CE 2292

# Sterile Anterior Cervical Plate System

## INSTRUCTIONS FOR USE

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|---|---|
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**Please read the Instruction for Use carefully before using the product.**

## 1. Description

The Sterile Anterior Cervical Plate System is a single use, anterior cervical spinal fixation device made of titanium alloy (Ti-6Al-4V). The implants are intended for stabilization of the cervical spine utilizing screw fixation at the anterior face of the vertebral bodies. The device is used by trained orthopedics surgeons and/or neurosurgeons in a standard operating environment.

Multiple choices of implants are offered by the Sterile Anterior Cervical Plate System, including various lengths of anterior cervical plates for single and multiple levels of fixation and different types of matching fixed screw, self-tapping screw, adjustable screw and self-tapping adjustable screws. Detailed information is listed in the following table 1.

Table 1 Sterile Anterior Cervical Plate System Specification

| Components | Specification | | |
|---|---|---|---|
| Anterior plate II | Length | | |
| | 22.5～85mm with 2.5mm increment;<br>90～110mm with 5mm increment | | |
| Fixed screw I & self-tapping fixed screw I | Diameter | Size | Length |
| | 4.0mm | 11-17 mm with 1mm increment | 14-20 mm with 1mm increment |
| | 4.5mm | 11、13、15、17mm | 14、16、18、20mm |
| Adjustable screw I & self-tapping adjustable screw I | Diameter | Length | Length |
| | 4.0mm | 11-17 mm with 1mm increment | 14-20 mm with 1mm increment |
| | 4.5mm | 11、13、15、17mm | 14、16、18、20mm |

## 2. Indications for Use

The Sterile Anterior Cervical Plate System is indicated for stabilization of the anterior spine during the development of cervical spinal fusion in patients with degenerative disc disease (DDD) of the cervical spine, spondylolisthesis, trauma (i.e., fractures or dislocations), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis and failed previous fusion. The system is intended for C2-C7.

## 3. Contraindications

Contraindications include but are not limited to:

1) Obvious risks for infections
2) Local inflammation

3) Fever
4) Morbid obesity
5) Pregnancy or lactation
6) Mental illness
7) Grossly distorted anatomy due to congenital anomalies
8) Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital malformations, acceleration of sedimentation rate and leukocytosis
9) Rapid joint diseases, bone resorption, decreased bone density, chondropathy and/or osteoporosis. (Decreased bone density and osteoporosis are relative contraindications that reduce the stability, correction efficacy and mechanical strength)
10) Suspected or documented allergy or intolerance to composite materials
11) Any case not needing implantation and bone fusion
12) Any case where the implant components selected for use would be too large or too small to achieve a successful result
13) Any case that requires the combined used of different materials or systems from more than one company
14) Any patients having inadequate tissue coverage over the operative site; inadequate bone stock or bone quality
15) Any patients in which implant utilization would interfere with anatomical structures or expected physiological performance
16) Any patients unwilling to follow postoperative instructions.
17) Any case not described in the indications

## 4. Warnings & precautions

### - General

1) The devices should only be used on patients between 12 and 80 years old. The device is not intended for the treatment of children below 12 years old.
2) Spinal fusion surgery should be performed only by trained orthopedic surgeons and/or neurosurgeons, as it demands both specialized skills and experience. Correctly performed preoperative and postoperative procedures are critical for the success of spinal fusion.
3) The implant and related specialized instruments cannot be used in combination with other products of different companies. Titanium alloy components must not be used with stainless steel components.
4) The system was designed for single use only. Never reuse the implants because the risks of infection, breakage and possibly other adverse events may increase. Used implants include any implant that has had contact with blood, bone, tissue and/or other body fluids. After removal, the device

should be disposed in such a manner that its reuse is not possible.

5) Proper selection of the size of the implant for each individual patient is important. Implants of different dimensions should be prepared for the surgery. The correct choice could increase the rate of success. The inappropriate selection, installation and position of the implant will greatly reduce its longevity.
6) During any stage of the surgery, minimizing the stress on the implant and optimizing the circumstances for fusion are crucial. High or repeated stress cycles can loosen, move, exhaust or break the implant before fusion is completed.
7) Follow the physician's instruction before any CT, MRI check.

- **Preoperative**

1) Only patients who meet the criteria described in the indications should be selected. Patient conditions and/or predispositions such as those mentioned in the contraindications should be avoided.
2) Patients should be carefully examined regarding contraindications. The user should also inform the patients about the potential risks and adverse events.
3) The implants should be handled and storage carefully. Collision, bending or scratching may greatly reduce the strength and lifetime of the device. Implants and instruments should be protected from corrosive environments.
4) Devices should be inspected for damage and integrity before use. Damaged or deformed devices should not be used.
5) Care should be taken to avoid damage to the device(s) and injury to the patients.
6) The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of sizes should be available at the time of surgery.
7) The surgeon should be familiar with the various implants before the surgery and should personally assemble the instruments to verify that all parts and necessary instruments are present before the surgery begins.
8) Prior to surgery, the patient must be informed to all potential risks and adverse effects contained in the present instruction for use.

- **Intraoperative**

1) The user should follow the instructions in the surgical technique manual.
2) Breakage, slippage and misuse of instruments or implants may cause injury to the patients or operative personnel.
3) The user should be extremely careful when using implants or instruments around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
4) To avoid over-reduction or over-extension, it is advised to operate under X-ray or spinal cord monitoring.
5) Always orient the Anterior Cervical Plate as close as possible to the spinal midline.

6) Before closing the soft tissues, all of the set screws should be tightened firmly. Recheck the tightness of all set screws after finishing to make sure that none have loosened during the tightening of the other set screws. Failure to do so may cause loosening.

- **Postoperative**

1) Patients should be aware of the post-operative limitations, such as weight-bearing, muscle activity and sudden movements. The patients should also be informed about the fact that implants are not as strong and reliable as healthy bones. Until fusion is finished, implants cannot restore the spine to its normal flexibility, strength and durability. Non-compliance with the post-operative limitations will increase the risk of breakage, migration or loosening of the implant and other complications. Smoking may result in delay or failure of graft fusion; smoking patients should be made aware of this postoperative limitation.
2) In the first 12 month after the surgery, the devices must be controlled periodically to ensure the earliest possible detection of loosening, migration or breakage, using appropriate radiographic techniques. If any of the mentioned complications occur, the risk of deterioration should be evaluated. Measures such as further lowering activity level and/or early revision should be considered.
3) It is advised to wear external support (i.e. neck support) for 3-6 months as auxiliary tension reliever.
4) To allow the maximum chances for a successful surgical result, the patient or device should not be exposed mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions, and any type of sport participation that may cause sharp forces to the cervical spine.

## 5. Potential adverse events

It is important to understand that not using the specified instruments may lead to adverse events. With proper equipment, potential adverse events include, but are not limited to:

1) Loosening, deformation and breakage of implant
2) Changes in spine curvature, loss of inter vertebral height
3) Infection
4) Inadequate tissue covering by the patients may affect the skin and lead to penetration of skin, irritation, fibrosis, necrosis and/or pain and bursitis. Inappropriate implantation or position of implants may lead to muscle and neurological damage.
5) Dural tear, pseudo encephalomyelitis, fistula, persistent cerebrospinal fluid leakage and meningitis.
6) Loss of neurological functions (e.g. sensory and/or motoric function), including paralysis (total or partial), loss of sensitivity, hyperalgesia,

numbness, paresthesia, nerve root disease symptoms, persistent and/or aggravated pain, neuroma, convulsion, tinnitus, and/or visual decline.

7) Cauda equina syndrome, neurological disease, neurologic decline (temporary or permanent), paraplegia, paresis, reflection decline, stimulation, arachnoid inflammation, and/or muscle loss.
8) Urinary retention, bladder control problems, or other types of urinary tract complications.
9) Scar formation may lead to neurological degeneration or nerve pressure and/or pain.
10) Bone fractures, micro fracture, resorption, damage or penetration on the horizontal level or up-down positions in any spine bone (including sacrum, pedicle, and/or vertebral body)
11) Disc hernia, debacle or penetration at the surgery site and its surrounding places.
12) Bone non-union (orpseudoarthrosis). Delayed bone union or bone mal-union.
13) Loss or increase of spinal motor function.
14) Inability of the patients to perform the activities of daily living
15) Loss of bone or bone mineral density caused by stress sheltering.
16) Difficulties at the implant site, including pain, fracture and healing of the injury
17) Intestinal obstruction, gastritis, intestinal occlusion or bowel disorders, or other types of gastrointestinal complications.
18) Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, thrombosis and stroke, excessive bleeding, phlebitis, wound necrosis, torn wound, blood vessel damage, or other types of cardiovascular system failures.
19) Reproductive complications, including sexual dysfunction.
20) Respiratory complications, such as pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
21) Changes in mental status.
22) Death.

## 6. User Group

The person or persons who will use our device:

1) Completed medical professions.
2) Have serious operational experience.
3) Careful during the operation.
4) Have adequate experience in the use of the device.

## 7. Packaging

Packages for each of the components should be intact upon receipt. Damaged packages and products must not be used and returned to Shanghai REACH Medical Instrument Co., Ltd.

## 8. Storage

Care should be taken in the handling and storage of the implants. Relative humidity of the storage room should be under 80%, with good ventilation. Implants and instruments should be protected from corrosive environments.

## 9. Sterilization

The implants which are delivered sterile have been exposed to of 25-45kGy of gamma irradiation from a cobalt 60 source.

To reduce the risk of infection the packaging, all sterile devices must be inspected for flaws in the sterile.

The implants package is valid for 5 years. In the presence of barrier destruction or expiration of shelf life, the device is considered non-sterile, and must be discarded.

## 10. Surgical Technique Guides

To obtain copies of the surgical technique guides, you can contact Shanghai REACH Medical Instrument Co., Ltd. customer service or local sales representative.

## 11. Product Complaints

Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any product should notify Shanghai Reach Medical, or, where applicable, their distributor. In the event of a serious incident, or risk of a serious incident, having resulted in, or that may potentially result in, the death or severe deterioration in the state of health of a patient or user, Shanghai Reach Medical or the distributor must be notified as soon as possible. When filing a complaint, please provide the component(s) reference number, manufacturing lot number(s), your name and address, and the nature of the complaint in full detail, as well as notification of whether a written report is requested.

## 12. MR Information

The Sterile Anterior Cervical Plate System has not been evaluated for safety, heating, migration, or compatibility in the magnetic resonance environment.

## 13. Symbols

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| CE 2292 | **The device complies with European Directive MDD93/42/EEC** | STERILE R | **Sterilized using irradiation** |

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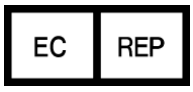
|---|---|---|---|
|  | **Batch code** |  | **Consult instructions for use** |
|  | **Do not re-use** |  | **Do not use if package is damaged** |
|  | **Date of Manufacture** |  | **Catalogue number** |
|  | **Caution** |  | **Use-by date** |
|  | **Medical Device** |  | **Keep away from sunlight** |
|  | **Keep dry** | | |
|  | **Manufacturer**<br>Shanghai REACH Medical Instrument Co., Ltd<br>Building 13,No.999 Jiangyue Road, Minhang District,201114 Shanghai, PEOPLE'S REPUBLIC OF CHINA<br>Floor 1, Building 6, No. 67, Lane 1768, Liyue Road, Minhang District,201114 Shanghai, PEOPLE'S REPUBLIC OF CHINA | | |
|  | **Authorized representative in the European Community**<br>CMC Medical Device & Drugs S.L.<br>C/Horacio Lengo, 18, 29006, Málaga, España<br>Tel:+34951214054 | | |

**Note: Not all of these symbols will appear on the labels you see, you may see them on labels in different regions/countries and understand what they mean.**

## 14. Contact Information

For further information, please contact:
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**15. Revision Status**
Latest revision number: 1.5
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