CE 2292

Sterile Cervical Interbody Fusion Cage

INSTRUCTIONS FOR USE

Company Name	Shanghai REACH Medical Instrument Co., Ltd
Address	Building 13,No.999 Jiangyue Road, Minhang District,201114 Shanghai, PEOPLE'S REPUBLIC OF CHINA
Phone Number	+86 021 54840582
Fax Number	+86 021 54840581
EC Representative	M/s CMC Medical Devices & Drugs S.L. C/Horacio Lengo N°18,CP29006,Málaga,Spain

Please read the Instruction for Use carefully before using the product.

1. Description

The Cervical Interbody Fusion Cage is a single-use fusion product developed for single or multi-segmental stabilisation of the cervical column. The implant components of the Cervical Interbody Fusion Cage system consist of a titanium alloy.The product is used in a normal operating environment by trained orthopedics and neurosurgeons. The Cervical Interbody Fusion Cage system are offered in a variety of implants geometries and sizes to accommodate patient anatomy. It is supplied sterile and is avaliable in a variety of heights, footprints and lordosis angles .

2. Indications For Use

The Cervical Interbody Fusion Cage is intended for spinal fusion procedures at one or more levels (C2-Tl) in skeletally mature patients with degenerative cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion at one or more levels of the cervical spine with accompanying radicular symptoms. Implants are to be packed with autogenous bone. They are placed via an anterior approach. In cases of segmental instability,this device is intended to be used with a supplemental internal fixation system appropriate for use in the cervical spine.

3. Contraindications

Contraindications include but are not limited to:

1) There is a significant risk of infection.
2) Local inflammation.
3) Fever.
4) Morbid obesity.
5) Pregnancy and lactation.
6) Mental illness.
7) Excessive anatomical distortion caused by congenital malformation.
8) Any medical or surgical conditions that hinder the success of spinal implantation, such as congenital malformation, acceleration of unidentified sedimentation caused by other diseases, increase of white blood cell number, etc.
9) Acute joint disease, bone resorption, bone sparseness, chondropathy and / or osteoporosis. Osteoporosis or osteopenia is a relative contraindication, which can reduce the degree of correction, stability and mechanical fixation.
10) Metal allergy, allergic constitution or allergy to multiple drugs.
11) No bone grafting or fusion is required.
12) Any implant that needs to be too large or too small.
13) Any combination of two sets of components or systems from different manufacturers is required.

14) Any patient does not have enough tissue to cover the surgical wound or does not have enough bone mass or poor bone quality.
15) Any patient's use of the implant in the body conflicts with the anatomical structure or expected physiological behavior.
16) Any patient fails to follow the doctor's order after operation.
17) Anything not within the scope of indications.

4. Warning and Precautions

- **General**

  - The devices should only be used for patients between 12 and 80 years old. The device is not intended for the treatment of children below 12 years old.
  - Cervical fusion surgery should be performed only by trained orthopaedic surgeons and neurosurgeons, as it requires both, specialized skills and experience. Correct preoperative and postoperative measures are critical for the success of cervical fusion.
  - The implant and related specialized instruments cannot be used in combination with other products of different manufacturers. Titanium alloy components must not be used in combination with stainless steel components.
  - The Cervical Interbody Fusion Cage systems are 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.
  - Proper selection of the size of the implant for each individual patient is important. Implants of different dimensions should be prepared for the surgery, because a correct choice of the device may increase the rate of success. The inappropriate selection, installation and position of the implant will greatly reduce its longevity.
  - During any stage of the surgery, minimizing the stress on the implant and optimizing the circumstances for fusion is crucial. High or repeated stress cycles can loosen, move, exhaust or break the implant before fusion is complete.

- **Preoperative**

  - Only patients who meet the criteria described in the indication´s section should be chosen.
  - Patient should be carefully examined regarding contraindications. The user should also inform the patient about the potential risks and adverse events.

- The implants should be handled and stored carefully. Collision, bending, scratching may greatly reduce the strength and lifetime of the implants. Implants and instruments should be protected from corrosive environments.
- Devices should be inspected for damage and integrity before use.
- Care should be taken to avoid damage to the device(s) and injury to the patient.

- **Intraoperative**

- The user should follow the instructions in the surgical technique manual.
- Breakage, slippage and misuse of instruments or implants may cause injury to the patient or operative personnel.
- The user should be extremely careful when using implants or instruments around the spinal cord and nerve roots. Damage to nerves will cause severe injuries to the patient.
- It is advised to operate under X-ray or spinal cord monitoring.
- **Warning：The Cevical Interbody Fusion Cage TypeⅠ(Closed) contains a screw plug. Please confirm it is tightened if still want to remain it.**

- **Postoperative**

- The user should follow the instructions in the operation manual.
- Patients should pay attention to postoperative limitations, such as weight pressure, excessive muscle activity and sudden exercise. Patients should also be told that implants are not as strong and reliable as healthy bones. The implants did not restore the normal flexibility, strength, and durability of the spine until the incorporation was completed. Failure to comply with postoperative limitations increases the risk of implant rupture, displacement or loosening, and other complications. Smoking can lead to delayed or failed graft fusion, so smokers should pay attention to this postoperative limitation.
- The device is intended for permanent implantation and is not intended for removal. However, if the combination fails, the risk of a second operation should be considered when removing the implant. Care should be taken to avoid fracture.

5. Potential Adverse Events

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

- Loosening, deformation and breakage of implant
- Changes in spine curvature, loss of intervertebral height
- Infection

- The implant 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.
- Dural tears, pseudo encephalomyelitis, spinal dural fistula, persistent cerebrospinal fluid leakage and meningitis.
- Loss of neurological function (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 aggravating pain, neuroma, convulsion, tinnitus, and/or visual decline.
- Cauda equina syndrome, neurological disease, neurologic decline (temporary or permanent), paraplegia, paresis, reflection decline, stimulation, arachnoid inflammation, and/or muscle loss.
- Urinary retention, bladder control problems, or other types of urinary tract complications.
- Scar formation that may lead to neurological degeneration or nerve pressure and/or pain.
- Bone fractures, micro fractures, resorption, damage or penetration on the horizontal level or up-down positions in any spine bone (pedicle, and/or vertebral body)
- Disc hernia, debacle or penetration at the surgery site and its surrounding places.
- Bone nonunion (or pseudoarthrosis). Delayed or insufficient bone healing.
- Spinal motor function loss or increase.
- Inability of the patient to perform the activities of daily living.
- Loss of bone or bone mineral density caused by stress sheltering.
- Difficulties at the implant site, including pain, fracture and healing of the injury.
- Intestinal obstruction, gastritis, intestinal occlusion or bowel disorders, or other types of gastrointestinal system diseases.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, thrombosis and stroke, excessive bleeding, phlebitis, wound necrosis, torn wound, blood vessel damage.
- Cardiovascular system failure complications.
- Reproductive complications, including sexual dysfunction.
- Respiratory complications, such as pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Changes in mental status.
- Death.

6. User Group

The person or persons who will use our device;

a) Completed medical professions

b) Have serious operational experience

c) Careful during the operation

d) 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. Store the implant in a dry and dust-free place.

Always store the implant in the original protective packaging.

Do not remove the implant from the packaging until immediately before use.

9. Sterile

The product is sterile products. The implant is sterilized with gamma sterilization.

The device is valid for 5 years. Never use the implants if the packageing is damaged and never use implnats that are past their expiration date.

The implant is not designed to be resterilized by the user.

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 an incident, or risk of an 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 Cervical Interbody Fusion Cage has not been evaluated for safety,heating,migration,or compatibility in the magnetic resonance environment

13. Symbols

PICTOGRAM			
	Manufacturer		Authorized representative in the European Community
	Date of Manufacture		Use-by Date
	Batch code		Reference Number
	Do not re-use		**Sterilized using irradiation**
	Do not use if package is damaged		Consult Instructions for use
	Caution		**The device complies with European Directive MDD93/42/EEC**
	**Medical Device**		**Keep away from sunlight**
	**Do not resterilize**		**Keep dry**

Not: 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. Further information

For further information, please contact:

Shanghai REACH Medical Instrument Co., Ltd.

Building 13,No.999 Jiangyue Road, Minhang District,201114 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Tel：(86)021—54840582

Postcode：201114

15. Revision Status

Latest revision number: 1.4

Revision Date: Aug.14.2023