Huvex™

Interspinous Fixation System

REV H – US ONLY

DIO MEDICAL®

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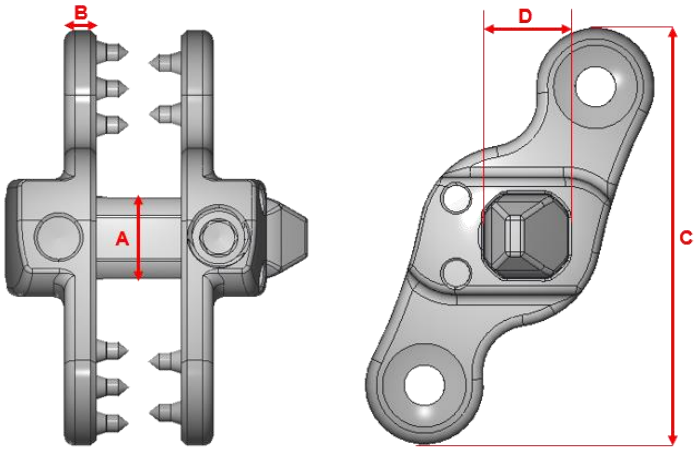
Images may not look the same as the actual product.

This surgical tech guide alone may not offer all information, or knowledge, required to perform spinal surgery, thus additional instruction, or performance, of an experienced surgeon is recommended.

IMPLANT OVERVIEW

FEATURES & BENEFITS

- Low profile design for atraumatic insertion
- Polyaxial central bar allows for a ligament sparing surgical technique
- Large bone graft packing area to promote fusion
- Spikes to engage spinous process
- Resists motion in all six degrees
- Wide variety of center bar heights for optimal distraction
- Titanium alloy (Ti-6Al-4V ELI)
- Additionally available L5-S1 implants
- Anatomical design for optimal fit

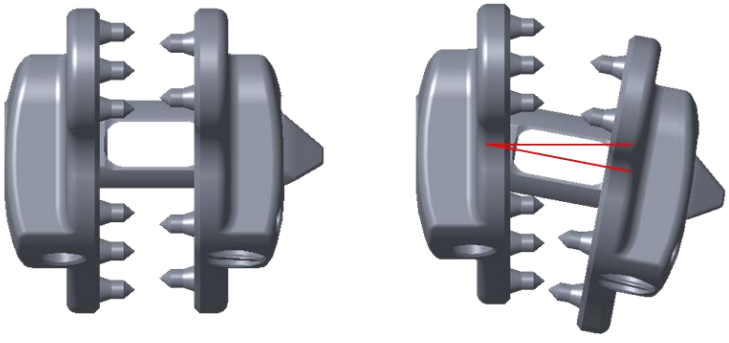


		Center Bar Height (A, mm)	Plate Thickness (B, mm)	Implant Length (C, mm)	Center Bar Depth (D, mm)	Set List
Huvex		6	3	35	7.8	o
		8		39		o
		10				o
		12		43	9.8	o
		14				o
		16				
Huvex L5-S1		6	3	36	7.8	o
		8				o
		10				o
		12		40	9.8	o
		14		44		o

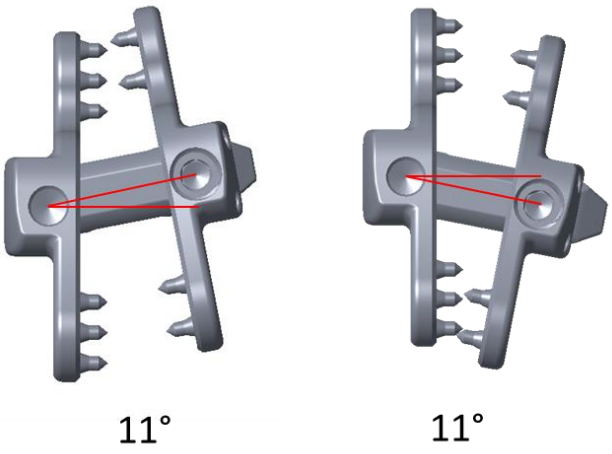
Additionally available

IMPLANT OVERVIEW

Angulation



Anterior-posterior center bar angulation



Cephalad-caudal center bar angulation

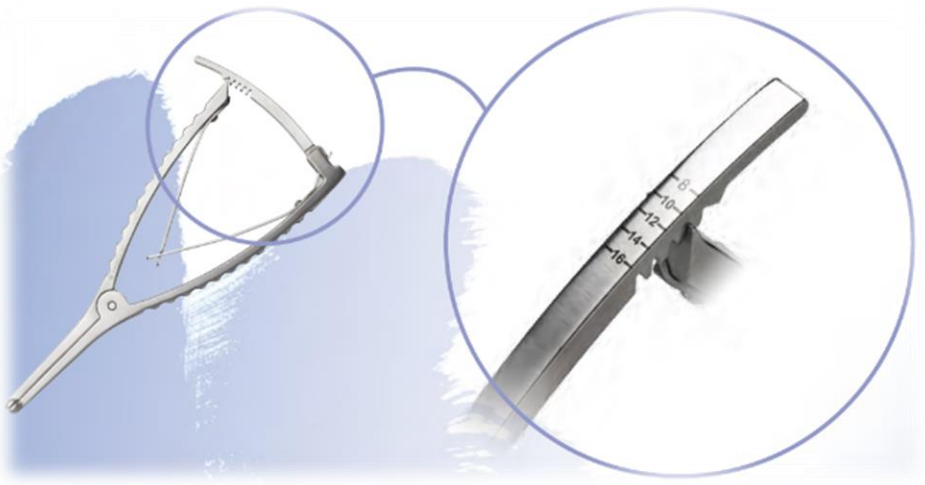
SURGICAL TECHNIQUE

STEP 1: PATIENT POSITIONING and APPROACH

Position the patient in the prone position on the operating table. Make a midline incision about 4~5cm in length to expose the spinous processes at the desired intervertebral disc level. Elevate the paraspinal musculature and other soft tissue to expose the spinous processes and lamina to the medial border of the facet joint. Depending on the surgeon's preferred technique, the supraspinous ligament may be left intact, partially dissected or removed entirely.

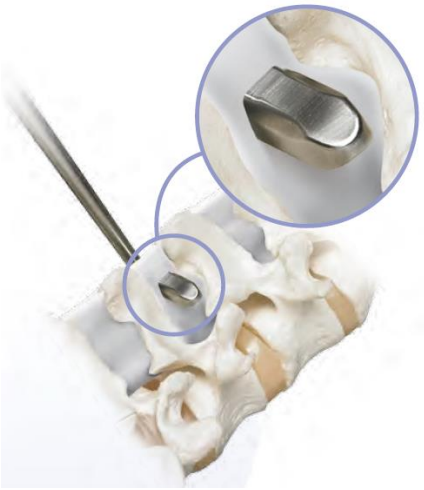
STEP 2: SPINOUS PROCESS PREPARATION

Insert the interspinous ligament perforator and puncture the interspinous ligament to a desired anterior-posterior area. The rasps can be used to sequentially remove soft tissue as well as decorticate the bony area for implant placement. The spreader tips can be inserted between the spinous process for distraction. Note that over distraction could damage the local anatomy.



STEP 3: SIZING

Trials can be used from the smallest height and increased sequentially until desired fit is achieved. The spreader and rasps can also be used to determine desired implant height.



STEP 4: IMPLANT PREPARATION and BONE PACKING

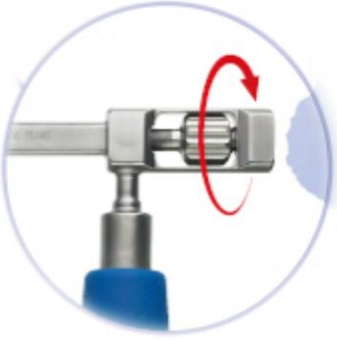
Loading Right Plate

Confirm that the holder is in the **open position** by turning the knob counter clockwise as shown in the image on the left. Align the two prongs on the holder with **the two holes on the side of the Right Plate**. Turn the knob clockwise until the prong is fully engaged with the hex. Confirm that the Right Plate is secure

Open position by turning the knob counter clockwise

Loading Left Plate

Confirm that the holder is in the **open position** by turning the knob counter clockwise as shown in the image. Align the prong on the holder with **the hole on the side of the Left Plate**. Position the Left Plate where the hole below the UP arrow is facing the holder as shown. Turn the knob clockwise until the middle prong is fully engaged in the hole. Confirm that the Left Plate is secure



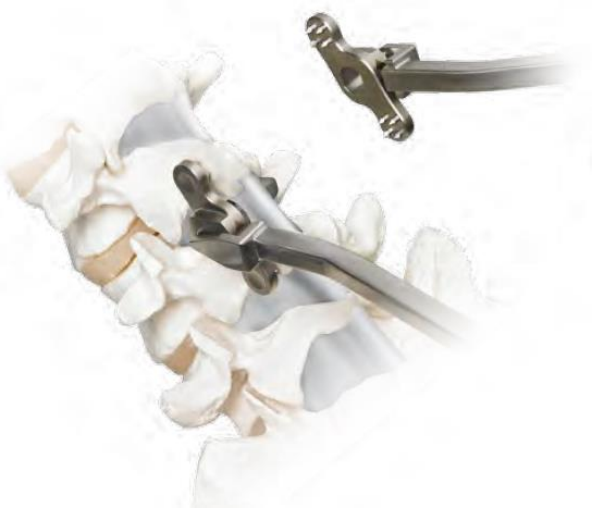
Secure the holder with the implant by turning the knob clockwise

Bone Packing

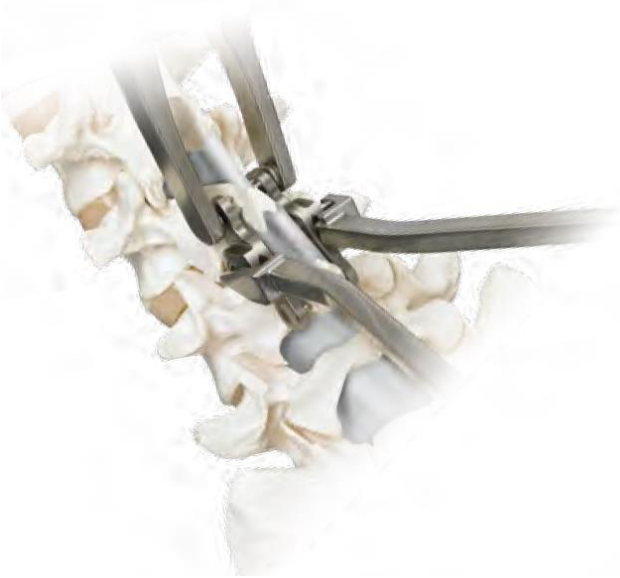
Slide the Left Plate into the corresponding center bar height slot of the bone backing block. Use the bone packing bar to fill the hole with the chosen bone void filler material.

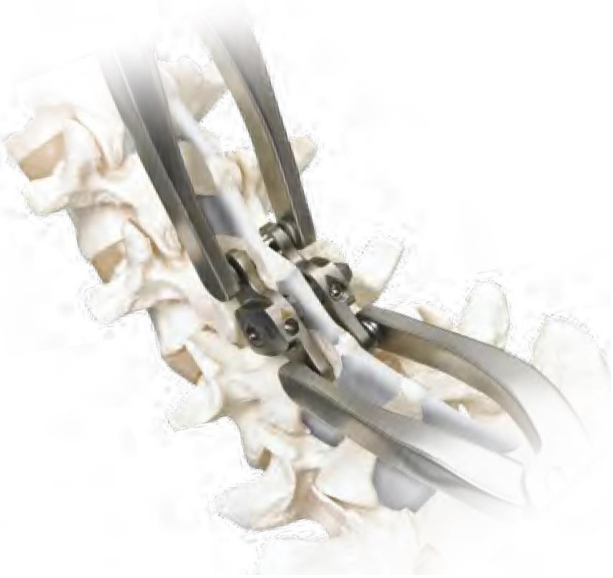
STEP 5: IMPLANT INSERTION and COMPRESSION

Insert the Left Plate between the spinous process. The leading chamfer on the center bar will assist with distraction during placement. Slide the corresponding Right Plate over the center bar and place in the desired position.



Compression, of the Right and Left Plate, to the surgeon's preference can be performed manually or with the compressors provided. Align the spherical tips of the compressor with the corresponding through holes on the plates as shown. Clamp plate in the cephalad and caudal position until the spikes engage the spinous process bone.





STEP 6: FINAL TIGHTENING

Remove the Right and Left holders by turning the wheel counter clockwise. While squeezing both compressors simultaneously use the 3.5Nm torque limiting handle to tighten the set screw until the torque limit is reached. During final tightening confirm that the set screw driver is fully seated within the set screw. Remove compressors and confirm final position of the implant.

Set Screw Tightening

Final Construct

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.
- 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.
- 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)

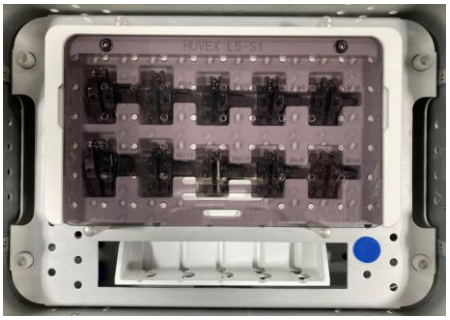
The insertion instruments can be used to engage the implant securely. The implant can then be extracted by following the implantation process in the reverse order. Optionally, other manual surgical instruments may be used to grasp and extract the implant.

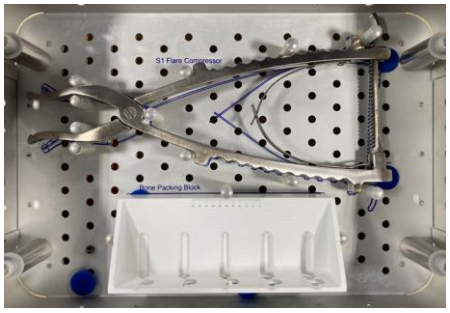
INSTRUMENT LIST

SO.IN.0001	Implant Holder Left
SO.IN.0002	Implant Holder Right
SO.IN.0033	Compressor
SO.IN.0035	Spreader/Sizer
SO.IN.0014	Perforator
SO.IN.0015	Set Screw Driver
SO.IN.0038	3.5 Nm Torque Limiting Handle
SO.IN.0034	Trial 6
SO.IN.0009	Trial 8
SO.IN.0010	Trial 10
SO.IN.0011	Trial 12
SO.IN.0012	Trial 14
SO.IN.0036	Rasp 6
SO.IN.0023	Rasp 8
SO.IN.0024	Rasp 10
SO.IN.0025	Rasp 12
SO.IN.0026	Rasp 14
SO.IN.0037	Bone Packing Block
SO.IN.0029	Bone Packing Bar
SO.IN.0031	I-Handle

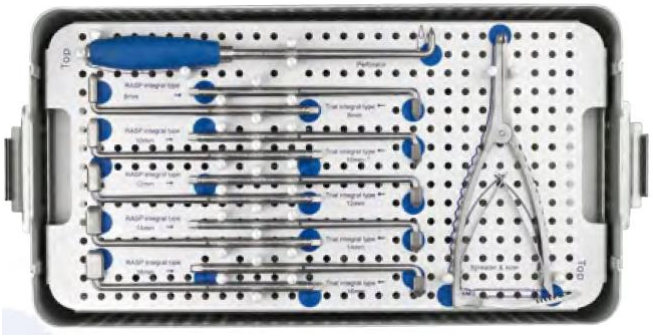
Instruments for L5-S1 System Only

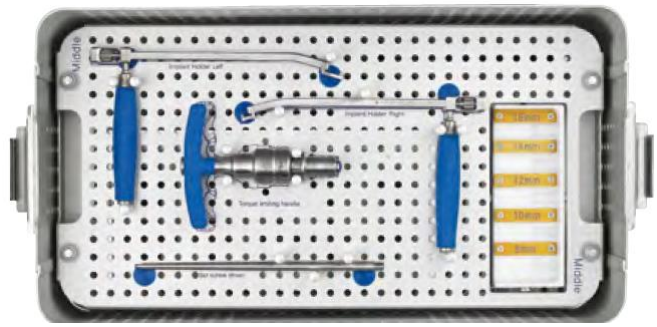
SO.IN.5101	L5-S1 Compressor
SO.IN.5100	L5-S1 Bone Packing Block

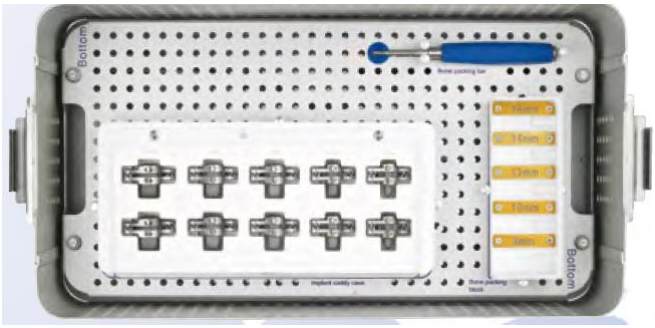


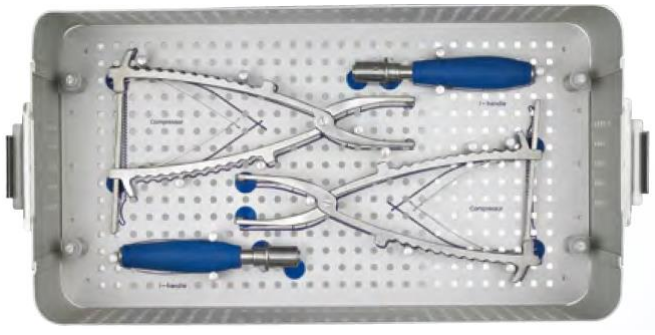


Huvex L5-S1









Huvex

INSTRUCTION FOR USE

Indications For Use

The Huvex interspinous Fixation system is a single-level, posterior, non-pedicle supplemental fixation device intended for use in the lumbar spine (T1~S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to the Huvex interspinous Fixation system for the purpose of achieving supplemental fusion in the following conditions : degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The Huvex interspinous Fixation system is intended for use at one level, with bone graft material, and not intended for stand-alone use.

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:

- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
- Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities.
- Use with components from other systems
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use.
- Reuse or multiple uses.
- Prior fusion at the level(s) 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 Huvex interspinous Fixation system is designed to be used with other fixation devices such as pedicle screw, facet screw or interbody fusion device. The device should NOT be implanted alone, without the support of pedicle screw, facet screw or interbody fusion device.
- Instruments designed for use with implantation of the Huvex interspinous Fixation 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 Huvex interspinous Fixation system.
- The implantation of the Huvex interspinous Fixation system 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 Huvex interspinous Fixation system, 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.
- The Huvex interspinous Fixation system have not been evaluated for safety and compatibility in the MR environment. The Huvex interspinous Fixation system have not been tested for heating or migration in the MR environment.
- Federal law restricts this deveice to sale by or on the order of a physician/surgeon (Rx only)

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:

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the
- components.
- 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;
- Decrease in bone density due to stress shielding;
- 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.Adverse effects may necessitate reoperation or revision. The surgeon must warn the patient of these adverse effects as deemed necessary
- 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.

Adverse effects may necessitate reoperation or revision. The surgeon must warn the patient of these adverse effects as deemed necessary.

NOTE

Indications

The Huvex Interspinous Fixation System is a single-level, posterior, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The Huvex Interspinous Fixation System is intended for use at one level, in conjunction with autogenous bone graft, and not intended for stand-alone use.

DIO MEDICAL CORP.
2100 Campus Lane, East Norriton, PA 19403
1-877-394-5407
info@dio-us.com
www.dio-us.com

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