



The Informed Patient's Guide to
**ANTERIOR CERVICAL
DISCECTOMY & FUSION**
for the Cervical Spine utilizing the

PRECISION SPINE
DAKOTA ACDF™
STANDALONE CERVICAL SYSTEM



An Introduction



This brochure is designed to provide patients with general information concerning cervical spine surgery utilizing the Precision Spine Dakota ACDF™ System. It is not intended to replace or supersede any consultations you might have had, or wish to have, with any physician.

ACDF stands for Anterior Cervical Discectomy and Fusion.

ANTERIOR

A surgical approach through a small incision made in the front of the neck utilizing natural tissue planes to minimize tissue and muscle damage as well as postoperative pain.

CERVICAL

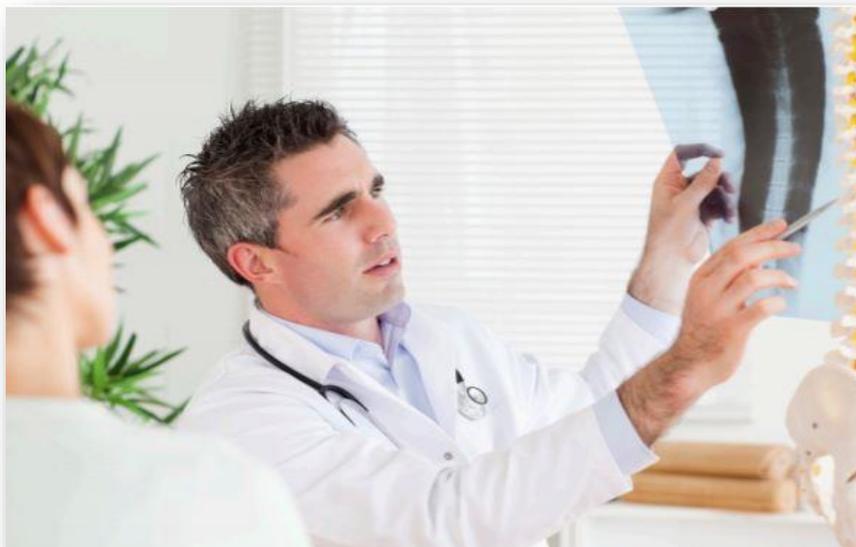
The cervical portion of your spine is located in your neck.

DISCECTOMY

The word literally means cutting out the disc. The intervertebral discs are located between the bony bodies of your spine and act like shock absorbers. Pain occurs when one or more of these discs is damaged. A discectomy removes the damaged disc to relieve pressure on the spinal cord and spinal nerves.

FUSION

An interbody spacer (often called a cage) is inserted into the area vacated by the removed disc and is held in place by a plate and screws.



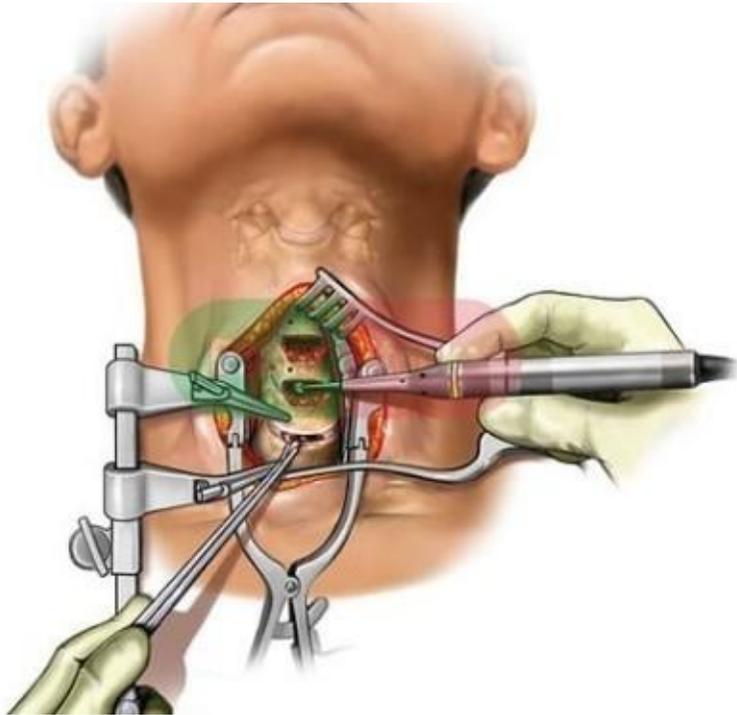
The ACDF Procedure

PATIENT PREP

You will lie face up on the operating table and administered anesthesia while your neck area is cleansed and prepped.

THE INCISION

A small incision is made in your neck. The surgeon creates a tunnel to your spine by moving aside muscles in your neck and retracting your trachea, esophagus and arteries. The muscles supporting the front of your spine are then lifted and held aside, giving your surgeon a clear view of your spinal vertebrae and discs.



LOCATING THE DAMAGED DISC

Using a fluoroscopic imaging device (a type of X-ray), your surgeon will pass a very thin needle into the area to identify the affected vertebra and disc. A special retractor is used to spread apart the vertebrae above and below the damaged disc.

REMOVING THE DISC

Your surgeon will cut the outer wall of the damaged disc then remove entire disc itself using small grasping tools. Any disc material that is pressing on the spinal nerves is also removed.

The ACDF Procedure (continued)

DECOMPRESSING THE NERVE

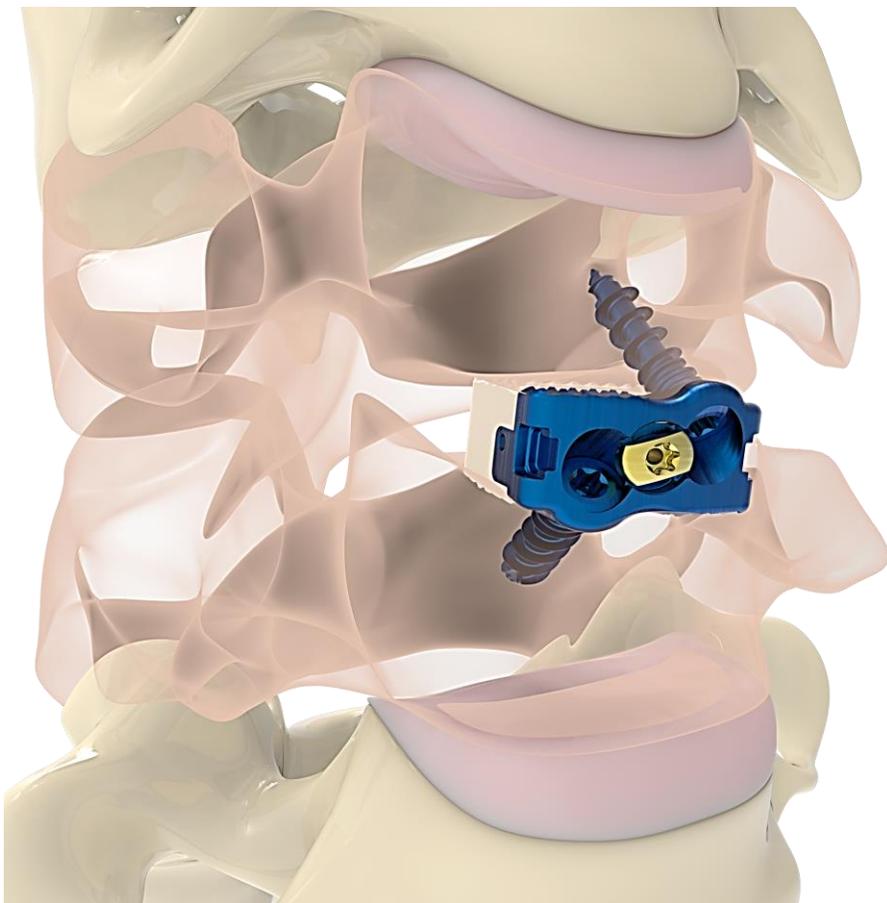
Your surgeon will remove bone spurs and free the nerve.

INSERTING THE DAKOTA ACDF DEVICE

The Dakota ACDF System is a standalone device, which means it integrates an interbody spacer, bone graft material and bone screws without a separate plate. The interbody spacer portion is packed with bone graft material and inserted into the empty disc space. The integrated device is held in place by screws to help secure the entire construct to the vertebrae while fusion occurs.

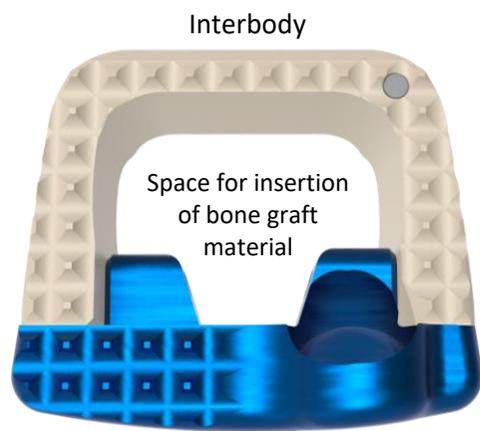
CLOSING THE INCISION

The retractors used to spread the tissue elements are removed. Your muscle and skin incisions are sutured, and a surgical glue may also be used to fully cover the incision for an added measure of protection.



Implants

Pictured on this page are the elements of the Precision Spine Dakota ACDF™ (Anterior Cervical Discectomy & Fusion) System that will be implanted in your spine during surgery.



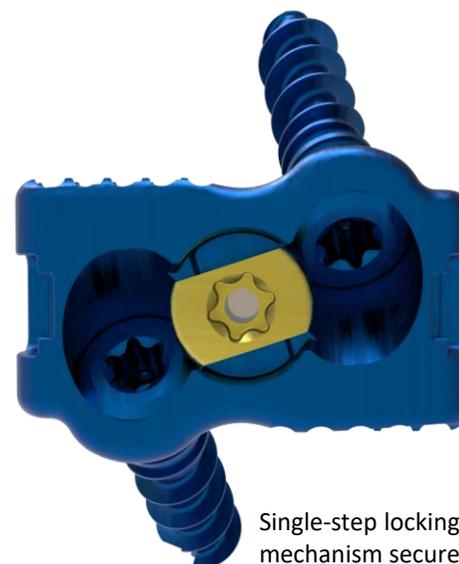
Interbody

Space for insertion of bone graft material

Integrated plate



Screws secure construct to bone



Single-step locking mechanism secures all elements of the construct



Profile view of Dakota ACDF construct



Dual thread screws maximize interface with cortical and cancellous bone. Cortical bone is compact bone imperative to body structure and weight bearing. Cancellous bone is the meshwork of spongy tissue of mature adult bone typically found at the core of vertebral bones in the spine.

Post-Op Care



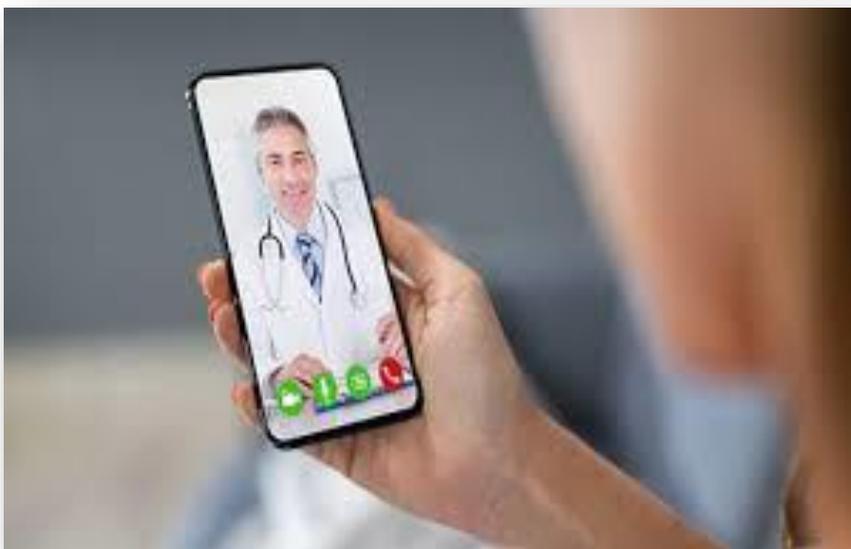
Your physician will provide you with detailed postoperative instructions, which may include, but not be limited to, the following:

- *Try not to bend or twist your neck*
- *Avoid lifting anything heavier than 5 pounds*
- *Do not engage in any strenuous activity including yard work, housework and sex*
- *Do not use ANY nicotine products as it prevents new bone growth and may cause a failed fusion*
- *Do not drive until your follow-up visit with the surgeon*
- *Do not drink alcoholic beverages of any kind*
- *Take any prescribed pain medication only as directed, and do not take any other medication with your surgeon's approval*

ALERT YOUR PHYSICIAN

Contact your physician immediately if you experience any of the following:

- *Fever over 101.5° F*
- *Nausea or vomiting*
- *Severe pain*
- *Rash or itching at the incision site*
- *Swelling or tenderness in the calf of one leg*
- *Onset of any new tingling, numbness or weakness in your arms or legs*
- *Dizziness, confusion or excessive drowsiness*



Risks Associated with ACDF Surgery



Undergoing any type of surgery contains risks and possible complications. These should be discussed with your physician well in advance of undergoing surgery. Your physician's guidance before and after the procedure will help lead to successful recovery. General complications include bleeding, infection, blood clots and reactions to anesthesia. Specific complications related to ACDF surgery may include:

HOARSENESS/SWALLOWING DIFFICULTIES

In some cases, you may become temporarily hoarse because the nerve that controls your vocal cords is affected during the procedure.

FAILED FUSION

It is possible that the bones might not fuse together. Commonly, this is because of smoking, osteoporosis, obesity and malnutrition.

HARDWARE ISSUES

The plates and screws used during ACDF surgery constitute the hardware and may move or break before the bones are completely fused. A second surgery may be needed to repair or replace the hardware.

BONE GRAFT MIGRATION

However rare, soon after surgery bone graft may move from its correct position between the vertebrae. A second surgery may be needed to reposition the bone graft so that fusion can take place.

ADJACENT SEGMENT DISEASE

When one spine segment is fused, it causes added stress to the discs and bones above and below. This can eventually cause degeneration of the adjacent level(s) and cause pain.

NERVE DAMAGE

Spine surgery of any kind carries with it the risk of nerve damage. This can lead to numbness or persistent pain.

Commonly Asked Questions

CAN I SHOWER AFTER SURGERY?

Depending upon your surgical incision, you may have restrictions regarding if or when you can take a shower. Ask your physician for appropriate instructions.

WILL I HAVE A SCAR?

Your physician will discuss the incision(s) that will be made during the procedure.

WHEN CAN I DRIVE?

Following surgery, you may be cautioned against engaging in certain activities, such as driving. Your physician will let you know when you may drive again.

CAN I TRAVEL?

The implants used in this procedure that you now carry in your body may activate an airport metal detector. It is suggested that you call your local airport authority before traveling to obtain information that might help you pass through security more quickly and easily. Ask your physician to provide a patient identification card that you can use to alert airport security workers.



Resources



For additional information about Precision Spine and its products, you may visit:

<https://www.precisionspineinc.com/index.html>

If you would like to learn more about patient support and education for chronic back, leg and neck pain sufferers and their loved ones, please visit:

<https://www.thebetterwayback.org>

If you have any questions about spine surgery, please call or visit your physician, who is the only person qualified to diagnose and treat your spinal condition.

This patient information brochure is not intended to be a replacement for professional medical device.

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration. Refer to:

<https://www.tga.gov.au/>



Australian Distributor:

E4 SURGICAL

www.e4surgical.com

Email: admin@e4surgical.com



Australian Distributor:

E4 SURGICAL

www.e4surgical.com

Email: admin@e4surgical.com

www.precisionspineinc.com

