TRIANGLE SPINE AND BACK CARE CENTER

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BACKGROUNDER — DEGENERATIVE DISK DISEASE AND TRADITIONAL TREATMENTS

WHAT IS DEGENERATIVE DISC DISEASE?

Between each of the 24 vertebrae of the human spine is a vertebral disc comprised of cartilage-like materials that separate the vertebrae and allow flexible movement. Injury, aging or repeated stress can produce degenerative disc disease, or a collapse of the disc, which can lead to excessive motion in the spine, inflammation of the nerves in an around the spine, nerve dysfunction and severe, debilitating pain in the back, arms or legs.

WHAT ARE THE COSTS?

In the United States, back pain is the leading cause of workers' compensation expense; it is the second leading cause of physician office visits, and the third leading reason for surgical procedures.

- 80% of the population will, at one point, have some spinal problem.
- Back pain affects 12 million people — most of them between the ages of 20 and 60 — during their most productive years, and it is the leading cause of medical expense for this age group
- The annual direct medical cost of treatment of back pain exceeds an estimated $25 billion; the indirect costs of lost worker productivity is an estimated $60 billion.
- More than five million Americans are disabled due to chronic back pain; within this group, more than 2.6 million are permanently disabled.

TRADITIONAL BACK PAIN TREATMENTS

INVASIVE BACK SURGERY

The most commonly performed surgical interventions for chronic back pain are discectomy and vertebral fusions.

BACKGROUNDER —THE INTERBODY FUSION DEVICE SYSTEM

The interbody fusion device system used by Dr. Lestini is an innovative series of FDA-approved spinal implants, surgical instruments and procedures that assist the surgical placement of implants between the vertebrae to stabilize the spine and facilitate the fusion of the vertebrae.

He also uses a newly developed "cage." These cages are the only such devices that can be inserted laparoscopically. Both devices help reduce the spinal instability that can cause chronic disabling back pain.

INNOVATIVE, COMPREHENSIVE SYSTEMS

The new systems facilitate fusion of spinal vertebrae in three areas of the spine: the lower, or lumbar spine; the neck, or upper spine; and the chest regions of the spine. Degenerative disc disease occurs most often in the lumbar region.

The interbody fusion system includes spinal implants, customized surgical instruments and techniques that facilitate the surgical placement of the implants. The fusion implants are hollow, threaded cylinders, or "cages," implanted between two or more vertebrae. The cages are packed with bone graft to facilitate the growth of the vertebral bones through holes in the cylinder. Fusion is achieved when adjoining vertebrae grow together through the implant.

IMPROVEMENTS OVER TRADITIONAL TECHNIQUES

- **Less patient trauma** — Surgery can be performed using less invasive or laparoscopic procedures. There are smaller incisions, less blood loss and less post-operative pain.

- **Reduced operating time** — Cages can be implanted in less time than conventional procedures, further reducing patient trauma and operating room costs.

- **Shorter hospitalizations and speedier recovery**— Cage procedures may reduce patient hospital stays, and in some cases, the procedure is performed laparoscopically on an outpatient basis. Rehabilitation and recovery time is much shorter than with traditional techniques.

- **Reduced costs** — Total cost for interbody fusion procedures is substantially less ($7-9,000) than traditional fusion procedures with implants.

- **Greater stability** — new devices cause less irritation and scarring of the nerves and muscles.

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Discectomy

Discectomy is the most commonly performed spinal procedure — in fact, more than 400,000 discectomies were performed in 1994. This procedure is typically intended to treat hip, leg or back pain or nerve dysfunction. It involves the surgical removal of herniated disc material through an incision usually made in the patient's back. Because a herniated disc may be evidence of degenerative disc disease, patients requiring discectomy are at higher risk of needing additional spinal surgery.

Vertebral fusion

Vertebral fusion helps eliminate spinal instability by fusing adjoining vertebrae. It involves the surgical implantation of bone graft into or around the disc space. The grafted bone fuses the vertebrae together over a period of several months. Typically, the implanted bone is harvested from the patient's hip.

There are two types of spinal fusion surgery: non-instrumented, without use of implants, and instrumented, with implants. Clinical analyses have demonstrated that spinal fusion surgery in the lumbar (lower) spine using spinal implants is more effective at providing structure and rigidity to the spine than surgery without implants. Instrumented fusion involves the surgical attachment of a metal implant to the vertebrae adjoining one or more diseased discs through an incision in the patients back or abdomen.

MINIMALLY INVASIVE SURGERY

To date, most fusion procedures have been performed through a large incision in the patient's back. Increasingly, procedures are being performed using minimally invasive tools and techniques which helps reduce the surgical trauma associated with incisions through the skin and muscles.

Laparoscopic surgery and minimally invasive anterior techniques involve small incisions or punctures in the skin and muscle, allowing patients speedier recovery time, shorter hospital stays, and faster return to work.

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"cage" technology

REVOLUTIONIZES APPROACH TO SPINAL FUSION SURGERY

"Cage" technology, coupled with such advances as the laparoscope, is revolutionizing the approach to spinal fusion surgery, and Dr. William F. Lestini and his colleagues at Triangle Spine and Back Care Center are in the forefront of the nation's orthopaedic surgeons in developing these new techniques.

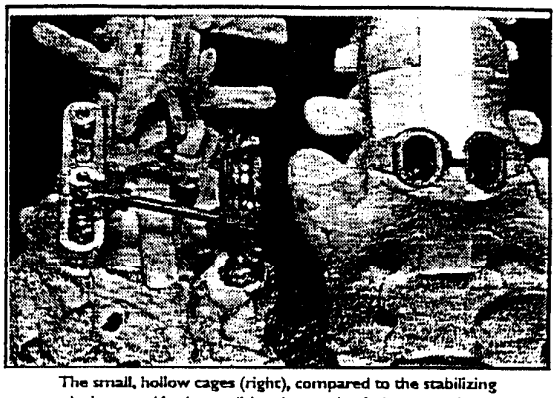
"The truth is, there are few human conditions more painful and debilitating—or more common—than acute and chronic back pain resulting from a herniated, collapsed, or degenerative disk," says Dr. Lestini. "Now we have minimally invasive surgical options to offer patients that represent dramatic improvements over traditional procedures of the past."

When Vertebrae Scrape

"What happens in the process is pretty straightforward," Dr. Lestini explains. "Between each pair of vertebrae is a disk that cushions the spinal column. When a disk degenerates, the vertebrae begin scraping against one another, causing severe pain. To relieve the pain, the surgeon's job is to remove the disk and attempt to fuse the affected vertebrae together."

In the traditional procedure, called a posterior fusion, surgeons cut through the thick musculature of the back and, in most cases, attach pedicle screws or rods to the spine, seeking stability. "Rehabilitation after the posterior fusion is lengthy; it takes about a year to get the involved muscles stabilized post-operatively," Dr. Lestini notes. "And then it takes another year or two after that to return those muscles to near-normal strength. The scarred muscles and nerves are never really normal again after extensive posterior surgery."

The new surgical procedure presents a markedly different picture, for the operation itself and for recovery.



The small, hollow cages (right), compared to the stabilizing devices used in the traditional posterior fusion procedure.

Titanium Cages

At the heart of the new surgical technique are small, hollow, extremely strong titanium fusion cages that are implanted between the affected vertebrae (see photos). Use of these cages has been rigorously tested over the past several years, with notable success.

Recently, Dr. Lestini and Triangle Spine were tapped as one of a dozen sites in the country (the only one in North Carolina) to conduct FDA clinical trials of a new type of fusion cage, intended specifically for use with the laparoscope. The procedure is called Instrumented Laparoscopic Spinal Fusion (ILSF). Dr. Lestini has received extensive training in implantation techniques for this new type of surgery.

Dr. Lestini views an X-ray film that shows a cage implant between two vertebrae.

During ILSF, Dr. Lestini makes tiny incisions in the patient's abdomen and inserts a laparoscope, a pencil-thin camera that allows him to see the internal anatomy on a video screen. Drs. Ng, Stirman, Powell, Faust, Covington, and Draeglin of Wake Surgical Center, Inc., assist Dr. Lestini in the abdominal surgery.

"The small, tapered, titanium tube that we call a 'cage' is packed with the patient's bone—which we harvest in very small quantity from the hip. The damaged disk is removed with instruments placed through the tiny portals without having to make standard surgical incisions. I use the scope to insert cages into the affected disk, thus providing stability to the spine. The important back muscles and nerves are not harmed in any way. They are left intact and unscarred."

In about three months, says Dr. Lestini, the grafted bone fuses to the bone of the spine above and below the affected disk. "This is the best way I've ever seen to fuse a disk," he says. "The idea is to put bone in and around the joint to stop the joint from pinching nerves and causing pain. The cages stabilize the spine and protect the bone graft until the graft fuses. They provide the same degree of stability as the posterior screws, plates, and rods, without the soft tissue trauma of the posterior approach. It's a non-invasive procedure with minimal muscle loss, compared with the traditional procedure, which involves six- to eight-inch incisions and a very long recovery time."

The cage procedure with a small, open incision "is in almost every respect as successful as the laparoscopic technique, and it has had FDA approval for some time," Dr. Lestini notes. "We've had about a 98 percent fusion rate with the one-level cage device and more than 90 percent fusion with the two-level device—when two disks are involved. These are really excellent results, in a group of patients with complicated, serious problems including workers' compensation cases."

With the cage technology, patients return to work in four to six weeks as compared with four to six months following posterior fusions. Hospital stays are usually no more than two days compared to about a week for the traditional procedure, and the cost for the new technique is about $9,000 less than the posterior fusion.

For more information about the treatment of spinal pain and disorders, contact:
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For Immediate Release

"Cage" Technology Revolutionizes Approach to Spinal Fusion Surgery

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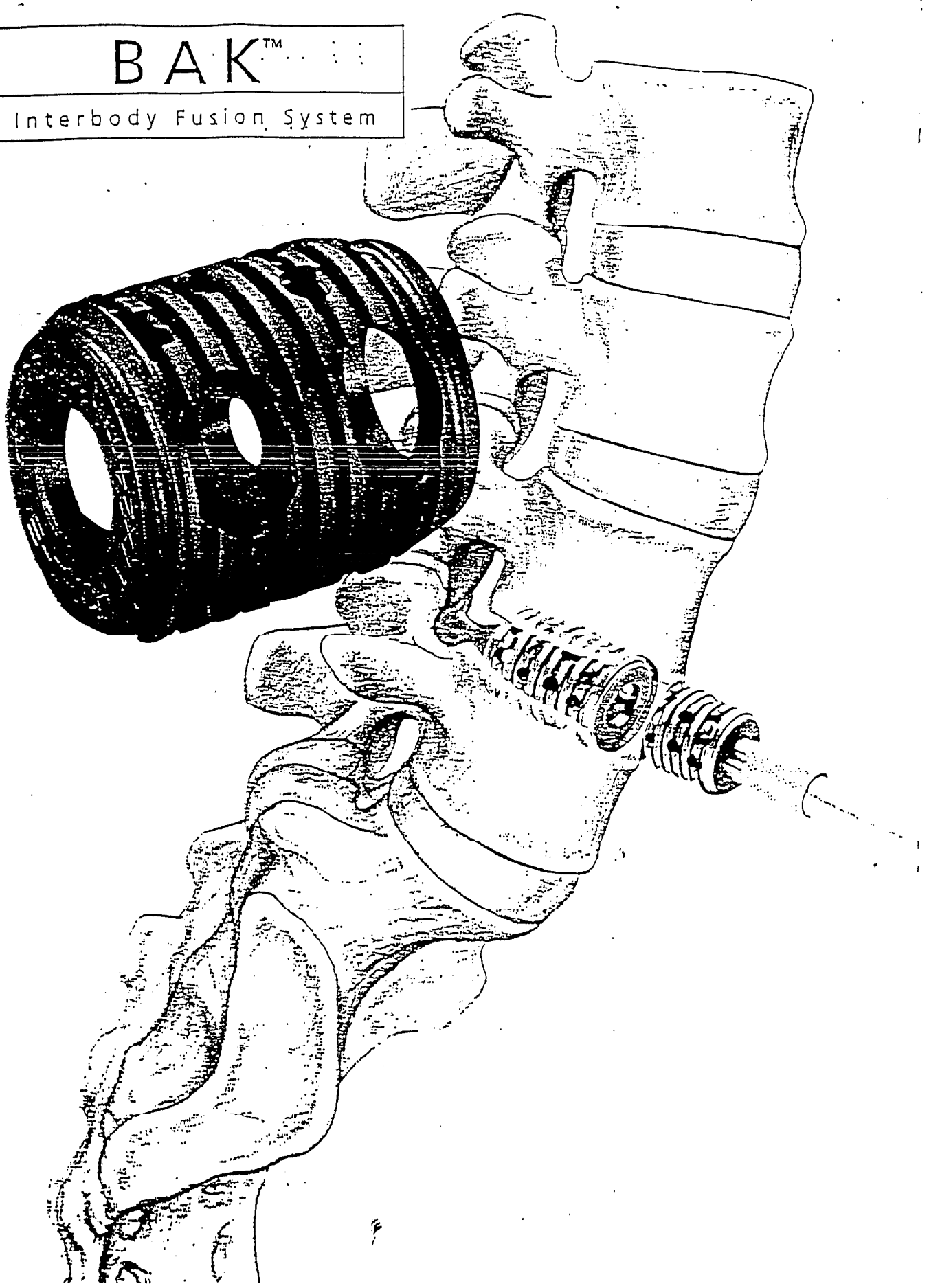
BAK™

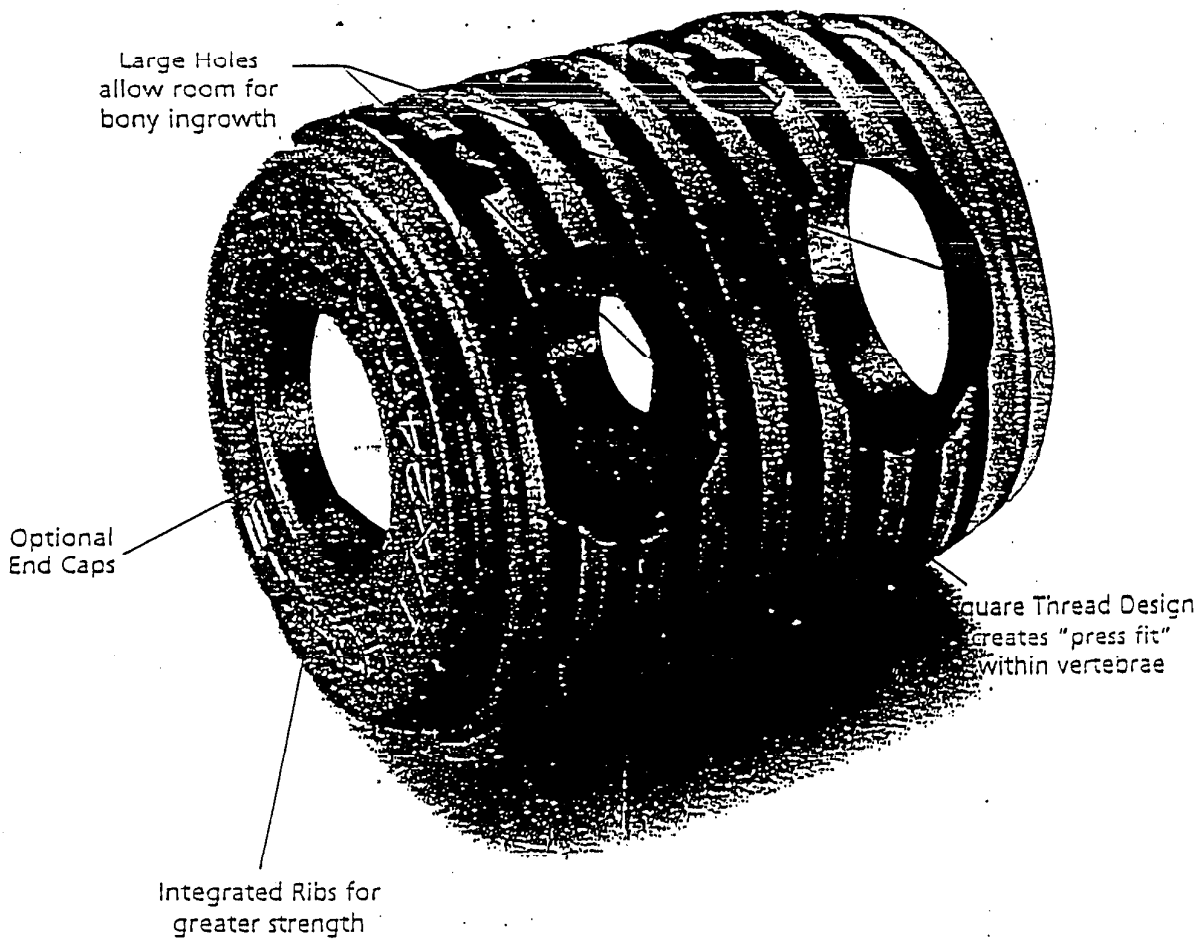
Interbody Fusion System



THE BAK™ INTERBODY IMPLANT

The BAK™ implant represents a breakthrough in the treatment of patients suffering from chronic low back pain of discogenic origin. The implant has several large fenestrations to promote bony through-growth, and is internally ribbed to enhance strength.

When placed into a re-established disc space, the square threads and annular tension create a press fit which provides excellent segmental stability.



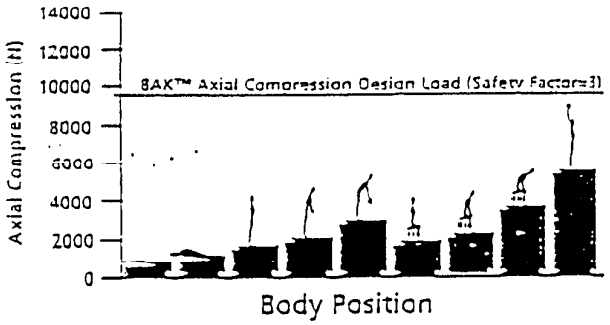
BIOMECHANICAL PROPERTIES

The biomechanical properties of the unique BAK™ implant design provide exceptional immediate stability, and the strength to ensure long-term viability.

STRENGTH

FATIGUE AND ULTIMATE: Axial compressive forces generated in the lumbar spine by activities of daily living (ADL) have been documented at 3200N (700 lb.).[1] Interbody fusion implants are intended to be permanent and will always experience loading, even after fusion. Therefore it is critical in cyclical fatigue strength testing that they far exceed this documented ADL level.

LUMBAR COMPRESSIVE STRENGTH



After five million cycles ranging from 880N to 9600N at 15 Hz, there were no device failures. (data on file)

This criterion established for the BAK™ implant accommodates compressive fatigue loads three times greater (9600N) than those of ADL. This ensures long-term structural integrity in worst-case scenarios.

The BAK™ System implant has withstood compressive loads beyond 30.6kN without failure. This is 2.5 to 7.5 times greater than other interbody implants[2,3], and more than 30 times greater than pedicle fixation systems.[4,5]

To reach this high level of performance, the BAK™ implant incorporates a series of integrated internal ribs at the ends and in the middle of the implant.