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

For detailed information on the Southern Sarah™ And Sentinel™, please consult the Surgeons' Manual.

Description:
The Southern Sarah™ And Sentinel™ range of devices includes an articulating implant head and an implant stem. All consists of non-magnetic cobalt-chromium-molybdenum BioDurr CCM+. Surgical instrumentation is produced from stainless steel (ASTM F899). The stems and heads of the implants come in different sizes to accommodate anatomical variations.

Radioactivity warning:
No radioactive substance or radioactivity.

Intended purpose:
The Southern Sarah™ And Sentinel™ ranges are designed for the replacement of the radial head and to ensure articulation, movement and rotation of the forearm.

Intended performance and undesirable side-effects:
Radial head replacement is indicated in displaced or comminuted fractures or when a reduction cannot be sufficiently accomplished with open reduction and internal fixation. The implant replaces the head of the radius at the elbow to maintain function of the elbow joint. CCM wear debris is generated by the articulation motion of the joint, possible side effects are a pseudo-tumor.

Indications:
- Comminuted radial head fractures requiring resection
- Degenerative or post traumatic disabilities
- Displacement or articular depression of 2-3mm
- Elbow instability with reconstruction of the ulnar humeral collateral ligaments
- Failed previous radial head resection with associated instability
- Failed prosthesis of a previous radial head replacement
- Fracture of more than 30% of the articular surface
- Radial head fracture associated with lesions of the interosseous membrane
- Radial head fracture with ligamentous injury
- Stabilization of the forearm after an Essex-Lopresti injury
- Subsequent to radial head excision with medial collateral ligament insufficiency

Contraindications:
- Bone, tendon or muscle compromised by disease or injury to the extent that adequate fixation or stability cannot be attained.
- Frail patients with a comminuted radial head fracture requiring radial head excision without evidence of elbow stability or other associated injuries
- Inadequate bone stock or soft tissue coverage
- Mason type I or II radial head fracture
- Mental illness.
- Metal Allergy
- Open fracture with the risk of infection
- Physical interference with or by other prostheses during implantation
- Prior sepsis
- Skeletal immaturity
- Skin, bone, circulatory and/or neurological deficiency at the implantation site.

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 (including the ulnar nerve)
- Neurovascular injury
- Osteoarthritis
- Periarticular calcification or ossification
- Post-operative infection
- Radial tunnel syndrome
- 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	