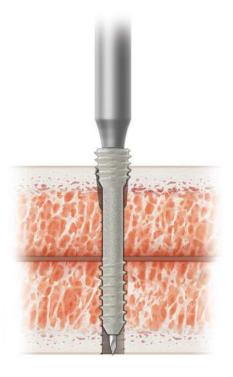


# OSSIOfiber® Compression Screw Surgical Technique Guide

Using Existing, Reproducible Surgical Techniques to Achieve Superior Fixation and Superior Healing

The OSSIOfiber® Compression Screws deliver superior compression strength and pull-out resistance compared to conventional metal compression screws¹-² while utilizing trusted, proven surgical techniques for fusion and fracture repair across upper and lower extremity surgical procedures. Bone gradually and predictably integrates into OSSIOfiber® enabling a true return to full strength and total healing without the risks and burdens associated with permanent hardware.³

Familiar design features for headless, partially threaded compression screws combined with the streamlined, cannulated instrumentation seamlessly fit into existing surgical approaches for reproducibility and precision. The convenience of the sterile, disposable instrumentation streamlines the time for OR preparation and reduces unnecessary exposure to pathogens.



## **Design Features**

### OSSIOfiber® Compression Screws

OSSIOfiber® Compression Screws deliver the same trusted performance and reproducible surgical techniques as conventional metal screws with the benefits of bio-Integration. Early bone attachment and in-growth serves to root the implant while gradual transfer of load with the surrounding bone progressively supports the natural return to full strength. Further boney in-growth supports natural bone healing and complete integration into the surrounding anatomy. Without the interference of metal, the patient can achieve maximum bone fusion - avoiding permanent interference at the fusion site and reducing the risk of long-term mechanical disadvantages (i.e. stress concentration, micro-motion, and screw back-out) often seen with permanent metal hardware.



Comprised of OSSIOfiber® Intelligent Bone Regeneration Technology

Natural mineral fiber matrix engineered to achieve the optimal balance of flexural, torque, axial, and shear strength for Compression Screws.

#### 4.0mm Cannulated

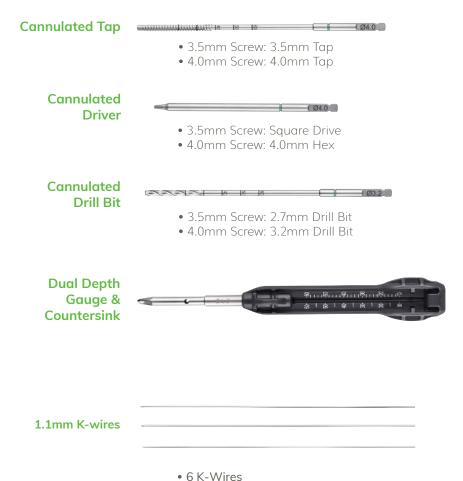


4.0mm diameter screws available in lengths 26-60mm in 2mm increments

3.5mm diameter screws available in lengths 14-24mm in 2mm increments

## Sterile, Disposable Instrumentation System

Sterile, disposable instrumentation will streamline OR preparation and turnover time between cases, eliminate the costs and time to clean and re-sterilize instrument trays, and reduce the risk of cross-contamination with single-use instrumentation compared to re-usable trays.





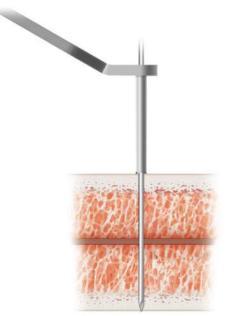
Ergonomic handle with AO quick connection mates with tap and driver



Dual-end Drill Guide for soft tissue protection with K-wires, Tap,and Drill Bit

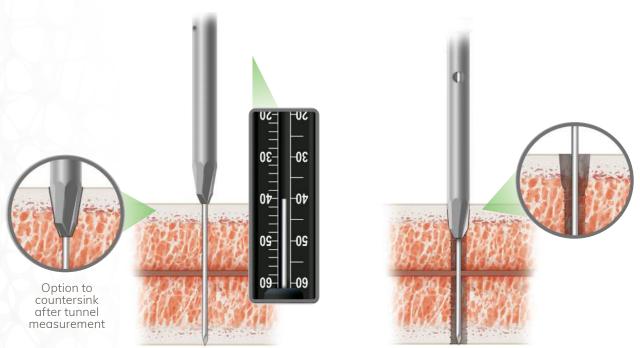
## **OSSIOfiber® Compression Screw Surgical Technique**





## 1 Position Drill Guide

Position the drill guide on bone and place one of the provided 1.1mm k-wires to the desired location.



## 2 Measure & Countersink

Measure the tunnel length depth with the cannulated dual depth gauge/counter sink tip, seated on cortical surface.

Center the cannulated dual depth gauge/countersink and provided k-wire within the newly created tunnel and prepare the tunnel aperture to fully seat the headless OSSIOfiber® Compression Screw.

**Important:** Countersinking is an important step to enable full insertion of the compression screw. **Note:** It is recommended to counter sink following the drilling of the pilot hole.

## **OSSIOfiber® Compression Screw Surgical Technique**

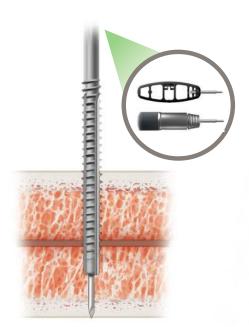




## 3 Drill

Create the tunnel with the drill guide and provided, cannulated drill bit.

**Note:** Laser marks are provided on the distal end of the the 3.2mm drill bit used with the 4.0mm screws starting at 20mm and proceed in 10mm increments to aid in measuring tunnel depth.



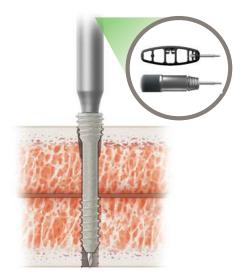
## 4 Tap

Connect the cannulated tap with the AO quick connect to the provided handle. Manually, tap the full length of the tunnel.

**Important:** If using a power drill, take care to tap under minimum RPM and reverse direction to remove the tap from the tunnel.

## **OSSIOfiber® Compression Screw Surgical Technique**

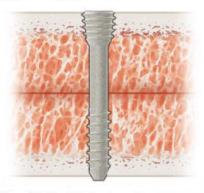




## 5 Insert Compression Screw

Connect the provided Driver with the AO quick connection to the provided handle (recommended) or to a standard power drill. Fully seat the desired length OSSIOfiber® Compression Screw onto the driver. Visually confirm on the Driver that the screw is fully seated. Manually (recommended) or under minimum power, insert the implant into the tunnel until the head is fully seated and flush at the tunnel aperture.

## Strong & Bio-Integrative Fixation with OSSIOfiber®



Superior compression and pull-out resistance compared to conventional metal compression screws<sup>1-2</sup>



Progressive load transfer enables a true return to full strength and total healing



Full integration into native anatomy with no adverse inflammation<sup>3</sup>

## **Post-Operative Protocol**



Bio-integrative OSSIOfiber® implants enable gradual, predictable bone and tissue in-growth into the micro-architecture of natural mineral fibers. There was no evidence of adverse or delayed inflammatory responses (commonly seen with bio-resorbables) in a prospective, multi-center clinical study on OSSIOfiber®; results documented excellent fusion rates and optimal bio-compatibility as seen in the CT and MRI scans.<sup>4</sup>

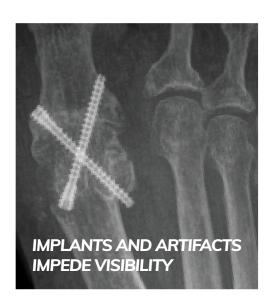
With strength above cortical bone, OSSIOfiber® implants offer a true match to boney fixation which we have been seeking for so many years. The OSSIOfiber® Compression Screws maintain mechanical strength and stable fixation beyond 12 weeks, which is what I need to achieve boney healing. In fact, over time, this construct may even get stronger as bio-integration takes place.<sup>5</sup>

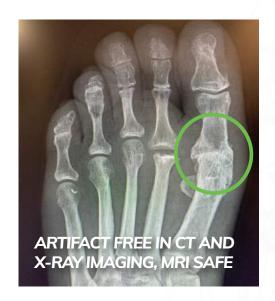
I have no reason currently to alter my standard post-op regimen when choosing OSSIOfiber® Compression Screws over metal compression screws."

#### -Stuart Miller, MD

Assistant Professor, Department of Orthopaedic Surgery Johns Hopkins University School of Medicine MedStar Union Memorial Hospital Baltimore, MD

## **Show Your Patients Hardware-Free Post-Op Scans**





OSSIOfiber® material technology has similar radiodensity to cortical bone and is artifact-free on X-ray/CT and MRI safe. Benefit from the full visibility of the fusion without obstruction of metal hardware. Showcase post-operative X-Rays to your patients with bony fusion achieved and the native anatomy completely restored.

#### **Indications For Use**

The OSSIOfiber® Compression Screws are indicated for maintenance of alignment and fixation of bone fractures, comminuted fractures, fragments, osteotomies, arthrodesis, and bone grafts, of the upper extremity, fibula, knee, ankle and foot in the presence of appropriate brace and/or immobilization.

Choose strong and bio-integrative OSSIOfiber® Compression Screws in lieu of standalone conventional, metal compression screws.

## 3.5mm

### 4.0mm

OSSIO® Compression Screw Instruments, For 4.0 mm Screws

Description	<b>Product Code</b>	Description	Product Code
OSSIOfiber® Compression Screw 3.5X14 mm	OF1073514S	OSSIOfiber® Compression Screw 4.0 x 26mm	OF1024026S
OSSIOfiber® Compression Screw 3.5X16 mm	OF1073516S	OSSIOfiber® Compression Screw 4.0 x 28mm	OF1024028S
OSSIOfiber® Compression Screw 3.5X18 mm	OF1073518S	OSSIOfiber® Compression Screw 4.0 x 30mm	OF1024030S
OSSIOfiber® Compression Screw 3.5X20 mm	OF1073520S	OSSIOfiber® Compression Screw 4.0 x 32mm	OF1024032S
OSSIOfiber® Compression Screw 3.5X22 mm	OF1073522S	OSSIOfiber® Compression Screw 4.0 x 34mm	OF1024034S
OSSIOfiber® Compression Screw 3.5X24 mm	OF1073524S	OSSIOfiber® Compression Screw 4.0 x 36mm	OF1024036S
OSSIO® Compression Screw Instruments, For 3.5 mm Screws	THN00132	OSSIOfiber® Compression Screw 4.0 x 38mm	OF1024038S
		OSSIOfiber® Compression Screw 4.0 x 40mm	OF1024040S
		OSSIOfiber® Compression Screw 4.0 x 42mm	OF1024042S
		OSSIOfiber® Compression Screw 4.0 x 44mm	OF1024044S
		OSSIOfiber® Compression Screw 4.0 x 46mm	OF1024046S
		OSSIOfiber® Compression Screw 4.0 x 48mm	OF1024048S
		OSSIOfiber® Compression Screw 4.0 x 50mm	OF1024050S
		OSSIOfiber® Compression Screw 4.0 x 52mm	OF1024052S
		OSSIOfiber® Compression Screw 4.0 x 54mm	OF1024054S
		OSSIOfiber® Compression Screw 4.0 x 56mm	OF1024056S
		OSSIOfiber® Compression Screw 4.0 x 58mm	OF1024058S
		OSSIOfiber® Compression Screw 4.0 x 60mm	OF1024060S

For more on OSSIO® and OSSIOfiber®, please visit **ossio.io** or call **833-781-7373** 

- $1. \ \ In \ Vitro \ Initial \ Compression \ Strength \ Test. \ Data \ on \ File \ at \ OSSIO.$
- $2. \ \ In \ Vitro \ Pull-Out \ Strength \ Test \ of \ 3.5x26mm \ OSSIO fiber \ Compression \ Screws. \ Data \ on \ File \ at \ OSSIO.$
- 3. Pre-clinical animal studies (in-bone implantation of OSSIOfiber and PLDLA control in rabbit femurs). Data on File at OSSIO.
- 4. Cicchinelli LD, Štalc J, Richter M, Miller S. Prospective, Multicenter, Clinical and Radiographic Evaluation of a Biointegrative, Fiber-Reinforced Implant for Proximal Interphalangeal Joint Arthrodesis. Foot & Ankle Orthopaedics. October 2020
- 5. Data on File at OSSIO.

Refer to the product Instructions for Use for warnings, precautions, indications, contraindications, and technique. ® OSSIO and OSSIOfiber are trademarks of OSSIO Ltd. All rights reserved 2021.

Not available for sale outside of US. Speak to your local sales representative for product availability.



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