

corra® cervical plating system

Instructions for Use

Caution: For product sold in the USA: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DESCRIPTION

The corra® cervical plating system, which is comprised of corra® cervical segmental plating system and the corra® cervical multilevel plating system configurations, is intended for anterior fixation of the cervical spine. The system consists of a variety of patient-specific segmental and multilevel plates that are additively manufactured from titanium alloy (Ti-4Al-6V ELI) per ASTM F3001 as well as a range of screws manufactured from titanium alloy (Ti-4Al-6V ELI) per ASTM F136. The associated system instruments, which facilitate the placement, adjustment, and removal, if necessary, of the implants, are manufactured from medical-grade materials, such as stainless steels and plastics.

INTENDED USE

The corra® cervical plating system is intended to provide immobilization and stabilization of the cervical spine to facilitate fusion.

INDICATIONS FOR USE

The corra® cervical plating system is intended for anterior cervical fixation (C2-T1) for the following indications:

- 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,
- Pseudoarthrosis, and
- Failed previous fusion.

The corra® cervical plating system is intended to be used in conjunction with the aprevo® cervical interbody system.

CONTRAINDICATIONS

Contraindications for the corra® devices include, but are not limited to:

- Active infectious process or previous history of infection
- Local inflammation
- Morbid obesity
- Fever or leukocytosis
- Pregnancy
- Mental illness, substance abuse, or patient unwilling or unable to follow instructions regarding post-operative care or limitations
- Suspected or documented allergy or sensitivity to implant materials
- Patients with inadequate tissue coverage over the operative site
- Patients with inadequate bone stock or quality
- Any other medical or surgical condition that would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count

WARNINGS & PRECAUTIONS

The corra® devices must only be used in the patient for whom they were designed and/or planned. Only use the corra® devices if the patient-specific ID markings on the package match the identification of the patient.

The corra® devices are supplied STERILE and should not be re-sterilized. The patient-specific devices should not be used if package is opened or damaged, if expiration date on the label has passed, or if the anatomy or condition of the intervertebral space has changed since the radiological images were acquired. The associated instruments are also provided sterile. The sterilization method used is indicated on the device packaging label by one of the sterile symbols shown in the Symbols Glossary section.

Implants should never be reused under any circumstances. Implants that have come in direct contact with blood, bone, tissue or other body fluids should be discarded. While the implant may appear undamaged, it may have small defects or internal stress patterns and if implanted, could fail to perform as intended and pose safety risks to the patient. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, difficulty with implantation, incompatibility with mating components, and transmission of infectious agents.

The implants are not prostheses. In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend, or fracture as a result of exposure to everyday mechanical stresses.

The corra® devices are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Compliance with pre-operative and perioperative procedures, including knowledge of the corra® surgical technique, as well as proper preoperative planning, surgical technique, and selection and placement of implants, are important factors in the successful use of the system by the surgeon. Further, the proper patient selection and compliance of the patient will greatly affect the results. The surgeon should consider the levels of implantation, patient weight, patient activity level, and all other patient conditions that may impact the performance of the device. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. No spinal implant can withstand body loads for an indefinite period of time without the support of bone. These devices can break when subjected to the increased load associated with delayed union or nonunion. Internal fixation devices are load-sharing devices that hold bony structures in alignment until fusion occurs. In the event that successful fusion is not achieved, bending, breakage, loosening, or disassembly of the device may occur.

These warnings and precautions do not include all of the adverse effects that could occur with implantation of the corra® device or with any surgery. Patients should be informed of the risks associated with spinal surgery, general surgery, and the use of general anesthesia. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

POSSIBLE ADVERSE EFFECTS

Pre-operatively, the patient should be made aware of the possible adverse effects of spinal surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

- Early or late loosening of components
- Bending, disassembly, or breakage of components

- Device malposition potentially requiring revision surgery
- Non-union (pseudarthrosis), delayed union, or malunion
- Implant material sensitivity or allergic reaction to a foreign body
- Infection
- Bursitis
- Change in mental status
- Postoperative change in spinal curvature, spinal correction, and/or gain or loss in height
- Loss of or increase in spinal mobility or function
- Bone loss or decrease in bone density, possibly caused by stresses shielding
- Bone graft, vertebral body, and/or sacral fracture
- Cessation of any potential growth of the operated portion of the spine
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Herniated nucleus pulposus or disc disruption or degeneration at, above, or below the level of surgery
- Nerve damage due to surgical trauma or presence of the device
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain
- Dural tear, chronic CSF leakage, and/or meningitis
- Urinary retention, loss of bladder control, or other types of urological system compromise
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise
- Loss of neurological function (e.g., sensory and/or motor) including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits
- Death

MRI SAFETY INFORMATION

The corra® devices have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the corra® devices in the MR environment is unknown. Scanning a patient who has these devices may result in patient injury.

PREOPERATIVE MANAGEMENT

- Only patients that meet the criteria described in the indications should be selected. Patient condition and/or predispositions, such as those addressed in the aforementioned contraindications, should be avoided.
- Confirm the patient specific ID markings on the package match the identification of the patient.
- The surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before surgery.
- Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
- For sterile devices, ensure highly aseptic surgical conditions, and use aseptic technique when removing the device from its packaging. Inspect the implant and packaging for signs of damage, including scratched or damaged devices or damage to the sterile barrier. Do not use the devices if there is any evidence of damage.
- Care should be used during surgical procedures to prevent damage to the devices and injury to the patient.

INTRAOPERATIVE MANAGEMENT

- The procedure should be performed by a surgeon who has received the necessary spinal surgery training.
- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- Use great care to ensure implant surfaces are not scratched or notched since such actions may reduce the functional strength of the construct.

- Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
- Prior to soft tissue closure, recheck all screws to ensure they are tightened. Failure to do so may cause loosening of the other components.

POSTOPERATIVE MANAGEMENT

- Postoperative management of the patient is essential. The patient should have a complete understanding of and compliance with the purpose and limitations of devices used in their surgery.
- Patients should be instructed to limit post-operative activity as determined by their surgeon.
- Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if components loosen, bend, or break, the devices should be revised or removed immediately before serious injury occurs.
- The patient should be advised not to smoke, use nicotine products, or consume alcohol, as well as avoid non-steroidal and anti-inflammatory medications, such as aspirin, during the bone graft healing process.
- The implants are designed to stabilize the spine during the normal healing process. After the spine is fused, any devices that serve no ongoing functional purpose may be removed.
- Retrieved implants should be properly disposed of and should never be reused under any circumstances.

CUSTOMER SERVICE

For further information regarding the corra® devices, or for a copy of the Surgical Technique Guide, please contact Carlsmed, Inc. or your local corra® device distributor.



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SYMBOLS GLOSSARY

	Manufacturer		Date of manufacture		Consult instructions for use
	Catalogue number		Use-by date		Sterilized using irradiation
	Lot number		Do not re-use		Sterilized using steam heat
	Unique Device Identifier		Do not re-sterilize		Single sterile barrier system with protective packaging inside
	Medical Device		Do not use if package is damaged and consult instructions for use		Non-sterile
	Prescription only				