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KINAMED® NeuroPro® System
Instruction for Use

CAUTION

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

⊗ Devices labeled for single use are intended to be used once only, for a single patient, because they may not perform as intended if they are reused. Reuse may lead to failure of the device to perform as intended.

MATERIALS

1. Screws: Ti 6Al 4V-ELI, ISO 5832-3, ASTM F-136
2. Plates and Panels: Ti CP, ISO 5832-2, ASTM F-67

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 or high load bearing applications.
4. Demonstrated sensitivity to Titanium or its alloy (Ti6Al4V-ELI).

WARNINGS

1. An implant should never be re-used. Even though an implant may appear undamaged, previous handling and inservice 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.
4. If extremely dense bone is encountered while using Quick Tap self-drilling screws, it is recommended that a pilot hole be drilled using a drill bit from the system to prevent possible screw breakage during insertion.
5. Patients should be questioned regarding sensitivity to metals. If there is a question pertaining to the patient's tolerance for titanium or its alloy appropriate testing should be performed.
6. Pilot hole drill bits should be used for a single surgical case only.
7. Once screw-head is fully seated into plate, avoid over-tightening to prevent possible screw breakage.

PRECAUTIONS

1. Once removed from their original packaging, implants and instruments 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 of each specific surgical case.
3. Following use, instruments should be thoroughly cleaned prior to being replaced in the organizer tray for sterilization.
4. Drills should be inserted only into the instruments for which they are labeled.

STERILITY AND HANDLING

All items in the system, including the implants, are supplied **non-sterile** and must be sterilized prior to surgical use per the following procedures:

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

Method	Cycle Type	Sterilization Temperature	Full Cycle Time	Dry Time
Steam Autoclave, Double Wrapped[1]	Pre-Vacuum	132° C, (270°F) minimum	15 minutes	80 minutes minimum

[1]Validated with KimGuard® KC600.
(Validated to the following standards: ASTM/AAMI ST8-2008, ANSI/AAMI/ISO 17665-1:2006 and ANSI/AAMI ST79-2010.)