corra™ cervical plating system

Instructions for Use

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 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.

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

CONTRAINDICATIONS

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

- Presence of fever, infection, or inflammation (systemic or localized)
- Morbid obesity
- Pregnancy
- Mental illness or drug abuse
- Severe osteopenia (or any other medical or surgical condition) that would preclude potential benefits of implants
- Suspected or documented allergy or intolerance to metals
- Patients unwilling or unable to follow instructions regarding post-operative care or limitations
- Diffuse multilevel neoplastic disease such that no adjacent normal segments exist for engagement of instrumentation
- Any case not listed in the indications

RELATIVE CONTRAINDICATIONS

- Osteoporosis
- Smoking
- Malnutrition
- Anemia

- Chronic hypoxemia
- Severe cardiopulmonary disease
- Severe depression/psychosocial issues
- Secondary gain issues

WARNINGS

The corra™ devices must only be used in the patient for whom they were designed and/or planned. Only use the corra™ device if the patient specific ID markings on the sterile package match the identification of the patient. The corra™ devices are supplied STERILE and should not be re-sterilized.

Do not use if package is opened or damaged or if expiration date has passed.

The corra™ devices may become loose or break if subjected to increased loading, especially in the condition of delayed union or non-union. The implant's longevity can be affected by the patient's weight, activity level, and adherence to load-bearing instructions. Delayed union or non-union can result in loads on the implant over time that are higher than expected, increasing the risk of implant breakage. The patient should be made aware of the risks of implant failure.

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

These warnings do not include all of the adverse effects that could occur with implantation of the corra™ devices or with any surgery. Patients should be informed of the risks associated with spinal surgery, general surgery, and the use of general anesthesia. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

PRECAUTIONS

The implantation of the corra™ devices should be performed only by experienced spinal surgeons with specific training in the use of the devices, due to the technically demanding nature of the procedure and the potential for serious injury to the patient.

The corra™ devices are designed to support physiologic loads. Damage to the devices from excessive forces or torque from the insertion instruments can cause defects in the devices that can lead to misalignment or breakage and should be avoided. Do not implant any device that has fractured or has visible cracks, surface imperfections, or other damage.

The patient should be adequately informed about the advantages, disadvantages, and limitations of the corra™ devices. The patient should be encouraged to ambulate as soon as possible following surgery, while limiting lifting and twisting motions and any type of sports activities until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend, or break if excessive demands are placed on it, especially if the bone has not completely healed. Implants displaced or damaged by improper activities may experience implant migration and subsequent damage to nerves or blood vessels.

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.

The removal of supplemental fixation following completion of its intended use should be carefully considered by the surgeon. While not removing the supplemental fixation eliminates the risk associated with this additional surgery, leaving the implants in place could result in complications that include, but are not limited to:

- Risk of additional injury from post-operative trauma
- Bending, loosening, or breakage of the fixation implant
- Possible increased risk of infection
- Pain or discomfort associated with the fixation implant
- Bone loss or reduced bone healing due to stress shielding

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:

- Bending or fracture of the implant
- Loosening or movement of the implant
- Implant material sensitivity or allergic reaction to a foreign body
- Infection, early or late
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma or presence of the device
- Neurological difficulties including bowel and/or bladder dysfunction, radicular pain, tethering of nerves in scar tissue, muscle weakness, gait instability, and paresthesia
- Vascular damage could result in catastrophic or fatal bleeding
- Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later post-operative period
- 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
- Bursitis
- Spinal cord impingement or damage
- Fracture of bony structures
- Reflex sympathetic dystrophy
- Degenerative changes or instability in segments adjacent to fused vertebral levels
- Esophageal perforation, erosion, or irritation
- Paralysis
- Death

DIRECTIONS FOR USE

The corra™ devices and instruments are 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.

Before using a corra™ device for the first time, the surgeon should be thoroughly familiar with the Surgical Technique Guide (available upon request) as well as the functionality and assembly of the devices. Lack of experience or expertise with these implants may result in complications.

The corra™ devices are designed to match a personalized surgical plan that is developed using the patient's radiological images. The patient-specific corra™ devices and associated sterile devices should not be used past the expiration date on the label.

POST-OPERATIVE PATIENT CARE

Post-operative external immobilization (e.g., bracing or casting) is recommended, at the surgeon's discretion. The patient should be encouraged to ambulate as soon as possible following surgery, while limiting lifting and twisting motions and any type of sports activities until the bone is healed.

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 resterilize		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				