CervAlign® Anterior Cervical Plate System

Non-sterile Implants and Instruments

GENERAL INSTRUCTIONS FOR USE

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect the success of the surgical procedure.

- All users are expected to read the instructions for use that accompany all devices being used with these implants.
- Inspect the product, including all packaging and labeling materials carefully:
  - Do not use if the device or packaging is damaged
  - Do not use if there are discrepancies in label information
- Promptly report all product defects and patient adverse events to Xtant (see Product Complaints section).

DEVICE DESCRIPTION

The CervAlign Anterior Cervical Plate System is designed to promote cervical fusion by providing temporary resistance to flexion, extension, lateral bending, and axial rotation with strength and stiffness in the cervical spine (C2-C7). The system includes implants of various sizes of screws and plates to accommodate varying patient anatomies. The plates have integrated cover-style locking mechanisms that actuate to cover each screw. Implants are manufactured from titanium alloy, Ti-6AI-4V (ASTM F136). The implants are supplied with instrumentation necessary to facilitate the insertion and removal.

The implants and instruments are provided non-sterile and must be sterilized before use. Sterilization cases and trays are provided to facilitate proper sterilization and storage.

INDICATIONS FOR USE

The CervAlign Anterior Cervical Plate System is intended for anterior cervical fixation (C2-C7) for the following conditions: degenerative disc disease (DDD) defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and failed previous fusion.

CONTRAINDICATIONS

The implant is contraindicated and should not be used on patients with the following:

- A demonstrated allergy or sensitivity to the implant material
- Conditions that may place excessive stress on bone and these implants
- A medical or surgical situation that would preclude the benefit of surgery

WARNINGS AND PRECAUTIONS

The same medical/surgical conditions or complications that apply to any surgical procedure may also occur during or following implantation of this device system. The surgeon is responsible for informing the patient of the potential risks associated with treatment, including complications and adverse reactions. Because this is a technically demanding procedure presenting a risk of serious injury to the patient, the surgeon must become familiar with the device system and the surgical procedure prior to use. Use the surgical instruments and accessories provided with this device system. The surgeon may need to perform additional surgery to address any complications or adverse reactions, which may or may not be device related.

Do not attach these devices to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Preoperative planning and patient anatomy should be considered when selecting cervical screw diameter and length. While proper selection can help minimize risks, the size, shape, bone quality, stock, and differentiation of anatomical structures of human bones present limitations on the size and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone and no implant can be expected to indefinitely withstand the unsupported stress of full weight-bearing.

These implants can break when subjected to the increased loading associated with delayed union or non-union. Typically, internal fixation devices are load-sharing devices, which hold a fracture in alignment until normal healing occurs. If healing is delayed or does not occur, the implant may break due to metal fatigue. Loads produced by load-bearing, the degree or success of union, and activity levels, among other conditions, will dictate the longevity of the implant.

Correct handling of the implant is extremely important. Contouring plates can weaken the mechanical integrity of the device; plates should not be contoured repeatedly, excessively, or in a kyphotic direction. Do not contour the plate over the screw holes or locking mechanism as it may hinder the ability of the locking mechanism to function properly. Avoid notching and scratching of the devices when contouring. Once the plate bender has been used to alter the contour of the plate, do not bend in the reverse direction as this may introduce micro fractures within the plate that can compromise its strength. If reverse plate bending or excessive bending has occurred, the bent plate must be discarded. Contact Xtant with any questions regarding plate contouring prior to surgery.

Do not bend screws. Bending screws will significantly decrease fatigue life and may cause loosening, or breakage. Mixing of implant components with different materials is not recommended for metallurgical, mechanical and functional reasons. Implants which contact other metal objects, must be made from like or compatible metals. Do not rotate locking mechanism beyond positive stop as this may damage the locking mechanism.

An explanted implant should never be re-implanted. Even though the implant appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. Alterations will produce defects in surface finish and internal stresses which may become the focal point for breakage of the implant. If reverse bending, repeated bending, notching, or scratching occurs, the implant must be discarded.

Instruments are subject to damage during use as well as long-term potentially damaging effects such as wear. Damage may result in significant risks to safety and/or inability to function as intended.

If implants or instruments are damaged or broken during use, metal fragments can be viewed by radiographic assessment. It is the surgeon's responsibility to carefully consider the risks and benefits of retrieving the fragments.

If the fragment is retained in the patient, it is recommended that the surgeon advise the patient of specific information regarding the fragment material, including size and location and the potential risks associated with the retained fragment.

POTENTIAL ADVERSE EFFECTS

These effects may or may not be device related.

- Post-operative change in spinal curvature, loss of correction, height and/ or reduction
- Device fragments
- Dysphagia
- Perforation of the esophagus
- Foreign body reaction
- Fracture, and/ or delayed union
- Implant failure
- Infection
- Nervous system injury
- Adjacent segment disease
- Bleeding
- Arachnoiditis
- Cessation of any potential growth of the operated portion of the spine
- Herniated nucleus pulposus at the adjacent level, and/or retro-pulsed graft at the adjacent level
- Inability to perform the activities of daily living
- Loss of spinal mobility or function
- Scar formation possible causing neurological compromise around nerves and/or pain
- C5 Palsy
- Dural tears/CSF Leak
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery
- Tissue damage caused by improper positioning and placement of implants or instruments
- Other tissue damage
- Death

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

Non-clinical testing and electromagnetic simulations demonstrated that the devices are MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 3000 Gauss/cm (30-T/m)

- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning in the Normal Operating Mode of operation for the MR system
- Under the scan conditions defined, the devices are expected to produce a maximum temperature rise less than 3.5˚C after 15-minutes of continuous scanning.
- When other methods of supplemental fixation are used, also follow the MR conditional labeling for the additional components.

Artifact Information
In non-clinical testing, the image artifact caused by the devices extends approximately 35 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

PATIENT SELECTION
In selecting patients for internal fixation devices, the following factors can be of extreme importance to the success of the procedure.

- Skeletally mature (greater than 21 years of age)
- The patient's weight. An overweight or obese patient can produce loads on the device, which can lead to bending, loosening, or breakage of the device.
- The patient's occupation or activity. If the patient is involved in an occupation or activity, which includes substantial walking, running, lifting or muscle strain, the resultant forces can cause bending, loosening, or breakage of the device.
- A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the device, leading to implant bending, loosening, or breakage or other complications.
- Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the device. For such cases, orthopaedic devices can only be considered a delaying technique or temporary relief.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
- Presence of documented infection or inflammation. Patients with infections and inflammation are more likely to encounter further complications.
- Presence of severe osteopenia and/or osteoporosis.

POSTOPERATIVE
The surgeon should provide clear directions, warnings and must obtain verification of patient understanding for patient postoperative compliance.

Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight-bearing have been implicated in bending or fracture of the device. The implant is neither designed nor intended to withstand such use. The

patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing (non-union). An active, debilitated, or demented patient who cannot properly use weight-supporting devices or follow instructions may be particularly at risk of bending or fracture during postoperative rehabilitation. Factors such as the patient's weight, activity level, and adherence to weight-bearing or load-bearing instructions affect the stresses to which the implant is subjected. Patients should be fully informed of the risks of implant bending, loosening, or breakage.

The implant is not intended to be permanent. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Metallic implants can loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. Implant removal should be followed by adequate postoperative management to avoid re-fracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.

CLEANING AND STERILIZATION

See Association of Operating Room Nurses (AORN) recommended practices for guidelines related to proper care and handling of surgical devices while cleaning and sterilizing per the provided instructions.

Implants:

- Implants are provided CLEAN and NON-STERILE.
- The implants must be cleaned and sterilized per the instructions below prior to introduction into a sterile surgical field or, if applicable, returned to Xtant.
- Unused implants subject to the sterile surgical field must be recleaned and re-sterilized per the instructions below.
- Inspect implants visually for damage, gross contamination or contamination by dried biological residue. If damage, gross contamination or dried biological residue is observed on the implant, it must be discarded.
- Never use steel brushes or abrasive pads, as these rupture the passive layer of the implant surface which can lead to corrosion.

Instruments:

- Instruments are provided CLEAN and NON-STERILE.
- The instruments must be cleaned and sterilized per the instructions below prior to introduction into a sterile surgical field or, if applicable, returned to Xtant.
- To minimize corrosion and prolong the usable life of instruments used during surgery, remove gross traces of blood and residues then thoroughly clean and dry immediately after use. Do not allow soils to dry.
- Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
- Prior to and during use, including reprocessing, inspect instruments for:
    - Damage such as wear, discoloration, corrosion, cracking, fracture, or unrecognizable markings.
    - Proper function including sharpness, movement of hinges and couplings, joint stability, and legible markings.
- Instruments that show signs of damage or an inability to function should not be used and should be returned to Xtant.

CLEANING

MANUAL CLEANING

1. Disassemble the device(s), if applicable.
2. Rinse soiled device under running, cold tap water for a minimum of two (2) minutes. Remove gross soil using a soft bristle brush or soft, lint-free cloth.
3. Prepare a neutral pH enzymatic solution per the manufacturer's recommended instructions in warm tap water (approximately 33-43 °C (92-110 °F)).
4. Soak devices in freshly prepared neutral pH enzymatic solution for a minimum of ten (10) minutes.
5. Rinse device using cool running tap water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels and other hard to reach areas. Actuate joints, handles and other moveable device features under running water, in order to rinse thoroughly.
6. Prepare a neutral pH enzymatic solution in warm tap water (approximately 33-43 °C (92-110 °F)), per the manufacturer's recommended instructions.
7. Manually clean devices for a minimum of five (5) minutes in freshly prepared neutral pH enzymatic solution. Use a syringe, pipette, or water jet to flush lumens and channels. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles, and other movable device features to expose all areas to enzymatic solutions. Clean device underwater to prevent aerosolization of contaminants.
8. Rinse device using deionized (DI) running water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels. Actuate joints, handles, and other moveable device features under running water, in order to rinse thoroughly.
9. Visually inspect device for residual soil. If present, repeat steps 1-7 above.
10. Gently dry the device components with a soft lint-free cloth. Ensure the device is completely dry. Visually inspect the device; it should be clean, dry and residue free.

AUTOMATED (MECHANICAL) CLEANING

Pre-Cleaning

1. Disassemble the device(s), if applicable.
2. Rinse the device components under running lukewarm tap water (22-43 °C (72-110 ºF)) for a minimum of one (1) minute. After rinsing, remove gross soil using a soft-bristled brush or clean, soft, lint-free cloth.
3. Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions.
4. Fully immerse the device components in the fresh, newly prepared enzymatic cleaning solution for a minimum of five (5) minutes.
5. After soaking, manually clean the device components for a minimum of two (2) minutes using a soft-bristled brush to remove soil and debris from the device and device lumens. Brush the device while fully immersed to prevent aerosolization of contaminants. After cleaning, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 mL of the cleaning solution.
6. Remove the device components from the cleaning solution and place the device components in a bath of lukewarm tap water (22–43 °C (72-110 ºF)) for a minimum of one (1) minute. Ensure that the water immerses the device components. Once the rinse time has elapsed, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 ml of the water.

Automated Cleaning:

1. Place the device components in the automated washer.
2. Perform the automated cycle per instructions in the table below.
3. Visually inspect the device; it should be clean, dry and residue-free.

Automated (Mechanical) Cleaning Parameters			
Cycle	**Time (Minutes)**	**Minimum Temperature**	**Detergent**
Enzyme wash	4:00	Hot water 60 °C (140 °F)	Enzymatic cleaner (neutral pH) prepared per manufacturer's instructions
Wash	2:00	Hot water	Neutral detergent prepared per manufacturer's instructions
Rinse	2:00	Heated deionized or high purity water 70 ºC (158 °F)	N/A
Dry	15:00	80 °C (176 °F)	N/A

STERILIZATION

AORN recommended practices for in-hospital sterilization should be followed for all devices. Use of an FDA cleared (or equivalent) wrap is recommended to ensure product sterility.

Independent testing has shown the following minimum conditions to be effective.

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-vacuum (Wrapped)	132 ℃ (270 ° F)	4 Minutes	40 Minutes

- Steam sterilization (moist heat) is the only method permitted for sterilization. Other sterilization methods are not permitted.
- The values specified here (duration / temperature) can achieve a Sterility Assurance Level (SAL) of at least 10^{-6}.

PRODUCT COMPLAINTS

Complaints or dissatisfaction with the device quality, safety, reliability, durability, effectiveness and/or performance, brought forth by a health care professional, whether via a customer or user of the product, should be immediately conveyed to Xtant customer service via telephone at (888) 886-9354 or email at CS@xtantmedical.com. It is important to note that when filing a complaint, the following information must be included to properly respond to the complaint:

Name and address; nature of the complaint; the component(s) trade name and catalog number; applicable lot number(s); and notification of whether a written report is being solicited.

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For product information including surgical techniques, brochures, or questions pertaining to sales and service, please contact Xtant customer service via telephone at (888) 886-9354 or email at CS@xtantmedical.com.

Symbol Definitions	
	Catalogue number
	Batch number
	Manufacturer
	Do not re-use
	Consult Instructions for Use
	Prescription only
	Non-sterile
	MR conditional