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**IMPORTANT: PLEASE READ**

 **For detailed information on the Southern Cannulated Screws, please consult the Surgeons Manual**

**Description:** The Southern Cannulated Screw implants are manufactured according to ASTM F136. Surgical instrumentation is produced from stainless steel (ASTM F899).

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

**Intended purpose:** The Southern Cannulated Screws range is intended for internal fixation in the treatment of displaced or unstable small bone fractures. The Southern Cannulated Screw comes in a variety of sizes to suit the needs of the patient.

**Indications for the use of arthrodesis cervical plates and screws are:**

- Fixation of small bone fragments, in long bones or small bone fractures.
- Arthrodesis in hand and/or foot surgery
- 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.)
- Intra-articular fracture fixation and arthrodesis of carpals and metacarpals
- Intra-articular wrist arthrodesis
- Intra-articular fixation of small fragments in the foot
- Radial head and radial styloid fractures
- Intercarpal arthrodesis
- Osteosynthesis of scaphoid fractures
- Weil Osteotomy

**Contraindications for the use of arthrodesis cervical plates and screws are:**

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.

**Risks Associated with surgery**

- Bending or breakage of implant 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 device
- Revision with or without replacement of 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. 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:**

Implants are disinfected and packed onto trays but are not supplied sterile and needs to be sterilized by an ISO 17665 validated moisture 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.

**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.

|                                       |   |
|---------------------------------------|---|
| <b>Warnings</b>                       | <ul style="list-style-type: none"> <li>• Aluminum instruments are damaged by alkaline (pH&gt;7) detergents and solutions.</li> <li>• Long narrow cannulations and blind holes require particular attention during cleaning.</li> <li>• Do not exceed 150°C</li> </ul>   |
| <b>Limitations on reprocessing</b>    | <ul style="list-style-type: none"> <li>• Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.</li> </ul>  |
| <b>Sterilization Instructions</b>     | <ul style="list-style-type: none"> <li>• Remove excess soil with disposable cloth/paper wipe.</li> </ul>  |
| <b>Point of use</b>                   | <ul style="list-style-type: none"> <li>• 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.</li> <li>• Thorough cleaning and rinsing should begin as soon as possible after use of the device</li> </ul>  |
| <b>Containment and transportation</b> | <ul style="list-style-type: none"> <li>• No particular requirements.</li> <li>• Disassembly not required.</li> </ul>  |
| <b>Preparation for cleaning</b>       | <ul style="list-style-type: none"> <li>• Devices capable of disassembly must be disassembled prior to cleaning</li> <li>• 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</li> </ul>  |
| <b>Cleaning: Automated</b>            | <ol style="list-style-type: none"> <li>1. Pre-cleaning should be through soaking in enzymatic detergent for 5 minutes and scrub surfaces including brackets and hinges with cleaning brush</li> <li>2. Rinse with warm water</li> <li>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).</li> <li>4. Run the automatic wash cycle: Minimum cycle parameters:</li> </ol> |

| 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    |

|  |  |
|--|--|
|  | <ol style="list-style-type: none"> <li>5. Check instruments for visible soil</li> <li>6. Repeat cleaning if soil is visible and re-inspect.</li> <li>7. Thermal disinfection Minimum cycle parameters: one (1) minute at 91° C</li> </ol>  |
| <b>Cleaning: Manually</b>                  | <ol style="list-style-type: none"> <li>1. Immerse instrument and soak for a minimum of ten (10) minutes in enzymatic detergent</li> <li>2. Blind holes should be repeatedly filled and emptied</li> <li>3. Use cleaning brushes/pipe cleaners to remove additional soil from challenging design features</li> <li>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.</li> <li>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</li> <li>6. Scrub around hinged surface areas with a brush or pipe cleaner</li> <li>7. Scrub crevices using a cleaning brush or pipe cleaner</li> <li>8. Rinse thoroughly with warm water, making sure to wet the challenging design features</li> <li>9. Check instruments for visible soil</li> <li>10. Repeat cleaning if soil is visible</li> </ol> |
| <b>Disinfection:</b>                       | <ul style="list-style-type: none"> <li>• Disinfectant solution (EndoZyme®) may be used in accordance with label instructions.</li> <li>• 3% hydrogen peroxide may be used on difficult to reach areas</li> </ul>   |
| <b>Drying</b>                              | <ul style="list-style-type: none"> <li>• When drying is achieved as part of a washer disinfectant cycle do not exceed 120°C.</li> </ul>  |
| <b>Maintenance, Inspection and Testing</b> | <ul style="list-style-type: none"> <li>• Visually inspect for damage or wear</li> <li>• Hinged instruments should be checked for smooth movement of hinge without excessive "play."</li> <li>• Locking mechanisms should be checked for action</li> <li>• All surfaces should be smooth and free of cracks and deep nicks</li> <li>• Reamer/drill bits should be inspected for deformities and distortion that might hinder insertion into a drill</li> <li>• Metal surfaces Inspect for corrosion and major deformation</li> <li>• Blunt or damaged instruments should be returned to sales representatives</li> </ul>  |
| <b>Packaging</b>                           | <ul style="list-style-type: none"> <li>• Instrument tray should be double wrapped with Steriwrap.</li> </ul>   |
| <b>Sterilization</b>                       | <ul style="list-style-type: none"> <li>• Specific instructions for sterilization listed in package inserts takes precedence over the information listed herein</li> </ul>  |

**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!**

**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, 132°-135°C (270°-275°F), 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: 134°C, 3 minutes exposure, 15 minute drying time.

|                |   |
|----------------|---|
| <b>Storage</b> | <ul style="list-style-type: none"> <li>• Reusable devices that will be stored between cleaning and sterilization should be dried with a low-linting, non-abrasive soft cloth to prevent microbial contamination that could result from wet instruments.</li> <li>• Containment devices can be stacked for storage.</li> </ul> |
|----------------|---|

The instructions provided above have been validated by the manufacturer of the medical device as being CAPABLE of preparing a medical device for re-use. 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                      |  | Attention: See Instructions For Use |  |
| Lot Number |  | Do not reuse (implant devices) |  | Caution                             |  |