SMV Scientific Bone Plate and Screw System Instructions for Use
Non-Sterile and Sterile
Prescription Use Only
Do Not Reuse

Description:
The SMV Bone Plate and Screw System consists of implants and instruments designed for fixation to treat fractures, deformations, revisions and replantations of bones and bone fragments. The system features nineteen (19) types of plates (one-third tubular plate without collar, one-third tubular plate with collar, straight compression plate, straight reconstruction plate, 2.7(2.4)/3.5mm lateral distal fibula plate, 2.7(2.4)/3.5mm posterolateral distal fibula plate, T-compression plate right angle 3 hole head, T-compression plate right angle 4 hole head, T-compression plate oblique angle 3 hole head, T-compression plate oblique angle 4 hole head, 3.5mm curved reconstruction plate, 3.5mm broad compression plate, 2.7mm quarter tubular plate with collar, 4.5mm narrow compression plate, 4.5mm broad compression plate, 4.5mm T-compression plate right angle 2 hole head, 4.5mm T buttress plate, 4.5mm L buttress plate, 4.5mm semi-tubular plate), bone screws for fixation, and a set of instruments to facilitate installation and removal of the implants. The plates have screw holes, which allow for attachment to the bones or bone fragments. The plates are fabricated from medical grade stainless steel (ASTM F138), and offered in various widths and lengths. Plates and screws are provided non-sterile and sterile.

Indications for Use:
The SMV Bone Plate and Screw System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, and fibula, including periarticular and intraarticular fractures.

Contraindications:
- Active or latent infection
- Insufficient quantity or quality of bone/soft tissue
- Material sensitivity - If suspected, tests should be performed prior to implantation.
- Sepsis
- Patients who are unwilling or incapable of following postoperative care instructions.
- Spinal fixation - This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Potential Adverse Events:
Adverse reactions may include but are not limited to:
- Clinical failure (i.e. pain or injury) due to bending, loosening, wear and tear, fracture of implant, loss of fixation, dislocation and/or migration
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant
- Primary and/or secondary infections
- Allergic reactions to implant material
- Limb shortening due to compression of the fracture or bone resorption
- Necrosis of bone or decrease of bone density
- Injury to vessels, nerves and organs
- Hematoma and/or impaired wound healing; hemorrhage
Warnings and Precautions:
For safe effective use of this system the surgeon must be thoroughly familiar with these types of implants, the methods of application, instruments, and the recommended surgical technique for this type of device. Weight bearing with these devices is at the risk of the surgeon’s understanding that device breakage or damage can occur when the implants are subjected to increased loading associated with delayed union, nonunion, or incomplete healing.

Improper insertion of the devices during implantation can increase the possibility of loosening or migration. The patient must be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this implant.

When contouring the plate to conform to patient anatomy, care should be taken to avoid repeated bending, which may result in a broken or weakened plate.

Single-Use Device:
Products intended for single-use must not be re-used. Contaminated implants must not be reprocessed. Any implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Combination of Medical Devices:
SMV Scientific has not tested compatibility between the SMV Scientific Bone Plate and Screw System and other devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance environment:
The SMV Scientific Bone Plate and Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the SMV Scientific Bone Plate and Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Cleaning & Reprocessing:
All devices should be positioned to allow sterilant to come in contact with all surfaces. Care should be taken to protect devices from mechanical damage.

1. Disassemble device, if device is able to be disassembled, prior to reprocessing. Unthread end caps of depth gauge and handles to remove the inner shaft prior to reprocessing. Remove the inner shaft from outer sleeve.
2. Further detailed instrument Dismantling instructions are available from your local sales representative.
3. Open devices with ratchets, box locks or hinges.
4. Remove sharp devices for manual cleaning or place into a separate tray.
5. Lumens/cannula of devices should be manually processed prior to cleaning. Lumens/cannula should first be cleared of debris. Lumens/cannula should be brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brushes should be tight-fitting. Brush size should be approximately the same diameter of the lumen/cannulation to be cleaned. Using a brush that is too big or too small for the diameter of the lumen/cannulation may not
effectively clean the surface of a lumen/cannulation.

6. Pre-Cleaning: Remove gross contaminants by immersing the devices in room temperature neutral pH enzymatic cleaner (i.e. Metrizyme). Scrub with appropriate soft bristle brush until visibly and thoroughly clean.

7. Washing: Immerse devices in washer/cleaner with room temperature neutral pH enzymatic cleaner and wash for 10 minutes.

8. Rinsing: Thoroughly rinse the devices with deionized or distilled water for 2 minutes, three (3) times.

9. Verification: Examine devices under normal lighting to ensure no visual contamination. Repeats steps 1-4 if not visibly clean.

10. Drying: Allow devices to air dry a minimum of 45 minutes prior to inspection and sterilization preparation.

11. Preparation: After cleaning/disinfection, visually inspect the devices. Check for burrs or scraps.

12. Sterilization: It is the end user’s responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specified in this package insert.

Cleaning instructions have been validated.

Reassembly of instruments can be accomplished by following step 2 in reverse.

It is recommended that devices should be reprocessed as soon as is reasonably practical following use.

Visually inspect all reusable devices for signs of wear and tear before each use. Any devices with corrosion, discoloration, or cracked seals should be disposed of properly.

**Instruments and Implants Provided Non-Sterile:**

Products that are supplied non-sterile must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an FDA approved wrap or container. Due to the variations in steam sterilization systems, sterilization parameters should be determined and validated by reference to current ANSI/AAMI standards in addition to your facility’s own procedures. The following parameters have been validated to a sterility assurance level (SAL) of $\leq 10^{-6}$:

<table>
<thead>
<tr>
<th>Method</th>
<th>Steam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle Type</td>
<td>Pre-Vacuum</td>
</tr>
<tr>
<td>Minimum Temperature</td>
<td>132°C</td>
</tr>
<tr>
<td>Full Cycle Time</td>
<td>4 minutes</td>
</tr>
<tr>
<td>Minimum Dry Time</td>
<td>30 minutes</td>
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</tbody>
</table>

Other sterilization methods have not been validated and may damage the product resulting in a device malfunction, injury to the patient, or both. FDA-cleared wraps should be utilized for steam sterilization.
**Implants Provided Sterile:**
Products that are supplied sterile are sterilized using gamma irradiation at a dose range of 25-40 kGy, and are delivered sterile. The packaged implant is sterile for 5 years provided that the packaging remains intact.

**Storage:**
Do not store in a damp environment. Keep implants covered until needed. Prior to use, inspect product for signs of damage or contamination. In the operating room and during transport, keep implants separate from contaminated instruments or implants.

**Disposal:**
Dispose of implants according to facility protocol.

**Manufacturer:**
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