IVA™ DLIF

Interbody Fusion Cage

REV C – US ONLY

DIO MEDICAL®

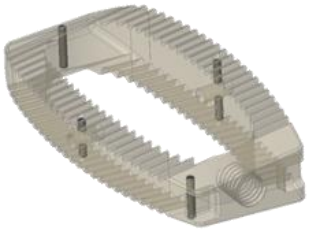
CONTENTS

IMPLANT OVERVIEW

FEATURES & BENEFITS

- PEEK material for postoperative visualization of fusion mass
- Anatomical design for optimal vertebral body contact
- Large graft windows for bone void filler
- Anti-migration teeth to prevent expulsion
- Streamlined instrumentation for reduced procedure steps
- 6 Tantalum markers for radiographic identification

6 Tantalum markers



L

Lordosis (0^o, 6^o, 10^o)

Length	40			45					50					55					60		
Width	18			18			22		18			22		18			22		18		
Height (H, mm)	0°	6°	10°	0°	6°	10°	6°	10°	0°	6°	10°	6°	10°	0°	6°	10°	6°	10°	0°	6°	10°
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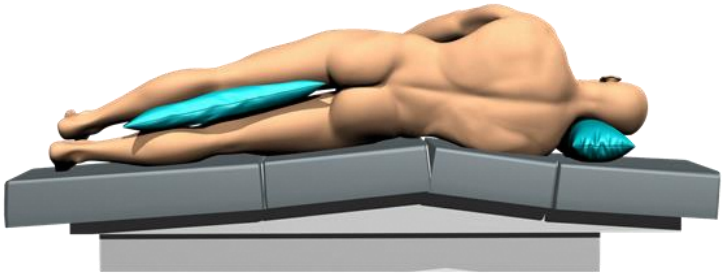
17				o					o												

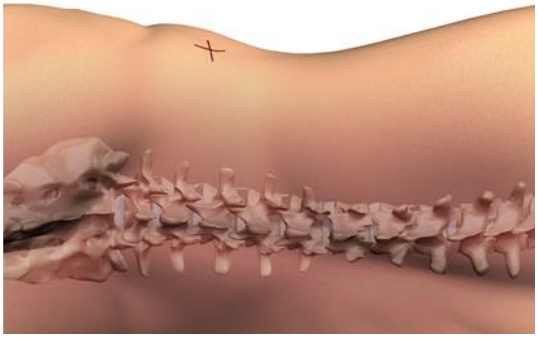
Additionally available

SURGICAL TECHNIQUE

STEP 1: PATIENT POSITIONING and EXPOSURE

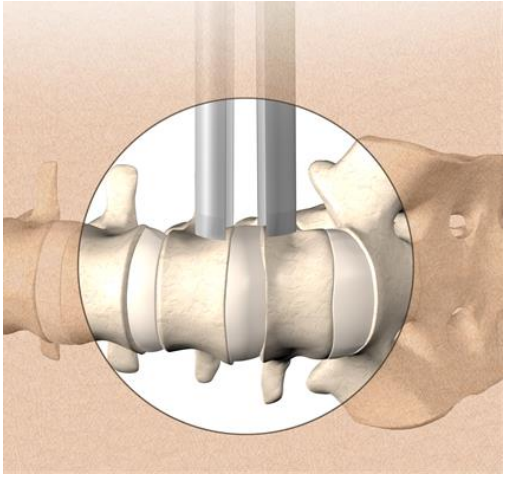
The patient is carefully placed in a direct lateral decubitus position on the operating table following the induction of anesthesia. If desired, tilt the pelvis away from the spine allowing direct access to the lateral lumbar levels. A/P fluoroscopy can be used to ensure the spine is oriented in a lateral position, and use two K-Wires to determine incision location. Create the appropriate posterolateral incision and direct lateral incision to access to the target disc space.





STEP 2: CREATING ACCESS

Use the index finger to enter the retroperitoneal space. After the retroperitoneum is released and critical soft tissues, or structures are moved, palpate the psoas muscle.
A probe is inserted through the muscle and it stimulates/detects the nerves around the spine. This helps the surgeon to avoid the nerves and to leave them undamaged. The dilators are sequentially introduced followed by the retractor to move aside the muscle tissues and to provide access to the spine.



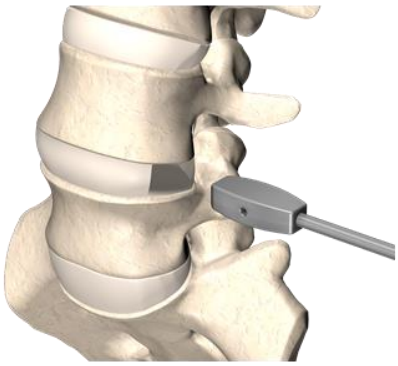
STEP 3: ANNULOTOMY AND ENDPLATE PREPARATION

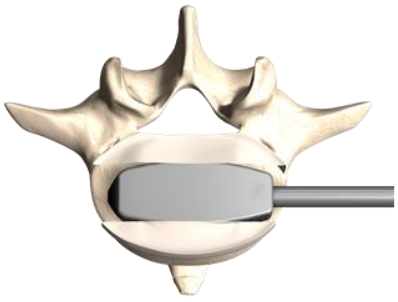
Insert the Cobb Elevator through the contralateral annulus and release the disc from the endplates. Use curettes or other preparation instruments as needed, for further discectomy and endplate preparation. Leave the posterior annulus intact. Confirm completion of discectomy and endplate preparation by fluoroscopy, and do not over-insert the instruments beyond the contralateral apophyseal ring.

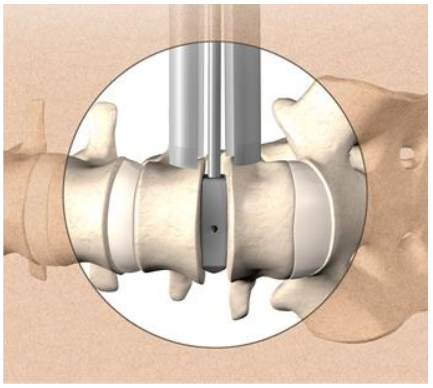
Note: Avoid excessive endplate preparation as this may weaken the vertebral endplates and result in postoperative subsidence.

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 7mm) into the disc space first, moving to the larger Trial as needed. The Trial size is 0.5 mm undersized.







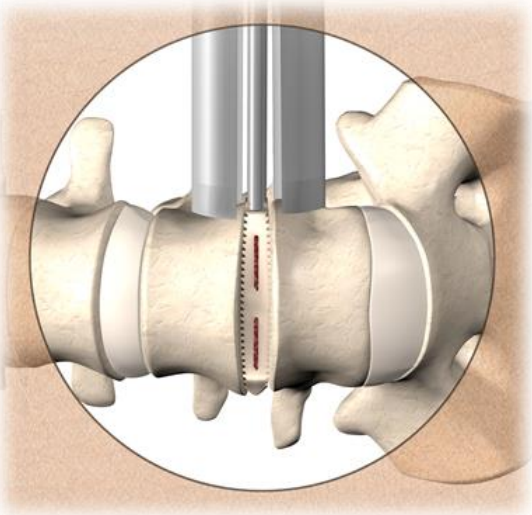
STEP 5: GRAFT FILLING

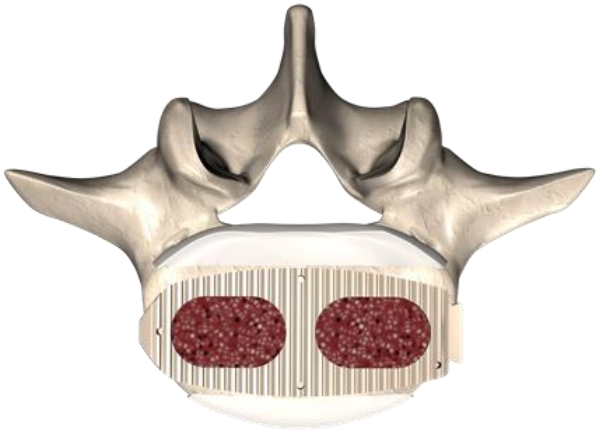
Attach carefully the selected IVA cage DLIF to the cage holder and place it in a bone packing block. Pack autogenous grafted material into graft hole of the implant with a bone packing bar.

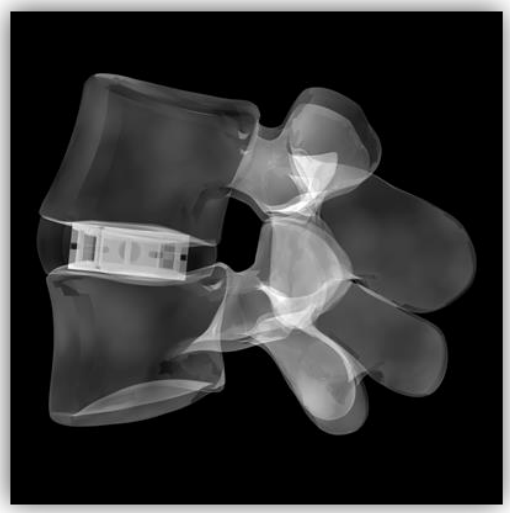
STEP 6: IMPLANT INSERTION

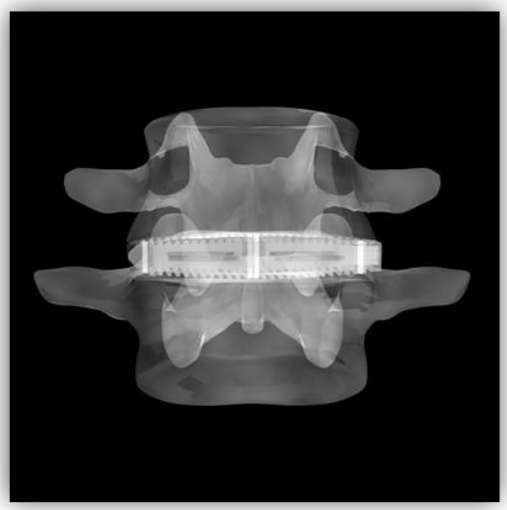
Insert the IVA cage into the prepared disc space up to the appropriate depth. Light impaction may be needed to assist with insertion. Confirm the final position of the implant according to the four radiographic pins under fluoroscopy imaging.
(Radiographic pins are only for IVA PEEK cage)

**Note: IVA cage is intended to be used with supplemental fixation*









STEP 7: CLOSURE

The operative site should be closed per hospital protocol and the surgeon's discretion.

STEP 8: POSTOPERATIVE CARE

Following are few of the recommended steps:

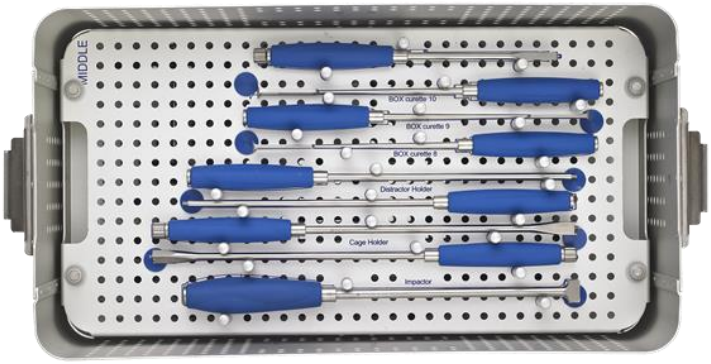
- Prior to adequate fusion, the physician may prescribe additional external support (e.g. braces) to accommodate full load bearing.
- Take anteroposterior and lateral X-rays to ensure correct positioning of the cages and pedicle screws before mobilization of the patient.
- Routine monitoring of the vital signs, and of the hemodynamic and neurologic status of the patient should be done 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 surgeon.

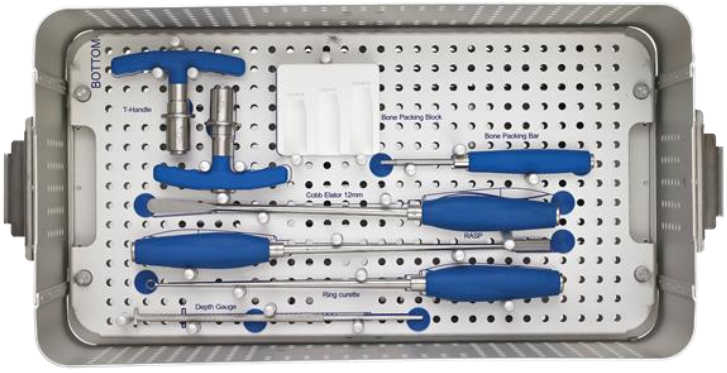
STEP 9: IMPLANT REMOVAL (OPTIONAL)

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. If necessary, distract the vertebrae inferior and superior to the implant for removal.

INSTRUMENT LIST

DI.0100	Bone packing bar
DI.0201	Bone packing block L45xW18, L50xW18, L55xW18
DI.0300	Impactor
DI.0400	Cage holder
DI.0401	Cage shaft
DI.0500	Distractor & Trial holder
DI.2034	TRIAL L45xW18xA0°xH7
DI.2036	TRIAL L45xW18xA0°xH9
DI.2038	TRIAL L45xW18xA0°xH11
DI.2040	TRIAL L45xW18xA0°xH13
DI.2042	TRIAL L45xW18xA0°xH15
DI.2044	TRIAL L45xW18xA0°xH17
DI.2067	TRIAL L50xW18xA0°xH7
DI.2069	TRIAL L50xW18xA0°xH9
DI.2071	TRIAL L50xW18xA0°xH11
DI.2073	TRIAL L50xW18xA0°xH13
DI.2075	TRIAL L50xW18xA0°xH15
DI.2077	TRIAL L50xW18xA0°xH17
DI.0601	Box curette 8
DI.0602	Box curette 9
DI.0603	Box curette 10
DI.0701	Ring curette





INSTRUCTION FOR USE

Indications For Use

The IVA (ACIF, TI ACIF) cage 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 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

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:

- IVA cage (ACIF, TI ACIF) should not be implanted in patients with an active infection at the operative site.
- IVA cage (ACIF, TI ACIF) 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

- This device is NOT intended to be used without the anterior cervical plate provided. Should removal of the anterior cervical plate be necessary during the surgery, the IVA cage (ACIF, TI ACIF) should NOT be implanted alone, without the support of the anterior cervical plate.
- Instruments designed for use with implantation of the IVA Cage (ACIF, TI ACIF) System are provided non-sterile and must be sterilized prior to use.
- This device is not intended for posterior surgical implantation.
- 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 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 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).

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.

INSTRUCTION FOR USE

- 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 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 autograft/allograft or the intervertebral body above or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.
- Adverse effects may necessitate reoperation or revision. The surgeon must warn the patient of these adverse effects as deemed necessary

NOTE

NOTE

Indications

The IVA Cage (ACIF, TI ACIF) are 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-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device 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

The IVA Cage (PLIF, TLIF, DLIF, ALIF, Ti PLIF, Ti TLIF, Ti DLIF and Ti ALIF) are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at one level of two continuous levels for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin 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.

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