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

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

Description:
The Southern Staples range consists of staples with varying length legs, with sharp tips joined by a bridge of varying width that is driven directly into the bone. All implant components are manufactured using Nitinol. Surgical instrumentation is produced from stainless steel (ASTM F899)

Radioactivity warning:
No radioactive substance or radioactivity.

Intended purpose:
The Southern Staples range provides fixation of small or long bone fractures and/or osteotomies, assisting in the fusion of small joints in the hand and/or foot.

Intended performance and undesirable side-effects:
The Southern Staples provides fracture reduction and comes in a variety of sizes to accommodate anatomical variations. Staple fixation includes approximation of fragments and compression.

Indications:
- Arthrodesis in hand and foot surgery
- Fracture management in the foot and hand.
- Mono or Bi-cortical osteotomies in the foot and hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for the hallux valgus treatment (such as scarf, chevron etc)
- The size of the chosen staple should be adopted to the specific indication
- Proximal and distal phalangeal osteotomies
- Metatarsophalangeal fusion
- Phalangeal shortening osteotomy
- Visual analog score (VAS score) of at least 40 on a 100 mm scale

Contraindications:
The implant should not be used in a patient who has currently, or who has a history of:
- Local or systemic acute or chronic inflammation or infection.
- Active infection or inflammation.
- Suspected or documented metal allergy or intolerance.
- As shape memory alloy contains a high Nickel rate, do not implant in Nickel sensitive patient

Surgical Risks:
- Bending or breakage of implanted components
- Change in mental status
- Death
- Foreign body (allergic) reaction
- Inadequate tissue coverage over the implant
- Infection
- Loosening of components
- Metal ion release
- Non-Union, delayed union or mal-union
- Postoperative removal/revision of the device
- Revision with or without replacement of a component
- Tumor formation/ carcinogenesis potential

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. In absence of fusion the implant or implant components can be expected to pull out, bend or fracture as a result of everyday mechanical stresses. 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.

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