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IMPORTANT: PLEASE READ

For detailed information on the Southern Modular Plate & Screw System, please consult the Surgeons' Manual.

Description:
The Wrist Fusion Plate (WFP) is purpose designed for wrist fusion procedures. There are two different types of wrist fusion plates. The spoon plate WFP includes only the carpals of the wrist, whereas the straight WFP includes the metacarpal in the fusion process. The spoon type WFP plate is fixed proximally with 3.0mm screws and distally by 2.4mm screws. The straight type WFP is fixed with 3.0mm screws only. The plates are assembled with fixed drill guides for correct screw placement. Implant devices are manufactured from implant grade titanium (ASTM F136).

Radioactivity warning:
No radioactive substance or radioactivity.

Intended purpose:
The WFP is intended to fuse the wrist for the treatment of arthritis amongst other conditions.

Intended performance and undesirable side-effects:
The WFP fuses the wrist and the radius of the forearm thereby restricting motion of the hand.

Indications:
- Adolescent spastic hemipligia with wrist flexion deformity.
- Degenerative joint disease and instability associated with restricted and painful range of motion.
- Paralysis of the wrist or hand with potential for reconstruction involving the use of wrist or finger motion for tendon transfer.
- Posttraumatic osteoarthrosis of the radiocarpal joint and midcarpal joints as commonly observed following chronic scapholunate dissociation complex features.
- Previous unsuccessful, more limited arthrodesis.
- Reconstruction following segmental tumor resection, infection or traumatic segmental bone loss of the distal radius and carpals.
- Rheumatoid arthritis.
- Unsuccessful total-joint or previous arthroplasty of the radiocarpal joint.

Contraindications:
- Active infection or inflammation
- Advance rheumatoid disease where stabilization techniques are more suitable than formal arthrodesis
- Local or systematic acute or chronic inflammation
- Neurological diseases or injury causing major sensory deprivation in the hand
- Physiologically or psychologically inadequate patient
- Quadriparetics who use their motors for modified grasp and transfer techniques
- General medical contra indications for surgical intervention
- Inadequate skin, bone and neurovascular status
- Metal allergy
- Open distal radial physis
- Possibility of conservative treatment
- Suspected or documented metal allergy or intolerance

Surgical Risks:
- Carpal tunnel syndrome
- Distal radioulnar joint pain or dysfunction
- Extensor/flexor tendon adhesion requiring tenolysis
- Extrusion
- Foreign body reaction
- Infection
- Malunion
- Neuropraxia of the superficial nerve
- Plate breakage or fracture
- Reflex sympathetic dystrophy
- Stiffness
- Complex regional pain syndrome
- Facial deformity
- Tendon rupture
- Incorrect positioning of the device
- Malocclusion
- Mental nerve paralysis
- Delayed union or Nonunion
- Implant (Plate and or screw) breakage or fracture
- Severe bleeding/ artery damage
- Tendon attrition
- Extensor tendon irritation
- Iliac crest donor complications
- Limited function with small objects
- Fatigue

Recommended Surgical Procedure:
Refer to the surgical procedure provided by Southern Medical (Pty) Ltd.

USAGE WARNING:
Improper technique in implant placement can result in implant failure. Surgical instrumentation is provided for specific use with the implant and no other instrumentation is intended to be used for the placement of the prosthesis. Placement of the WFP device is only to be done by trained surgeons. Refer to the surgical procedure and product brochure for more information.

Sterility:
All implants are supplied sterile, and are for single use only before the labeled expiration date. Do not re-use implants. Do not use implants if the packaging has been damaged or previously opened, or if the expiration date has passed. If uncertain be sure to contact a Southern Medical Representative.

RE-STERILIZATION and RE-USE WARNING:
Do not re-sterilize implants produced sterile. Implants are sterilized by gamma irradiation. Re-sterilization could cause material degradation and could result in surgical rejection and/or post-operative infection. The implant is designed for single patient use only and must never be re-implanted. Re-use or re-implantation may result in cross-contamination or infection.

Magnetic Resonance Imaging (MRI)
Southern Modular Plate and Screw System devices have not been evaluated for adverse effect under MRI. The Modular Plate and Screw System components are manufactured from non-ferromagnetic materials. Risks of placing implants in or near a magnetic field include: (1) movement of ferromagnetic components, (2) localized heating of components caused by radio frequency induction heating and (3) image artefacts created by interaction between metallic components and the magnetic field.

Post Implantation:
The surgeon/physician's postoperative directions, indications and warnings to the patient with subsequent patient compliance are vital to successful fusion. The subject must refrain from physical activity for several months. Physical movement must be minimized. Subjects will be instructed not to engage in activities requiring lifting, bending, twisting or excessive movement after surgery per the discretion of the surgeon. The subject must not be exposed to electrical shock and mechanical vibrations. Per approval from the surgeon, subjects may return to the workplace if the work environment does not entail excessive physical activities. Car journey duration must be minimized, preferably avoided.

Descriptions of Symbols Used in Packaging:

USE BY	
LOT NUMBER	
DATE OF MANUFACTURE	
MANUFACTURER ADDRESS	
DO NOT REUSE	
STERILIZED USING IRRADIATION	
CAUTION	
AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	
CONSULT THE INSTRUCTIONS FOR USE	
DO NOT RESTERILIZE	
DO NOT USE IF PACKAGING IS DAMAGED