Manufactured by:
Southern Medical (Pty) Ltd.
P O Box 17198
Lyttelton, 0140
South Africa
Tel: +27 12 667 6243/4 |
Email: info@southmed.co.za

IMPORTANT: PLEASE READ

For detailed information on the JUNO Proximal Radial Head Plate and Screw System, please consult the Surgeons' Manual.

Description:
The JUNO plate is anatomically designed for use on the radius for fractures of the proximal radial head. At the proximal end of the plate the plates are assembled with fixed drill guides for correct screw alignment. Variable angle locking holes are present on the proximal end of the plate. The JUNO plate is used in conjunction with 2.4mm locking and non-locking screws of the MINI plate and screw set. The plate is available in 4 sizes and can be placed on both the left and right arm. 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 JUNO is intended for the treatment of proximal radial head fractures.

Intended performance and undesirable side-effects:
The JUNO provides stability to the proximal radial head whilst bone growth takes place to heal the fractured bone. The plate has a low profile to reduce tendon irritation and wear.

Indications:
- Radial head fractures of less than 30% of the articular surface

Contraindications:
- Mason type III radial head fracture
- General medical contraindications for surgical intervention
- Inadequate skin, bone and neurovascular status
- Irreparable tendon system
- Suspected or documented metal allergy or intolerance
- Physiologically or psychologically inadequate patient
- Possibility of conservative treatment
- Local or systematic acute or chronic infection/inflammation

Surgical Risks:
- Complex regional pain syndrome
- Foreign body reaction
- Implant (Plate and or screw) breakage or fracture
- Incorrect positioning of the device
- Infection
- Malocclusion
- Malunion
- Nonunion
- Plate or screw mobility
- Severe bleeding/ artery damage
- Stiffness
- Tendon attrition
- Tendon rupture

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 JUNO device 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 fusion. Movement of the operation site will be restricted according to the discretion of the surgeon.

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