#150-039

LUMBAR I/F CAGE® WITH VSP® SPINE SYSTEM

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) who has appropriate training or experience.

DEVICE DESCRIPTION

The Lumbar I/F Cage with VSP Spine System is a multi-component device which includes the Lumbar I/F Cage, AcroMed Pedicle Screws, VSP spine plates, VSP washers and VSP transverse connectors (see **How Supplied – Components Available** for a complete description of component sizes, etc.).

The Lumbar I/F Cage component is made of a polymer/carbon fiber composite material and is supplied as either sterile or non-sterile. The I/F Cage is radiolucent.

The VSP Spine System components are manufactured from various grades of stainless steel (see **Conformance to Standards** for detailed information) and include the following:

The AcroMed Pedicle Screws are composed of two parts: a long cancellous section with an integral fixed lower nut, and a machine threaded section topped with a hexagonal drive head. The AcroMed pedicle screws are adjoined to spinal plates utilizing two locking nuts.

The VSP plates have nested slots and are available in a variety of lengths.

Washers are available and have a chamfered inner hole for proper fit over the integral nut.

The VSP transverse connector is intended to connect to VSP plates. The transverse connector construct is composed of two connectors and a 3/16 inch transverse rod.

INDICATIONS

The Lumbar I/F Cage with VSP Spine System is indicated for an open posterior approach using autogenous bone graft in patients with degenerative disc disease (DDD) at one or two spinal levels from L2-S1 whose condition requires the use of interbody fusion combined with posterolateral fusion (360° fusion) and posterior pedicle screw fixation. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

CONTRAINDICATIONS

The Lumbar I/F Cage with VSP Spine System should not be implanted in patients with active systemic infection or infection localized to the site of implantation.

WARNINGS

- When more than two involved spinal levels are treated, longer operative times and higher blood loss are likely to occur.
- As the number of previous surgeries at the involved spinal level(s) increases, the potential for intra-operative dural tears increases.
- Do not use the Lumbar I/F Cage with VSP Spine System with any other device components. There are no data to support the use of the Lumbar I/F Cage with any other pedicle screw fixation device system other than the VSP Spine System.

PRECAUTIONS

Forty patients (40/92 = 43%) required a subsequent intervention (surgical or otherwise) prior to their 24 month follow-up evaluation.

The probability of a patient having a successful outcome and not needing a subsequent intervention (surgical or otherwise) was 43% (95% confidence interval = 33, 53).

- Use of the Lumbar I/F Cage with VSP Spine System should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics; has had experience with PLIF procedures and pedicle screw spinal system fixation; and has had hands-on training in the use of this device.
- Two Lumbar I/F Cages should be implanted at each surgical level. Safety and effectiveness have not been established for the use of a single Lumbar I/F Cage component in conjunction with the VSP Spine System components.
- Safety and effectiveness have not been established for the use of the Lumbar I/F Cage component without the use of the VSP Spine System component.
- The Lumbar I/F Cage with VSP Spine System should not be implanted in patients with severe osteoporosis or osteopenia.
- Safety and effectiveness have not been established in patients who did not receive an interbody fusion in conjunction with a posterolateral fusion (360° fusion).
- Safety and effectiveness have not been established in patients with the following conditions: three or more levels to be fused; morbid obesity; or pregnancy.
- The VSP Spine System components are supplied clean and non-sterile and must be sterilized before use according to the complete sterilization instructions below.
- The Lumbar I/F Cage component may be supplied either sterile or non-sterile. When provided non-sterile, it must be sterilized before use according to the complete sterilization instructions below. When supplied sterile, it should be handled with appropriate precautions to maintain sterility.
- Implant components can break when subjected to the increased loading associated with delayed union or nonunion.

ADVERSE EVENTS

The following complications were reported during a multi-center clinical study of 221 patients treated with the Lumbar I/F Cage with VSP Spine System for the approved indication listed above, as well as other indications.

Complication	Observation 3 mo % (n) (n=221)	6 mo % (n) (n=219)	12 mo % (n) (n=215)	18 mo % (n) (n=215)	24 mo % (n) (n=213)	30 mo % (n) (n=186)	36 mo % (n) (n=92)	Overall % (n) (n=221)
Arrhythmia	0.5 (1)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.5 (1)
Broken Cage	0.5 (1)	0.5 (1)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.9 (2)
Broken Pedicle	1.8 (4)	0.0 (0)	0.5 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (0)	2.3 (5)
Broken screw	0.0 (0)	0.0 (0)	0.0 (0)	1.4 (3)	1.9 (4)	3.8 (7)	1.0	6.3 (14)
Cage displacement	0.5 (1)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.5 (1)
Cardiac[α]	0.0 (0)	1.4 (3)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	1.4 (3)
Death	0.0 (0)	0.9[β] (2)	0.5 (1)	0.0 (0)	0.9 (2)	0.9 (2)	0.0 (0)	3.2 (7)
DIC	0.5 (1)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.5 (1)
Dural tears								
•"incidental" tears[δ]	16.3 (36)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.5[ε] (1)	0.0 (0)	16.7 (37)
•tears requiring post-operative treatment	0.9 (2)	1.8 (4)	0.5 (1)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	3.2 (7)
DVT	0.0 (0)	0.5 (1)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.5 (1)
Embolus	0.0 (0)	0.9 (2)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.9 (2)
Foot drop	0.0 (0)	0.9 (2)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.9 (2)
Ileus	0.0 (0)	0.5 (1)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.5 (1)
Loose screw(s)	0.0 (0)	0.0 (0)	0.0 (0)	0.5 (1)	0.9 (2)	2.2 (4)	0.0 (0)	2.7 (6)

Migrating screw(s)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.9 (2)	0.0 (0)	0.0 (0)	0.9 (2)
Nerve damage	0.5 (1)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.5 (1)
Pneumonia	0.0 (0)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (0)	0.0 (0)	0.0 (0)	0.5 (1)
Psychosocial	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.5 (1)	0.5 (1)	0.0 (0)	0.9 (2)
RSD	0.0 (0)	0.5 (1)	0.5 (1)	0.0 (0)	0.5 (1)	0.0 (0)	0.0 (0)	1.4 (3)
Seroma	0.0 (0)	1.4 (3)	0.9 (2)	0.5 (1)	0.0 (0)	0.5 (1)	0.0 (0)	3.2 (7)
Urinary frequency	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.5 (1)
UTI	0.0 (0)	2.7 (6)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)	2.7 (6)
Wound infection	0.5 (1)	4.1 (9)	0.9 (2)	0.0 (0)	0.5 (1)	1.1 (2)	0.0 (0)	6.3 (14)

[α]"Cardiac" includes a patient with atrial fibrillation and flutter, a patient who had myocardial infarction that required coronary bypass surgery and a patient with post-operative hypertension. All patients recovered during the post-operative period.

[β]One of these deaths occurred immediately post-operatively as a result of an intra-operative vascular injury with concomitant large blood loss.

[δ]This category describes dural tears which occurred during the index surgery, were repaired during that procedure and had no clinical sequelae.

[ε]This patient experienced a dural tear during surgery to remove the VSP Spine System components at 24 months.

A revision is a procedure which adjusts or in any way modifies the original implant configuration, *e.g.*, adjusting the position of the original configuration, removal of components with their subsequent replacement. A removal is a procedure which removes one or more components of the original implant configuration without replacement of any components. A reoperation is a procedure which involves any surgical procedure at the involved spinal level(s) which does not remove, modify or add any components. The following table describes the time course distribution of revisions, removals and reoperations for the entire population:

[illegible]								
Revision	0.0 (0)	0.0 (0)	0.0 (0)	0.5 (1)	0.9 (2)	3.2 (6)	1.0 (1)	4.1 (9)
Removal of VSP	0.0 (0)	0.0 (0)	0.0 (0)	1.4 (3)	8.0 (17)	28.0 (52)	10.1 (10)	35.7 (79)
Reoperation	0.0 (0)	4.6 (10)	0.9 (2)	0.5 (1)	0.9 (2)	2.7 (5)	0.0 (0)	8.1 (18)

There were a total of 123 subsequent interventions in the 221 patients that received the Lumbar I/F Cage with VSP Spine System. 60 patients treated for DDD had some form of subsequent intervention. These interventions included, but were not limited to, removal of broken drains, removal of VSP Spine System components, treatment of infections, augmentation of bone graft and epidural/nerve root injections. They are described in the table below.

[illegible]	Number of incidences	
	[illegible]	[illegible]
Aspiration of fluid	0.0 (0)	0.5 (1)
Bursitis/seromas over hardware	0.9 (1)	0.5 (1)
Coronary bypass surgery	0.0 (0)	0.5 (1)
Debridement deep infection	2.7 (3)	3.2 (7)
Donor site deep infection	0.9 (1)	0.5 (1)
Excision of lipomas overlying spine	0.9 (1)	0.5 (1)
Morphine pump implantation	0.0 (0)	0.5 (1)
Nerve root sleeve or steroid injection, sympathetic/caudal block	2.7 (3)	2.7 (6)
New pathology	1.8 (2)	2.7 (6)
Removal of broken drain	1.8 (2)	1.4 (3)
Repair of dural tear	3.6 (4)	2.7 (6)
Removal of broken hardware[κ]	2.7 (3)	2.7 (6)
Removal of hardware	17.3 (19)	16.3 (36)
Removal of hardware after trauma	0.0 (0)	0.5 (1)
Removal of loose hardware	2.7 (3)	1.8 (4)
Removal of painful hardware	14.5 (16)	14.9 (33)
Replacing hardware with new hardware	1.8 (2)	4.1 (9)

[α]One patient required a coronary bypass operation that was not related to implantation of the Lumbar I/F Cage with VSP Spine System.

[β]Some patients experienced more than one intervention.

[π]The word "hardware" refers to the VSP Spine System components.

The following table contains the averages and ranges (in parentheses) of blood loss and operative time for the Lumbar I/F Cage with VSP Spine System. Values for the Lumbar I/F Cage with VSP Spine System are reported as those for the total population studied and those for the approved indication of DDD. As noted by the upper end of the ranges from the IDE population, some patients had large amounts of blood loss. Because a definition for a "normal" amount of blood loss is not available, ranges from the literature are provided for comparison.

	IDE population (Ave. (range))		Literature range	
	DDD (n = 110)	all indications (n = 220)	randomized	non-randomized
Blood loss (ml)	1489 (100 – 8200)	1463 (100 – 18,000)	355 - 2760	421 – 1155
Operative time (minutes)	287.5 (175 - 520)	288.5 (120 - 607)	155 - 342	127 - 305

N.B. Although the average values listed above for the DDD patients were often similar to or higher than those for the population as a whole, it should be noted that the width and upper ends of the ranges for the DDD patients were smaller.

Seven patients from the total population who received the Lumbar I/F Cage with VSP Spine System died during the course of the clinical trial. One of the deaths occurred immediately post-operatively. Two of the deaths occurred peri-operatively. None of the deaths were device-related.

The following potential adverse events (singly or in combination) which might be expected to occur, but were not observed in the clinical trial, could also result from the implantation of the Lumbar I/F Cage with VSP Spine System:

1. Bursitis.
2. Decrease in bone density due to stress shielding.
3. Degenerative changes or instability of segments adjacent to fused vertebral levels
4. Fracture of bony structures.
5. Implant material sensitivity, or allergic reaction to a foreign body.
6. Infection, early or late.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
8. Nonunion, delayed union.
9. Discomfort, or abnormal sensations due to the presence of the device.
10. Paralysis.
11. Spinal cord impingement or damage.
12. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late post-operative period.

CLINICAL STUDIES

Clinical data to support the safety and effectiveness of the Lumbar I/F Cage with VSP Spine System were collected as part of an FDA-approved investigational device exemptions (IDE) clinical trial. The original IDE consisted of 4 study arms that were either prospective and randomized (2 arms) or prospective and non-randomized (2 arms). Patient enrollment as proposed in the original IDE

was never completed. The data from the prospective randomized study group and from the two prospective non-randomized study groups regarding DDD patients were sufficient to evaluate the safety and effectiveness of the device.

The inclusion criteria for the DDD population were as follows: males and females between the ages of 18 and 89 with persistent back and/or leg pain refractory to 6 weeks of non-surgical therapy; a diagnosis of DDD at one, two, three or four levels of the lumbar spine; degenerative changes or herniation of the disc at the affected level(s) with or without instability as confirmed by appropriate imaging studies. Patients were allowed to have had one or more previous non-fusion surgeries at the involved spinal level(s), depending on their original study arm. The exclusion criteria included significant osteoporosis or metabolic bone disease; past or present infection in the disc or the spine; tumor; spondyloptosis; past or present illicit drug abuse and current alcohol abuse; and clinically significant abnormalities at more than three levels.

Because of an inadequate number of prospective, randomized control patients, historical literature, as originally approved for the non-randomized arms, was used as the control population. Control articles that more closely matched the IDE protocol and PMA patient population, evaluation criteria and timepoints were selected.

All patients were treated with the Lumbar I/F Cage with VSP Spinal System. The Lumbar I/F Cage component was filled with autologous cancellous bone. Post-operative care included use of external immobilization for the first month; avoidance of bending, lifting, stooping and twisting for the first 3 months; and avoidance of heavy lifting for the first 6 months.

Patients were evaluated pre-operatively and at 1, 3, 6, 12 and 24 months post-operatively. Evaluations were also made biennially after the 24 month follow-up evaluation. Complications and adverse events, device-related or not, were evaluated over the course of the clinical trial. At each evaluation timepoint, fusion status, pain, function and neurological status were evaluated. Success was determined from data collected during the 24 month follow-up evaluation.

An analysis was performed to assess the ability to pool data across investigational sites, between the indications originally used to describe the DDD patients in the various arms and across the number of levels treated. The pre-operative evaluations, 24 month follow-up evaluations and demographic data were utilized. While some statistically significant differences were identified, these were determined to not be clinically significant.

A multivariable analysis of the safety data demonstrated that certain events could be attributed to identifiable factors:

1. **Blood loss** was higher in patients who had more spinal levels treated. This parameter was also investigator-dependent.
2. **Operative time**, as expected, increased as more spinal levels were treated. This parameter was also investigator-dependent.
3. **Dural tear rate** was dependent on the number of previous spinal surgeries at the involved levels.
4. **Removal of the VSP Spine System component** was higher for smokers (although the clinical significance of this correlation is not known). While not statistically significant ($p < 0.1$), there was a trend that this parameter was investigator-dependent.

Fusion was evaluated using plain radiographs (standing views only, flexion/extension views were not taken) and assessed by a seven point descriptive rating scale. Ratings of 1-4 were various descriptions of pseudarthrosis. A rating of 5 was used to describe "bone bridging fusion area"; a rating of 6 was used to describe "increased density of fusion bone" and a rating of 7 was used to describe "continuous trabecular bone bridging fusion". A fusion rating of 6 or 7 was considered a success.

Pain was assessed with a five point scale, ranging from 1 describing "excruciating and unbearable pain" to 5 describing "no pain". Pain was measured separately for back, right leg, left leg, graft donor site and overall. Overall pain was used in determining success. An improvement of at least one level between the pre-operative and 24 month follow-up evaluation was considered a success.

Function was measured on a five point scale ranging from 1 describing "total incapacity" to 5 describing "able to do all social and recreational activities including sports, without pain". All patients who maintained their function or improved it by at least one point between the pre-operative and 24 month follow-up evaluation were considered to be a success.

The evaluation of neurological status in the clinical trial was determined during a physical examination consisting of assessments of reflexes, sensation, straight leg raises and muscle strength. The neurological status analysis presented below is based only on the evaluation of muscle strength. Muscle strength was evaluated bilaterally for ten muscle groups in the hips, legs and feet. Each muscle group was rated using a 6 point scale ranging from 0 describing "no movement" to 5 describing "normal power". All patients who maintained their muscle strength or improved it by at least one point between the pre-operative and 24 month follow-up evaluation were considered to be a success.

To be considered an overall success for the clinical trial, a patient must have met each of the following six criteria:

1. interbody fusion of the I/F Cage treated level(s);
2. improvement in pain;
3. maintenance or improvement in function;
4. maintenance or improvement in muscle strength;
5. no serious or permanent complication; and
6. no revision at the I/F Cage treated level(s).

Success rates for the individual outcome parameters and the overall success were analyzed two ways. The first analysis utilized only the available data from patients who had returned for their 24 month follow-up evaluation (92 patients out of the total DDD population of 110 patients). The second analysis utilized an intent-to-treat evaluation which assumes that all patients who were lost-to-follow-up at the 24 month evaluation are failures. The 7 DDD patients who died during the course of the clinical trial are not counted in the denominator as part of this type of analysis. This resulted in an expected 24 month DDD patient population of 103 patients.

	Available data		Intent-to-treat		Literature controls
Parameter	n	% (CI)	n	% (CI)	% (CI)
fusion[χ]	82/91	90 (84, 96)	82/103	80 (72, 87)	84 (81, 87)
pain	81/92	88 (81, 95)	81/103	79 (71, 87)	76 (63, 87)
function	89/92	97 (93, 100)	89/103	86 (80, 93)	93 (77, 99)
muscle strength	85/92	92 (87, 98)	85/103	83 (75, 90)	98 (92, 100)
overall success	67/91	74 (65, 83)	67/103	65 (56, 75)	59 (49, 69)

[α]One patient did not have radiographic data at the 24 month follow-up evaluation, but had all other information.
[β]CI = 95% confidence interval
[π]Success rate provided for literature controls is a weighted average of values presented in articles. The weighting factor was the number of patients reported in each article.
[χ]The fusion success rates are based on assessments of only the interbody fusion mass.

A longitudinal analysis demonstrated that patients with worse pain and function preoperatively had a better chance of clinical success postoperatively.

INFORMATION FOR PRESCRIBERS

- Correct selection of the appropriate implant size is extremely important.
- Mixing metals can cause corrosion and may lead to device failure. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion can accelerate fatigue fracture of implants. The amount of metal compounds released into the body system could also increase.
- Contouring of metal implant components should be done only with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses that may become the focal point for breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.
- Excessive loads, such as excessive torque applied to long-handle insertion tools attached to threaded insertion holes or direct application of loads to the threads or a small area of the Lumbar I/F Cage component, can split or fracture the cage implants. Split or fractured cages should be removed and replaced.
- Post-operative care should include external immobilization (such as a TLSO brace), which is recommended for the first month. Patients should be asked to avoid bending, lifting, stooping, or twisting for at least 3 months, and to avoid heavy activity for 6 months.
- Surgical implants must never be reused or reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
- Once the fusion has healed, the surgeon and patient should carefully weigh the risks and benefits if considering to remove the VSP Spine System components.

DEVICE RETRIEVAL EFFORTS

Should it be necessary to remove a Lumbar I/F Cage, please call DePuy AcroMed at the number below to receive instructions regarding data collection, including histopathological, mechanical and adverse event information.

HOW SUPPLIED

1. STERILIZATION

VSP Spine System components:
VSP Spine System components are supplied clean and not sterile. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components.

Laboratory testing was conducted to develop the following RECOMMENDATIONS FOR STEAM STERILIZATION:

Cycle:	Vacuum
Temperature:	270° F (132° C)
Exposure time:	6 min.

Lumbar I/F Cage component:
Lumbar I/F Cage components are supplied non-sterile and sterile:

NON-STERILE
Laboratory testing was conducted to develop the following RECOMMENDATIONS FOR STEAM STERILIZATION:

Cycle:	Vacuum
Temperature:	270° F (132° C)
Exposure time:	6 min.

STERILE
The sterile Lumbar I/F Cage component has been sterilized by exposure to gamma irradiation. Packaging material should be inspected for damage prior to use. If the seal of either the inner or outer cavity is broken, or if the cavities are otherwise damaged, the product must be assumed to be non-sterile. In the event of damage to the sterile packaging or inadvertent contamination, the Lumbar I/F Cage component may not be resterilized and should not be used.

2. COMPONENTS AVAILABLE

Lumbar I/F Cage component:
The Lumbar I/F Cage is available in three lengths, 21mm, 23mm and 25mm. The 21mm length I/F Cage is available in 2 sizes (width x height): 9mm x 9mm and 9mm x 11mm. The 23mm length I/F Cage is available in 2 sizes: 11mm x 11mm and 11mm x 13mm. The 25mm length I/F Cage is available in 9 sizes: 9mm x 9mm, 9mm x 11mm, 9mm x 13mm, 11mm x 11mm, 11mm x 13mm, 13mm x 13mm, 13mm x 15mm, 15mm x 15mm, 15mm x 17mm.

VSP Spine System components:

AcroMed Pedicle Screws:
The AcroMed Pedicle Screws are available in the following diameters: 5.5mm, 6.25mm, 7.0mm and 7.75mm, and available in cancellous thread lengths in 5mm increments from 25mm to 70mm.

VSP Spinal Plates:
The plates have between one to four slots (41mm to 159mm length) with their length increasing by half slot increments.

VSP Washers:
Washers are available in tapered, 3mm and 5mm heights.

VSP Transverse Connector:
The connector is composed of one left and one right connector and a 3/16 inch transverse rod.

CONFORMANCE TO STANDARDS

The material used in the fabrication of the following device components are in accordance with ASTM material specifications as cited below:

- The AcroMed Pedicle Screws are fabricated from stainless steel alloy conforming to ASTM F-1314.
- The VSP Spine Plates are fabricated from implant grade stainless steel alloy conforming to ASTM F-138 specifications.
- All VSP washers are manufactured from stainless steel alloy conforming to ASTM F-138 or F-1314 specifications.
- The VSP transverse connectors are fabricated from implant grade stainless steel alloy conforming to ASTM F-138 specifications.

Limited Warranty And Disclaimer: DePuy AcroMed products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

IF MORE THAN THREE YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION AND THE DATE OF CONSULTATION, CONTACT DEPUY ACROMED FOR CURRENT INFORMATION AT 800-365-6633 or 1-216-431-9900.

REVISED: FEBRUARY, 1999.
DEPUY ACROMED, INC.
3303 CARNEGIE AVENUE,
CLEVELAND, OH 44115

Authorized European Representative:
AcroMed b.v., Seinhuiswachter 12, 3034 KH Rotterdam, PO Box 3183, 3003 AD Rotterdam
The Netherlands

DePuy AcroMed, Inc.'s Lumbar I/F Cage® with VSP® Spine System Patient Information Brochure

Introduction

Your surgeon has provided you with this patient information brochure to help you make an informed decision on your back surgery using DePuy AcroMed's Lumbar I/F Cage with VSP Spinal System. Your surgeon has decided that you need spine surgery after carefully examining you, reviewing your history and x-rays and taking into account the results of other diagnostic studies.

Description

DePuy AcroMed's Lumbar I/F Cage with VSP Spine System is a medical device consisting of two components. The Lumbar I/F Cage component is made from a carbon fiber/polymer composite. The VSP Spine System component is made from stainless steel. These materials usually do not harm the human body.

Lumbar I/F Cage component is rectangular with "teeth-like" ridges on the top and bottom (see Figure 1). It is hollow and will be filled with bone graft, usually bone taken from your hip.

The VSP Spine System component is a pedicle screw fixation device. It consists of plates, screws, washers, nuts and connectors (see Figure 2).

Figure 1 - Lumbar I/F Cage Implant

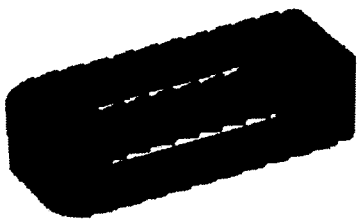
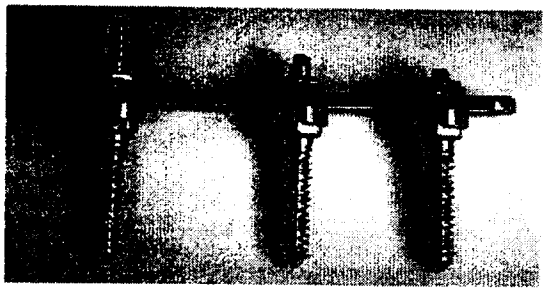


Figure 2 - VSP Spine System Implants

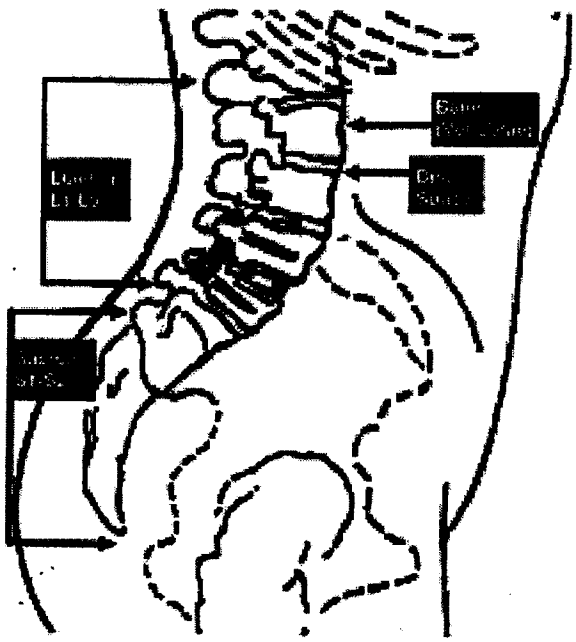


Benefits

Your spine is a column of bones (vertebrae) in your back. Soft discs between each bone allow your back to move and bend (see Figure 3). Doctors number the bones L1, L2, L3, L4, and L5 in the lower back (lumbar spine), and S1 and S2 in the sacrum.

When the discs wear out or are injured, they cannot function normally and may cause pain or limit your daily activities. This can produce a condition that is called Degenerative Disc Disease or DDD (see Figure 3).

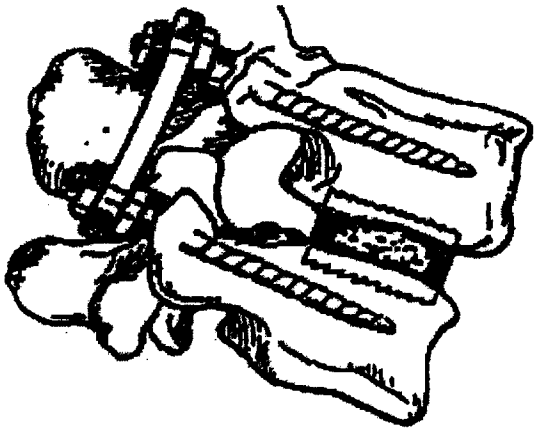
Figure 3 - Treatment of DDD with DePuy AcroMed's Lumbar I/F Cage with VSP Spine System.



Surgery may sometimes help to reduce this pain and restore activity. The fusion surgery you are considering uses VSP Spine System components (screws and plates) designed to hold the bones securely and Lumbar I/F Cage components to help support your weight in place of your worn out disc (see Figure 4). Bone graft placed

inside the Lumbar I/F Cage components and along the back of the vertebrae then help to create a solid bony bridge across the disc space, connecting the two vertebrae.

Figure 4 - DePuy AcroMed's VSP Spine System components are designed to hold the bones securely, while Lumbar I/F Cage components help to support your weight in place of your worn out disc and hold the graft material in its proper position



Indication for Use

DePuy AcroMed's Lumbar I/F Cage with VSP Spine System is indicated for the treatment of DDD at one or two spinal levels from L2-S1 in patients who require 360° fusion and pedicle screw fixation These people may also have had a previous non-fusion spinal surgery at the level(s) to be treated with this device. DDD is defined as a disc that has deteriorated and causes back pain. The disc deterioration is confirmed by history and x-ray studies. A 360° fusion consists of bone placed between the vertebrae and along the back of the vertebrae.

Contraindications

DePuy AcroMed's Lumbar I/F Cage with VSP Spine System should not be used if you have either an infection throughout your body or localized to your spine

Warnings and Precautions

You should not receive the Lumbar I/F Cage with VSP Spine System if you have poor bone quality (osteoporosis or osteopenia). Your occupation or activity levels, smoking or tobacco use, your weight, the condition of other levels of your spine, whether or not you are pregnant, and any allergies you have may influence whether you should have surgery with the DePuy AcroMed Lumbar I/F Cage with VSP Spine System. If any of these factors apply to you, please discuss them with your doctor.

Surgery

When undergoing surgery with DePuy AcroMed's Lumbar I/F Cage with VSP Spine System, most or all of the disc will be removed. Bone graft, taken from your hip area, will be placed inside and between the Lumbar I/F Cage components. Bone graft will also be placed along the back of the vertebrae.

Your surgeon will operate on your back to implant two Lumbar I/F Cage components side by side in your disc space. The VSP Spine System components are implanted in the vertebrae above and below this disc space and then connected to stabilize the spine and promote a fusion.

There are alternative treatments to this surgery. You should discuss these other possibilities with your surgeon before you make your decision.

After Surgery

After your surgery with DePuy AcroMed's Lumbar I/F Cage with VSP Spine System, it is important that you follow your surgeon's instructions for recovery.

In most cases, immediately after surgery, your heart and lung function will continue to be monitored, a drainage tube will have been left in your wound and your doctor will prescribe medicines to control pain and nausea. The average hospital stay for spinal fusion surgery patients in the study used to evaluate DePuy AcroMed's Lumbar I/F Cage with VSP Spine System was 5 to 7 days.

A nurse will show you how to care for your wound before you are sent home and your doctor will discuss a program to gradually increase your activity. It is likely that most patients will be asked to wear a back brace for at least 1 month after surgery.

Contact your doctor immediately if you get a fever, if the wound starts leaking fluids, if you have trouble swallowing or breathing, if you have trouble urinating, or if you have new or increased back or leg pain or numbness.

Your doctor will schedule office visits to check on how you are doing and see if anything else needs to be done. You may need a second surgery later on to remove the VSP Spine System components. The Lumbar I/F Cages almost never removed.

Possible Complications

As with any surgery, there are possible complications related to use of the Lumbar I/F Cage with VSP Spine System. Complications can occur singly or in combination, and may include:

- allergic reaction to the implant materials;
- bleeding, which may require a blood transfusion;
- bone graft shifting or failure to fuse;
- damage to nearby tissues;
- death;
- implants that bend, break, loosen or move;
- infection;
- pain or discomfort;
- paralysis;
- side effects from anesthesia;
- spinal cord or nerve damage;
- subsequent surgical intervention;
- tears of the dura (a layer of tissue covering the spinal cord); or
- vascular problems other than bleeding.

Clinical Results

A number of U.S. hospitals have participated in a clinical study involving DePuy AcroMed's Lumbar I/F Cage with VSP Spine System. A total of 247 patients were included in the study. 110 of these patients were treated for DDD similar to yours.

The following chart indicates the success rates 24 months after surgery for study patients undergoing surgery for the treatment of DDD with DePuy AcroMed's Lumbar I/F Cage with VSP Spine System compared to a group of control patients undergoing alternate spinal fusion treatments that were reported in the medical literature:

Parameter	DePuy AcroMed devices	Literature control patients
spinal fusion	90%	84%
pain improvement	88%	76%
function maintenance or improvement	97%	93%
muscle strength maintenance or improvement	92%	98%
overall success	74%	59%

Based on the findings of this clinical study, about ½ of patients who received this device had another surgery or invasive treatment afterward. If surgery was required, it generally involved removal of the VSP Spine System components. The probability of having a successful outcome without the need for having a subsequent intervention (surgical or otherwise) was 43%.

Of course, patients differ and no one can predict or guarantee the results of your surgery. Your doctor may have clinical experiences different from, or similar to, the findings listed above. Write down your questions and discuss them with your doctor before making your decision to have surgery with DePuy AcroMed's Lumbar I/F Cage with VSP Spine System. If you have questions on this patient education brochure, please contact DePuy AcroMed at 1-800-365-6633 or 1-216-431-9900.

DePuy AcroMed™
3303 Carnegie Avenue
Cleveland, Ohio 44115

February, 199