

# Instructions for Use - Warnings and Precautions

## OSSforce™ Fixation System

### I. General

The OSSforce™ fixation system, made up of various types of implants including the OSStaple™, OSSplate™, Step OSStaple™, OSSArc™, Barbed OSStaple™, and the OSSAnchor™ give the surgeon a means of bone fixation and help in the management of fracture and reconstructive surgery. The implants of the OSSforce™ Fixation system are not intended to replace normal body structures, so when the implant's service as an aid to healing is accomplished, it should be removed (when practical and possible) at the surgeon's discretion.

### II. Basic Structure

The implants of the OSSforce™ Fixation System are made of Nitinol (~50% nickel and 50% titanium). Due to the compressive properties of Nitinol, application of heat to the implants will cause their legs to deflect toward each other (on some implants the back will shrink as well) resulting in compression. In good bone quality, this deflection may not be visible as the legs are constrained by the surrounding tissue. It is recommended that the implants be heated ONLY by the OSSforce™ Implant Controller to minimize the potential for tissue necrosis.

BME offers several different types of implants. The implant model number designates its dimensions. EX1: OS-1512 has a 15mm back length, and a 12mm leg length. EX2: OS-111513 has an 11mm back length, one 15mm leg and one 13mm leg. The plate model number designates plate back and leg length. EX3: OP-1510 has a 15mm back length and 10mm legs. Some implants have an additional set of numbers to further describe their dimensions. EX4: OS-2020-06 has a 20mm back length, 20mm legs and 6mm step-off along the back. EX5: OSARC-111512-18 has an 11mm back length, a 15mm leg, a 12mm leg and an 18-degree slope along the back.

### III. Indications For Use

- Small bone fragment adjunctive fixation.
- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.
- Fixation of soft tissue to bone such as anterior cruciate reconstruction.
- Fixation of maxillofacial and mandibular bone fractures and osteotomies.
- Fixation of unloaded craniofacial bone fractures and cranioplasty.

### IV. Contraindications

- Cranioplasty where bone thickness is less than the length of the implant's legs.
- Comminuted bone surface which would militate against staple placement.
- Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the staple.
- Foreign body sensitivity to metals including nickel. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

### V. Warnings

- Repeated applications of the heating cycle or control settings higher than the maximum recommended can raise the temperature of the intraosseous elements sufficiently high as to cause thermal necrosis of bone adjacent to the staple. The Electrode Handle may begin to warm after several applications in quick succession. Allowing the Electrode Handle to cool for approximately 2 minutes after 4 successive warming cycles will maintain user comfort.
- Immobilization, in addition to this internal fixation, until bone healing (4–6 weeks) should be achieved by routine methods (casting, splints, intermaxillary fixation, etc.).
- The safety and effectiveness of the OSStaple™ in the temporomandibular region has not been demonstrated.
- Reduction of the site should be achieved and maintained prior to implanting the staple. The compressive force of the staple closing should not be relied upon to achieve closure or reduction of a fracture line.

### VI. Clinical Use Considerations

- OSStaple™ implants of equal leg length (OS-0705 through OS-3030) are used for the fixation of metaphyseal bone osteotomy or fracture.
- Asymmetric OSStaple™ implants (OS-111513, etc.) are useful when engagement of the opposing cortex with one leg is beneficial.
- Four leg OSSplate™ implants (OP) plates are provided for use where multiaxial loads are applied and plating is beneficial.
- Step OSStaples™ (OS-2020-02, 04, 06, 09, 12W2x3 and OS-1520-02, 04, 06, 09, 12W2) are for calcaneal slide osteotomies or other fixation requirements where there is a step or offset between bone surfaces to be fused.
- OSSArc™ implants (OSARC) are useful for concave or sloping surfaces such as metaphyseal flares.
- OSSAnchor™ implants (OSAN) are for fixation of soft tissue to bone.

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### VII. Clinical Use Examples

- Hand Surgery: intracarpal and interphalangeal arthrodesis, carpal, metacarpal and phalanges fracture or osteotomy.
- Foot Surgery: bunionectomy; tibiotarsal, Lisfranc's, calcaneocuboidal, and talonavicular arthrodesis; hind, mid, or forefoot bone fracture or osteotomy fixation.
- General Skeletal Surgery: bone fragment retention or adjunct fracture, osteotomy or arthrodesis fixation in the femur, fibula, tibia, humerus, ulna, radius, clavicle, ribs, pelvis, scapula and sternum.
- Cranial Surgery: cranioplasty, periorbital fracture.
- Maxillofacial Surgery: Le Fort I, II, and III, maxillary and mandibular fractures and osteotomies.

### VIII. Instructions

1. After site reduction, select the desired implant and drill template. When using the Adjustable Two-Prong Drill Guide, set the guide to the length corresponding to the back length of the selected staple.
2. Using a drill bit with the diameter that corresponds to the wire size of the staple (indicated by color on the drill bit and staple box), drill to the depth that corresponds to the staple's leg length. Recommended drill bit diameters are provided on the label of the staple box.
3. Remove the selected staple from its polyethylene block using the appropriately sized staple forceps.
4. Position the staple in the drilled holes and remove the forceps. If necessary, impact the staple in place using one of the provided impactors.
5. When using the OS-0705 and OS-0907 implants place the Small Electrode Adaptor onto the Electrode Prongs to reduce the electrode spacing.
6. Set the OSSforce™ Implant Controller as indicated on the implant packaging
7. Heat the staple with the OSSforce™ Implant Controller as described in the notes section of these instructions.

### IX. Care and Caution

- Ancillary equipment should be sterilized by a gravity feed autoclave cycle at 121°C (250°F) for 30 minutes. Alternatively, a pre-vac autoclave cycle of 135°C (275°F) for 4 minutes is acceptable. These recommended cycle times presuppose properly maintained autoclave equipment used with due diligence by the operator. Inspect each item prior to use. Do not use if there is any indication of cracks or crazing.
- Inspect the sterile pouches used for the implants prior to use. Sterilization cannot be assured and staple should not be used if pouch or seal is damaged.

- Staples should not be subjected to storage temperatures in excess of 75 °C (167 °F.) Staples should be allowed to cool to normal room temperature prior to removing from the polyethylene block.

### OSSforce™ Instructions

1. Set the Time and Power setting according to the implant packaging.
2. Firmly apply the Electrode Prongs to the back of the staple at the desired point of heating. Reference Notes below.
3. The green Indicator Light on the Electrode Handpiece indicates positive contact between the Electrode Prongs and the staple. (The newer OSSforce™ Implant Controller model has an audible tone that indicates positive contact in conjunction with the green Indicator Light.)
4. Press and hold the Electrode Handpiece Pushbutton to energize the staple. Current flow is indicated in three ways: the green Handpiece and OSSforce™ Indicator Lights turn red, vibration is felt in the Electrode Handpiece and an audible tone is heard. (On the newer OSSforce™ Implant Controller model, the tone will change in pitch to indicate current flow.) These signals indicate that the Pushbutton is engaged and that the preset time interval has begun. If the Electrode Handpiece is lifted and contact with the staple is broken, the red Indicator Lights will turn off until contact is re-established. Heating will continue when contact is re-established unless the preset time interval ends or the Electrode Handpiece Pushbutton is released.
5. Repeat the cycle at all desired heating points.

### Notes

1. Use one application of the heating cycle for implants with a back length of 13mm or less.
2. Use two successive applications of the heating cycle, one at each corner to the middle of the back for implants with a back length of 15, 18 or 20mm.
3. Use three successive applications of the heating cycle, one at each corner and one in the middle section of the back for implants with a back length of 25 or 30mm.
4. For the OSSplates™ (OP-1506, OP-1508, OP-1510), use one application of the heating cycle with the electrodes making contact at the corners across each short side of the implant's back.
5. Reference warning statement concerning use of the OSSforce™ Implant Controller.

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