Medtronic

THERAPIES

CD HORIZON® SOLERA™ Fenestrated Screw Spinal System

Surgical Technique

4.75mm and 5.5/6.0mm

CD HORIZON® SOLERA™ Fenestrated Screws provide immediate enhanced fixation in poor bone quality through the application of Fenestrated Screw Cement

ENABLING TECHNOLOGIES

SERVICES & SUPPORT

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MICHELSON TECHNOLOGY AT WORK

Surgical **Synergy**™

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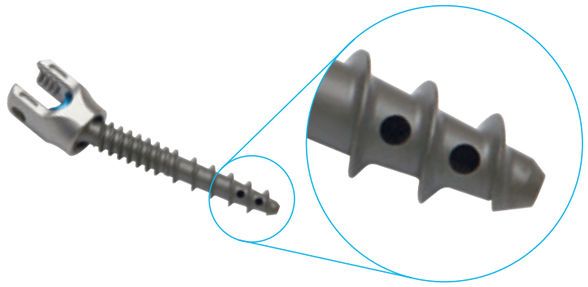
Implant Features and Instrument Set

CD HORIZON® SOLERA™ Fenestrated Screw Spinal System offers the same design and capabilities of the CD HORIZON® SOLERA® Cannulated Multi-Axial Screw, 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 poor bone quality.

IMPLANT
CD HORIZON® SOLERA™ FENESTRATED SCREW

Available for CD HORIZON® SOLERA® 4.75mm and 5.5/6.0mm Spinal Systems



4.75mm 5.5/6.0mm

INSTRUMENTS
ADAPTER DRIVER

The CD HORIZON® SOLERA™ Fenestrated Screw Adapter Driver comes in three parts.

Lock Sleeve 4.75mm or 5.5/6.0mm (reusable item)

Adapter Driver QC Shaft (reusable item)

Adapter Driver T25 Tip (disposable item)

Implant Features and Instrument Set

CEMENT MIXING

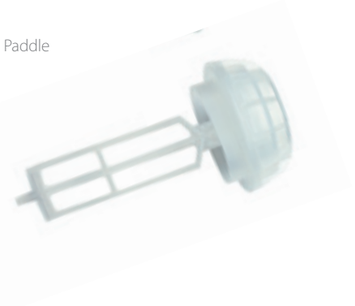
Kyphon® Mixer

Luer Lock

Cartridge

Syringe

Paddle



Funnel

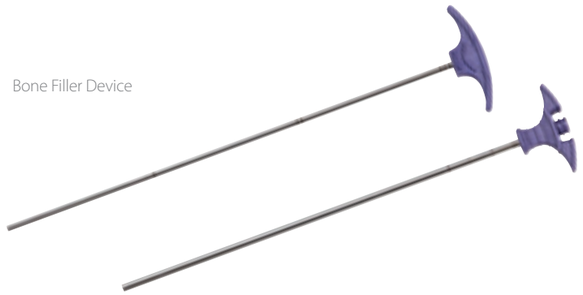
Plunger

Fenestrated Screw (FS) Cement powder packet and liquid bottle

Implant Features and Instrument Set

CEMENT INJECTION

Bone Filler Device



Stabilisation Clip

CDS Gun

CDS Bone Filler Device
(included in CDS Pack)

Quick Connect (QC) Handle

The Locking Mechanism of the Lock Sleeve

Locked position
Latch is closed (**Figure 1.1**)

Engaged position
Latch is opened until the hard stop (**Figure 1.2**)

Released position
Push the latch down and continue rotating until fully opened (**Figure 1.3**)

Figure 1.1 Locked position
Adapter Driver and screw are fully secured and cannot be disengaged

Figure 1.2 Engaged position
Adapter Driver is secure, screw can be attached and disconnected

Figure 1.3 Released position
Adapter Driver can be assembled/disassembled

Assembling the Adapter Driver

» Place the Lock Sleeve in the released position (**Figure 1.3**)

» Insert the Adapter Driver T25 Tip into the top of the Lock Sleeve ensuring the T25 portion is inserted first (**Figure 2.1**)

The T25 Tip will extend out of the bottom of the Lock Sleeve (**Figure 2.2**)

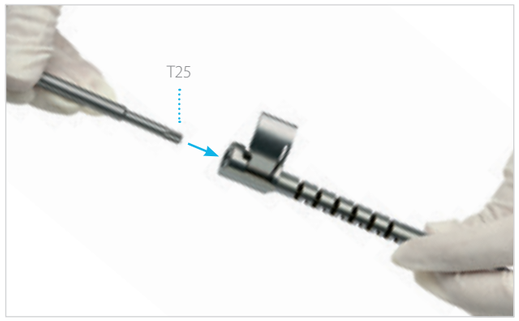


Figure 2.1 Insert the Tip with T25 portion leading

Figure 2.2

» Insert the Adapter Driver QC Shaft into the top of the Lock Sleeve (**Figure 3.1**)

Figure 3.1

» Ensure that the QC Section extends above the Lock Sleeve (**Figure 3.2**)

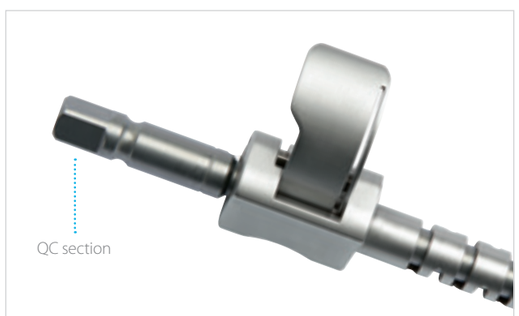


Figure 3.2

Assembling the Adapter Driver

» Rotate the latch until it clicks into the engaged position (**Figure 4**)

Figure 4

» Press the tip of the Adapter Driver against a hard surface to move the inner shafts upwards (**Figure 5.1**) and rotate the latch to the locked position (**Figure 5.2**)

Figure 5.1

Figure 5.2

Preparation of the Spine

Prepare the spine according to the appropriate CD HORIZON® Spinal System Surgical Technique.

Attaching the Fenestrated Screw to the Adapter Driver

» Ensure the assembled Adapter Driver is in the locked position (refer back to **Figure 5.2**)

» Thread the Adapter Driver to the selected Fenestrated Screw from the screw caddy (**Figure 6**)

» Ensure the Fenestrated Screw is securely tightened onto the Adapter Driver to prevent cement leakage and screw toggling

Note

*If the Adapter Driver is not engaging with the screw, ensure the inner drive was properly stacked-up before locking the latch (**Figure 5.1**)*

Important

*After tightening the screw, ensure the latch is fully closed (**Figure 5.2**)*

Figure 6

Attaching the Fenestrated Screw to the Adapter Driver

» Break off the VERIFYI® Implant Tracking Tag as shown (**Figure 7**)

Figure 7

Screw Insertion

» Attach the Quick Connect Handle to the Adapter Driver (**Figure 8**)

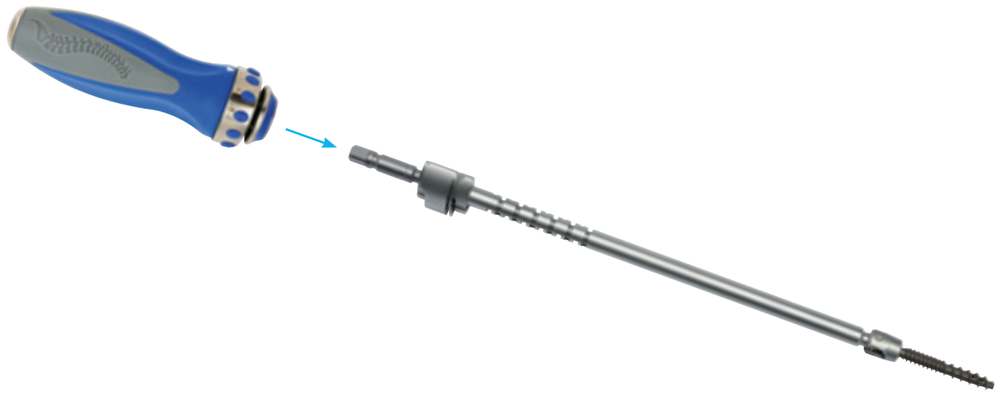


Figure 8

» Using the assembled Fenestrated Screw Adapter Driver and Quick Connect Handle, insert screws into levels to be instrumented. **The Adapter Driver must remain attached to the screw to allow for cement injection** (**Figure 9**)

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

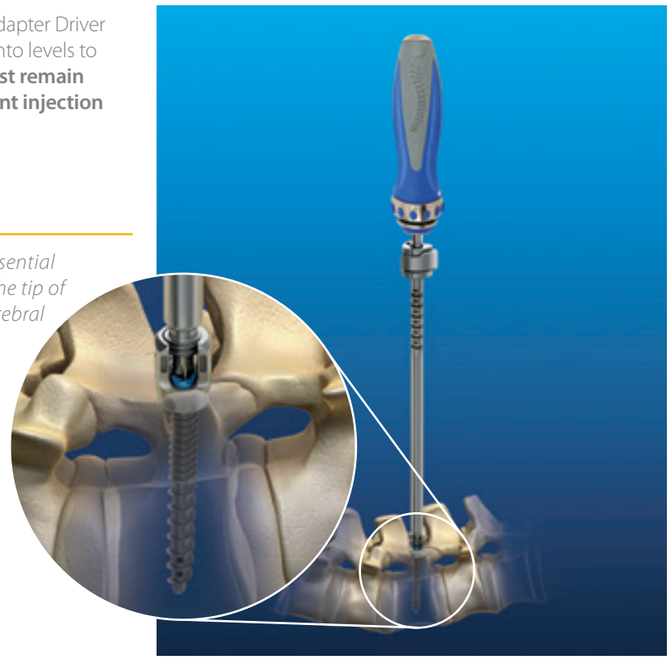


Figure 9 Screw insertion

Mixing the Cement

» To prepare the FS Cement, insert the funnel into the Kyphon® Mixer. Make sure the purple latches are facing up so they are in the **closed position**. If using the CDS, thread the Luer Lock adapter onto the spout at the bottom of the mixer body (**Figure 10**)

Figure 10

» Pour entire contents of the FS Cement powder packet into the Kyphon® Mixer (**Figure 11**)

Figure 11

Mixing the Cement

» Take the syringe and blunt needle and thread together. Snap off the cap of the FS Cement liquid bottle and withdraw the contents of the FS Cement liquid with the syringe and needle assembly (**Figure 12.1, 12.2**)

Figure 12.1

Figure 12.2

» Inject the liquid into the Kyphon® Mixer (**Figure 13**)

Figure 13

Mixing the Cement

» Remove the funnel and insert the paddle (**Figure 14.1**)

2 min.

» Mix the cement for approximately two minutes by agitating the paddle (**Figure 14.2**)

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 instruction for use

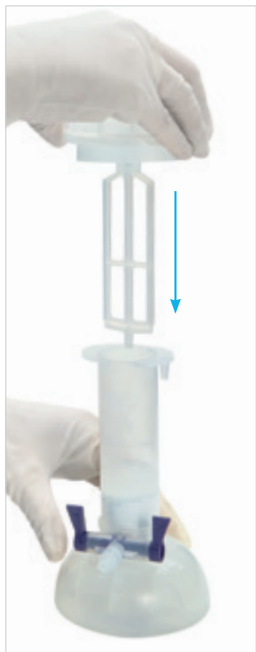


Figure 14.1

Figure 14.2

» Remove the paddle and insert the plunger (**Figure 15**)

Figure 15

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. Lower both valve levers and fill the Bone Filler Devices by depressing the plunger (**Figure 16**)

Note

Each Bone Filler Device distributes 1.5cc of cement

Figure 16

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, extrude a small amount from the tip of a filled Bone Filler Device.

If the cement is sticky, it is not ready and should be allowed to stand further. The cement should retain its shape when compressed into a ball (**Figure 17**).

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. Check to make sure that the cement has lost its sheen, a sign that it has become doughy and is ready for application

Figure 17

Option A. Using the Bone Filler Device for Delivery

STEP 3: INJECTING THE CEMENT

» Remove the Quick Connect Handle from the Adapter Driver (**Figure 18**)

Figure 18

» Insert the Bone Filler Device (**Figure 19**)

Figure 19

Option A. Using the Bone Filler Device for Delivery

STEP 3: INJECTING THE CEMENT

Note

*As an option, the Stabilisation Clip can be used to hold the Bone Filler Device in place during cement injection (**Figure 20**)*

Figure 20

» Insert the plunger portion of the Bone Filler Device into the outer sheath (**Figure 21**) and inject the cement by depressing the plunger until the desired volume of cement is delivered (**Figure 22**)

Important

Cement injection should only be performed under fluoroscopic control

Note

Each Bone Filler Device can distribute 1.5cc of cement. The Fenestrated Screw and Adapter Driver cannula will fill with approximately 0.4cc of cement before any is ejected 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

Figure 21

Option A. Using the Bone Filler Device for Delivery

STEP 3: INJECTING THE CEMENT

» Repeat injection for each Fenestrated Screw

Important

» Remove the Stabilisation Clip and Bone Filler Device from the Adapter Driver before cement is cured

» Leave the Adapter Driver in place until the cement is fully cured to avoid pulling cement into the saddle of the screw

Once the cement is set, see page 27 for removal of the Adapter Driver and completing the procedure.

Figure 22

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 23**)

Figure 23

» Squeeze the handle several times to ensure the saline is flowing out of the rubber tubing (**Figure 24.1, 24.2**)

At this point you can mix the cement (see page 13 for instructions)

Figure 24.1

Figure 24.2

Note

The cartridge should be loaded immediately once the cement is mixed

Option B. Using the CDS Cement Delivery System

STEP 1: PREPARING THE CDS GUN

» Attach the cartridge to the Kyphon® Mixer by threading it onto the Luer Lock at the base of the mixer (**Figure 25**)

Lower both valve levers and fill the cartridge by depressing the plunger

Figure 25

» Return the valve levers to the locked position and unthread the cartridge from the mixer (**Figure 26**). Wipe away any excess cement from the end of the cartridge

» Attach the second cartridge and fill as previous

Figure 26

Option B. Using the CDS Cement Delivery System

STEP 1: PREPARING THE CDS GUN

» Firmly thread the connector at the end of the tubing to the cartridge (**Figure 27**)

Figure 27

STEP 1: PREPARING THE CDS GUN

» A tight connection is necessary to maintain the internal pressure. Prime the gun several times until cement flows through the cartridge (**Figure 28**)

» When cement starts flowing out the end of the cartridge you can begin to test the viscosity of the cement

Ensure that you keep the tip of the cartridge clean from excess cement

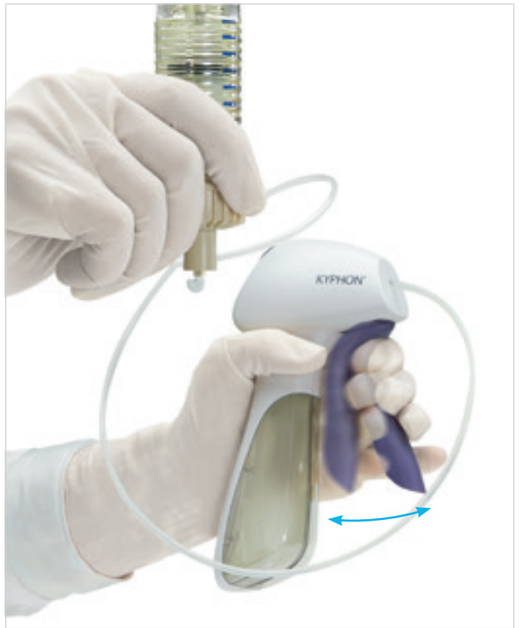


Figure 28

Option B. Using the CDS Cement Delivery System

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, extrude a small amount from the tip of the cement cartridge.

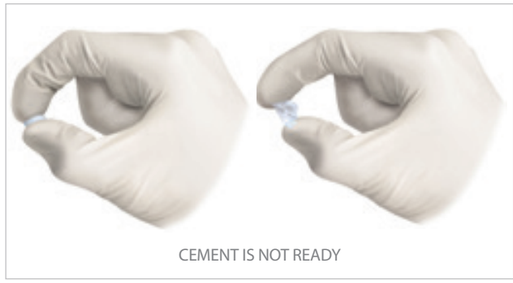
If the cement is sticky, it is not ready and should be allowed to stand further. The cement should retain its shape when rolled into a ball (Figure 29).

✓ Note

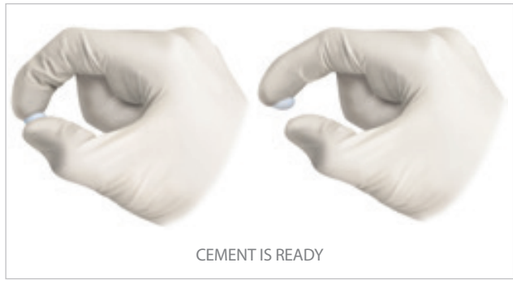
Do not roll between fingertips; use a pinching motion

✓ Note

Time should be measured beginning with initial mixing of the cement, not from the filling of the cartridge. Check to make sure that the cement has lost its sheen, a sign that it has become doughy and is ready for application



CEMENT IS NOT READY



CEMENT IS READY

Figure 29

STEP 3: PRIMING THE BONE FILLER DEVICE

» Thread the Bone Filler Device onto the end of the cartridge (**Figure 30**)

Figure 30

Option B. Using the CDS Cement Delivery System

STEP 3: PRIMING THE BONE FILLER DEVICE

» Pull the trigger several times until cement is flowing from the end of the Bone Filler Device (**Figure 31**)

Figure 31

» To stop cement flow, depress the purple button for 1-2 seconds (**Figure 32**)

Figure 32

Option B. Using the CDS Cement Delivery System

STEP 4: INJECTING THE CEMENT

» Remove the Quick Connect Handle from the Adapter Driver and insert the Bone Filler Device (**Figure 33**)

Figure 33

» Take the Stabilisation Clip and attach this to the Adapter Driver and Bone Filler Device (**Figure 34.1, 34.2**)

The Bone Filler Device is now locked onto the Adapter Driver and will not eject upwards during cement injection

Figure 34.1 Figure 34.2

Option B. Using the CDS Cement Delivery System

STEP 4: INJECTING THE CEMENT

» Pull the trigger until the desired volume of cement is delivered (**Figure 35**). To stop cement flow, depress the purple button for 1-2 seconds (refer back to **Figure 32** 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 cannula will fill with approximately 0.4cc of cement before any is ejected 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

Figure 35

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

If you require the second cartridge, unscrew the first cartridge and secure firmly the new cartridge to the tubing and the connector (see **Figure 27**).

Important

» *Remove the Stabilisation Clip and Bone Filler Device from the Adapter Driver before cement is cured*

» *Leave the Adapter Driver in place until the cement is fully cured to avoid pulling cement into the saddle of the screw*

Removal of the Adapter Driver

DISENGAGING THE ADAPTER DRIVER FROM THE FENESTRATED SCREW

» Once the cement is fully cured, place the Adapter Driver in the engaged position (**Figure 36**)

Important

*Firmly hold the outer sleeve to avoid rotation while opening the latch (**Figure 36 – zoom**)*

Figure 36

» With your thumb in-between the latch and the driver, unthread the driver in an anticlockwise direction (**Figure 37**). Your thumb will prevent the latch from re-locking

The Adapter Driver can then be removed and disassembled on the back table

Important

Do not rotate the QC attachment at this stage. This will unthread the screw from the bone

Figure 37

Completing the Procedure

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

Disassembling the Adapter Driver

» Place the Adapter Driver in the released position (**Figure 38**)

Figure 38 Adapter Driver in released position

» Remove the Adapter Driver QC Shaft and the Adapter Driver T25 Tip from the Lock Sleeve by tipping the assembly upside down (**Figure 39.1, 39.2**)

The Adapter Driver QC Shaft and the Lock Sleeve can be reprocessed

Important

The Adapter Driver T25 Tip is discarded

Figure 39.1 Removal of the Adapter Driver QC Shaft

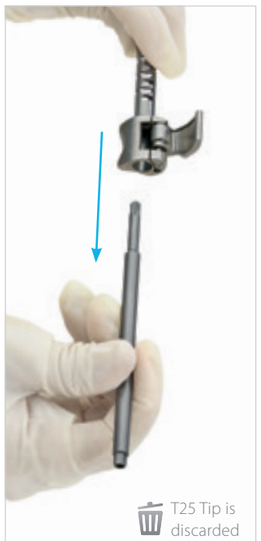


Figure 39.2 Removal of the Adapter Driver T25 Tip

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 anticlockwise until the Fenestrated Screw has been 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® System Surgical Technique for proper explantation of the other CD HORIZON® implants

Product Ordering Information

COBALT CHROME/TITANIUM MULTI-AXIAL SCREWS

4.75mm	5.5/6.0mm	Description	4.75mm	5.5/6.0mm	Description
54840024530*	55840024530*	4.5mm x 30mm	54840027570*	55840027570*	7.5mm x 70mm
54840024535*	55840024535*	4.5mm x 35mm	54840027575*	55840027575*	7.5mm x 75mm
54840024540*	55840024540*	4.5mm x 40mm	54840027580*	55840027580*	7.5mm x 80mm
54840024545*	55840024545*	4.5mm x 45mm	54840028530*	55840028530*	8.5mm x 30mm
54840024550*	55840024550*	4.5mm x 50mm	54840028535*	55840028535*	8.5mm x 35mm
54840024555*	55840024555*	4.5mm x 55mm	54840028540*	55840028540*	8.5mm x 40mm
54840024560*	55840024560*	4.5mm x 60mm	54840028545	55840028545	8.5mm x 45mm
54840024565*	55840024565*	4.5mm x 65mm	54840028550	55840028550	8.5mm x 50mm
54840024570*	55840024570*	4.5mm x 70mm	54840028555	55840028555	8.5mm x 55mm
54840024575*	55840024575*	4.5mm x 75mm	54840028560*	55840028560*	8.5mm x 60mm
54840024580*	55840024580*	4.5mm x 80mm	54840028565*	55840028565*	8.5mm x 65mm
54840025530*	55840025530*	5.5mm x 30mm	54840028570*	55840028570*	8.5mm x 70mm
54840025535	55840025535	5.5mm x 35mm	54840028575*	55840028575*	8.5mm x 75mm
54840025540	55840025540	5.5mm x 40mm	54840028580*	55840028580*	8.5mm x 80mm
54840025545	55840025545	5.5mm x 45mm	–	55840029530*	9.5mm x 30mm
54840025550	55840025550	5.5mm x 50mm	–	55840029535*	9.5mm x 35mm
54840025555	55840025555	5.5mm x 55mm	–	55840029540*	9.5mm x 40mm
54840025560*	55840025560*	5.5mm x 60mm	–	55840029545*	9.5mm x 45mm
54840025565*	55840025565*	5.5mm x 65mm	–	55840029550*	9.5mm x 50mm
54840025570*	55840025570*	5.5mm x 70mm	–	55840029555*	9.5mm x 55mm
54840025575*	55840025575*	5.5mm x 75mm	–	55840029560*	9.5mm x 60mm
54840025580*	55840025580*	5.5mm x 80mm	–	55840029565*	9.5mm x 65mm
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54840026535*	55840026535*	6.5mm x 35mm	–	55840029575*	9.5mm x 75mm
54840026540	55840026540	6.5mm x 40mm	–	55840029580*	9.5mm x 80mm
54840026545	55840026545	6.5mm x 45mm	–	55840021540*	10.5mm x 40mm
54840026550	55840026550	6.5mm x 50mm	–	55840021545*	10.5mm x 45mm
54840026555	55840026555	6.5mm x 55mm	–	55840021550*	10.5mm x 50mm
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54840027530*	55840027530*	7.5mm x 30mm	–	55840021580*	10.5mm x 80mm
54840027535*	55840027535*	7.5mm x 35mm			
54840027540*	55840027540*	7.5mm x 40mm			
54840027545	55840027545	7.5mm x 45mm			
54840027550	55840027550	7.5mm x 50mm			
54840027555	55840027555	7.5mm x 55mm			
54840027560*	55840027560*	7.5mm x 60mm			
54840027565*	55840027565*	7.5mm x 65mm			

* Available as Add-Ons

Product Ordering Information

INSTRUMENTS (NON-STERILE, MULTI-USE)

Reference	Description
7480741	Adapter Driver QC Shaft
7480745	Lock Sleeve 4.75
7480755	Lock Sleeve 5.5/6.0
7480760	Stabilisation Clip

INSTRUMENTS (STERILE, DISPOSABLE)

Reference	Description
F04B	Size 3 KyphX® Bone Filler Device
A07A	Kyphon® Mixer
CDS3A	CDS Cement Delivery System
CC02A	2x Cement Cartridges

INSTRUMENTS (NON-STERILE, DISPOSABLE)

Reference	Description
7480740	Adapter Driver T25 Tip

CEMENT (STERILE)

Reference	Description
7480724	Fenestrated Screw Cement

Important Information on the CD HORIZON® SOLERA™ Fenestrated Screw Spinal System

NOT FOR DISTRIBUTION IN THE USA OR ITS TERRITORIES

CD HORIZON® SOLERA™ FENESTRATED SCREW SPINAL SYSTEM

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PURPOSE

The CD HORIZON® SOLERA™ Fenestrated Screws are an addition to the CD HORIZON® Spinal System intended to help provide immobilisation and stabilisation of spinal segments as an adjunct to fusion of the thoracic, lumbar, or sacral spine.

DESCRIPTION

The CD HORIZON® SOLERA™ Fenestrated Screw Spinal System consists of a variety of cannulated screws. These screws contain fenestrations which allow polymethylmethacrylate (PMMA) bone cement (Fenestrated Screw Cement) to be injected into the treated site. The cement is used to augment screw fixation in vertebral bone, especially in cases of diminished bone quality.

The CD HORIZON® SOLERA™ Fenestrated Screws are specifically designed to connect to rods of Ø4.75, 5.5 and 6.0mm in medical grade titanium and/or medical grade titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy and associated connecting components contained within the CD HORIZON® Spinal System. Refer to the CD HORIZON® Spinal System package insert for information regarding those implants. Care should be taken to ensure the correct components are used in the spinal construct.

The CD HORIZON® SOLERA™ Fenestrated Screw Spinal System implant components are fabricated from medical grade titanium and/or medical grade titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy. No warranties express, or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Never use stainless steel and titanium implant components in the same construct.

To achieve best results, do not use CD HORIZON® SOLERA™ Fenestrated Screws with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic document. As with all orthopaedic and neurosurgical implants, the CD HORIZON® SOLERA™ Fenestrated Screw implants should never be reused under any circumstances.

INDICATIONS

The CD HORIZON® SOLERA™ Fenestrated Screw Spinal System is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumour, pseudarthrosis, and/or failed previous fusion. When used in conjunction with Fenestrated Screw Cement, CD HORIZON® SOLERA™ Fenestrated Screws are intended to provide enhanced pedicular fixation in the treatment of patients with poor/compromised bone quality.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Active infectious process or significant risk of infection (immunocompromise)
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental illness
- Grossly distorted anatomy caused by congenital abnormalities
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Pedicular/posterior wall defects when used with cement
- Any allergy or contra-indication to PMMA cement when used with cement
- In fractures and tumours with severe anterior vertebral body disruption when used with cement
- Suspected or documented metal allergy or intolerance
- Any case not needing a bone graft and fusion
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality
- Any patient in which implant utilisation would interfere with anatomical structures or expected physiological performance
- Any patient unwilling to follow postoperative instructions
- Any case not described in the indications

POTENTIAL ADVERSE EVENTS

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

- Early or late loosening of any or all of the components
- Disassembly, bending, or breakage of any or all of the components
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, or general corrosion) including metallosis, staining, tumour formation, or autoimmune disease
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, or pain
- Bursitis
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments
- Postoperative change in spinal curvature, loss of correction, height, or reduction
- Infection
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis
- Loss of neurological function (e.g., sensory or motor) including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, or visual deficits
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, muscle loss
- Urinary retention or loss of bladder control or other types of urological system compromise
- Scar formation possibly causing neurological compromise or compression around nerves or pain
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, or vertebral body) or bone graft or bone graft harvest site at, above, or below the level of surgery
- Retropulsed graft
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery
- Non-union (or pseudarthrosis), delayed union, or mal-union
- Cessation of any potential growth of the operated portion of the spine
- Cement leakage
- Loss of or increase in spinal mobility or function
- Inability to perform the activities of daily living
- Bone loss or decrease in bone density, possibly caused by stresses shielding
- Graft donor site complications including pain, fracture, or wound healing problems
- Ileus, gastritis, bowel obstruction or loss of bowel control, or other types of gastrointestinal system compromise
- Hemorrhage, haematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise
- Reproductive system compromise including sterility, loss of consortium, and sexual dysfunction
- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.)
- Change in mental status
- Death

NOTE: Additional surgery may be necessary to correct some of these potential adverse events

WARNING

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumour, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prostheses. In the absence of fusion, the instrumentation or one or more of its components can be expected to pull out, bend, or fracture as a result of exposure to every day mechanical stresses.

An implanted device should never be reused unless otherwise specified. Implants which have come in contact with the patient are designed for single patient use only. Do not reuse, reprocess, or re-sterilise used implants. Reuse, reprocessing, or re-sterilisation may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death. Unused implants that have not been in contact with the patient or the patient's blood may be re-sterilised and used in subsequent procedures.

The volumes of cement used in the CD HORIZON® SOLERA™ Fenestrated Screw should ultimately be determined by the surgeon based on the individual patient anatomy.

The following should be noted as warnings and precautions specific to the instruments used in the injection of cement:

- Always use live imaging when injecting material
- Strict sterile technique must be used throughout the procedure

PRECAUTION

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, or breakage of the device(s) will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilisation of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality or nerve paralysis are also poor candidates for spine fusion.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician

Important Information on the CD HORIZON® SOLERA™ Fenestrated Screw Spinal System

IMPLANT SELECTION

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimise stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending, or loosening of the device before the healing process is complete which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE

- Only patients that meet the criteria described in the indications should be selected
- Patient conditions and predispositions such as those addressed in the aforementioned contraindications should be avoided
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments
- An adequate inventory of implants should be available at the time of surgery; normally a quantity in excess of what is expected to be used
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify all parts and necessary instruments are present before the surgery begins. The CD HORIZON® SOLERA™ Fenestrated Screw Spinal System components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer
- All components and instruments should be cleaned and sterilised before use. Additional sterile components should be available in case of an unexpected need

INTRAOPERATIVE

- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel
- When used without cement, refer to the CD HORIZON® Spinal System surgical techniques for procedural steps
- When used with cement, refer to the CD HORIZON® Spinal System surgical techniques to the point of attaching the driver, then follow the proceeding steps:

1 Attach the applicable adapter driver connected to the quick connect handle and insert all required CD HORIZON® SOLERA™ Fenestrated Screws

2 Use an imaging system to facilitate surgery. Ensure the tip of the screw remains within the confines of the vertebral body and just beyond the mid-point

3 Prepare the cement according to the Fenestrated Screw Cement instructions for use. After cement is prepared, immediately load the bone filler devices. Note: Approximately 1½ bone filler devices will be used for each CD HORIZON® SOLERA™ Fenestrated Screw from T11 to L5 and approximately ¾ of one bone filler device will be used per CD HORIZON® SOLERA™ Fenestrated Screw in the remainder of the thoracic spine

4 When the viscosity is correct according to the Fenestrated Screw Cement instructions for use, remove the quick connect handle from the adapter. Insert the Bone Filler Device into the adapter. Each Bone Filler Device can distribute 1.5cc of cement. CD HORIZON® SOLERA™ Fenestrated Screws and Adapter Driver cannulae will collect approximately 0.4cc of cement before any is injected into the vertebral body and will remain in the cannulae. It is recommended that 1.8cc of cement be injected in the vertebral body for each CD HORIZON® SOLERA™ Fenestrated Screw from T11 to L5 and 0.8cc of cement be used for each CD HORIZON® SOLERA™ Fenestrated Screw in the remainder of the thoracic spine

5 Once the cement has been delivered, wait for cement polymerisation before disconnecting the adapter driver, then complete the procedure using the standard CD HORIZON® Spinal System surgical techniques

CAUTION: Do not overtap or use a screw that is either too long or too large. Overtapping, using an incorrectly sized screw or accidentally advancing the guidewire during tap or screw insertion may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screws are being inserted into spinal pedicles, use as large a screw diameter as will fit into each pedicle

- Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused
- To ensure maximum stability, two or more CROSSLINK® plates or DTT Transverse Links on two bilaterally placed, continuous rods should be used whenever possible
- Before closing the soft tissues, provisionally tighten (finger tighten) all nuts or screws, especially screws or nuts that have a break-off feature. Once this is completed, go back and firmly tighten all screws and nuts. Recheck the tightness of all nuts or screws after finishing to ensure none loosened during the tightening of other nuts or screws. Failure to do so may cause loosening of other components

POSTOPERATIVE

- The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important
- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening, or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breaking of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position
- To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco, use nicotine products, or consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process
- Patients should be advised of their inability to bend or rotate at the point of spinal fusion. The patient should be taught to compensate for this permanent physical restriction in body motion
- Failure to immobilise a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilisation of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, or break, the device(s) should be revised or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed
- As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients
- The CD HORIZON® SOLERA™ Fenestrated Screw Spinal System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilise the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) corrosion, with localised tissue reaction or pain; (2) migration of implant position possibly resulting in injury; (3) risk of additional injury from postoperative trauma; (4) bending, loosening, and breakage which could make removal impractical or difficult; (5) pain, discomfort, or abnormal sensations due to the presence of the device; (6) possible increased risk of infection; (7) bone loss due to stress shielding; and (8) potential unknown or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, the CD HORIZON® SOLERA™ Fenestrated Screw Spinal System components should never be reused under any circumstances

PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure there is no damage prior to use. Damaged packages or products should not be used and should be returned to Medtronic.

STERILISATION

Unless marked sterile and clearly labelled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilised by the hospital prior to use. Remove all packaging materials prior to sterilisation. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilised by the hospital using one of the sets of the following process parameters:

Table 1: Sterilisation Cycle Parameters

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	MINIMUM DRY TIME[1]
Steam	Gravity Displacement	250°F (121°C)	30 Minutes	30 Minutes
Steam	Gravity Displacement	270°F (132°C)	15 Minutes	30 Minutes
Steam	Gravity Displacement	275°F (135°C)	10 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	270°F (132°C)	4 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	275°F (135°C)	3 Minutes	16 Minutes
Steam[2]	Gravity Displacement	273°F (134°C)	20 Minutes	30 Minutes
Steam[2]	Dynamic-Air-Removal	273°F (134°C)	4 Minutes	30 Minutes
Steam[2]	Dynamic-Air-Removal	273°F (134°C)	20 Minutes	30 Minutes

1 The minimum dry times were validated using sterilisers having vacuum drying capabilities. Drying cycles using ambient atmospheric pressure may require longer dry times. Refer to the steriliser manufacturer's recommendations

2 Some non-U.S. health care authorities recommend sterilisation according to these parameters to minimise the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system

NOTE: Because of the many variables involved in sterilisation, each medical facility should calibrate and verify the sterilisation process (e.g., temperatures, times) used for their equipment

PRODUCT COMPLAINTS

Any health care professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, or performance should notify the distributor or Medtronic. Further, if any of the implanted spinal system component(s) ever "malfunctions" (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Medtronic product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax, or written correspondence. When filing a complaint, provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the distributor is requested.

MRI INFORMATION

The CD HORIZON® SOLERA™ Fenestrated Screw Spinal System has not been evaluated for safety, heating, migration, or compatibility in the magnetic resonance environment.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, contact Medtronic.

Explanation of Symbols

EC REP — Authorised representative in the European Community

NON STERILE — Non-sterile

℞ only — **CAUTION:** Federal law (USA) restricts these devices to sale by or on the order of a physician

!USA — For US Audiences only

Consult instructions for use

CE 0123 — The device complies with European Directive MDD 93/42/EEC

Do not reuse

STERILE R — Sterilised by irradiation

LOT — Batch/Lot code

STERILE EO — Sterilised by ethylene oxide

Manufacturer

Use-by date

REF — Catalogue number

Important Information on Resin for Fenestrated Screw (FS) Cement High Viscosity, Radiopaque Bone Cement

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INSTRUCTIONS FOR USE

For the attention of the surgeon. Carefully read all instructions prior to use.

INDICATION FOR USE

FS Cement is a radiopaque acrylic resin to be used in screw augmentation surgical procedures to increase the fixation strength of bone screws. In particular this cement is used to augment pedicle screw fixation in patients diagnosed with osteoporosis.

STERILE

FS Cement is supplied sterile. The powder and the package are sterilised with gamma irradiation. The liquid is sterilised using filtration and is contained in a glass vial. The outside of the glass vial is sterilised with ethylene oxide gas. This device is intended for single use only. Do not re-sterilise. Do not use if package is open or damaged.

DESCRIPTION

FS Cement is a polymethylmethacrylate (PMMA) that contains approximately 30% barium sulphate. It is designed for delivery in a highly viscous state.

COMPOSITION OF FS CEMENT

POWDER – 20 g of sterile powder	20 g packet of sterile powder
Methylmethacrylate – Styrene colpolymer	68.0% w/w
Barium sulphate	30.0% w/w
Benzoyl peroxide	2.0% w/w
LIQUID – 9,0 g phial of sterile liquid	**Gravity displacement**
Methylmethacrylate	99.1% w/w
N,N-dimethyl-p-toluidine	0.9% w/w
Hydroquinone	75ppm

CONTRAINDICATIONS

- Active infections
- Haemorrhagic diathesis
- Fractured or partially resected vertebral bodies
- Severe Osteopenia
- Fever

The use of the device must be carefully considered in presence of hypersensitivity to monomer or to any of the other components of the resin

WARNINGS

NOTE: The use of this product is not recommended in patients that do not exhibit a pathological condition, such as primary or secondary osteoporosis or a tumour, which would impair the ability of the patient to heal using conservative treatment methods

- The sterile FS Cement is designed and intended for one time use only. DO NOT reuse, reprocess, or re-sterilise this product. This device is designed for single patient use only. Reuse, reprocessing, or re-sterilisation may compromise the properties of the cement and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Avoid the partition of the product in two or more portions to be used in different moments. This would also be classified as a reuse which could lead to a ratio error between powder and liquid components and loss of sterility with subsequent risk of infection to the patient. Moreover there would be the risk of inadequate cement volume to complete the surgical operation thus potentially lengthening the surgery time. The residual material must be considered surgical waste and therefore it must be eliminated at the end of the surgical procedure. Sterility is assured only if the unit container is not damaged
- Maintain aseptic surgical technique to prevent possible infection including treatment site infection
- Always use live imaging when injecting the material
- Monitor patients carefully for any change in blood pressure during and immediately following the application of bone cement. Adverse patient reactions affecting the cardiovascular system, including Bone Cement Implantation Syndrome (BCIS), have been associated with the use of bone cements. Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement; they have lasted from 30 seconds to 5 or more minutes. Some have progressed to cardiac arrest. Patients should be monitored carefully for any change in blood pressure during and immediately following the application of bone cement, especially those potentially at increased risk for peri-operative death, including elderly patients, patients with underlying cardiac or pulmonary compromise, and patients being treated for multiple vertebral body fractures in one procedure
- Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapours of the monomer, which may produce irritation of the respiratory tract, eyes, and possibly the liver
- Polymerisation of the bone cement is an exothermic reaction, which occurs while the cement is hardening in situ. The released heat may damage bone or other tissues surrounding the implant. The heat produced in situ has a long term effect, and positioning of the patient should be maintained securely to obtain proper fixation
- The liquid component is a powerful lipid solvent. It should not be allowed to come into contact with rubber or latex gloves. Should contact occur, the gloves may dissolve and tissue damage may occur. Wearing a second pair of gloves and adherence to mixing instructions may diminish the possibility of hypersensitivity reactions. The mixed bone cement should not make contact with the gloved hand until the bone cement is being tested for the consistency of dough
- Personnel wearing permeable contact lenses should NOT be near or involved in mixing the bone cement; soft contact lenses are permeable
- The handling characteristics of bone cements are affected by operating room conditions, including the room temperature, temperature of the cement components prior to mixing, humidity, the geometry of the mixing apparatus, time spent mixing, and the geometry of the delivery device. Any change in one or more of these conditions can alter the handling characteristics of the bone cement, including the time it takes for bone cement to reach the doughy state (the handling period), the time the bone cement remains in the doughy state (the working time), and the time the bone cement hardens (the setting time). The user must be aware of these factors and adjust technique to account for variability in operating room conditions
- Avoid over-pressurisation of the bone cement and do not insert the bone cement into the cavity of the vertebral body until the bone cement has reached the doughy state. Maintain patient positioning until the end of the polymerisation process. Failure to do so may lead to extravasation of the bone cement beyond the site of its intended application and may or could damage the surrounding tissues
- The safety of the bone cement in pregnant women, breastfeeding women or in children has not been established. Bone cement may adversely affect bone growth and foetal health
- Difficulty in swallowing and blistering of the throat, alleged to be an allergic reaction to the use of bone cement, have also been reported
- DO NOT mix more than one vial of liquid and one packet of powder together at any one time. Never modify the ratios between the liquid and solid components. Doing so could affect bone cement properties, including handling characteristics
- Long-term follow-up is advised for all patients on a regularly scheduled basis. Inadequate filling or unanticipated postoperative events may affect the stability of the bone cement and/or the bone cement-bone interface. A fibrous tissue layer may develop between the cement and the bone, and loosening of the bone cement may occur leading to failure
- FS Cement is provided in finished form with all the necessary components for use. The addition of radiopacifier, e.g. barium; antibiotics; or other drugs or materials to FS Cement is not recommended. The safety and effectiveness of adding such drugs or materials has not been evaluated and may cause patient harm
- Modifying the polymerisation time by either warming or cooling the bone cement and/or associated delivery devices has not been tested and could affect bone cement properties, including handling characteristics
- If bone cement is seen outside of the pedicle or in the circulatory system during the procedure, immediately stop the injection

PRECAUTIONS

- Store product at room temperature below 25°C and away from light. Do not use the product if the powder has a yellowish or brownish color or if the liquid is syrupy. These two conditions indicate that the product has not been stored correctly. Do not use monomer if the liquid component shows any sign of thickening or premature polymerisation. Keep the product at a temperature of 23 ± 1°C for a period of 24 hours prior to use
- Never deliver bone cement into the vertebral body without the use of high quality fluoroscopic guidance capable of visualising movement of bone cement
- The operator should have specific training and be familiar with the properties, handling characteristics, and application of the bone cement and adhere to the instructions for use
- Do not use after the expiration date printed on the package. The device may not be safe or effective beyond its expiration date
- Follow the mixing and handling instructions to avoid contact dermatitis. Strict adherence to the instructions for mixing the powder and liquid components may reduce the incidence of this complication
- Adequately ventilate the operating room to eliminate as much monomer vapour as possible. The liquid monomer is highly volatile and flammable. Ignition of monomer fumes caused by use of electrocautery devices in surgical sites near freshly implanted bone cements has been reported
- Dispose of the polymer component in an authorised waste facility. The liquid component can be evaporated under a well-ventilated hood or absorbed by an inert material and transferred in a suitable container for disposal

ADVERSE EVENTS

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements include:

- Cardiac arrest
- Cerebrovascular accident
- Myocardial infarction
- Pulmonary embolism

Adhere strictly to good surgical principles and techniques. Deep wound infection is a serious postoperative complication and may require total removal of the embedded cement. Deep wound infection may be latent and not manifest itself even for several years postoperatively.

Other reported adverse events relevant to the anatomy being treated with acrylic bone cements include:

- Fistula
- Haematoma
- Hemorrhage
- Heterotopic new bone formation

Extravasation of bone cement potentially resulting in but not limited to:

- Compression or irritation of nerve structures, such as the spinal cord or nerve roots, causing radiculopathy, paresthesia, paraplegia or paralysis and/or;
- Introduction into the vascular system resulting in embolism of the lung and/or heart or other clinical sequelae
- Pyrexia due to allergy to bone cement
- Short-term conduction irregularities
- Thrombophlebitis
- Transitory fall in blood pressure
- Migration of hardened bone cement bolus
- Fracture of the pedicle

Important Information on Resin for Fenestrated Screw (FS) Cement High Viscosity, Radiopaque Bone Cement

INSTRUCTIONS FOR THE PREPARATION AND CLINICAL USE OF FS CEMENT

TIMING FOR THE PREPARATION AND APPLICATION OF FS CEMENT

The handling characteristics of bone cements are affected by operating room conditions, including the room temperature, temperature of the cement components prior to mixing, humidity, the geometry of the mixing apparatus, time spent mixing, and the geometry of the delivery device. Any change in one or more of these conditions can alter the handling characteristics of the bone cement, including the time it takes for bone cement to reach the doughy state (the handling period), the time the bone cement remains in the doughy state (the working time), and the time the bone cement hardens (the setting time). Under specific conditions in our laboratory, FS Cement had a mixing and handling period of 9.5 ± 1.2 minutes at a room temperature of 22°C and 9.3 ± 0.6 minutes at 23°C.

The bone cement remained in the doughy state for the next 8.4 ± 1.3 minutes at 22°C and 9.5 ± 0.8 minutes at 23°C, to allow sufficient time for careful, minimally-invasive surgical introduction. Lower temperatures or other changes in operating room conditions can increase the handling, doughy (working) and setting times. Conversely, higher temperatures or other changes in operating room conditions can decrease the handling, doughy (working) and setting times.

HANDLING CHARACTERISTICS OF FS CEMENT AT 22°C AND 23°C IN LABORATORY CONDITIONS

PERIOD	ACTIVITY	APPROX. CUMULATIVE TIME FROM INITIATION OF MIXING*
Mixing	Mix liquid and powder	0-2 Minutes
Handling	Transfer into delivery system	2-8 Minutes
Working	Inject through screw to be augmented	8-16 Minutes
Setting	Wait before completing procedure	16-20 Minutes

* Times may vary when other mixing methods and delivery devices are used

NOTE: These cumulative time periods will vary depending on temperature and other factors. For example, the colder the environment, the longer the time necessary for the cement to develop the required doughy consistency. Warmer temperatures require more rapid preparation and handling. Ensure the cement's viscosity is high enough (doughy) before delivery begins

PREPARATION PROCEDURES

- Per the note above, temperature can affect the handling of the cement. Prior to use, it is advised to keep the product at a temperature of 23 ± 1°C for a period of 24 hours
- Prior to use, FS Cement packaging should be examined for damage and the presence of all required components
- Maintain aseptic transfer surgical technique to prevent possible infection
- Maintain strict adherence to the instructions for mixing the powder and liquid to prevent possible dermatitis from the liquid monomer during handling
- Assure that the inner package is undamaged, that the powder is not discolored (yellow or brown) and the liquid is not syrupy

These conditions indicate that the product has not been stored correctly:

- Assure that the preparation accessories are specifically compatible with the bone cement product
- Do not open the vial of liquid over the mixing bowl to avoid the risk of glass fragments entering the dough
- Never add other substances or foreign bodies to the acrylic resin. Never modify the ratios between the liquid and solid components
- Care should be taken in the mixing of the liquid and powder components such that the entire contents of the vial and packet are utilised. The liquid monomer and the powder component should be thoroughly mixed

CLINICAL APPLICATION PROCEDURES

1. Insert all of the screws
2. Always use sterile technique when mixing the bone cement
3. Open powder packet and break open the vial. Immediately combine the powder and liquid into a mixing bowl
4. When using the Kyphon® Mixer, follow the Kyphon® Mixer Instructions for Use
5. When mixing by hand, mix with a spatula until the ingredients are smoothly and uniformly combined, approximately one minute or longer as necessary. The liquid must moisten all the powder; use the spatula to carefully work any lumps of unmoistened powder into the overall mass of moist dough
6. After the powder and liquid have been thoroughly mixed, the delivery device can be filled with the cement
7. Check the consistency of the cements (approximately after 8 minutes from the initial mixing). To check the viscosity, extrude a small amount from the tip of the delivery system onto fingers. The cement should retain its shape when compressed into a ball. If the cement is sticky; it is not ready and should be allowed to stand further
8. When the viscosity is correct the cement can be injected following the screw surgical technique. Experimental data suggest using 0.8 cc of cement when implanting in the thoracic spine; when implanting cement in the lumbar spine, it is recommended to use 1.8 cc of cement
9. While the bone cement hardens, it is important to maintain patient positioning until the end of the polymerisation or setting process. For proper fixation, 1-2 hours or longer may be required, as determined by the patient's medical condition and the attending physician

HOW SUPPLIED

FS Cement is supplied sterile. The powder and package are sterilised with gamma radiation. The liquid is sterilised using filtration and is contained in a glass vial. The outside of the glass vial is sterilised with ethylene oxide gas. This device is intended for single use only. Do not re-sterilise. Do not use if package is open or damaged.

STORAGE

FS Cement should be stored in its original shipping materials. Proper care should be taken to ensure that FS Cement will not be damaged. Store below 25°C and away from sunlight.

LIMITATION OF LIABILITY

Medtronic will not be responsible for any direct, indirect, consequential or exemplary damages resulting from reuse of the Fenestrated Screw FS Cement. In no event shall Medtronic be liable for any direct, indirect, incidental, consequential or exemplary damages arising out of or in connection with the FS Cement, based upon breach of contract (including breach of warranty).

Notes

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THERAPIES

SERVICES & SUPPORT

ENABLING TECHNOLOGIES

NOT FOR DISTRIBUTION IN THE USA OR ITS TERRITORIES

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.

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