



Ardis™

Interbody System

*Surgical Technique*



Delivering enhanced  
interbody design.

On the nose.

**Expertise at your side.**

 **Abbott**  
A Promise for Life



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# Introduction

The easily inserted Ardis interbody system facilitates an efficient, reproducible fusion procedure with a self-distracting nose, convex geometry and versatile range of size offerings. This unique interbody system is part of Abbott Spine's Minimally Invasive Surgery (MIS) portfolio and is designed to provide surgeons with new-found levels of precision and control. Ardis comes complete with best-in-class instrumentation and is backed by the training, service and expertise that surgeons have come to expect from Abbott Spine.

Customized to fit your needs. And your patient's anatomy.

- Self-distracting design
- Easy, controlled positioning
- Unsurpassed versatility
- Low profile, glare resistant instrumentation
- Compatible with both MIS and open surgical methods

A complete MIS solution.

Ardis is part of Abbott Spine's industry-leading MIS portfolio. Minimally invasive procedures deliver less operative trauma to the patient when compared to open procedures. The benefits of this approach can include less pain and scarring, reduced operating time, accelerated patient recovery and minimized hospital stays.

Abbott Spine offers a complete MIS solution with best-in-class devices for disc preparation, access and fixation. Ardis can work in conjunction with the following MIS products:

- PathFinder® Minimally Invasive Pedicle Screw System
- Harmony™ Posterior Instruments
- Harmony Retractor
- Harmony Port System



Compatible with Harmony™ Posterior discectomy instrumentation

# Indications/Contraindications

## **Indications**

The Ardis System is indicated for use with autogenous bone graft as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at the involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment.

The Ardis System is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation.

## **Contraindications**

Disease conditions which have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.

Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.

Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other posterior spinal instrumentation system.

Any entity or condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis or osteopenia, is a relative contraindication.

Other relative contraindications include obesity, pregnancy, certain degenerative disease, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant.

Known patient sensitivity to device materials (PEEK OPTIMA®).

Prior fusion at the level(s) to be treated.

Any condition not described in the indications for use.

# Key Instruments

## Harmony Posterior



### Curettes

Prepare vertebral body endplates and remove disc material. Feature bayoneted shaft and reduced glare finish. Curettes available: straight, right, left, up-biting, down-biting, ring and O'Brien.



### Distractors

Incrementally distract disc space, shave endplates. Cutting, smooth distractors available in 6–15mm sizes.



### Rongeurs

Cut bony structures, remove disc material. Kerrison, pituitary rongeurs, with bayoneted shaft and reduced glare finish, available in 2–4mm sizes.

## Ardis



### 3250-06 to 3250-16 Shavers

Incrementally distract disc space, shave endplates. Available in 6-16mm sizes.



### 3252-01 Rasp, Straight

Prepares vertebral body endplates by clearing cartilage and creating bleeding bone.



### 3252-02 Rasp, Curved

Prepares vertebral body endplates by clearing cartilage and creating bleeding bone.



### 3254-080922 to 3254-161134 Ardis Trial

Bullet-nosed trials in 20 sizes used to estimate implant fit.



### 3256-01 Ardis Inserter

Inserts the implant into the disc space. Threads into the implant's posterior hole. Silver and gold knobs tighten to create a more secure inserter/implant connection.



### 3258-01 Ardis Straight Tamp

Advances the implant into its final position.



**3258-02 Ardis Angled Tamp**

Advances the implant into its final position.



**3260-01 Ardis Threaded Extractor**

Removes the implant if the inserter cannot be reattached. Use of this instrument will bite into the implant's material and a new implant should be implanted.



**3262-01 Slaphammer**

Provides additional force in removal of trials, inserter or extractor (if needed).



**3264-01 T-Handle, 1/4" Square Drive**

Attaches to shavers for controlled insertion, removal and rotation.



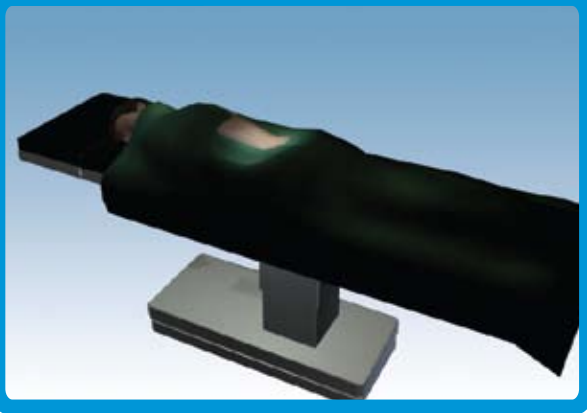
**2760-1 Bone Funnel**

**2755-1 Bone Tamp**

Used to pack autograft material into disc space or implant.

# Surgical Technique

**Figure 1**

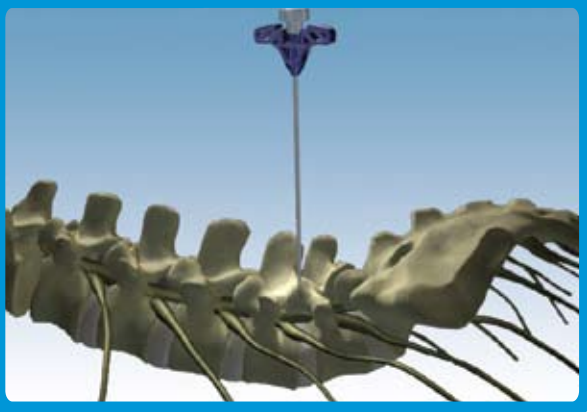


## Patient Positioning

Position on radiolucent table with adequate clearance for a fluoroscopic C-arm (for A/P, lateral and oblique images of pedicle and vertebral body).

All other hardware utilized for patient positioning should be checked for radiolucency.

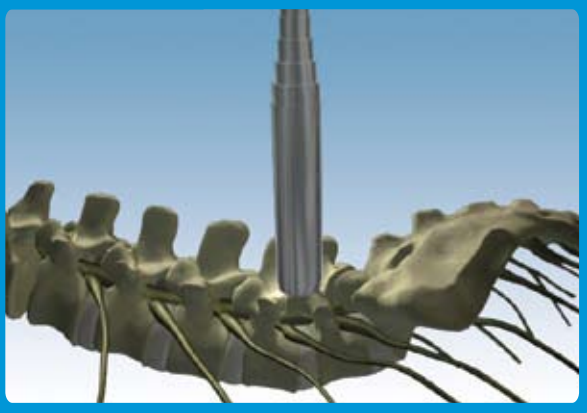
**Figure 2**



## Pedicle Targeting

Obtain A/P, lateral images of affected level. Begin Harmony Port placement, accessing facet with targeting needle and k-wire.

**Figure 3**



## Sequential Dilation

Sequentially slide dilators #1 – 6 over k-wire; slide matching depth gauge over largest dilator, flange positioned distally.

**Note:** Depth gauges may be used as pushers to advance dilators through musculature.

**Figure 4**



#### Port Measurement

Rest flange against skin, locating proximal end of dilator #4, 5 or 6 in depth gauge window. Identify necessary port length, referencing measurements on side of depth gauge and rounding up. The #4 dilator correlates to a 19mm port, the #5 dilator correlates to a 22mm port and the #6 dilator correlates a 26mm port.

**Figure 5**



#### Port Placement

Remove port from sterile package, slide over dilator and dock on facet. Adjust angle by wanding dilators. Attach port to snake arm or surgical assist mechanism (SAM) arm.

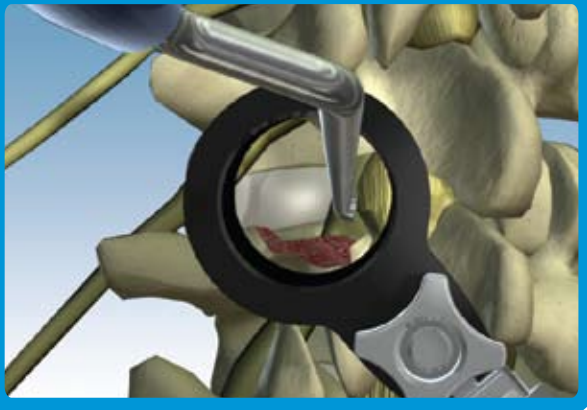
**Figure 6**



#### Bony Decompression

Using osteotomes and Kerrison rongeurs, remove facet and portions of lamina.

**Figure 7**



#### Ligamentum Flavum

Cut ligamentum flavum from inferior portion of lamina. Mobilize with Woodson or fine curettes. Control epidural bleeding with bipolar cautery, **avoiding contact with port or other instruments.**

**Figure 8**



#### Nerve Root, Dura Mobilization

Free nerve root and dura from soft tissue; probe bony structures with ball probe. Retract nerve root and dura.

**Figure 9**



#### Annular Window

Remove blood, small tissue fragments with suction catheter; create annular window with annulus knife.

**Figure 10**



#### Remove Disc Tissue

Connect Harmony cutting distractor or Ardis shaver to its respective t-handle and insert into disc space; rotate to free disc tissue. Remove disc fragments with pituitary rongeurs.

**Note:** The distance from the tip to the laser-marked line on the Ardis shaver indicates the approximate length of a 26mm implant. The distance from its tip to the point where the gold stops indicates the approximate length of a 34mm implant.

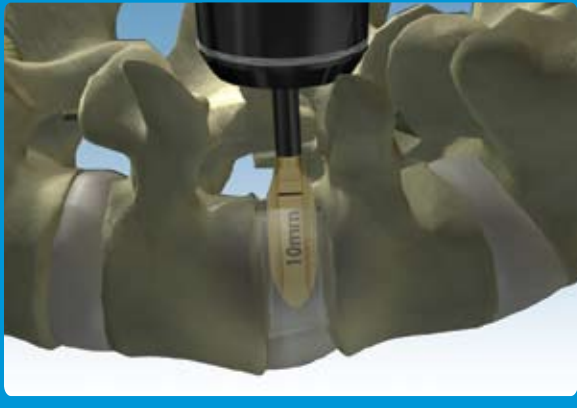
**Figure 11**



#### Endplate Preparation

With osteomes, remove osteophytes and posterior lip of adjacent vertebral bodies. Remove remaining endplate cartilage with curettes or the Ardis straight or angled rasps.

**Figure 12**



#### Distraction

With progressively sized Harmony smooth distractors, Harmony cutting distractors or Ardis shavers, open space to the desired height. Connect distractor or shaver to its respective t-handle. Insert into disc space and rotate axis, opening space to a height equal to the distractor.

**Note:** The distance from the tip to the laser-marked line on the Ardis shaver indicates the approximate length of a 26mm implant. The distance from its tip to the point where the gold stops indicates the approximate length of a 34mm implant.

**Figure 13**



#### Implant Sizing

Insert trial into disc space and view under fluoro to determine proper implant size. The slaphammer can be used to remove the trial, if necessary.

**Figure 14**



#### Final Implant Preparation

Select implant size based on trial fit. With bone tamp, pack implant with autograft material. Ensure silver and gold knobs on inserter are flush. Attach implant to inserter. First tighten the silver knob finger-tight to engage with the implant's posterior threaded hole. Then finger-tighten the gold knob to complete engagement with the implant. Use bone funnel/bone tamp to pack autograft material into disc space prior to inserting implant.

**Note:** the silver and gold knobs must be fully engaged for secure connection of the implant to the inserter.

**Figure 15**



#### Implant Insertion

Insert implant into disc space. A mallet can be used for insertion.

Confirm position radiographically and detach implant from inserter. First loosen the gold knob, then the silver knob (on the inserter).

**Note:** Ardis is not designed to insert and turn.

**Figure 16**

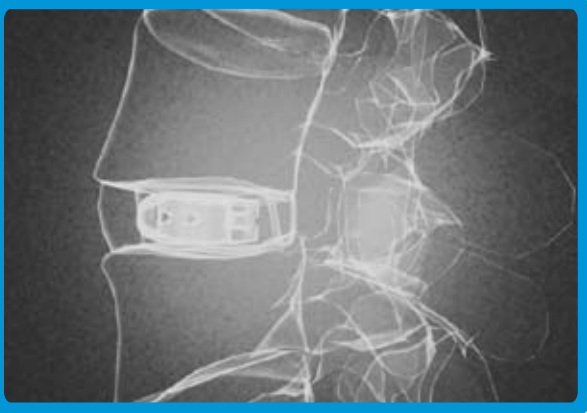


#### Final Positioning

Mate either straight or angled tamp onto posterior portion of implant. Mallet tamp to drive implant in desired direction.

**Note:** If using the angled tamp, make sure that the center nub is engaged in the posterior hole of the implant. If an implant needs to be removed from the disc space, either attempt to reengage the inserter or thread the extractor into the posterior threaded hole at the end of the implant. The extractor should not be inserted at a severe angle. Engage the extractor perpendicular to the posterior end of the implant. The slaphammer can be used. A new implant should be implanted.

**Figure 17**

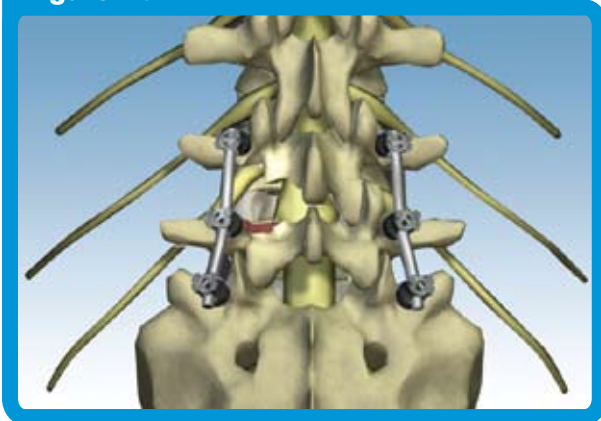


#### Position Confirmation

Confirm position radiographically.

Use bone funnel/bone tamp to pack graft material into disc space around implant.

**Figure 18**



#### Implant Compression

Insert rods into pedicle screw construct, completing assembly. Using compressor from pedicle screw system kit, apply load to Ardis implant and lock construct.

# Kit Contents

## Ardis

Part Number	Description	Standard Quantity
3201-080922	8mm x 9mm x 22mm Ardis (PEEK) Implant	2
3201-080926	8mm x 9mm x 26mm Ardis (PEEK) Implant	2
3201-080930	8mm x 9mm x 30mm Ardis (PEEK) Implant	2
3201-081126	8mm x 11mm x 26mm Ardis (PEEK) Implant	2
3201-081130	8mm x 11mm x 30mm Ardis (PEEK) Implant	2
3201-081134	8mm x 11mm x 34mm Ardis (PEEK) Implant	2
3201-100922	10mm x 9mm x 22mm Ardis (PEEK) Implant	2
3201-100926	10mm x 9mm x 26mm Ardis (PEEK) Implant	2
3201-100930	10mm x 9mm x 30mm Ardis (PEEK) Implant	2
3201-101126	10mm x 11mm x 26mm Ardis (PEEK) Implant	2
3201-101130	10mm x 11mm x 30mm Ardis (PEEK) Implant	2
3201-101134	10mm x 11mm x 34mm Ardis (PEEK) Implant	2
3201-120922	12mm x 9mm x 22mm Ardis (PEEK) Implant	2
3201-120926	12mm x 9mm x 26mm Ardis (PEEK) Implant	2
3201-120930	12mm x 9mm x 30mm Ardis (PEEK) Implant	2
3201-121126	12mm x 11mm x 26mm Ardis (PEEK) Implant	2
3201-121130	12mm x 11mm x 30mm Ardis (PEEK) Implant	2
3201-121134	12mm x 11mm x 34mm Ardis (PEEK) Implant	2
3201-140922	14mm x 9mm x 22mm Ardis (PEEK) Implant	2
3201-140926	14mm x 9mm x 26mm Ardis (PEEK) Implant	2
3201-140930	14mm x 9mm x 30mm Ardis (PEEK) Implant	2
3201-141126	14mm x 11mm x 26mm Ardis (PEEK) Implant	2
3201-141130	14mm x 11mm x 30mm Ardis (PEEK) Implant	2
3201-141134	14mm x 11mm x 34mm Ardis (PEEK) Implant	2
3201-160922	16mm x 9mm x 22mm Ardis (PEEK) Implant	2
3201-160926	16mm x 9mm x 26mm Ardis (PEEK) Implant	2
3201-160930	16mm x 9mm x 30mm Ardis (PEEK) Implant	2
3201-161126	16mm x 11mm x 26mm Ardis (PEEK) Implant	2
3201-161130	16mm x 11mm x 30mm Ardis (PEEK) Implant	2
3201-161134	16mm x 11mm x 34mm Ardis (PEEK) Implant	2
3250-06	Shaver, 6mm	1
3250-07	Shaver, 7mm	1
3250-08	Shaver, 8mm	1
3250-09	Shaver, 9mm	1
3250-10	Shaver, 10mm	1
3250-11	Shaver, 11mm	1
3250-12	Shaver, 12mm	1
3250-13	Shaver, 13mm	1
3250-14	Shaver, 14mm	1

**Ardis**

<b>Part Number</b>	<b>Description</b>	<b>Standard Quantity</b>
3250-15	Shaver, 15mm	1
3250-16	Shaver, 16mm	1
2760-1	Bone Funnel	1
2755-1	Bone Tamp	1
3252-01	Rasp, Straight	1
3252-02	Rasp, Curved	1
3254-080922	Ardis Trial 8mm x 9mm x 22mm	1
3254-080926	Ardis Trial 8mm x 9mm x 26mm	1
3254-080930	Ardis Trial 8mm x 9mm x 30mm	1
3254-081134	Ardis Trial 8mm x 11mm x 34mm	1
3254-100922	Ardis Trial 10mm x 9mm x 22mm	1
3254-100926	Ardis Trial 10mm x 9mm x 26mm	1
3254-100930	Ardis Trial 10mm x 9mm x 30mm	1
3254-101134	Ardis Trial 10mm x 11mm x 34mm	1
3254-120922	Ardis Trial 12mm x 9mm x 22mm	1
3254-120926	Ardis Trial 12mm x 9mm x 26mm	1
3254-120930	Ardis Trial 12mm x 9mm x 30mm	1
3254-121134	Ardis Trial 12mm x 11mm x 34mm	1
3254-140922	Ardis Trial 14mm x 9mm x 22mm	1
3254-140926	Ardis Trial 14mm x 9mm x 26mm	1
3254-140930	Ardis Trial 14mm x 9mm x 30mm	1
3254-141134	Ardis Trial 14mm x 11mm x 34mm	1
3254-160922	Ardis Trial 16mm x 9mm x 22mm	1
3254-160926	Ardis Trial 16mm x 9mm x 26mm	1
3254-160930	Ardis Trial 16mm x 9mm x 30mm	1
3254-161134	Ardis Trial 16mm x 11mm x 34mm	1
3256-01	Ardis Inserter	1
3258-01	Ardis Straight Tamp	1
3258-02	Ardis Angled Tamp	1
3260-01	Ardis Thread Extractor	1
3262-01	Slaphammer	1
3264-01	T-Handle, 1/4" Square Drive	2
3290-01	Ardis General Tray	1
3290-011	Ardis Silicone Mat, General Tray	1
3290-02	Ardis Shaver Therm Tray	1
3290-03	Ardis Sm Trial Therm Tray	1
3290-04	Ardis Lg Trial Therm Tray	1
3290-100	Ardis 4" Outer Base	1
3391-02	Sequoia Degen Implant Lid	1

## Harmony Posterior

<b>Part Number</b>	<b>Description</b>	<b>Standard Quantity</b>
1006-1	Comfort T-Handle	2
2655-06	Cutting Distractor - 6mm	1
2655-07	Cutting Distractor - 7mm	1
2655-08	Cutting Distractor - 8mm	1
2655-09	Cutting Distractor - 9mm	1
2655-10	Cutting Distractor - 10mm	1
2655-11	Cutting Distractor - 11mm	1
2655-12	Cutting Distractor - 12mm	1
2655-13	Cutting Distractor - 13mm	1
2655-14	Cutting Distractor - 14mm	1
2655-15	Cutting Distractor - 15mm	1
2654-06	Smooth Distractor - 6mm	1
2654-07	Smooth Distractor - 7mm	1
2654-08	Smooth Distractor - 8mm	1
2654-09	Smooth Distractor - 9mm	1
2654-10	Smooth Distractor - 10mm	1
2654-11	Smooth Distractor - 11mm	1
2654-12	Smooth Distractor - 12mm	1
2654-13	Smooth Distractor - 13mm	1
2654-14	Smooth Distractor - 14mm	1
2654-15	Smooth Distractor - 15mm	1
2855-1-2	Kerrison Rongeur - 2mm Forward	1
2855-1-3	Kerrison Rongeur - 3mm Forward	1
2855-1-4	Kerrison Rongeur - 4mm Forward	1
2855-2-3	Kerrison Rongeur - 3mm Straight	1
2856-1-2	Pituitary Rongeur - 2mm Straight	1
2856-1-3	Pituitary Rongeur - 3mm Straight	1
2856-1-4	Pituitary Rongeur - 4mm Straight	1
2856-2-2	Pituitary Rongeur - 2mm Up	1
2856-2-3	Pituitary Rongeur - 3mm Up	1
2856-2-4	Pituitary Rongeur - 4mm Up	1

## Harmony Posterior

Part Number	Description	Standard Quantity
2752-1	Large Curette, Up	1
2752-2	Large Curette, Straight	1
2752-3	Large Curette, Left	1
2752-4	Large Curette, Right	1
2751-1	O'Brien Curette	1
2762-1	Ring Curette	1
2753-2	Down Biting Curette - Right	1
2753-3	Down Biting Curette - Left	1
2851-1-01	Small Curette, Down	1
2851-3-01	Small Curette, Down Reverse	1
2851-6-01	Small Curette, Straight	1
2851-8-01	Small Curette, Forward	1
2851-9-01	Small Curette, Left	1
2851-0-01	Small Curette, Right	1
2763-1-1	Osteotome, Straight	1
2763-1-2	Osteotome, Curved	1
2763-1-3	Osteotome, Angled	1
2852-4	Penfield Dissector	1
2854-1	Woodson Elevator	1
2858-1	Nerve Hook	1
2859-1	Ball Probe	1
2861-5	Nerve Root Retractor - Full Angle, 5mm	1
2861-9	Nerve Root Retractor - Full Angle, 9mm	1
2866-5	Nerve Root Retractor - Bayonet, 5mm	1
2866-9	Nerve Root Retractor - Bayonet, 9mm	1
2764-1	Annulus Knife Handle	1
2865-1-12	Retractor with Suction - 12F	2
2864-1-2	Bipolar Forceps	1

# Warnings

Following are specific warnings, precautions, and adverse effects, which should be understood by the surgeon and explained to the patients. These warnings do not include all adverse effects, which can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Potential risks identified with the use of this device system, which may require additional surgery, include:
  - a. Device component fracture.
  - b. Loss of fixation.
  - c. Non-union.
  - d. Fracture of the vertebra.
  - e. Neurological injury.
  - f. Vascular or visceral injury

2. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.

The potential for satisfactory fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Use of provided trials is recommended.

3. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED

LOADING ASSOCIATED WITH DELAYED UNION OR NON-UNION. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

4. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
- a. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to a loss of interbody height or failure of the device and/or the operation.
  - b. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause loss of disc height and/or failure of the device.
  - c. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
  - d. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary relief.
  - e. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
5. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
6. These warnings do not include all adverse effects that can occur with surgery in general. General surgical risks should be explained to the patients prior to surgery.
7. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

# Precautions

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The Ardis device is a single use device and should not be reused. An explanted device should never be reimplanted.

**Invibio (2001):** PEEK-OPTIMA®, Technical Information for the Medical Profession.

**CLEARANCE:** Ardis is 510(K) cleared for use as an intervertebral body fusion device intended for use in the lumbar spine (L2-S1).

To order, call Abbott Spine Customer Service at (800) 326-0635.

## Expertise at your side.

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All while helping you extend yours.

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