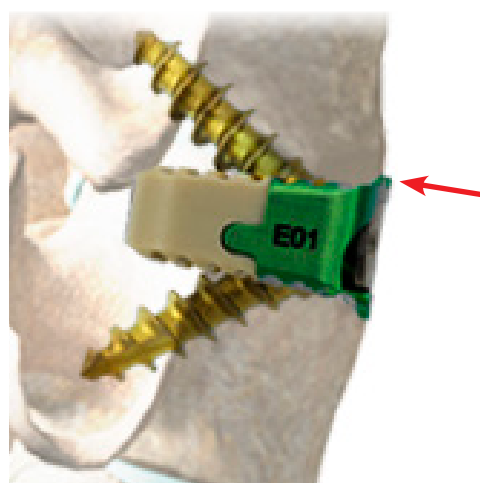


Fig. 7

4. HOLE PREPARATION FOR SCREW PLACEMENT

This system includes self-drilling and self-tapping screws. The following options are provided for creating the starter holes through the cortical bone.

Awls

After determining which awl will be used, sleeved **Awl (83-9002)** or **Angled Awl (83-9044)**, fully seat the awl through the interbody screw hole and impact through the cortical bone (**Fig. 8**). The awl is designed to penetrate 12mm into the vertebral body when fully impacted.

NOTE: The Awl's sleeve should remain in the covered position during initial insertion and impaction.

NOTE: Recommended procedure is to place the first screw without fully tightening it before creating the second starter hole.

Drill

When using the **Drill (83-9012)**, always use the **Drill Guide (83-9004)** to establish accurate trajectory and depth for each pilot hole (**Fig. 9**). Note that the drill is single use, and offered in sizes corresponding to the available screw lengths (10-18mm).

- Attach the drill to the modular handle (**69-1030**).
- Insert the drill guide into the interbody spacer screw hole.
- Place the drill through the drill guide.
- Drill by turning the handle clockwise until the drill bottoms out on the drill guide.
- To reverse, turn the handle counterclockwise.

The trajectory and depth of drilling and screw length selection should be guided by lateral fluoroscopic monitoring to ensure the depth is appropriate for the vertebral body.

83-9004	DRILL GUIDE
83-9010*	DRILL – 10mm
83-9012	DRILL – 12mm
83-9014	DRILL – 14mm
83-9016	DRILL – 16mm
83-9018*	DRILL – 18mm

*By special request only

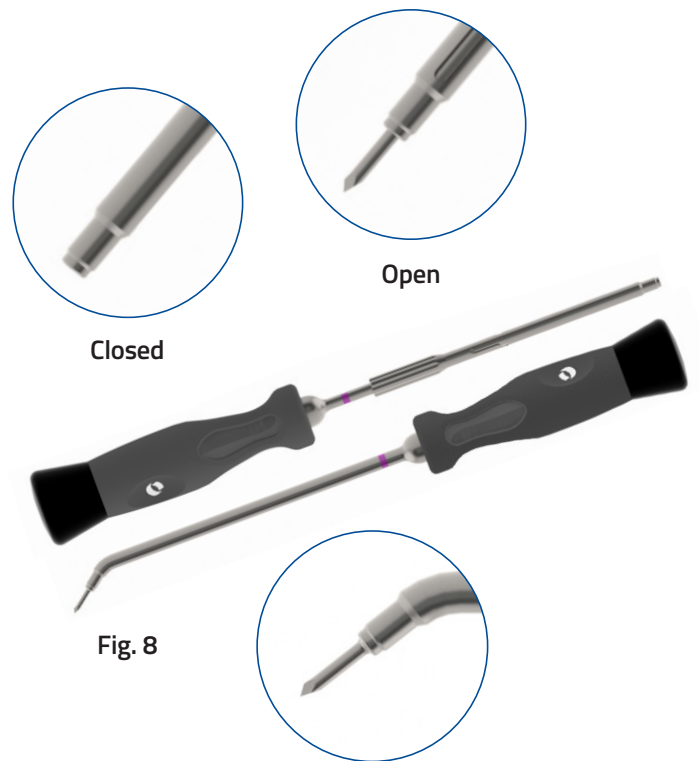
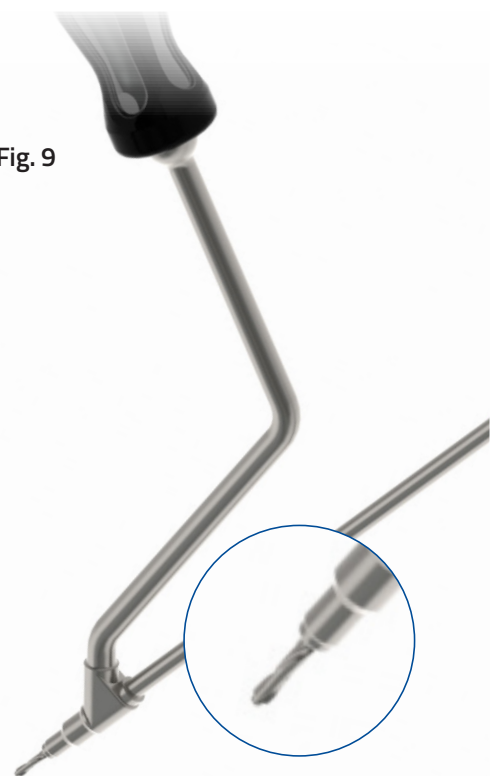


Fig. 8






Fig. 9



5. SCREWS

Ø3.6mm primary screws are offered in both self-tapping and self-drilling options in lengths ranging from 10-18mm. The screws come color coded according to length for ease of use.

Ø4.0mm rescue screws are available as well in the same configurations

Purple	10mm	
Magenta	12mm	
Gold	14mm	
Dark Blue	16mm	
Green	18mm	

There are two screw driver options for use with all screws. Both screw drivers have a square drive mechanism to reduce stripping (**Fig. 10**).



1. Screw Driver (83-9001)

2. Jointed Screw Driver (83-9048)

To implant the screws, load the screw onto the desired driver, which will self-retain the screw during placement. Begin by threading the screw through either interbody spacer screw hole, turning the handle clockwise until finger tight.

CAUTION: To avoid stripping the screw hole, do not overtighten the screw into the interbody spacer.

NOTE: It is recommended to place the first screw then awl or drill the second hole and place the second screw. Once the two screws are inserted, fully tighten the screws.

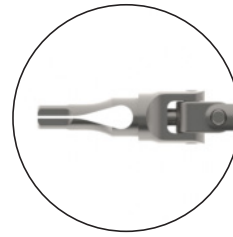


Fig. 10



2. Jointed Screw Driver

1. Screw Driver

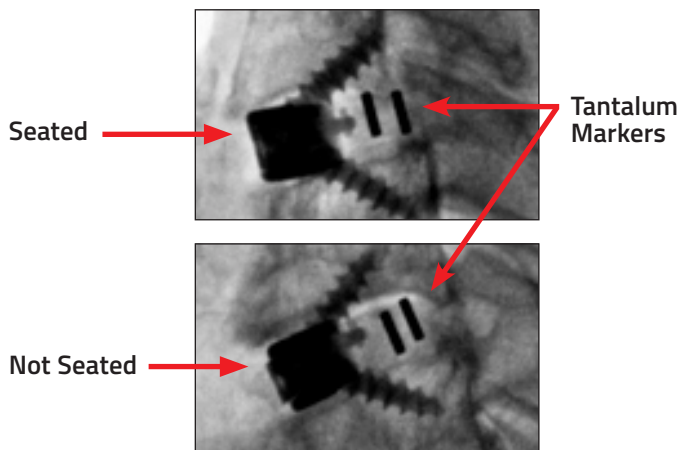
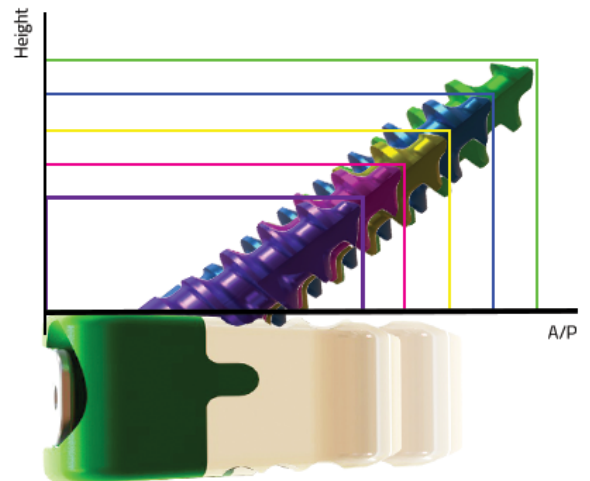


Fig. 11

CAUTION: Once seated, the position of the screw heads should be completely recessed within the Interbody Spacer. The Cover Plate will not engage the Interbody Spacer properly if the screws are not fully seated (Fig 11).



NOTE: The screws engage the bone at a 38° angle. Therefore the total distance the screw engaged the vertebrae is as follows:

Bone Screw Length	A / P (mm)	Height (mm)
10	11.16	3.78
12	12.71	5.01
14	14.26	6.25
16	16.81	7.48
18	17.37	8.71

6. COVER PLATE

In order to secure the screws in place, a cover plate is provided to prevent screw back out. The cover plates are available in two sizes corresponding to the interbody spacer height:

1. 6-9mm	(83-7110)
2. 10-14mm	(83-7120)*

*By special request only

To load the cover plate onto the **Cover Plate Holder (83-9041)**, align the two holes of the cover plate to the pins of the cover plate holder and press down until cover plate snaps onto the cover plate holder (**Fig 12**).

Once the Cover Plate is loaded on the holder, center the cover plate inside the recess in the interbody spacer and thread the Cover Plate Screw into the threaded hole. The **Cover Plate Driver (83-9042)** has a "click out" torque limiting mechanism which provides audible and tactile confirmation of torque to assure the Cover Plate Screw was tightened.

CAUTION: To ensure proper engagement, prior to final tightening, ensure that the Cover Plate is fully aligned within the recess in the Interbody Spacer.

CAUTION: To ensure that the Cover Plate is properly seated on the implant after final tightening, the screw head should be completely seated into the LONESTAR implant. Improper seating of the Cover Plate is seen in this fluoroscopic image (**Fig. 13**).



Fig. 12

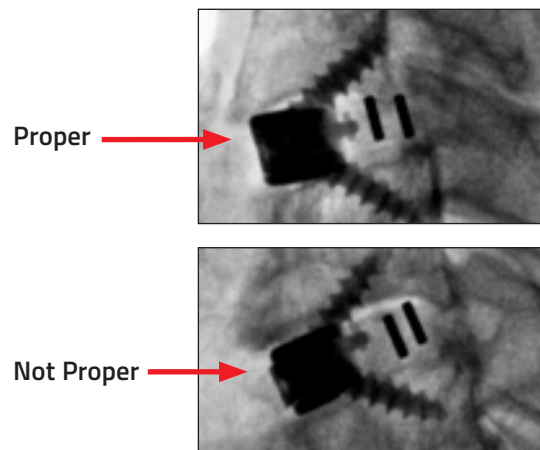
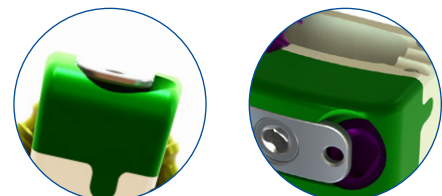


Fig. 13



7. IMPLANT REMOVAL

If removal of the construct is required:

1. Attach the Cover Plate Driver to the Cover Plate Screw and turn counterclockwise (**Fig. 14**).
2. Once the cover plate is removed, use the Screwdriver to remove the bone screws by turning counterclockwise.
3. Remove the interbody spacer by engaging the Implant Inserter with the threaded hole of the interbody spacer and turning the center knob clockwise until finger tight (**Fig. 15**). Then pull out the interbody spacer. If necessary, distract the vertebrae inferior and superior to the interbody spacer for removal.

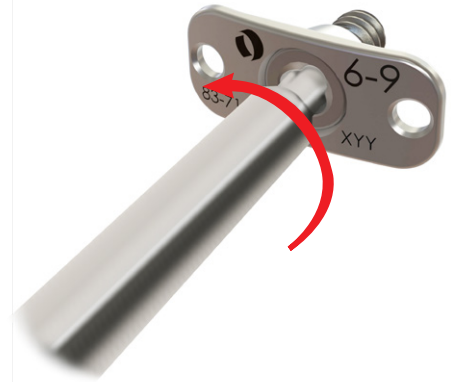


Fig. 14

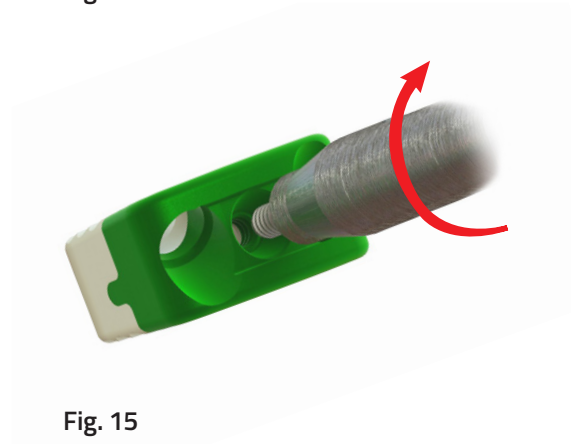


Fig. 15



LONESTAR Implant Components

Standard BOM

Part #	Description	Height	Qty
Self-Drilling & Self-Tapping Screws			
83-3412	3.6mm x 12mm Primary Self-Drilling Screw	NA	6
83-3414	3.6mm x 14mm Primary Self-Drilling Screw	NA	6
83-3416	3.6mm x 16mm Primary Self-Drilling Screw	NA	4
83-3512	3.6mm x 12mm Primary Self-Tapping Screw	NA	6
83-3514	3.6mm x 14mm Primary Self-Tapping Screw	NA	6
83-3516	3.6mm x 16mm Primary Self-Tapping Screw	NA	4
83-3812	4.0mm x 12mm Rescue Self-Drilling Screw	NA	4
83-3814	4.0mm x 14mm Rescue Self-Drilling Screw	NA	4
83-3816	4.0mm x 16mm Rescue Self-Drilling Screw	NA	4
83-3912	4.0mm x 12mm Rescue Self-Tapping Screw	NA	4
83-3914	4.0mm x 14mm Rescue Self-Tapping Screw	NA	4
83-3916	4.0mm x 16mm Rescue Self-Tapping Screw	NA	4
Interbody			
83-5306	15mm W x 13mm L, 7° Lordotic	6mm	3
83-5307	15mm W x 13mm L, 7° Lordotic	7mm	3
83-5308	15mm W x 13mm L, 7° Lordotic	8mm	3
83-5309	15mm W x 13mm L, 7° Lordotic	9mm	3
83-7506	17mm W x 15mm L, 7° Lordotic	6mm	3
83-7507	17mm W x 15mm L, 7° Lordotic	7mm	3
83-7508	17mm W x 15mm L, 7° Lordotic	8mm	3
83-7509	17mm W x 15mm L, 7° Lordotic	9mm	3
Interbody-Serrated Radial Ribs			
84-5306	15mm W x 13mm L, 7° SRR	6mm	3
84-5307	15mm W x 13mm L, 7° SRR	7mm	3
84-5308	15mm W x 13mm L, 7° SRR	8mm	3
84-5309	15mm W x 13mm L, 7° SRR	9mm	3
84-7506	17mm W x 15mm L, 7° SRR	6mm	3
84-7507	17mm W x 15mm L, 7° SRR	7mm	3
84-7508	17mm W x 15mm L, 7° SRR	8mm	3
84-7509	17mm W x 15mm L, 7° SRR	9mm	3
Cover Plate			
83-7110	Cover Plate	6mm - 9mm	6

Standard BOM

Part #	Description	Height	Qty
Rasp/Trial			
83-9226	Rasp-15mm W x 13mm L, 7° Lordotic	6mm	1
83-9227	Rasp-15mm W x 13mm L, 7° Lordotic	7mm	1
83-9228	Rasp-15mm W x 13mm L, 7° Lordotic	8mm	1
83-9229	Rasp-15mm W x 13mm L, 7° Lordotic	9mm	1
83-9526	Trial-15mm W x 13mm L, 7° Lordotic	6mm	1
83-9527	Trial-15mm W x 13mm L, 7° Lordotic	7mm	1
83-9528	Trial-15mm W x 13mm L, 7° Lordotic	8mm	1
83-9529	Trial-15mm W x 13mm L, 7° Lordotic	9mm	1
83-9846	Rasp-17mm W x 15mm L, 7° Lordotic	6mm	1
83-9847	Rasp-17mm W x 15mm L, 7° Lordotic	7mm	1
83-9848	Rasp-17mm W x 15mm L, 7° Lordotic	8mm	1
83-9849	Rasp-17mm W x 15mm L, 7° Lordotic	9mm	1
83-9746	Trial-17mm W x 15mm L, 7° Lordotic	6mm	1
83-9747	Trial-17mm W x 15mm L, 7° Lordotic	7mm	1
83-9748	Trial-17mm W x 15mm L, 7° Lordotic	8mm	1
83-9749	Trial-17mm W x 15mm L, 7° Lordotic	9mm	1
Instruments			
69-1030	Modular Handle A/O Quick Connect	NA	4
83-9001	Screw Driver	NA	1
83-9002	Awl	NA	1
83-9003	Implant Inserter	NA	2
83-9004	Drill Guide	NA	1
83-9005	Tamp	NA	1
83-9012	Drill - 12mm	NA	2
83-9038	Mallet	NA	1
83-9040	Universal Rasp	NA	1
83-9041	Cover Plate Holder	NA	1
83-9042	Cover Plate Driver	NA	2
83-9044	Angled Awl	NA	1
83-9048	Joint Screw Driver	NA	1
Case			
83-9000	Instrument Tray Kit	NA	1
83-9105	Implant Caddy Kit	NA	1
83-9106	Serrated Radial Ribs -Implant Caddy Kit	NA	1
83-1000	Implant/Instrument Case	NA	1
83-0105	Implant Caddy	NA	1

Order by Request Only

Part #	Description	Height	Qty*
Self-Drilling & Self-Tapping Screws			
83-3410	3.6mm x 10mm Primary Self-Drilling Screw	NA	–
83-3418	3.6mm x 18mm Primary Self-Drilling Screw	NA	–
83-3510	3.6mm x 10mm Primary Self-Tapping Screw	NA	–
83-3518	3.6mm x 18mm Rescue Self-Drilling Screw	NA	–
83-3810	4.0mm x 10mm Rescue Self-Drilling Screw	NA	–
83-3818	4.0mm x 18mm Rescue Self-Drilling Screw	NA	–
83-3910	4.0mm x 10mm Rescue Self-Tapping Screw	NA	–
83-3918	4.0mm x 18mm Rescue Self-Tapping Screw	NA	–
Interbody			
83-5310	15mm W x 13mm L, 7° Lordotic	10mm	–
83-5311	15mm W x 13mm L, 7° Lordotic	11mm	–
83-5312	15mm W x 13mm L, 7° Lordotic	12mm	–
83-5313	15mm W x 13mm L, 7° Lordotic	13mm	–
83-5314	15mm W x 13mm L, 7° Lordotic	14mm	–
83-5406	15mm W x 13mm L, 0° Parallel	6mm	–
83-5407	15mm W x 13mm L, 0° Parallel	7mm	–
83-5408	15mm W x 13mm L, 0° Parallel	8mm	–
83-5409	15mm W x 13mm L, 0° Parallel	9mm	–
83-5410	15mm W x 13mm L, 0° Parallel	10mm	–
83-5411	15mm W x 13mm L, 0° Parallel	11mm	–
83-5412	15mm W x 13mm L, 0° Parallel	12mm	–
83-5413	15mm W x 13mm L, 0° Parallel	13mm	–
83-5414	15mm W x 13mm L, 0° Parallel	14mm	–
83-5510	15mm W x 15mm L, 7° Lordotic	10mm	–
83-5511	15mm W x 15mm L, 7° Lordotic	11mm	–
83-5512	15mm W x 15mm L, 7° Lordotic	12mm	–
83-5610	15mm W x 15mm L, 0° Parallel	10mm	–
83-5611	15mm W x 15mm L, 0° Parallel	11mm	–
83-5612	15mm W x 15mm L, 0° Parallel	12mm	–
83-7306	17mm W x 13mm L, 7° Lordotic	6mm	–
83-7307	17mm W x 13mm L, 7° Lordotic	7mm	–
83-7308	17mm W x 13mm L, 7° Lordotic	8mm	–
83-7309	17mm W x 13mm L, 7° Lordotic	9mm	–
83-7310	17mm W x 13mm L, 7° Lordotic	10mm	–
83-7311	17mm W x 13mm L, 7° Lordotic	11mm	–
83-7312	17mm W x 13mm L, 7° Lordotic	12mm	–
83-7313	17mm W x 13mm L, 7° Lordotic	13mm	–
83-7314	17mm W x 13mm L, 7° Lordotic	14mm	–
83-7410	17mm W x 13mm L, 0° Parallel	10mm	–
83-7411	17mm W x 13mm L, 0° Parallel	11mm	–
83-7412	17mm W x 13mm L, 0° Parallel	12mm	–

Order by Request Only

Part #	Description	Height	Qty*
Interbody- Con'd			
83-7510	17mm W x 15mm L, 7° Lordotic	10mm	–
83-7511	17mm W x 15mm L, 7° Lordotic	11mm	–
83-7512	17mm W x 15mm L, 7° Lordotic	12mm	–
83-7513	17mm W x 15mm L, 7° Lordotic	13mm	–
83-7514	17mm W x 15mm L, 7° Lordotic	14mm	–
83-7606	17mm W x 15mm L, 0° Parallel	6mm	–
83-7607	17mm W x 15mm L, 0° Parallel	7mm	–
83-7608	17mm W x 15mm L, 0° Parallel	8mm	–
83-7609	17mm W x 15mm L, 0° Parallel	9mm	–
83-7610	17mm W x 15mm L, 0° Parallel	10mm	–
83-7611	17mm W x 15mm L, 0° Parallel	11mm	–
83-7612	17mm W x 15mm L, 0° Parallel	12mm	–
83-7613	17mm W x 15mm L, 0° Parallel	13mm	–
83-7614	17mm W x 15mm L, 0° Parallel	14mm	–
Interbody-Serrated Radial Ribs			
84-5310	15mm W x 13mm L, 7° SRR	10mm	–
84-7510	17mm W x 15mm L, 7° SRR	10mm	–
Cover Plate			
83-7120	Cover Plate	10mm-14mm	–
Rasp/Trial			
83-9220	Rasp-15mm W x 13mm L, 7° Lordotic	10mm	–
83-9221	Rasp-15mm W x 13mm L, 7° Lordotic	11mm	–
83-9222	Rasp-15mm W x 13mm L, 7° Lordotic	12mm	–
83-9223	Rasp-15mm W x 13mm L, 7° Lordotic	13mm	–
83-9224	Rasp-15mm W x 13mm L, 7° Lordotic	14mm	–
83-9520	Trial-15mm W x 13mm L, 7° Lordotic	10mm	–
83-9521	Trial-15mm W x 13mm L, 7° Lordotic	11mm	–
83-9522	Trial-15mm W x 13mm L, 7° Lordotic	12mm	–
83-9523	Trial-15mm W x 13mm L, 7° Lordotic	13mm	–
83-9524	Trial-15mm W x 13mm L, 7° Lordotic	14mm	–
83-9840	Rasp-17mm W x 15mm L, 7° Lordotic	10mm	–
83-9841	Rasp-17mm W x 15mm L, 7° Lordotic	11mm	–
83-9842	Rasp-17mm W x 15mm L, 7° Lordotic	12mm	–
83-9843	Rasp-17mm W x 15mm L, 7° Lordotic	13mm	–
83-9844	Rasp-17mm W x 15mm L, 7° Lordotic	14mm	–
83-9740	Trial-17mm W x 15mm L, 7° Lordotic	10mm	–
83-9741	Trial-17mm W x 15mm L, 7° Lordotic	11mm	–
83-9742	Trial-17mm W x 15mm L, 7° Lordotic	12mm	–
83-9743	Trial-17mm W x 15mm L, 7° Lordotic	13mm	–
83-9744	Trial-17mm W x 15mm L, 7° Lordotic	14mm	–
Instrument			
83-9043	Wedge Distractor	2-6mm	–

* Quantities represented with a dash are not included in the set and can be ordered separately.

Please visit [Orthofix.com/IFU](https://www.orthofix.com/IFU) for full information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.



Orthofix
3451 Plano Parkway
Lewisville, Texas 75056-9453 USA
1.214.937.3199
1.888.298.5700
www.orthofix.com



Medical Device Safety Services (MDSS):
Schiffgraben 41
30175, Hannover
Germany
+49 511 6262 8630
www.mdss.com

Rx Only
CE ²⁷⁹⁷

Orthofix products or services referenced herein are trademarks or registered trademarks of Orthofix Medical Inc. and its group of companies. Any rights not expressly granted herein are reserved.