IMPORTANT INFORMATION

Please Read Before Use

CAUTION – Federal Law (USA) restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

The CONFIDENCE SPINAL CEMENT SYSTEM®– 5cc Kit is intended for percutaneous delivery of the CONFIDENCE 5cc Spinal Cement, which is indicated for fixation of pathological fractures of the vertebral body during vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancer, myeloma).

The CONFIDENCE High Viscosity Spinal Cement may also be used in conjunction with the VIPER® and EXPEDİUM® Fenestrated Screw Systems, including VERSE®. For Indications, Contraindications, Warnings and Precautions associated with this use, please reference the appropriate Fenestrated Screw System Instructions for Use.

CONTRAINDICATIONS

When used for vertebral augmentation procedures, the use of CONFIDENCE 5cc High Viscosity Spinal Cement is contraindicated in patients presenting with any of the following conditions:

- Use of CONFIDENCE 5cc High Viscosity Spinal Cement for prophylaxis (such as in metastatic or osteoporotic patients with no evidence of acute vertebral fracture).
- Coagulation disorders or severe cardiopulmonary disease.
- Haemorrhagic diasthesis.
- Non-pathological, acute, traumatic fractures of the vertebra.
- Patient clearly improving on medical therapy.
- Spinal stenosis (> 20% by retropulsed fragments).
- Compromise of the vertebral body or walls of the pedicles.
- Compromise or instability of vertebral fractures due to posterior involvement.
- Anatomical damage of the vertebra that prevents safe access of the needle to the vertebral body.
- Vertebral body collapse to less than 1/3 (33%) original height.
- Vertebral plana (collapse >90%).
- Active or incompletely treated infection.
- Coagulopathy or inability to reverse anti-coagulant therapy (both during and approximately 24 hours post-procedure).
• Severe pulmonary insufficiency.
• Allergic reaction to any of the components of the CONFIDENCE 5cc High Viscosity Spinal Cement.

DESCRIPTION

1. CEMENT DESCRIPTION

The CONFIDENCE 5cc High Viscosity Spinal Cement is a self-curing polymethylmethacrylate (PMMA) radiopaque bone cement. Its package includes two sterile components: a sachet containing powder polymer and an ampoule containing liquid monomer.

Composition

Powder Component (16 g)
- Methyl Methacrylate Polymer  18.5% w/w
- Methyl Methacrylate/Methyl Acrylate Copolymer 51.0% w/w
- Benzoyl Peroxide  0.6% w/w
- Barium Sulphate  29.9% w/w

Liquid Component (7.4 g)
- Methyl Methacrylate  ≥97.5% w/w
- N,N-Dimethyl-p-toluidine  ≤2.5 % w/w
- Hydroquinone  75 ppm

2. DELIVERY SYSTEM DESCRIPTION

The CONFIDENCE SPINAL CEMENT SYSTEM – 5cc Kit (Figure 1) comprises a cement reservoir (barrel), a hand-operated hydraulic pump that is provided pre-filled with sterile water and a flexible tube connecting the reservoir to the pump. The reservoir is connected to an introducer needle. The CONFIDENCE Spinal Cement System – 5cc Kit does not include any introducer or biopsy needles; the needles can be ordered as accessories. However, the instructions to use the needles are included within this package insert.

The system accessory instruments include mixing tools (mixer and a cement reservoir adaptor) and a removal nut. The cement reservoir adaptor is used to assist in filling the cement reservoir with cement. The removal nut is provided to facilitate with unthreading of 5cc reservoir from the mixer adaptor.

The introducer needle is a combination of a cannula and stylet to provide percutaneous access and cement introduction into the vertebral body. Arrows on the handle of the needle indicate the tip orientation.

The CONFIDENCE Cement Reservoir is designed to be attached to an oversized (9mm) luer. A Cement Reservoir Adapter is available in a separate packaging if needed in order to connect the CONFIDENCE Cement Reservoir to an introducer needle that has a standard luer. The CONFIDENCE Cement Reservoir Adapters should only be used with introducer needles with stainless steel tubing that are 6 inches (150mm) or shorter, and have an inner diameter of 13G (2.06mm) or larger.
A CONFIDENCE Needle Adapter is also available and provided in separate packaging to connect the CONFIDENCE Introducer Needles to a standard syringe as needed.

Figure 1: The CONFIDENCE 5cc High Viscosity Spinal Cement Delivery System

PACKAGING, HANDLING, AND STERILIZATION

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<th>Designation</th>
<th>Powder</th>
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<td>7.4 g</td>
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</table>

The cement should be stored unopened in its original packaging, in a dry, clean place away from light, at a temperature between 41°F (5°C) and 77°F (25°C).

The liquid in the ampoule is sterilized by ultra-filtration, and the ampoule blister is sterilized by ethylene oxide. The powder, in a double sachet, is sterilized by gamma irradiation.

The sterile-supplied components of the CONFIDENCE SPINAL CEMENT SYSTEM - 5cc Kit are sterilized by ethylene oxide or gamma radiation (as indicated on the individual packaging), with the exception of the cement liquid component, which is sterilized by filtration under aseptic conditions, and all are intended for single use.

The sterile packaging should be inspected for damage and expiration date prior to use. Do not use if the package is damaged or if you suspect that sterility has been compromised. Do not reuse or resterilize the device.
ADVERSE EVENTS

Serious adverse events, some with fatal outcome, associated with the use of polymethylmethacrylate (PMMA) bone cement include:

- Myocardial infarction
- Cardiac arrest
- Sudden death
- Cerebrovascular accident
- Pulmonary embolism
- Cardiac embolism
- Anaphylaxis

Although the majority of these adverse events may present early within the post-operative period, there is potential for diagnoses beyond a year or more after the procedure.

The most frequently reported adverse reactions with PMMA bone cement are:

- Transitory fall in blood pressure
- Thrombophlebitis
- Hemorrhage and hematoma
- Hypertension or hypotension
- Superficial or deep wound infection
- Bursitis
- Cardiac arrhythmia
- Heterotopic bone formation

Other potential adverse events reported for PMMA bone cement include:

- Hypoxemia.
- Bronchospasm.
- Adverse tissue reaction.
- Pain and/or loss of function.
- Allergic pyrexia.
- Pyrexia.
- Hematuria.
- Dysuria.
- Bladder fistula.
- Local neuropathy.
- Local vascular erosion and occlusion.
- Transitory worsening of pain due to heat released during polymerization.
- Nerve entrapment and dysphagia due to extrusion of the bone cement beyond its intended application.
- Intestinal obstruction because of adhesions and stricture of the ileum due to heat released during polymerization.

Potential adverse events associated with the spinal bone cement procedure include:

- Pneumonia
- Pulmonary infection
- Intercostal neuralgia, neuritis, nerve root pain, radiculopathy
- Pneumothorax
- Collapse of a vertebra adjacent to a treated level, due to osteoporotic disease
- Cement extravasation into soft tissue
- Cement leakage into intervertebral disc(s)
- Leakage of the bone cement beyond the site of its intended application with introduction into the vascular system resulting in embolism persisting in the lung and/or heart or other clinical sequelae of cement extravasation
- Tumor extravasation
- New vertebral fracture
- Fracture of a pedicle
- Rib fracture in patients with diffuse osteopenia, especially during thoracic vertebroplasty procedures, due to the significant downward force exerted during needle insertion
- Compression of the spinal cord with paralysis or loss of feeling
- Skin burns from fluoroscopy exposure
WARNINGS

1. An adequate course of conservative management should be considered for patients with acute osteoporotic vertebral body compression fractures before vertebroplasty or kyphoplasty.

2. Follow carefully the supplied instructions for handling and mixing the CONFIDENCE 5cc High Viscosity Spinal Cement.

3. Strict adherence to good surgical principles and techniques is essential. Deep wound infection is a serious post-operative complication and may require total removal of the embedded cement. Deep wound infection may be latent and may not manifest itself even for several years post-operatively.

4. Do not re-sterilize. The CONFIDENCE 5cc High Viscosity Spinal Cement is for single patient use only. The CONFIDENCE 5cc High Viscosity Spinal Cement is sterile only if the package is unopened and undamaged. The manufacturer and distributor will not be responsible for any product that is re-sterilized, nor accept for credit or exchange any product that has been opened but not used.

5. Store this package at a temperature between 41°F (5°C) and 77°F (25°C) and protect it from light to prevent premature polymerization of the liquid monomer component. Always check the condition of the liquid monomer before performing the procedure by ensuring it pours as a typical liquid. Do not use the liquid monomer if it shows any sign of thickening or premature polymerization. Do not use the product after the expiration date.

6. The use of the CONFIDENCE 5cc High Viscosity Spinal Cement is not recommended in patients that do not exhibit a pathological condition, such as primary or secondary osteoporosis or a tumor, which would impair the ability of the patient to heal using available conservative treatment methods.

7. Adverse patient reactions affecting the cardiovascular system have been associated with the use of bone cements for joint arthroplasty. Hypotensive reactions have occurred and some have progressed to cardiac arrest. For this reason, patients should be monitored for any change in blood pressure during and immediately following the application of the CONFIDENCE 5cc High Viscosity Spinal Cement. Acute hypotensive reaction may be associated with absorption of Methyl Methacrylate into the vascular system.

8. Exercise caution in cases involving extensive vertebral destruction and significant vertebral collapse. Such cases may lead to a technically difficult procedure. Please note that cement use in a vertebral body less than 1/3 of its original height is contraindicated.

9. Methyl Methacrylate has been demonstrated to cause hypersensitivity in susceptible persons, which may result in an anaphylactic response.

10. The liquid component has caused dermatitis in its handling and mixing. Follow handling, mixing and preparation instructions carefully.

11. Extreme caution should be exercised when there is disruption to the posterior cortex of the vertebral body as this increases the risk of cement extravasation into the neural foramen or spinal canal.

12. If the bone is particularly hard the clinician should reconsider using the Side Fire introducer needle.

13. To avoid excessive loads at the region surrounding the distal side port, insert the Side Fire introducer needle in a straight in-line fashion (do not rock or swivel) into the pedicle for a depth...
of at least 15 mm. In cases where the desired trajectory is not accomplished the needle should be removed, evaluated before reinserted in a straight-line fashion at the new desired trajectory.

14. Cement leakage can also occur when injecting the CONFIDENCE 5cc High Viscosity Spinal Cement if the needle is in a vein or if unseen microfractures are prevalent, cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events.

15. If the CONFIDENCE 5cc High Viscosity Spinal Cement is seen outside of the vertebral body or in the circulatory system during the procedure, immediately stop the injection of the cement by turning the pump handle counter-clockwise.

16. Careful attention should be paid during fluoroscopic guidance. Fluoroscopy (including bi-planar or CT guided imaging) is required to safely introduce the spinal needle and to adequately monitor the cement injection.

17. Clinical literature suggests complete lesion filling is not necessary to achieve relief of pain. Excessive filling of cement may increase the risk of cement extravasation. As in all vertebral body augmentation procedures, there is a risk of cement embolism to lungs or heart with the use of a spinal cement.

18. You may wish to consider the additional precaution of using Computerized Tomography (CT) guidance for high-risk cases, such as severe posterior cortical osteolysis.

19. Assure all system components are firmly connected prior to cement introduction.

20. Always cancel the pressure within the system when cement introduction is no longer desired (by counter-clockwise rotation of the pump handle).

21. Precise introducer and biopsy needle placement is required for this procedure. Incorrect introducer and biopsy needle placement could result in patient injury. When using the biopsy needles, care must be taken regarding the depth of insertion so that the extension of the biopsy needle beyond the depth of the introducer needle does not injure non-target tissue.

22. The CONFIDENCE Cement Reservoir Adapters should only be used with introducer needles with stainless steel tubing that are 6 inches (150mm) or shorter, and have an inner diameter of 13G (2.06mm) or larger.

23. The CONFIDENCE Spinal Cement System or any of its components have not been designed to undergo or withstand any form of alteration, including cleaning or re-sterilization. Due to cement curing and hardening, the system components cannot be reused. Reuse can compromise device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.

24. Follow the mixing instructions carefully to ensure that the cement has reached the appropriate consistency. This will prevent incompletely mixed material from either being injected or clogging the injection device. Failure to follow the mixing instructions or premature injection of material may negatively affect the outcome of the procedure.

25. Do not attempt to force the injection of material if excessive resistance is felt. Always determine the cause of the resistance and take appropriate action.

26. Following injection of the CONFIDENCE 5cc High Viscosity Spinal Cement into the vertebral body, positioning of the patient should be maintained securely throughout the setting phase described in these instructions for use.

27. Inadequate fixation or unanticipated post-operative events may affect the cement-bone interface and lead to micromotion at the cement-bone interface. A fibrous tissue layer may develop at this interface. Long-term follow-up is advised for all patients on a regularly scheduled basis.
28. The completion of cement polymerization occurs in the patient and is an exothermic reaction with considerable liberation of heat. According to the ISO 5833 standard, the temperature of this reaction can be as high as $90 \pm 5^\circ C$. The long term effects of the heat produced in situ have not yet been established.

29. The long-term safety and efficacy of the CONFIDENCE 5cc High Viscosity Spinal Cement in the spine have not yet been established.

30. The safety and efficacy of the CONFIDENCE 5cc High Viscosity Spinal Cement in pregnant women or in children has not yet been established.

**PRECAUTIONS**

1. For safe and effective use of the CONFIDENCE 5cc High Viscosity Spinal Cement in vertebral augmentation, the physician should be qualified to complete vertebral body augmentation procedures and percutaneous needle access to the vertebral body under the appropriate imaging (eg. bi-planar fluoroscopy, or CT guidance).

2. The physician should have good anatomic understanding of the spine, and thorough familiarity with the properties, handling characteristics, and application of this product. Because the handling and curing characteristics of this cement vary with temperature and mixing technique, they are best determined by the physician's actual experience.

3. The CONFIDENCE 5cc High Viscosity Spinal Cement should only be used by qualified physicians with training in the surgical use of spinal bone cements. The physician should be familiar with the principles and technique of spinal cement delivery, including possible side effects and limitations, and with the physiology and pathology of the selected anatomy. These procedures should only be performed in medical settings where emergency surgery is available.

4. A thorough pre-operative check-up of the patient must be carried out before the operation.

5. Proper handling and storage of the system is mandatory. Damage or alterations may cause defects, which could become the source of failure.

6. During the application of the cement, radiological control is essential so that the operator can follow the progress of the filling and stop the procedure if the slightest leakage of cement is detected. Use appropriate imaging techniques to confirm correct needle placement, absence of damage to surrounding structures and appropriate location of injected cement. Imaging, such as venography, may also be used to assess the ability of the vertebra to contain the injected cement.

7. Ensure that the powder and liquid components are thoroughly mixed before beginning the injection. The powder and liquid components to be mixed together should be from the same batch, since the composition of each batch of the powder component is specifically formulated to a corresponding batch of liquid component.

8. The liquid monomer is highly volatile and flammable. The operating room should be well ventilated so as to minimize the concentration of monomer vapor. Ignition of monomer fumes caused by the use of electrocautery devices in surgical sites near freshly implanted bone cements for joint arthroplasty has been reported. Care should be exercised to prevent exposure to the monomer vapors, which may produce irritation of the respiratory tract and eyes and possibly liver. Concentrated vapors of the liquid component may have an adverse reaction with soft contact lenses. Personnel wearing contact lenses should not be near or involved with the mixing of this product.
9. Liquid Methyl Methacrylate is a powerful lipid solvent; it should not be allowed to come in direct contact with sensitive tissue or be absorbed by the body. The liquid component should not be allowed to come into contact with surgical gloves. Wearing of a second pair of gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. Wear safety glasses or a face shield when delivering the material.

10. Methyl Methacrylate is a volatile and flammable material, and classed as a hazardous substance. It should therefore be treated as hazardous waste and disposed of in accordance with all applicable regulations. Any waste liquid component should be evaporated under a well-ventilated hood or absorbed by an inert material and transferred to a suitable container (which does not react with the monomer) for disposal. Prior to disposal, the surplus cement should be allowed to set. The polymer component and waste powder should also be disposed of as clinical waste.

11. Exercise caution when removing the needles from the package and when removing the protective tip covers. Needle size should be chosen based on patient's anatomy and pathology.

12. Do not continue injection beyond the delivery time of the cement. Attempting to inject the cement beyond the delivery time may result in failure of the delivery system. All needles must be removed prior to setting time.

13. If a bilateral approach is utilized, leave both needles in place to avoid leakage of the resinous material out of the cortical hole on the contralateral side.

14. Ensure that all connections are tightly secured. Improperly secured connections could result in the unintended disconnection of components.

15. The mixing/delivery device is designed for single use with one package of spinal cement. If additional material is needed, use a second CONFIDENCE SPINAL CEMENT SYSTEM – 5cc Kit and added accessories.

16. The CONFIDENCE SPINAL CEMENT SYSTEM 5cc Kit is designed for use only with the CONFIDENCE 5cc High Viscosity Spinal Cement. The device may not be compatible with alternate materials.

**PROCEDURE**

**CAUTION:** It is essential to maintain strict sterile technique during the spinal cement procedure and during all phases of handling this product.

Follow the cement preparation instructions carefully to ensure the cement has reached the appropriate consistency. Failure to follow those instructions or premature injection of the radiopaque spinal cement may negatively affect the outcome of the procedure.

1. In addition to carefully reading and following the procedure instructions below, please reference the CONFIDENCE SPINAL CEMENT SYSTEM – 5cc Kit Surgical Technique Manual for more detailed instructions.

2. The CONFIDENCE 5cc High Viscosity Spinal Cement is ready for use immediately following mixing of the cement components.

3. The introduction of the cement should be performed under continuous radiological control.

4. The introduction should be stopped when the operator judges the vertebral filling to be satisfactory, or when a risk of leakage of cement appears.

5. With the operating room and material temperature of 20°C, the different phases are as follows:
   - Mixing: 40-60 seconds
• Filling the delivery system: 1-2 minutes
• Application phase: 9 minutes (following components mixing)
• Hardening (Setting): 4 minutes

6. Acrylic cements are heat sensitive. Any increase or decrease in temperature (either ambient, and/or of the cement components), from the recommended temperature of 68°F (20°C) will affect the handling characteristics and setting time of the cement. Refer to the Temperature-Time chart at the end of these instructions for further information. Note 1: Manual handling and body temperature will reduce the final setting time. Note 2: When used with the CONFIDENCE PERIMETER SPINAL CEMENT SYSTEM®, please follow the Temperature-Time Table provided in the CONFIDENCE PERIMETER package insert.

7. Variations in humidity will affect the cements characteristics and setting time.

8. The handling characteristics and setting time can vary if the product has not been fully equilibrated to 68°F (20°C) before use. Store the unopened product at 68°F (20°C) for a minimum of 24 hours before use.

9. As with all acrylic cement, variations to the expected setting time over the shelf life can occur. This variation in setting time can be reduced to a minimum providing the cement is stored under the recommended conditions throughout its shelf life.

10. Injection should not be attempted beyond the delivery time shown in the Temperature-Time Chart at the end of these instructions.

11. After injection, the patient must lie flat until the cement has hardened. Bed rest is recommended and is determined by the patient's medical condition and the attending physician.

12. Prepare the operation site according to standard surgical techniques and hospital procedures.

13. Needle size should be chosen based on patient's anatomy and pathology. Under fluoroscopy, insert the introducer needle (cannula and stylet assembly) down to the target location (the introducer needle tip is typically positioned several millimeters from the anterior vertebral body wall). If performing a procedure with multiple needles, insert these needles before proceeding.

14. Perform the following steps (Figures 2 and 3) to prepare the cement:
   a. Open the sachet with care. With the mixing bowl sitting on a flat surface as shown in Figure 2, pour all the powder into CONFIDENCE mixing bowl.
   b. Open the ampoule – do not break the ampoule over the bowl (risk of glass splinters).
   c. Pour all the liquid onto the powder and mix thoroughly until homogenous mixture is obtained.
   d. Keeping the mixing bowl in the vertical orientation shown in Figure 2, screw the mixer handle onto the mixing bowl, and turn the handle 20-30 seconds clockwise and 20-30 seconds counter-clockwise. Note: It is important to hold the CONFIDENCE Mixer in the vertical orientation during the entire mixing procedure to ensure uniformity of mixing. Unscrew and remove the mixer handle.

15. Fill the cement reservoir with the cement, according to the following instructions:
   a. Push and completely screw the cement reservoir adapter (which is provided already connected to the cement reservoir) onto the mixing bowl. This will result in cement entering the reservoir.
   b. Once cement transferring is completed, unscrew the cement reservoir from its adapter using the provided removal nut shown in Figure 3.
   c. Screw the reservoir cap to the cement reservoir, and hand-tighten it thoroughly.
Figure 2: CONFIDENCE – 5cc Spinal Cement Mixer

Figure 3: 5cc Cement Transfer into Reservoir
16. Connect the flexible tube (which is attached to the pump) to the fitting on the proximal end of the reservoir cap.  
   **Note:** Prior to connection, rotate the pump handle counter-clockwise (about two full turns) and remove the stylet from the introducer needle cannula.

17. Attach the distal tip of the reservoir to the threaded connection of the introducer needle cannula.

18. SLOWLY rotate the pump handle clockwise in order to introduce the cement. Use fluoroscopic imaging throughout the procedure to verify and monitor cement flow as appropriate.  
   **Note:** The volume of the cannula may reach up to approximately 1cc.

19. If required, stop cement introduction by quickly rotating the pump handle counter-clockwise, until force-free handle rotation is achieved (about three full turns).

20. When the appropriate amount of cement has been introduced, stop cement introduction as indicated in step 19, and disconnect the reservoir from the introducer needle. Repeat steps 17-20 for multiple introducer needles. Do not attempt to perform more than two vertebra levels using the cement in the reservoir.

21. Carefully remove the introducer needle using rotational oscillating motions, prior to cement setting.
IMPORTANT PHYSICIAN INFORMATION

1. Spinal cement procedures should only be performed in medical settings in which emergency surgery is available.

2. Some literature and reported serious adverse events suggest that the increase in amount of cement injected and the number of levels performed during vertebroplasty and kyphoplasty procedures using any PMMA cement may be associated with an increased risk of circulatory collapse and possibly death.

3. Adverse reactions affecting the cardiovascular system have been attributed to recent data that indicate that the monomer undergoes rapid hydrolysis to methacrylic acid and that a significant fraction of the circulating methacrylate is in the form of the free acid rather than the methyl ester. The correlations between changes in circulating concentrations of Methyl Methacrylate/Methacrylic Acid and the changes in blood pressure have not been established.

4. The physician is responsible for any complication or harmful consequences, which may result from the inappropriate use of the CONFIDENCE SPINAL CEMENT SYSTEM – 5cc Kit. This may be a result of erroneous indication, inappropriate operating technique, or non-observation of the safety instructions that appear in the instructions for use.

5. Additives (such as antibiotics) are not to be mixed with CONFIDENCE 5cc High Viscosity Spinal Cement, as this will alter the cement’s properties.

6. The dough and setting times of the spinal cement vary with temperature, as indicated in the Temperature-Time Chart below:

![Temperature-Time Chart](chart)

PATIENT INFORMATION

The patient should be informed by the physician of the potential consequences of the factors mentioned in the contraindications and adverse effects, that is, those liable to hinder the success of the operation, as well as possible complications, which may arise. The patient should also be informed of the measures to be taken to diminish the possible consequences of these factors.
The Confidence Spinal Cement System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Confidence Spinal cement in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

**LIMITED WARRANTY AND DISCLAIMER**

PRODUCTS FROM DEPUY SYNTHES PRODUCTS, INC. ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION OF THIS INSERT AND THE DATE OF CONSULTATION, CONTACT DEPUY SYNTHES SPINE FOR CURRENT INFORMATION AT +1-800-365-6633 OR AT +1-508-880-8100.

**HIGH VISCOSITY SPINAL CEMENT LABEL TRANSLATIONS:**

Radiopaque ~5cc  
Sterile Content unless opened or damaged.  
Manufactured By  
Distributed By

### SYMBOL TRANSLATION

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<th>Translation</th>
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<td>ACROFLEX®/Ti ACROFLEX®/Titanium</td>
</tr>
<tr>
<td>A</td>
<td>Aluminum</td>
</tr>
<tr>
<td>A/P</td>
<td>Aluminum/Plastic</td>
</tr>
<tr>
<td>B/R</td>
<td>Barium/RADEL® Barium/RADEL®</td>
</tr>
<tr>
<td>Ba/PEEK</td>
<td>Barium Sulfate (BaSO₄)/PEEK Polymer</td>
</tr>
<tr>
<td>CaP</td>
<td>CALCIUM PHOSPHATE Calcium Phosphate</td>
</tr>
<tr>
<td>CM</td>
<td>CoCrMo Cobalt Chromium Molybdenum</td>
</tr>
<tr>
<td>CMTC</td>
<td>CoCrMo/Ti/CALCIUM PHOSPHATE Cobalt Chromium Molybdenum/Titanium/Calcium Phosphate</td>
</tr>
<tr>
<td>CoNiCrMo</td>
<td>Cobalt Nickel Chromium Molybdenum</td>
</tr>
<tr>
<td>F</td>
<td>FOAM Foam</td>
</tr>
<tr>
<td>HA</td>
<td>Hydroxyapatite</td>
</tr>
<tr>
<td>NiTi</td>
<td>Nickel/Titanium</td>
</tr>
<tr>
<td>PL</td>
<td>Plastic</td>
</tr>
<tr>
<td>P/F</td>
<td>Plastic/Foam</td>
</tr>
<tr>
<td>PY</td>
<td>Polyester</td>
</tr>
<tr>
<td>PEEK/C</td>
<td>PEEK/CARBON FIBER COMPOSITE Polyether Ether Ketone/Carbon Fiber Composite</td>
</tr>
<tr>
<td>P/C</td>
<td>POLYMER/CARBON FIBER COMPOSITE Polymer/Carbon Fiber Composite</td>
</tr>
<tr>
<td>P/CM</td>
<td>Polyethylene/CoCrMo Polyethylene/Cobalt Chromium Molybdenum</td>
</tr>
<tr>
<td>S</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>S/A</td>
<td>Stainless Steel/Aluminum</td>
</tr>
<tr>
<td>S/P</td>
<td>Stainless Steel/Phenolic</td>
</tr>
<tr>
<td>S/PL</td>
<td>Stainless Steel/Plastic</td>
</tr>
<tr>
<td>SRSI</td>
<td>SS/RADEL®/SILICONE Stainless Steel/RADEL®/Silicone</td>
</tr>
<tr>
<td>SRSN</td>
<td>SS/RADEL®/SILICONE/Ti Al Nitride Stainless Steel/RADEL®/Silicone/Titanium Al Nitride</td>
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<tr>
<td>SRTA</td>
<td>SS/RADEL®/Ti Al Nitride Stainless Steel/RADEL®/Titanium Al Nitride</td>
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<tr>
<td>STA</td>
<td>SS/Ti Al Nitride Stainless Steel/Titanium Al Nitride</td>
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<tr>
<td>S/U</td>
<td>Stainless Steel/Ultem</td>
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<tr>
<td>S/R</td>
<td>SS/RADEL® Stainless Steel/RADEL®</td>
</tr>
<tr>
<td>R/T</td>
<td>POLYOLEFIN RUBBER/Ti Polyolefin Rubber/Titanium</td>
</tr>
<tr>
<td>T/A</td>
<td>Ti/Al Titanium/Aluminum</td>
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<tr>
<td>T/CoCrMo</td>
<td>Titanium/Cobalt Chromium Molybdenum</td>
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<tr>
<td>Ti/HA</td>
<td>Titanium/Hydroxyapatite</td>
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<tr>
<td>Ti/UHMWE/HA</td>
<td>Titanium/Ultra-High Molecular Weight Polyethylene/Hydroxyapatite</td>
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<td>Stainless Steel/Titanium</td>
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<tr>
<td>SS/AI/SILICONE</td>
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</tr>
<tr>
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<td>Stainless Steel/Silica Glass</td>
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<tr>
<td>SS/SILICA GLASS/PL/SILICONE</td>
<td>Stainless Steel/Silica Glass/Plastic/Silicone</td>
</tr>
<tr>
<td>SS/SILICA GLASS/RADEL®/SILICONE</td>
<td>Stainless Steel/Silica Glass/RADEL®/Silicone</td>
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<tr>
<td>SS/SILICA GLASS/SILICONE</td>
<td>Stainless Steel/Silica Glass/Silicone</td>
</tr>
<tr>
<td>S/SI</td>
<td>SS/SILICONE Stainless Steel/Silicone</td>
</tr>
<tr>
<td>SS/WC/SILICONE</td>
<td>Stainless Steel/Tungsten Carbide/Silicone</td>
</tr>
<tr>
<td>W/C</td>
<td>Tungsten Carbide</td>
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</tbody>
</table>