Manufactured by:
Southern Medical (Pty) Ltd.
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IMPORTANT: PLEASE READ

For detailed information on the Southern Sentry™, please consult the Surgeons' Manual.

Description:
The Southern Sentry™ range of devices includes an implant head, a fixed implant stem and locking nut. The implant head consists of non-magnetic cobalt-chromium-molybdenum BioDurr CCM+, the implant stem consists of Titanium (ASTM F136) and the locking nut is manufactured using PEEK (ASTM F2026). Surgical instrumentation is produced from stainless steel (ASTM F899). The stems, locking nuts and heads of the implant come in different sizes to accommodate anatomical variations.

Radioactivity warning:
No radioactive substance or radioactivity.

Intended purpose:
The Southern Sentry™ Ulnar implant is designed for the replacement of the ulnar head to ensure rotation of the forearm with a stable ulnar and wrist.

Intended performance and undesirable side-effects:
The prosthesis can be used for treatment of failed ulnar head resection and osteoarthritis of the DRUJ. The implant replaces the ulnar head to maintain the function of the wrist joint and forearm. CCM wear debris generated by the articulation motion of the joint, possible side effects are a pseudo-tumor.

Indications:
- Salvage of previous Darrach, Bowers or Sauve-Kapandji procedures
- Osteoarthritis including posttraumatic osteoarthritis due to Radial fractures, TFCC tears and ulnar impingement
- Fracture of the ulnar head/neck
- Rheumatoid arthritis
- Tumours

Contraindications:
- Inadequate bone stock
- Inadequate soft tissue
- Excessive radial deformity
- Skeletal immaturity
- Infection
- Sensitivity to implant material
- Inadequate bone stock or soft tissue coverage

Surgical Risks:
- Compartment syndrome
- Cubitus valgus
- Degenerative arthritis
- Dislocation and sublaxation due to inadequate fixation or improper placement
- Fatigue fracture due to loss of fixation
- Fretting and crevice corrosion
- Heterotropic calcification
- Improper size selection
- Inadequate range of motion
- Intraoperative bone perforation or fracture
- Intraoperative or postoperative bone fracture
- Loosening or migration of the implant
- Loss of strength
- Material sensitivity reaction
- Nerve injuries
- Periarticular calcification or ossification
- Post-operative infection
- Stiffness and Heterotropic Bone
- Sympathetic mediated pain syndrome
- Synostosis
- Undesirable lengthening or shortening of the limb
- Wear and/or deformation of articulating surfaces

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. Placement of devices is limited to 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.

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. 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 for several months post-operatively. The subject must not be exposed to electrical shock and mechanical vibrations. Directly after the operation, subjects will be placed in a brace until fusion occurs.

Descriptions of Symbols Used in Packaging:

USE BY	
LOT NUMBER	LOT
DATE OF MANUFACTURE	
DO NOT REUSE	
STERILIZED USING IRRADIATION	STERILE R
CAUTION	
CONSULT THE INSTRUCTIONS FOR USE	
DO NOT RESTERILIZE	STERILIZE
DO NOT USE IF PACKAGING IS DAMAGED	