



ANTERIOR CERVICAL DISCECTOMY & FUSION

A C D F

# Anterior Cervical Discectomy and Fusion

## Patient Information

This brochure will help you understand more about:

- ▶ **General conditions of the spine**
- ▶ **Information about surgical treatment of the cervical spine**
- ▶ **What to expect from surgery**

The decision to receive medical treatment is individualized to the patient and the patient's symptoms. The information presented within this brochure may not apply to your condition, treatment, or outcome, as surgical techniques vary and complications can occur. It is important to discuss the viability of this procedure with your physician to decide whether this treatment option is right for you.

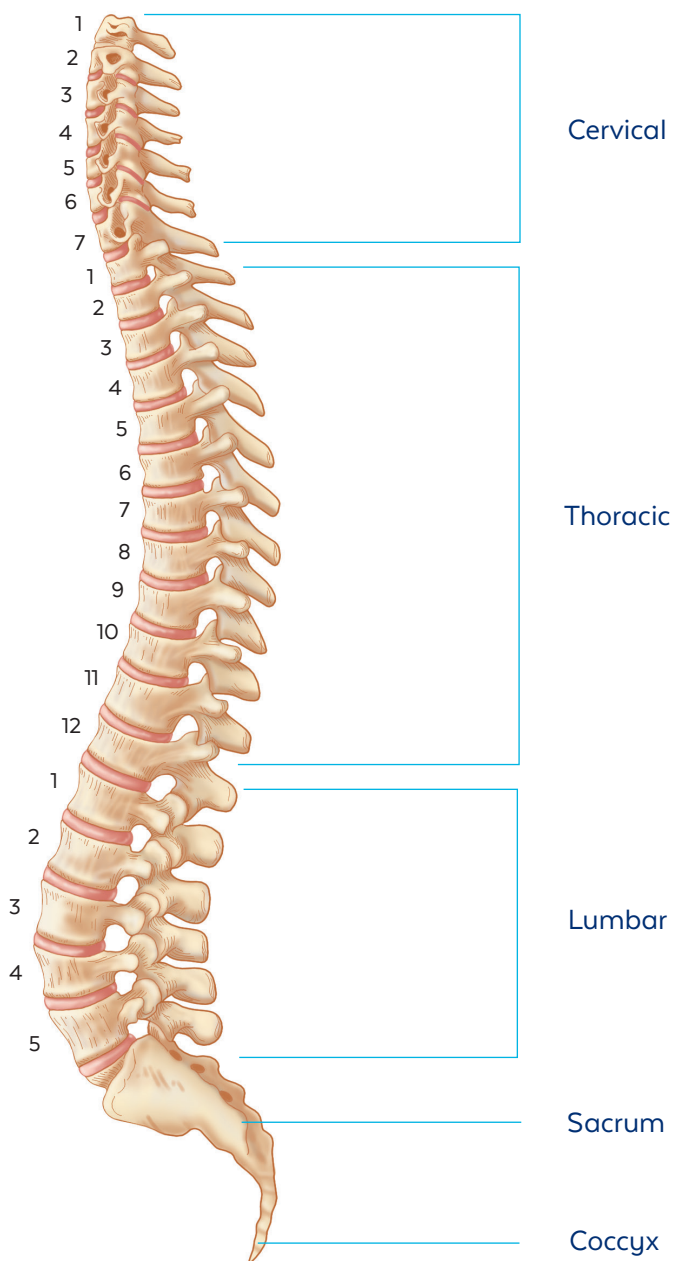
This brochure is intended to be an educational resource only and is not meant to be a warranty or to replace a conversation between a patient and their physician or member of their health care team. Please consult your physician for a complete list of indications, precautions, clinical results, and other important medical information that pertains to this procedure.



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# Anatomy of the Spine



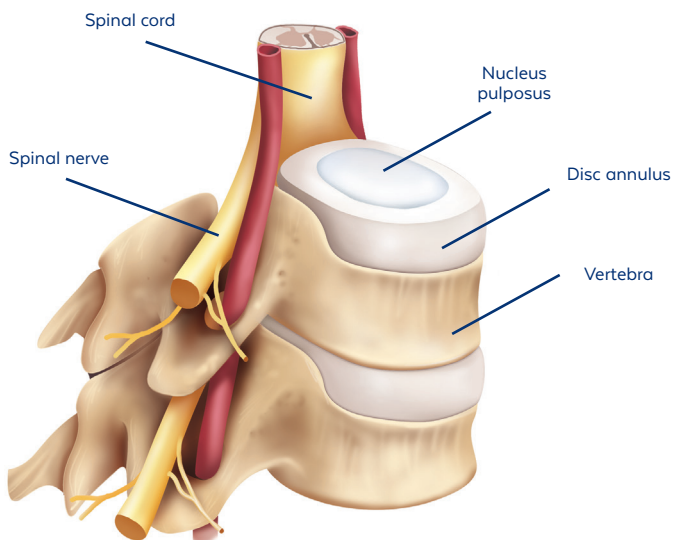
The spine is composed of vertebrae divided into three main parts:

- ▶ Cervical (7 vertebrae)
- ▶ Thoracic (12 vertebrae)
- ▶ Lumbar (5 vertebrae)

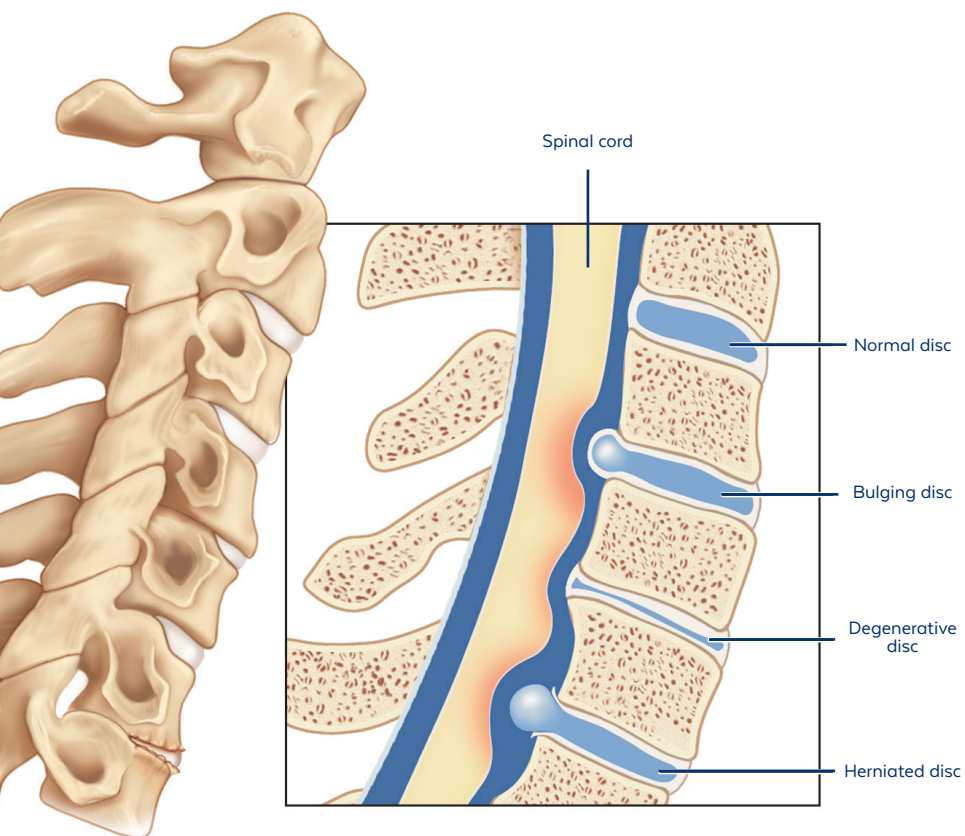
Below the lumbar spine is the sacrum, which is comprised of five fused vertebrae. At the end of the spine is the coccyx, or the tailbone.

The vertebrae bear the weight of the upper body and provide points of attachment for muscles and ligaments. They also protect the spinal canal (the cavity that runs successively through each of the vertebrae and contains the spinal cord) and provide exit points for spinal nerves.

The individual vertebrae are separated by intervertebral discs, which act as cushions or shock absorbers between the vertebral bodies.



# Conditions of the Cervical Spine



In the normal spine, intervertebral discs act as a cushion between vertebrae. Age, genetics, injury, and everyday wear and tear caused by routine activities can contribute to damage and deterioration of the discs in your neck. As a result, someone may experience one or more of the following conditions.

### ***Degenerative Disc Disease***

Over time, the discs can lose flexibility, elasticity, and height. When this happens, the discs' shock-absorbing characteristics are reduced, which can lead to abnormal motion or alignment and instability of the spine.

### ***Herniated Disc***

Degeneration can cause cracks and tears in the outer layer of the intervertebral disc, through which material inside the disc can be forced out, causing the disc to bulge (protrusion), break open (extrusion), or break into pieces (sequestration), putting pressure on a nerve root or the spinal cord. Myelopathy is a condition that can result from compression on the spinal cord.

### ***Spinal Stenosis***

Narrowing of areas in the spine that cover and protect the nerve roots and the spinal cord. This can be caused by herniated discs, osteophytes (bony projections), or ligaments compressing the spinal cord.

### ***Spinal Instability***

Condition that occurs when the stabilizing structures of the spine become compromised by disease, age, or damage. Numerous factors can lead to spinal instability, including degeneration or trauma.

### ***Trauma***

Traumatic events such as car accidents, sports injuries, and other serious incidents can cause injury to the spine, including fractures and dislocations.

# Conditions of the Cervical Spine (Cont'd)

## ***Spinal Deformity***

Spinal deformity is an abnormal curvature to the spine. The type of deformity depends on the curvature.

- ▶ Scoliosis – abnormal sideways curve
- ▶ Kyphosis – abnormal outwards curve that may create the appearance of a hunch back
- ▶ Lordosis – abnormal inward curve

## ***Pseudarthrosis***

Pseudarthrosis refers to failed previous fusion.

## ***Spondylolisthesis***

Spondylolisthesis is a condition in which one of the vertebrae slips forward or backward. If left untreated, this can lead to deformity of the spine and narrowing of the spinal canal.

Symptoms of these conditions can include:

- ▶ Loss of motion and dexterity, gait imbalance, and incontinence
- ▶ Tingling or numbness in the arm or hand
- ▶ Radiating pain, weakness, and/or numbness in the shoulders, arms, and neck

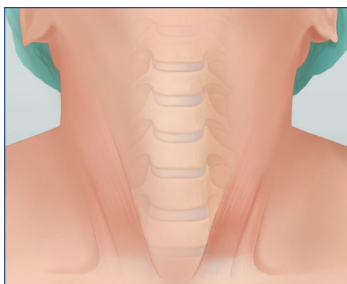
These symptoms may be treated with non-surgical methods for as long as possible. Treatments include rest, ice or heat, weight control, exercise, physical therapy, epidural injections for pain management, and medication.

If these non-surgical treatments do not bring relief after a period of time, surgical treatments may be recommended to take pressure off the nerves that are causing pain by restoring alignment of the spine and/or the space between the vertebrae.



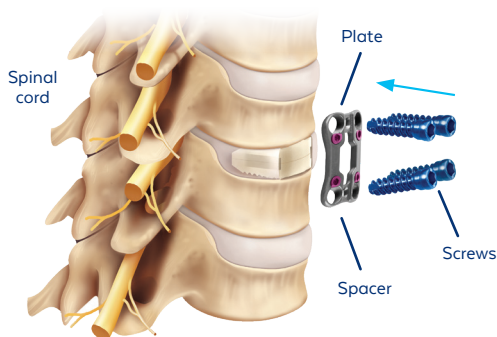
# What Is an Anterior Cervical Discectomy and Fusion (ACDF)?

The primary goal of this procedure is to relieve pressure on either the nerve roots or spinal cord and/or treat an unhealthy disc in the cervical spine.

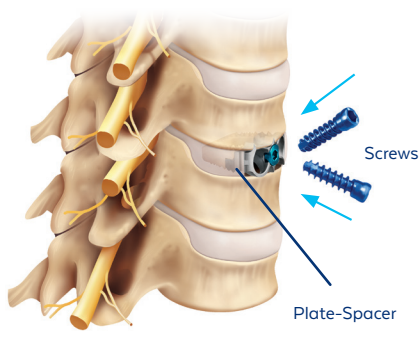


Anterior cervical means  
"front of the neck"

The unhealthy disc is removed, via discectomy, and replaced with an interbody fusion implant. A plate, spacer, and screws construct, or an integrated plate-spacer with fixation (i.e., screws or anchors), may be used to hold the vertebrae in place while fusion (joining of two bones) occurs.






Interbody spacer with cervical  
plate and screws



Integrated plate-spacer  
with screws

# What Is an Anterior Cervical Discectomy and Fusion (ACDF)? (Cont'd)

Globus Medical offers a variety of implants for ACDF surgery.

Implant Type	Implant Name*	Cervical Spine Conditions**
Interbody Spacers 	PATRIOT® COLONIAL® SUSTAIN® Medium SUSTAIN®-R Medium REVEL® HEDRON C™ HEDRON IC™	Degenerative disc disease, instability, trauma, fractures, deformity (scoliosis, kyphosis, lordosis), myelopathy, spinal stenosis, pseudarthrosis
Integrated Plate-Spacers (and screws or anchors) 	COALITION® COALITION MIS® COALITION AGX® COALITION® RP REVEL®-S HEDRON IC™	Degenerative disc disease, instability, trauma, fractures, deformity (scoliosis, kyphosis, lordosis), myelopathy, spinal stenosis, pseudarthrosis
Cervical Plates (and screws) 	ASSURE® ASSURE®-T PROVIDENCE™ UNIFY® VIP® XTEND® RESONATE®	Degenerative disc disease, trauma, fractures, tumors, deformity (scoliosis, kyphosis, lordosis), spondylolisthesis, spinal stenosis, pseudarthrosis

Visit Globus Medical's website at <https://www.globusmedical.com/international/>

\*These products may not be available in your region.

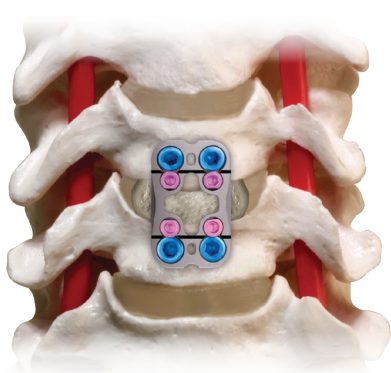
\*\*See definitions starting on page 8.

These implants are composed of polyetheretherketone (PEEK), titanium alloys, commercially pure titanium, cobalt chromium alloy, tantalum, and/or nitinol. These materials are biocompatible and have a history of clinical use. If you have an allergy to any of these materials, please consult your physician.

## How Is an ACDF Performed?

A small horizontal incision (a surgical cut made in skin) is made in the anterior (front) of the neck to either the left or right of the center. The soft tissues of the neck are gently separated to allow access to the surgical site. Surgical instruments are used to remove the intervertebral disc and decompress (relieve pressure on) the nerve structures.

To fill the vacant disc space and join the vertebrae together, an interbody fusion implant is used. If a combination of a spacer and a plate is used, the spacer is placed into the disc space with the plate placed over top to hold it in place and screws are inserted through the plate into the upper and lower vertebrae. Or, if an integrated plate-spacer implant is used, the implant is placed into the disc space and fixation hardware, screws in the below example, are inserted to secure the implant in place.



Spacer with cervical plate and screws



Integrated plate-spacer with screws

Over time, the vertebrae can grow together through fusion. This process varies among patients and can take anywhere from a few months to a year.

# Frequently Asked Questions

## What Should I Expect From Surgery?

Treatment with a minimally invasive ACDF may help you return to normal activities. Patients may notice improvement of some or all symptoms, and pain from surgery may diminish 2 to 4 weeks after surgery. However, recovery time varies among patients.

It is the surgeon's goal for the patient to eventually return to their preoperative activities. A positive attitude, reasonable expectations, and compliance with your doctor's post-surgical instructions may all contribute to a satisfactory outcome.

## When Will I Be Able to Return to Work?

The amount of recovery time needed prior to returning to work will vary depending on the surgery, your job, and you as an individual. Please consult your surgeon for an individual recommendation.

## How Long Will I Have Restricted Activities?

As with any surgery, the duration of time between procedure and return to normal activities is different for every patient. Your surgeon may provide a list of activities you should avoid during the first 6 weeks after surgery.

## How Long Will My Implant Last?

The device lifetime for these implants is one year, in which it is expected that the devices will achieve their intended purpose (to support fusion) and maintain performance until fusion occurs. After fusion occurs, the devices are made to survive the life of the patient. Cervical plates can be removed after fusion occurs; however, this is ultimately determined by the surgeon and patient.

## Can I Have an MRI After the Devices Are Implanted?

MR compatibility is shown below for these devices. Your radiologist may request this information prior to taking an MRI. These instructions are also provided in the device insert.

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### ***Cervical Spacers and Integrated Plate-Spacers***

These devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/cm) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scan conditions defined above, the devices are expected to produce a maximum temperature rise of less than or equal to 3.9°C after 15 minutes of continuous scanning.

The image artifact caused by these devices is not expected to extend beyond 35mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

### ***Cervical Plates***

These devices can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (normal operating mode)
- Quadrature body coil only

Under the scan conditions defined above, these devices are expected to produce a maximum temperature rise of less than or equal to 3.5°C after 15 minutes of continuous scanning.

The image artifact is not expected to extend beyond 55mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

## Contraindications and Adverse Effects

You may be contraindicated (not suitable) for these devices if you have an infection, congenital abnormality, tumors, degenerative diseases, fever or high white blood cell count, rheumatoid arthritis, osteoporosis, or cancer, have had prior fusions at the level(s) to be treated, or are obese, pregnant, diabetic, or not fully grown. In addition, a patient whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions may place undue stresses on the implant during healing and may be at a higher risk of implant failure.

As with any surgical procedure, complications or adverse effects may occur following the placement of these devices. These can include but are not limited to early or late implant bending, device fracture or failure, loss of fixation, subsidence, loosening, movement/migration, decrease in bone density or bone fracture, abnormal sensations, and allergic reaction to implant material.

Other adverse effects that may be associated with any spinal procedure include non-union or delayed union, pseudarthrosis (failed spinal fusion), pain, secondary surgery, bleeding, early or late infection, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, organ damage, joint inflammation, changes in spinal curvature, loss of correction, cardiovascular system compromise, respiratory problems, complications due to bone grafting, reactions to anesthesia, impotence, sexual dysfunction, restriction of activities, lack of effective treatment, paralysis, and death.

If you experience any of the above adverse effects, please contact a health professional. This list does not include all possible contraindications and adverse effects. Please consult your surgeon for additional information on this topic and how it applies to your particular medical condition.

If you experience a serious adverse effect with your implant, please report the incident to your local health authority and to Globus Medical. Some health authorities are listed below for convenience.

<b>Region</b>	<b>Authority</b>	<b>Website</b>
All	Globus Medical	<a href="https://www.globusmedical.com/international/about/contact/">https://www.globusmedical.com/international/about/contact/</a>
Australia	Therapeutic Goods Administration (TGA)	<a href="https://www.tga.gov.au/">https://www.tga.gov.au/</a>
New Zealand	Medicines and Medical Device Safety Authority (MEDSAFE)	<a href="https://www.medsafe.govt.nz/">https://www.medsafe.govt.nz/</a>
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)	<a href="https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency">https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency</a>
Other	Report to your local health authority per local guidelines	

**About Globus Medical:** Globus Medical, Inc. is a leading musculoskeletal implant company based in Audubon, PA. The company was founded in 2003 by an experienced team of professionals with a shared vision to create products that enable surgeons to promote healing in patients with musculoskeletal disorders.



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M E D I C A L

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