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

Instruction for Use

Orthopedic Instrument

1. Product name

Orthopedic Instrument

2. Intended use

Orthopedic Instrument is primarily used in conjunction with spinal implants/invasives during spinal surgery. Suitable for spinal fixation surgery, spinal fusion surgery, decompression surgery, vertebroplasty surgery and revision surgery.

3. Product description

These Orthopedic Instrument contains various tools for use with spinal implants/invasives, mainly made of stainless steel 17-4PH,304,420B,440B,silicone,POM,PEEK-CF,PEEK,PPSU materials. They are supplied non-sterile, sterilized by hospitals before use, and they are reusable for use by specialized physicians in standard operating rooms.

4. Product components

For product components, please refer to Appendix 1.

Different surgeries and different doctors require different instruments, so not all the above tools will appear at your site, we will choose and distribute them according to customer needs.

5. 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. Metal allergy, allergic constitution or allergic to multiple drugs.
8. Any need to choose too big or too small tools.
9. Anything not within the scope of the indication.

6. General requirements

All instruments labeled as non-sterile are to be cleaned, disinfected, and sterilized prior to each application; this is

required as well for the first use after delivery of the non-sterile instruments (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the instruments.

The sterility of the instruments falls under your responsibility. Please ensure that only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection, and sterilization, that the used devices will be maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.

Additionally, please pay attention to the legal provisions valid for your Country as well as to the hygienic instructions of the hospital.

Caution: Non-sterile instruments are provided in a protective packaging designed for maintaining the integrity and cleanliness of the product. However, in no case the product shall be sterilized within this packaging, but needs to be removed from the package and be treated as follows.
Reprocessing procedures have only limited implications to these instruments. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation or malfunction.

7. Cleaning And Disinfection

Reprocessing Instructions

1. Preparation at the Point of Use: Remove gross soiling of the device with cold water (<40°C) immediately after use, if applicable. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process.

2. Transportation: Safely store the device in a humid surrounding and transport it to the reprocessing area to avoid any damage and contamination to the environment.

3. **Preparation for Decontamination:** The devices must be reprocessed in a disassembled state, as far as possible.

4. Pre-Cleaning: Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution. Clean the surfaces with a soft bristle brush.

5. Cleaning: Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better reproducibility and standardisation, and in personnel protection.
Automated Cleaning:
Use a washer-disinfector meeting the requirements of the EN ISO 15883 series.

The products in the washer-disinfector are arranged in such a way that there is no rinsing shadow and the water drains off quickly. Start the program:

- 4 min pre-washing with cold water (<40°C);
- emptying
- 5 min washing with a mild alkaline cleaner at 55°C
- emptying
- 3 min neutralising with warm water (>40°C);
- emptying
- 5 min intermediate rinsing with warm water (>40°C)
- Emptying

6. Disinfection: A disinfection cycle of 5 min disinfection at 90°C has been validated for the device to achieve an A0 value of > 3000. Here Shanghai REACH suggests a disinfection cycle of 5 min disinfection time at 93 °C.

7. Drying: Drying the products through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of products by using sterile compressed air.

8. Functional Testing, Maintenance:

Visual inspection for cleanliness of the products and reassembling, if required.

All products should be checked again for dryness.

After cleaning and disinfection, a thorough inspection and maintenance ensures that the products are fit for use.

- Check that the product has no dents, cracks, deformations, scratches, etc.;
- Check all markings on the product for clear visibility.

Discard and replace any components as necessary.

Do not use the device with following defects: material deformation, cracks on the product, brittle or other change in the material, etc.

9. Sterilization

Sterilization of products by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN ISO 17665) under consideration of the respective country requirements.

Following sterilization parameters are commonly used: 134 °C, 5 min (standard program in EU)

Drying time:

For steam sterilization, we recommend a drying time of 20 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use.

After sterilization:

- Remove the product from the autoclave.
- Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling.
- Check that the sterilization wraps or pouches are not damaged.

Storage

Please store the instruments after sterilization in the sterilization packagings at a dry and dust-free place.

Material resistance

Please take care that the listed substances are not ingredients of the cleaning or disinfection detergent:

1.Organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)

2.Strong lyes (maximum admitted pH-value 11, neutral/enzymatic, weak alkaline, or alkaline cleaner recommended)

3.Organic solvents (for example: acetone, ether, alcohol, benzine)

4.Oxidizing agents (for example: peroxide)

5.Halogens (chlorine, iodine, bromine)

6.Aromatic, halogenated hydrocarbons

Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments.

Acid neutralizing agents or rinse aids must not be applied.

Please do not clean any instruments by use of metal brushes or steel wool.

Please do not expose any instruments to temperatures higher than 142°C (288°F)

8. Reusability

Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on Shanghai REACH Medical reusable surgical instruments.

End of life of a reusable surgical instrument is normally determined by wear and damage due to use. Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used and must be absolutely replaced by a new one. The user is responsible for each further use as well as for the use of damaged and dirty instruments (no liability in case of disregard).

9. Additional Information for Attention

It remains the responsibility of the processor to ensure that the processing is actually performed, using equipment, materials and personnel in the Central Sterile Supply Department, and achieves the desired result. This requires verification/validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.

All users shall be qualified personnel with documented expertise, competency and training. Users shall be trained on hospital policies and procedures along with current applicable guidelines and standards.

Users shall wear appropriate personal protective equipment when processing devices in accordance with the Department of Environmental and Occupational Health and Safety’s bloodborne pathogen guidelines.

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. Further Information

Surgical operative techniques

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact Shanghai REACH Medical.

Date of manufacture

You could find it in the product label,

Parts list

You could find it in the instrument box or pack.

12. Explanation of Symbols

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.

CE	The device complies with Council Directive 93/42/EEC concerning medical devices	UK CA	UKCA mark
EC REP	European Authorized Representative	LOT	Batch Code
REF	Catalogue number		Importer in the EU
	Consult the Instructions for use		Caution
	Non-sterile	UDI	Unique Device Identification
MD	Medical Device		Date of manufacture
	Keep away form sunlight		Keep dry

Σ	The package contains product's quantity	SN	Serial number
UKRP	Name and Address of UK responsible person		Manufacturer
	Shanghai REACH Medical Instrument Co.,Ltd Address: Building 13, No.999 Jiangyue Road, Minhang District, 201114 Shanghai,PEOPLE'S REPUBLIC OF CHINA Contact Email:info@reach-med.com Tel.: +86 021- -54840582		
EC REP	M/s CMC Medical Devices & Drugs S.L. Address: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain Contact Email: mmateos@cmcmedicaldevices.com Tel: +34951214054		
UKRP	SUNGO Certification Company Limited 3rd floor, 70 Gracechurch Street, London. EC3V 0HR		

13. Revision History

Version Number	Change state	Brief description (Content and scope of change)	Revise date
V1.0	C		2022.3.25
V1.1	M	Revised grammar and fonts, organized layout Refine the content of the appendix 1	2022.4.6
V1.2	M & A	Revised the content of the appendix 1 and added UK Responsible information	2023.8.11

Change state：A：Add M：Modify C:Creation D:Delete

Appendix 1

Note : Only include all categories, not all specifications.

No.	Product Categories	No.	Product Categories	No.	Product Categories
1	Instrument Box	23	Breaker	45	Rod Reducer
2	Case	24	Compressor	46	Power Grip
3	Handle	25	Distractor	47	Pusher
4	Holder	26	Retractor	48	Rocker
5	Driver	27	Hammer	49	Cutter
6	Torx Driver	28	Tube	50	Supporter
7	Hex Driver	29	Sleeve	51	Rod Inserter
8	Forceps	30	Shaft	52	Graft Impactor
9	Wrench	31	Connector	53	Bone Grafting
10	Counter Torque	32	Trocar	54	Scraper
11	Screw Tap	33	Detacher	55	Rasper
12	Trial	34	Periostal Elevator	56	Drill
13	Guide Wire	35	Remover	57	Reamer
14	Guider	36	Pedicle Probe	58	Paddle Shaver
15	Dilator	37	Pedicle Finder	59	Curette
16	Locating Pin	38	Awl	60	Adjuster
17	Distraction Screw	39	Osteotome	61	Locator
18	Bender	40	Bone Cement Injector	62	Clip
19	Measurer	41	Safety Stopper	63	Flexible Arm
20	Test Rod	42	Funnel	64	Needle
21	Blade	43	Reverser	65	Cage Finder
22	Hook	44	Blade Opener		