

BAK[®] Interbody Fusion Systems

The Complete Interbody Fusion System for the Spine

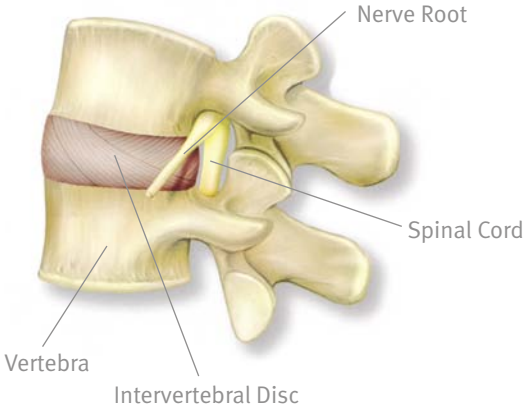


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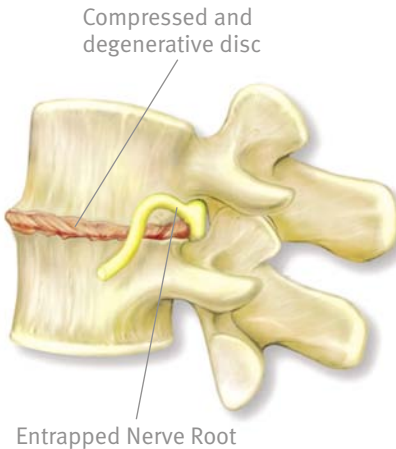
BAK[®] Interbody Fusion Systems

This Patient Information Brochure is provided to help you make an informed decision about your back surgery.

Normal



Abnormal



This surgical procedure will be using the BAK® Interbody Fusion Systems.

Some common causes of back problems are disc injury (e.g., herniation) and disc degeneration.

Disc degeneration affects about 12 million people in the U.S., of whom most are within the ages of 20 to 65. Approximately 10 percent of patients with degenerative discs are candidates for some type of spinal surgery.



In your lower back there are five vertebrae (bones). Between each of the vertebra is a disc. Discs are the “shock absorbers” of your spine and act as spacers between vertebrae. As discs degenerate, they lose their water content and height, bringing the vertebrae closer together. This results in a weakening of the shock absorption properties of the disc and a narrowing of the nerve openings between the vertebrae which may pinch your nerves. This disc degeneration can eventually cause back and leg pain or numbness.

The *BAK* systems are designed to stabilize and fuse the degenerative disc space(s), with the intent of providing a better alternative treatment for disc disorders.



What Are the BAK Interbody Fusion Systems?

The *BAK* Interbody Fusion Systems are an innovative technique for spinal fusion, which is less invasive than other methods. This procedure utilizes small, threaded cylinders to restore the degenerated disc space to or near its original height, relieving pressure on your nerves. These systems are approved for patients with degenerative disc disease (DDD) at one or two levels and may be implanted from the second lumbar disc (L2) down to the sacrum.

In addition, patients should be skeletally mature and should have had six months of non-operative treatment. The *BAK* systems should not be used in patients with severe infection.

What Happens During Surgery?

During surgery, your doctor will remove portions of the painful disc and vertebral bones, allowing the implants to be inserted into the disc space. A small amount of bone may then be taken from your hip and packed inside the *BAK* systems. The *BAK* systems can be implanted from either a front (anterior), back (posterior) or laparoscopic surgical approach. If the *BAK* systems are to be implanted through a laparoscopic approach, surgery is limited to the L4-L5 and L5-S1 disc levels. However, patients with multiple previous abdominal surgeries should not have the *BAK* systems implanted through the laparoscopic approach. Your doctor will make the decision on surgical approach based upon your condition.

What are Some of the Benefits of the BAK Procedure?

Part of the development process for the *BAK* systems was a tightly regulated clinical study. Clinical outcomes of this study have shown reductions in pain and increased activity levels. Based upon the findings of this clinical study, the *BAK* systems were shown to offer many advantages over traditional fusion methods. The following are some advantages:

- The procedure has been found to have a low overall complication rate.
- The amount of blood loss during surgery can be much less than other types of spinal fusion.
- Postoperative pain may be minimized through a decrease in the amount of surgical intervention.
- Operative procedure time and length of stay in the hospital can be less than other fusion methods.
- Return to daily activities can be much quicker.

These findings follow the general trend in medical care toward less invasive surgical techniques that provide better outcomes for patients.



What Were the Results of the Clinical Study?

The clinical study was conducted by 42 doctors at 19 hospitals across the U.S. The study included a total of 947 patients treated by either an anterior or posterior open approach and measured success in different areas. The success rates are shown below for overall success and for each measure of success. The clinical success rates for patients two years after surgery were measured in the following areas:

Complications requiring additional surgery:

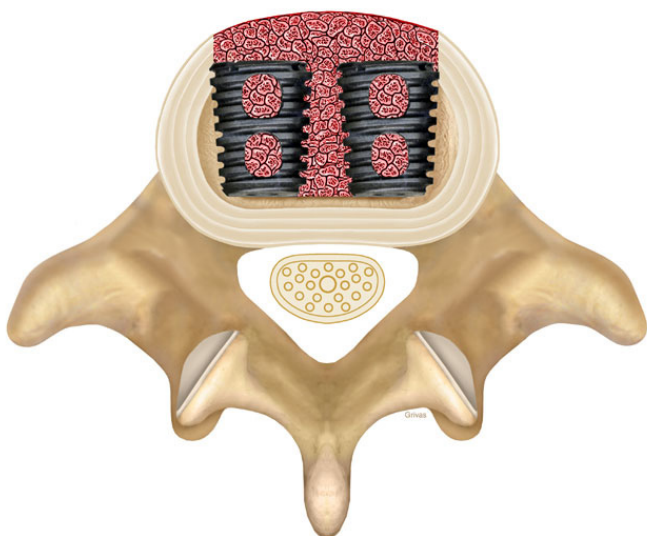
| | Anterior | | Posterior | |
|---------------------------------|----------|---------|-----------|---------|
| | 1 Level | 2 Level | 1 Level | 2 Level |
| Fusion Rate | 98% | 80% | 94% | 71% |
| Pain Improvement | 84% | 86% | 87% | 81% |
| Function Maintained or Improved | 95% | 94% | 92% | 95% |
| Strength Maintained or Improved | 94% | 94% | 94% | 100% |
| Overall Success | 81% | 59% | 78% | 50% |

Note that the number of patients used to calculate the success rates were slightly different for each of the measurements above due to unavailable data.

For a patient to be considered an overall success, improvement was required in all four of the major measurements (fusion, pain, function and muscle strength).

Based on this clinical study of the open procedure, the following statements may also be made about the *BAK* systems:

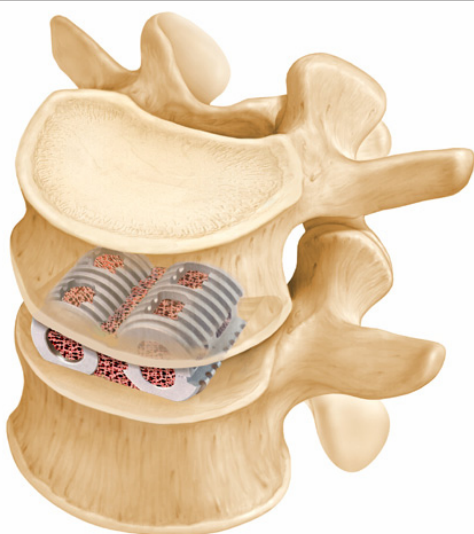
- The two-year data indicate the likelihood of needing additional supplemental fixation increases over time in patients who were not fused or showed no improvement in pain.
- For both anterior and posterior approaches, patients with one disc space fused had lower overall complication rates than patients with two disc spaces fused.
- Patients implanted with a *BAK* system from the posterior approach had higher rates of operative complications and early postoperative surgical interventions than patients from the anterior approach.
- Patients implanted from the anterior approach had a higher overall rate of early postoperative complications than patients implanted from the posterior approach.



BAK® *Vista*® Interbody Fusion Systems

A separate clinical study was conducted that evaluated the short-term safety of the *BAK* systems implanted through a laparoscopic surgical approach. Based on this clinical study, the following statements may be made:

- Laparoscopic patients had a longer surgical time, but shorter hospital stay and lower blood loss, compared to open procedure patients. Clinical outcomes were similar between the laparoscopic patients and open procedure patients with the following exceptions: there was a higher incidence of ileus (slow movement of the intestines), retrograde ejaculation into the bladder, postoperative disc herniation, and reoperations in the laparoscopic study group.
- Ten percent of the laparoscopic patients were converted to an open procedure resulting in longer surgical time and greater blood loss.



BAK® Interbody Fusion Systems

What Are Some Possible Complications of the BAK Procedure?

Spinal surgery is not without risk. It is normal to have concerns about possible complications. Complications related to spinal implant surgery include, but are not limited to, the following: tear in the outer lining of the spinal cord (dura); spinal fluid leak; nerve complications; infection; slow movement of the intestines (ileus); implant migration; blood vessel damage/bleeding; leg pain; hematoma; pneumonia; retrograde ejaculation into bladder; fractured sacrum; blood clots; wound closure problems; and bladder problems.

Specific information on the rates of complications for the *BAK* systems and spinal surgery should be discussed with your doctor. Please talk with your doctor about the results from the research study and the possibility that you might need more than one operation.

General Surgical Complications Not Specifically Related to the Implant May Include:

- reactions to anesthesia
- attack
- infection
- bruise (hematoma)
- blood vessel damage/bleeding
- pneumonia
- blood clots
- wound closure problems
- death

Please consult your doctor about the complication rates related to treatment with the *BAK* systems.

What Should I Do Before Surgery?

It is well known that smokers experience lower surgical success rates than non-smokers. If you smoke, please consider terminating your habit as far in advance of the surgical procedure as possible to increase your chances of a successful outcome. In addition, poor nutrition impacts a body's ability to heal itself. If you eat well-balanced, nutritional meals as far in advance of surgery as possible, this will also help to increase your chances of a successful outcome.

What Should I Expect After Surgery?

After the surgery is completed, your pain and activity level will continue to be evaluated. You will be expected to see your doctor several times after surgery to evaluate your pain and function. Your doctor may take X-rays to check the fusion of your spine. Ask your doctor about the postoperative rehabilitation program and required follow-up. It is important to follow your doctor's directions carefully in order to recover from surgery as quickly as possible.

NOTE: Please call your doctor if you experience any of the following symptoms:

- Signs of infection (i.e. fever, chills, redness around incision, increased pain, the feeling of pressure in the spine)
- Bleeding or excessive drainage from your incision(s)
- Sudden onset of severe pain, or significant increase in your pain level
- Loss of sensation, or significantly decreased sensation in your legs/feet
- Increased or persistent shortness of breath

Who Do I Talk To if I Still Have Questions?

This brochure is provided to give you information about your treatment options, but it is not intended to replace professional medical care or provide medical advice. If you have any further questions or need additional information about the *BAK* systems, please call or see your doctor, who is the only one qualified to diagnose and treat your condition.

What Patients Should Not Be Implanted with the *BAK* systems?

The *BAK* system should not be implanted in patients that have infection at the site of operation. The *BAK* system also should not be implanted laparoscopically in patients that have had previous multiple abdominal surgeries.

In addition, safety and effectiveness have not been established in patients with the following conditions: gross obesity, three or more levels to be fused, symptomatic cardiac disease, pregnancy, previous fusion attempts at the involved level(s), a severe slipped vertebrae, systemic or terminal illness, fragile or soft bones or a loss of bone density, a condition requiring steroid use or active drug abuse.

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