Manufactured by: Southern Medical (Pty) Ltd.

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European Representative:
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IMPORTANT: PLEASE READ

For detailed information on the Southern Modular plate and Screw System, please consult the Surgeons Manual

Description: *The Southern Micro set implants are manufactured from Grade 2 Titanium (ASTM F67) and the fixed and variable angle screws from Grade 23 Titanium (ASTM F136). Surgical instrumentation is produced from stainless steel (ASTM F899).*

***RADIOACTIVITY WARNING*:** No radioactivity substance or radioactivity.

***Intended purpose*:** The Southern Micro Set is intended maxilla-facial procedures; including revision fractures, replantations & reconstruction. The plates and screws are intended to immobilize fractures and resection lines in order to enhance the rate of fusion in a set orientation. The MICRO set consists of 0.6mm thick plates that are designed for maxilla-facial fractures and are used in combination with either 1.5mm (purple) or 1.7mm (blue) non-locking screws.

Indications for the use of arthrodesis cervical plates and screws are:
- Cranial fractures
- Facial injuries/fractures
- Congenital defects
- Facial cosmetic surgery
- Corrective jaw surgery

Contraindications for the use of arthrodesis cervical plates and screws are:
- Active infection or inflammation
- General medical contra indications 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

Risks Associated with Surgery
- Carpal tunnel syndrome
- Mucoceles
- Extrusion
- Foreign body reaction
- Incorrect positioning of the device
- Malocclusion
- Mental nerve paralysis
- Nonunion
- Plate or screw mobility
- Severe bleeding/ artery damage
- Tendon attrition
- Subjective discomfort; sensitivity to cold or palpability
- Complex regional pain syndrome
- Extensor/flexor tendon adhesion requiring tenolysis
- Iliac crest donor complications
- Infection
- Malunion
- Neuropraxia of the superficial nerve
- Plate breakage or fracture
- Reflex sympathetic dystrophy
- Stiffness
- Tendon rupture
- Temporary sensory disturbance
- Mild wound pain

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 implant. Placement of this device is limited to qualified surgeons. Refer to surgical procedure and product brochure for more information.

STERILITY:
Plates and screws are disinfected and packed onto instrument sets as non-sterile and require sterilization by an ISO 17665 validated steam sterilization (autoclave) method. It is the responsibility of the hospital to ensure equipment and cycles are validated on site. Personnel responsible for the cleaning and sterilization of the instruments must be a fully trained hospital staff member. If uncertain contact a Southern Medical representative.

Magnetic Resonance Imaging (MRI)
The Southern Micro plates and screws have not been evaluated for adverse effect under MRI. The Southern Micro components are manufactured from non-ferromagnetic materials. Risks of placing implants in or near a magnetic field include: (1) movement of ferromagnetic components, (2) localized heating of components caused by radio frequency induction heating and (3) image artefacts created by interaction between metallic components and the magnetic field.

STERILIZATION WARNING:
Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Sterilization must be done in time before implanting the prosthesis. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below. If uncertain contact a Southern Medical representative

Warnings	• Aluminum instruments are damaged by alkaline (pH>7) detergents and solutions • Long narrow cannulations and blind holes require particular attention during cleaning. • Do not exceed 150°C
Limitations on reprocessing	• Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.
Point of use	• These practices include keeping devices moist after use to prevent soil from drying and removing gross soil from the surfaces, crevices, mating surfaces, joints, and all other hard-to-clean design features. • Thorough cleaning and rinsing should begin as soon as possible after use of the device
Containment and transportation	• No particular requirements. • Disassembly not required.
Preparation for cleaning	• Devices capable of disassembly must be disassembled prior to cleaning • Dried-on soil is difficult to remove with automatic washing, especially at challenging design features on devices like interfaces, crevices, joint etc. The removal of gross soil from these areas prior to washing in the automatic washer is critical for achieving adequate cleaning
Cleaning: Automated	1. Pre-cleaning should be through soaking in enzymatic detergent for 5 minutes and scrub surfaces including brackets and hinges with cleaning brush 2. Rinse with warm water 3. Load the instruments in the washer such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (for example, hinges should be open and cannulations and holes positioned to drain). 4. Run the automatic wash cycle: Minimum cycle parameters:

Phase	Function	Duration (min)
2 Rinse cold + warm water	Rinse, mixed water	2
5Wash I detergent	Wash with detergent	7
13 Rinse warm water	Rinse, warm water	2
16 Disinfection temperature is set at A0 = 600; 90°C (+1°C)/1 min	Disinfection	1 + heating

	5. Check instruments for visible soil 6. Repeat cleaning if soil is visible and re-inspect. 7. Thermal disinfection Minimum cycle parameters: one (1) minute at 91° C
Cleaning: Manually	1. Immerse instrument and soak for a minimum of ten (10) minutes in enzymatic detergent 2. Blind holes should be repeatedly filled and emptied 3. Use cleaning brushes/pipe cleaners to remove additional soil from challenging design features 4. Scrub interfaces several times using a twisting action. If components of the instrument can be disassembled or moved, it is necessary to retract or open the part in order to access and clean these areas. 5. Scrub inside holes with a tight-fitting brush or pipe cleaner using a twisting action. The brush or pipe cleaner should be of an appropriate size to ensure that full depth of the feature is reached 6. Scrub around hinged surface areas with a brush or pipe cleaner 7. Scrub crevices using a cleaning brush or pipe cleaner 8. Rinse thoroughly with warm water, making sure to wet the challenging design features 9. Check instruments for visible soil 10. Repeat cleaning if soil is visible
Disinfection:	• Disinfectant solution (EndoZyme®) may be used in accordance with label instructions. • 3% hydrogen peroxide may be used on difficult to reach areas
Drying	• When drying is achieved as part of a washer disinfector cycle do not exceed 120°C.
Maintenance, Inspection and Testing of Instrumentation	• Visually inspect for damage or wear • Hinged instruments should be check for smooth movement of hinge without excessive “play.” • Locking mechanisms should be checked for action • All surfaces should be smooth and free of cracks and deep nicks • Reamer/drill bits should be inspected for deformities and distortion that might hinder insertion into a drill • Metal surfaces Inspect for corrosion and major deformation • Blunt or damaged instruments should be returned to sales representatives
Packaging	• Instrument tray should be double wrapped with Steriwrap.
Sterilization Instructions	• Specific instructions for sterilization listed in package inserts takes precedence over the information listed herein

Instruments (reusable devices) cleaning:
- Reusable devices are sold non-sterile. It is critical to properly clean all reusable devices prior to sterilization
- Instrument should be placed in Instrument Trays prior to sterilization
- It is important that proper cleaning of instrument cases/trays be performed prior to sterilization. Preparation for Sterilization Single-Use

Devices Only
- Prior to sterilization of the device, remove all original packaging and labeling inserts. Place the device in a suitable packaging for the sterilization process, i.e., central supply wrap, autoclave pouches, etc.
- Special care should be taken to protect the device from contact with other metal or hard objects that could damage the implant
- Packaging should be inspected for punctures or other damage before and after sterilization

Reusable Instruments
- It is important that adequate cleaning be performed prior to sterilization.
- Reusable devices must be placed in a suitable packaging for the sterilization process, i.e., autoclave pouches.
- Sterilization cases/trays must be wrapped with an approved autoclave wrap prior to sterilization. The case/tray by itself does not provide a sterile barrier.
- **Do not stack sterilization cases/trays in the sterilizer!**

Limitations on reprocessing:
- Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

Recommended Sterilization Parameters:
- Instrument sets produced by Southern Medical can be sterilized to a sterility assurance level (SAL) of 10E-6 in a pre-vacuum, 4 pulse, 132º-135ºC (270º-275ºF), 12 minute exposure, 30 minute vacuum dry, steam sterilization cycle
- Some health care authorities recommend sterilization according to these parameters to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system. Should this be required, the following temperature and time is required: 134ºC, 20 minutes exposure, 30 minute drying time.

Storage	• If stored between cleaning and sterilization, dry instruments with a low-linting, non-abrasive soft cloth to prevent microbial contamination that could result from wet storage. • Containment devices can be stacked for storage.

The instructions provided above have been validated by Southern Medical. It remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process.

Post Implantation: Movement of the operation site will be restricted according to the discretion of the surgeon.

Description of Symbols Used in Packaging

Use by		Sterility	NON STERILE	Consult the Instructions For Use	
Lot Number	LOT	Do not reuse (implant devices)		European Representative	EC REP
Sterilization (Gamma)	STERILE R	Manufacturer address		Date Of Manufacture	
Do not resterilize		Do not use if packaging is damaged		Caution	

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Approved By:

(CO-336) Removal of CE on IFUs

Description

CE Mark removed from IFU

Justification

CE Mark is no longer permitted on the IFU's

Assigned To:	Initiated By:	Priority:	Impact:
Helen Bosma	Helen Bosma	High	Major

Version History:

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