

What is PCM[®]?



What is the PCM[®] Cervical Disc?

The PCM Cervical Disc is a motion preserving device that is placed in between your cervical vertebrae (Fig. 1). The PCM Cervical Disc is designed to help stabilize the spine and preserve, rather than eliminate, motion.



Figure 1

Anterior Cervical Discectomy and Fusion (ACDF) Surgery

An Anterior Cervical Discectomy and Fusion (ACDF) is a surgical procedure that aims to fuse two spine vertebrae together into one solid piece of bone. This procedure may alleviate the pain and other symptoms of cervical disc disease. While an ACDF usually relieves pain and other symptoms, it does result in loss of motion in the fused joints.

Cervical Disc Replacement Surgery

An alternative procedure to an ACDF is a cervical disc replacement surgery, which aims to stabilize the spine while still allowing motion to occur at the joint instead of fusing the vertebrae together. For that reason, artificial cervical disc replacement devices such as the PCM Cervical Disc have been developed.

What is the PCM Cervical Disc made out of?

The PCM Cervical Disc consists of the following parts: an upper metal (cobalt chromium alloy) endplate, and a lower metal endplate to which a plastic (polyethylene) spacer is attached (Fig. 2). These materials are the same materials as the ones used for most spinal and orthopedic devices (e.g., hip and knee replacements). Several device sizes are available to best fit the disc space.

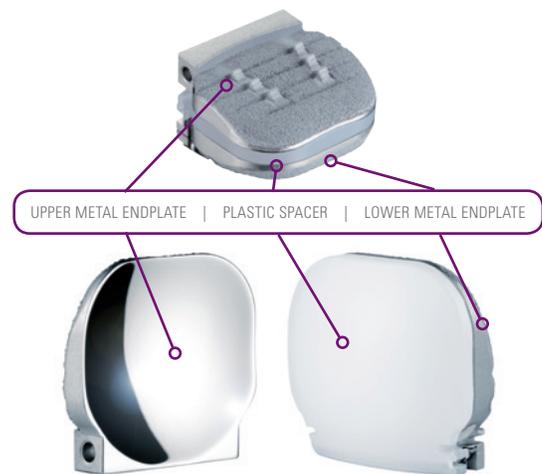


Figure 2

How does the PCM Cervical Disc work?

The PCM Cervical Disc is implanted into your spine as a two-piece device. The bottom (plastic) portion articulates with the top (metal) portion, to help allow the three types of spinal motion to occur (Fig. 3).

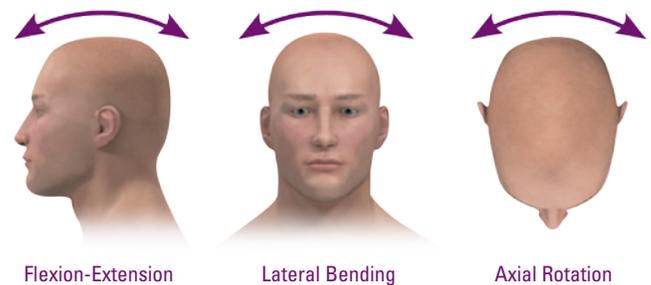


Figure 3

What can I expect during surgery?

During the PCM Cervical Disc surgery, you will be under general anesthesia. The surgeon will access your spine from the front of your neck, and will remove the damaged disc and any tissue or obstructions that are compressing the nerves or spinal cord. After shaping the edges of the vertebrae to ensure a proper fit, the PCM Cervical Disc is inserted. The surgery lasts approximately one to two hours and most patients leave the hospital the following day.

As with any spine surgery, there are potential benefits and possible risks associated with the PCM cervical disc replacement procedure. Individual results will vary. It is important to discuss the possible risks and potential benefits of a PCM cervical disc replacement with a physician prior to receiving treatment, and that you rely on your physician's judgment. Only your physician can determine whether you are a suitable candidate for this procedure.

**For more information please refer to the PCM Patient Brochure or ask your doctor.*

What is PCM®?



INDICATIONS

The PCM® Cervical Disc is indicated for use in skeletally mature patients for reconstruction of a degenerated cervical disc at one level from C3-C4 to C6-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit), with or without neck pain, or myelopathy due to a single-level abnormality localized to the disc space and manifested by at least one of the following conditions confirmed by radiographic imaging (CT, MR, x-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. The PCM Cervical Disc is implanted using an anterior approach. Patients should have failed at least 6 weeks of conservative treatment prior to implantation of the PCM Cervical Disc.

THE PCM CERVICAL DISC SHOULD NOT BE IMPLANTED IN PATIENTS WITH THE FOLLOWING CONDITIONS:

- Active infection of the whole body or the operating site, because any pre-existing infection will increase the risk of infecting the PCM Cervical Disc
- Osteoporosis or osteopenia of the bone, because weak or thinning bone could increase the risk of bone fracture or loosening of the PCM Cervical Disc
- Allergies or sensitivities to metals (cobalt, chromium, molybdenum, and titanium), plastics (polyethylene), or calcium phosphate, because these make up the PCM Cervical Disc and could cause an allergic reaction if implanted
- Congenital stenosis, a condition of narrowing of the spinal canal since birth

It is extremely important that you let your doctor know about any medications you are taking, any allergies you have, if you are pregnant, or if you have any other illnesses or medical conditions that may help your doctor decide if the PCM Cervical Disc is the right choice for you.

WARNINGS AND PRECAUTIONS

The clinical study was limited to patients that met certain criteria, therefore the safety and effectiveness of the PCM device has not been established in patients with the following conditions:

- Intractable radiculopathy or myelopathy due to disease at more than one level or disease outside of the disc space;
- Marked cervical instability as determined by your doctor;
- Significant cervical anatomical deformity or clinically compromised vertebral bodies at the affected level due to current or past trauma or disease;
- Those under the age of 21 or over the age of 65;
- More than one immobile vertebral level;
- Severe spondylosis as determined by your doctor;
- Patients whose bones are still growing;
- Previous spine surgery at the level to be treated;
- Symptoms attributed to more than one vertebral level;
- Neck pain alone;

- Neck or arm pain of unknown origin;
- Severe facet joint arthritis of the level of spine for which surgery is planned;
- Paget's disease, osteomalacia, or other metabolic bone disease;
- Cancer;
- Those taking medications known to potentially interfere with bone or soft tissue healing (e.g., steroids);
- Diabetes mellitus;
- Systemic disease including AIDS, HIV, and hepatitis;
- Auto-immune disorders that impact the musculoskeletal system such as lupus, rheumatoid arthritis, or ankylosing spondylitis;
- Neuromuscular disorders such as muscular dystrophy (progressive loss of muscle), spinal muscular atrophy (decreased muscle), amyotrophic lateral sclerosis (Lou Gehrig's disease);
- Morbid obesity;
- Pregnancy;
- Mental illness and substance abuse;
- Prior fusion at an adjacent vertebral level. Similar to the experience in the ACDF control group, the use of the PCM Cervical Disc at a spinal level adjacent to a previous fusion may lead to clinical outcomes inferior to those observed for patients without a prior adjacent level fusion. For the PCM Cervical Disc, these include, but are not limited to, possible implant migration and a higher incidence of subsequent device removal.

Magnetic Resonance (MR) safety: The PCM Cervical Disc has not been evaluated for safety and compatibility in the MR environment. The PCM Cervical Disc has not been tested for heating or migration in the MR environment.

RISKS

As with any surgery, there are some possible serious risks that can occur when receiving the PCM Cervical Disc. Potential risks associated with the use of the PCM Cervical Disc include: 1) those commonly associated with any surgery; 2) those specifically associated with cervical spinal surgery using an anterior approach; and 3) those associated with a spinal implant, as well as those pertaining to the PCM Cervical Disc. However, the causality of these adverse events is not exclusive to these categories. Some of the following effects were observed in the clinical study.

- Risks associated with any surgical procedure are those such as: Edema (abnormal excess accumulation of fluid in connective tissue); hematoma (a mass of usually clotted blood that forms in a tissue, organ, or body space as a result of a broken blood vessel); injury or damage to the blood vessels, heart, lungs, stomach, intestines, bowels, bladder, or other organs, during surgery; scarring of tissue in or around your surgical wound; adverse reactions to anesthesia; seizure, convulsion, or changes to mental status; and complications of pregnancy including miscarriage and fetal birth defects.
- Risks associated with anterior interbody surgery of the cervical spine include: dysphagia (difficulty

- swallowing); dysphonia (defective use of the voice); tracheal, esophageal and pharyngeal perforation; airway obstruction; neck and/or arm pain; development or progression of disease at other levels in your surgical spine; loss of motion (unintentional fusion) at the treated level; warmth or tingling in the extremities; deficit or damage to the spinal cord, nerve roots, or nerves possibly resulting in paralysis or pain; dural (membrane that envelops spinal cord) tears or leaking; cerebrospinal fistula (an abnormal passage that leads from the spinal canal to another area of the body allowing for cerebrospinal fluid to leak out); loss of proper curvature, correction, height or reduction of the spine;
- Risks associated with implants in the spine, including the PCM Cervical Disc: Bending, breakage, or loosening of any or all of the components; implant migration; malpositioning of the implant; sizing issues with components; allergic reaction to the implant material; possible tissue reaction; bone resorption (loss of bone); bone formation (heterotopic ossification) that may reduce spinal motion or result in a fusion, either at the treated level or at adjacent levels; decreased strength of extremities.
- Wound, local and/or systemic infections
- Surgical instrument bending or breakage, as well as the possibility of a fragment of a broken instrument remaining in the patient
- Inability to resume activities of normal daily living
- Death

It is also possible that the surgery will not reduce or relieve your symptoms, and that treatment may not result in therapeutic or direct health benefits or may cause worsening of preoperative symptoms. Promptly notify your surgeon if the preoperative symptoms fail to improve or worsen, or new symptoms develop. This cannot be predicted for either the PCM Cervical Disc or fusion surgery. If the implant does not relieve symptoms or if there is a problem with the device, it is usually possible to have it removed. This would require another surgery.

POTENTIAL ADVERSE EFFECTS

In the U.S. clinical study of 214 patients who received the PCM Cervical Disc, the most commonly or clinically significant reported device or surgery related adverse events included neck and arm pain 9.8% (21 patients), dysphagia/dysphonia 6.5% (14 patients), incision site complications 5.6% (12 patients), neurologic 5.6% (12 patients), spinal events 5.6% (12 patients), and implant loosening or dislodgement 4.7% (10 patients). In addition, 6.1% (13 patients) required removal of the PCM Cervical Disc device and 1.4% (3 patients) required reoperations. There may be other risks associated with using the PCM Cervical Disc. Of the 190 patients who underwent ACDF, the most commonly reported device or surgery related adverse events included neck/arm pain 17.4% (33 patients), adjacent level disease 14.2% (27 patients), dysphagia/dysphonia 12.1% (23 patients), spinal events 6.3% (12 patients), nonunion 5.8% (11 patients), and neurologic 5.3% (10 patients).