

Distribuidor exclusivo em Portugal:



G Cage

TREND Intervertebral Spacer System
G Type Intervertebral Spacer
Surgical Procedure

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G Type Intervertebral Spacer

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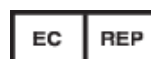
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Surgical Procedure
G Type Intervertebral Spacer

Introduction

The G cages (Trend G-Type Intervertebral Spacer) implanted via posterior approach are intended to facilitate interbody arthrodesis. These cages allow restoration of the disc height and natural lordosis. Nerve-root decompression is also achieved by opening the neural foramen.

The G cages (Trend G-Type Intervertebral Spacer) are entirely made of poly-etherether-ketone (PEEK) and Ti6Al4V ELI, a biocompatible material with modulus characteristics similar to vertebral bone. They are fully radiolucent, which enables optimum follow-up with diagnostic imaging, as the interbody fusion progresses. Metal Pins at the opposite ends of the cage allow radiological confirmation of the cage position post operatively.

The cages are available in several sizes with implant selection based on each individual clinical case.

We recommend that interbody cages should, in most cases, be augmented with a posterior osteosynthesis system.

Indications

G cages are a support to spinal arthrodesis.

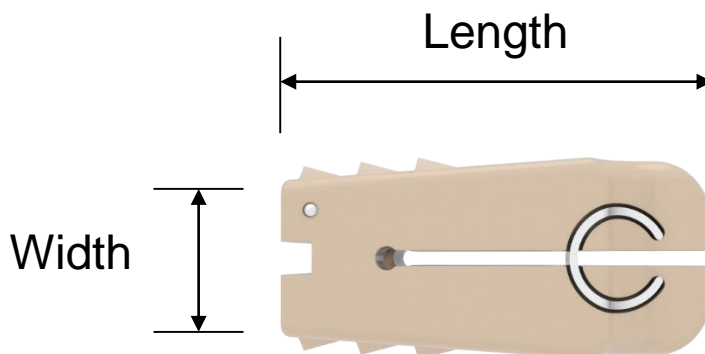
The indications are:

- isthmic spondylolisthesis,
- degenerative spondylolisthesis,
- lumbar discoligamentary instability,
- disc collapse with lateral and foraminal stenosis,
- post surgical iatrogenic lumbar destabilization,
- discal hernia recurrence.

Implants



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REF	Description		
2700-4008C	Degree 4°	W8.0mm	L28.0mm
2700-8008C	Degree 8°	W8.0mm	L28.0mm
2700-1208C	Degree 12°	W8.0mm	L28.0mm
2700-1508C	Degree 15°	W8.0mm	L28.0mm



Instruments

Surgical Procedure
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420-0706

Shaver #6



420-0707

Shaver #7



420-0708

Shaver #8



420-0709

Shaver #9



420-0710

Shaver #10



420-0711

Shaver #11



420-0712

Shaver #12



420-0713

Shaver #13



420-0714

Shaver #14



270-0704

Trial #4



270-0708

Trial #8

Instruments



Surgical Procedure
G Type Intervertebral Spacer



270-0712

Trial #12



270-0715

Trial #15



420-2205

Straight scraper



420-2108

Final Impactor



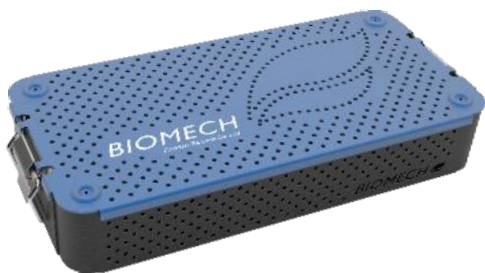
420-2100

G-cage driver



406-0101

T-Handle



420-0002

Instrument Tray



Instruments

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OPTIONAL INSTRUMENTS Index



420-0103	Cage Trial Reducer
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270-0002	Instrument Tray
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420-2120	Bone Impactor
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420-0506	Nerve Retractor 6mm
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420-0508	Nerve Retractor 8mm
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420-0001-A	Shaver Handle
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Surgical Technique Steps



Surgical Procedure
G Type Intervertebral Spacer

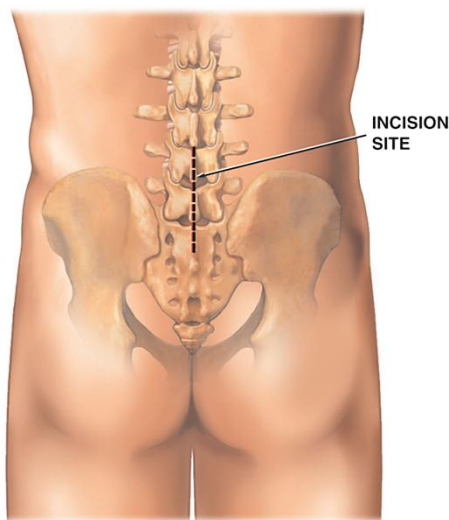
Surgical protocol

Patient's position / Posterior approach:

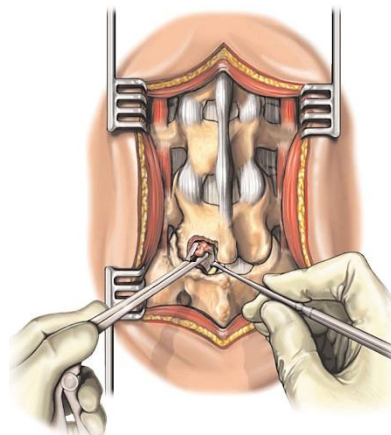
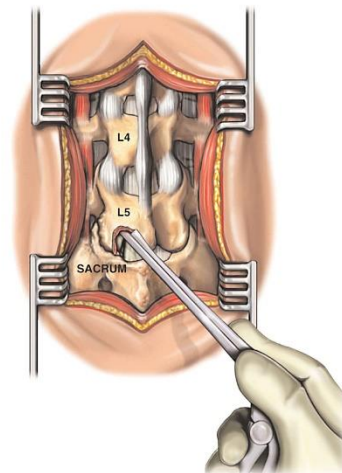
The operation is carried out under general anaesthesia. The patient is placed either in a prone position or in knee chest position, avoiding vascular compression. It is essential to avoid abdominal compression as much as possible to minimize bleeding.

The use of an image intensifier should be used to confirm the operative level. The spine is approached via a posterior medial skin incision, at the appropriate surgical level. The aponeurosis is incised on each side of the spinous process.

The spinal and lumbar muscles are dissected until maximum exposure of the posterior edges of the laminae, the articular processes, and the posterior edges of the transverse processes, is obtained.



POSTERIOR (BACK) VIEW





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Surgical Technique Steps

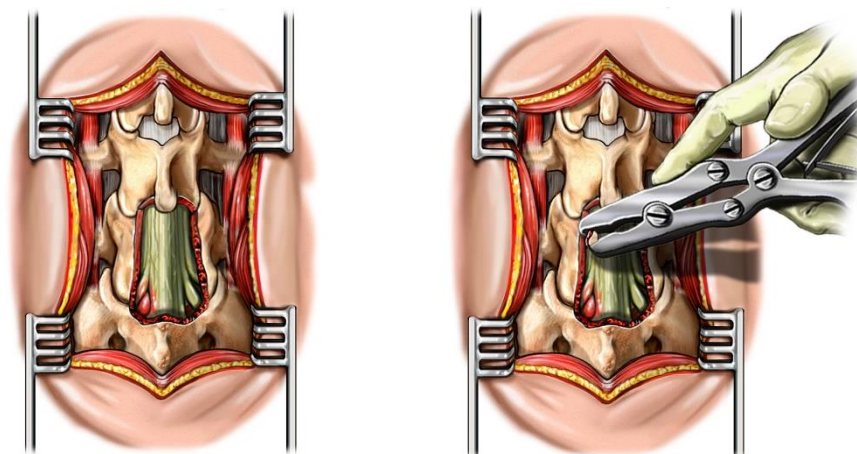
Laminectomy and Decompression

Partial laminectomy of the levels to be fused is performed to gain access to the intervertebral disc. The lateral halves of the articular processes must be preserved to retain some natural stability of the posterior column via a posterior lateral graft.

Following the laminectomy, the excision of the ligamentum flavum is performed.

It is not necessary to perform a total laminectomy and / or facetectomy, provided exposure allows good visualization of:

- The root above
- The root below
- The lateral margins of the disc
- The external edge of the dural sac



The nerve roots are explored and decompressed.

The dural sac is retracted towards the midline, in order to expose each lateral margin of the disc, facilitating the discectomy.

While retracting the dural sac, careful haemostasis of the posterior-body epidural veins is performed.

Note: the bone, resected during laminectomy and facetectomy, is preserved for the interbody or posterior lateral graft. If the amount of the graft is insufficient, graft can be harvested from the iliac crest at this stage of the operation.

Surgical Technique Steps



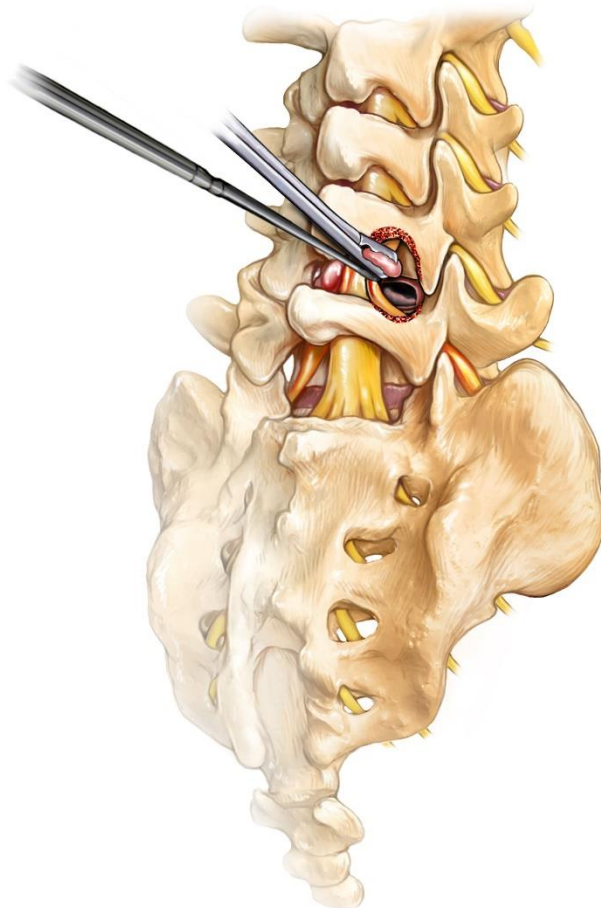
Surgical Procedure
G Type Intervertebral Spacer

Discectomy

Discectomy starts by using a scalpel to make a bilateral rectangular incision through the posterior longitudinal ligament and annulus fibrosus.

- The disc material is resected using various disc rongeurs.
- Finishing and evacuation of the interbody space is carried out using a curette.
- All disc fragments are removed using disc rongeurs.

Note: during the above surgical stages, it is essential to protect the nerve elements (dural sac, roots above and below), using either the nerveroot retractor or a spatula.





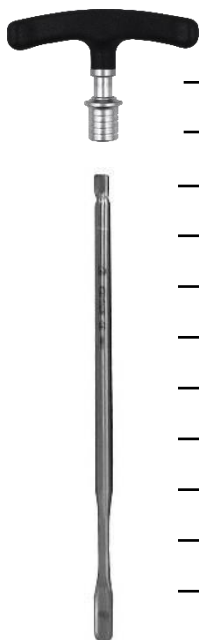
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Surgical Technique Steps

Determining the Interbody Distraction

Interbody distraction is done gradually, using the distracting blades, to restore the disc height. The first Shaver (size: 6mm) is inserted into the disc space with its thinner end first.



406-0101	T-Handle
420-0706	Shaver #6
420-0707	Shaver #7
420-0708	Shaver #8
420-0709	Shaver #9
420-0710	Shaver #10
420-0711	Shaver #11
420-0712	Shaver #12
420-0713	Shaver #13
420-0714	Shaver #14

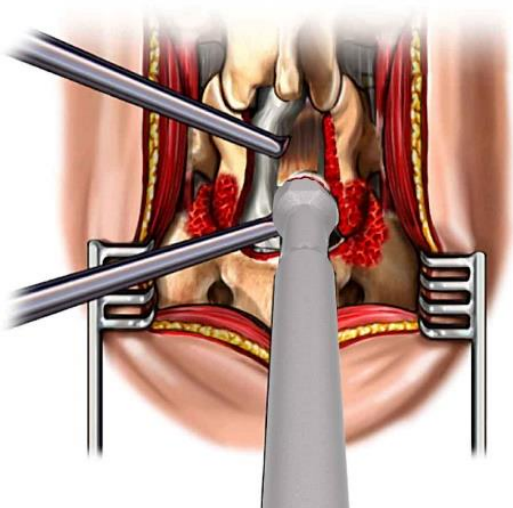




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Insertion depth is identified via the mark on the instrument. Choose the right trial to increase the disc height. During this stage, the dural sac and the roots above and below are retracted and protected, using the nerveroot retractor.



406-0101	T-Handle
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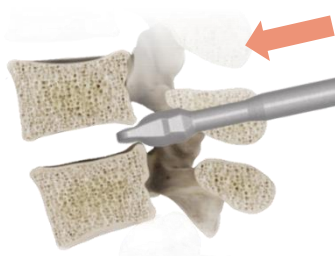
270-0704	Trial #4
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270-0708	Trial #8
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270-0712	Trial #12
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270-0715	Trial #15
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Step.1



Step.2



Step.3



Step.1 :

Slightly insert an appropriately sized trial with the curved sides touching the endplates

Step.2 :

and then rotate right or left for 90 degrees.

Step.3 :

Continue to impact on the end of trial until the desired height is obtained. With the segment fully distracted, the trial must fit tightly and accurately inside the disc space.



Surgical Technique Steps

Surgical Procedure
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Preparing the Plates

The final access path for the cage is then prepared, using the cylindrical reamer. The height of the selected reamer corresponds to the height of the cage to be implanted. The reamer is inserted by a rotational movement in order to remove the disc and to free space for the cage.

Then, the reamer is removed and replaced by the distracting probe of the same height, to confirm the size of the cage to be implanted.

The opposite side of the plate is prepared in the same way.

Endplate preparation can be completed using a curette. Endplate preparation should involve minimal debridement of the cortical bone without penetration. The aim is to remove any “soft” material (cartilage for example) without compromising the solid foundation for the cages to rest upon.

The plate preparation is essential to ensure optimum contact between the graft bone contained within the implant and the adjacent vertebral plates.

For the first time a real possibility to obtain natural lordosis in Disc L5/S1 or L4/L5

Angle values for lumbosacral, lumbolumbar, vertebral bodies, and intervertebral discs curvatures in both age groups.

	Age	Sample	Average(°)	Standard Deviation	Range	Significance (°)
L1-L2	Group1 Group2	207 143	-5.02 -4.94	2.92 2.87	3.0 to-12.0 4.0 to-11.0	p=0.829
L2-L3	Group1 Group2	207 143	-6.79 -7.03	2.78 2.67	0.0 to-14.0 -1.0 to-15.0	p=0.413
L3-L4	Group1 Group2	207 143	-8.97 -9.65	2.62 2.38	-2.0 to-20.0 -3.0 to-15.0	p=0.008*
L4-L5	Group1 Group2	207 143	-12.23 -12.38	3.40 3.39	-3.0 to-26.0 -2.0 to-21.0	p=0.423
L5-S1	Group1 Group2	207 143	-15.56 -15.62	5.54 5.28	-4.0 to-35.0 -5.0 to-30.0	p=0.879

Surgical Technique Steps



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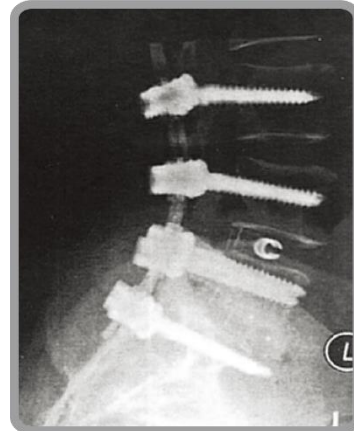
Special Shape of G-cage

Twist PLIF

New Insertion by rotation

1. Nose as a disc opener

2. Shoulder as a root retractor



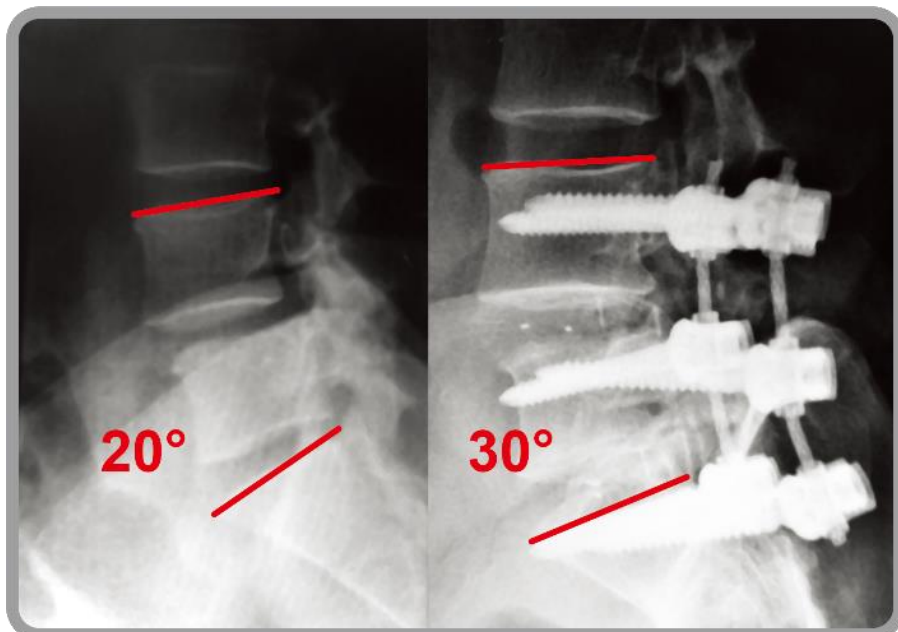
G-cage is a normo-lordotic cage

Patients with poor lordosis are painful due to muscular spasm .

Sagittal unbalance overstress adjacent segment

15° in L5/S1 , 12° in L4/L5 and get a global lordosis in Lumbo-sacral junction up to 30°

4° to 8° is the lordosis of cages on the market. Very insufficient ! compare to needed 15° in L5/S1 or 12° in L4/L5





Surgical Technique Steps

Surgical Procedure
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Positioning the First Cage

The first cage must be inserted by impaction, the opened faces directed towards the intervertebral plates. The cage should be inserted so that its posterior edge is driven approximately 5 mm beyond the posterior wall of the vertebral body (see note after). The holder is then removed from the implant.

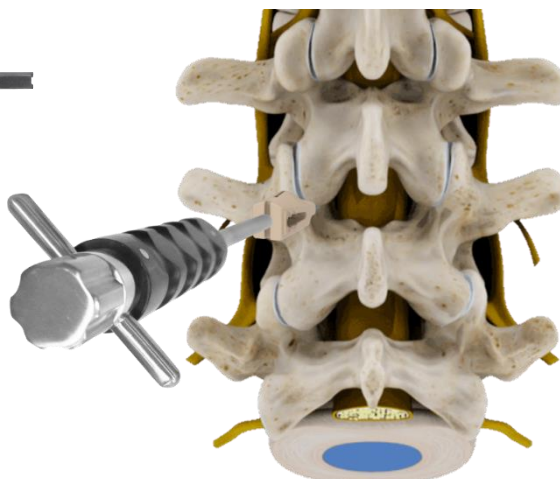
Note: the cage installation can be performed in two stages.

1. Positioning of the cage using the holder so that its posterior edge remains approximately 5 mm out of interbody space.
2. Definitive impaction so that its posterior edge is driven approximately 5 mm from the posterior wall of the vertebral body, using the last impactor.

Cage Handling

Before filling the cage with bone graft, the posterior edge of the cage is screwed firmly to the cage holder. The extremity of the holder has to be parallel with the horizontal plane of the cage.

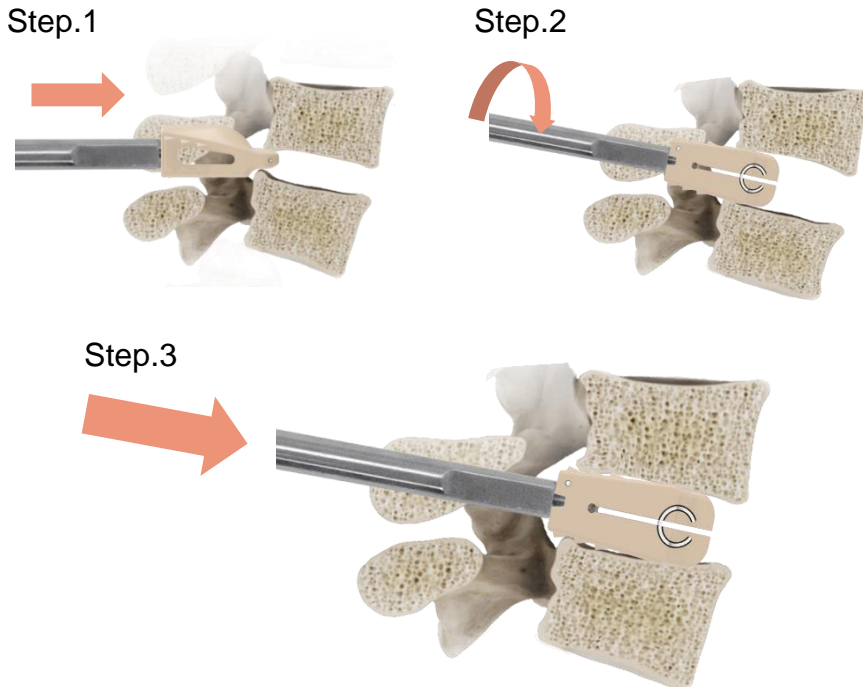
420-2100 G-cage driver



Surgical Technique Steps



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Step.1 :

Slightly insert an appropriately G-Cage with the curved sides touching the endplates

Step.2 :

and then rotate right or left for 90 degrees.

Step.3 :

Continue to impact on the end of G-Cage until the desired height is obtained. With the segment fully distracted, the G-Cage must fit tightly and accurately inside the disc space.

Step.4 :

Use X-Ray Checking the Position.

Positioning the Second Cage

The distracting probe is removed to install the second cage.

Insertion should follow the same guidelines as the first cage.

Impaction should always be directed along the cage axis.

Cages must be inserted symmetrically, in pairs.

At this stage of the procedure, a radiograph should be taken to check cages positioning.

This allows visualisation of markers alignment.



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Surgical Technique Steps

Related Osteosynthesis

Posterior augmentation of the interbody cage implantation is recommended using a posterior fixation system. The use of a posterior system in conjunction with interbody cages can facilitate cage installation, by maintaining disc distraction, and also provide additional stability to the construct with enhanced redundancy.

It is recommended to use the posterior fixation system to slightly compress the vertebral bodies against the implants to stabilize the cages, ensure graft to bone contact and restore lumbar lordosis.

Closing the Incision

A drain is installed and the wound-site closed layer by layer, using standard surgical procedures.

Post-Operative Care

Since the cages provide good stabilization of the motion segment, the patient can usually begin mobilization on the first or second day following the operation.

According to the physician's advice, wearing an external brace may help the patient's comfort.

Important Information



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WOUND CLOSURE

1. If needed, the diaphragm is repaired prior to routine muscle closure. Drains are used on the instructions of the surgeons.
2. Remove all instruments and carefully checked to ensure nothing is left inside the patient.
3. The wound is subsequently closed in the routine manner.

POSTOPERATIVE MANAGEMENT

1. Patient may be allowed to sit in bed with back support 1-3 days after the operation.
2. Wound drains are removed 48 hours after the operation.
3. If the patient is able to be ambulated with or without crutches, he is allowed to do so 5 days after the operation.
4. Respiratory therapy, particularly during the first 3 days after operation, for expansion of the lungs is recommended.
5. Patients should be instructed to wear a spinal collar for 1–2 months following surgery.

POSTSCRIPT

The above description is only the standard installing procedure of the Trend® Intervertebral Spacer System. Since every patient's physiological condition is different, the surgeon should take detail examination and careful judgment before surgery, so that the operation will go through smoothly and the patient may also recover earlier.

INSTRUCTIONS FOR PATIENT

1. The patient must be aware of all postoperative restrictions, particularly limitations related to occupational and sports activities.
2. The patient should be warned that non-compliance with the postoperative instructions may lead to failure of the implant. Additional surgery may also be required to remove the device.

Precautions to Patients:

1. Although the use of internal fixation implants has given the surgeons a mean of bone fixation and help generally in the management of fracture and re-constructive surgery, these implants are only intended to be a temporary device to assist normal healing and are not intended to replace normal body structures. Bone fixation devices are internal splints which provide a means of bone fixation while normal bone healing occurs.
2. Postoperative care is extremely important. The patient must be instructed in the limitations of this implant and must be warned regarding weight-bearing and body stress on the device prior to firm bone healing. The patient should be warned that non-compliance with postoperative instructions could lead to failure of the device and the possible need thereafter for additional surgery to remove the device.

Precautions to Surgeons:

1. The Trend® Intervertebral Spacer System should not be used to span more than three segments.
2. The surgeons must be thoroughly knowledgeable of the mechanical
3. The patient should be adequately instructed. Postoperatively 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 limitations of the implant, and that physical activity and full weight bearing have been implicated in premature failure of internal fixation devices. The patient should be made aware that an implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An over-active, debilitated or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
4. Removal of the implant after healing: Implants can be loose, fracture, corrode, migrate, possibly increase the risk of infection, cause pain or stress shield bone even after healing, particularly in young, active patients. The surgeons should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant, thus eliminating the risks involved with a 2nd surgery.
5. Until firm bony union (confirmed by clinical and radiographic examination) is established, the patient should employ adequate external support and restrict physical activities which would place excessive stresses upon the implant or allow movement and delay or prevent healing.

Possible Adverse Effects:

- The following are specific adverse effects which should be understood by the surgeon and explained to the patient. These do not include all adverse effects which can occur with surgery in general, but are important considerations particular to internal fixation devices. General surgical risks should be explained to the patient prior to surgery.
- . Infection
 - . Pain, discomfort or abnormal sensations due to presence of the device.
 - . Sensitivity or allergic reaction to a foreign body.
 - . Bending or fracture of the implant; loosening of the implant
 - . Decrease in bone density due to stress shielding
 - . Bursitis

Warnings:

The above information is provided by the manufacturer as an educational material for the surgeon in understanding the product and other related knowledge. However, the procedure used in each patient should be based on his (her) individual circumstance under the professional judgment of the operating surgeon with sound planning prior to the implant operation.