

Kinamed NeuroPro™ System

INDICATIONS

1. Internal fixation of fractures and osteotomies of the craniofacial skeleton.
2. Internal fixation of cranial bone flap osteotomies.
3. Reconstruction of bony defects and deficits in the craniofacial skeleton.

CONTRAINDICATIONS

1. Active or suspected infection, either systemic or localized, in or around the implant site.
2. Patient conditions, mental or neurological, that would tend to impact the patient's ability to follow physician's instructions during the post-operative healing phase.
3. The Kinamed NeuroPro™ System is not indicated for use in the spine.

WARNINGS

1. An implant should never be re-used. Even though an implant may appear undamaged, previous handling and in-service stresses may have created imperfections that would reduce the service life of the implant.
2. Repeated bending back and forth of the plates should be avoided as this action may weaken the plate leading to plate breakage.
3. In the absence of functional, healed bone, implant failure may occur if the bone segments are subjected to repetitive loading over time.

PRECAUTIONS

1. Once removed from their original packaging, implants should be stored and autoclaved in the organizer trays provided in the system to prevent contact with items of dissimilar metals.
2. Adequate inventory of the various sizes and configurations of implants should be available in the organizer tray at the time of surgery to meet the requirements for that specific surgical case.

STERILITY AND HANDLING

All items in the system, including the implants, are supplied non-sterile. Sterilization of the instruments and implants is accomplished by autoclaving. The following are recommended procedures:

Note: Sterilization times given below represent exposure time only and not total cycle time.

Pre-Vac Autoclave

270°F, +/- 2° (132° C, +/- 1° C)

10 minutes wrapped, 8 minutes unwrapped

Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.

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