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English **KINAMED[®] NeuroPro[®] Low Profile System** Instruction for Use

CAUTION

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

② 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.

The NeuroPro[®] System has not been evaluated for safety and compatibility in the MR environment. The NeuroPro[®] System has not been tested for heating or migration in the MR environment.
 Do not use if package is damaged.

MATERIALS

1. Screws: Ti 6AI 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 cranial skeleton.
- 2. Internal fixation of cranial bone flap osteotomies.
- 3. Reconstruction of bony defects and deficits in the cranial skeleton.

CONTRAINDICATIONS

- 1. Active or suspected infection, either systemic or localized, in or around the implant site.
- 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 (Ti6AI4V-ELI).

WARNINGS

- 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.
- 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. Drill bits provided in the system must be used to assure correct pilot hole size.
- 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.
- 7. Pilot hole drill bits should be used for a single surgical case only.
- Once screw-head is fully seated into plate, avoid over-tightening to prevent possible screw breakage or pressure necrosis of the bone under the plate.

PRECAUTIONS

- 1. The 3.5 or 4mm screws require less torque to seat fully in dense bone due to less frictional resistance over their shorter length.
- The 5mm screws are used in soft bone where more resistance to stripping is required and the bone thickness is great enough to prevent penetration of the screw through the inner cortex or "table" of the skull.
- 3. 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.
- 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.
- 5. Following use, instruments should be thoroughly cleaned prior to being replaced in the organizer tray for sterilization.
- 6. 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 **<u>non-sterile</u>** and must be sterilized prior to surgical use. The following parameters apply to the tray (part numbers 16-1T1-0600 and 16-1T1-0610) shown below:

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16-1T1-0610 is designed to be nested within 16-1T1-0600.

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 ¹ , Double Wrapped	Pre- Vacuum	132° C, (270° F) minimum	10 minutes minimum	40 minutes minimum

Validated with KimGuard[®] KC600. (Validated to the following standards: ANSI/AAMI/ISO 17665-1:2006, 17665-2:2009 and ANSI/AAMI ST79-2010 A1:2010, A2:2011, A3:2012 and A4:2013.)

¹ This pre-vacuum steam sterilization cycle is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

CLEANING AND MAINTENANCE

All implants and instruments must be free of packaging material and biocontaminants prior to sterilization. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures of contaminant removal and use. For manual cleaning, completely submerge instruments in neutral pH endozime detergent for 5 minutes. Use a soft bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention should be given to hard to clean areas. Remove instruments from the enzymatic solution and rinse thoroughly under running tap water. Thoroughly and aggressively brush and flush through cannulated areas using a water jet with the exit end submerged. For automated washing and drying following manual cleaning and rinsing, place instruments in a suitable washer basket and load in an automatic washer/drier. Cycle should be set for a Non-Caustic wash cycle for a duration of 45 minutes using a neutral pH endozime detergent. The endozime detergent should be used at a specified concentration in a 2 minute cleaning cycle. Allow adequate time for drying. Inspect instruments for dryness prior to sterilization. Compliance with equipment instructions and/or recommendations for chemical solutions is required.