

I-FLY™ Threaded Fusion Device

Instrument Set Surgical Technique



The I-FLY™ Threaded Fusion Device offers surgeons an implant that spares the articular facets.

- Stand-alone
- Self-threading
- Self-distracting
- Bilateral, posterior insertion
- Open posterior approach

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Instrument Set



Root Retractor
 6mm (8926006)
 8mm (8926008)
 10mm (8926010)



Disc Distractor
 7mm (8926017)
 8mm (8926018)
 9mm (8926019)
 10mm (8926020)



Straight Reamer, Small (8926150)



Curved Reamer, Small (8926140)



Round Scraper, 5mm (8926105)



T-Handle (907-406)



Implant Holder (8926000)

The patient is placed on the operating table in a prone position (Figure 1). Fluoroscopy can be made available for intraoperative verification. Care should be used to maintain the patient in a lumbar lordotic position in order to reduce venous bleeding, reduce laminar bone removal and facilitate opening of the disc space.

A midline incision (from 4cm to 6cm) provides the approach and exposure to the interlaminar space and facet joints at the affected level.

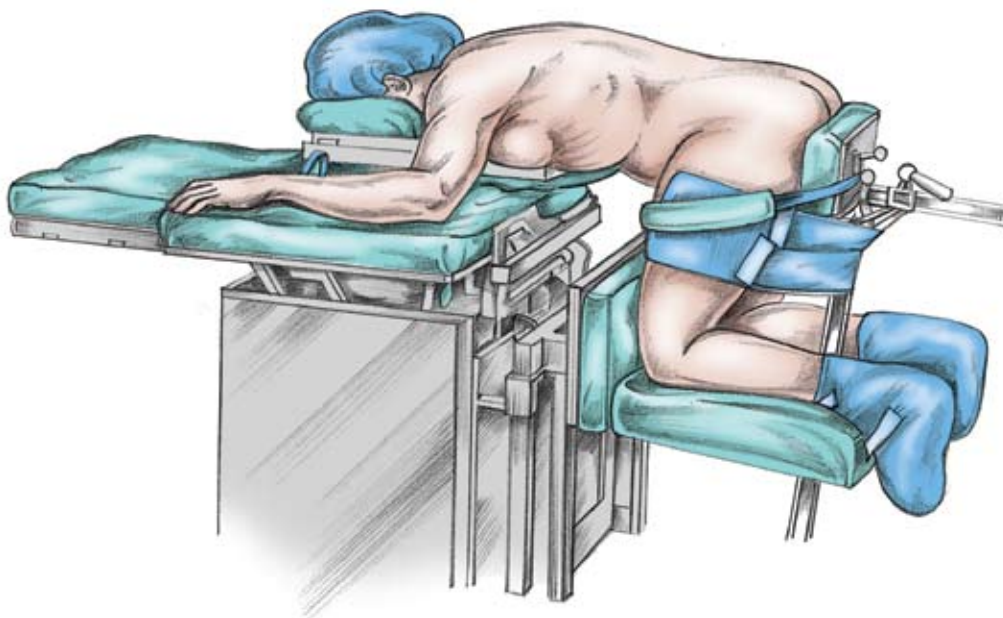


Figure 1

Discectomy

A conventional discectomy is performed by incising the annulus with a 15-scalpel blade lateral to the dural sac (Figures 2a and 2b). After this is done bilaterally, soft fragments from the intradiscal space or extruded fragments are then removed with disc rongeurs in a conventional fashion. The main goal of this step is to remove extruded fragments, decompress neural elements and provide entry to the disc space for distraction with minimal or no nerve root retraction. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished.

The spinous processes, the interspinous ligament and the articular facets are left intact.

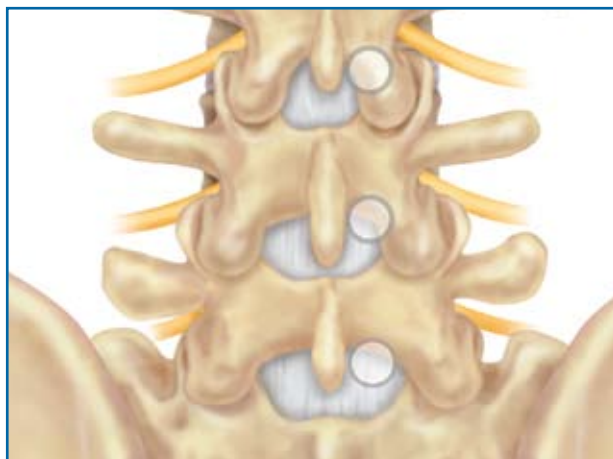


Figure 2a

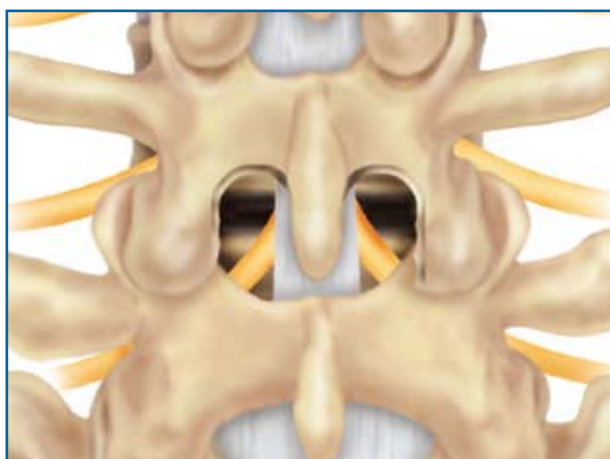


Figure 2b

Distraction of the disc should be initiated on one side in order to minimize trauma to the articular facets when ligamentum flavum and laminar bone removal have been performed on both sides. The disc space is sequentially distracted until appropriate disc space height is obtained and the foraminal opening is restored. With the T-Handle attached, insert the smallest Disc Distractor with the flat surfaces parallel to the end plates (Figure 3). It is then rotated 90° to distract the space, and the T-Handle is removed (Figure 4). The Disc Distractor that is 1mm larger is then inserted on the contralateral side using a similar technique. This distraction process is carried out on alternating sides until the desired height is obtained. The size of the Disc Distractor should not exceed the size of the implant. The largest Disc Distractor is left in the disc space in the distracted position while disc space preparation is performed on the opposite side.

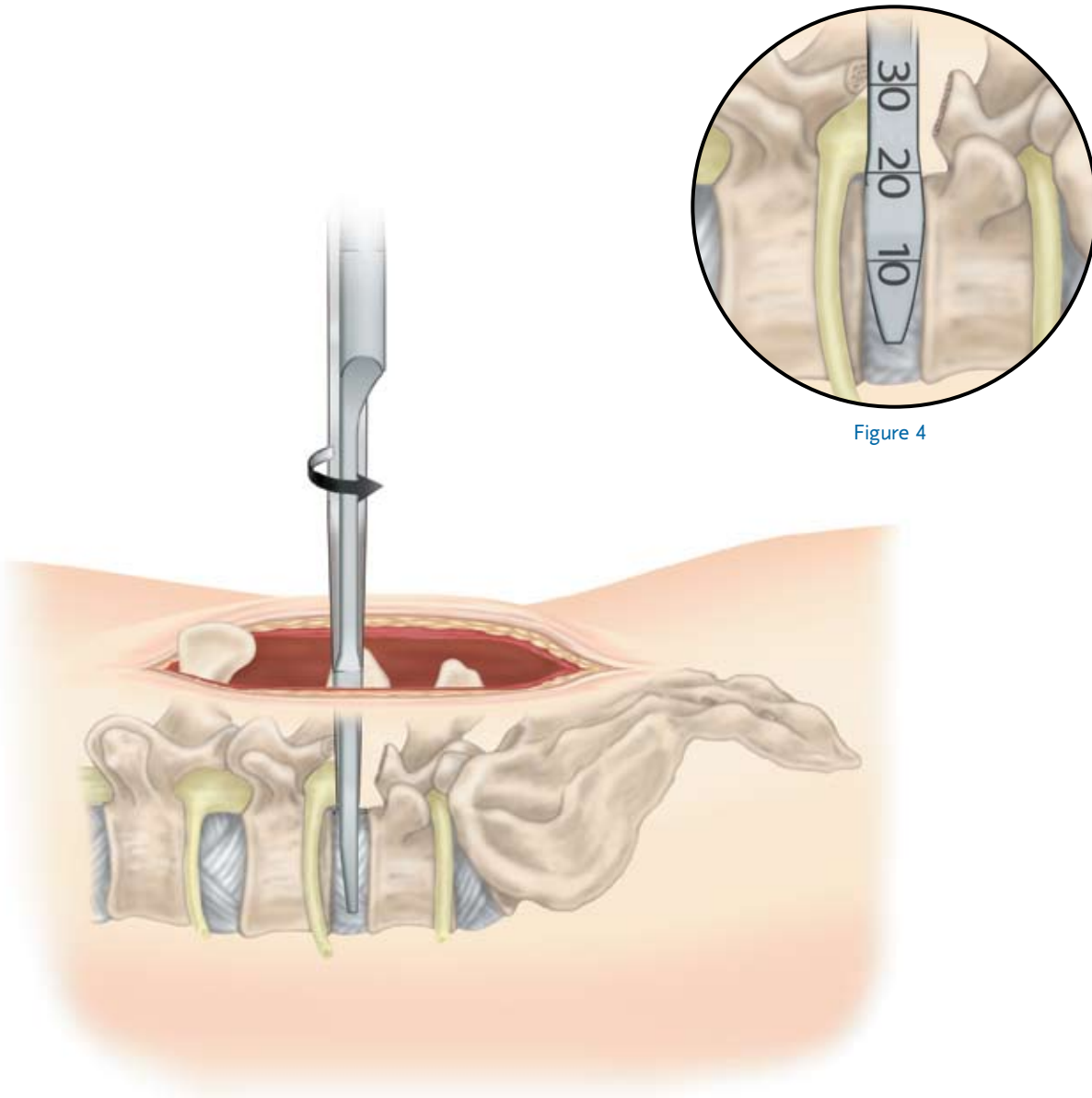


Figure 3

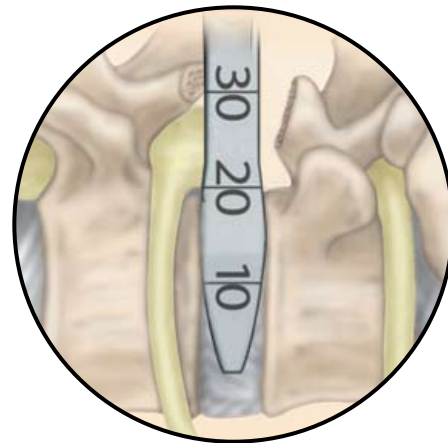


Figure 4

Disc Space Preparation

Remove the disc by using either the Straight or Curved Reamer (Figure 5). The Reamers are blunt-tipped and side-cutting for safety. A T-Handle or a handheld power drill may be used for more efficient disc removal.

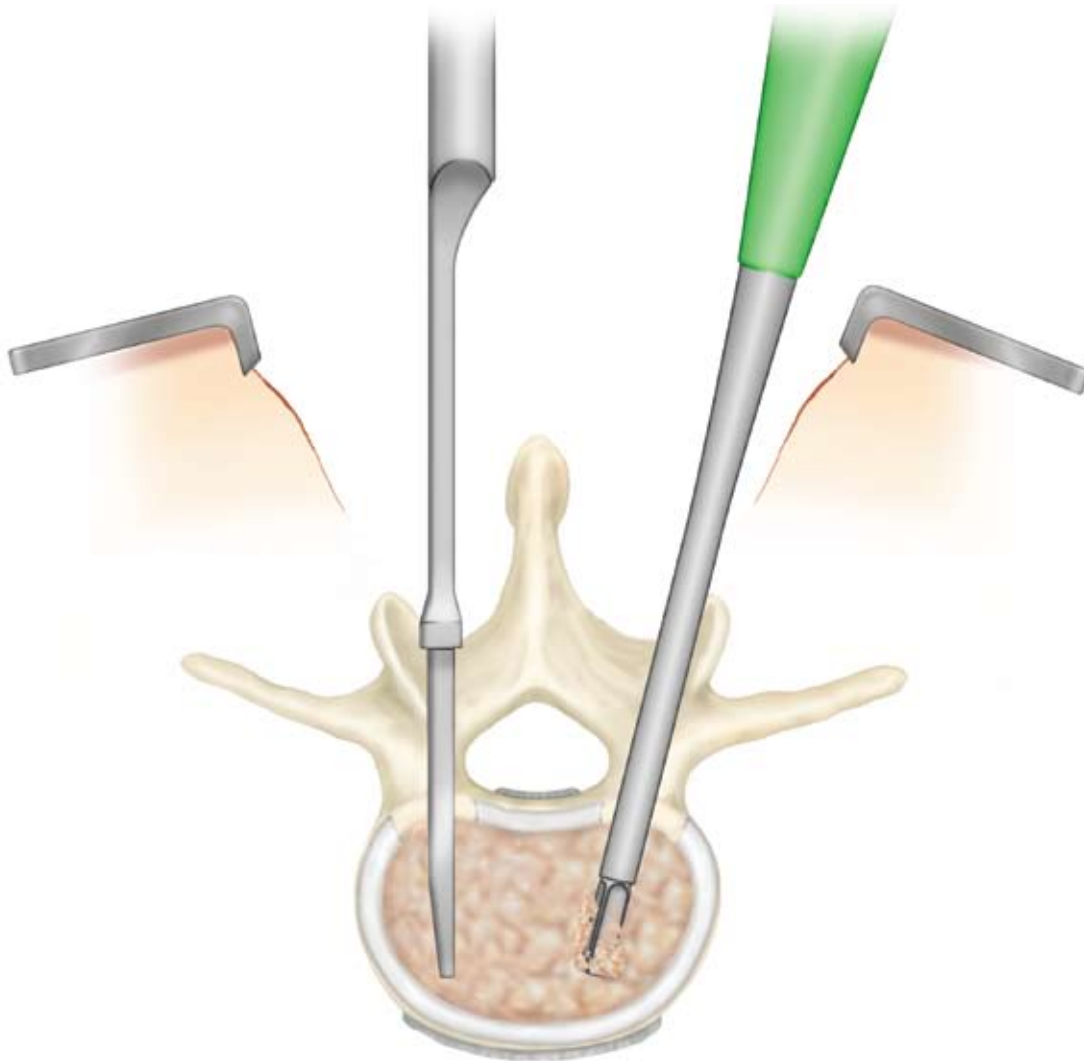


Figure 5

Remaining soft tissue or cartilaginous end plate is removed with the scraper or with curettes (Figure 6). Scrape medially under the midline and gradually work laterally in a sweeping motion until both caudal and cephalad end plates are cleared of soft tissue. The removal of soft tissue from the end-plate surface allows ideal graft incorporation.

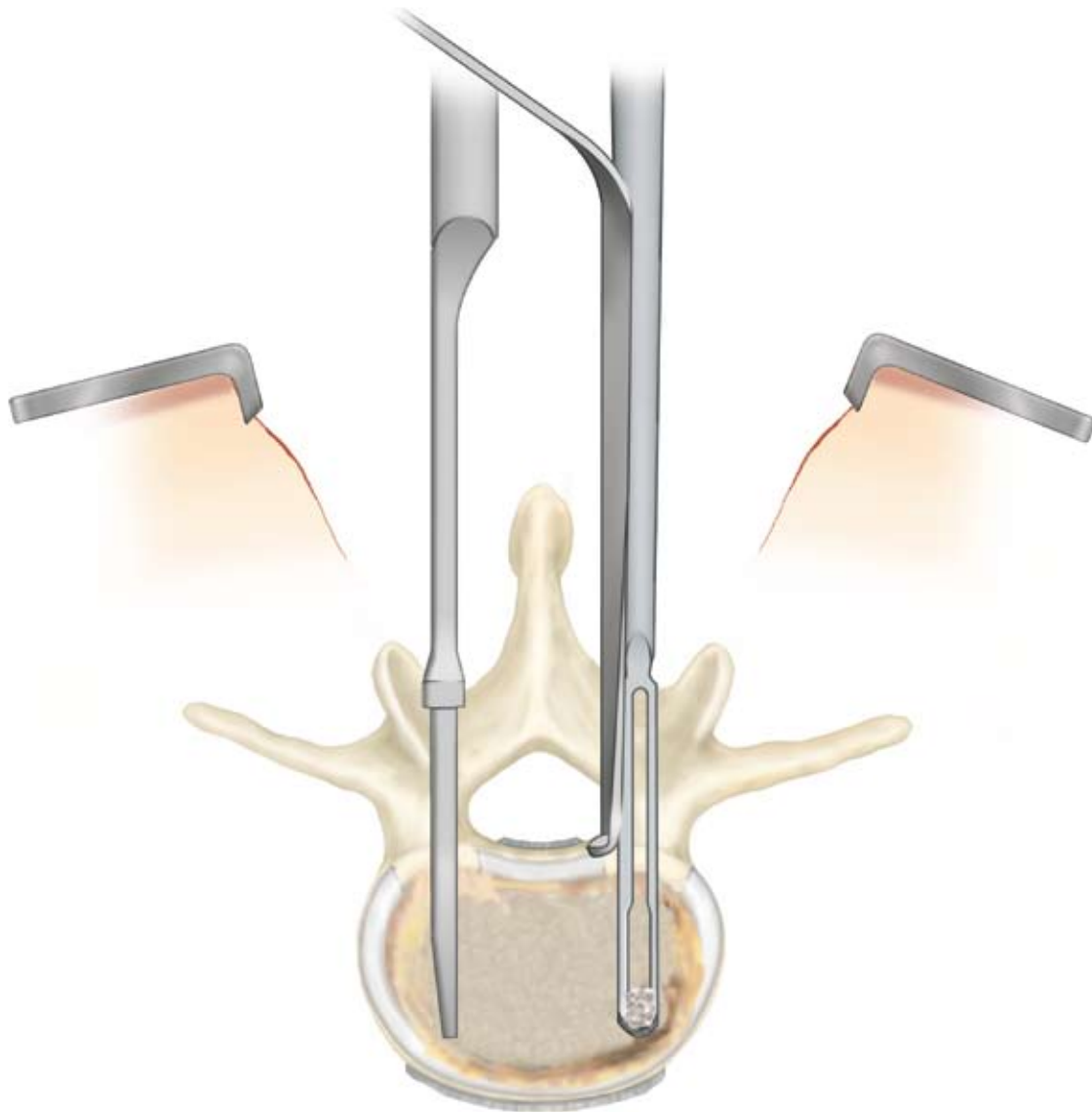


Figure 6

Trial Insertion

The width and depth of the disc removal are accurately controlled at the end of the discectomy on both sides by using the Disc Distractor as a probe (Figure 7).

The depth of the disc removal should be at least 30mm (the implant length plus approximately 5mm) (Figure 8). The width varies according to the implant size and can also be verified by positioning the implant within the exposed disc space.

The lateral edges of the end plates can be gently smoothed with a diamond drill in order to avoid excessive medial positioning of the implant.

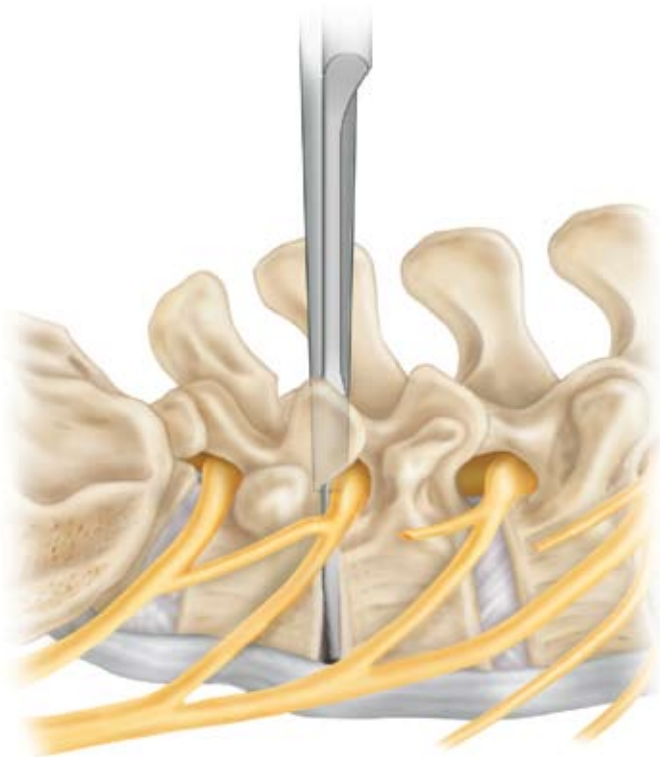


Figure 7

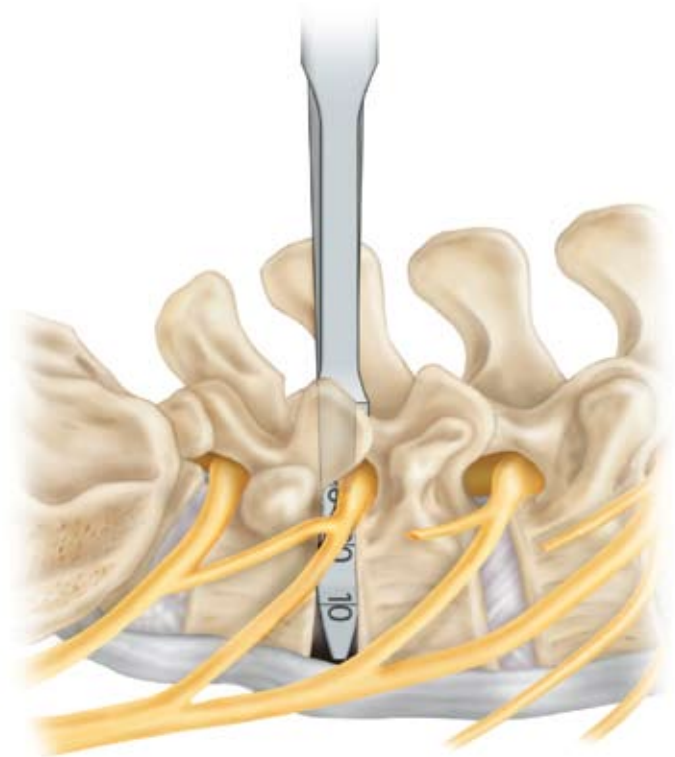


Figure 8

The implant size should exceed the initial height of the intervertebral space, by more than 3mm, in order to achieve a stable construct. The implant is packed with autograft acquired from local bony elements or the iliac crest.

Protect and retract the dural sac with the Root Retractor. Attach the implant to the Implant Holder. Gently impact the implant until the first two threads are inserted within the intervertebral disc space. (The smallest dimension of the implant conical tip should be aligned with the disc space.) Thread the implant into the disc until it is at least 5mm below the posterior wall of the vertebral body (use the measuring scale on the Implant Holder as a reference) (Figures 9 and 10).

When the insertion is completed, adjust the Implant Holder until the handle is parallel to the disc space. This position indicates that the portion of the implant with the larger hole is properly facing the end plates.

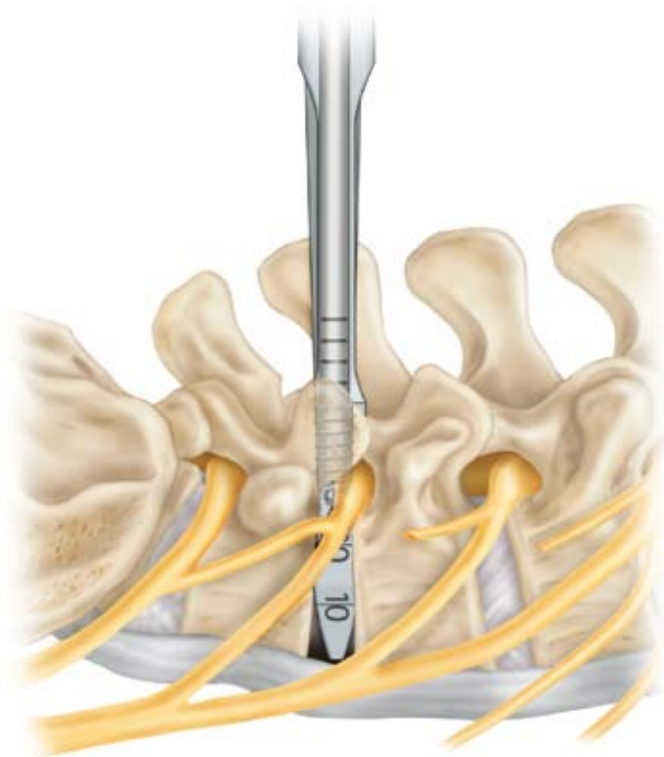


Figure 9

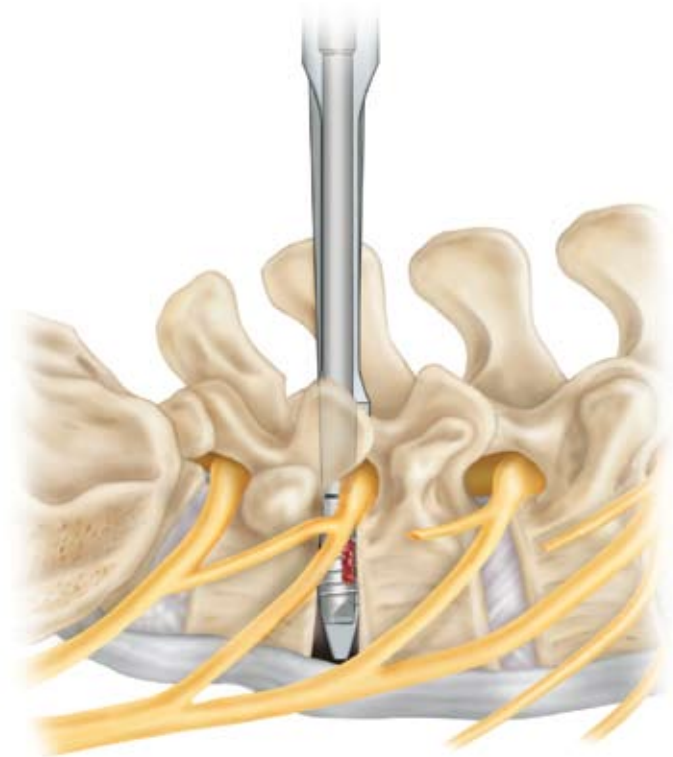


Figure 10

Implant Insertion (Continued) and Explantation

Fluoroscopic images should be taken to ensure proper implant placement. Remove the Implant Holder and the Root Retractor. Remove the Disc Distractor on the opposite side. Repeat the disc space preparation through the implant insertion steps for the opposite side (Figures 11a and 11b).

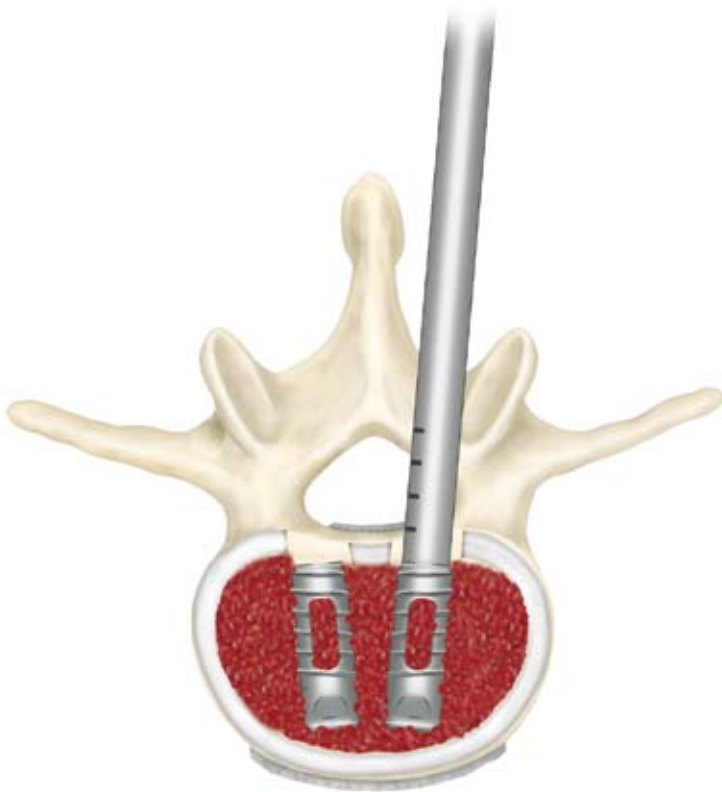


Figure 11a

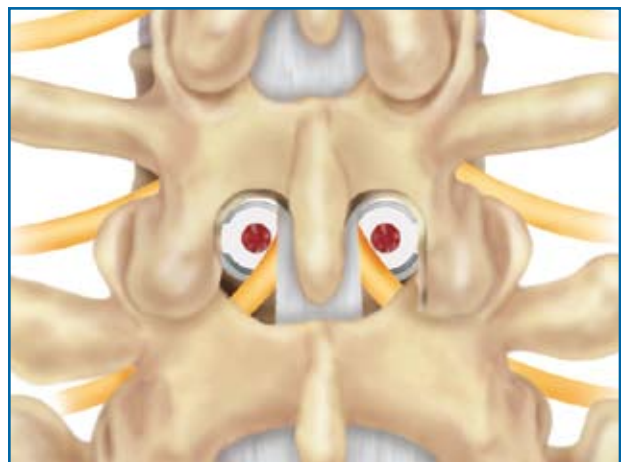


Figure 11b

Explantation

For implant explantation, use the Root Retractor to access the implant. Attach the Implant Holder to the implant and remove the implant. Repeat these steps on the opposite side.

Product Ordering Information

Part Number	Description	Quantity
8927010	Base	1
8926000	Implant Holder	1
8926006	6mm Root Retractor	1
8926008	8mm Root Retractor	1
8926010	10mm Root Retractor	1
8926017	7mm Disc Distractor	1
8926018	8mm Disc Distractor	1
8926019	9mm Disc Distractor	1
8926020	10mm Disc Distractor	1
8926105	5mm Round Scraper	1
8926140	Curved Reamer, Small	1
8926150	Straight Reamer, Small	1
907-406	T-Handle	1
8927030	Cage Plastic Block	1
8928007	7mm Diameter Cage	2
8928008	8mm Diameter Cage	4
8928009	9mm Diameter Cage	4
8928010	10mm Diameter Cage	4
8927020	Lid	1

Important Product Information

PURPOSE

This device is a metallic implant intended for stabilisation use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant's medical and surgical aspects and who has been instructed as to its mechanical and material applications and limitations.

DESCRIPTION

The I-FLY™ Threaded Fusion Devices are made from titanium alloy Ti-6Al-4V. These implants are available in different sizes to meet the anatomic needs of the patients.

They consist of a perforated and metallic cylinder. Both ends of the I-FLY are closed. One of the ends is a nose that allows an easy insertion of the cage. They can be inserted between two lumbar vertebral bodies to give support and stabilization during bone fusion.

Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the Medtronic Catalog or price list for further information about warranties and limitations of liability.

Indications

The I-FLY™ Threaded Fusion Devices are indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2–S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. The I-FLY™ Threaded Fusion Devices are to be used with autogenous bone graft and implanted via an open posterior approach.

CONTRAINDICATIONS

This device is not intended for cervical spine use.

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked leftshift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, osteoporosis.
9. Suspected or documented allergy or intolerance to composite materials.
10. Any case not needing a fusion.
11. Any case not described in the indications.
12. Any patient unwilling to cooperate with postoperative instructions.
13. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
14. These devices must not be used for paediatric cases, nor where the patient still has general skeletal growth.
15. Any case of spondylolisthesis or retrolisthesis.
16. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
17. Any case that requires the mixing of metals from two different components or systems.
18. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
19. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

POTENTIAL ADVERSE EVENTS

Adverse effects may occur when the device is used either with or without associated instrumentation.

The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include but are not limited to:

1. Implant migration.
2. Breakage of the device(s).
3. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
4. Pressure on the surrounding tissues or organs.
5. Loss of proper spinal curvature, correction, height, and/or reduction.
6. Infection.
7. Bone fracture or stress shielding at, above, or below the level of surgery.
8. Non-union (or pseudoarthrosis).
9. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis temporary or permanent retrograde ejaculation in males, or other types of serious injury. Cerebral spinal fluid leakage.
10. Haemorrhage of blood vessels and/or hematomas.
11. Discitis, arachnoiditis, and/or other types of inflammation.
12. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.

13. Bone graft donor site complication.
14. Inability to resume activities of normal daily living.
15. Early or late loosening or movement of the device(s).
16. Urinary retention or loss of bladder control or other types of urological system compromise.
17. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
18. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
19. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
20. Loss of or increase in spinal mobility or function.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Cessation of any potential growth of the operated portion of the spine.
25. Death.

WARNING(S) AND PRECAUTION(S)

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without a bone graft or bone substitute material or in cases that do not develop a union will not be successful.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol / drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.

Other preoperative, intraoperative, and postoperative warnings are as follow:

Implant Selection

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metal surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the human anatomy. Unless great care is taken in patient selection, placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage or loosening of the device before the fusion process is complete, which may result in further injury or the need to remove the device prematurely.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

USA For US audiences only.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

DEVICE FIXATION

Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by MEDTRONIC SOFAMOR DANEK. In the interests of patient safety, it is therefore recommended that MEDTRONIC SOFAMOR DANEK implants are not used with devices from any other source.

Never under any circumstances reuse an I-FLY™ Threaded Fusion Device. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be taken in the handling and storage of the device(s). They should not be scratched or damaged. Devices should be protected during storage especially from corrosive environments.
4. Further information about this system will be provided upon request.
5. The surgeon should be familiar with the various devices before use and should personally verify that all devices are present before the surgery begins.
6. The size of device for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. Unless supplied sterile all devices should be cleaned and sterilized before use. Additional sterile components should be available in case of any unexpected need.

Important Product Information (Continued)

INTRAOPERATIVE

1. The instructions in any available I-FLY™ Threaded Fusion Device surgical technique manual should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.
4. To assure proper fusion below and around the location of the fusion, a bone graft should be used. A proven bone grafting material must be used, for example cancellous autogenous bone.
5. Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur as result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine.
2. The patient should be advised not to smoke or consume excess alcohol, during period of the bone fusion process.
3. The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and/or break, the devices should be revised and/or removed immediately before serious injury occurs.
5. The I-FLY™ Threaded Fusion Device implants are interbody devices and are intended to stabilize the operative area during the fusion process.
6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

REMOVAL OF IMPLANTS

The I-FLY™ Threaded Fusion Device is intended to remain in place. Where there is evidence or indication of localised tissue reaction or pain, breakage, migration, fracture or loosening of these support devices, or infection or bone loss, then removal should be considered.

There may be reasons for removal of any other jointly used internal support instrumentations after fusion has taken place.

PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to MEDTRONIC SOFAMOR DANEK.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened MEDTRONIC SOFAMOR DANEK package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to MEDTRONIC SOFAMOR DANEK. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes
Steam*	Pre-Vacuum*	273°F (134°C)*	20 Minutes*
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g., temperatures, times) used for their equipment.

*For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or MEDTRONIC SOFAMOR DANEK. Further, if any of the implanted spinal system component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC SOFAMOR DANEK PRODUCT ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact MEDTRONIC



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Notes

Notes

listen. respond. deliver.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the package insert for the complete list of indications, warnings, precautions, and other medical information.

Not for distribution in the US or its territories.

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