

## Questions and Answers

Q. Have the materials in the PCM Artificial Cervical Disc been used in the human body before?

A. Yes, the PCM Artificial Cervical Disc utilizes the same metal and plastic materials that have been used for the last 30 years in artificial hip and knee prostheses, and for over 15 years in artificial disc implants

Q. Is the procedure covered by insurance?

A. The PCM Artificial Cervical Disc is part of an FDA approved clinical investigation. Medicare and, in most cases, your insurance company will pay for the procedure.

Q. Where is the PCM Artificial Cervical Disc manufactured?

A. The PCM is manufactured in Germany by a company named Waldemar Link GmbH & Co. Waldemar Link has been making replacement joints since the 1960's.

Q. Where can I find more information about Cervitech, Inc. on the internet?

A. More information about Cervitech, Inc. is available at [www.cervitech.com](http://www.cervitech.com).

# Patient Information

## The Porous Coated Motion (PCM) Artificial Cervical Disc



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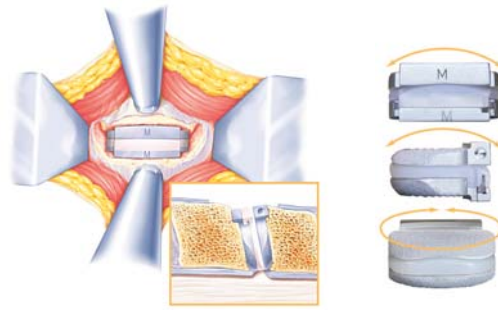
Caution: Investigational device limited by  
United States law to investigational use.

## About Artificial Cervical Discs

The area of the spine in your neck is called the cervical spine. The cervical spine has seven bones, called vertebrae. The tissue between the vertebrae is called a disc. The disc is a flexible material that holds the two bones together while still allowing for movement. Because of the demands put on the disc, it sometimes can “herniate” or wear down causing pain, numbness, tingling, and/or weakness in the neck, arms or shoulders. If treatments, such as rest, medications and activity modification, are not successful, the standard surgical treatment for these symptoms is to remove the disc and then to use a graft of bone and a plate with screws to fuse the two vertebrae together. This treatment usually relieves pain and other symptoms, but does result in loss of motion in the fused joint. For that reason, devices such as the Porous Coated Motion Artificial Disc (“PCM”) have been developed to provide the relief of pain and symptoms, without losing motion at the treated joint.

## The PCM Artificial Cervical Disc

The PCM Artificial Cervical Disc has been designed specifically to replace the damaged disc, providing support for the vertebrae



while allowing for movement of the joint. The implant has two halves: an upper metal (Cobalt Chrome alloy) endplate, and a lower metal endplate to which a plastic spacer (Polyethylene) is attached. The endplates are designed to bond with the neighboring vertebrae. The interface between the two halves is like a ball and socket, allowing the upper half to slide and rotate forward and backward relative to the lower half. During the surgery, the surgeon will access your spine from the front of your neck, and will remove the damaged disc and any tissue that is compressing nerves. After shaping the edges of the vertebrae to ensure a proper fit, the PCM Artificial Disc is inserted. The surgery lasts approximately one to two hours and most patients leave the hospital the following day.

The PCM Artificial Cervical Disc is considered to be an investigational device in the United States by the Food and Drug Administration. The FDA is allowing

selected doctors to use the PCM Artificial Cervical Disc on a specific number of patients that meet certain eligibility criteria. Eligible patients will randomly receive either the PCM Artificial Cervical Disc or the current “gold standard” fusion procedure using a bone graft and a plate with screws. Following treatment, the doctor checks each patient selected at specific times for at least two (2) years to observe the patient’s progress. After all of the patients’ results are given to the FDA and the treatment options compared, they will decide if the PCM Artificial Cervical Disc may be offered to the general public.

## Your Decision

Discuss the PCM Artificial Cervical Disc with your physician, as well as other possible treatments for your pain and symptoms. As with all surgical procedures, the desired relief of pain and symptoms may not result, and there are potential complications. It is important to fully understand the risks and benefits of each type of surgery before you make your decision. Please discuss any questions you may have with your doctor, in order to make the treatment decision that is best for you.