



MANUFACTURED FOR:
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IMPORTANT MEDICAL INFORMATION
Warnings & Precautions

NON STERILE

English



ORTHOPEDIATRICS INSTRUMENTATION

Description

ORTHOPEDIATRICS instrumentation consists of medical devices and their accessories used in surgical procedures. The range includes manual surgical instruments from Class I and surgical instruments driven by power sources from class II a. (Ref. 93/42/EEC Directive).

ORTHOPEDIATRICS devices should only be used by qualified personnel trained in the use of surgical instruments and the relevant surgical procedures.

Use

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedures and the limitations of the instrumentation.

Warnings

- Care should be taken not to cut through surgical gloves when handling any sharp-edged surgical instrument and to take into account the risk of infection if a cut appears.

Cleaning/sterilization

- This instrument is not sterile when shipped from ORTHOPEDIATRICS.
- All instruments and instrument components must be sterilized before use.
- Remove all instruments from their packaging prior to sterilization.
- Recesses and hidden areas within an instrument should be inspected periodically to ensure that entrapped or other residual materials are completely removed.
- ORTHOPEDIATRICS instruments are recommended to be sterilized by steam autoclaving procedure regularly used in the hospital as detailed in OrthoPediatrics Instrument Care, Cleaning, and Sterilization Instructions CI-0001.
- Reusable instruments must be disinfected and sterilized immediately after use.
- ETO sterilization and cold sterilization techniques are not recommended. ORTHOPEDIATRICS disclaims any liability for any problems further to the use of these sterilization methods.
- The instruments must not enter into contact with fluoride or chloride based products nor with fat-based detergents. Instruments which have synthetic (plastic) components must not be in contact with strong acid solutions (pH<4), alkalis, organic or ammonia-based solvents as well as oxidizing chemicals or any other agent which could adversely alter the material.

Important Statement

- It is strictly prohibited to carry out any modification whatsoever on an ORTHOPEDIATRICS instrument. Only ORTHOPEDIATRICS has the competence to carry out such work. If this recommendation is not followed, ORTHOPEDIATRICS disclaims any liability for any subsequent consequences.

Storage and Handling

- Surgical instruments are sensitive to damage. Even small surface scratches can increase wear and the risk of corrosion. Instruments should be handled with care at all times.
- Storage zones for surgical instruments should be away from areas of humidity to avoid excessive corrosion. This recommendation is equally valid for transport and packaging of surgical instruments.
- Surgical instruments are susceptible to wear and tear, and therefore should be checked for defects before use.