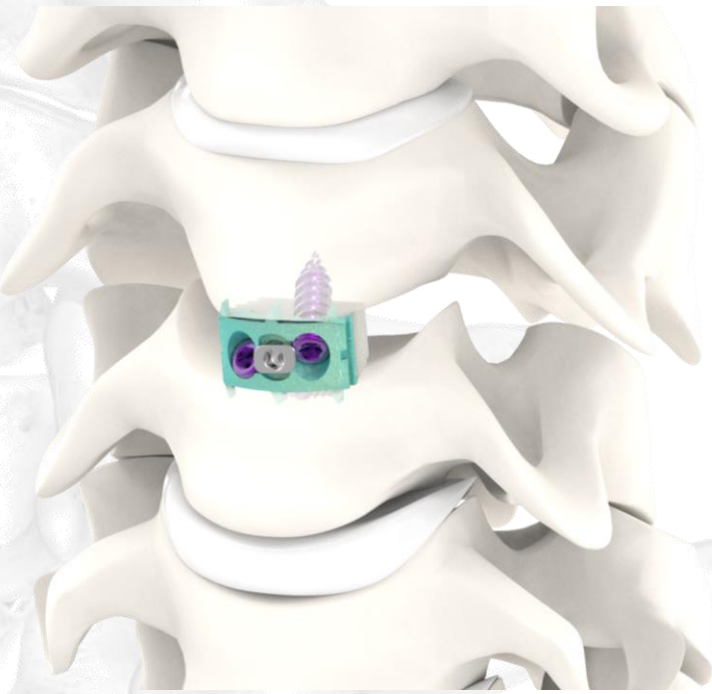
AEON-C™

Anterior Cervical Stand Alone System



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CONTENTS

IMPLANT OVERVIEW

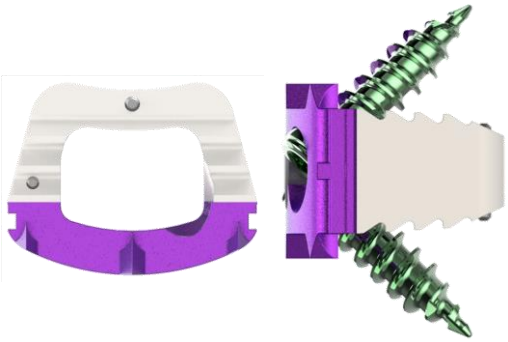
FEATURES & BENEFITS

- Large bone graft packing area
- Fits anatomical profile of vertebral endplates
- Visual and tactile confirmation of screw blocking
- Spikes on cephalad and caudal plate for additional stability
- True zero profile design in the sagittal plane for reduced esophageal irritation
- Streamlined instrumentation for reduced implantation steps
- Color coded on titanium plate and screw for easy identification

CAGE

- Footprints: 12 x 14*, 12 x 16, 14 x 16, 15 x 18*, 16 x 16mm*
- Heights: 5 to 9mm (1mm increments), 10 to 15mm*
- Sagittal profiles: 0°, 7°, 15°*

(*) Additionally available

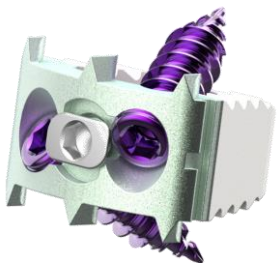


SCREW

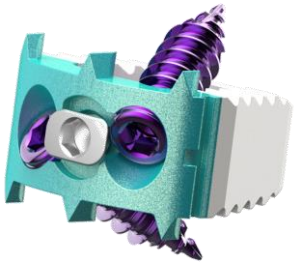
- 3.6 mm and 4.2mm diameter
- Length from 12 to 20mm (2mm increments)
- Self-drilling and self-tapping
- Variable and fixed angle screws
- Pre-biased angulation (cephalad-caudal): 35°

Fixed screw (Left) and Variable screw (Right)

12 x 16, Purple



14 x 16, Light Green

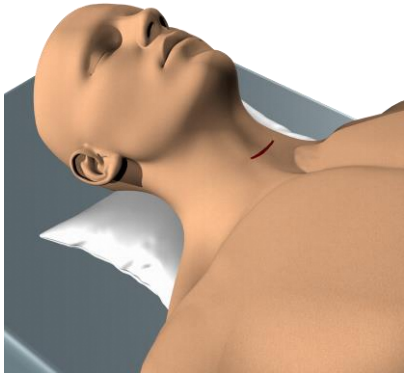


16 x 16, Teal

SURGICAL TECHNIQUE

STEP 1: PATIENT POSITIONING and EXPOSURE

The patient is carefully placed in the supine position on the operating table following the induction of anesthesia. The head is placed in a neutral position. A transverse or oblique skin incision is made, and the incision site is held open by a longitudinal self-retaining retractor.

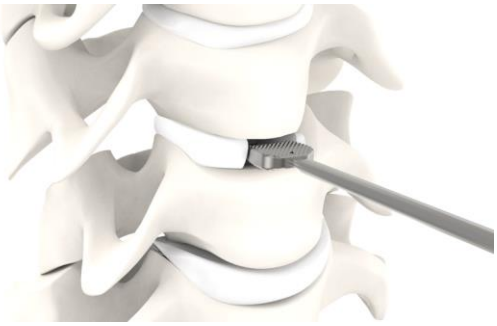


STEP 2: DISTRACTION

The distraction pins are positioned midline in the vertebral bodies adjacent to the disc, and the distractor is placed over pins. Distract gently.

Note: Do not over-distract the disc space. Distraction instrument and distraction pins should be removed before closure.

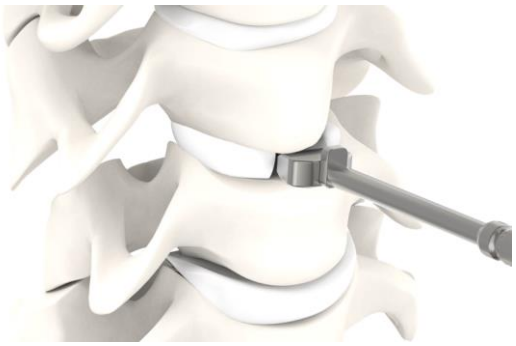
STEP 3: DISCECTOMY and ENDPLATE PREPARATION



Discectomy is performed using a high-speed drill with a burr (match tip/round) or using rongeurs and other preparation instruments as needed. While leaving the lateral annulus intact, a rasp or equivalent instrument can be used to remove superficial layers of the endplates for the exposure of bleeding bone and creating a gap for the AEON-C cervical standalone cage.

Note: Avoid excessive endplate preparation as this may weaken the vertebral endplates and result in postoperative subsidence.

STEP 4: IMPLANT SIZING (TRIALING) and IMPLANT SELECTION



Choose a Trial dependent upon the height and depth of the intervertebral space, the individual patient anatomy, and disc preparation. Insert the smallest permissible Trial (starting at 5mm) into the disc space first, moving to the larger Trial as needed.

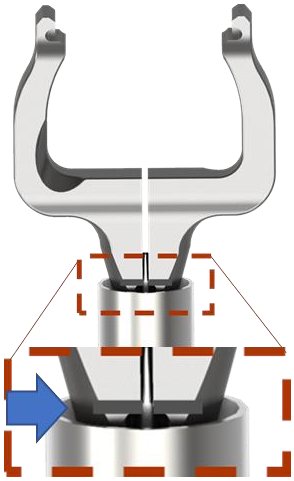
Note: Additional distraction may be used; however, care should be taken not to over-distract the intervertebral space.

STEP 5: IMPLANT ASSEMBLY

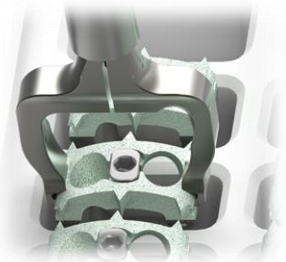
Once the cage size has been determined, attach the cage onto the Cage Holder. There are two types of holders offered with AEON-C (Midline Holder and Standard Holder-images on the right).

The Cage Holder should be in a neutral position when the spacer is being attached. If it is not at the neutral position, rotate the outer sleeve so that ***the outer sleeve is aligned with black neutral position line***.

Not at Neutral Position



Neutral Position



Turn the knob to secure the cage to the holder. Rotate the knob of the holder clockwise until finger tight.

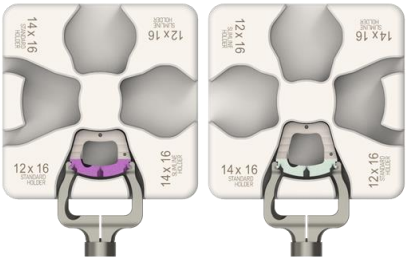
Note: Do NOT overtighten the knob.

STEP 6: GRAFT PACKING

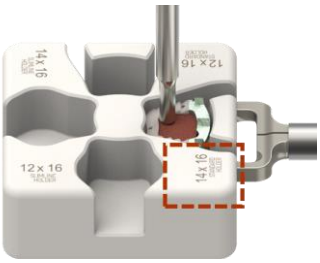
Place carefully the appropriate AEON-C Cage Holder with the cage on the bone packing block.

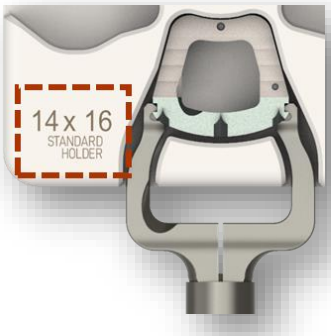
Use the bone packing bar, or the impactor, to firmly pack the bone graft material into the cage cavity.

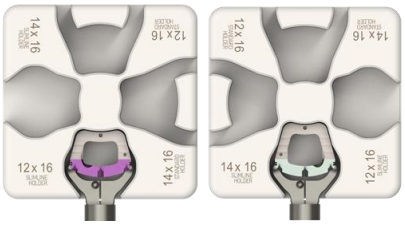
Note: The appropriate cage size and holder type is indicated to the left of each pocket (see image below).



Standard Cage Holder
12x16 (Left) and 14x16 (Right)

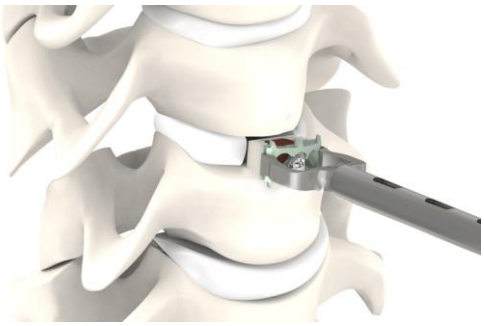






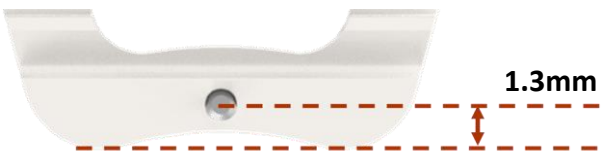
Midline Cage Holder
12x16 (Left) and 14x16 (Right)

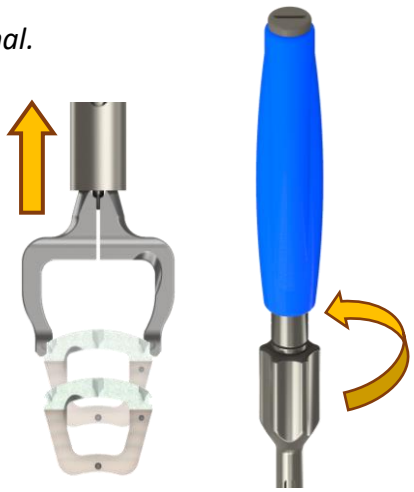
STEP 7: CAGE INSERTION



Gently insert the spacer into the disc space. The depth of the cage can be assessed by visualizing the tantalum markers on the posterior aspect of the implant which are 1.3mm from the edge of the implant under the guidance of fluoroscopy.

Note: Impactor is optional.





Turn the knob to release the cage from the holder. Rotate the knob of the holder counterclockwise beyond the black neutral line and gently angle the holder off the implant

Note: Do NOT over release the knob.

STEP 8: SCREW HOLE PREPARATION

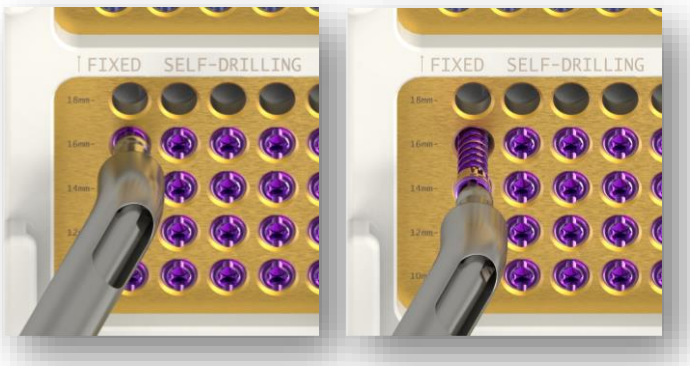
Use free hand Angled Awl (standard or modular) to penetrate the anterior cortex of the vertebral body and provide an initial trajectory for the screw. The awl is designed to penetrate 7 mm into the vertebral body when fully impacted.

Standard Angled Awl (Left), Modular Angled Awl (Right)

STEP 9: SCREW INSERTION

Load the Angled Driver with an appropriate screw. Lightly push the Driver onto the screw so that the driver may snap onto the screw head. Gently lift the loaded Driver to insert screw into the cage.

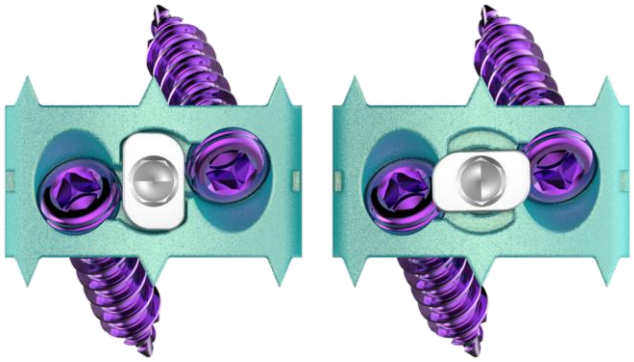
Insert the screw through the screw hole of the spacer. Repeat loading to insertion for the second screw



Stab (Left) and Grab (Right)

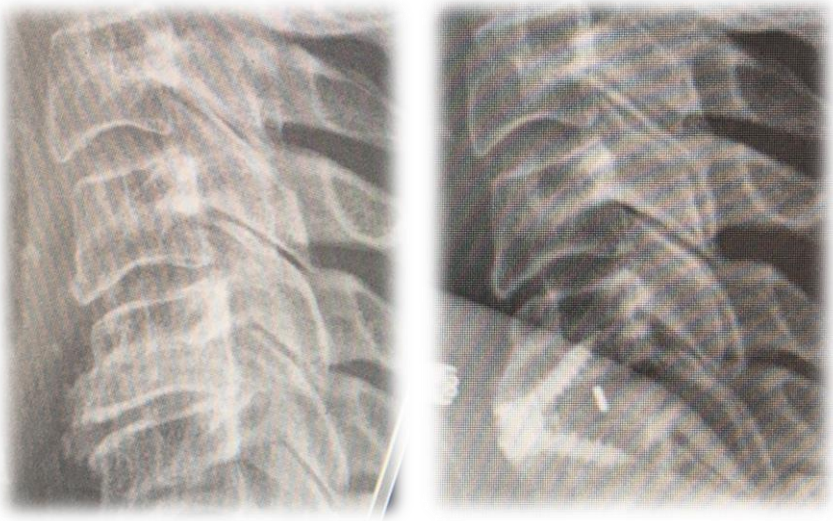
STEP 10: LOCKING

Once the bone screws are fully tightened, lock the lock-plate by turning clockwise until giving a tactile feedback and visual confirmation.



Unlock (Left) and Lock (Right)

Below: Final x-ray view



STEP 11: CLOSURE and POSTOPERATIVE CARE

Following are few of the recommended steps:

- The operative site should be closed per hospital protocol and the surgeon's discretion. Prior to adequate fusion, the physician may prescribe additional external support (e.g. braces) to accommodate full load bearing
- Routine monitoring of the vital signs, and of the hemodynamic and neurologic status of the patient per hospital protocol and the surgeon's discretion
- Pain Medication per hospital protocol and the surgeon's discretion
- Diet is restricted to small amounts of liquids until return of bowel function per hospital protocol and the surgeon's discretion
- The patient is encouraged to ambulate as soon as possible based on the activity level determined by the individual surgeon.

STEP 12: REMOVAL

If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the AEON-C™ Stand Alone System are not intended to be removed unless the management of a complication or adverse event requires the removal. Any decision by a physician to remove the device should take into consideration such factors as:

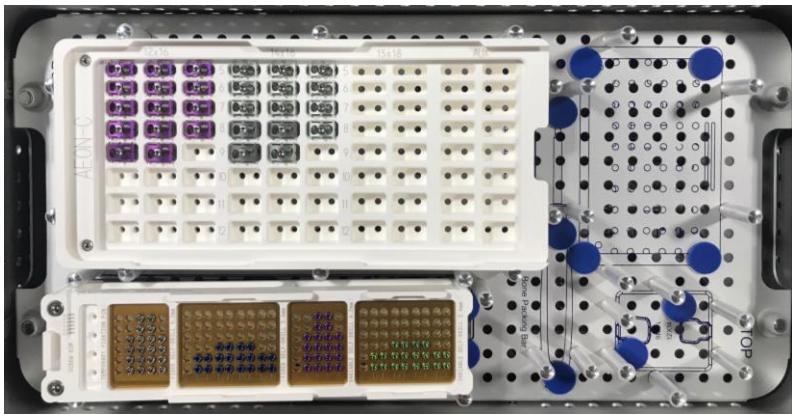
- The risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains.

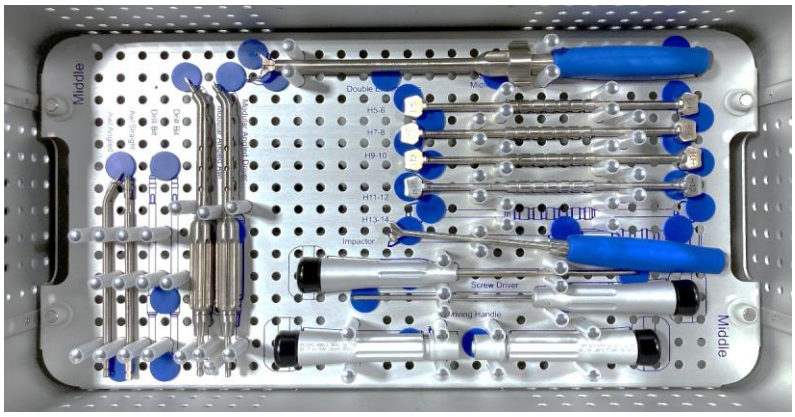
Optional – Implant Removal: The insertion instruments can be used to engage the implant securely. The implant can then be extracted by following the implantation process in the reverse order. Optionally, forceps or other manual surgical instruments may be used to grasp and extract the implant.

INSTRUMENT LIST

Standard Set

CSA.0001	Screwdriver, 2.3mm Hex
CD.TP.IN.0005	A-O Quick Connect Handle, Swivel
CSA.0004	Disassembled Angled Driver
CSA.0013	Awl with Sleeve
CSA.0014	Angled Awl
CSA.0166	Double Ended Trials L12xW16xA7 H5 & 6 w Hard Stop
CSA.0167	Double Ended Trials L12xW16xA7 H7 & 8 w Hard Stop
CSA.0168	Double Ended Trials L12xW16xA7 H9 & 10 w Hard Stop
CSA.0178	*Double Ended Trials L14xW16xA7 H5 & 6 w Hard Stop*
CSA.0179	*Double Ended Trials L14xW16xA7 H7 & 8 w Hard Stop*
CSA.0180	*Double Ended Trials L14xW16xA7 H9 & 10 w Hard Stop*
CSA.1200	Screw Caddy
CSA.1002	Implant caddy (12x16)
CSA.2000	AL case (Streamline)





INSTRUCTION FOR USE

Indications

The AEON-C™ Stand Alone System is a stand-alone anterior cervical intervertebral fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one or two contiguous levels from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The AEON-C™ Stand Alone System should be packed with autograft and/or allograft comprised of cancellous, cortical and/or corticocancellous bone graft and implanted with an anterior approach. Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with a cervical intervertebral fusion device.

Note: The AEON-C™ Stand Alone System's Surgical Technique Manual should be followed carefully. Important information on the proper usage of implants and instruments is included. Obtain for surgical manual please contact Huvexel or distributor.

Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- AEON-C™ Stand Alone System should not be implanted in patients with an active infection at the operative site.
- AEON-C™ Stand Alone System is not intended for use except as indicated.
- Marked local inflammation.
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic
- disorders affecting osteogenesis.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Open wounds.
- Pregnancy.
- Inadequate tissue coverage over the operative site.
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself. Obesity is defined according to the W.H.O. standards.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests must be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.
- Prior fusion at the levels to be treated.
- These contra-indications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive. Surgeons must discuss the relative contraindications with the patients.

Caution

- The AEON-C™ Stand Alone System is not intended for posterior surgical implantation.
- Instruments designed for use with implantation of the AEON-C™ Stand Alone System are provided non-sterile and must be sterilized prior to use.
- Based on the fatigue testing results, the physician/surgeon must 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.
- The implantation of the stand-alone cervical intervertebral body fusion device must be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Potential risks identified with the use of this stand-alone cervical intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e. non-union), fracture of the vertebrae, neurological injury, and vascular or
- visceral injury.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- The components of the system should not be used with components of any other system or manufacturer. Any such use will negate the responsibility of Huvexel for the performance of the resulting mixed component implant
- Rx only, Federal law restricts this device to sale by or on the order of a physician.

INSTRUCTION FOR USE

Pre-Operative Precautions

The surgical indication and the choice of implants must take into account certain important criteria such as:

- Patients involved in an occupation or activity that applies excessive loading upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Surgeons must instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and the patient should not have unrealistic functional expectations.
- A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests should be made prior to material implantation.
- Surgeons must advise patients who smoke have been shown to have an increased incidence of non-unions. Such patients must be advised of this fact and warned of the potential consequences.
- Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects.

Intra-Operative Precautions

- The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by Huvexel.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.

Adverse Effects

Include but are not limited to:

- Late bone fusion or no visible fusion mass and pseudarthrosis;
- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone;
- Superficial or deep-set infection and inflammatory phenomena;
- Allergic reactions to the implanted materials, although uncommon, can occur;
- Dural leak requiring surgical repair;
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Cessation of growth of the fused portion of the spine;
- Loss of proper spinal curvature, correction, height and/or reduction;
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to
- excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) must be revised or removed immediately before serious injury occurs;
- Neurological and spinal dura mater lesions from surgical trauma;
- Early loosening may result from inadequate initial fixation, latent infection, premature loading of the device or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, or pain.
- Serious complications may occur with any spinal surgery. These complications include, but are not limited to, genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft or the intervertebral body above or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

The surgeon must warn the patient of these adverse effects as deemed necessary.

NOTE

Indications

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