Instructions for Use
SynJect Cement Delivery System

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

Manuals are subject to change;
the most current version of each
manual is always available online.
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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

CE
0123

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Instructions for Use

Devices in scope:

03.702.511S	Cement Delivery System	SynJect Single	1 × 9 ml
03.702.512S	Cement Delivery System	SynJect Single	2 × 9 ml
03.702.517S	Cement Delivery System	SynJect Dual	2 × 9 ml
03.702.520S	Cement Delivery System	SynJect Cartridges	1 × 9 ml

Introduction
The SynJect Cement Delivery product family consists of syringe-based injection devices in combination with cartridges which will be filled with the acrylic bone cement. A stop-cock is provided for the transfer of the bone cement into the cartridges. All products are sterile packed, single use devices.

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use, the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Materials

Device:	Materials:
Syringe	PC (Polycarbonate) PBT (Polybutylene Terephthalate) Stainless Steel Silicone PA12 (Polyamide) LDPE (Low-density Polyethylene)
Cartridge	PA12 (Polyamide) PBT (Polybutylene Terephthalate) Silicone
Stop-Cock	PA12 (Polyamide) PBT (Polybutylene Terephthalate)
Reservoir	PC (Polycarbonate) ABS (Acrylonitrile Butadiene Styrene) Silicone

Intended Use
The SynJect Cement Delivery System is intended for the application of DePuy Synthes PMMA-based bone cement, Vertecem V+ Cement Kit, with the intent to augment cancellous bone. Refer to the corresponding instruction for use regarding indications, contraindications, compatibility, use, precautions, warnings and side effects of the bone cement and access solution used in conjunction with the SynJect Cement Delivery System. For information on compatibility with other devices or systems, consultation with a DePuy Synthes representative is recommended.

Patient Target Group
Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The patient target group is based upon the implant devices rather than the instruments. Specific patient target group for the Implants can be found in the respective Synthes implant instructions for use.

Intended User
This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, radiologists, OR Staff, and professionals involved in preparation of the device. All personnel handling the device should be fully aware of the intended use of the products, the applicable surgical procedures and the Synthes "Important Information" leaflet.

Expected Clinical Benefits
The expected clinical benefits for the instruments are based upon the implant device (i.e., bone cement) rather than the instruments. Specific clinical benefits for the implants can be found in the respective Synthes implant instructions for use.

Performance Characteristics of the Device
Synthes has established the performance and safety of SynJect Cement Delivery System when used per its instructions for use and labeling.

Potential Adverse Events and Undesirable Side Effects
Synthes manufactures surgical instruments intended to prepare the site and aid in implantation of Synthes implants. The adverse events/side effects are based upon the implant devices rather than the instruments. Specific adverse events/side effects for the Implants can be found in the respective Synthes implant instructions for use.

Sterile Device

Sterilized using irradiation

Store sterile implants in their original protective packaging, and do not remove them from the packaging until immediately before use.


Do not use when packaging is damaged

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.


Do not resterilize

Re-sterilization of the SynJect Cement Delivery System can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single-use Device


Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Warnings and Precautions
- Releasing the applicator plunger (2b) will immediately stop cement flow out of the cement cartridge (3a/3b). Cement already injected into a vertebral body, however, may continue to flow due to external influences.
- The purpose of the milliliter (ml) scale on the side of the cement cartridge (3a/3b) is to give physicians an indication of how much bone cement has been injected. This scale is for information purposes only.
- Confusing injection sides can favor the occurrence of cement leakage. Cement leakage can cause severe consequences such as tissue damage, paraplegia or fatal cardiac failure. It is strongly recommended not to work on multiple fracture sites simultaneously to avoid the risk of confusion.
- The SynJect Cement Delivery System is used in technically demanding procedures. Therefore, only physicians familiar with the proper technique and instrumentation used for the delivery and use of bone cement should use SynJect Cement Delivery System.
- The SynJect Cement Delivery System should only be used to deliver bone cement in conjunction with the use of fluoroscopy imaging equipment capable of delivering high-quality images.
- Ensure a good fit between cement cartridge (3a/3b) and stop-cock (4) but make sure to be on axis and avoid using excessive force when coupling them. They are both made of plastic and could otherwise break.
- Always make sure the bone cement has reached the preferred viscosity prior to injection.
- After filling a cartridge (3a/3b) with cement, grip it by its lid (3d). Gripping it anywhere else could transfer heat from your hand to the cement, shortening the working time of the bone cement.

– To halt the flow of cement out of the cartridge (3a/3b) at any given time, simply stop pushing the plunger (2b).
– Make sure to always inject cement in a slow, controlled fashion.
– If cement flow is hindered at any time during injection, halt, investigate and correct the reason for the flow hindrance.
– Do not use tools or excessive force to operate the SynJect Cement Delivery System. The cement cartridge is made of rigid plastic material. During cement injection, the pressure in the cement cartridge increases creating a theoretical risk for the cartridge to explode. Therefore, the user should wear safety glasses when using the device.
– The shape and size of bone cement containers influence working time. Larger containers generally give a slightly faster setting of the bone cement than smaller containers. This should be considered when planning a procedure.
– For SynJect Cement Delivery System dual, water may drip from the center of the line selection lever when alternating between injection lines.

Combination of Medical Devices
The SynJect Cement Delivery System should only be used in combination with DePuy Synthes augmentation hardware with which it has been tested and validated. DePuy Synthes assumes no liability in other instances. For information on compatibility, consultation with a DePuy Synthes representative is recommended.

Magnetic Resonance Environment
The SynJect Cement Delivery System has not been evaluated for safety and compatibility within the MR environment.

Treatment before Device is Used
The SynJect Cement Delivery System is supplied in sterile form. Prior to use, check the product expiration date and verify the integrity of the sterile packaging. If it is opened or otherwise damaged, do not use. If the product has expired, do not use. If all packaging appears to be intact, remove product(s) from the package using aseptic technique.

Troubleshooting
If water flow between reservoir (1) and applicator body (2) is hindered, simply press the reservoir plunger until water once again fills the applicator body. If the force needed to inject cement becomes too high, this indicates that the maximum working time for the combination of bone cement and access solution used has been reached.

Device-related Storage and Handling Information

 Keep dry

 Keep away from sunlight

Additional Device-specific Information

 Reference number

 Lot or batch number

 Legal manufacturer

 Expiration date

 Does not contain latex

 Consult instructions for use

Disposal
Any single-use Synthes instrument that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be disposed of per the healthcare facility's protocol.

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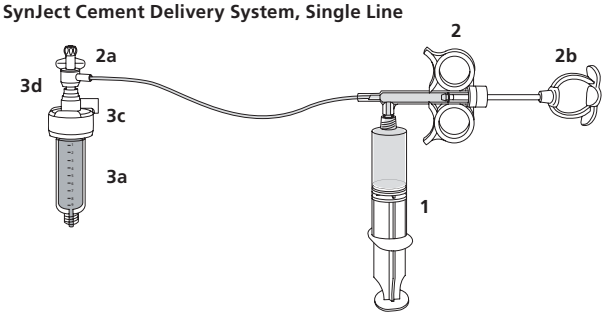
Special Operating Instructions
Operating instructions (see illustration below 'Device Overview' or refer to the Quick Step Handling Guide SE_722260)

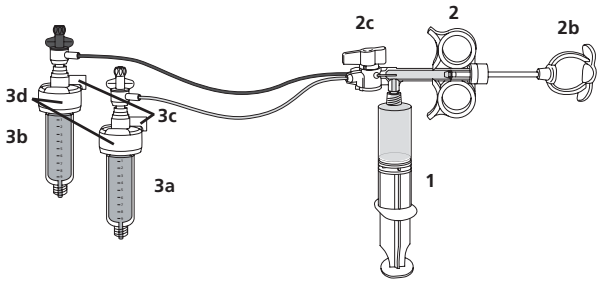
1. Fill the cup in the plastic tray or another sterile vessel with sterile fluid* and aspirate it using the water reservoir.
2. Fill the water reservoir (1) with sterile fluid*.
3. Remove excessive air from the water reservoir by holding it vertically and pushing the plunger until a little water runs out at the top.
4. Connect the water reservoir to the injector body (2).
5. Put the cement cartridge(s) in an upright position into the plastic tray.
6. Prepare bone cement per the corresponding directions for use for the bone cement.
7. Remove the plug from the mixer lid and attach the stop-cock.
8. Rotate the blue handle from the mixer clockwise until you see cement extruding from the stop-cock outlet and then move the stop-cock lever to the vertical position (closed).
9. Attach the cartridge to the stop-cock (funnel side) and rotate the blue lever on the stop-cock to a horizontal position (open).
10. Transfer cement to the cartridge (3a) by rotating the cement handle clockwise in a controlled manner. Do not push it. Close the stop-cock by rotating the blue lever to a vertical position (closed) and disconnect the cartridge.
11. Place the cartridge(s) filled with cement into the plastic tray. Make sure the lever on the cartridge lid (3c) is in the "vent" position. Repeat step 9 to 11 for the second cartridge (3b), if applicable.
12. Connect a cartridge to an injection line (2a). Hold the cartridge in an upright position.
13. Remove remaining air from the system by pumping 2–3 strokes with the injector plunger (2b).
14. Once water drops start to form on the cartridge lid (3d), turn the lever (3c) to the "inject" position. For SynJect Cement Delivery System with dual injection lines, activate the second injection line by turning the line selection lever (2c) into the proper position. Note: The injection lines have different colours to assist in identifying which line is active. Repeat step 13 for the second cartridge (3b).
15. Test the cement viscosity before commencing the injection.
16. Per the corresponding bone cement directions of use, once the viscosity is deemed appropriate attach the cartridge(s) to an access solution and perform cement injection.

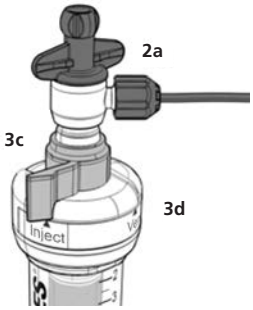
* Sterile water or sterile saline solution (0.9 % NaCl).

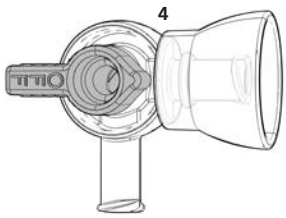
Device Overview
SynJect Cement Delivery System, Single Line



SynJect Cement Delivery System, Dual Line







1 Reservoir
2 Injector body
2a Injection line
2b Injector plunger
2c Line selection lever (applicable only for SynJect Dual)
3a Cartridge 1
3b Cartridge 2 (if applicable)
3c Cartridge lever
3d Cartridge lid
4 Stop-cock