FLAREHAWK

INTERBODY FUSION SYSTEM

PATIENT GUIDE TO A TRANSFORAMINAL LUMBAR INTERBODY FUSION (TLIF)

Accelus

PATIENT INFORMATION

This leaflet will help you understand more about:

01 Your surgical treatment

02 A transforaminal lumbar interbody fusion (TLIF)

03 Information about the FlareHawk® Expandable Interbody Fusion System

04 What to expect from your surgery

Information in this brochure is intended for educational information on the transforaminal lumbar interbody fusion procedure only. Medical treatment decisions are individualized to each patient's anatomy, conditions, and symptoms. There are many treatment options for conditions affecting the spine. Information contained within this guide may not be applicable to your treatment. It is important to discuss treatment options, information, indications, and precautions with your physician and healthcare team.

This patient guide is given to assist in your decision-making process and understanding of the FlareHawk Interbody Fusion System made by Accelus as a surgical treatment option.

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ANATOMY OF THE SPINE

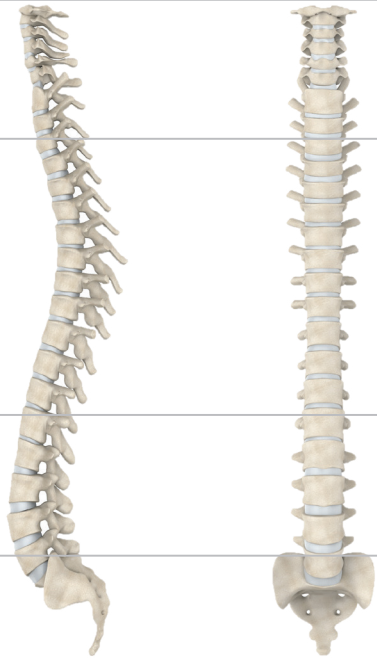
CERVICAL

THORACIC

LUMBAR

THE FLAREHAWK SYSTEM IS INDICATED FOR TREATMENT OF YOUR LUMBAR SPINE.

SACRUM



The spine provides support and structure to your entire body.

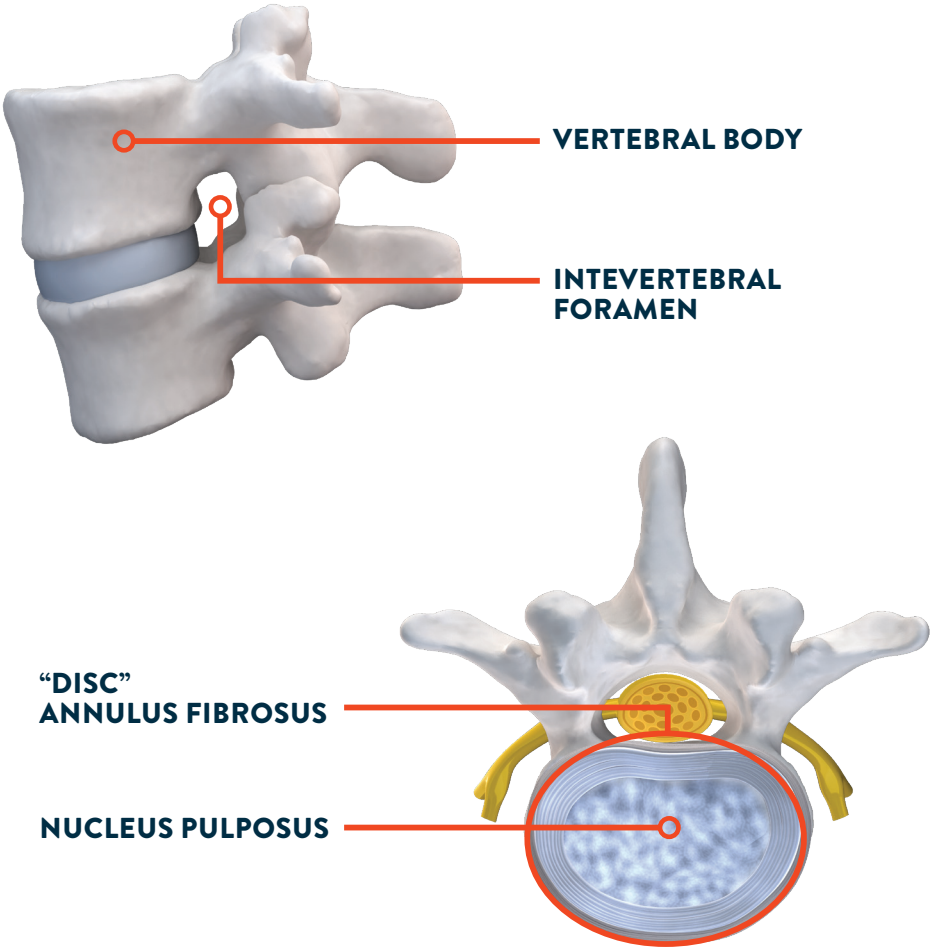
The spine is comprised of 24 small bones, referred to as “vertebrae”. The vertebrae bear the weight of the upper body and provide points of attachment for muscles and ligaments. Discs separate each vertebra and serve to provide cushion and shock absorption.

The vertebrae are stacked on one another to form your spinal column. The spinal column is divided into three main sections:

- Cervical Spine (seven vertebrae)
- Thoracic Spine (twelve vertebrae)
- Lumbar Spine (five vertebrae)

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

ABOUT THE LUMBAR SPINE



The lumbar spine has several important functions: it allows for movement of the trunk and legs, it supports and stabilizes the weight of the upper body, and it protects the spinal cord and nerves. It includes five vertebrae (L1-L5).

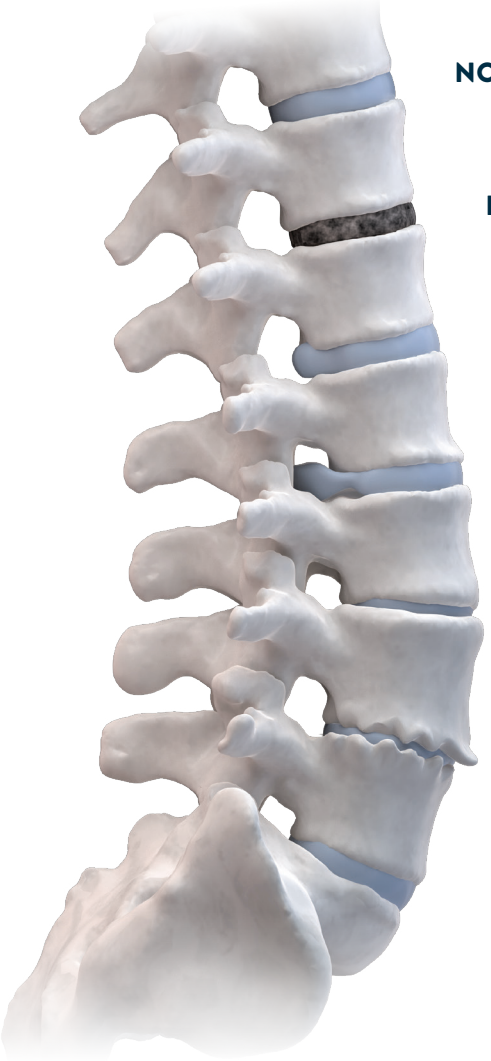
WHAT'S CAUSING MY PAIN?

GENERAL CONDITIONS OF THE LUMBAR SPINE

There are several common spine conditions that can create changes in your anatomy, potentially causing pain and loss of function. The most common conditions are degenerative disc disease, spondylolisthesis, and spinal stenosis.

These conditions can be degenerative, a function of the natural aging process, or part of a traumatic event that happens to you.

DEGENERATIVE DISC DISEASE



NORMAL DISC

DEGENERATED DISC

BULGING DISC

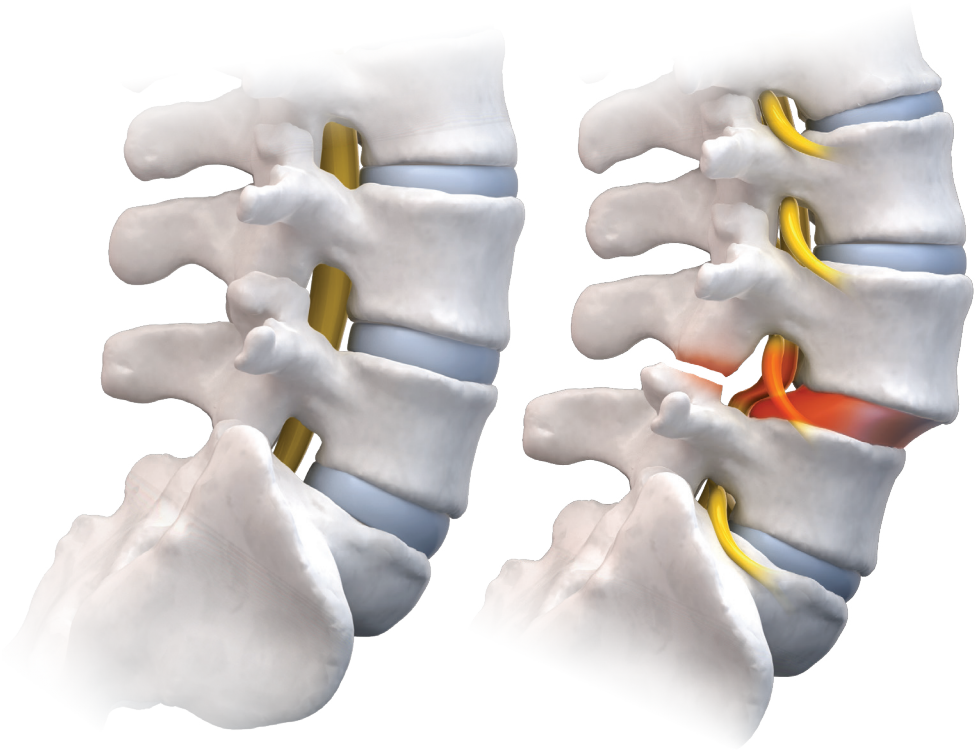
HERNIATED DISC

THINNING DISC

DISC DEGENERATION WITH OSTEOPHYTE FORMATION

Degenerative disc disease (DDD) is a term that describes deteriorating conditions of the intervertebral disc. In a healthy spine, the discs function to cushion and absorb shock between the vertebra. Over time the discs can lose flexibility, lubrication, elasticity, and height. When this occurs, abnormal alignment of the spine, bulging of the disc material, or abnormal motion can follow, resulting in pain.

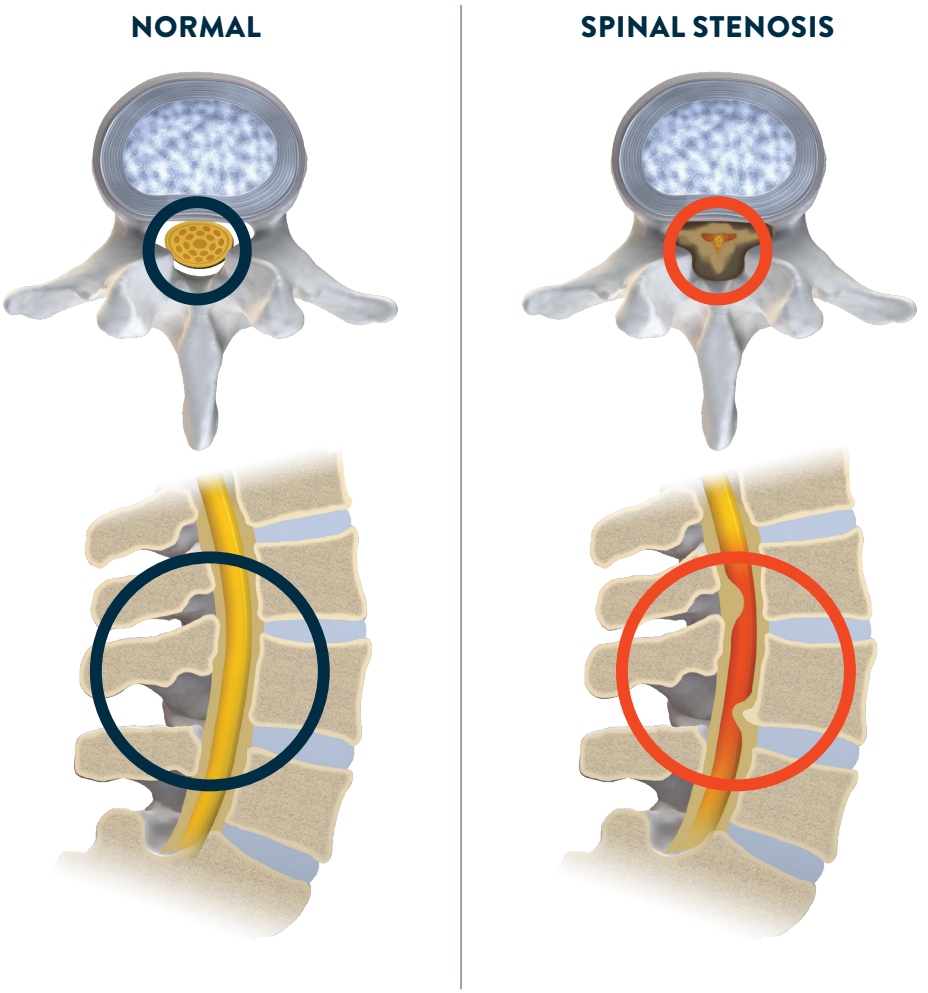
SPONDYLOLISTHESIS



NORMAL **SPONDYLOLISTHESIS**

Spondylolisthesis is a condition where one of the vertebrae slips forward or backward over the vertebrae it is between. This can be part of the natural aging process or due to an injury to your back. The word spondylolisthesis (pronounced spohn-di-low-liss-THEE-sis) comes from the Greek words “spondylos”, which means “spine” or “vertebra,” and “listhesis”, which means “slipping, sliding, or movement.” This condition can cause instability in your spine which can result in pressure being placed the nerves, causing you pain.

SPINAL STENOSIS



Spinal stenosis is a narrowing of the spinal canal where the spinal nerves and spinal cord pass through the spine. When this narrowing occurs, pressure can be placed on the spinal nerves or cord causing pain, numbness, or weakness.

WHAT ARE MY TREATMENT OPTIONS?

If your doctor has diagnosed you with lumbar degenerative disc disease, spondylolisthesis, or spinal stenosis, there many operative and nonoperative therapies that you may benefit from.

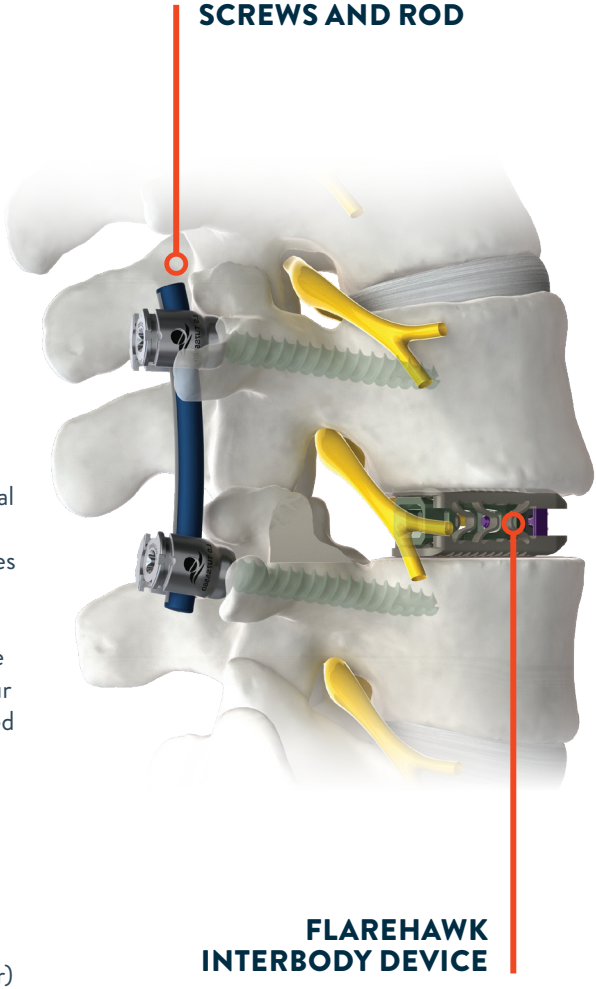
If nonoperative treatment measures fail to relieve the pain you are experiencing, or your condition worsens, your doctor may recommend a transforaminal lumbar interbody fusion (TLIF).

TRANSFORAMINAL LUMBAR INTERBODY FUSION OVERVIEW

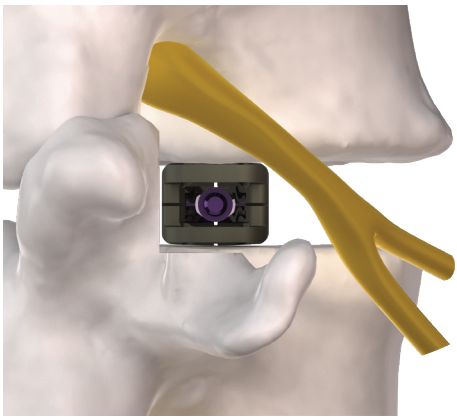
A transforaminal lumbar interbody fusion is a type of spinal fusion that aims to restore disc height, realign the spine, alleviate nerve impingement, and ultimately allow the bones to permanently fuse.

After you are asleep with the use of anesthesia you will be placed face down, so that the surgeon can access your spine from your back. The procedure involves removing the intervertebral disc material from the disc space. Once cleared, an implant, sometimes referred to as an interbody device, spacer, or cage, is inserted in the disc space. The surgeon will then stabilize your spine by securing the indicated vertebral levels together with screws and rods.

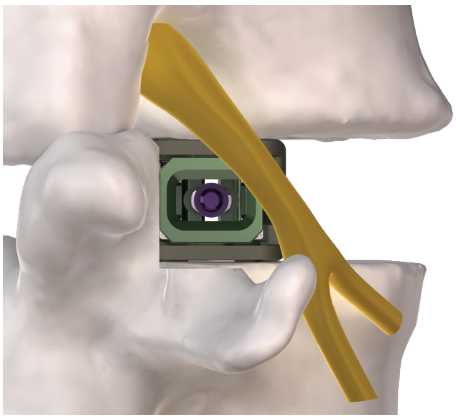
Similar to the healing process of broken bones of the arm or legs, the goal of surgery is to stabilize the spine to allow fusion (bone to grow together) to occur over the next few weeks to months of the postoperative period.



WHAT IS THE FLAREHAWK INTERBODY FUSION SYSTEM?



INSERTION PROFILE



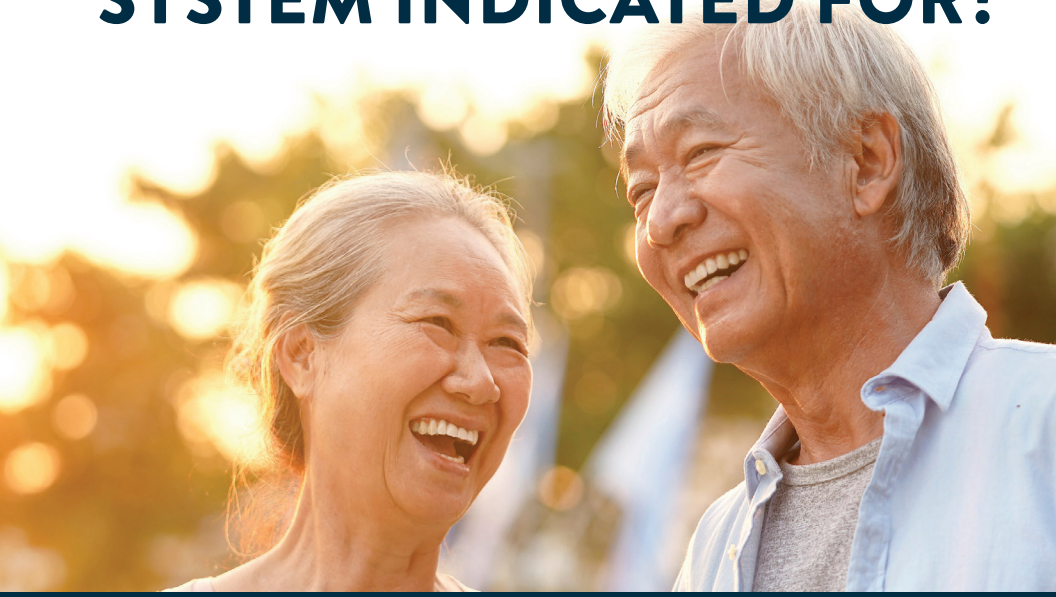
EXPANDED PROFILE

The FlareHawk device was designed by the makers of medical stent technologies with the reasoning that surgeries should be as minimally invasive as possible.

The FlareHawk device allows surgeons to insert the cage with a small incision, due to the minimal size of the implant. Once in the desired location, the surgeon is then able to expand the device into a wide and supportive footprint for your anatomy.

The device is made of polyetheretherketone (PEEK), a medical-grade plastic, tantalum, and titanium alloys.

WHO IS THE FLAREHAWK SYSTEM INDICATED FOR?



When your doctor has diagnosed that your pain is being caused by conditions of your spine from your lower back (lumbar spine areas L2-5, or the top of the sacrum, S1), they may recommend a procedure with the FlareHawk Interbody Fusion System.

Your doctor will review surgical and nonsurgical options available to you. Only your doctor can decide if you are a candidate for a procedure with the FlareHawk Interbody Fusion System. In order to be a candidate, you need to meet the following criteria:

- Be diagnosed with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1.
- Have been through at least six (6) months of nonoperative treatment.
- You are old enough that your bones have completed growing.
- You also may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

FlareHawk system spacers are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

Please consult your physician to discuss clinical indications of the FlareHawk procedure.

CONTRAINDICATIONS

You may not be a good candidate for use of the FlareHawk Interbody Fusion System If you have any of the following conditions:

- Signs of local inflammation.
- Fever or other signs of infection.
- Morbid obesity.
- Pregnancy.
- You do not need a spinal fusion.
- Unwilling to cooperate with postoperative instructions.
- Hereditary or acquired bone friability or calcification problem.
- You are a child or adolescent where you are still going through general skeletal growth.
- Prior fusion at the level(s) to be treated.
- Severe osteoporosis, which may prevent adequate fixation.
- Your activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with your ability to follow postoperative restrictions and which may place undue stresses on the implant during bony healing as this may put you at a higher risk of implant failure.
- Have a condition not described in the indications for use.
- Allergy to any device materials, including polyetheretherketone, tantalum, or titanium alloy.
- Irreversible bleeding or blood clotting disorder.
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.

The decision whether to use these devices in such conditions must be made by the physician considering the risks versus the benefits of the procedure.

REFER TO THE FLAREHAWK INTERBODY FUSION SYSTEM
PRESCRIBING INFORMATION FOR FULL CONTRAINDICATIONS

WHAT WILL THE RECOVERY BE LIKE?

Recovery can vary from patient to patient depending on many factors such as overall health status, age, weight, lifestyle, and adherence to the postoperative instructions. You may need to stay in the hospital after the procedure. Strategies to help you heal may include physical therapy, medications, bracing, limitations on your normal activities, and proper supportive nutrition. Your surgeon will provide instructions tailored to your abilities and needs for your postoperative instructions. It is imperative that you follow these recommendations for the success of your procedure and goal of returning to everyday activities.

RISKS AND WHEN TO CALL YOUR DOCTOR

ARE THERE ANY RISKS OF THIS PROCEDURE POTENTIALLY RELATED TO THE DEVICE?

All spine fusion surgeries have the potential for complications. Thankfully, most of the complications occur infrequently. Potential risks, which could require additional surgeries, include:

- device component fracture
- device or device component migration
- device subsidence
- loss of fixation
- non-union
- fracture of the vertebrae
- neurological injury, and
- vascular or visceral injury

Other complications include those that would be associated with any type of surgery, including infection, bleeding, and anesthetic complications. Mortality is rare for lumbar spine surgeries.

Certain degenerative diseases or underlying physiological conditions such as diabetes, rheumatoid arthritis, or osteoporosis may alter the healing process, thereby increasing the risk of implant breakage or spinal fracture. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

The FlareHawk Interbody Fusion System should only be used by physicians with experience and training in spine surgery.

WHEN TO CALL YOUR DOCTOR:

Call your doctor immediately if you have any of the following symptoms:

- New or increased pain, numbness, or weakness in your back or legs
- Develop a fever
- Have fluid drainage or swelling from your incision
- Trouble swallowing or breathing
- Loss of control of bladder or bowels, with loss of urine or stool, or both
- Pain, swelling, or redness in one of your legs
- A severe headache
- If you have any other questions about the way you are recovering

REFER TO THE FLAREHAWK INTERBODY FUSION SYSTEM PRESCRIBING INFORMATION FOR FULL WARNINGS AND PRECAUTIONS.

SURGEON CONSULTATION NOTES

SURGEON: _____

DIAGNOSIS: _____

PREOPERATIVE APPOINTMENT DATE: _____

SURGERY DATE: _____

MEDICAL CLEARANCE: YES / NO

NOTES

INDICATIONS FOR USE/INTENDED USE

The FlareHawk Interbody Fusion System is indicated for spinal intervertebral body fusion with autogenous bone graft and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone in skeletally mature individuals with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1, following discectomy. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have at least six (6) months of non-operative treatment. Additionally, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). FlareHawk system spacers are intended to be used with supplemental fixation instrumentation, which has been cleared for use in the lumbar spine.

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