INTER FIX™ THREADED FUSION DEVICE
Important Medical Information

The following contains important medical information on the INTER FIX™ Threaded Fusion Device.

DESCRIPTION:

The INTER FIX™ Threaded Fusion Device consists of a hollow, perforated, metallic cylinder and endcap. The INTER FIX™ implants are available in diameters ranging from 12mm to 20mm and in lengths ranging from 20mm to 29mm. The endcaps are sized according to the diameter of the cylinders and are applied to the open end of the cylinders after they are filled with autogenous bone graft.

The INTER FIX™ implants are made from implant grade titanium alloy (Ti-6Al-4V) conforming to ASTM F136.

INDICATIONS:

The INTER FIX™ Threaded Fusion Device is 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. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level. INTER FIX™ implants are to be used with autogenous bone graft and implanted via an open anterior approach.

CONTRAINDICATIONS:

The INTER FIX™ Threaded Fusion Device should not be implanted in patients with an active infection at the operative site or with an allergy to titanium or titanium alloy.

WARNINGS:

- The INTER FIX™ Threaded Fusion Device should only be used by surgeons who are experienced in spinal fusion procedures and have undergone adequate training with this device.

- A lack of adequate experience and/or training may lead to a higher incidence of adverse events such as vascular injuries, neurological events, and/or urogenital events (including retrograde ejaculation).

PRECAUTIONS:

- The safety and effectiveness of the INTER FIX™ Threaded Fusion Device have not been established in patients with any of the following conditions:
  - spondylolisthesis or retrolisthesis of Grade II or greater;
  - more than one level to be fused;
  - revision of previous interbody fusion procedure(s);
  - postoperative steroidal or nonsteroidal anti-inflammatory medication requirements;
  - gross obesity;
  - ages less than 18 years or greater than 65 years;
  - osteoporosis, osteopenia, and/or osteomalacia;
  - pregnancy.

- The safety and effectiveness of the INTER FIX™ Threaded Fusion Device have only been established in anterior lumbar interbody fusion (ALIF) procedures using autologous bone graft.

- Patients receiving the INTER FIX™ Threaded Fusion Device should have had at least six months of nonoperative treatment.

- Two INTER FIX™ Threaded Fusion Devices should be implanted side by side at the surgical level.

- The long axis of the INTER FIX™ Threaded Fusion Devices should be in the anterior-posterior direction.

- The implants and instruments must be sterilized prior to use according to the sterilization instructions provided in this package insert, unless supplied sterile and clearly labeled as such.

ADVERSE EFFECTS:

The adverse effects, as shown in Table I, were reported from the 181 INTER FIX™ device patients and 62 control patients enrolled in the multi-center clinical study of the INTER FIX™ Threaded Fusion Device. The rates presented are the number of occurrences for the adverse effect divided by the total number of patients with available data at a given time period. The adverse effects occurring in the randomized and nonrandomized INTER FIX™ device treatment groups are combined in order to present an overall rate.

Table I - Adverse Effects[1]

Complication	Operative [Number (%)]		Post-operative (1 Day-<2 Months) [Number (%)]		3 Month (≥2-<5 Months) [Number (%)]		8 Month (≥5-<9 Months) [Number (%)]		12 Month (≥9-<19 Months) [Number (%)]		24 Month (≥19-< 30 Months) [Number (%)]		TOTAL ADVERSE EVENTS	
	INTER FIX™ N=181	Control N=62	INTER FIX™ N=179	Control N=62	INTER FIX™ N=172	Control N=60	INTER FIX™ N=153	Control N=59	INTER FIX™ N=133	Control N=54	INTER FIX™ N=72	Control N=48	INTER FIX™ # (% of 181)	Control # (% of 62)
Vascular Intra-Op	15 (8.3)			2 (3.2)									15 (8.3)	2 (3.2)
Sacroiliac Pain			4 (2.2)		3 (1.7)		3 (2.0)	1 (1.7)	4 (3.0)	1 (1.9)	1 (1.4)		15 (8.3)	2 (3.2)
Neurological	3 (1.7)		3 (1.7)	2 (3.2)	4 (2.3)	2 (3.3)	1 (0.7)	1 (1.7)	1 (0.8)	2 (3.7)	1 (1.4)	3 (6.3)	13 (7.2)	10 (16.1)
Back Pain			1 (0.6)		3 (1.7)	2 (3.3)	5 (3.3)	1 (1.7)	2 (1.5)	3 (5.6)		6 (12.5)	11 (6.1)	12 (19.4)
Incisional			7 (3.9)	6 (9.7)	1 (0.6)			1 (1.7)	1 (0.8)				9 (5.0)	7 (11.3)
Spinal Event	1 (0.6)		1 (0.6)	1 (1.6)	1 (0.6)		1 (0.7)	1 (1.7)	3 (2.3)		2 (2.8)		9 (5.0)	2 (3.2)
Urological	1 (0.6)		6 (3.4)	2 (3.2)	1 (0.6)								8 (4.4)	2 (3.2)
Other	2 (1.1)			2 (3.2)	2 (1.2)		3 (2.0)		1 (0.8)				8 (4.4)	2 (3.2)
Other Pain			3 (1.7)	1 (1.6)	3 (1.7)			2 (3.4)	1 (0.8)			1 (2.1)	7 (3.9)	4 (6.5)
Gastrointestinal			5 (2.8)	3 (4.8)				1 (1.7)	1 (0.8)			1 (2.1)	6 (3.3)	5 (8.1)
Retrograde Ejaculation			2 (1.1)		3 (1.7)		1 (0.7)						6 (3.3) (7.4)[2]	
Respiratory			3 (1.7)	1 (1.6)	1 (0.6)		1 (0.7)						5 (2.8)	1 (1.6)
Leg Pain			1 (0.6)		1 (0.6)		1 (0.7)		1 (0.8)				4 (2.2)	
Trauma					3 (1.7)				1 (0.8)				4 (2.2)	
Peritoneal	3 (1.7)												3 (1.7)	
Vascular Post-Op			2 (1.1)	2 (3.2)									2 (1.1)	2 (3.2)
Bone Fracture	1 (0.6)		1 (0.6)										2 (1.1)	
Implant Displacement/ Loosening	1 (0.6)	1 (1.6)		5 (8.1)			1 (0.7)						2 (1.1)	6 (9.7)
Graft Site Pain			1 (0.6)							1 (1.9)			1 (0.6)	1 (1.6)
Non-Union							1 (0.7)						1 (0.6)	
Subsidence							1 (0.7)						1 (0.6)	
Non-Union (OUTCOME ENDING)								1 (1.7)	1 (0.8)			1 (2.1)	1 (0.6)	2 (3.2)
Meningitis						1 (1.7)								1 (1.6)
Implant Breakage		4 (6.5)												4 (6.5)
Death										1 (1.9)				1 (1.6)

The most common and serious adverse events were intraoperative vascular and neurological injuries. A total of 15 vascular intraoperative events occurred in 14 patients in the INTER FIX™ device group. These events included: 2 injuries to the vena cava, 9 injuries to the iliac vein, 1 lacerated hypogastric vein, 1 segmental vein bleeder, 1 sacral vein injury, and 1 superficial bleeder. A total of 2 vascular intraoperative injuries occurred in 2 patients in the control group. These included: 1 injury to an iliac vein and 1 bleeding from the bone bed.

A total of 13 neurological events occurred in 13 patients in the INTER FIX™ device group. These events included: 1 footdrop; 2 nerve root injuries; 1 foraminal stenosis; 1 reflex sympathetic dystrophy; 3 numbness or burning of legs; 2 dysthesia; 2 paresthesia; and 1 shooting pain in lower back. A total of 10 neurological events occurred in 8 patients in the control group. These events included: 1 radiculopathy with tingling extremities; 1 chronic back pain with radiculitis; 1 debilitating distribution symptoms; 2 back and leg pain with other symptoms; 1 denervated abductor magnus muscle; and 4 with numbness or warmth in legs. In addition, the adverse effects table presents leg and back pain adverse events and/or spinal events, such as disc space collapse, that, in some instances, had a neurological component.

Some of the adverse effects led to surgical interventions subsequent to the clinical trial surgery. These additional surgical interventions can be classified as revisions, removals, supplemental fixations, or reoperations.[3] Table II summarizes the secondary surgical interventions in the INTER FIX™ device (randomized and nonrandomized combined) and control treatment groups.

---

[1] Since fusion is a primary effectiveness endpoint, nonunions reported as adverse events by the investigator are not included in the table if the nonunion resulted in a second surgery. These nonunion events are captured in the secondary surgery table and the fusion table.

[2] Percent of 81 male patients.

[3] **Revision:** A procedure that adjusts or in any way modifies the original implant configuration.

Table II - Secondary Surgical Procedures		
	INTER FIX™ Device N=181	Control N=62
Revisions	4 (2.2%)	3 (4.8%)
Removals	2 (1.1%)	0 (0.0%)
Supplemental Fixations	7 (3.9%)	11 (17.7%)
Reoperations	11 (6.1%)	6 (9.7%)

Potential Adverse Effects:

The following is a list of potential adverse effects which may occur with spinal fusion surgery with the INTER FIX™ Threaded Fusion Device. Some of these adverse effects may have been previously reported in the adverse effects table.

- Disassembly, bending, breakage, loosening, and/or migration of components.
- Foreign body (allergic) reaction.
- Tissue or nerve damage.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears.
- Neurological system compromise.
- Urological system compromise.
- Scar formation.
- Bone fracture.
- Non-union (or pseudarthrosis), delayed union, mal-union.
- Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function.
- Graft donor site complications.
- Damage to blood vessels and cardiovascular system compromise.
- Gastrointestinal complications.
- Reproductive system compromise.

Removal: A procedure that removes one or more components of the original implant configuration without replacement with the same type of trial device.
Supplemental Fixation: A procedure in which additional spinal devices not approved as part of the protocol are placed.
Reoperation: Any surgical procedure that does not remove, modify or add any original implant components.

- Damage to internal organs and connective tissue.
- Development of respiratory problems.
- Incisional complications.
- Change in mental status.
- Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

CLINICAL RESULTS:

A multi-center equivalency[4] clinical trial of the INTER FIX™ Threaded Fusion Device was conducted in the United States comparing the anterior spinal use of the INTER FIX™ device filled with autogenous bone to femoral ring allograft filled with autogenous bone, the control, in the treatment of patients with symptomatic degenerative disc disease. Initially, the clinical trial had a prospective, randomized, controlled design. Subsequently, the investigational plan was revised to allow patients to be entered into a non-randomized arm, i.e., patients treated with INTER FIX™ device only.

Inclusion criteria for the clinical trial included symptomatic degenerative disc disease as noted by intractable leg and/or back pain with positive diagnostic imaging finding(s); spinal instability as defined by greater than 4 mm of translation or greater than 5° of angulation on flexion/extension radiographs; single level symptomatic involvement from L2-S1; and no greater than Grade 1 spondylolisthesis. Specifically excluded from the study were patients who: had a previous anterior interbody fusion procedure at the involved spinal level; had osteopenia, osteoporosis, or osteomalacia; or required bone growth stimulation.

A total of 181 patients were enrolled in the investigational INTER FIX™ device treatment group. Seventy-seven (77) patients were in the randomized INTER FIX™ device treatment arm and 104 patients were in the nonrandomized arm[5]. A total of 62 control patients were entered into the randomized arm of the clinical trial.

All patients involved in the clinical trial of the INTER FIX™ Threaded Fusion Device, regardless of treatment group, were enrolled under the same inclusion/exclusion criteria. To substantiate the comparability of the randomized INTER FIX™ device patients and the nonrandomized INTER FIX™ device patients, the demographic characteristics, preoperative medical conditions, diagnostic imaging findings characteristic of degenerative disc disease, operative approach, and the location of the lumbar treated level were examined. The population was statistically comparable except for operative approach, preoperative work status, and the preoperative diagnostic imaging findings of osteophyte formation of the vertebral endplates; scarring and/or thickening of the annulus fibrosis, ligamentum flavum, and/or facet joint capsule; and herniated nucleus pulposus. Further statistical analyses showed that these variables were not associated with differences in the 12 month clinical

[4] INTER FIX™ device statistically no worse than the control.
[5] Includes 3 patients who did not receive the INTER FIX™ device treatment due to surgical adverse events.

outcomes of fusion, Oswestry Pain/Disability improvement, neurological status, or overall success, with the exception of herniated nucleus pulposus. More patients in the nonrandomized group had a finding of herniated nucleus pulposus, which was found to increase the probability of overall success.

For this clinical trial, fusion was defined as the evidence of bridging trabecular bone, translation (≤3mm) and angular motion (<5°) stability, and no radiolucencies surrounding more than 50% of either implant. Also, patients having secondary surgeries due to nonunions were considered failed fusions in the calculations. Oswestry Pain/Disability success was defined as at least a 15 point improvement in the postoperative score as compared to the preoperative score. Neurological status success was defined as a maintenance or improvement in at least 3 of the 4 neurological categories (motion, sensory, reflexes, and straight leg raise) postoperative as compared to the preoperative condition. Overall success was based on a patient demonstrating fusion, Oswestry Pain/Disability success, and neurological status success, and no secondary surgical procedure classified as a "failure".

An "intent-to-treat" analysis was performed. For this analysis, secondary surgery failures, deaths, patients lost-to-follow-up, and missing observations due to other causes resulted in missing observations for the outcome variables and therefore were included in the denominators of the calculated rates, i.e., considered as "failures". By treating these patients as treatment failures, the clinical outcome rates in the intent-to-treat analysis were considerably lower than those in the actual observed clinical data. The following table (Table III) provides the results for the intent-to-treat analysis of INTER FIX™ device patients, but does not include the results of the control patients.

Table III: Intent-to-Treat Analysis for INTER FIX™ Devices – Deaths, Secondary Surgery Failures, Lost-to-Follow-up and Missing Observations Are Considered as Failures and Are Included in the Denominator of the Rates

	12 Month Rates Randomized	12 Month Rates Randomized and Nonrandomized	24 Month Rates Randomized
Fusion	75.3% (58/77)	67.3% (107/159)	85.1% (63/74)
Oswestry Pain/Disability Improvement Patients with at least 15 Point Improvement from Pre-Op	44.2% (34/77)	42.1% (67/159)	54.1% (40/74)
Neurological Status Maintenance or Improvement	85.7% (66/77)	78.6% (125/159)	85.1% (63/74)
Overall Success	36.4% (28/77)	34.0% (54/159)	50.0% (37/74)
Secondary Surgery Failures			
Nonunions[6]	2	2	2
Other[7]	1	8[8]	3
Deaths	0	0	0

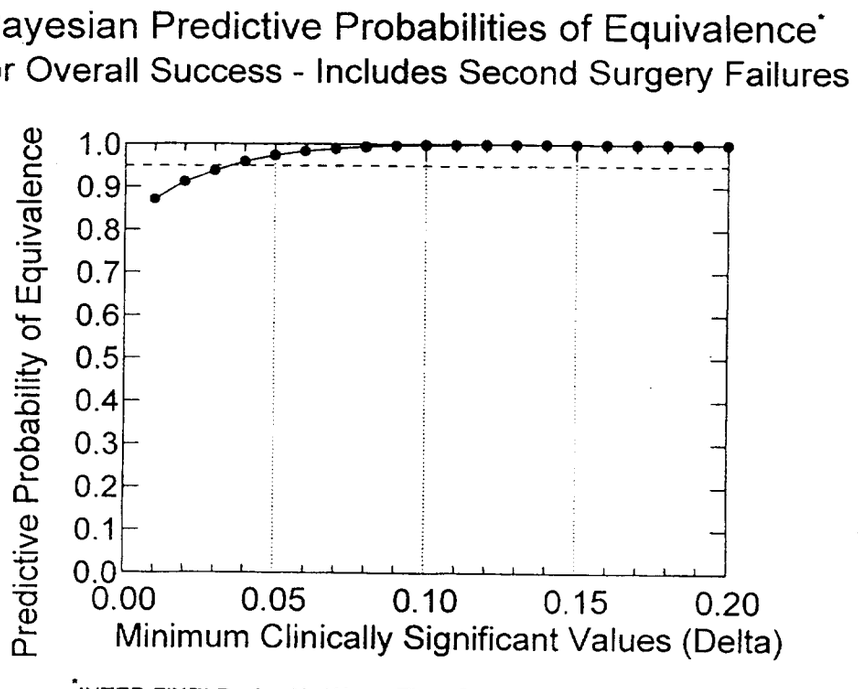
The success of this clinical trial was noted on the basis of an equivalence analysis between the INTER FIX™ device and control. The overall success results at 12 and 24 months postoperative from the randomized arm of the clinical trial can be found in Table IV.

[6] These patients are included in the fusion rate calculations but are otherwise considered as failures for clinical trial purposes.
[7] Patients due for follow up at that period who had secondary surgeries for reasons other than nonunions are considered failures for clinical trial purposes.
[8] Includes 3 patients who did not receive study treatments due to surgical events.

Table IV - Clinical Results from Patients with Available Data in the Randomized Arm[9]						
	12 Month Rates			24 Month Rates		
	INTER FIX™ Device N=77	Control N=60	Delta (Δ)	INTER FIX™ Device N=72	Control N=58	Delta (Δ)
Overall Success Accounting for Second Surgery Failures	46.7% (28/60)	28.6% (12/42)	0.01	55.2% (37/67)	37.8% (17/45)	0.01

There were approximately 100 INTER FIX™ device patients who were not yet due for their 24 month postoperative evaluations at the time of the data analyses. A Bayesian statistical analysis was performed to determine the possible impact of these patients on the conclusions. Bayesian techniques can determine the probability that for the next 100 patients, a certain number will have a successful outcome on each clinical parameter. Since this trial was designed to show that the INTER FIX™ device is statistically no worse than the control, the Bayesian analysis provides the probability that equivalence would be shown when all the outstanding INTER FIX™ device results are obtained. Figure 1 presents the results of the Bayesian analysis for overall success.

Figure 1



*INTER FIX™ Device No Worse Than Control

Note: Overall success rates were based on patients with available data and did not include deaths, loss-to-follow-ups, or missing observations.

[9] Patient numbers (N) represent the numbers of patients theoretically due for follow-up excluding patients that are due for follow-up which are classified as either cumulative deaths or patients lost-to-follow-up, but including patients who were evaluated prior to their anniversaries but still within the period window.

Predictive probabilities of equivalence were calculated for overall success rates for minimum clinically significant (delta) values ranging from 0.00 to 0.20. As shown in the figure above, the probability is greater than 0.95 (dashed line) that the INTER FIX™ Threaded Fusion Device results will still be statistically no worse than the control results for overall success using a delta value of 0.04. Based on these results, it is very unlikely that the outstanding 24 month patients will significantly impact the existing results.

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 Sofamor Danek.

CLEANING AND DECONTAMINATION:

If not supplied sterile, all implants and instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Used instruments must be decontaminated, cleaned, and sterilized before reuse.

Note: Do not use cleaning solutions containing bleach or formalin since they may damage the device.

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

STERILIZATION:

If not supplied sterile, the implants and instruments must be sterilized prior to use. Non-sterile implants and instruments are recommended to be steam sterilized by the hospital using one of the following process parameters:

NOTE: The following note applies to the process parameter identified with the ** below: For use of this product and instruments 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 onto contact with the central nervous system.

Method	Cycle	Temperature	Exposure Time
Steam	Gravity	250°F (121°C)	30 Min.
** Steam	Gravity	273°F (134°C)	18 Min.
Steam	Pre-Vacuum	270°F (132°C)	5 Min.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. No implant should be re-used once it comes into contact with human tissue or body fluid. Always immediately clean and re-sterilize components that have

been used in surgery. This process must be performed before handling or (if applicable) returning to Sofamor Danek.

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 quality, identification, durability, reliability, safety, effectiveness and/or performance of this product, should notify the distributor, Sofamor Danek. Further, if any of the implanted INTER FIX™ Threaded Fusion Device components ever "malfunction," (i.e., do not meet any of their performance specifications or otherwise do not perform as intended), or are suspected of doing so, the distributor should be notified immediately. If any 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 name and number, lot number, your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience.

DEVICE RETRIEVAL EFFORTS:

Should it be necessary to remove an INTER FIX™ Threaded Fusion Device, please call Sofamor Danek.

IN USA

Manager
Customer Service Division **Telephone:** 800-876-3133
Sofamor Danek USA 800-933-2635
1800 Pyramid Place or 901-396-3133
Memphis, Tennessee 38132 **Telefax:** 901-396-0356
USA or 901-332-3920

Supplied by
Sofamor Danek

IN EUROPE

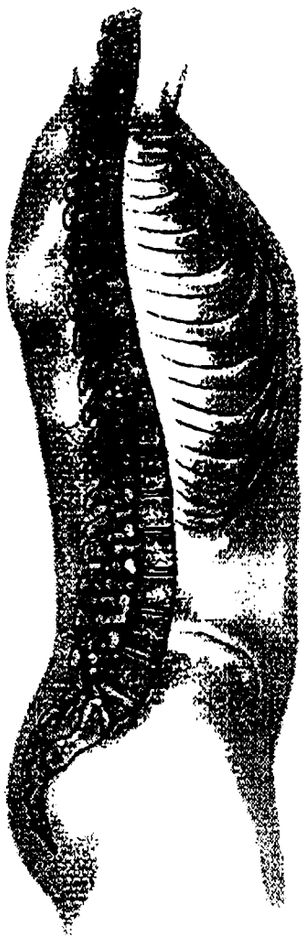
Customer Service **Telephone:** (33) 3 21.89.50.00
Telefax: (33) 3 21.89.50.09

Sofamor Danek
13 rue de la Perdrix
93290 TREMBLAY EN FRANCE

Sofamor, SNC au capital de 33418 000Fr
RCS Bobigny B 617 320 486

inter fix™

THREADED FUSION DEVICE



PATIENT INFORMATION BROCHURE

41

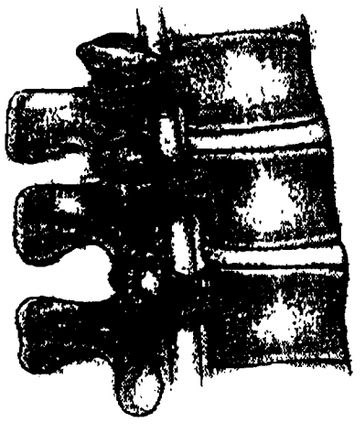
This Patient Guide is designed to help you make an informed decision about treatment for your back pain and related problems. Your doctor has proposed surgery to relieve your back discomfort using the INTER FIX™ Threaded Fusion Device. The purpose of this brochure is to give you some background about back surgery and this medical device system.

Some common causes of back problems are disc injury (e.g., herniation or rupture) and degenerative discs. Disc degeneration affects about 12 million people in the U.S., of which most are within the ages of 20 to 65.

Persistent pain in your low back and/or legs caused by spinal disc problems can be frustrating because it limits your ability to move and do the things you enjoy. To manage your low back (lumbar) problem, you may have followed your doctor's non-operative treatment plan—rest, medication, physical therapy, and exercise. But, despite your best efforts, the pain won't go away. Surgery may help relieve your pain by treating your disc problem.

Your Lower Back

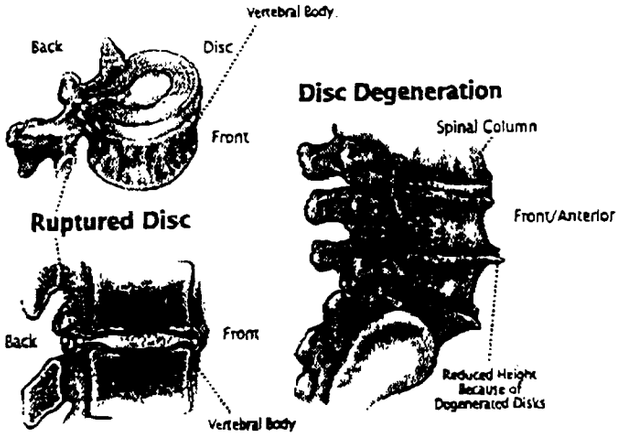
The bony vertebrae, which encircle and protect your spinal cord, are separated by shock-absorbing discs. The discs give your spine the flexibility to move. Nerves branching from the spinal cord pass through openings in the vertebrae to other parts of your body. Several of these nerves join at the base of the spine to form the sciatic nerve, which runs down your leg. As discs lose their water content because of disease or age, they lose their height, bringing the vertebrae closer together. The consequence is a weakening of the shock absorption properties of the disc and a narrowing of the nerve openings in the sides of the spine that pinch your nerves. Disc degeneration may cause back and/or leg pain. Each disc has a spongy center (nucleus) surrounded by tough outer rings. Wear and tear, poor posture and incorrect body movements can weaken the disc.



Disc Problems

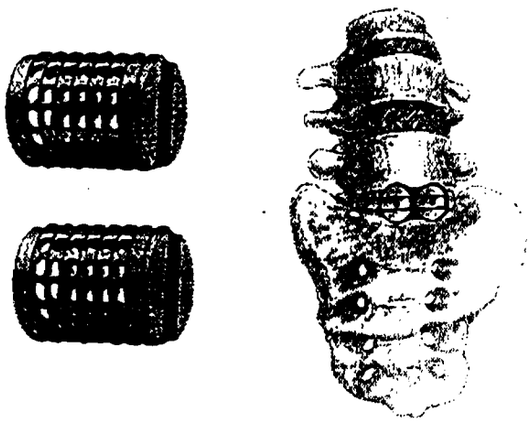
Pressure On The Nerve

The INTER FIX™ Threaded Fusion Device was designed to aid in the treatment for disc disorders.



Surgical Intervention

The INTER FIX™ Threaded Fusion Device is a small, hollow, threaded metal cylinder that is intended to restore the degenerated disc space to its original height, thereby relieving the pressure on your nerves. Two implants are to be used.



During your surgery, your doctor will remove portions of the degenerated disc and vertebral body to allow the implants to be inserted. Bone will then be taken from your hip or from the area in which the implants will be inserted and packed inside the hollow implants. Although this treatment may help relieve your pain, spinal surgery is not without risks. Please consult your doctor about the rates and types of possible complications related to treatment with the INTER FIX™ Threaded Fusion Device.

After Surgery

Ask your doctor about your specific recovery plan following surgery. It is important to follow your doctor's instructions carefully to recover from surgery as quickly as possible and increase your chances of a successful outcome.

Recovering from back pain and surgery is an ongoing process. How fast you recover depends on the type of surgery you had, your commitment to working closely with your physical therapist, and moving and exercising correctly, as recommended by your surgeon.

Physical Therapy

After surgery, your surgeon may refer you to a physical therapist who will teach you exercises to improve your strength and increase your mobility. The goal of physical therapy is to help you become active as soon as possible, using safe body movements that protect your back.

Your Role In Recovery

The ongoing health of your back really depends on you. It's up to you to follow your surgeon's recommendations, such as seeing your physical therapist regularly. Remember to move and exercise properly as you return to a more active lifestyle.

Good body mechanics keep your spine well-aligned and reduce pain, but maintaining a safe, balanced position may require some changes in how you go about daily activities. For instance, you may need to learn different ways of standing, sitting, or lifting to avoid reinjuring your back.

Exercise Regularly

Your recovery plan prescribed by your doctor may include back and stomach exercises, such as sit-ups, to strengthen muscles that help support your back. Done regularly, under your doctor's supervision, these exercises can help you build the strong, flexible muscles you need to protect your back.

Follow-up Care

You and your surgeon will continue to work together during your recovery. Before you leave the hospital, your surgeon may schedule follow-up visits with you so that he or she can evaluate your progress, advise you about your activity level, and adjust any medication, if necessary. Sometimes your doctor may recommend follow-up tests to make sure you are healing properly.

Possible Outcomes and Complications

Consult your physician for expected treatment results for your situation. He or she will have the clinical results from prior use of the device and be in a position to relate the results to your particular case.

Furthermore, spinal surgery is not without risk. A variety of complications, some of which may be severe, may occur affecting your outcome, and the results achieved in a clinical trial may not be the same as in the population at large.

Specific information on the rates and types of complications for the INTER FIX™ Threaded Fusion Device and spinal surgery can be discussed with your doctor.

Comments

This patient guide is made possible through cooperation between your physician and Sofamor Danek.

While this brochure has hopefully provided you with the information you need to make an informed decision about your treatment options, it is not intended to replace professional medical care or provide medical advice.

If you have any questions or need additional information about the INTER FIX™ Threaded Fusion Device, please call or see your doctor, who is the only one qualified to diagnose and treat your back.