activL® Artificial Disc

Patient Information

AESCULAP®
Implant Systems

Patient Information

For the activL® Artificial Disc Keel Endplate

This patient information brochure explains:

- How the healthy low back works
- What happens when a lumbar disc wears out
- What are the risks and benefits of lumbar artificial disc surgery
- How the activL Artificial Disc may help your back and leg pain and related problems

This brochure is intended to provide you with information about a treatment option for your low back and leg pain. After reviewing and discussing your medical history, x-rays, and the results of other evaluations you have completed, you and your doctor have determined that an option for improving your condition may be to undergo lumbar spine (low back) surgery using the activL Artificial Disc.

Please read through this brochure to learn about the anatomy of the lumbar spine, spinal disorders that cause low back pain, and various treatment options that are available.

Detailed information about the activL Artificial Disc is also included to assist you with making an informed decision regarding the treatment of your back and leg pain. This brochure will help answer questions on what to expect before, during, and after surgery.

This brochure should not take the place of talking with your doctor. Please go to your doctor with questions about how you are feeling and talk to a doctor about the best way to treat your back and leg pain.

Table of Contents

Patient Information

For the activL® Artificial Disc Keel Endplate

Glossary

Artificial disc – A medical implant designed to replace a worn out disc.

Blood vessel – Flexible tube that carries blood throughout the body.

CT (Computerized tomography) – A tool used by doctors that combines many x-ray images to create cross-sectional images (like slices) of the body.

Degeneration – The breakdown or deterioration of tissue.

Degenerative Disc Disease (DDD) – Back pain related to the breakdown or deterioration of a disc which is confirmed by patient history, physical examination, and imaging studies (like x-rays, CT, and/or MRI).

Disc – The soft tissue found between the bones of the spine (vertebrae) that helps to hold the vertebrae apart, cushion the spine, and allow the vertebrae to move relative to one another.

Facet joint – Joints that connect the bones of the spine (vertebrae) together in the back and slide against one another during motion.

Fluoroscopy – Type of x-ray used to take moving pictures of a body part.

Food and Drug Administration (FDA) – Part of the United States government. One of the FDA's jobs is to help protect people who need medicine or medical implants. The FDA also helps decide which medical implants can be used and how they can be used.

Fusion – When two bones grow together so that they no longer move.

Heterotopic ossification – Unintended bone growth around the bones of the spine (vertebrae) or across the disc space between the vertebrae.

Implant – A device that is put in the body to fix or take the place of a damaged body part.

Incision – A cut in the skin made during surgery.

Provided for your understanding is a glossary of terms that may be used in this brochure

Investigational Device Exemption (IDE) Study – A clinical trial required by the FDA to allow certain devices such as Artificial Disc Replacements to be marketed to potential U.S. patients.

Joint – Where two or more bones meet, normally to allow movement.

Ligament – A short strip of strong, flexible soft tissue that connects two bones.

Lordosis - The normal curve of the lumbar area of the spine (low back).

Lumbar discectomy – A surgical procedure in which part or all of a degenerated lumbar disc is removed.

Lumbar spine – The lower part of the spine that may be involved in low back pain. There are five spinal bones (vertebrae) in the lumbar spine, and they are numbered from L1 to L5 starting from the top of the lumbar spine.

MRI (Magnetic Resonance Imaging) – A tool used by doctors that uses magnets to create cross-sectional images (like slices) of the body.

Nerves – Fibers that move messages to and from the brain. Nerves control feeling and movement. Nerves connect the skin, organs, and muscles through the spinal cord to the brain.

Nucleus pulposus – The soft center of a disc.

Osteopenia – A condition in which the bones are somewhat thin or weak, resulting from a loss of calcium, which may cause problems during surgery and may develop into osteoporosis.

Osteoporosis – A condition in which the bones are thin and weak and may become brittle and fragile which may cause problems during surgery.

Physical Therapy (PT) – Using exercise and massage to help regain strength and movement.

Post-Approval Study (PAS) – An extension of a clinical trial that may be required by the FDA to understand the longer term safety and effectiveness of FDA approved devices such as Artificial Disc Replacements.

Prolapse (slipped disc) - When part of the disc overlaps the outside of the spinal bones (vertebrae) and presses on the spinal cord or nerves that are branching out from the spinal cord.

Randomized Controlled Trial (RCT) – A clinical trial that often includes two arms (investigational arm and control arm) to compare the safety and effectiveness of a new technology (investigational) to a technology whose associated outcomes are already widely understood (control).

Skeletal muscle – The type of muscle that powers movement of the body.

Soft tissue – Connects, supports, or surrounds the organs and other structures of the body.

Spinal canal – Hole in each of the spinal bones (vertebrae) that surrounds and protects the spinal cord.

Spinal cord – Bundle of spinal nerves. The spinal cord starts at the bottom of the brain and runs down to the lower back. The spinal cord moves messages between the brain and the body.

Spine – The 33 vertebrae starting under the skull and ending in the lower back. Grouped into sections: cervical (upper), thoracic (middle), lumbar (lower), sacral (sacrum) and coccyx (tailbone). Protects the spinal cord and provides body support.

Spondylolisthesis - A spinal bone (vertebra) that has moved out of place relative to the other bones.

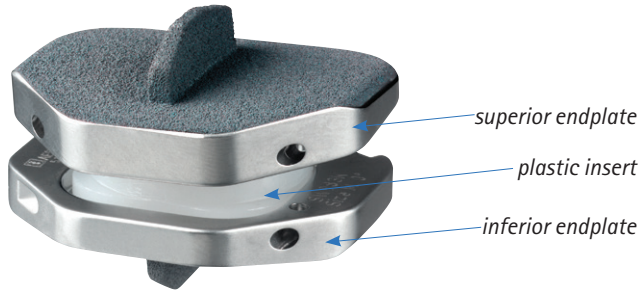
Surgery – An operation on the body to fix, remove, or replace diseased or injured tissue.

Vertebrae – The bones that form the spine with a hole for the spinal cord to pass through.

X-ray – A tool used by doctors to take a picture of a patient's bones.

Patient Information

For the activL® Artificial Disc Keel Endplate



Assembled activL® Artificial Disc Keel Endplate

The top metal plate is designed to move over the plastic insert. The plastic insert is attached to the bottom plate. The design is intended to allow motion in all directions (forward and backward, side to side bending, and twisting).

What is the activL Artificial Disc?

The activL Artificial Disc consists of two endplates made of a mix of metals commonly used in spine surgery (cobalt-chromium metal alloy with a titanium coating) and a plastic (polyethylene) insert that fits between the two endplates. The plastic insert is flat on the bottom and round on the top and is designed to move as you move during daily activities.

The two endplates are held to the top and bottom surfaces of the involved vertebrae (the bones of the spine), and the plastic insert fits between them.

The activL Artificial Disc is designed to allow motion at the treated level of the spine as the plastic insert can move front to back within the metal endplates but not side to side; however, not all patients will achieve motion after treatment with the activL Artificial Disc.

The activL Artificial Disc is available in different sizes to fit different patients.

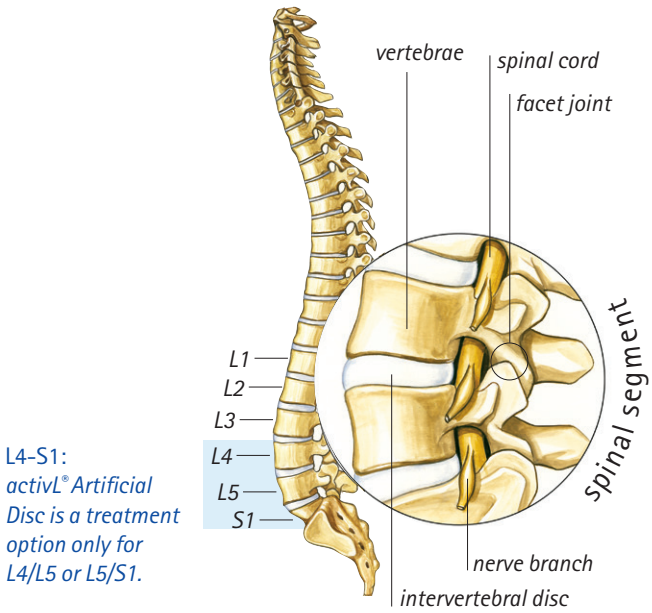


Fig. 1: Side view of the spine

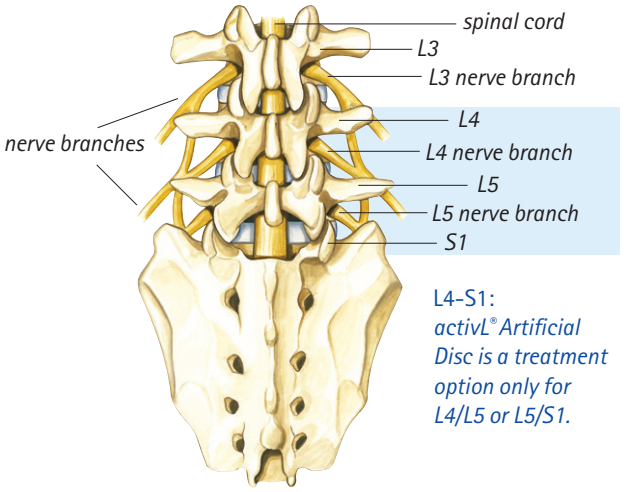


Fig. 2: Back view of spine showing nerve branches branching out from the spinal cord

What is the lumbar spine and how does it normally work?

The human spine is part of the body's skeletal system that provides balance and stability, protects the spinal cord, and allows you to turn, stretch and bend.

A normal spine allows you to move about freely and bend with flexibility. Your low back, or lumbar spine, is made up of five bones (vertebrae) which are numbered L1 to L5 and are stacked on top of each other to form a column *(see Fig. 1)*. Each lumbar vertebra has a hole for the spinal cord which contains nerves that carry signals from your brain to the rest of your body. Below the lumbar spine is the sacrum.

The spine's vertebrae (or bones) absorb the impact from walking, climbing or jumping. The spinal cord runs through the spinal canal at the back of the spine and is protected by the vertebrae *(see Fig. 2)*.

There are also discs between the vertebrae which act as shock absorbers to cushion impact and to keep the distance between the vertebral bodies. Each disc has a thick outer layer (annulus) that surrounds a soft gel-like center (nucleus).

A spinal joint consists of two vertebrae in the front of the spine separated by a flexible disc and two facet joints in the back of the spine. *See figure 1 for a diagram of the lumbar spine and a spinal joint.*

Smaller nerves branch out from the spinal cord at each level and lead to specific areas of the body. *See figure 2 for a diagram of the lumbar spinal cord and the nerve branches at each level.*

Patient Information

For the activL® Artificial Disc Keel Endplate

What may be causing your back and leg pain?

Degenerative Disc Disease (DDD)

Normally the discs between the vertebrae provide the cushioning space that keeps the bones separated. Degenerative Disc Disease (DDD) is a condition that can occur when a disc in your spine no longer functions normally because of aging, wear, or from being injured. The disc may shrink and lose height which can cause pain or make the spinal joint unstable. A worn out disc or spinal joint can also press on the nerves that branch out from the spinal cord which may cause leg or back pain when you move certain ways.

See figure 3 for a diagram showing some of the differences between a healthy disc and a degenerated disc.

DDD can often be treated non-surgically with medications, physical therapy, spinal injections, chiropractic care, braces, exercise programs, or rest.

However, in some cases, the symptoms may not improve or may get worse, and then your doctor may suggest surgery.

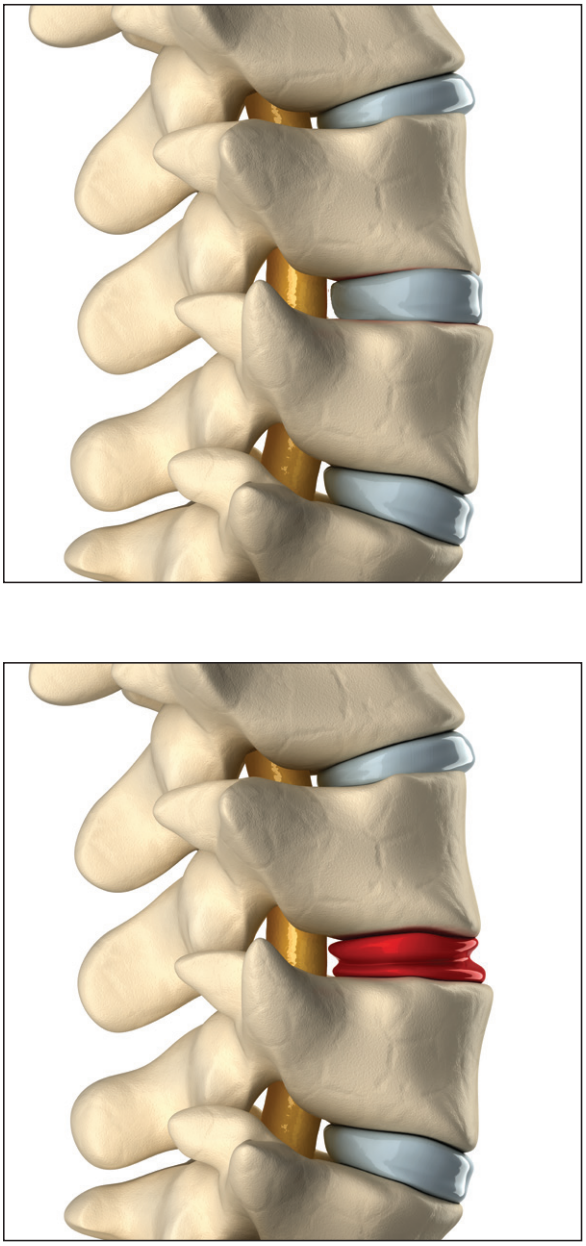


Fig. 3: Healthy vs Degenerated Disc

How does surgery using the activL® Artificial Disc compare to Fusion?

The traditional surgery for treating DDD has been spinal fusion surgery. In spinal fusion surgery, the unhealthy disc is removed, bone graft or a plastic spacer is placed in the area, and often medical implants (such as rods, screws, or plates) are used to hold the bones in position so that they are stable. *(see Fig. 4)*.

In some cases, the bone for the graft is obtained from the patient's hip bone through a separate cut. After surgery, bone is supposed to grow between the two vertebrae, creating one solid piece of bone.

The goal is to permanently fuse the vertebrae together so that they cannot move except as a single unit and therefore reduce the movement of that part of your spine. If you have fusion surgery, it may take away your pain, but you may have less motion in your back.

Another option your doctor may consider is surgery with an artificial disc replacement device *(see Fig. 5)*. The activL Artificial Disc is one artificial disc replacement device. The activL Artificial Disc has been developed to provide pain relief while potentially still allowing motion of your lower back (lumbar spine). In an activL Artificial Disc procedure, after the unhealthy disc is removed, it is replaced with the activL Artificial Disc alone (no bone graft or plastic spacer).

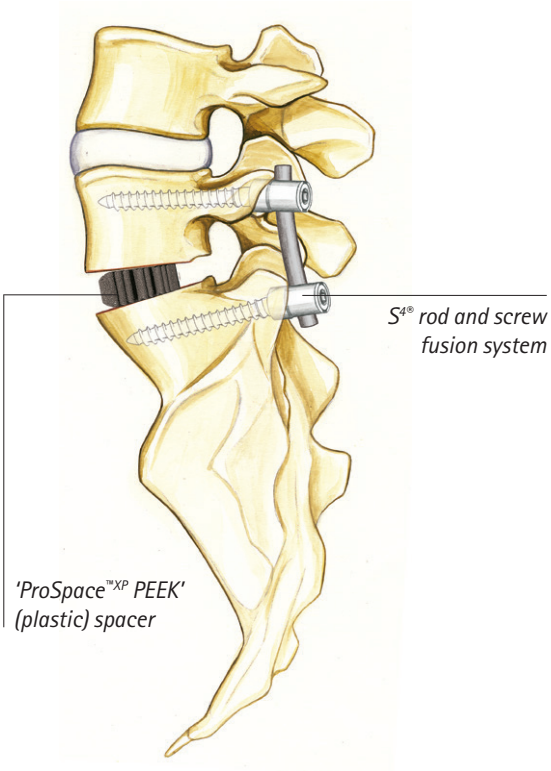


Fig. 4: Fusion surgery with bone graft or plastic spacer

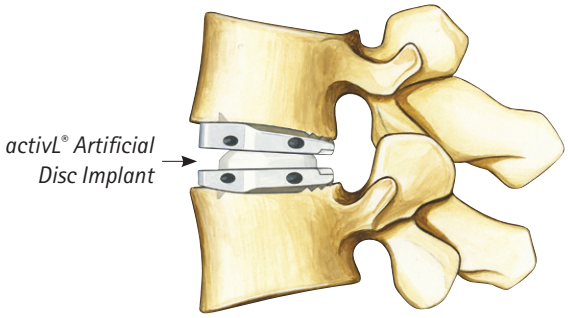


Fig. 5: activL® Artificial Disc surgery

Patient Information

For the activL® Artificial Disc Keel Endplate

Who should be treated with the activL Artificial Disc?

The activL Artificial Disc may be considered in patients who:

- Are skeletally mature (have vertebrae that are fully formed and grown).
- Have low back pain with or without leg pain due to a problem with one (1) degenerated lumbar disc at either level L4/L5 or level L5/S1 (as determined by a doctor).
- May have neurological symptoms such as weakness or numbness if the damaged disc is irritating the nerve roots (radiculopathy).
- Have proven disc degeneration at only one lumbar disc level (L4/L5 or L5/S1) and have been diagnosed as having Degenerative Disc Disease (DDD) at that level as confirmed by a doctor's review of their medical history, physical examination and medical images.
- Have gone through at least six months of non-surgical treatment without relief.

Will your doctor recommend the activL Artificial Disc surgery for you?

First your doctor will prescribe non-surgical treatments, such as medications, physical therapy and/or injections.

If these treatments do not relieve your pain, your doctor may determine that you are a candidate for artificial disc replacement.

Talk to your doctor about your options including the risks and benefits of surgery using the activL Artificial Disc to treat your condition. Surgery with the activL Artificial Disc may be an option to help your pain and other problems related to a damaged lumbar disc.

Who should not be treated with the activL® Artificial Disc (Contraindications)?

If you have any of the following conditions, you should not have surgery with the activL Artificial Disc:

- Active whole body (systemic) infection such as pneumonia or infection near the surgical site because undergoing surgery could interfere with your ability to heal and could increase the chance of spreading or worsening the infection.
- Osteoporosis or osteopenia (thin or weak bones). These conditions could increase the risk of your bones breaking or could cause the implant to loosen.
- Allergy or sensitivity to the materials that make up the activL Artificial Disc (cobalt, chromium, polyethylene, titanium, tantalum, or calcium phosphate). Talk to your doctor if you have a metal allergy because use of the activL Artificial Disc could cause an allergic reaction.
- Leg pain caused by single nerve root compression ("pinched nerve") because your pain may be treated with a different surgical procedure.
- Narrowing of the spinal canal (stenosis), nerve root damage (chronic radiculopathy), disc fragment that has separated and moved from the disc space, or spinal deformity such as scoliosis because surgery with the activL Artificial Disc may not be able to treat your symptoms.
- Too much forward slippage of your upper vertebra with respect to your lower vertebra (spondylolisthesis > grade 1) or a fracture (break) in a specific location in your vertebrae (referred to as a pars defect) as determined by your doctor which could cause instability within your spine.
- A lumbar spine that shows an unhealthy amount of extra movement (instability) on x-rays because the activL Artificial Disc may not provide enough stability.
- Damaged lumbar vertebrae due to an accident (trauma) or disease (including inflammatory diseases where the vertebrae swell or grow together and limit movement such as ankylosing spondylitis and rheumatoid arthritis). Use of the activL Artificial Disc in these situations may lead to poor performance of the implant.
- Severe disease or degeneration in the joints in the back of spine (facet joints) as determined by your doctor because surgery with the activL Artificial Disc will not treat this.
- Too little space remaining between the vertebrae because the disc has collapsed too much. In these cases, the activL Artificial Disc will not be able to function properly.
- Disc degeneration requiring treatment at more than one level as the activL Artificial Disc has only been evaluated in patients with one lumbar disc requiring treatment.
- Existing conditions that would make surgery through the belly impossible.

Patient Information

For the activL® Artificial Disc Keel Endplate

How was the activL Artificial Disc Studied?

In order for the manufacturer (Aesculap Implant Systems, LLC) to gain approval to market the activL Artificial Disc in the United States, the activL was studied in a Food and Drug Administration (FDA) clinical trial known as an Investigational Device Exemption (IDE) study.

The IDE was intended to determine the safety and effectiveness of the activL Disc for reconstruction of a degenerated lumbar disc in the low back at one level (L4-L5 or L5-S1) (as determined by a doctor) following single-level discectomy in skeletally mature (have vertebrae that are fully formed and grown) people with symptomatic degenerative disc disease (DDD) and no more than Grade I spondylolisthesis (too much forward slippage of your upper vertebra with respect to your lower vertebra) at the involved level who had been unresponsive to at least six months of prior non-operative treatment (non-surgical treatment without relief).

The trial design was:

- **Prospective** (patients had their device implanted with the intention of participating in the study and their outcomes were measured from that point forward);
- **Multi-center** (18 different hospitals participated in enrolling patients).
- **Randomized** (patients who elected to participate in the study did not know if they would receive the activL Artificial Disc (the investigational device) or a control device (one of the previous generation FDA approved lumbar artificial discs either the DePuy Spine Charite™ or the Centinel Spine ProDisc®-L Artificial Disc).
- **2:1** (there were 218 randomized patients who were treated with the activL Artificial Disc and 106 randomized patients who were treated with either the Charite™ or the ProDisc®-L Artificial Disc in the control group).

There were two (2) design versions of the activL studied as part of the clinical trial (spike version and keel version). Both versions are identical except for the method of initial stabilization. Longer-term fixation of the activL to the vertebral bodies is intended to be achieved through bone growth, with initial stabilization by either the spike or keel endplate design. During the IDE trial, the choice of the spike or keel endplate version was at the discretion of the spine surgeon to allow selection of an optimal endplate to fit each individual patient's anatomy and to accommodate physician preference.

The study was designed to be able to determine whether or not the activL Disc was as good as the previous generation devices (this is referred to as a non-inferiority study) for the treatment of DDD in this specific patient population.

Patients were treated between January 30, 2007 and December 3, 2009.

Patient characteristics (for example age, sex, prior surgeries) and outcomes were recorded at the time of the operation and at time points out to five (5) years after the study. Patients initially agreed to participate in the IDE study for five (5) years following their surgery. For those five (5) years patients often took surveys to measure their pain and disability levels and had radiographic studies like X-Rays performed.

Two (2) years after surgery 191 of the randomized patients treated with the activL (87.6%) and 91 randomized patients who were treated with either the Charite or the ProDisc-L Artificial Discs (85.8%) returned for follow-up with their surgeon.

Based on the outcomes of the group of investigational and control patients two (2) years after their surgery the FDA granted Aesculap, the manufacturer of the activL Disc, approval to market the disc to U.S. spine surgeons and their prospective patients.

The FDA later requested that the manufacturer conduct a Post-Approval Study (PAS), which required the manufacturer to get permission from the same original study patients, who had agreed to participate in the study for five (5) years, to be able to study their outcomes for two (2) additional years. This meant the patients would be required to visit their surgeons and undergo radiographic testing for a total of seven (7) years after their Disc Replacement surgery.

While a smaller number of patients agreed to provide data for the two (2) additional years, the PAS provided valuable insight into the long-term performance of the investigational (activL) and control devices up to seven (7) years after their surgery.

At seven (7) years after surgery 121 of the original 218 randomized patients treated with the activL 55.5% of the original ITT patients) and 57 of the original 106 randomized patients who were treated with either the Charité or the ProDisc-L Artificial Discs (53.8% of the original ITT patients) provided follow-up information. The manufacturer has worked with the FDA to provide additional best and worst-case scenario analysis on what the outcomes might have looked like in the patient group that did not report their experienced through seven (7) years to their spine surgeon.

A summary of the outcomes of the patients from the IDE study at both two (2) and seven (7) years following surgery can be found on page 22–23.

Patient Information

For the activL® Artificial Disc Keel Endplate

WARNINGS

Possible Danger

Implanting an artificial disc in the spine is serious surgery. There are blood vessels and nerves very close to where the implants enter the body.

Your doctor will take care to find and protect the blood vessels and nerves.

Potential Consequences

- A small cut to a blood vessel could cause dangerous or even fatal loss of blood (hemorrhage).
- Damage to a nerve could cause long-term loss of movement (paralysis) or feeling.

Possible Complication

As with any artificial disc surgery, there are steps your doctor should take to make the surgery safer.

The activL Artificial Disc should only be used by doctors, who:

- Are skilled in back surgery.
- Are specifically trained in the proper use of the activL Artificial Disc including who it should be used in, how it works, how to choose the correct size, and how to implant it correctly.
- Understand the risks and complications of lumbar disc surgery.

Potential Consequences

- If your doctor does not have enough experience or training, there may be a higher chance of problems during and after surgery.

Possible Complication

Bone could grow outside the vertebrae (heterotopic ossification (HO)). HO can happen after lumbar artificial disc surgery and may cause less lumbar motion.

Potential Consequences

- If HO forms, the potential consequences are not fully understood.

Patient Information

For the activL® Artificial Disc Keel Endplate

What are the WARNINGS and PRECAUTIONS associated with using the activL Artificial Disc?

As described on page 12, there was a clinical trial in the United States to evaluate patients treated with the activL Artificial Disc. To participate in the clinical trial, patients had to meet certain criteria. For example, patients could not be included in the trial if they were older than 60 years, if they had undergone previous low back surgery*, or if they were taking steroids. As a result, it is unknown if the activL Artificial Disc will perform as well in other types of patients compared to those included in the trial.

Take time to understand the possible dangers from lumbar artificial disc surgery.

Talk to your doctor about the possible dangers and complications of the activL Artificial Disc surgery.

PRECAUTIONS

Because the clinical trial only evaluated patients who met certain criteria, the safety and effectiveness of the activL Artificial Disc has not been tested in patients with the following conditions:

- More than one lumbar spine level that is damaged and needs surgery
- The young (younger than 18) and the elderly (older than 60)
- Patients whose bones are still growing
- Previous lumbar spine surgery
- Back or leg pain from an unknown source
- Disease of the bone caused by low mineral levels or genetic problems (Paget's disease, osteomalacia, or other metabolic bone diseases)
- Very overweight/obese (Body Mass Index (BMI) greater than 35 based on NIH Clinical Guidelines)
- Pregnancy
- Taking medicine that is known to get in the way of bone or soft tissue healing (such as steroids)
- Diseases that cause the vertebrae to swell or grow together and limit movement, such as rheumatoid arthritis, lupus or other autoimmune diseases
- Whole body (systemic) diseases, including AIDS, HIV, and hepatitis
- Active cancer (malignancy)
- Diseases that affect muscle movement because of problems with nerves or muscles (neuromuscular disorders). Disease examples include: Parkinson's disease, amyotrophic lateral sclerosis (ALS), or multiple sclerosis.
- Serious mental illness or drug abuse
- Insulin dependent diabetes

* *With the exception of previous intradiscal electro-thermal annuloplasty (IDET), percutaneous nucleoplasty, microdiscectomy, hemilaminectomy, or laminotomy procedures. A doctor can help you determine if you have had one of these previous procedures.*

Your medical history is very important in your doctor's decision to choose the activL Artificial Disc for you.

Before recommending the activL Artificial Disc, your doctor will take into account your past and present health such as:

- Your job and activity level
- Your current and past mental and physical health
- Alcoholism or drug abuse
- Medicine use
- Previous treatments

You may be asked questions to help decide if you have a risk of low bone mineral density. Based on your answers, your doctor may order a bone test (DEXA measurement). The activL Artificial Disc has not been tested in patients with a spinal DEXA T score less than or equal to -1.0 (who may have osteoporosis or osteopenia).

Your doctor will choose the best activL Artificial Disc size for your body.

A correctly sized activL Artificial Disc is important so that the implant stays in place and works right for you. Your doctor should not start surgery without the right implant size or instruments that are in good working order.

This implant is placed close to major blood vessels and nerves. There is a risk of nerve damage and/or serious or fatal bleeding if these structures are damaged during surgery.

Your doctor should talk to you about all of the risks and complications associated with the activL Artificial Disc and give you plenty of time to ask questions. You can also ask to see the full list of precautions and risks and complications which are listed in the activL Artificial Disc package insert.

It is extremely important that you let your doctor know about any medications you are taking, any allergies you have, if you are pregnant, may become pregnant, or if you have any other illnesses or medical conditions that may help your doctor decide if this implant is right for you. Failure to fully inform your doctor about your overall state of health and existing medical conditions may create unnecessary complications if you are treated with this implant.

It is also very important that you carefully follow your doctor's instructions after surgery. Extreme activities like lifting very heavy weights may result in failure of the implant.

Patient Information

For the activL® Artificial Disc Keel Endplate

What are the potential RISKS and ADVERSE EFFECTS associated with using the activL Artificial Disc?

Complications may occur when you are treated with the activL Artificial Disc, as with any surgery. Although many of the major risks are covered in this patient information, a full list is provided in the package insert for the implant, which your doctor has received. Please ask your doctor for more information about any additional risks that could be related to your planned surgery.

Possible complications may include, but are not limited to the following:

Risks associated with low back surgery:

- Injury to surrounding organs and structures including nerves, surrounding spinal bones, structures that carry lymph (lymphatic vessels), blood vessels, soft tissue, the membrane that surrounds the spinal cord (dura), intestines, kidneys and ureters
- Problems controlling bowel or bladder function
- Sexual and reproductive problems including ejaculation of semen into the bladder (retrograde ejaculation)
- Muscle weakness or loss of movement (paralysis)
- Numbness or tingling
- Back or leg pain
- Swelling from a mass of clotted blood inside the spinal canal (epidural hematoma) or in the region next to where the abdominal organs are located (retroperitoneal hematoma)
- Scarring in the belly (adhesions)
- Weakness in the belly muscles (hernia)
- Swelling or infection in the outside cover of the spinal cord or brain (meningitis)

Risks associated with any surgery:

- Problems with anesthesia including an allergic reaction
- Infection involving the wound, near the wound, or elsewhere in the body
- Problems with the wound including wound opening (dehiscence) or unhealthy tissue within the wound (wound necrosis)
- Swelling (edema)
- Soft tissue damage or a fluid collection (hematoma or seroma)
- Pain around the surgical cut including in the muscles or skin
- Heart or vascular problems including bleeding, deficient blood supply to a body part (ischemia), abnormal blood pressure, heart attack, stroke, formation of a blood clot, or obstruction of a blood vessel by a clot or abnormal particle in the blood (embolism)
- Lung complications, including lung collapse or pneumonia
- Gastrointestinal complications including slowing of the intestines (ileus) or blockage of the intestines (bowel obstruction)
- Problems with controlling bowel or bladder function including incontinence or other dysfunction
- Sexual or reproductive problems
- Nerve problems including nerve damage, loss of movement (paralysis), seizures, changes to mental status, or burning nerve pain with swelling and motor and sensory changes (reflex sympathetic dystrophy)
- Problems with pregnancy including miscarriage or birth defects
- Inability to return to daily activities
- Death

Risks specifically associated with implanted artificial discs including the activL® Artificial Disc:

- An issue with the implant including poor positioning of the implant, movement of the implant out of place, sinking of the implant into the bone resulting in loss of disc height, breakage of the implant, disassembly (coming apart) of the implant, or early or late loosening of the implant. Any of these issues may cause pain or injury to surrounding organs and structures including nerve or spinal cord compression or damage (which could cause paralysis) or damage to blood vessels (which could cause a lot of bleeding).
- Worsening (deterioration) in neurological status including muscle weakness or loss of movement (paralysis) or numbness or tingling
- Development of new pain
- Failure of the artificial disc to improve symptoms or function
- Problems during placement of the implant including trouble sizing the implant or issues with the implant instruments including the possibility that part of an instrument may remain in your body
- Reaction of your body to wear debris from the implant (particles of either plastic or metal that come off the implant) or a reaction to the entire implant which may lead to loosening of the implant, bone loss (osteolysis), tumor formation, autoimmune disease, inflammation around the implant because it is made of metal (metallosis), scarring, or other symptoms
- A change in the alignment or curvature of your spine including abnormal movement of one vertebra compared to the vertebrae below it (spondylolisthesis, instability) or development of an unnatural curvature of the spine
- Degeneration of other parts of your spine including the joints that connect the vertebrae together in the back of the spine (facet joints) or adjacent discs
- Narrowing of the spinal canal (spinal stenosis) which may cause symptoms
- Breakage (fracture) of the surrounding spinal bones
- Formation of extra bone (heterotopic ossification, anular ossification) which may reduce movement and may result in unintended fusion at either the treated level or another lumbar spinal level
- The need for additional surgery which could include removal of the activL Artificial Disc

Patient Information

For the activL® Artificial Disc Keel Endplate

ADVERSE EFFECTS

In addition to the risks listed previously, there is also the risk that the surgery may not be effective in relieving your symptoms, or may cause worsening of your symptoms. If this occurs, you may need another surgery in order to help you feel better.

As described in detail on page 12, the activL Artificial Disc was studied by enrolling patients into a clinical trial in the United States approved by the FDA. There were 218 randomized patients that received the activL and 106 randomized patients that received a Control disc as part of the study's Intent to Treat (ITT) Population. At end of the Post-Approval Study (PAS), seven (7) years after the initial surgery, 121 randomized patients that received the activL and 57 randomized patients that received a Control device (178 patients total) from the original ITT population made themselves available for follow-up. Some of the notable adverse effects at any time point after surgery, as reported by patients available through seven (7) years were:

- Continued lower extremity (leg) pain in 16% (19 out of 121) of activL patients and 18% (10 out of 57) of control group patients.
- Continued lumbar (low back) pain in 24% (29 out of 121) of activL patients and 33% (19 out of 57) of control group patients.
- Continued lumbar (low back) and lower extremity (leg) pain in 24% (29 out of 121) of activL patients and 19% (11 out of 57) of control group patients.
- Complications related to the ability to move (motor function) in 7% (8 out of 121) of activL patients and 12% (7 out of 57) of control group patients. Complications related to feeling (sensation) in 22% of (27 out of 121) of activL patients and 25% (14 out of 57) of control group patients.
- 17 patients (8%) treated with the activL Artificial Disc and ten patients (9%) had additional surgery at the same level as their original surgery within the seven (7) year study.

In the clinical study through seven (7) years after surgery, the safety profile for the activL Artificial Disc, in general, was shown to be comparable, if not better than, that of the control group, and is consistent with the safety profile seen at two (2) years after surgery.

A complete list of risks are provided in the package insert for the implant, which your doctor has received. Please ask your doctor for more information about any additional risks that could be related to your planned surgery.

Patient Information

For the activL® Artificial Disc Keel Endplate

What are the expected outcomes and benefits of surgery with the activL Artificial Disc?

The patient brochure describes many possible problems. These facts are given to help you make the right choice about artificial disc surgery.

There are good reasons to choose an artificial disc. The activL Artificial Disc may help end or lessen your pain and discomfort.

Surgery with the activL Artificial Disc:

- Will remove your worn out disc
- May help maintain motion in your low back
- May match the disc height to the levels above and below which may help un-trap nerves
- May lessen your back and/or leg pain
- May lessen any leg tingling
- May help you return to your normal life

Some of the safety and effectiveness results of the U.S. clinical trial (described on page 12) are described below. The clinical benefit to the patient beyond seven (7) years has not been measured. Ask your doctor for more details about the clinical trial and its results.

- Patients in both treatment groups experienced significant improvements in clinical outcomes at all postoperative follow-up visits (including pain, function and quality of life questionnaires).
- **Clinical Improvement in Oswestry Disability Index (ODI) Score** – An outcome measure designed to evaluate patient function In the trial:

	activL Artificial Disc	Control Discs
24-Month Outcomes	88% (88 out of 100)	80% (80 out of 100)
7-Year Outcomes	88% (88 out of 100)	86% (86 out of 100)

- **Maintenance or Improvement in Neurological Status:**

	activL Artificial Disc	Control Discs
24-Month Outcomes	93% (93 out of 100)	93% (93 out of 100)
7-Year Outcomes	95% (95 out of 100)	95% (95 out of 100)

- **Maintenance or Improvement of Significant Range of Motion (greater than or equal to 3 degrees):**

	activL Artificial Disc	Control Discs
24-Month Outcomes	74% (138 out of 187)	59% (51 out of 86)
7-Year Outcomes	64% (76 out of 119)	59% (33 out of 56)

- **Freedom from Implant Failure Requiring Surgery at the Same Lumbar Level:**

	activL Artificial Disc	Control Discs
24-Month Outcomes	96% (96 out of 100)	97% (97 out of 100)
7-Year Outcomes	91% (91 out of 100)	90% (90 out of 100)

- **Freedom from Serious Implant Related Complications:**

	activL Artificial Disc	Control Discs
24-Month Outcomes	86% (86 out of 100)	79% (79 out of 100)
7-Year Outcomes	67% (67 out of 100)	73% (73 out of 100)

- A similar number of patients in both the activL® Artificial Disc group and the control group had improvement in low back and leg pain in the first two (2) years after surgery.
- Moreover, 82% of activL Artificial Disc patients (82 out of 100) were very satisfied with the results of their surgery two years after the surgery, compared to 78% of control group patients (78 out of 100).
- Treatment satisfaction at seven (7) years following surgery was comparable between the two (2) patient groups; the rate of patients indicating they would have the surgery again for the same condition was slightly higher in the activL group; slightly more investigational subjects felt their treatment was effective in eliminating symptoms.

When patients meet the selection criteria as described in the clinical study, and as determined by a doctor, the study's outcomes support the reasonable assurance of safety and effectiveness of the activL Artificial Disc.

Based on the clinical trial results, it is reasonable to conclude that a significant portion of well-selected patients will achieve clinically significant positive results and that the clinical benefits of the use of the activL Artificial Disc in terms of improvement in pain and function, and the potential for motion preservation, outweigh the risks associated with the device and surgical procedure through seven (7) year follow-up.

Patient Information

For the activL® Artificial Disc Keel Endplate

Preparing for your activL Artificial Disc surgery

Follow your doctor's directions when getting ready for your surgery.

Here is a list with examples of things you may be asked to do before surgery.

Your doctor's directions may be different.

- Check whether the medicine(s) you are currently taking (including non-prescription drugs, herbal supplements, and vitamins) will still be OK to take after having back surgery.
- Take time before going to the hospital to arrange for your life after surgery:
  - Move anything you use a lot to an easy to reach spot.
  - Remove safety hazards that may cause you to fall or lose your balance.
  - Arrange to have family or friends around to help you.
- You will likely be told not to eat or drink the night before the surgery.
- Ask your doctor to tell you what to expect from this surgery.

What will happen during your activL® Artificial Disc surgery?

In the operating room:

- You will lie on your back on a table and be put into a deep sleep (general anesthesia).
- Once asleep your belly area will be washed. A clean (sterile) sheet will be taped around your belly.
- A 2-3 inch (5-8 centimeter) long cut (incision) will be made on your lower belly. Your doctor will move the muscles and blood vessels to the side. This will make a tunnel to your spine.
- Your doctor will remove the damaged discs and put in the proper size activL Artificial Disc. Fluoroscopy (X-rays) may be taken during surgery to check the placement of the activL Artificial Disc.
- The cut muscle and skin will be sewn together with surgical thread (sutures). A bandage or biologic glue will be placed across the cut.
- While asleep, you will be moved to a new area (recovery room). Nurses will check your blood pressure, heart rate, and breathing. If you are in pain, you may be given medicine.
- Once awake, you may be moved to a different room.

What will happen after your activL Artificial Disc surgery?

Ask your doctor to describe how you will feel and what you will need to do after surgery. Replacing your disc with the activL Artificial Disc is a major surgery. Getting better will take time. How fast you get better will depend on your age, your general health, and the reason for your surgery. Your doctor may recommend exercise with the help of a physical therapist. As with any surgery, it is very important to follow your doctor's directions after surgery.

Here are some examples of directions you may be asked to follow after your surgery. Your doctor's directions may be different:

- You will likely stay one to three nights in the hospital.
- You will likely be asked to sit, stand, and walk within 24 hours after the surgery.
- You may be asked to wear a back brace to help lessen back movement for about a week after surgery.
- You may be given medicine (by mouth) for pain or sickness of the stomach (nausea).
- You will be given a new, clean bandage for your incision as needed. The doctor or nurse may show you how to change the bandage.
- You will be asked to set up a time to visit your doctor to check your healing. Your doctor may take X-rays to look at the activL Artificial Disc placement in your back.
- After your surgery, do not do any heavy lifting, excessive bending of your back, or any long or difficult activity. You may need to limit your activity for weeks to months depending on your level of healing. Your doctor will give you more specific directions on when it is OK to return to your normal bending and turning.
- After your surgery, talk to your doctor about the proper way to recover including a physical therapy plan.

It is very important to closely follow your doctor's specific instructions so that you recover as quickly as possible and have the best possible outcome.

Patient Information

For the activL® Artificial Disc Keel Endplate

Frequently asked questions after activL Artificial Disc surgery

When should I call my doctor after surgery?

Talk to your doctor about when to call with problems after surgery. Some pain and discomfort is normal. The problems you had before surgery may not lessen right away. If you have any of the following problems at any point after surgery, call your doctor.

- Signs that your cut may not be healing (infection)
- The cut is draining fluid (although you can expect a small amount of wetness)
- The skin around the cut becomes red, warm, swollen, or increasingly painful
- You have a fever
- Your wound is opening
- New or increased tingling, numbness, or weakness
- New or increased pain in your back or leg as compared to before surgery
- Any signs of bladder or bowel issues (including trouble urinating or having a bowel movement)
- Any other things that the doctor may have discussed with you

What will my surgical incision look like?

The cut will be about 2-3 inches (5-8 centimeters) long on your belly. Once the cut heals, you may have a small scar.

When can I shower after the surgery?

You will need to keep the cut dry immediately after the surgery. Some doctors allow early showering. Patients normally take baths for 1-2 weeks after surgery. Get direction from your doctor on when it is OK to start showering or bathing.

When can I drive after surgery?

Ask your doctor when you can start driving after surgery. The timing varies from patient to patient.

Will my activL Artificial Disc affect travel through airport security?

It is very unlikely that the metal in the activL Artificial Disc will set off airport security detectors. However, the Transportation Security Administration (TSA) rules state, "TSA Security Officers will need to resolve all alarms associated with metal implants." Additional information can be found on the TSA website at http://www.tsa.gov/traveler-information/internal-medical-devices or contacted via phone at (866) 289-9673.

How long is my activL Artificial Disc expected to last?

It is not exactly known how long the device will last. Consult with your doctor about the evidence available for artificial disc replacement.

Will my activL Artificial Disc be safe during an MRI exam?

You may safely receive an MRI exam that uses very specific scan conditions. Scanning under different conditions may result in injury. Inform your doctor and the MRI staff that you have an activL Artificial Disc before you receive the exam. Full MRI safety information for your implant is available in the MRI section of the Instructions for Use or the Surgical Technique Manual, which can be obtained at www.aesculapimplantsystems.com or by calling 1-866-229-3002.

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician.

For more information on the activL® Artificial Disc
www.aesculapimplantsystems.com/patient

Aesculap Implant Systems, LLC
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(800) 234-9179

Reading this patient brochure should not take the place of talking with a doctor. Please go to your doctor with questions about how you are feeling. Talk to a doctor about the best way to help your back and leg problems.

Through collaborative excellence we will improve the quality of a patient's life and meet the needs of the changing healthcare environment.

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