The technique description herein is made available to the healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.
The Smith & Nephew STRUCSURE® CP Macroporous Calcium Phosphate Bone Graft Substitute is an advanced injectable, hard-setting bone graft substitute designed to gradually resorb while being replaced with natural bone. STRUCSURE CP is mixed in a unique dual chambered syringe that minimizes preparation efforts prior to use and also includes a dispenser gun for precision placement of material. This allows for an efficient technique for fracture reinforcement. The proprietary combination of materials, which includes a viscoelastic polymer, creates a porous scaffold ideal for bone osteoconductivity and may be injected through a 7-gauge cannula. STRUCSURE CP provides good compressive strength, radio-opacity and is cohesive enough to address surgical situations with significant blood flow. STRUCSURE CP is designed to set in eight minutes in-vivo to avoid losing operative time for fracture support.
Introduction
Dispenser gun

Keyed Syringe Slot
Dispenser Plunger
Release Lever
Trigger
Handle
Introduction
Quick assembly

1
Lift up on the release lever located on the back of the dispenser gun and hold

2
Insert the flat end of dispenser plunger with the teeth facing down and the rib facing up

3
With the syringe measurements facing up, slide the syringe into the keyed syringe slot
STRUCSURE™ CP is a composite synthetic biomaterial consisting of a resorbable ceramic and polymer. Its physiochemical features provide advanced, osteoconductive properties ideal for trauma, extremities procedures and hip and knee revision.

The ceramic material provides a scaffold-like support structure which forms a close bond with the native bone. The material is gradually resorbed by osteoclastic cells which participate in the natural bone remodeling cycle. Conduction and formation of mineralized healthy bone occurs as the material resorbs without the formation of voids (rapid dissolution leads to fibrosis and seroma).

The polymer confers wettability and porosity to facilitate percolation of body fluids throughout the implant and improves cohesion, elasticity, rheology and injectability.

Physiochemical properties are as follow:

- Overall porosity 66%
  - Micro porosity (<10µm): 88%
  - Meso porosity (10-100µm): 2%
  - Macro porosity (>100µm): 10%
- No shrinkage during the crystallization process
- Non-exothermic reaction 1-3°C
- Mechanical compressive strength: 24MPa (equal to twice the strength of healthy cancellous bone 24 hours after implantation).
- Cohesiveness: Excellent resistance to fluid
The STRUCSURE™ CP Resorbable Calcium Phosphate bone graft substitute contains the following components:

- Ancillary Device
  - The powder mineral phase – a premeasured combination of calcium phosphates and organic phase polysaccharide that confers wettability and porosity to facilitate percolation of the body fluids throughout the implant.
  - The liquid phase – sodium phosphate solution that allows homogenous mixing and reproducible setting time (crystallization) of the bone graft substitute comprised of hard apatite crystals similar to native bone crystals.
  - Dual independent chambered (powder and liquid side) Luer-Lok™ syringe with a multi-position selector at the end for transferring and injecting
    - A built-in mixer on the powder side
    - A pushrod or plunger
  - 7-gauge Luer-Lok cannula
  - Dispenser gun

Available kit size: 5cc, 8cc and 16cc
1 Secure a 4.5mm drill bit (4.5 drill bit can be found in most large fragment plate and screw systems).

2 Use the 4.5mm drill bit to drill a pilot hole in the desired area of the defect.

3 If needed, use a 7-gauge cannula to place material in desired location.
Surgical Technique
Preparation of bone graft substitute

1. Hold the syringe with the Luer-Lok™ tip in the upright position.

2. Turn the syringe selector, located on the Luer-Lok end of the syringe, to “transfer” by rotating the collar clockwise.

3. Connect the transfer plunger to the liquid chamber piston.

4. Slowly advance the transfer plunger until all liquid has passed into the powder chamber.

5. Remove the transfer plunger.
Surgical Technique
Mixing powder and liquid

1. Hold the syringe with the Luer-Lok™ tip in the downward position.

2. Mix for 2 minutes, use the mixer rod connected to the piston and in a twisting motion move the mixer rod up and down (full strokes) in the syringe barrel.
1 Turn the syringe selector, located on the Luer-Lok™ end of the syringe, to “inject” by rotating the collar clockwise.

2 Pull the mixing rod to the back of the syringe and bend the rod until it breaks (mixing rod is designed to break).

3 Lift up on the release lever located on the back of the dispenser gun and hold.
Surgical Technique
Inject using dispenser gun (continued)

4 Insert the flat end of dispenser plunger with the teeth facing down and the rib facing up.

5 With the syringe measurements facing up, slide the syringe into the keyed syringe slot.

6 Connect a Luer-Lok™ cannula (if needed) and hold the Luer-Lok end in the upright position while slowly squeezing the trigger to the dispenser gun to expel air (if needed).

7 To apply, place cannula in desired location and squeeze trigger.

8 To remove syringe, lift up on dispenser release lever and pull dispenser plunger back.
Surgical Technique
Inject manually

1. Turn the syringe selector, located on the Luer-Lok™ end of the syringe, to “inject” by rotating the collar clockwise.

2. Pull the mixing rod to the back of the syringe and connect the transfer plunger to the mixing rod.

3. Connect a Luer-Lok cannula (if needed) and hold the Luer-Lok end in the upright position while advancing the piston to expel air (if needed).

4. To apply, place cannula in desired location and press down on mixing rod.
STRUCSURE® CP is intended for bony voids or defects that are not intrinsic to the stability of the bony structure. STRUCSURE CP is intended to be placed or injected into bony voids or gaps of the skeletal system (the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides bone void filler that resorbs and is replaced with bone during the healing process.
STRUCSURE™ CP must not be used in the following cases:

- An infected site, or one suspected of being so
- A bone site which can lead to the product passing into the joint cavities or into the meningeal spaces
- A site which cannot be stabilized
Warnings and Precautions

• STRUCSURE® CP must be prepared and implanted under aseptic conditions by qualified personnel who have carefully read these instructions for use. Any product surplus which might be present in the adjacent soft tissue must be removed. Extrusion of the device beyond the site of its intended application could damage the surrounding tissues.

• STRUCSURE CP syringe is specifically designed so that a syringe accessory can be fitted to the Luer-Lok tip (catheter or trocar). In order to maintain the injection properties of the STRUCSURE CP, the diameter of the accessory used must be less than or equal to 7G. When the STRUCSURE CP syringe is used with an accessory, the loss of useful volume of the injected product must be anticipated.

• The operation site must be cleaned with a sterile saline solution or sterile water. It must be as clean and dry as much as possible and must not be irrigated after the implantation.

• A pre-operative plan which includes the preparation, injection, setting time, and the number of STRUCSURE CP syringe required to complete the filling operation is recommended.

• STRUSURE CP is not intended to be a load bearing device. Therefore, rigid fixation techniques may often be recommended.

• The setting time in vivo is approximately eight minutes for STRUCSURE CP, provided that during this time the implanted product is neither re-worked nor rinsed.

• In order to provide an optimum mode of action, the implant needs to be complete and appropriate contact with the bone.

• Closed and deep sites should be preferred and will have to be completely filled.

• Caution: injecting STRUCSURE CP under high pressure in a closely confined and/or highly irrigated bone site is inadvisable due to the risk of embolism.

• The radiopacity of STRUCSURE CP must be taken into account when taking radiographs.

• The safety and efficacy of STRUCSURE CP on contact with allografts, or acrylic, or silicon, or polymer devices have not been established.

• The safety and efficacy of STRUCSURE CP when combined with devices with similar indications or medicinal substances have not been established.
• The safety and efficacy of STRUCSURE® CP have not been established in the following populations:
  - Patients with acute or chronic infections, particularly near or in the implantation site
  - Patients with inflammatory bone diseases such as osteomyelitis
  - Patients with a calcium metabolism anomaly, severe metabolic, vascular or neurological diseases, or immunological deficiencies
  - Patients not having reached bone maturity
  - Pregnant or breast-feeding women
  - Patients undergoing radiotherapy or chemotherapy
Adverse effects

The adverse effects of STRUCSURE™ CP are those related to this type of surgery. They include but not restricted to:

- Wound infection
- Non-consolidation
- Wound dehiscence
- Delayed consolidation
- Loss of reduction
- Re-fracture

The occurrence of any of these effects may require additional surgery and/or removal of the material.

Material removal

If removal of bone graft is required, use a high or low speed burr for removal.
STRUCSURE® CP and STRUCSURE CP dispenser gun are sterilized by gamma radiation. The cannula is sterilized by ethylene oxide. STRUCSURE CP must be kept at room temperature (between 10°C/50°F and 40°C/104°F).

Before use: check the expiration date, ensure that the sterility protector is intact, and that the sterilization indicator is red. Do not use if the product packaging is opened, damaged or sterilization indicator is not red.

STRUCSURE CP and STRUCSURE CP dispenser gun and cannula are single-use products which must be neither reused re-used nor re-sterilized.
Caution

Federal law restricts this device to sale by or on the order of a physician
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*Components cannot be purchased separately, only sold as a kit.