Trauson (China) Medical
Instrument Co.,Ltd.
9 Longmen Road,
Changzhou, Jiangsu, China
Zip Code: 213164
Tel: +86-519-86387075
Fax: +86-519-86387279

Europe Representative:
Shanghai International Holding
Corp. GmbH (Europe)
Eiffestrasse 80, 20537
Hamburg, Germany
Tel: +49-40-2513175
Fax: +49-40-255726

Orthopedic Instruments

INSTRUCTION FOR USE

CE

GRAPHICAL SYMBOLS	
	Manufacturer
	LOT number
	Do not re-use
	Non sterile
	Consult instructions before use
	Catalog number
	Quantity
	Date of Manufacture

	Do not use if package is damaged
	Humidity limitation
EC REP	European Community Representative
MATL	Material
	Caution, consult accompanying documents
CE 0123	Applicable to Class Is, Im, IIa, IIb, III only

DESCRIPTION

Instruments are made of a variety of materials commonly used in orthopedic and neurological procedures including stainless steel which meets available national or international standards specifications as applied to these devices. Some instruments are made out of aluminum, and while these can be steam autoclaved, certain cleaning fluids must not be employed.

The instruments are precision devices which may incorporate a measuring function. Unless labeled for single use, instruments may be reused.

INTENDED USE

The orthopedic instruments are indicated for use in the operative surgery, with the help of orthopedic instruments, the surgeon can easy to finish the orthopedic surgery.

INDICATIONS FOR USE

Surgical instruments are manually operated devices indicated for use during orthopedic surgery.

CONTRAINDICATIONS

Contraindications include but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Patients with known sensitivity to the materials contacted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
6. Use with components of other systems, unless otherwise specified.
7. Any condition that precludes or compromise the procedure.

WARNINGS AND CAUTIONS

WARNINGS

1. Non-sterile products: The instruments to be used must be cleaned carefully in a clean environment and sterilized thoroughly with appropriate temperature and pressure before they are used.
2. Guide Wires are single use products and therefore must be discarded at the end of a surgical procedure and not be re-used, even if they appear to be undamaged.
3. The methods of use of instruments are to be determined by the user's experience and training in surgical procedures.
4. Do not use these instruments for any action for which it was not intended such as hammering, prying, or lifting. These instruments should be treated as any precision instrument and should be carefully placed on trays, cleaned after each use, and stored, according to generally accepted hospital methods and practices.
5. All parts must be cleaned and sterilized before use. The instruments should be carefully examined prior to use for functionality, excessive wear, or damage. A damaged instrument should not be used as this may increase the risk of malfunction and potential patient injury.
6. Single use devices should not be reused, as they are not designed to perform as intended after the initial use
7. Some devices may develop changes in mechanical, physical or chemical characteristics introduced under conditions of repeated use, cleaning and re-sterilization that may compromise the integrity of the design and/or material leading to diminished safety, performance and/or compliance with relevant specifications. Please refer to the device label to identify single or multiple use devices and components.
8. Some surgeries require the use of instruments which incorporate a measuring function. Ensure that these are not worn and that any surface markings are clearly visible.
9. Trauson does not and cannot warrant the use of instruments nor any of the component parts upon which repairs have been made or attempted except as performed by Trauson or an authorized Trauson repair representative.
10. If there is any doubt or uncertainty concerning the proper use of instruments please contact Trauson Customer Service. Any available operation brochure will be provided upon request. For optimal results, the same type of instruments used for implantation should be used for implant removal.

CAUTION

1. Before using this product, the users must read carefully Surgical Technique published by Trauson and are skilled in the operation process of this product.

2. It is not recommended to use Trauson products together with other brands, as it is not verified or

validated.

PACKAGING

Packages for each of the components should be intact upon receipt. All instrument sets should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to Trauson.

CLEANING AND DECONTAMINATION

Products delivered in non-sterile condition, must be cleaned, disinfected, and sterilized prior to use. For cleaning and sterilization, remove the product from its packaging before cleaning, disinfecting and sterilizing the product. A suitable cleaning, disinfection and sterilization process must be applied by the user. Only pH-neutral cleaning agents should be used. The preparation instructions of the respective cleaning and disinfection agent manufacturer must be considered.

All instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

All instrument moving parts should be well lubricated. Be careful to use surgical lubricants and not industrial oils.

Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and must not be used.

STERILIZATION

The following sterilization process parameters are validated by Trauson and recommended for sterilization:

Method	Moist heat sterilization according to ISO 17665
Cycle	Saturated steam with fractional forced air removal
Temperature	132-137°C (270-277°F)
Exposure Time	4 minutes (minimum)
Drying Time	30 minutes (minimum, in chamber)

Additionally, the method of sterilization utilized by end users should be validated, as suggested by Trauson.

TRANSPORTATION AND STORAGE CONDITIONS

The relative humidity of transportation and storage is no more than 80%. Keep products in draughty room without corrosive gas.

INFORMATION

To obtain Operation Technique or should any information regarding the products or their uses be required, please contact your local representative or Trauson directly at +86-519-86387075. You may also email: info@trauson.com .