Shanghai REACH Medical Instrument Co.,Ltd.

Please read the instruction for use carefully before using the product.

Disposable Spinal Fixation Instrument Set

Instruction for use

1. Description

The Disposable Spinal Fixation Instrument Set, including 34 types ,is a set of surgical tools for fixation of the spine. The product is intended to be used in a standard operating environment.All surgical instruments require exact knowledge of spine stabilization by trained orthopaedic surgeons and neurosurgeons.

2. Indications for use

The disposable spinal fixation instrument set is intended for pedicle fixation in a percutaneous approach for the following indications：

1）thoracolumbar vertebral fracture,

2）degenerative disc disease，

3）spondylolisthesis,

4）trauma (i.e., fracture or dislocation),

5）spinal stenosis,

6）curvatures,

7）pseudoarthrosis,

8）tumor,

9）failed previous fusion in mature patients

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 anomalies.
8) Any other condition which would preclude the potential benefit of spinal fixation surgery, such as the presence of congenital malformations, accelerated unexplained sedimentation caused by other diseases, increased white blood cell count, etc.
9) Acute 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) Metal allergies, allergic constitutions or those who are allergic to multiple drugs.
11) Any case where spinal fixation or spinal fusion is not necessary.
12) Any case where the implant components 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 patients without adequate tissue coverage on the surgical area or adequate bone stock or bone quality.
15) Any patient that implant utilization would interfere with anatomical structures or expected physiological performance.
16) Any patient unwilling to cooperate with postoperative instructions by the doctors.
17) Person whose age is not between the age of 12 to 80.
18) Any case not described in the indications.

4. Safety warning

1) This product is sterile. It is a disposable product and should not be reused.
2) This product and its supporting special instruments must not be mixed with similar products of other manufacturers. Titanium alloy and stainless steel materials must not be mixed.
3) Only trained physicians who are familiar with the appropriate surgical techniques can use this product and give detailed medical advice to the patient.

5. Precautions

1) Users should be proficient in the operation of this product and follow the instructions in the Surgical Technical Manuals. A preoperative plan should be created in advance.
2) This product must be used by experienced and trained spine surgeons. This is a high-risk surgical procedure that is potentially harmful to the patient.
3) Preoperative, the physician should fully understand the physical and psychological limitations of the patient's use of the product, and must inform the patient of the risks of surgery and possible adverse factors.
4) The product should be transported and stored carefully. Collision, bending, and scratching can significantly reduce tool strength and fatigue life, which may cause the tool to break. The process has to be stopped and identified immediately if any instrument damage or deformation.
5) Preoperative, the integrity of the package should be checked. Damaged packaging and products should not be used, and the sterilization status has to be clarified.
6) Intraoperative, a complete set of equipment kits must be prepared.To increase the success rate of surgeries it is necessary to choose the right tool. Conversely, incorrect usage can cause damage and breakage of the tool, which can result in a shorter life span of the tool.
7) Postoperative, the product should be disposed in accordance with hospital regulations.

6. Packaging

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

7. Transport and storage

Product transportation and storage conditions: The product is to be stored in a place with a relative humidity of not more than 80%, good ventilation, and no corrosive gas.

8. Repair and maintenance

If the product is damaged or needs to be repaired, please contact us for repairing under the guidance of a professional.

9. Surgical Technique Guides

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

10. Product Complaints

Any health care professional (e.g. a surgeon using the product) who has a complaint or dissatisfied with the quality, identity, reliability, safety, efficacy, and/or performance of products should notify Shanghai Reach Medical or, where applicable, their distributor. In case of an incident, risk or already resulted incident 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 details, as well as the notification of whether a written report is requested or not.

11. Label Symbol

LOT	Batch Code		Do not re-use
	Consult instructions for use		Use-by date
	Caution	STERILE EO	Sterilized using ethylene oxide
	Date of manufacturer	CE 0123	The device complies with European Directive MDD93/42/EEC
	Do not use if package is damaged		Do not resterilize
REF	Catalogue number		Keep away from sunlight
MD	Medical Device		Keep dry
	Manufacturer		
EC REP	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.

12. Other Information

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13. Revision History

	Revise contents	Revise date
A/1	Adding file No.TCF-RZ-GJ-01-B6-02	2019.06.17
A/2	Modifying the writing of manufacturer's address, from “13th, No.999 Jiangyue Road, Minhang District, Shanghai, P. R. China” to “Building 13, No.999 Jiangyue Road, Minhang District, 201114 Shanghai, PEOPLE'S REPUBLIC OF CHINA”, the actual address is the same.	2019.08.19
A/3	Modify grammatical errors and INDICATIONS	2019.09.24
A/4	Modify grammatical errors and INDICATIONS	2020.7.30
A/5	Add some symbols information	2022.3.31
A/6	Change the EC representative	2023.7.11