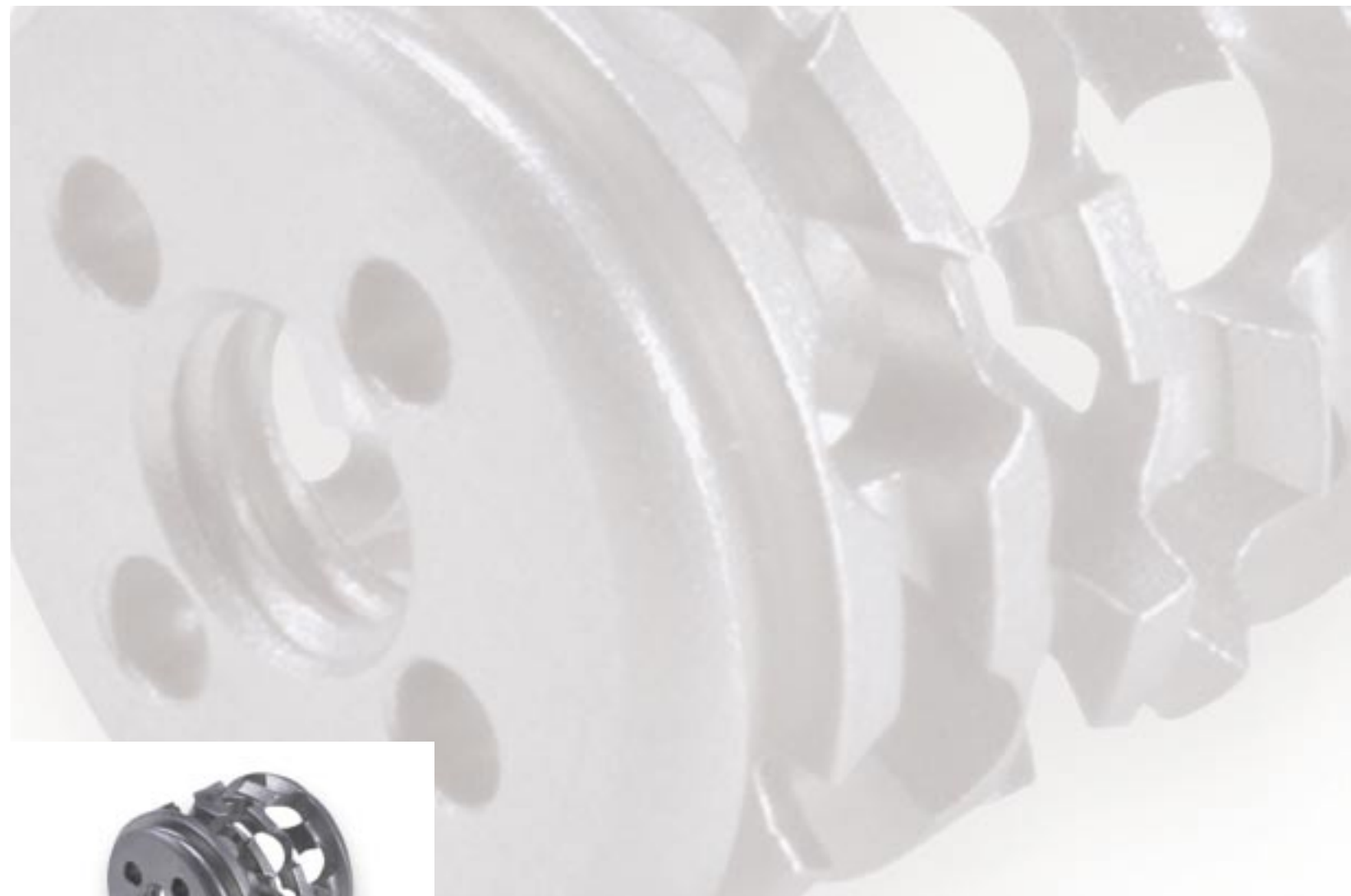




**BAK/C[®]
Cervical
Interbody
Fusion System**



The Comfortable Choice for Cervical Fusion



BAK/C[®] Cervical Interbody Fusion System

The **BAK/C[®] Cervical Interbody Fusion System** represents a breakthrough for patients experiencing degenerative disc disease of the cervical spine. The system gathers bone during decompression, bone bed preparation and implantation. The self-packing of bone into the implant's chamber produces a local autograft, eliminating the need to harvest from the iliac crest.

Unique Design Yields Distinct Results

- Leading V-shaped threads shave local bone into the implant's chamber, creating local autograft
- Chamfered leading edge for easy insertion
- Square-thread design creates a press fit within vertebral endplates
- Titanium alloy provides high fatigue strength
- Hollow, porous design enables bony growth through all sides
- Available in four sizes to match anatomical needs



The Comfortable Choice for Cervical Fusion

No-harvest autograft

The *BAK/C* Cervical Interbody Fusion System creates autograft without harvesting additional bone from the iliac crest. The self-packing feature of the *BAK/C* implant draws bone into the implant's chamber during insertion, creating local autograft. The no-harvest feature eliminates morbidity associated with harvesting from the iliac crest while preserving the benefits of autograft. The bone graft inside the implant and cancellous bone from the vertebral bodies traverse the entire implant, producing a solid bony union between the vertebral bodies.

Clinical studies indicate the *BAK/C* system:

- Reduces patient pain during recovery¹
- Shortens patient recovery time¹
- Allows for efficient use of surgical time¹

Built-in stability

The *BAK/C* implant is constructed of a titanium alloy with a long history of use in a wide variety of implants. The square threads and cylindrical design provide resistance to pull-out. The implant's holes, spaced around the implant, allow for bony through-growth. Further facilitating initial stability of the construct is the pre-distraction technique that tenses ligamentous structures.

Clinical study results demonstrate long-term effectiveness in:

- Fusion success^{1,2}
- Neck pain success¹
- Overall radicular success¹
- Function success¹

No-profile comfort

The *BAK/C* system is a no-profile option to traditional and low-profile fusion systems. The interbody placement of the *BAK/C* implant provides an anatomic profile and normal anatomic contact between the anterior cervical spine and surrounding soft tissue. Patients do not experience the pain and discomfort of esophageal dysphagia common with other implants.¹

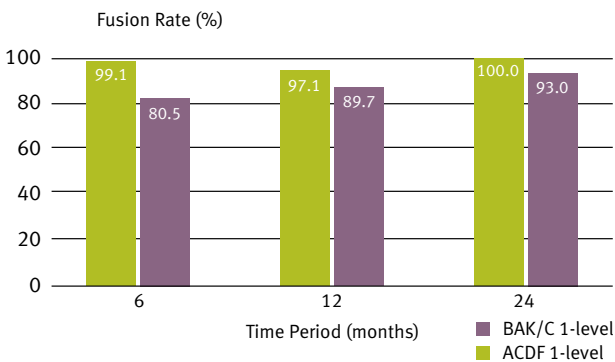


Clinical Success Backs Up the *BAK/C* System

Clinical studies demonstrate that the *BAK/C* Cervical Interbody Fusion System is safe and effective in the treatment of degenerative cervical disc disorders.

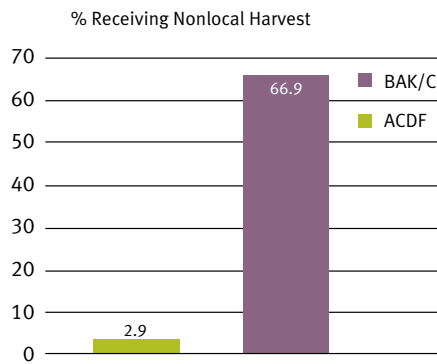
“The use of interbody fusion rates in this study produced comparable results to anterior fusion with iliac crest autograft, and they appear safe and effective in the treatment of degenerative disc disease.”²

Fusion Rates¹



Fusion rates occurred early in the *BAK/C* implant group.

Nonlocal Bone Harvest Rates¹

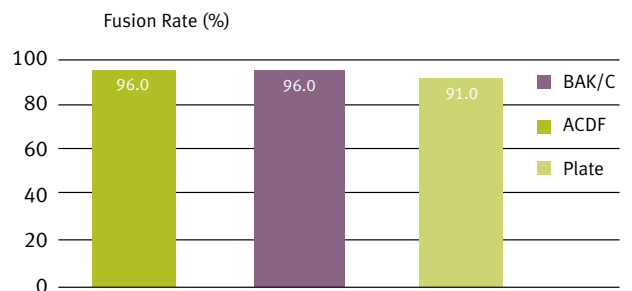


The need to harvest nonlocal autogenous bone was minimized for patients receiving *BAK/C* implants.



Post-operative radiograph taken at seven months.

Fusion Rates³



The *BAK/C* implant group presented successful fusion rates when compared with ACDF and plates at a minimum of one year of follow-up.

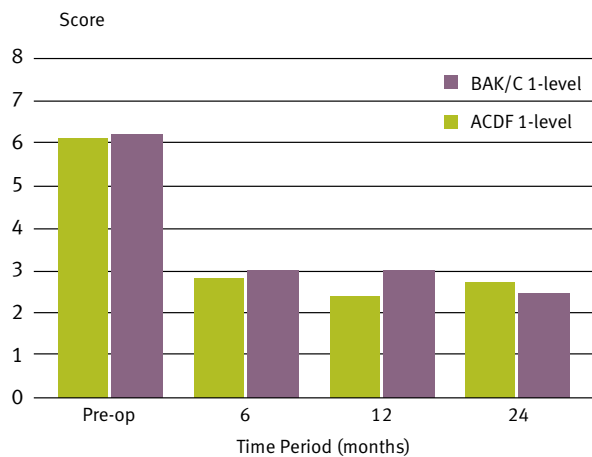
Surgical Variables and Outcomes²

	BAK/C n=37	ACDF n=17
Duration of hospital stay		
<1 day	11%	12%
>1 day	89%	88%
Operating time (min)	58.1 ± 15.3	55.7 ± 10.8
Blood loss (ml)	70.7 ± 30.2	79.4 ± 29.4
Graft pain		
1st post-op visit	0%	94%
Last post-op visit	0%	31%

The *BAK/C* implant group compared favorably with the Anterior Cervical Discectomy and Fusion (ACDF) group in surgery-related variables and outcomes.

“... outcomes after a cervical fusion procedure with a threaded cage are the same as those of a conventional uninstrumented bone-only anterior discectomy and fusion, with a low risk of complications and rare need for autogenous bone graft harvest.”¹

Neck Pain¹



Significant relief of pain after surgery was experienced by both the *BAK/C* implant and ACDF groups.

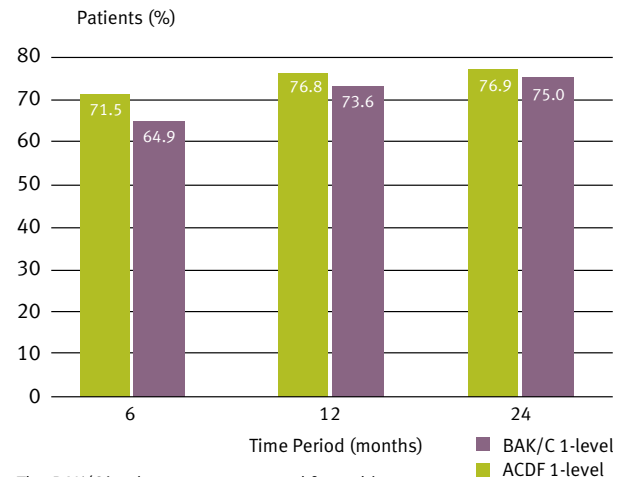
Selected Complication Rates¹

	BAK/C n=179	ACDF n=142
Continued/new symptoms	0	0.7%
Degeneration of another disc	0	1.4%
Graft collapse/implant failure	0	4.2%
Pseudoarthrosis	0.6%	0.7%

The complication rate in the *BAK/C* implant group was lower overall than in the ACDF group.

“... the *BAK/C* cage for anterior cervical interbody fusion has economic advantages while achieving at least equal fusion rates and avoiding donor-site morbidity compared to conventional ACDF and plate fusions.”³

Radicular Symptom Improvement¹



The *BAK/C* implant group compared favorably with the ACDF group at 6, 12 and 24 months.

DEVICE DESCRIPTION: The *BAK/C* Interbody Fusion System consists of hollow, perforated, threaded, cylindrical implants. The *BAK/C* implants are available in several diameters to accommodate variations in patient anatomy; all implants are 12mm in length. Implants are made from titanium alloy (Ti-6Al-4V), conforming to ASTM F136. Instruments designed for implantation of implants are made from stainless steel, conforming to ASTM F899. Implants may be implanted singularly or in pairs at the affected disc level.

INTENDED USE/INDICATIONS: The *BAK/C* implant is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. *BAK/C* implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone.

CONTRAINDICATIONS: *BAK/C* devices should not be implanted in patients with: an active infection, an allergy to titanium or titanium alloy.

PRECAUTION: Surgeons should not implant the *BAK/C* Interbody Fusion System until receiving adequate training regarding the surgical technique. Inadequate training may result in poor patient outcomes and/or increased rates of adverse events. See the *BAK/C* Interbody Fusion System Surgical Technique Manual for more information on proper implantation technique.

- ¹ Hacker RJ, et al. A prospective randomized multicenter clinical evaluation of an anterior cervical fusion cage. *Spine*. 2000;25:2646-2654.
- ² Hacker RJ. A randomized prospective study of an anterior cervical interbody fusion device with a minimum of 2 years of follow-up results. *Journal of Neurosurgery*. 2000;93:222-226.
- ³ Cauthen JC. Anterior cervical fusion: a comparative analysis of cage, dowel, and dowel-plate constructs. Presented at the Cervical Spine Research Society; December 2000; Charleston, South Carolina.

Contact your Zimmer Spine representative or visit us at www.zimmerspine.com



Zimmer Spine, Inc.
7375 Bush Lake Road
Minneapolis, MN 55439-2027
U.S.A.

Phone 952.832.5600
or 800.655.2614
Fax 952.832.5620