CE 2292

Sterile Posterior Spinal Fixation System

INSTRUCTIONS FOR USE

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

1. Description

The Sterile Posterior Spinal Fixation System, containing the sets RS8 LONG system and LEGEND system is a single-use fixation device which has been developed for single or multi-level thoracolumbar and/or lumbosacral stabilization of the spine. The RS8 LONG and LEGEND system implant components are made of titanium alloy (Ti-6Al-4V).The device is used by trained surgeons in a standard operating room environment .

Multiple choices of implants are offered by the RS8 LONG and LEGEND system, including various lengths and diameters of reduction screws.

2. Indications for Use

The Sterile Posterior Spinal Fixation System is designed for posterior, non-cervical fixation of the spine for the following indications: degenerative disc disease; spondylolisthesis; trauma; spinal stenosis; curvatures; tumor resection; pseudo-arthrosis; and/or failed previous fusion.The devices are used by trained surgeons in a standard operating room environment.

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) Excessive anatomical distortion caused by congenital malformation.
8) Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital malformations, of indications of ongoing infection or inflammation, such as acceleration of sedimentation rate and leukocytosis.
9) Rapid joint diseases, bone resorption, decrease 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 the composite materials.
11) Any case not needing a spinal fixation and/or spinal fusion.
12) Any case where the implant components selected for use would be too large or too small to achieve a beneficial result.
13) Any case that requires the combined use of different devices or systems from more than one company.
14) Any patient without adequate tissue coverage over the operative site or adequate bone stock or bone quality.
15) Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
16) Any patient unwilling to follow postoperative instructions.
17) Any case not described in the indications.

4. Warnings & precautions

- General

1) 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.
2) Spinal fusion surgery should be performed only by trained surgeons, as it requires both, specialized skills and experience. Correct preoperative and postoperative measures 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 manufacturers. Titanium alloy components must not be used in combination with stainless steel components.
4) The RS8 LONG and LEGEND 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. After removal from the patient, it shall be disposed and cannot be reused again.
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, 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.
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.
8) Note no test or evaluation has been carried out on the temperature elevation, displacement status and artifact of this product under the MR environment.

- **Preoperative**

1) Only patients who meet the criteria described in the indications should be selected.
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 stored carefully. Collision, bending, scratching may greatly reduce the strength and lifetime of the implants. Implants and instruments should be protected from corrosive environments.
4) Devices should be inspected for damage and integrity before use.
5) Care should be taken to avoid damage to the device(s) and injury to the patients.

- **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 patient 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 severe injuries to the patients.
4) To avoid over-reduction or over-extension, it is advised to operate under X-ray or spinal cord monitoring.

- **Postoperative**

1) Patients should be aware of the postoperative limitations, such as weight-bearing, excessive muscle activity and sudden movements. Patients should also be informed about the fact that implants are not as strong and reliable as healthy bones. The implants cannot restore the normal flexibility, strength and durability of the spine until the fusion is completed. Noncompliance with the postoperative 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, so smoking patients should be made aware of this postoperative limitation.
2) During the first 12 month following the surgery, the devices must be checked 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. It is recommended to wear external support for 3-6 months as auxiliary tension release device.
3) Even after fusion is achieved, implants may still loosen, break and corrode. If the implants remain in the body for more than 1.5 years, complications may occur, including functional failure of the implants, corrosion, soft tissue response and pain, harm to soft tissues, nerves and joints due to migration, difficulty in removing the implants, pain and discomfort caused by the implants, increasing risk of infection and reduction of load-bearing capacity of normal bones. If these occur, implants should be removed.
4) When removing the implants, the risk of a second surgery should be taken into consideration. Care should be taken to avoid bone 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:

1) Loosening, deformation, and breakage of implant.
2) Changes in spine curvature, loss of intervertebral height.
3) Infection.
4) 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.
5) Dural tears, pseudo encephalomyelitis, spinal dural fistula, persistent cerebrospinal fluid leakage and meningitis.
6) 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.
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 that may lead to neurological degeneration or nerve pressure and/or pain.

10) Bone fractures, micro fractures, 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 nonunion (or pseudoarthrosis). Delayed or insufficient bone healing.
13) Spinal motor function loss or increase.
14) Inability of the patient 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 system diseases.
18) Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, thrombosis and stroke, excessive bleeding, phlebitis, wound necrosis, torn wound, blood vessel damage.
19) Cardiovascular system failure complications.
20) Reproductive complications, including sexual dysfunction.
21) Respiratory complications, such as pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
22) Changes in mental status.
23) Death.

6. User Group

The person or persons who will use our device should have:

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. Barrier or expiration of shelf life must be checked before opening. In the presence of such a flaw or expiration of shelf life, the implants are 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

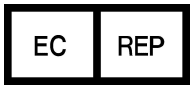
Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any product should notify Shanghai Reach Medical, or, where applicable, their distributor. In the event of 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

The Sterile Posterior Spinal Fixation System has not been evaluated for safety, heating, migration, or compatibility in the magnetic resonance environment.

13. Symbols

CE 2292	**The device complies with European Directive MDD93/42/EEC**	STERILE R	**Sterilized using irradiation**
LOT	**Batch Code**		**Consult instructions for use**
	**Do not re-use**		**Do not use if the package is damaged**
	**Date of Manufacture**	REF	**Catalogue number**

	**Caution**		**Use-by date**
	**Medical Device**		**Keep away from sunlight**
	**Do not resterilize**		**Keep dry**
	**Manufacturer**		
	**Authorized Representative in the European Community**		

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. Other Information

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15. Revision Status

Latest revision number: 1.4

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