



PATIENT INFORMATION LEAFLET



Anterior Cervical Discectomy and Fusion

with the
Aquila® Spinal System

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General Information

You have been provided with this patient information brochure to help you understand your back surgery using the Aquila Spinal System for Anterior Cervical Discectomy & Fusion (ACDF) from Prism Surgical. Your surgeon has decided that you need spine surgery after carefully examining you, reviewing your history and taking into account the results of other diagnostic studies.

Your spine is an important structure in your body. It gives you support. It allows you to move and bend freely. Without it, you could not sit or stand up. To provide support, your spine contains 24 bones known as vertebrae. They are arranged in a column, stacked one on top of the other. The vertebrae protect and support the spinal cord, which houses many nerves. The area of the spine in your neck is called the cervical spine. It is made up of seven bones, called vertebrae. These vertebrae are connected by several joints, which allow you to bend, twist, and move your neck. The main joint between two vertebrae is called a disc. The disc is comprised of two parts, a tough and fibrous outer layer (annulus fibrosus), and a soft, gelatinous center (nucleus pulposus). These two parts work in conjunction to allow the spine to bend, twist, and also provide shock absorption.

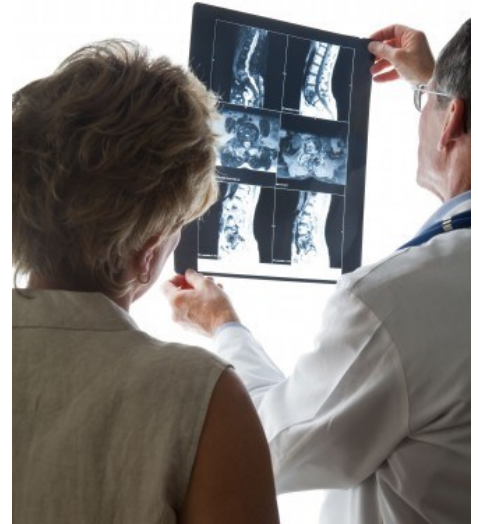
There are several primary causes of cervical spine problems. The majority of the symptoms are degenerative and caused by disc, bone, or ligaments pressing onto the nerve roots or cord.



Patient Information

This leaflet will help you understand more about;

- About your surgical treatment
- Anterior Cervical Discectomy & Fusion (ACDF)
- Information about the Aquila Spinal System
- What to expect from your surgery



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

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

What is an Anterior Cervical Discectomy & Fusion (ACDF)?

An Anterior Cervical Discectomy and Fusion (ACDF) procedure is a type of cervical spine surgery from the front (anterior) of the neck (cervical) that often successfully addresses spinal symptoms. ACDF surgery is a very common procedure relative to overall spine surgeries and has a long and studied record of positive outcomes. An ACDF surgery consists of removing the damaged disc and then growing bone between the vertebrae above and below. ACDF procedures may be performed with the use of an implant, such as a plate, to provide support until fusion occurs.

Your ACDF surgery will be performed under general anesthesia. When undergoing ACDF surgery with the Aquila Spinal System, your surgeon will operate on your spine through an incision in your neck, approaching your spine from the front. During surgery, your surgeon will remove the diseased disc and replace it with a cage filled with bone grafting (fusion) material. Figure 2. An anterior plate and screws may be used to hold the vertebrae in place while the fusion (bones grow together) occurs. Figure 1.

Figure 1

Plate with screws

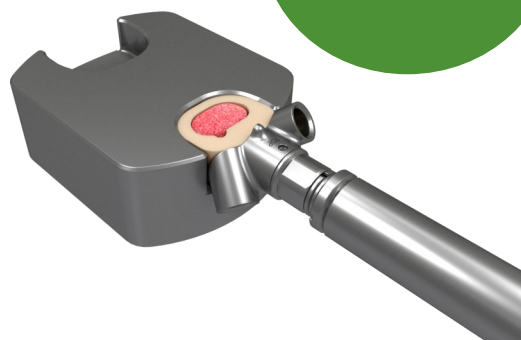


What Implants are used?

Below are some examples of the implants that may be used during your ACDF procedure.

Figure 2

Cage filled with bone graft



What is the Aquila Spinal System?

The Aquila Spinal System consists of plate and screws that are intended for Anterior Cervical Discectomy & Fusion (ACDF) by a qualified surgeon in skeletally mature patients. An cage containing bone graft material is implanted between your cervical vertebra that replaces the painful disc that has been removed by your surgeon.

Right: An ACDF cage is implanted in the anterior cervical spine.



The Aquila ACDF plate and screws are made of medical grade titanium alloy. The Aquila plate and screws may be used to hold the vertebrae in place while the fusion (bones grow together) occurs.

Right: Aquila ACDF plate and screws implanted in the spine.



These implants are available to your surgeon in a variety of shapes and sizes to match each patients' individual anatomy and clinical pathology. The materials used usually do not harm the human body and are commonly used in medical implants for bone surgery. The Aquila implants are intended to remain in your body. Non-clinical testing of the worst-case scenario has demonstrated that the implants of the Aquila Spinal System have been designed to withstand anticipated loads until fusion occurs or up to 2 years in-vivo (whichever occurs first).

Talk to your Doctor

It is important to always follow your surgeons' recommendations. Your surgeon may advise you that some activities may increase the risk of loosening, bending or breaking the implants. If you have any questions about the Aquila Spinal System, please call or see your doctor, who is the only one qualified to treat your spinal condition.

Contact your doctor immediately after surgery if;

- You get a fever
- The wounds starts leaking fluids
- You have trouble swallowing or breathing
- You have new or increased neck or arm pain or numbness

What possible side-effects could occur?

Potential risks to any surgical procedure include unforeseeable complications caused by anesthesia, the surgical procedure, undiagnosed medical problems and rare allergic reactions. Most of these complications can be treated once they are detected but sometimes they require a longer period of hospitalization or recovery, additional medications, and sometimes even additional surgery. These risks will be explained by your surgeon. In general these complications happen very infrequently, but it is important to remember that surgery is a difficult process and therefore, unforeseeable complications do occur. As a patient it is important to understand and follow your doctors advice so that the best possible outcome can be achieved.

As with any surgical procedure, the following implant related side effects can occur;

- Implant material sensitivity; allergic reaction
- Discomfort or abnormal sensations
- Loosening, degradation, bending, failure, movement/migration or fracture of the implants

MRI Safety Information

After your surgery, it is important to Inform your healthcare professional about your implants if you are having an MRI. Worst-case, non-clinical testing has demonstrated the Aquila Spinal System is MR Conditional.



After your surgery, you will have an Aquila spinal system implant/s and can safely undergo an MR exam only under very specific conditions. Scanning under different conditions may result in injury. Full MRI safety information is available in the MRI Safety Information section of the Aquila spinal system instructions for use (IFU), which can be obtained at www.prismsurgical.com.au or by calling +61 7 3720 8882.

Contact Information

If a serious incident has occurred as a result of the devices listed in this leaflet, please report incident details immediately to the following;

- AU Sponsor
Prism Surgical Designs Pty Ltd
www.prismsurgical.com.au
+61 7 3720 8882
enquiries@prismsurgical.com.au
- Therapeutic Goods Administration (TGA)
<https://www.tga.gov.au>

Please ask your surgeon if you would like additional information or if you have more questions about anterior cervical discectomy and Fusion (ACDF) surgery. Only your surgeon is qualified to treat your spine.

SURGEON INFORMATION

