fuse MAXIM™

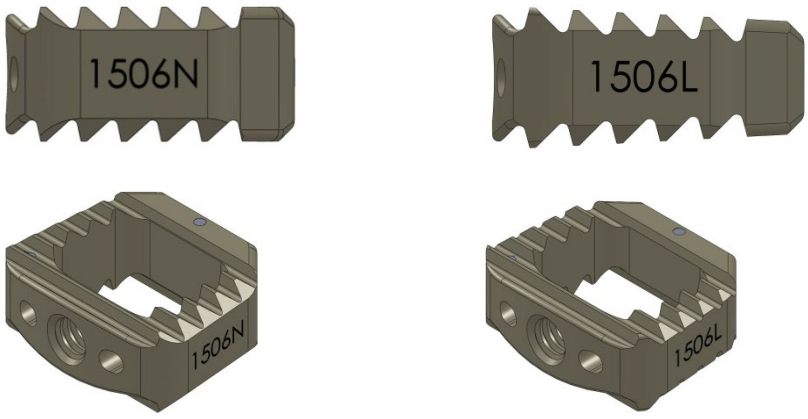
CERVICAL INTERBODY FUSION SYSTEM

SURGICAL TECHNIQUE

The Maxim Cervical Interbody Fusion System implant components are hollow rectangular shaped blocks with tapered lateral sides that contain three (3) tantalum markers to assist the surgeon with proper placement of the device.

The cervical implants are hollow to allow for placement of autograft and facilitate fusion. The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the implants.

The small footprint has a width of 15mm and a length of 13mm. The large footprint has a width of 17mm and a length of 14mm. Each footprint has a neutral design, where the superior and inferior implant surfaces are parallel with each other, as well as a lordotic design in which the inferior and superior surfaces form a wedge angle of 6 degrees. Each of the four implant designs has a height between 6mm to 10mm, in 1mm increments. The figures below provide illustrations of the cervical interbody fusion implants.



Neutral **Lordotic**

Surgical Opening:

Once the patient has been intubated in the supine position, the surgical level is localized with intraoperative fluoroscopic guidance and marked. Then the patient's ventral neck is prepped and draped in the usual sterile fashion.

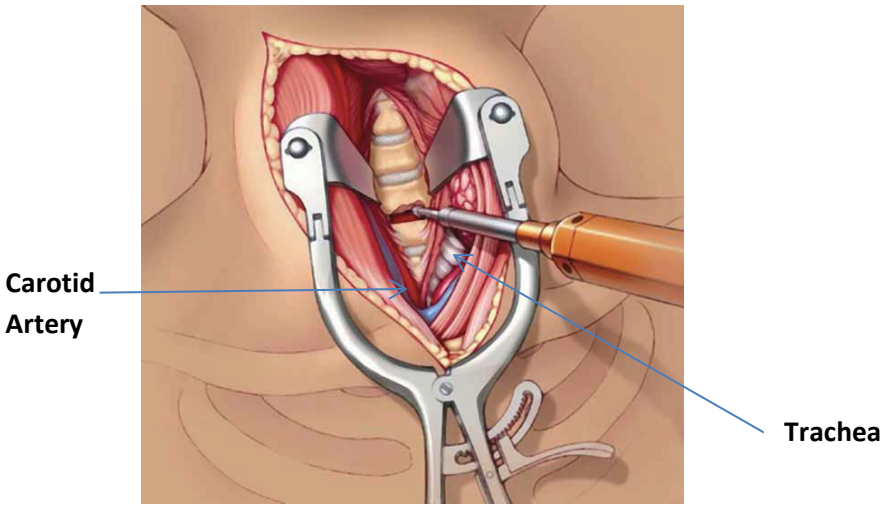
The operative incision can be made either side midline of the neck depending on surgeon preference. Subcutaneous dissection is done to expose the platysma muscle. The platysma muscle is then opened in either the caudal rostral direction or in a horizontal direction. The opening of the platsysma should not extend laterally past the sternocleidomastoid muscle and should not extend past the ventral midline of aspect of the neck.

Careful subplatysma dissection is extended towards the prevertebral fascia. The subplatsymal dissection is made between the sternocleidomastoid muscle and carotid artery laterally and the esophagus and trachea medially of the dissection.

Intraoperative radiographs are used to localize the appropriate level of treatment. Careful elevation of the longus colli muscle is done on either side of the vertebral bodies to expose the disc space of interest. Once the longus colli muscle is elevated, retracting plates are placed under the longus colli bilaterally. Utilize caution to ensure no direct compression or direct retraction of the esophagus, trachea or vascular structures is made by the retraction plates.

Discectomy and Decompression:

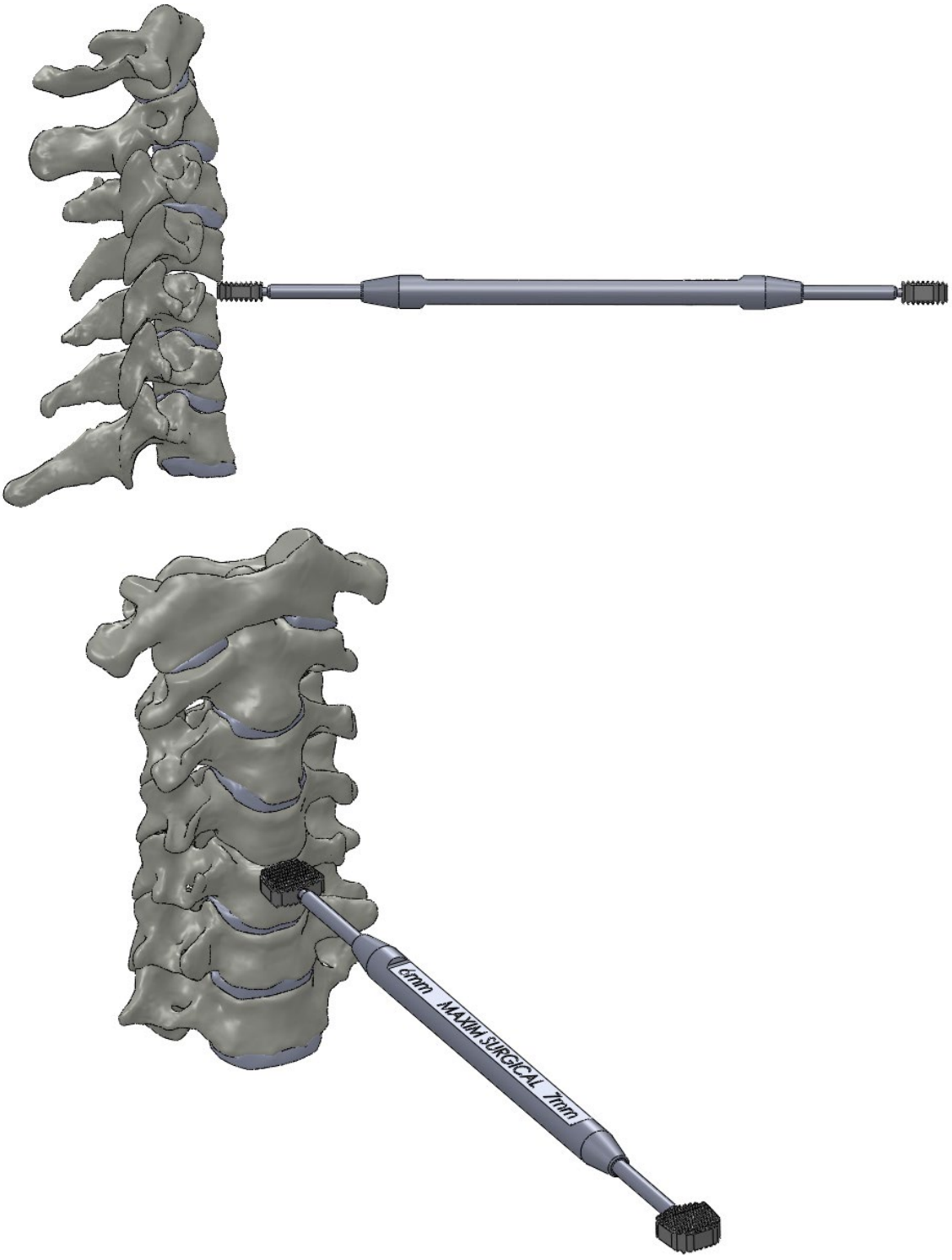
Once localization of the disc space is verified, a rectangular incision is made in the annulus anteriorly of the disc space. The incision should extend from bilateral uncovertebral joints. The disc material is then removed with pituitary rongeurs. A high-speed drill can be used to prepare the adjacent endplates and remove the anterior and posterior osteophytes of the vertebral bodies encompassing the disc space.



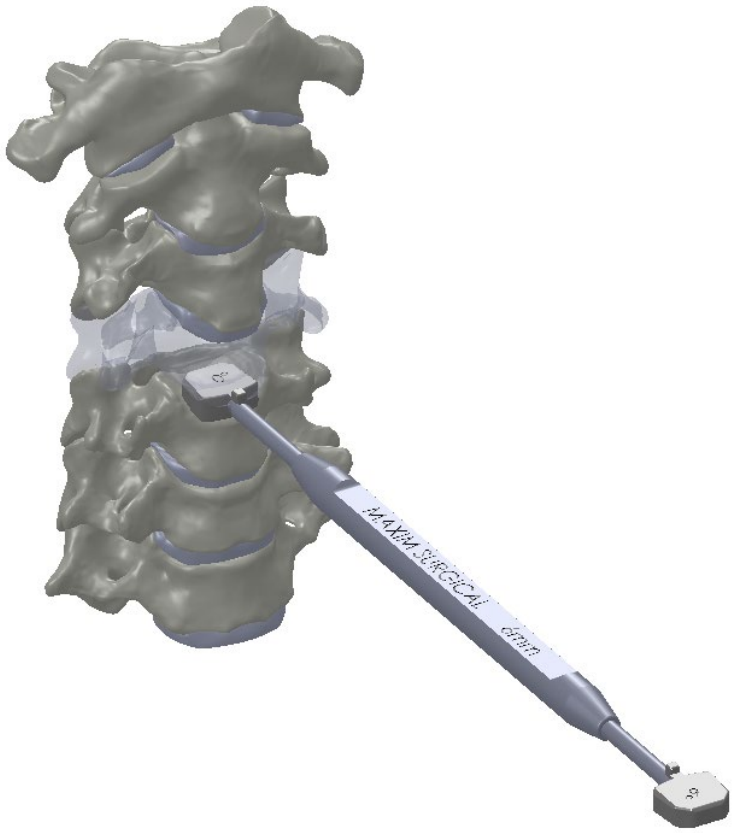
Kerrison punches are used to aid in the removal of disc material.

Arthrodesis and Fusion:

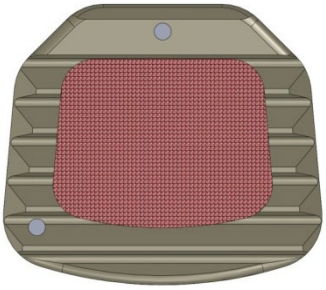
A rasp may be used to decorticate the superior and inferior endplate surfaces.

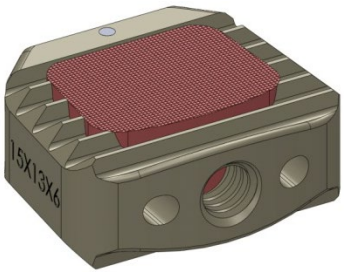


Once the endplates have been prepared, trial sizers are used to determine the implant size. Trials may be viewed by the aid of intraoperative fluoroscopic images to determine the placement and adequate size of the implant for the disc space. Care must be taken to prevent the placement of the trial dorsally against the neurologic structures.



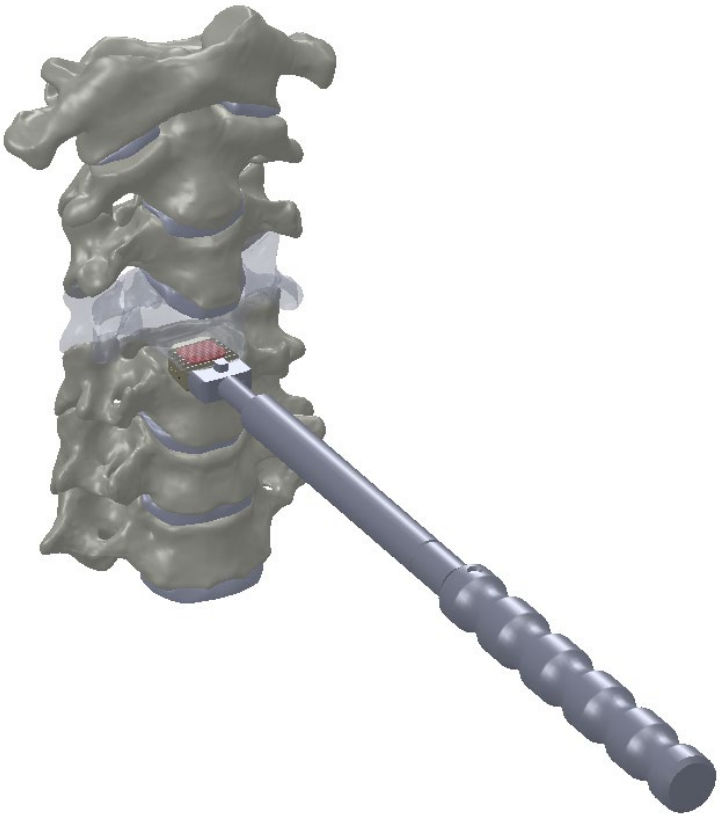
Once the trial has been verified for proper size and position, a PEEK interbody implant is selected and packed with autograft.





An inserter is attached to the PEEK implant by aligning inserter and implant interface and turning inserter handle to engage threads.

Introduction of the implant into the disc space is done cautiously. Intraoperative fluoroscopic guidance is used to insure proper placement of the PEEK implant and to prevent any injury to any neurologic structures. The PEEK implant has three tantalum markers that are radiopaque and mark the most ventral and dorsal aspect of the implant.



The inserter is removed from the implant. Fluoroscopy should be utilized to confirm implant position.

The final positioner can be used to fine tune placement of the PEEK implant and move it dorsally to keep the PEEK implant and ventral bodies in line in the caudal rostral direction. Again verification of the PEEK implant must be done after any manipulation with fluoroscopic images.

Supplemental fixation, such as an anterior cervical plate, should be used in addition to the implant. Failure to provide supplemental fixation may result in loosening, displacement or expulsion of the implant.

Closure:

Retraction blades are carefully removed to ensure there is no active bleeding, as well as no apparent injury to the vascular, tracheal or esophageal structures.

The closure of the skin is done by suture preference of the surgeon.

Revision / Removal Step:

No specific instruments are provided with the Maxim Cervical Interbody Fusion System relative to revision surgery. Use a standard operating instrument, such as Kocher forceps, to remove the implant. If the implant cannot be easily removed, a Cobb Elevator or Osteotome should be used to loosen the bone to implant interface.

Post Operative Management Step:

The surgeon may advise the patient to limit their activity or wear a brace. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

Indications:

When used as an intervertebral body fusion device, the Maxim Cervical Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-TI disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Contraindications:

Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.

Known sensitivity to PEEK material.

Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation.

Any condition that significantly affects the likelihood of fusion may be a relative contraindication (e.g. cancer, diabetes, osteomalacia, heavy smoker, morbid obesity) and the surgeon must evaluate the relative risks and benefits individually with each patient.

Other relative contraindications may include mental illness, drug abuse or alcoholism as these may cause the patient to be non-compliant with post-operative guidance (e.g. bracing and physical therapy).

Prior fusions at the levels to be treated.

Any condition not described in the indications for use.

Warnings:

Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to spinal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
2. Do not use if package is opened or damaged or if expiration date (if applicable) has passed.
3. Care should be used in the handling and storage of the implant components. Implants and instruments should be stored at room temperature. The implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
   a) A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc, facets or bony stenosis). These conditions may be present at the index level or adjacent levels. Careful review of the clinical record, including radiographic studies and applicable diagnostic tests, should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and this should be discussed with the patient.
   b) The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
   c) The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant or subsidence.
   d) Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
   e) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.

f) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

Precautions:

1. THE IMPLANTATION OF SPINAL FIXATION DEVICES SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF SUCH DEVICES. THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.
2. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the intervertebral body fusion device.
3. PROPER SIZING OF THE IMPLANTS IS IMPORTANT. The surgeon should use trials to determine the appropriate implant to use. The implant should be tall enough to provide segmental distraction and stability. The implant should be wide enough to maintain contact with the cortical rim of the vertebral body else the risk of subsidence may increase.
4. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
5. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
6. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body's response to the implant and how the fusion mass is expected to develop. A patient that is non-compliant with post-operative guidance is particularly at risk during the early postoperative period.
7. MAGNETIC RESONANCE (MR) ENVIRONMENT. The Maxim Cervical Interbody Fusion System has not been evaluated for safety and compatibility in the MR environment. The Maxim Cervical Interbody Fusion System has not been tested for heating or migration in the MR environment.

Possible adverse effects:

Potential risks identified with the use of this device system, which may require additional surgery, include:

1. Pseudoarthrosis (i.e. non-union), delayed union.
2. Bending or fracture of implant.
3. Loss of fixation.
4. Fracture of the vertebra.
5. Anterior or posterior migration of the implant.
6. Allergic reaction to a foreign body.
7. Infection.
8. Decrease in bone density due to stress shielding.
9. Pain, discomfort, or abnormal sensations due to the presence of the device.
10. Loss of proper spinal curvature, correction height and/or reduction.
11. Vascular and/or nerve damage due to surgical trauma or presence of the device.

12. Visceral injury.
13. Neurological injury, including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
14. Paralysis.
15. Death.
16. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

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Implants

0 Degree

Item	Item Description
1506N	15x13x06mm, 0 Deg, PEEK Cervical Interbody
1507N	15x13x07mm, 0 Deg, PEEK Cervical Interbody
1508N	15x13x08mm, 0 Deg, PEEK Cervical Interbody
1509N	15x13x09mm, 0 Deg, PEEK Cervical Interbody
1510N	15x13x10mm, 0 Deg, PEEK Cervical Interbody
1706N	17x14x06mm, 0 Deg, PEEK Cervical Interbody
1707N	17x14x07mm, 0 Deg, PEEK Cervical Interbody
1708N	17x14x08mm, 0 Deg, PEEK Cervical Interbody
1709N	17x14x09mm, 0 Deg, PEEK Cervical Interbody
1710N	17x14x10mm, 0 Deg, PEEK Cervical Interbody

6 Degree

Item	Item Description
1506L	15x13x06mm, 06 Deg, PEEK Cervical Interbody
1507L	15x13x07mm, 06 Deg, PEEK Cervical Interbody
1508L	15x13x08mm, 06 Deg, PEEK Cervical Interbody
1509L	15x13x09mm, 06 Deg, PEEK Cervical Interbody
1510L	15x13x10mm, 06 Deg, PEEK Cervical Interbody
1706L	17x14x06mm, 06 Deg, PEEK Cervical Interbody
1707L	17x14x07mm, 06 Deg, PEEK Cervical Interbody
1708L	17x14x08mm, 06 Deg, PEEK Cervical Interbody
1709L	17x14x09mm, 06 Deg, PEEK Cervical Interbody
1710L	17x14x10mm, 06 Deg, PEEK Cervical Interbody

Instruments

Standard

Item	Item Description
CT1506-0	15x13x06mm, Cervical Trial
CT1507-0	15x13x07mm, Cervical Trial
CT1508-0	15x13x08mm, Cervical Trial
CT1509-0	15x13x09mm, Cervical Trial
CT1510-0	15x13x10mm, Cervical Trial
CT1706-0	17x14x06mm, Cervical Trial
CT1707-0	17x14x07mm, Cervical Trial
CT1708-0	17x14x08mm, Cervical Trial
CT1709-0	17x14x09mm, Cervical Trial
CT1710-0	17x14x10mm, Cervical Trial
CI1001	Implant Inserter
CR1517	Cervical Rasp
CR1517-05	05mm, Cervical Rasp
FP2001	Final Positioner

Special Request

Item	Item Description
CT1506	15x13x06mm, Cervical Trial +Stop
CT1507	15x13x07mm, Cervical Trial +Stop
CT1508	15x13x08mm, Cervical Trial +Stop
CT1509	15x13x09mm, Cervical Trial +Stop
CT1510	15x13x10mm, Cervical Trial +Stop
CT1706	17x14x06mm, Cervical Trial +Stop
CT1707	17x14x07mm, Cervical Trial +Stop
CT1708	17x14x08mm, Cervical Trial +Stop
CT1709	17x14x09mm, Cervical Trial +Stop
CT1710	17x14x10mm, Cervical Trial +Stop
CR1517-06	06mm, Cervical Rasp
CR1517-07	07mm, Cervical Rasp
CR1517-08	08mm, Cervical Rasp
CR1517-09	09mm, Cervical Rasp
CR1517-10	10mm, Cervical Rasp

Manufactured by:
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STG-MAX-001 Rev B
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