BettaTech®

Patient Information Leaflet for Cervical Plate

This leaflet has information about your implant. It does not contain all the information and if you have any questions, talk to your healthcare team. All implants have risks and benefits. Follow your healthcare team's advice even if it differs from what is in this leaflet. Please read this leaflet carefully and keep it in a safe place so you may refer to it in the future if needed.
The name and number of your Plate can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Product Name

Cervical Plate System (Anterior and Posterior)

Implant Description

The Cervical Plate System contains temporary implants that are intended for interbody screw fixation of the cervical spine during the development of a cervical spinal fusion. The plate system consists of a variety of bone plates and screws. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The plates include anti-migration caps that cover the heads of the bone screws to reduce the potential for screw back-out. The anti- migration caps come pre-assembled to the plate. Associated instruments are available to facilitate the implantation of device. The Cervical Plate System implant components are made from titanium alloy. This material is not compatible with other metal alloys. The Cervical Plate System components are not to be combined with the components from another manufacture. Different metal types should not be used together.

Implant Material

Your implant may contain the following materials: Ti6Al4V ELI, Nickel-Titanium, Alloy.

Information for Safe Use

Always follow your doctor's instructions after surgery. Failure to follow your doctor's advice may result in complications or the need for additional surgery. Talk to your doctor about any questions, concerns and possible side effects.

Magnetic Resonance Imaging

Before having a magnetic resonance imaging (MRI), it is important to inform your doctor about the possibility of implants. The implants included in the scope of this leaflet are MR conditional and may be safe for post-operative MRI scans under certain conditions. Show your implant card to your doctor and MRI technician when you request an MRI scan. If the technician doesn't know the implant, the MRI scan can interact with the implant and cause problems.

Possible Side Effects/ Risks

Your doctor will provide information about the side effects of your surgery. All surgeries have risks. While many possible reactions may occur, some of the most common may include:
1) Non-union (or pseudarthrosis), delayed union, mal-union.
2) Early or late loosening, disassembly, bending, and/or breakage of any or all of the components.
3) Pain, discomfort, or abnormal sensations due to the presence of the device.
4) Decrease in bone density due to stress shielding.
5) Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including

metallosis, staining, tumor formation, and/or auto-immune disease, dysphagia.
6) Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments.
7) Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
8) Infection, early or late.
9) Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
10) Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
11) Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft harvest site at, above, and/or below the level of surgery.
12) Damage to lymphatic vessels and/or lymphatic fluid exudation.
13) Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
14) Graft donor site complication including pain, fracture, or wound healing problem.
15) Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
16) Degenerative changes or instability in segments adjacent to fused.
17) Spinal cord impingement or damage.
18) Esophageal perforation, erosion or irritation.
19) Paralysis.
20) Death.

These risks may require additional surgeries or treatments. This list does not include all risks. Your doctor can further explain the risks of your operation.

Expected Implant Lifetime and Follow Up

The Cervical Plate System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed where there is evidence or indication of localized tissue reaction or pain, breakage, migration, fracture or loosening of these support devices, or infection or bone loss, then removal should be considered. Any decision by a physician to remove the device should take into consideration such factors as:
1) The risk to the patient of the additional surgical procedures as well as the difficulty of removal.
2) Pain or abnormal sensations due to the presence of the implants.
3) Infection or inflammatory reactions.
4) Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains. The spine may get fracture after the removal of implant.
Information specific to your implant, such as lot number/serial number and unique device identifier are included on the implant card. This information is also located in the patient records kept by your health care provider.

Reporting Adverse Effects

If you wish to report any adverse effect you believe are a result of your implant, please speak with your doctor/medical team or report the information to Wiselink Group Pty Ltd, Suite 31, 427-441 Victoria Avenue, Chatswood NSW 2067, Australia. Telephone 1300 76 80 90.

List of products

Tab. 01-1 Plate specification

Name	Specification			
	L(mm)	W(mm)	δ (mm)	Hole
1-Ⅰ 1-Ⅱ	15, 17.5, 20, 22.5, 25, 27.5, 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60, 62.5, 65, 67.5, 70, 72.5, 75, 77.5, 80, 82.5, 85	15 18 20 22	2.0 2.5 3.0	4 6 8 10
2-Ⅰ 2-Ⅱ	15, 17.5, 20, 22.5, 25, 27.5, 30, 32.5, 35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55, 57.5, 60, 62.5, 65, 67.5, 70, 72.5, 75, 77.5, 80, 82.5, 85	15 18 20 22	2.0 2.5 3.0	/

Tab. 01-2 Screw specification

Name	Specification	
	D (mm)	L (mm
Fixed Angel & Self-Drilling Screw	Φ 3.5 Φ 4.0 Φ 4.3 Φ 4.5 Φ 4.8	10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24
Variable Angel & Self-Drilling Screw		
Fixed Angel & Self-Tapping Screw		
Variable Angel & Self-Tapping Screw		