**Silver Bullet Therapeutics OrthoFuzIon Screw System**

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**Manufacturer:**

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English

Non-Active Implant

***Explanation of symbols and abbreviations used on product labels:***

|  |  |
| --- | --- |
|  | Sterilized Using Irradiation |
| 2195005000500050 | CE Mark |
|  | Date of Manufacture |
|  | Do not use if package is damaged |
|  | MR Conditional - MR Conditional - Non-clinical testing and analysis has demonstrated that the OrthoFuzIon Bone Screw is MR Conditional as defined in ASTM F2503. At any time after implantation, a patient with an OrthoFuzIon Bone Screw can be scanned safely in a clinical MR scanner with field strength of 3.0 T or less. |
|  | Caution |
| http://www.fertipro.com/images/symbols/read_ifu.jpg | Consult Instructions for Use |
|  | Use by YYYY-MM |
|  | Single Use |
|  | Lot or batch number |
| Catalog/Reorder Number | Catalog or Model Number |
|  | Do not re-sterilize |
|  | Non-pyrogenic |

**Device Description**

The Silver Bullet Therapeutics OrthoFuzIon Bone Screw System is a bone screw system composed of single use devices for the fixation, correction and/or stabilization of bones. The OrthoFuzIon Bone Screw System includes two screw types:

1. A standard medical grade titanium alloy (ASTM F-136) cannulated screw that is plated with both platinum and silver to inhibit the growth of microorganisms on the screw.
2. A standard medical grade titanium alloy (ASTM F-136) solid screw that is plated with both platinum and silver to inhibit the growth of microorganisms on the screw.

***Indication For Use:***

OrthoFuzIon Bone Screws are indicated for open reduction and internal fixation (ORIF) fracture surgeries and are plated to inhibit microbial colonization and reduce implant related infection in revision surgery due to implant infection or primary surgery in patients who are at-risk of implant infections.

***Contraindications:***

* Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
* Material sensitivity, including silver, documented or suspected.
* Patients having inadequate tissue coverage over the operative site.
* Bone stock compromised by diseases, infection or prior implantation that cannot provide adequate support and/or fixation.
* Implant utilization that would interfere with anatomical structures or physiological performance.
* An overweight or obese patient can produce loads on the implant which can lead to failure of the fixation or to failure of the device itself.
* Any mental or neuromuscular disorder which could create an unacceptable risk of fixation failure or complications in postoperative care.
* Other medical or surgical conditions, which would preclude the potential benefit of the surgery.

***Warnings and Precautions:***

* The OrthoFuzIon screws should not be used in skeletally immature individuals or pregnant patients.
* Implant selection and sizing: The correct selection of the fracture fixation device is extremely important.
* OrthoFuzIon screws are Not For Reuse. To avoid risks from cross-contamination, infection, loss of product integrity, or patient injury, do not re-use or re-sterilize.
* Failure to use the appropriate implant may accelerate clinical failure*.*
* Do not use in the presence of an active systemic infection.
* Use of a torque limiter is recommended.
* If the skin turns blue or bluish-grey, either in large patches or localized, the patient should be evaluated for argyria.
* Physicians should warn patients about contraindications when appropriate.
* Caution should be taken if used with another device that contains silver to prevent a possible additive effect of silver.
* Presence of silver does not negate the need for additional treatments including systemic antibiotics in cases of infection.
* Any implants subjected to excessive post-operative physical activity are more prone to premature failure. Postoperative instructions to patients and appropriate nursing care are critical. Early weight bearing may substantially increase implant loading and may increase the risk of loosening, bending or breaking the device.
* The physician should be familiar with the devices, instruments and surgical technique prior to surgery.

***Potential Adverse Effects:***

The following potential adverse effects may be clinically related and not specific to an OrthoFuzIon device. The following are the most frequent adverse effects related to the use of all internal fixation devices including OrthoFuzIon screws:

* Delayed or non-union of the fracture site.
* Devices can break when subjected to increased loading associated with delayed unions and/or non-unions.
* Avascular necrosis.
* Deep vein thrombosis.
* Early or late infection, both deep or superficial.
* Shortening of the affected bone/fracture site.
* Improper alignment can cause a mal-union of the bone and/or bending, cracking or even breakage of the device.
* Metal sensitivity reactions and/or allergic reactions to foreign materials of the implant.
* Pain, discomfort, or abnormal sensations due to presence of the implant.
* Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.
* Conditions attributable to non-union, osteoporosis, osteomalicia, diabetes, inhibited revascularization, and poor bone formation can cause loosening, bending, cracking, fracture of the device or premature loss of rigid fixation with the bone.

***MRI Compatibility:***

The OrthoFuzIon Bone Screw System was determined to be MR-conditional according to the terminology specified in the American Society of Testing and Materials (ASTM) International, Designation F2503-05. A patient with this device can be scanned safely, immediately after placement under the following conditions:

* Static magnetic field of 3-Tesla or less;
* Maximum spatial gradient magnetic field of 720-Gauss/cm or less;
* Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence); and
* Normal Operating Mode of operation for the MR system.

All OrthoFuzIon bone screws have a Hex head. Use the appropriate driver to implant the screw as any other commercially available bone screws are utilized. The following drill pilot hole guidance is for the OrthoFuzIon screws:

|  |  |
| --- | --- |
| **Screw OD (mm)** | **Drill Size** **(mm)** |
| **4.00** | **2.70** |
| **4.50** | **3.00** |
| **5.00** | **3.50** |
| **5.50** | **4.00** |
| **6.00** | **4.40** |
| **6.50** | **4.80** |
| **7.00** | **5.20** |

The safety and effectiveness of the OrthoFuzIon Bone Screw System has been demonstrated with standard GLP Biocompatibility studies and ASTM Biomechanical testing.

The antimicrobial effects of the OrthoFuzIon Bone Screw System has been demonstrated in-vitro against the following representative organisms commonly found in orthopedic infections:

One study showed the amount of growth around the device were reduced at 72 hours for:

* Escherichia coli
* Staphylococcus aureus
* Staphylococcus epidermidis
* Pseudomonas aeruginosa
* Enterococcus faecalis

A subsequent study showed methicillin-resistant Staphylococcus aureus (MRSA) was not detected on the device after 24, 48, and 72 hours.

Another study showed the following were not detected on the device at 24 hours:

* Carbapenem-Resistant Enterobacteriaceae K. Pneumoniae ATCC BAA-2473
* Methicillin-resistant Staphylococcus Aureus S. aureus ATCC 33591
* ESBL-producing Enterobacteriaceae (extended-spectrum β- lactamases) E. coli 1744318
* Vancomycin-resistant Enterococcus (VRE) E. faecium 1674620
* Multidrug-resistant P. aeruginosa 1674623
* Multidrug-resistant Acinetobacter A. baumannii 1674627.