Manufactured by:
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IMPORTANT: PLEASE READ

For detailed information on the Southern Medical Distal Radius Plate, please consult the Surgeons' Manual.

Description:
The Distal Radius Plate (DRP) is anatomically designed for use on the volar side of the radius for severe fractures of the distal radius. The plates are assembled with fixed drill guides for correct screw alignment and it is used in conjunction with 3.0mm screws of the MAXI plate and screw set. The plate is available in 3 sizes for both the left and right arm and trials are included on the set for correct size selection. Implant devices are manufactured from implant grade titanium (ASTM F136).

Radioactivity warning:
No radioactive substance or radioactivity.

Intended purpose:
The DRP is intended for the treatment of distal radius fractures.

Intended performance and undesirable side-effects:
The DRP provides stability to the distal radius whilst bone growth takes place to heal the fractured bone. The plate has a low profile to reduce tendon irritation and wear.

Indications:
- Distal intra-articular radius fractures with impacted articular fragments and displaced dorsoulnar fragments
- Distal intra-articular radius fractures with bony or ligamentous injury of the proxima carpal row.

Contraindications:
- Active infection or inflammation
- Distal radius fractures with palmar tilt of the distal fractures
- General medical contra indications for surgical intervention
- Inadequate skin, bone and neurovascular status
- Irreparable tendon system
- Local or systematic acute or chronic inflammation
- Suspected or documented metal allergy or intolerance
- General medical contra indications for surgical intervention
- Physiologically or psychologically inadequate patient
- Possibility of conservative treatment
- Local or systemic acute or chronic infection/inflammation
- Osteoporosis (premenstrual or postmenstrual)

Surgical Risks:
- Carpal tunnel syndrome
- Complex regional pain syndrome
- Distal radioulnar joint pain or dysfunction
- Extensor/flexor tendon adhesion requiring tenolysis
- Extrusion
- Foreign body reaction
- Iliac crest donor complications
- Implant (Plate and or screw) breakage or fracture
- Incorrect positioning of the device
- Infection
- Malocclusion
- Malunion
- Mental nerve paralysis
- Neuropraxia of the superficial nerve
- Nonunion
- Plate or screw mobility
- Reflex sympathetic dystrophy
- Severe bleeding/ artery damage
- Stiffness
- Tendon attrition
- Tendon rupture
- Thumb interphalangeal (IP) joint flexion loss

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 DRP device is only to be done by trained surgeons.

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.

STERILIZATION 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 reused. An explanted implant must never be re-implanted.

Post Implantation:
The surgeon/physician's postoperative directions, indications and warnings to the patient with subsequent patient compliance are vital to successful fusion. Movement of the operation site will be restricted according to the discretion of the surgeon.

Descriptions of Symbols Used in Packaging:

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