



# Surgical Technique

**OSTEOBONE** Dual Thread Screw

# about us

Auxein Medical is an integrated, research based, orthopaedic Implants & instruments manufacturing company, producing a wide range of quality, affordable generic implants, trusted by healthcare professionals and patients across geographies. It is the Company's constant endeavor to provide a wide basket of generic and our innovator products that exceed the highest expectations of customers in term of quality and safety. The company has world-class manufacturing unit established in india and serves customers in over 75 countries worldwide.

# Guidelines

This publication sets forth detailed recommended procedures for using Auxein Medical devices and instruments.

It offers guidance that needs to be heeded. However, with any such technical guide, each surgeon must consider the unique needs of each patient and make appropriate adjustments when and as required.

A workshop training under DAIS Academy by Auxein will provide assistance prior to first surgery. It is vital to know that all non-sterile devices must be cleaned and sterilized before use.

Moreover, multi-component instruments must be disassembled for cleaning. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.





**Please NOTE** that all the bone screws referenced in this document here are not approved for screw attachment or fixation in the areas not mentioned in this publication.

**Warning:**

This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.



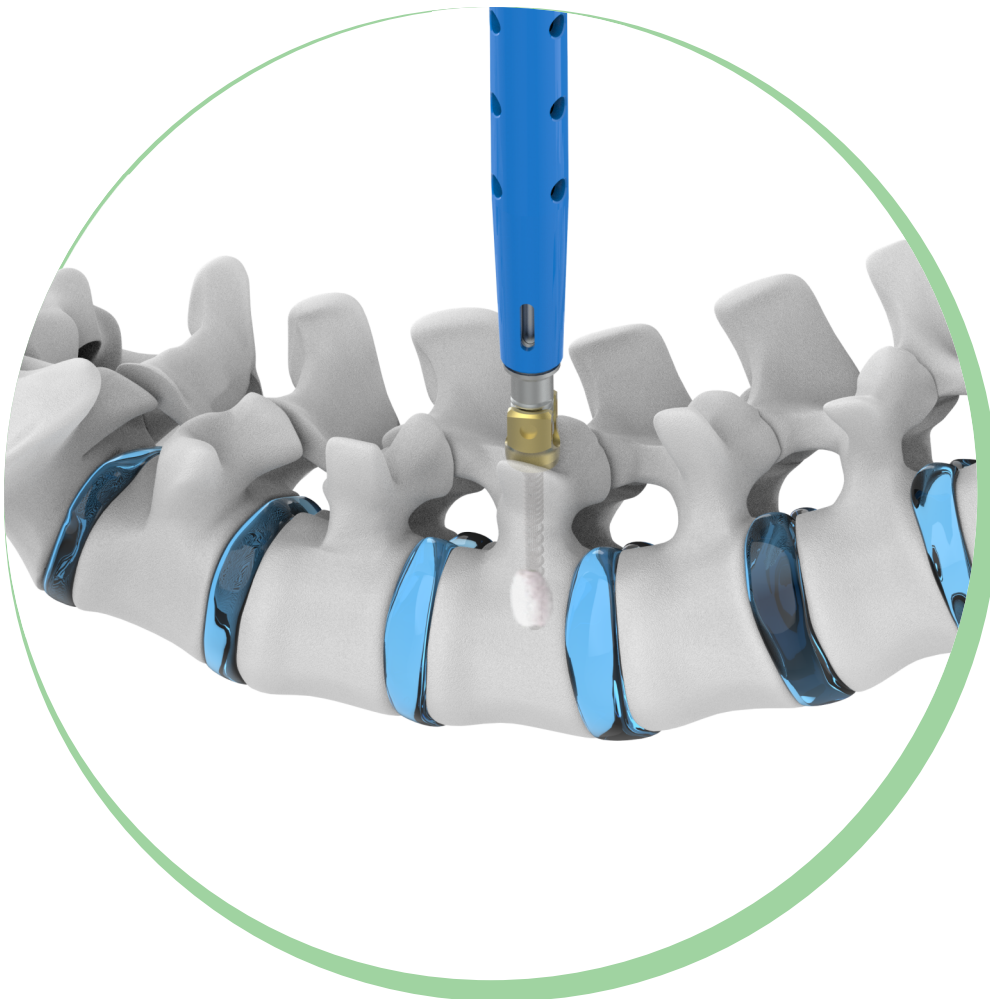
Colour Parameters as per Ø

			
Pink Ø 4.5	Green Ø 5.5	Golden Ø 6.5	Brown Ø 7.0

## OSTEOBONE Dual Thread Screw

The Osteobone Dual Thread Screw is a specialized medical implant used in orthopedic and spinal surgeries for bone fixation. This innovative screw is designed to provide excellent stability and secure fixation, promoting bone fusion and facilitating the healing process.





The Osteobone Dual Thread Screw features a unique dual-threaded design. It has two separate threads with different pitches along its length. The distal portion of the screw has a finer thread pitch, while the proximal portion has a coarser thread pitch. This dual-thread configuration offers several advantages.



### OSTEOBONE Multiaxial Pedicle Fenestrated Dual Thread Screw

First, the finer distal thread allows for easy and smooth insertion into the bone. It helps to reduce the risk of bone fractures or damage during the screw insertion process. The fine thread design also improves the overall pullout strength of the screw, enhancing its stability within the bone.

Colour Parameters as per Ø

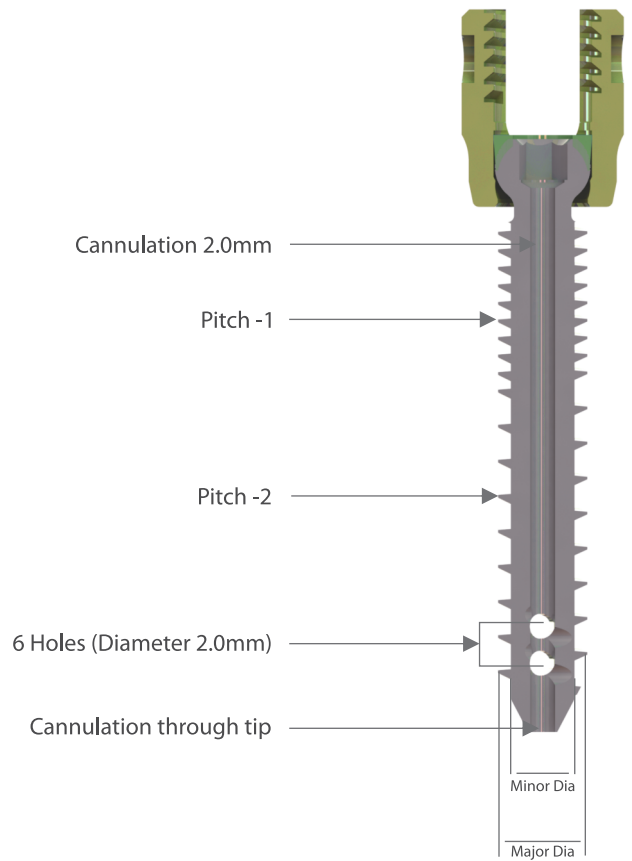
			
Pink Ø 4.5	Green Ø 5.5	Golden Ø 6.5	Brown Ø 7.0

## OSTEOBONE Multiaxial Pedicle Fenestrated

### Dual Thread Screw

These screws are used to correct deformity, and/or treat trauma. The screws may also be used to immobilize part of the spine (T1-L5) to assist fusion by holding bony structures together.

Dual Threaded pitches provide increased superior to inferior facet compression



These fenestrations near the distal tip of the screw provides a controlled means to deliver a small amount of polymethylmethacrylate (PMMA) bone cement into a targeted vertebral body.

## PREPARATION OF THE SPINE:

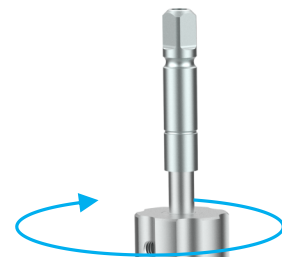
Prepare the spine according to the appropriate Vertaux 5.5mm Pedicle Screw System Spinal System Surgical Technique. The Osteobone Dual Thread Screw is compatible with MIS or open procedures.

## FENESTRATED SCREW ADAPTER DRIVER ASSEMBLY:

- OSTEOBONE Multiaxial Pedicle Screwdriver is a single part device. The distal end of the driver is compatible with ratchet handle to insert and tighten the screw. The hex recess helps in alliging the screw and the threads lock the orientation of the screw.

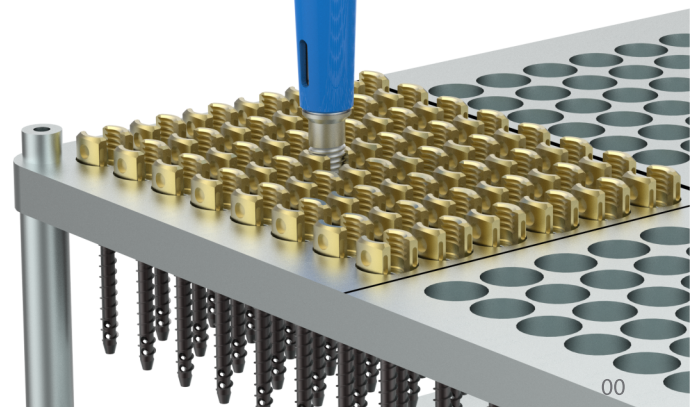
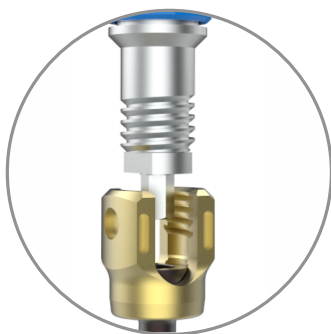


- U Notch screw driver shaft to align the screwdriver accurately with screw.
- Cannulated screw driver with movable shaft and thread to fix the orientation and allignment.



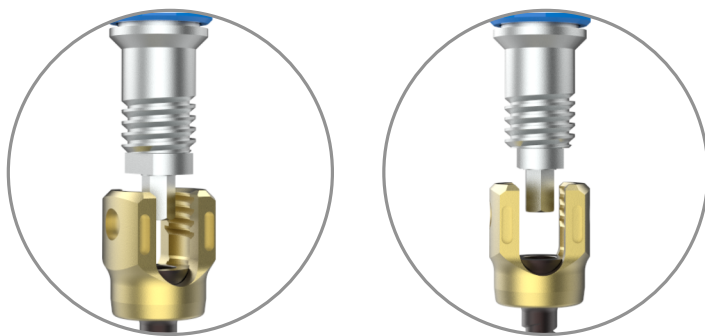
## ATTACHING THE FENESTRATED SCREW TO THE ADAPTER DRIVER:

Thread the screw driver into the selected screw based on the calculation While threading the driver make sure the rounded edge at proximal end of driver shaft would not interfere with the polyhead side walls.



**FENESTRATED SCREW ADAPTER DRIVER ASSEMBLY:**

OSTEOBONE Multiaxial Pedicle Screwdriver is a single part device. The distal end of the driver is compatible with ratchet handle to insert and tighten the screw. The hex recess helps in alliging the screw and the threads lock the orientation of the screw.



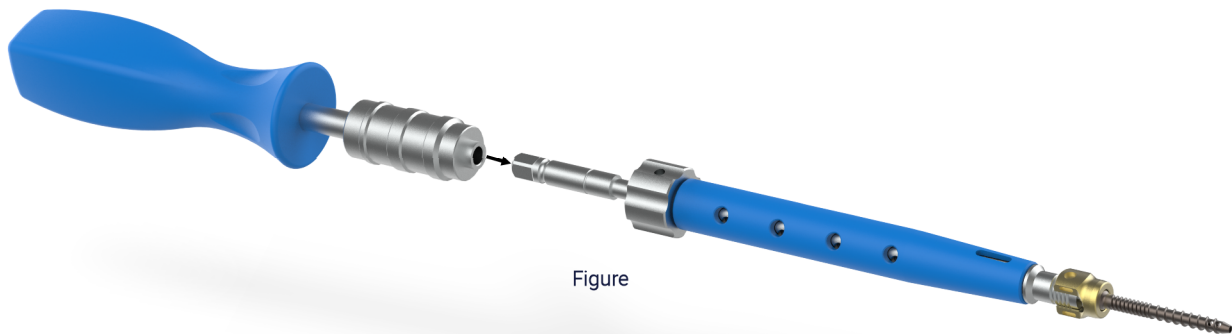
While threading the driver make sure the rounded edge at proximal end of driver shaft would not interfere with the polyhead side walls.



Figure

**SCREW INSERTION**

Couple the ratchet handle with the driver by pulling the distal end of handle and push the handle so that the ball of handle will sit into the driver cavity to insert the screw into the bone.

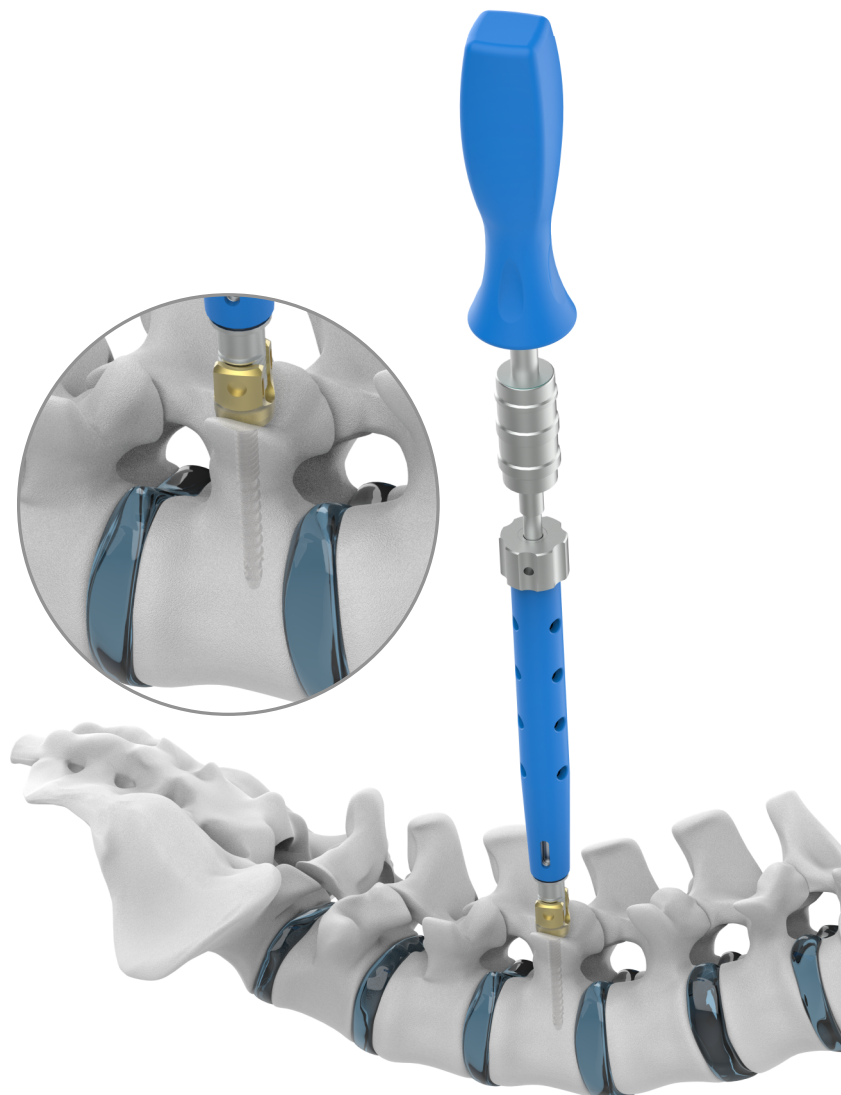


Figure

- Using the Screw Driver and Ratchet Handle, insert screws into the levels to be instrumented. The Screw Driver must remain attached to the screw to allow for cement injection.

**Note**

To reduce the risk of cement leakage, it is essential to verify with intraoperative imaging that the tip of each screw is within the confines of the vertebral body, just beyond the midpoint.





**MIXING THE CEMENT**

Osteobone Fenestrated screw is compatible with Kyphon Mixer or similar cement preparation apparatus available at the hospital or facilities. An example of cement mixing process is shown below.

To prepare the FS Cement, insert the funnel into the Kyphon™ Mixer. Make sure the purple valve levers are facing up so they are in the closed position (Figure).



Figure

Pour the entire contents of the Fenestrated screw Cement powder packet into the Kyphon Mixer (Figure) Remove the funnel from the mixer.



Figure

## MIXING THE CEMENT

Take the syringe and blunt needle and thread together. Snap off the bottle cap of the FS Cement liquid and use the syringe and needle assembly to extract the contents (Figures).



Figure



Figure

Inject the liquid into the Kyphon Mixer (Figure).



Figure

## MIXING THE CEMENT



2 min.

- Insert the paddle (Figure).
- Hold the Kyphon Mixer at the base and mix the cement for approximately two minutes by agitating the paddle (Figure).

### Note:

The mixing and curing characteristics of the cement will vary according to temperature and other factors. For example, in cooler environments it may be desired to mix for slightly longer to achieve a more viscous consistency before filling the Bone Filler Devices. Refer to the FS Cement instructions for use.



Figure



Figure

Remove the paddle and insert the plunger (Figure).

### IMPORTANT

The Bone Filler Device should be loaded immediately once the cement is mixed.



Figure

## OPTION A.

### USING THE BONE FILLER DEVICE FOR DELIVERY

## STEP 1:

### Loading the Bone Filler Device

- Attach the Bone Filler Device to the Kyphon Mixer by threading it onto the Luer Lock at the base of the mixer. Alternatively, the Kyphon Multi-tap Adapter can be used to fill eight bone fillers. Attach the eight bone fillers to the Multi-tap Adapter and attach the assembly to the Kyphon Mixer (Figure). Lower both valve levers and fill the Bone Filler Devices by pressing down on the plunger (Figure).

### Note

Each Bone Filler Device distributes 1.5cc of cement.



Figure



Figure

## OPTION A.

### USING THE BONE FILLER DEVICE FOR DELIVERY

## STEP 2:

Checking the Viscosity of the Cement



8 min.

Begin checking the viscosity of the cement after approximately eight minutes. To check the viscosity, eject a small amount from the tip of a filled Bone Filler Device. Lightly pinch the cement between gloved fingers. If fiber tendrils are seen and the cement is sticky, it is not ready and should be allowed to stand further. The cement has become doughy and is ready for application when the gloved finger separates cleanly and the cement has lost its sheen (Figure).



Figure

#### Note

Do not roll between finger tips; use a pinching motion.

#### Note

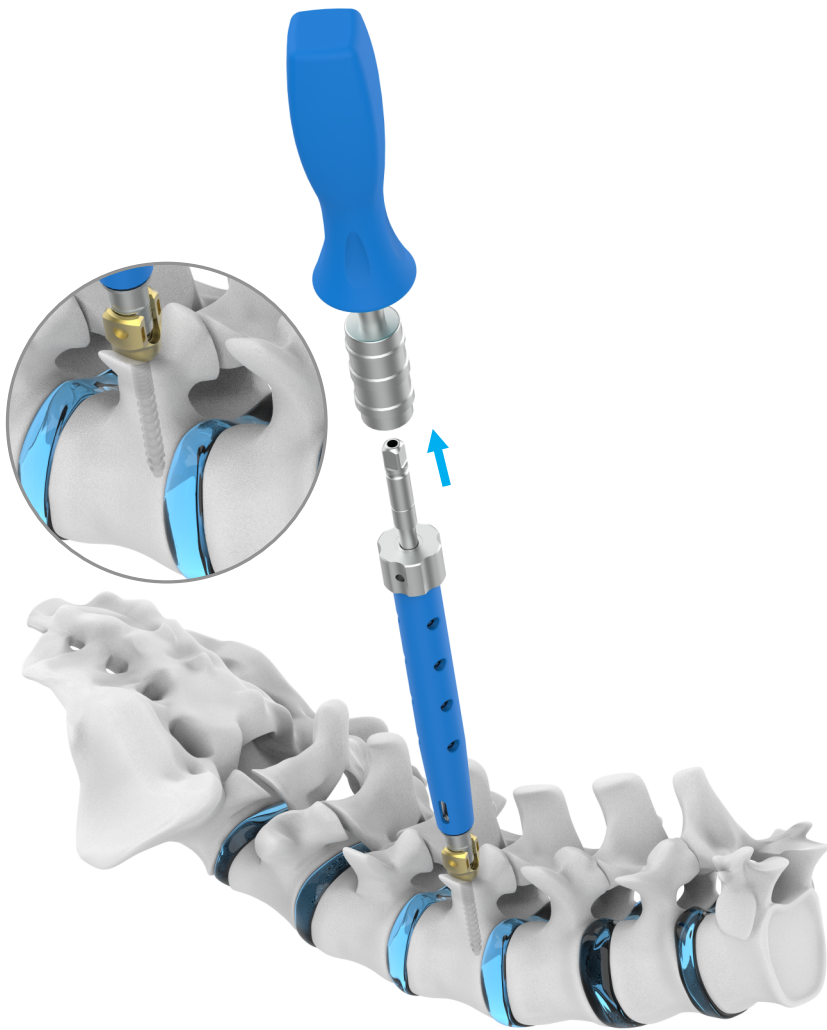
Time should be measured beginning with initial mixing of the cement, not from the loading of the Bone Filler Device.

**OPTION A.****USING THE BONE FILLER DEVICE FOR DELIVERY****STEP 3:**

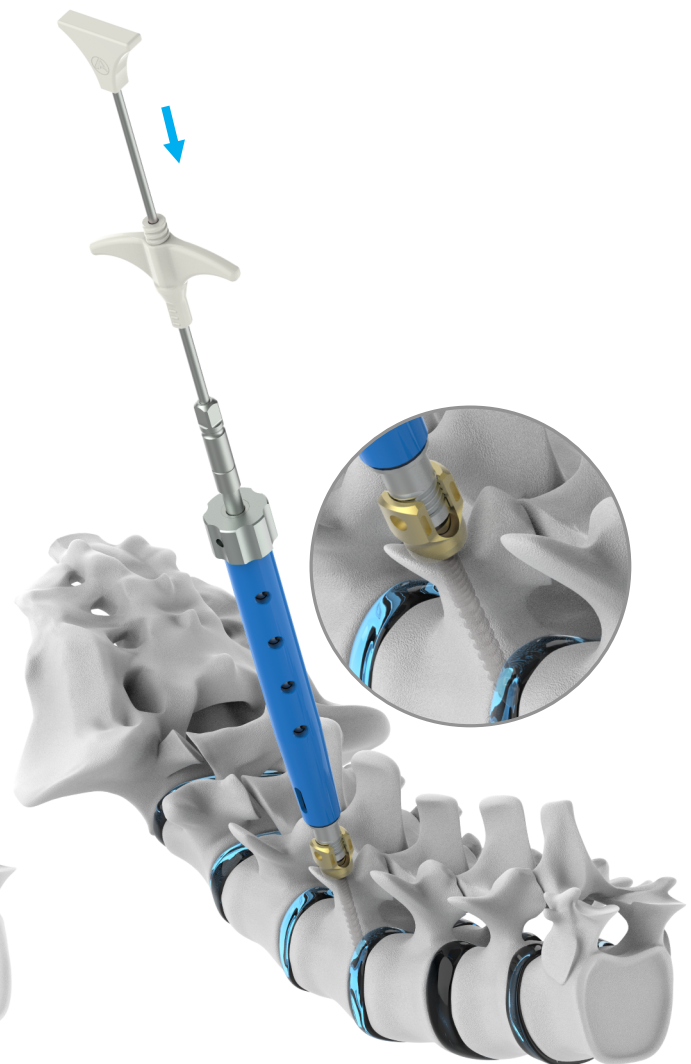
## Injecting the Cement

Remove the Ratchet handle from driver assembly as shown in figure.

- Insert the Bone Filler Device (Figure).



Figure



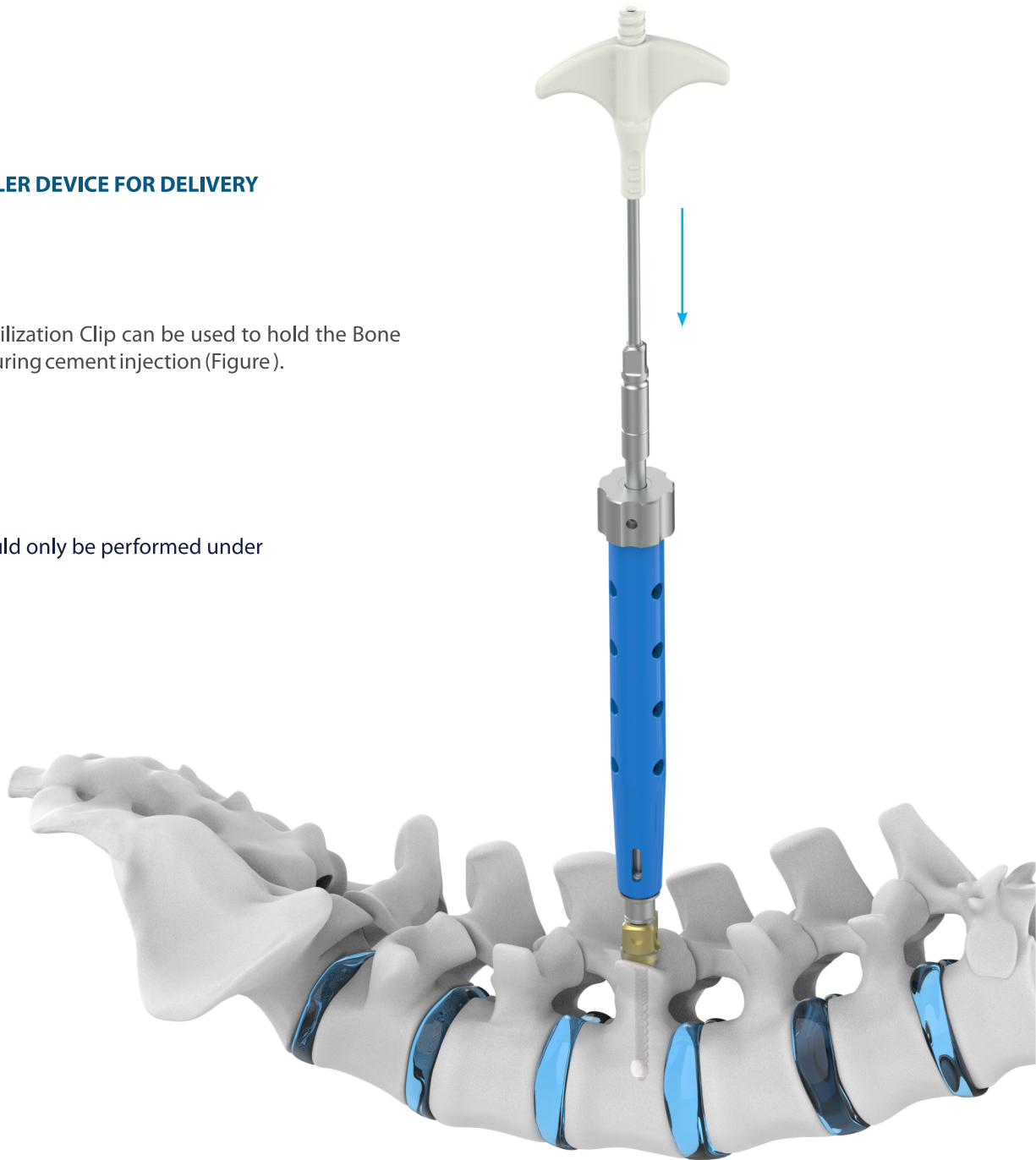
Figure

**OPTION A.****USING THE BONE FILLER DEVICE FOR DELIVERY****Note**

As an option, the Stabilization Clip can be used to hold the Bone Filler Device in place during cement injection (Figure).

**IMPORTANT**

Cement injection should only be performed under fluoroscopic control.



Figure

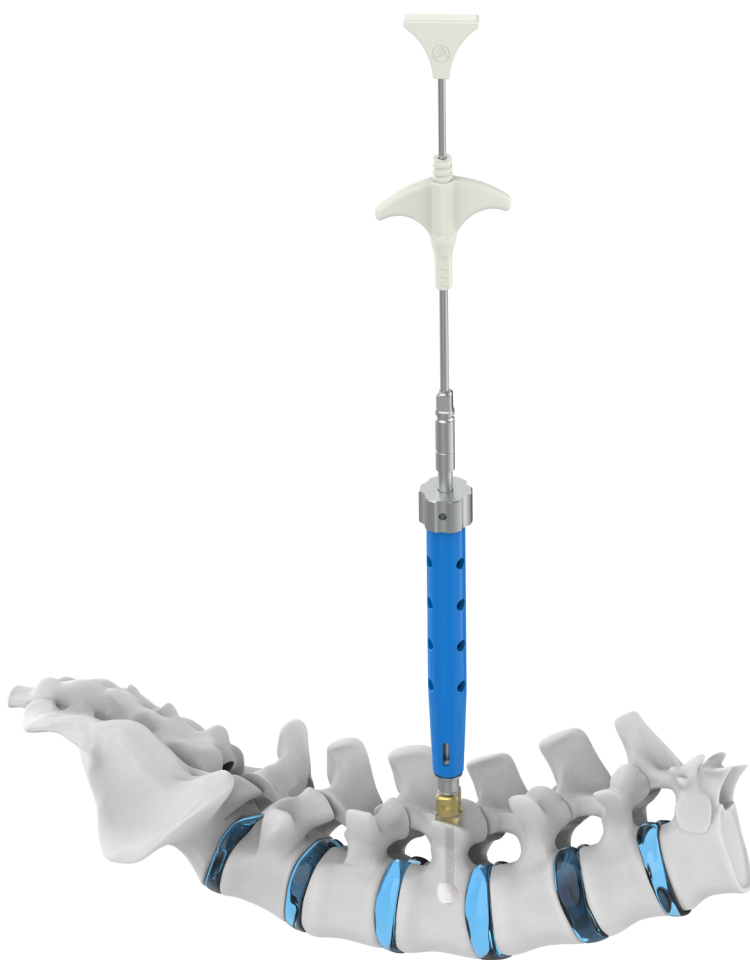
**Note:**

Each Bone Filler Device can distribute 1.5cc of cement. The plunger portion of the Bone Filler Device has three position markers each at 0.5cc increments. The Fenestrated Screw and Adapter Driver cannula will fill with approximately 0.4cc of cement before any is injected into the vertebral body. To achieve adequate fixation, it is recommended that 0.8cc of cement be implanted in the vertebral body for each screw in the thoracic spine (except for T11 and T12) and 1.8cc of cement be used for each screw in the lumbar spine along with T11 and T12.

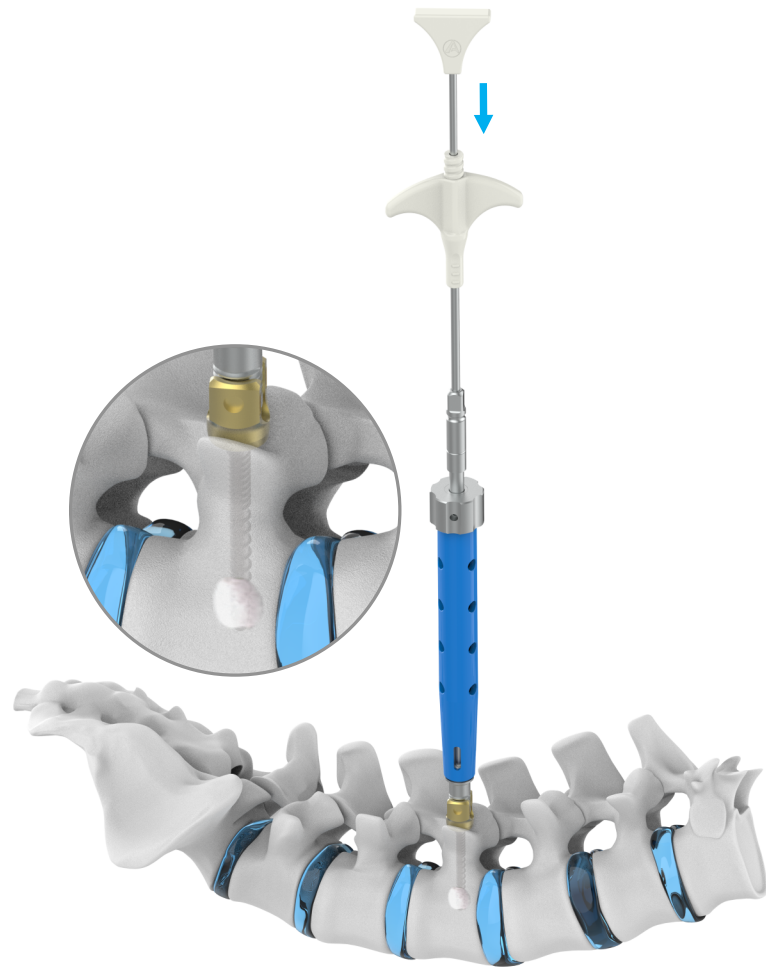
## OPTION A.

### USING THE BONE FILLER DEVICE FOR DELIVERY

Insert the plunger portion of the Bone Filler Device into the outer sheath (Figure) and inject the cement by depressing the plunger until the desired volume of cement is delivered (Figure).



Figure



Figure

Repeat injection for each Fenestrated Screw.

## IMPORTANT

- Remove the Bone Filler Device from the Adapter Driver post-cement injection.
- Remove the Adapter Driver at approximately 3 minutes post-cement injection to avoid pulling cement into the saddle of the screw.

Once the cement is set, [see page 23](#) for steps to remove the Adapter Driver and steps to complete the procedure.



## COMPLETING THE PROCEDURE

See the appropriate CD Horizon Solera Spinal System Surgical Technique for guidance in rod, set screw and transverse link placement, final tightening, and bone grafting.

## OPTIONAL SUPPLEMENTAL PROCEDURES

A corpectomy procedure may be used as a supplemental procedure to a fenestrated screw construct as deemed necessary by a physician. The CD Horizon Solera Fenestrated Screws may be used with any Medtronic corpectomy device cleared for use in the thoracic and/or lumbar spine and is indicated for a tumor pathology. Refer to the appropriate surgical technique and package insert for guidance, indications, contraindications, and warnings for cleared Medtronic corpectomy devices.

## SCREW EXPLANTATION

If removal of a Fenestrated Screw is necessary, attach a standard Medtronic Quick Connect Handle to the T25 screwdriver.

Next, fully engage the T25 end of the driver into the screw head; then thread the instrument sleeve into the screw head. Turn counterclockwise until the Fenestrated Screw is removed.

### **Note**

The cured cement will break away from the screw under this torsional force to allow for screw removal. Refer to the appropriate CD Horizon Solera System Surgical Technique for proper explantation of the other CD Horizon Solera implants.

## Osteobone Multiaxial Pedicle Fenestrated Dual Thread Screw



Code	Dia X Length
SP-OS-100	Ø4.5mm X 20mm
SP-OS-101	Ø4.5mm X 25mm
SP-OS-102	Ø4.5mm X 30mm
SP-OS-103	Ø4.5mm X 35mm
SP-OS-104	Ø4.5mm X 40mm
SP-OS-105	Ø4.5mm X 45mm
SP-OS-106	Ø4.5mm X 50mm
SP-OS-107	Ø5.5mm X 20mm
SP-OS-108	Ø5.5mm X 25mm
SP-OS-109	Ø5.5mm X 30mm
SP-OS-110	Ø5.5mm X 35mm
SP-OS-111	Ø5.5mm X 40mm
SP-OS-112	Ø5.5mm X 45mm
SP-OS-113	Ø5.5mm X 50mm
SP-OS-114	Ø5.5mm X 55mm
SP-OS-115	Ø5.5mm X 60mm
SP-OS-116	Ø6.5mm X 20mm
SP-OS-117	Ø6.5mm X 25mm
SP-OS-118	Ø6.5mm X 30mm
SP-OS-119	Ø6.5mm X 35mm
SP-OS-120	Ø6.5mm X 40mm
SP-OS-121	Ø6.5mm X 45mm
SP-OS-122	Ø6.5mm X 50mm
SP-OS-123	Ø6.5mm X 55mm
SP-OS-124	Ø6.5mm X 60mm
SP-OS-125	Ø6.5mm X 65mm
SP-OS-126	Ø7.0mm X 20mm
SP-OS-127	Ø7.0mm X 25mm
SP-OS-128	Ø7.0mm X 30mm
SP-OS-129	Ø7.0mm X 35mm
SP-OS-130	Ø7.0mm X 40mm
SP-OS-131	Ø7.0mm X 45mm
SP-OS-132	Ø7.0mm X 50mm
SP-OS-133	Ø7.0mm X 55mm
SP-OS-134	Ø7.0mm X 60mm
SP-OS-135	Ø7.0mm X 65mm

### STERILE

Code	Dia X Length
SP-OS-100-S	Ø4.5mm X 20mm
SP-OS-101-S	Ø4.5mm X 25mm
SP-OS-102-S	Ø4.5mm X 30mm
SP-OS-103-S	Ø4.5mm X 35mm
SP-OS-104-S	Ø4.5mm X 40mm
SP-OS-105-S	Ø4.5mm X 45mm
SP-OS-106-S	Ø4.5mm X 50mm
SP-OS-107-S	Ø5.5mm X 20mm
SP-OS-108-S	Ø5.5mm X 25mm
SP-OS-109-S	Ø5.5mm X 30mm
SP-OS-110-S	Ø5.5mm X 35mm
SP-OS-111-S	Ø5.5mm X 40mm
SP-OS-112-S	Ø5.5mm X 45mm
SP-OS-113-S	Ø5.5mm X 50mm
SP-OS-114-S	Ø5.5mm X 55mm
SP-OS-115-S	Ø5.5mm X 60mm
SP-OS-116-S	Ø6.5mm X 20mm
SP-OS-117-S	Ø6.5mm X 25mm
SP-OS-118-S	Ø6.5mm X 30mm
SP-OS-119-S	Ø6.5mm X 35mm
SP-OS-120-S	Ø6.5mm X 40mm
SP-OS-121-S	Ø6.5mm X 45mm
SP-OS-122-S	Ø6.5mm X 50mm
SP-OS-123-S	Ø6.5mm X 55mm
SP-OS-124-S	Ø6.5mm X 60mm
SP-OS-125-S	Ø6.5mm X 65mm
SP-OS-126-S	Ø7.0mm X 20mm
SP-OS-127-S	Ø7.0mm X 25mm
SP-OS-128-S	Ø7.0mm X 30mm
SP-OS-129-S	Ø7.0mm X 35mm
SP-OS-130-S	Ø7.0mm X 40mm
SP-OS-131-S	Ø7.0mm X 45mm
SP-OS-132-S	Ø7.0mm X 50mm
SP-OS-133-S	Ø7.0mm X 55mm
SP-OS-134-S	Ø7.0mm X 60mm
SP-OS-135-S	Ø7.0mm X 65mm



## OSTEOBONE - Pedicle Screw Cap, M9



Star Head



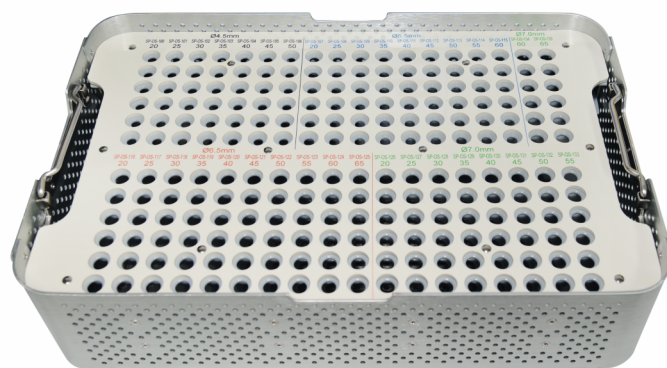
**STERILE**

Product Specification	Titanium
M9	<b>SP-OS-136</b>

Product Specification	Titanium
M9	<b>SP-OS-136-S</b>

## 7-015-01 Screw Tray for Osteobone Multiaxial Pedicle Fenestrated Dual Thread System

Code	Dia X Length	Unit
SP-OS-100	Ø4.5mm X 20mm	6
SP-OS-101	Ø4.5mm X 25mm	6
SP-OS-102	Ø4.5mm X 30mm	6
SP-OS-103	Ø4.5mm X 35mm	6
SP-OS-104	Ø4.5mm X 40mm	6
SP-OS-105	Ø4.5mm X 45mm	6
SP-OS-106	Ø4.5mm X 50mm	6
SP-OS-107	Ø5.5mm X 20mm	6
SP-OS-108	Ø5.5mm X 25mm	6
SP-OS-109	Ø5.5mm X 30mm	6
SP-OS-110	Ø5.5mm X 35mm	6
SP-OS-111	Ø5.5mm X 40mm	6
SP-OS-112	Ø5.5mm X 45mm	6
SP-OS-113	Ø5.5mm X 50mm	6
SP-OS-114	Ø5.5mm X 55mm	6
SP-OS-115	Ø5.5mm X 60mm	6
SP-OS-116	Ø6.5mm X 20mm	6
SP-OS-117	Ø6.5mm X 25mm	6
SP-OS-118	Ø6.5mm X 30mm	6
SP-OS-119	Ø6.5mm X 35mm	6
SP-OS-120	Ø6.5mm X 40mm	6
SP-OS-121	Ø6.5mm X 45mm	6
SP-OS-122	Ø6.5mm X 50mm	6
SP-OS-123	Ø6.5mm X 55mm	6
SP-OS-124	Ø6.5mm X 60mm	6
SP-OS-125	Ø6.5mm X 65mm	6
SP-OS-126	Ø7.0mm X 20mm	6
SP-OS-127	Ø7.0mm X 25mm	6
SP-OS-128	Ø7.0mm X 30mm	6
SP-OS-129	Ø7.0mm X 35mm	6
SP-OS-130	Ø7.0mm X 40mm	6
SP-OS-131	Ø7.0mm X 45mm	6
SP-OS-132	Ø7.0mm X 50mm	6
SP-OS-133	Ø7.0mm X 55mm	6
SP-OS-134	Ø7.0mm X 60mm	6
SP-OS-135	Ø7.0mm X 65mm	6



**7-015-04** Cement Insertion Attachment



**SP-OS-146** Cleaning Pin (Optional)



**SP-OS-147** OSTEOBONE Multiaxial Pedicle Screwdriver



**7-015-02** Quick Coupling Handle



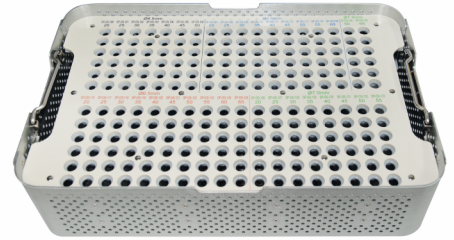
**SP-OSI-01** Bone Filler Device Outer Sheath - Sterile (Optional)



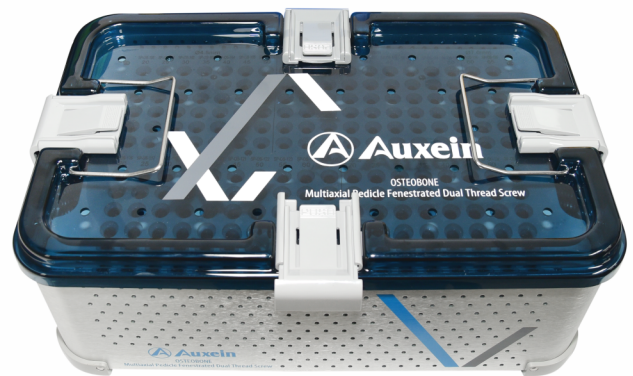
**SP-OSI-02** Bone Filler Device Plunger - Sterile (Optional)



**7-015-01** Screw Tray for Osteobone Multiaxial Dual Thread System



**7-015-03** Container with PPSU Lid for Osteobone Multiaxial Dual Thread Instrument Set



## 7-015 Osteobone Multiaxial Instrument Set

Code	Set Consisting of	Units
<b>7-015-04</b>	Cement Insertion Attachment	8
<b>SP-OS-146</b>	Cleaning Pin (Optional)	1
<b>SP-OS-147</b>	OSTEOBONE Multiaxial Pedicle Screwdriver	8
<b>7-015-02</b>	Quick Coupling Handle	2
<b>SP-OSI-01</b>	Bone Filler Device Outer Sheath - Sterile (Optional)	8
<b>SP-OSI-02</b>	Bone Filler Device Plunger - Sterile (Optional)	8
<b>7-015-01</b>	Screw Tray for Osteobone Multiaxial Dual Thread System	1
<b>7-015-03</b>	Container with PPSU Lid for Osteobone Multiaxial Dual Thread Instrument Set	1

# NOTES



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