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

For detailed information on the Southern MIRA-DC Arthroplasty Prosthesis, please consult the Surgeons' Manual.

Description:
The implant is manufactured from biocompatible PEEK Optima (ASTM F2026) with the inside surface titanium plasma sprayed with Sondicoat-T-LTA for Osseo-integration and for verifying the position of the device on x-ray. A tapered pin allows for location and fixation of the device on the distal cap of the metacarpo-phalangeal (MCP) or proximal interphalangeal (PIP) joint. The instrument set supplied with the MIRA-DC implant consists of trials, colour coded reamers and forceps for handling the implant. Southern Medical (Pty) Ltd manufactures the various surgical instrumentation required for the procedure from a combination of autoclave safe PEEK, titanium (ASTM F136), Cobalt Chrome (ASTM F1537) and stainless steel (ASTM F899).

Radioactivity warning:
No radioactive substance or radioactivity.

Intended purpose:
The Southern MIRA-DC is intended as an interphalangeal joint resurfacing arthroplasty.

Intended performance and undesirable side-effects:
The aim of the device is to replace destroyed articular surfaces in digital joints to address instability and deformity in the digits due to arthritis. The device may be used in the metacarpo-phalangeal joint (MCP) or proximal interphalangeal joint (PIP). It provides flexion & extension of the digital joint and also allows for translation in the joint. The aim is to restore flexion and stablitity to the MCP and/or PIP joint. Incorrect placement can result in the implant sublaxing.

Indications:
- Primary and secondary osteo-arthritis of proximal interphalangeal joints (PIPJ) and metacarpophalangeal joints (MCPJ) of the fingers.

Contraindications:
- Poor, unbalanced soft tissue as in Rheumatoid Arthritis
- The proximal interphalangeal joint of the index finger in high demand hands

Surgical Risks:
- Nerve damage leading to chronic numbness, weakness & pain
- Infection
- Painful post-surgical recovery
- Prolonged rehabilitation;
- Chronically limited range of motion;
- Decreased activity level;
- Pain in other parts of the hand due to new stress;
- Limited range of motion;
- Implant sublaxing;
- Malpositioning of the fingers;
- Risks associated with general anesthetic;

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 MIRA-DC prosthesis 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 implantation. Finger is splinted with adjacent finger and remains immobile for 2-3 weeks.

Descriptions of Symbols Used in Packaging:

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