

# OSSforce™ Implant Controller used with the OSStaple™ Dynamic Compression System

## OSSforce™ Implant Controller

The use of shape memory implants to assist bone fracture and osteotomy healing has been attempted with various degrees of success for a number of years. More specifically, creating the effect of Wolff's Law with this type of implant has been unsuccessful in almost every single attempt. However, the OSSforce™ Implant Controller achieves this effect by giving the surgeon full control of the implant's shape change. With the use of this system, the surgeon can carefully control the extent of bone reduction and compression. The OSSforce™ Implant Controller allows the surgeon to adjust each implant's compressive force at a predetermined level. This ability to control and adjust the amount of compression optimizes the implant fixation force for a broad range of patient bone quality while avoiding implant overheating and thermal necrosis.

The OSSforce™ Implant Controller, consisting of the OSSforce™ Electronic Console, OSSforce™ Electrode Handle and OSSforce™ Power Cord, heats the implant by the joule effect to a temperature of approximately 55°C and automatically turns off after a preset time interval. Visual, audible and tactile signals are provided to assist the surgeon in this process.

*Over 80 different sizes and types of implants are available for various surgical procedures, including the OSStaple™, Step OSStaple™, OSSplate™, OSSArc™, OSSpine™, OSSAnchor™ Grip, Barbed OSStaple™ (BOSS) and Step Barbed OSStaple™ (Step BOSS). All implants are compatible with the OSSforce™ Implant Controller.*

### Instructions

- 1 Connect the "Hospital Grade" OSSforce™ Power Cord to the back of the OSSforce™ Electronic Console as well as to a "Hospital Grade" power receptacle.
- 2 Connect the sterilized OSSforce™ Electrode Handle to the OSSforce™ Electronic Console.
- 3 Place the Small Electrode Adaptor over the Electrode Prongs for use with the OS-0907 and OS-0705 implants.
- 4 Switch the OSSforce™ Electronic Console to "ON" and ensure the ON-switch light is illuminated. Set the appropriate power level and time interval for the selected implant. See the Instructions for Use provided with the BME Implant for proper power and time settings.
- 5 When the implant is inserted and impacted flush with bone, apply both Electrode Prongs to the back of the implant and hold securely. The Handpiece and OSSforce™ Indicator Lights will turn green, indicating positive contact with the implant. (The newer OSSforce™ Implant Controller model has an audible tone that indicates positive contact in conjunction with the green Indicator Light.)
- 6 Press and hold the Electrode Handpiece Pushbutton to energize the implant. Current flow is indicated in three ways: the green 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.)
- 7 After the preset time interval: the red indicator lights return to green, the audible tone stops and power is automatically cut to the OSSforce™ Electrode Handle. *Note: If Electrode Prong contact with the implant is broken during the heating cycle, the red indicator lights will turn off. If contact is re-established prior to the timer shut-off, the heating cycle will continue for the remainder of the time cycle. Release of the pushbutton resets the OSSforce™ Implant Controller, allowing a new heating cycle.*
- 8 Repeat the cycle as appropriate for the specific implant. Refer to the "Instructions For Use" provided with the implant.
- 9 The Electrode Handpiece may begin to warm after numerous applications in quick succession. Allow the Electrode Handpiece to cool for two minutes after four successive heating cycles.



# OSSforce™ Implant Controller used with the OSStaple™ Dynamic Compression System (continued)

## Cleaning and Sterilization

The OSSforce™ Power Cord and OSSforce™ Electronic Console may be cleaned with a sponge or cloth that is dampened with a mild cleaning solution. The power cord and electronic console should not be sterilized or placed in the operative field.

The electrode handle is unplugged from the electronic console for cleaning and sterilization. Cleaning of the electrode handle should be achieved by wiping with an instrument cleaning solution such as Cidexplus™. Immersion in cleaning solutions or Cidexplus™ is not recommended but if immersion occurs, the Electrode Handpiece and Electrode Connector should be drained and thoroughly dried with forced warm air.

The OSSforce™ Electrode Handle (Electrode Probes, Electrode Handpiece, Electrode Cable and Electrode Connector) and Small Electrode Adaptor may be sterilized by autoclave using standard gravity feed or pre-vac methods. Maximum temperature should not exceed 135 °C (275 °F).

## Maintenance

Other than routine cleaning no preventative maintenance is required. No changes to internal components, settings or configuration are required or authorized. The equipment must be returned to the manufacturer if corrective maintenance is required.

## Storage

The OSSforce™ Implant Controller should be stored in an area normally associated with routine indoor storage.

## Safety Instructions

Warning: When using any electrical apparatus basic safety precautions should always be followed to reduce the risk of fire, electric shock, and personal injury, including the following:

Do not abuse cords. Protect cords from sharp edges, heat sources and corrosive materials. Do not pull or use force on the cord to disconnect from receptacles.

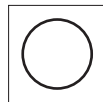
Inspect for damage. Before using the OSSforce™ Implant Controller, verify that there are no signs of damage to the OSSforce™ Electronic Console. If the console is dropped or experiences a severe blow it should be examined carefully to ensure safety prior to use.

Do not use in the presence of flammable anesthetics or high concentrations of oxygen.

## Symbols (IEC 601-1)



Identifies that additional information is available and should be consulted.



Indicates the switch is "off."



Identifies equipotential ground (located next to ground stud on the rear panel).



Indicates the device provides isolated patient connection (IEC 601-1 Type BF).

## Warranty

BME warrants this unit to be free of defects in materials and workmanship and to give satisfactory service for a period of 12 months from the date of purchase. This warranty does not apply if the product has been damaged by accident or misuse, exposed to ionizing radiation or corrosive materials, has foreign material penetrating to the inside of the product, or as a result of service or modification except as specifically authorized by BME.

To the extent allowable under applicable law, BME's liability for consequential and incidental damages is expressly disclaimed.

## Return of Items

Authorization must be obtained from BME before returning items for any reason. When applying for authorization, please include the reason items are to be returned.

For your protection items being returned must be carefully packed to prevent damage in shipment and insured against possible loss. We will not be responsible for damage resulting from careless or improper packing.

**BME**  
Changing the Shape  
of Orthopaedics  
A108-039 Rev E