

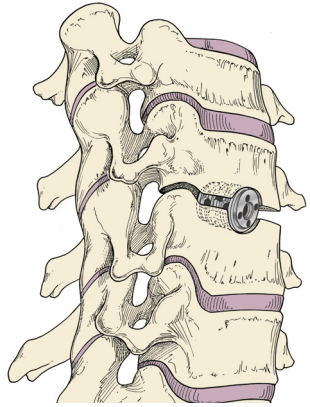
BAK/C[®] Anterior Cervical Interbody Fusion System

The Comfortable Choice for Cervical Fusion



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Confidence in your hands[®]

This Patient Information Brochure is provided to help you make an informed decision about your neck surgery, specifically with the BAK/C® Cervical Interbody Fusion System.



Which Patients Might Benefit from the BAK/C System?

In your cervical spine (neck) there are seven vertebrae (bones). Between each of the vertebra is a disc that is made of a cushion-like material. Your disc can become ruptured or collapse. In some cases excess bone grows along the edges of the vertebrae. As a result of this disc space collapse and excess bone formation, the small spaces that allow nerves to pass through can become narrowed, pinching the nerves and causing neck pain, shoulder pain, arm pain, or numbness. This is often referred to as a degenerative (that is, decreasing in quality) condition of the spine or degenerative disc disease.

Based on your examination, your doctor has asked you to consider a spinal fusion procedure with the *BAK/C* Interbody Fusion System. The purpose of this surgery is to stabilize and fuse the disc space between two of your vertebrae in your cervical spine to relieve your neck pain, shoulder pain, arm pain, or numbness. The *BAK/C* System is approved for use in patients with painful degenerative disc disease at one disc level of the cervical spine. The *BAK/C* System may be placed between the third cervical disc (C-3) down to the seventh cervical disc (C-7).

What is the BAK/C Interbody Fusion System?

The *BAK/C* System consists of implants made from titanium alloy. This material is safe to use within the human body. The implants are similar to hollow screws with holes in them. This device is implanted singularly or in pairs in the space between the vertebral bodies of the spine known as the disc space. The implants are filled with bone obtained from the vertebrae during surgery. In rare cases, a small amount of bone must be obtained from the hip. Bone grows through the holes in the implant to fuse the vertebrae.



What Are Some Benefits of the BAK/C Procedure?

The *BAK/C* System surgery provides stability to the painful region of the neck by fusing the bone above and below the degenerated disc. When this stabilization is achieved, you may experience relief from neck pain, shoulder pain, arm pain, muscle weakness, and/or numbness. In a research study conducted by the implant manufacturer, 100% of patients receiving the *BAK/C* System were fused, 84% felt relief from neck pain, 80% had improvements in arm pain, shoulder pain, muscle weakness, and numbness, and 79% experienced some improvements in physical and/or mental function (in examinations conducted 24 months after the *BAK/C* System operation). A total of 64% of *BAK/C* System patients experienced successful outcomes for all measured symptoms (fusion, neck pain, shoulder pain, arm pain, muscle weakness, numbness, physical and/or mental function); these results are comparable to those experienced in the group of patients receiving an alternative treatment. Please talk with your doctor for a more complete discussion of the results from the research study.

Note: Although this research study included some patients with degenerative disc disease at two disc levels, not enough information was available to determine whether this implant is a good treatment for these patients. This study did not include patients with:

- rheumatoid disease of the cervical spine
- significant loss of quantity or quality of spinal bone (osteoporosis)
- a previous fusion attempt at the same place in the spine

When Should the BAK/C Not Be Used?

The *BAK/C* System should not be used in patients with:

- an active infection
- an allergy to titanium metal

Are There Alternative Treatments?

Although your doctor is planning to use the *BAK/C* System for your condition, you should be aware that there are alternative treatments to this type of device. Other treatments may include the following:

- **Surgical:** Bone grafting techniques have been used to treat degenerative conditions of the cervical spine. These procedures are often used in conjunction with surgical removal of the cervical disc with subsequent fusion of the bones. This procedure is known as Anterior Cervical Discectomy and Fusion or ACDF. The fused bones may be reinforced with a metal plate that is attached directly to the affected area of the cervical spine.
- **Non-Surgical:** Conservative therapies may differ depending on the frequency and intensity of pain. Intermittent pain may be treated with analgesics, muscle relaxants, heat, rest, patient education, stretching exercises, and use of good body mechanics. Continuous pain may be treated with rest, transcutaneous nerve stimulation (TENS), traction, hydrotherapy, strengthening exercises, local injections, strong analgesics, braces and chiropractic care.

If you want information on these options, please discuss them with your doctor.

What Are Some Possible Complications of the BAK/C Procedure?

Complications associated with this type of surgery include, but are not limited to, the following:

- nerve complications causing pain or physical dysfunction (for example, numbness in arms, hands or fingers; or continuing or increased neck/shoulder/arm pain)
- hoarseness, difficulty swallowing
- dural tear or spinal fluid leak
- damage to adjacent bones, discs, or soft tissue
- failure to achieve a fusion and new or continued symptoms
- additional surgery (see below)

Additional Surgery: In a research study conducted by the implant manufacturer, patients receiving the BAK/C System were compared to patients undergoing ACDF surgery. Some patients in both treatment groups needed to have more than one cervical spine operation to resolve ongoing complications. Table 1 below summarizes the percentage of patients that needed more than one operation during the study. The types of operations included:

Revision: an operation that adjusts the original implant

Removal: an operation that removes the implant and does not replace it

Supplemental fixation: an operation that implants additional devices

Reoperation: an operation that does not remove, modify, or add any implants

TABLE 1. COMPLICATIONS REQUIRING ADDITIONAL SURGERY

	Post-op (1 day to 1½ Months)		3-month (1½ to 4½ Months)		6-month (4½ to 9 Months)		12-month (9 to 18 Months)		24-month (18 Months or more)		Cumulative Complication Rate 24-months	
	BAK/C n=154	Control n=125	BAK/C n=147	Control n=118	BAK/C n=116	Control n=86	BAK/C n=126	Control n=94	BAK/C n=101	Control n=80	BAK/C	Control
Additional Surgery	0	Less than 1%	Less than 1%	Less than 1%	2½%	3½%	4%	7½%	3%	2½%	6%	11%

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

Please consult your doctor about the complication rates related to treatment with the *BAK/C* System.

What Should I Do Before Surgery?

It is well known that smokers experience lower surgery 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 Happens During the BAK/C Interbody Fusion System Surgery?

Portions of the disc and bone are removed from the front of the spine. The *BAK/C* System Cervical Implant(s) is advanced into the disc space. One or two devices may be implanted at the affected disc level, depending on your anatomy, surgical exposure, and surgeon preference. Bone graft obtained from your vertebrae is placed inside the implant to help bone grow through the device, bridging the disc space or “fusing” the two vertebrae together.

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 neck, or difficulty swallowing)
- 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 arms/hands/fingers
- 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/C* System, please call or see your doctor, who is the only one qualified to diagnose and treat your condition.



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