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## IMPORTANT: PLEASE READ

***For detailed information on the Southern Modular Plate & Screw System, 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 a fixed drill guide for correct screw alignment and it is used in conjunction with 3.0mm screws. 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 proximal carpal row.
- Barton fractures
- Articular step of more than 2 mm
- Proximal extension
- Associated ulna injuries
- Volar comminution

**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 (CRPS)
- 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
- Joint flexion loss
- Wound dehiscence

**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.

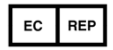
**Sterility:**
All implants are supplied sterile, and are for single use only before the labeled expiration date. Do not re-use implants. Do not use implants if the packaging has been damaged or previously opened, or if the expiration date has passed. If uncertain be sure to contact a Southern Medical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

# IFU-015.4-T02-03 (DOC-2729) Ver. 1

**Approved By:**

**(CO-336) Removal of CE on IFUs**

**Description**

CE Mark removed from IFU

**Justification**

CE Mark is no longer permitted on the IFU's

| Assigned To: | Initiated By: | Priority: | Impact: |
|---|---|---|---|
| Helen Bosma | Helen Bosma | High | Major |

**Version History:**

| Author | Effective Date | CO# | Ver. | Status |
|---|---|---|---|---|
| Helen Bosma | March 2, 2021 7:49 AM GMT | CO-336 | 1 | Published |
| Helen Bosma | March 18, 2020 12:00 AM GMT | CO-12 | 0 | Superseded |