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IMPORTANT: PLEASE READ

For detailed information on correct & safe device use, please consult the Surgical Manual.

DESCRIPTION

The WFP and screw system is proposed as an internal fixation device for wrist fusion procedures. It is designed for surgical procedures including the treatment of arthrodesis of the wrist, posttraumatic osteoarthritis of the radio carpal and mid carpal joints, unsuccessful arthroplasty, arthritis, revisions of fractures, re-plantations and reconstruction. The DRP and screw system is proposed as an internal fixation device to treat bone fractures of the hand. It is designed for surgical procedures including the revision of fractures, re-plantations, and reconstruction. The systems enable precise reduction, stable fixation, and preservation of blood supply. They allow for their construction of the anatomy and restoration of the functionality as well as enhancement of the rate of fusion in a pre-set orientation.

INDICATIONS FOR USE

The Indications for the Wrist Fusion Plate (WFP):
•Arthrodesis of the wrist is indicated in degenerative joint disease and instability associated with restricted and painful range of motion.
•A previous unsuccessful, more limited arthrodesis
•An unsuccessful total-joint or previous arthroplasty of the radiocarpal joint.
•Paralysis of the wrist or hand with potential for reconstruction involving the use of wrist or finger motion for tendon transfer.
•Reconstruction following segmental tumor resection, infection, or traumatic segmental bone loss of the distal radius and carpals.
•Adolescent spastic hemiplegia with wrist flexion deformity
•Rheumatoid arthritis.
The indications for the Distal Radius Plate (DRP):
•Distal intra-articular radius fractures with impacted articular fragments and displaced dorso-ulnarfragments.
•Distal intra-articular radius fractures with bony or ligament injury of the proximal carpal row

CONTRAINDICATIONS

The contradictions for the WFP are as follows:
•A contraindication to wrist arthrodesis is an open distal radius physis. A relative contraindication is an elderly patient with sedentary lifestyle, especially if the targeted wrist is the nondominant wrist. In this situation, arthroplasty may be more suitable.
•Quadriparetics who use their motors for modified grasp and transfer techniques
•Neurological disease or injury causing major sensory deprivation in the hand
•Advanced rheumatoid disease where stabilization techniques are more suitable than formalarthrodesis.
The contradictions for the DRP
•General medical contraindications for surgical intervention
•Distal radius fractures with palmar tilt of the distal fractures

RISKS & UNDESIRABLE SIDE-EFFECTS

- Limited mobility & function of wrist joint
- Reduced grip strength
- Soft tissue injury.
- Wrist Fusion scarring.
- Swelling & Inflammation post-surgery
- Infection.
- Foreign body (allergic) reaction to implant.
- Excess Bleeding
- Nerve injury including, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
- Disassembly, bending, and/or breakage of the implant.
- Implant loosening and/or migration.
- Subsidence of the device into the vertebral body(ies).
- Wound necrosis or wound dehiscence.

Additional surgical intervention may be required to correct/prevent some of these possible adverse events.

WARNINGS & PRECAUTIONS: STERILITY, PACKAGING & RE-USE

The devices are sterilized via gamma irradiation and are provided **STERILE**. Do not re-sterilize the device. Re-sterilization could cause material degradation and could result in mechanical failure of the device, host rejection and/or post-operative infection.

Do not use implants if the packaging has been damaged or previously opened, or if the expiration date on the label has been exceeded.

The devices are **SINGLE-USE**. Do not re-use implants. An explanted implant must never be re-implanted. Re-use or re-implantation may result in cross-contamination or infection.

WARNINGS & PRECAUTIONS: CORRECT & SAFE USE

The device should only be implanted by qualified surgeons with knowledge of the correct and safe use of the device and associated instrumentation. Refer to the Surgical Manual provided by Southern Medical (Pty) Ltd. If uncertain, please contact a Southern Medical Representative.

INSTRUMENTS

Only the instruments provided by the manufacturer should be used. Instruments are provided non-sterile and should be cleaned and sterilized before use in accordance with the instructions provided in IFU-100.

STORAGE

There are no special storage instructions. Storage conditions must not lead to degradation or contamination of the packaging or its contents. Handle with care.

POST-OPERATIVE CARE INSTRUCTIONS

The surgeon/physician should provide appropriate postoperative care instructions to the patient and should ensure that the patient understands the potential consequences of non-compliance. To achieve the desired clinical outcome, the patient should be instructed to minimize physical activity as far as possible and avoid activities that require lifting, bending, twisting or excessive movement of the wrist. Follow-up consultations should be arranged with the patient at appropriate intervals, as deemed necessary by the physician. The patient should only resume their normal activities once cleared to do so by their physician.

MRI SAFETY INFORMATION

The WRIST devices have not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the WRIST devices in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

DEVICE REMOVAL

Surgical removal of the device is possible. A decision to remove the device must be made by a healthcare professional after taking into consideration the patient's general medical condition and the potential risk of a subsequent surgical procedure. Refer to the Surgical Manual for removal instructions.

DISPOSAL

Single-use devices that have been in contact with blood or bodily fluids/tissues should be disposed of in accordance with the hospital's procedure for disposal of hazardous and/or biological waste. Users must wear surgical gloves and take care to avoid sharp edges. Devices that cannot be used because the packaging has been damaged, but have not been in contact with blood or bodily fluids/tissues, should be returned to the manufacturer.

REPORTING

Any device-related adverse events must be reported to the manufacturer as soon as possible.

DESCRIPTIONS OF SYMBOLS USED IN PACKAGING

MANUFACTURER		USE BY	
CONSULT INSTRUCTIONS FOR USE		CATALOGUE NUMBER	REF
DO NOT RE-USE		CAUTION	
DO NOT RE-STERILIZE		LOT NUMBER	LOT
DATE OF MANUFACTURE		STERILIZED USING IRRADIATION	STERILE R
DO NOT USE IF PACKAGING IS DAMAGED			