

**SURGICAL
TECHNIQUE**

CD Horizon™ Solera™ 5.5/6.0mm Fenestrated Screw Set

CD Horizon Solera Fenestrated Screws provide immediate enhanced fixation in poor bone quality due to advanced stage tumors through the application of Medtronic Fenestrated Screw Cement.



Medtronic





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IMPLANT FEATURES AND INSTRUMENT SET

The CD Horizon Solera Fenestrated Screw Set offers the same design and capabilities of the CD Horizon Solera Spinal System Screws, with the addition of six fenestrations near the tip. These features allow cement to pass directly through the screw shaft and fenestrations, providing immediate enhanced fixation in cases with poor bone quality.

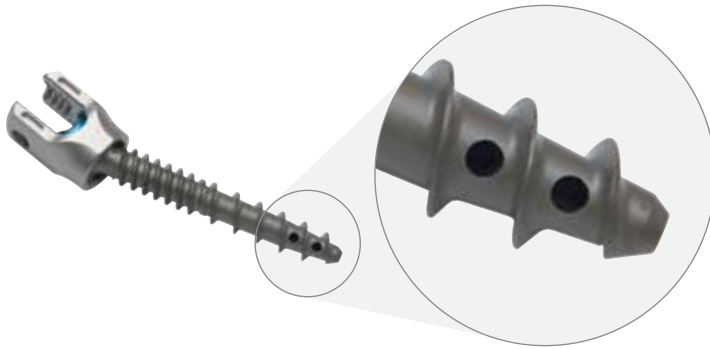
When used in conjunction with Medtronic Fenestrated Screw Cement, the CD Horizon Solera Fenestrated Screws are

intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CD Horizon Solera Fenestrated Screws augmented with Medtronic HV-R Fenestrated Screw Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

IMPLANT

CD Horizon Solera Fenestrated Screw

Available for CD Horizon Solera
5.5/6.0mm Spinal Systems



5.5/6.0mm

INSTRUMENTS

ADAPTER DRIVER

The CD Horizon Solera Fenestrated Screw Adapter Driver comes in two parts.



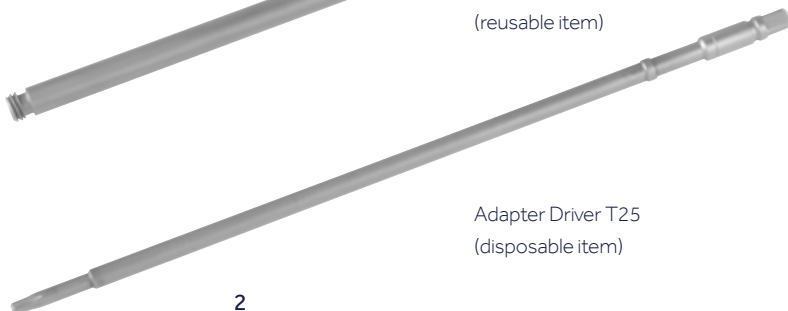
Quick Connect (QC) Handle



5.5/6.0mm Adapter Driver



5.5/6.0mm Lock Sleeve
(reusable item)



Adapter Driver T25
(disposable item)

CEMENT MIXING



Syringe



Kyphon™ Mixer



Paddle



Funnel

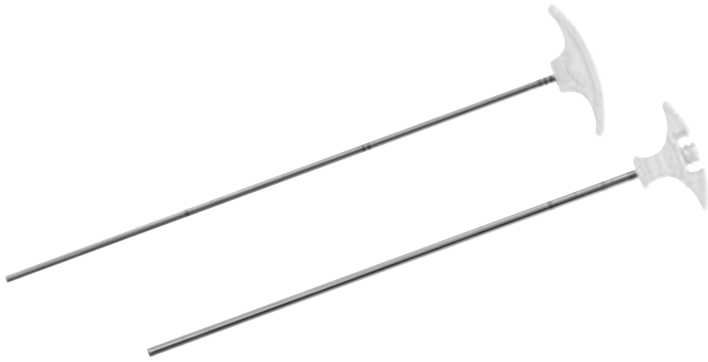


Plunger



Medtronic Fenestrated Screw (FS) Cement powder packet and liquid bottle

CEMENT INJECTION



Bone Filler Device



Luer Lock



Cartridge

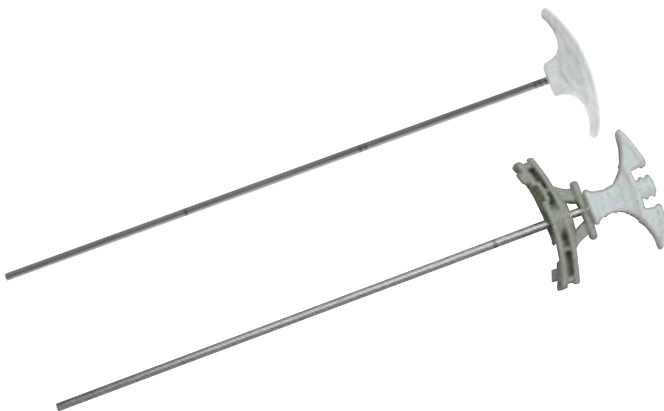


CDS Gun

Connector



Stabilization Clip



CDS Bone Filler Device with Fixator
(included in CDS Pack)



Multi-tap Adapter

PREPARATION OF THE SPINE

Prepare the spine according to the appropriate CD Horizon Spinal System Surgical Technique. The CD Horizon Solera Fenestrated Screw Set is compatible with MIS or open procedures.

FENESTRATED SCREW ADAPTER DRIVER ASSEMBLY

- Press the button on the Lock Sleeve Driver and slide the Adapter Driver T25 into the Lock Sleeve Driver (Figure 1a).
- Release the button on the Lock Sleeve Driver and pull back on the Adapter Driver T25 to ensure it is locked into the Lock Sleeve Driver.

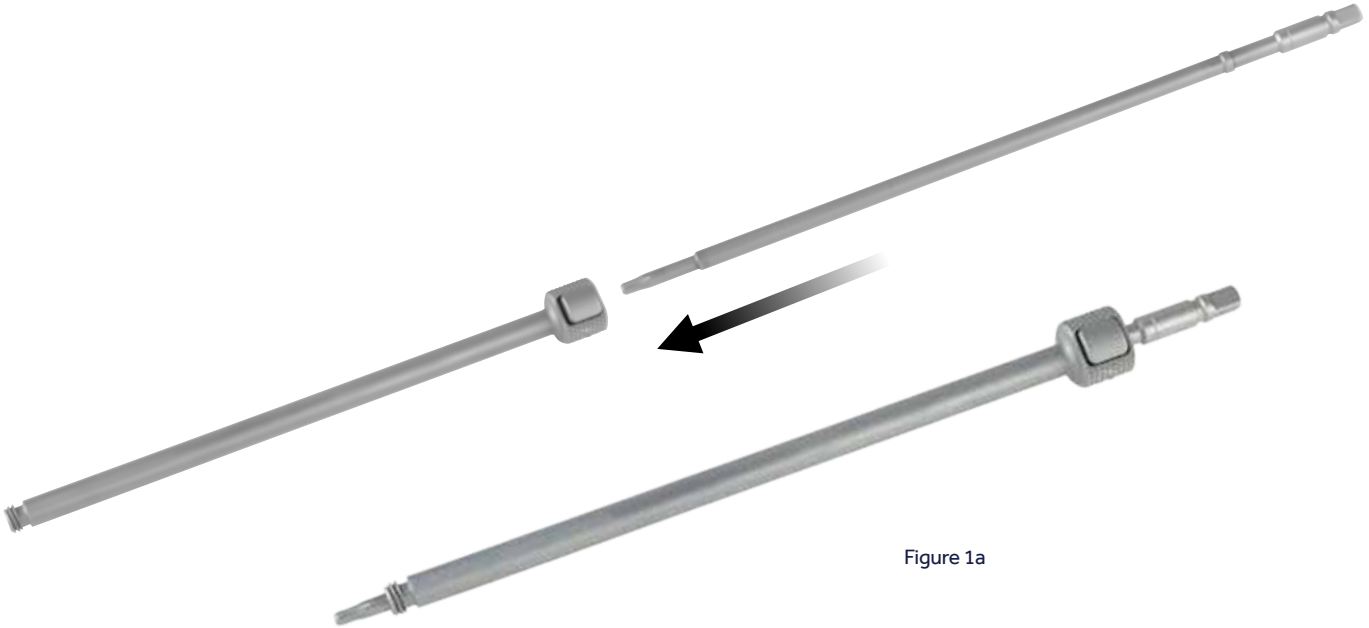


Figure 1a

ATTACHING THE FENESTRATED SCREW TO THE ADAPTER DRIVER

- Thread the Adapter Driver to the selected Fenestrated Screw from the screw caddy (Figure 1b).
- Ensure the Fenestrated Screw is securely tightened onto the Adapter Driver to prevent cement leakage and screw toggling.



Figure 1b

- Break off the Verify™ Implant Tracking Tag as shown (Figure 2).



Figure 2

SCREW INSERTION

- Attach the Quick Connect Handle to the Adapter Driver (Figure 3).

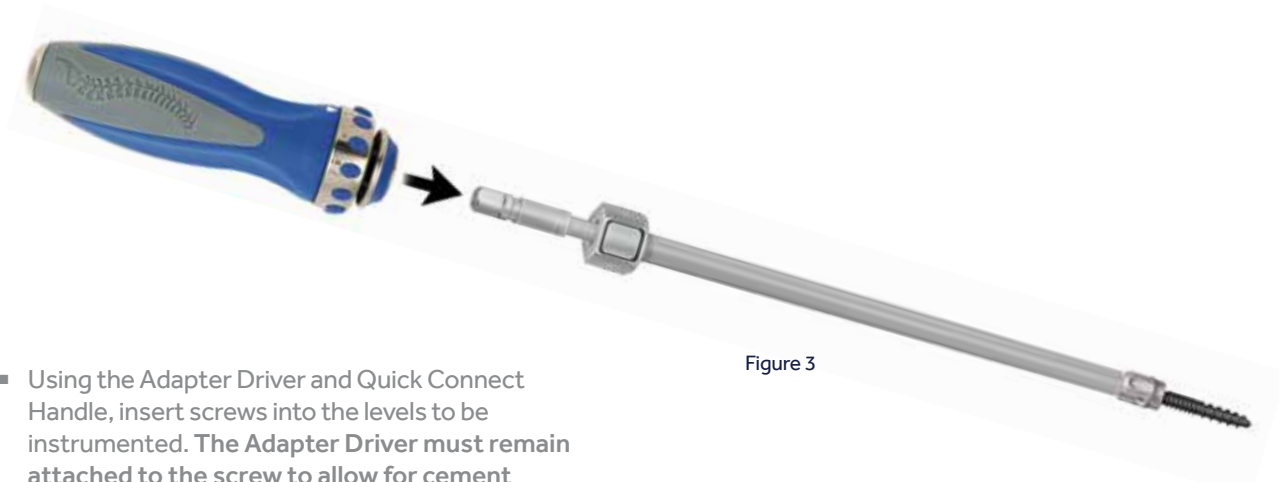


Figure 3

- Using the Adapter Driver and Quick Connect Handle, insert screws into the levels to be instrumented. The Adapter Driver must remain attached to the screw to allow for cement injection (Figure 4).

Important

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.

Important

If there is a need to re-attach the Adapter Driver to a Fenestrated Screw in situ, ensure the Adapter Driver is securely tightened to the screw. A secure connection is confirmed by:

1. Ensure the Adapter Driver T25 seats into the screw head. The Adapter Driver T25 should not rotate when it is properly seated in the screw head.
2. Turn the Lock Sleeve Driver approximately 2.5 turns to tighten the driver onto the screw.
3. Press the release button on the Lock Sleeve Driver while pulling up on the T25 to confirm that the release button cannot be compressed and the Adapter Driver T25 cannot be removed.

If a secure connection is not confirmed, remove the Lock Sleeve Driver and Adapter Driver T25 and re-assemble the Adapter Driver.

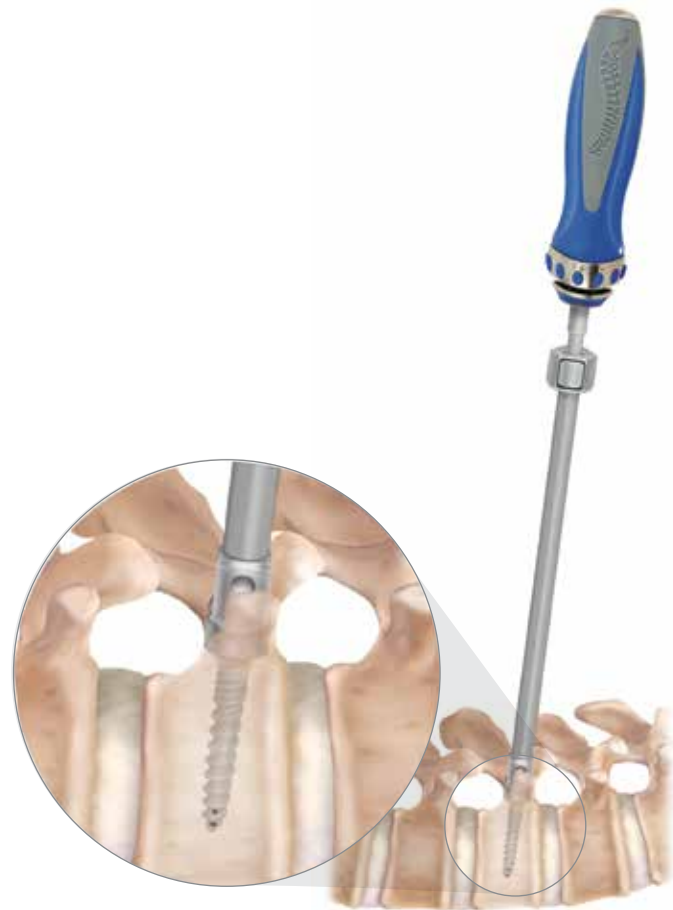


Figure 4

MIXING THE CEMENT

- 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 5).



Figure 5

- Pour the entire contents of the FS Cement powder packet into the Kyphon Mixer (Figure 6). Remove the funnel from the mixer.



Figure 6

- 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 7a and 7b).



Figure 7a



Figure 7b

- Inject the liquid into the Kyphon Mixer (Figure 8).



Figure 8



2 min.

- Insert the paddle (Figure 9a).
- Hold the Kyphon Mixer at the base and mix the cement for approximately two minutes by agitating the paddle (Figure 9b).

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.

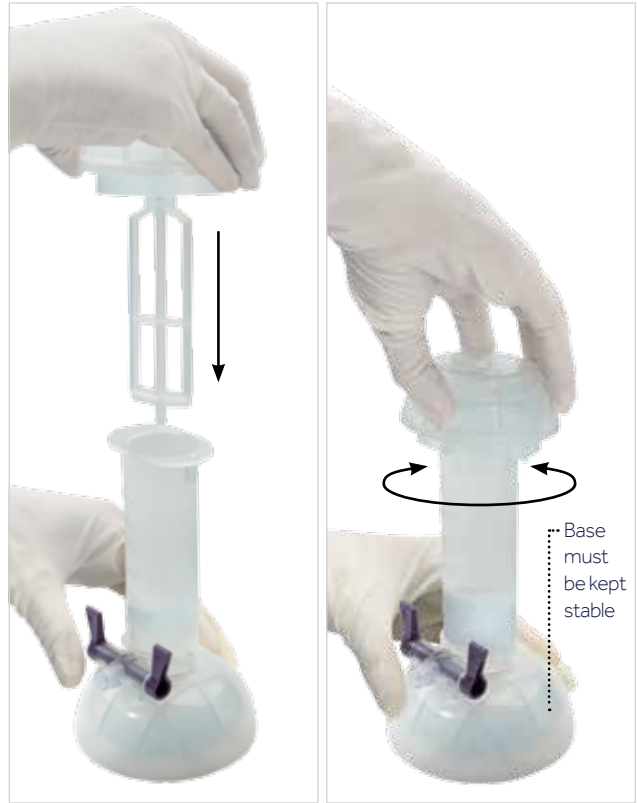


Figure 9a

Figure 9b

- Remove the paddle and insert the plunger (Figure 10).

Important

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



Figure 10

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 11a). Lower both valve levers and fill the Bone Filler Devices by pressing down on the plunger (Figure 11b).

Note

Each Bone Filler Device distributes 1.5cc of cement.



Figure 11a

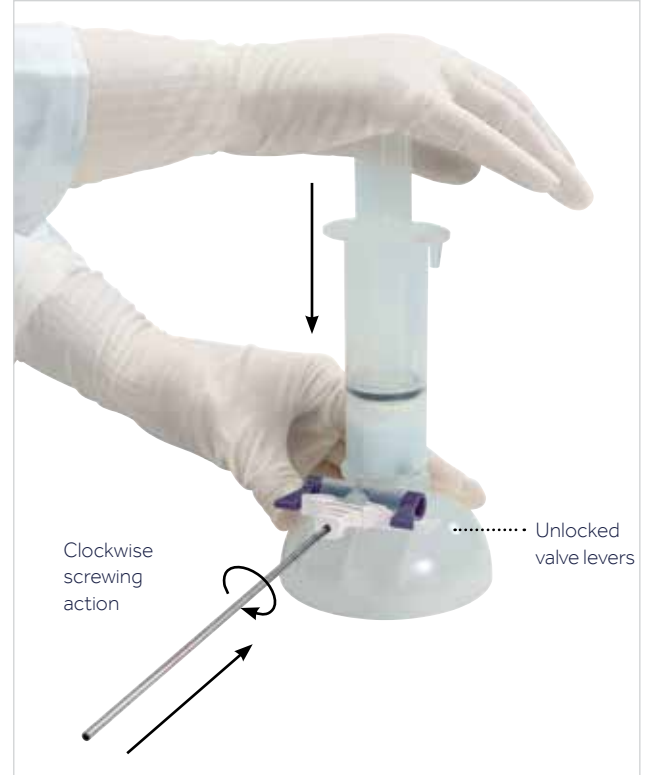


Figure 11b

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 12).

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.



Figure 12

STEP 3: Injecting the Cement

- Remove the Quick Connect Handle from the Adapter Driver (Figure 13).
- Insert the Bone Filler Device (Figure 14).



Figure 13



Figure 14

Note

As an option, the Stabilization Clip can be used to hold the Bone Filler Device in place during cement injection (Figure 15).



Figure 15

Important

Cement injection should only be performed under fluoroscopic control.

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.

Based on internal cadaveric testing (Source: Medtronic TR08-426).

Testing is not indicative of human clinical outcome.

- Insert the plunger portion of the Bone Filler Device into the outer sheath (Figure 16) and inject the cement by depressing the plunger until the desired volume of cement is delivered (Figure 17).



Figure 16



Figure 17

- 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.

OPTION B. USING THE CDS CEMENT DELIVERY SYSTEM

STEP 1:

Preparing the CDS Gun

- Ensure the gun is working properly by removing the protective rubber stopper from the metal part at the end of the tubing (Figure 18).



Figure 18

- Squeeze the handle several times to ensure the sterile water is flowing out of the rubber tubing (Figures 19a and 19b).

At this point, the cement can be mixed (see page 8 for instructions).



Figure 19a

Important

The cartridge should be loaded immediately once the cement is mixed.



Figure 19b

- Attach the Luer Lock to the Kyphon Mixer and then attach the cartridges by threading them onto the Luer Lock at the base of the mixer (Figures 20a and 20b).
- Lower both valve levers and fill the cartridges by depressing the plunger (Figures 21 and 22).
- Return the valve levers to the locked position and unthread the cartridges from the mixer (Figure 23). Wipe away any excess cement from the end of the cartridges.



Figure 20a



Figure 20b



Figure 21



Figure 22



Figure 23

- Firmly thread the cartridge onto the connector at the end of the tubing (Figure 24).



Figure 24

- A tight connection is necessary to maintain the internal pressure. Prime the gun several times until cement flows through the cartridge (Figure 25).

Ensure that the tip of the cartridge is kept clean from excess cement.



Figure 25

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 the cement cartridge.

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 26).

Note

Do not roll between fingertips; use a pinching motion.

Note

Time should be measured beginning with initial mixing of the cement, not from the filling of the cartridge.

Note

Do not attach the Bone Filler Device to the Cement Cartridge until the cement has been tested and reached the doughy state.



Figure 26

STEP 3:

Priming the Bone Filler Device

- Remove the Fixator from the Bone Filler Device. Attach the Stabilization Clip to the Bone Filler Device.
- Thread the Bone Filler Device onto the end of the cartridge (Figure 27).



Figure 27

- Pull the trigger several times until cement is flowing from the end of the Bone Filler Device (Figure 28).

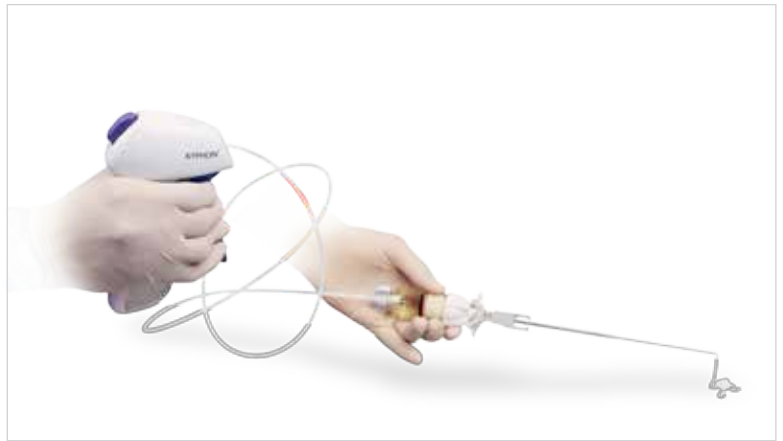


Figure 28

- To stop cement flow, depress the purple button on top of the CDS Gun for 1-2 seconds (Figure 29).



Figure 29

STEP 4: Injecting the Cement

- Remove the Quick Connect Handle from the Adapter Driver and insert the Bone Filler Device (Figure 30).
- Attach the Stabilization Clip to the Adapter Driver (Figure 31).
- The Bone Filler Device is now locked onto the Adapter Driver and will not eject upwards during cement injection.



Figure 30



Figure 31

- Pull the trigger until the desired volume of cement is delivered (**Figure 32**). To stop cement flow, press the purple button on top of the CDS Gun for 1-2 seconds (refer back to **Figure 29** if required).

Important

Cement injection should only be performed under fluoroscopic control.

Note

Each squeeze of the CDS trigger will deliver 0.2cc of cement. The Fenestrated Screw and Adapter Driver 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.

Based on internal cadaveric testing (Source: Medtronic TR08-426).

Testing is not indicative of human clinical outcome.

- Disconnect the Stabilization Clip from the Adapter Driver and move the Bone Filler Device and cartridge to the next screw. Reconnect the Stabilization Clip and repeat injection.

If you require the second cartridge, unscrew the first cartridge and firmly secure the new cartridge onto the connector at the end of the tubing (see **page 17**).

Important

- Remove the Stabilization Clip and 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.



Figure 32

REMOVAL OF THE ADAPTER DRIVER

Disengaging the Adapter Driver from the Fenestrated Screw

- At approximately 3 minutes post-cement injection, unthread the Lock Sleeve in a counterclockwise direction (Figure 33).

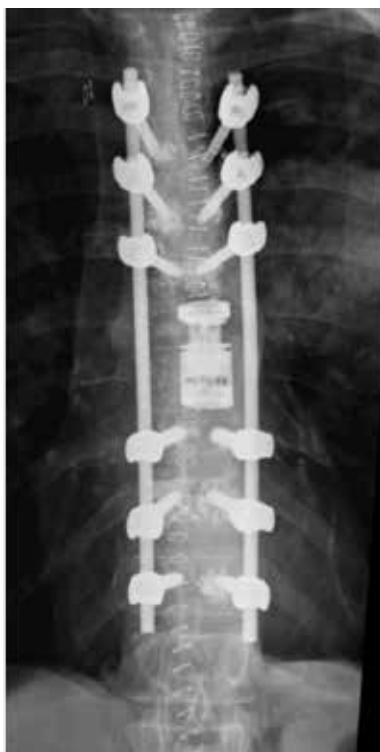
Important

Do not rotate the Adapter Driver T25 at this stage. This will unthread the screw from the bone.

The Adapter Driver can then be removed and disassembled on the back table. The Adapter Driver T25 should be discarded.



Figure 33



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.

PRODUCT ORDERING INFORMATION

SPSSF550 CD Horizon Solera Fenestrated Screw Set 5.5/6.0mm 5.5/6.0mm Fenestrated Multi-Axial Screws, Cobalt Chrome

Item Number	Description	Quantity
55840024530	4.5mm x 30mm	6
55840024535	4.5mm x 35mm	6
55840024540	4.5mm x 40mm	6
55840024545	4.5mm x 45mm	4
55840024550	4.5mm x 50mm	4
55840025530	5.5mm x 30mm	6
55840025535	5.5mm x 35mm	8
55840025540	5.5mm x 40mm	12
55840025545	5.5mm x 45mm	12
55840025550	5.5mm x 50mm	8
55840026530	6.5mm x 30mm	4
55840026535	6.5mm x 35mm	6
55840026540	6.5mm x 40mm	12
55840026545	6.5mm x 45mm	12
55840026550	6.5mm x 50mm	12
55840026555	6.5mm x 55mm	6
55840027530	7.5mm x 30mm	4
55840027535	7.5mm x 35mm	6
55840027540	7.5mm x 40mm	6
55840027545	7.5mm x 45mm	8
55840027550	7.5mm x 50mm	8
55840027555	7.5mm x 55mm	4
7480741T	Adapter Driver T25	10
7480755T	Lock Sleeve Driver for 5.5/6.0	10
7480760	Stabilization Clip	2

Bone Filler Device (BFD) Disposable add on items:

Reference	Description	Quantity
A07A	Cement Mixer	1
A22	Multi-Tap Adapter Size 2	1

CDS Disposable add on items:

Reference	Description	Quantity
A07A	Cement Mixer	1
CC02A	CDS Cement Cartridges	1
CDS3A	Cement Gun And Bone Filler Size 3	1

Bone Cement add on item:

Reference	Description
7480724-CAN	Medtronic Fenestrated Screw Cement

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

NOTES

NOTES

Medtronic

Medtronic

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.