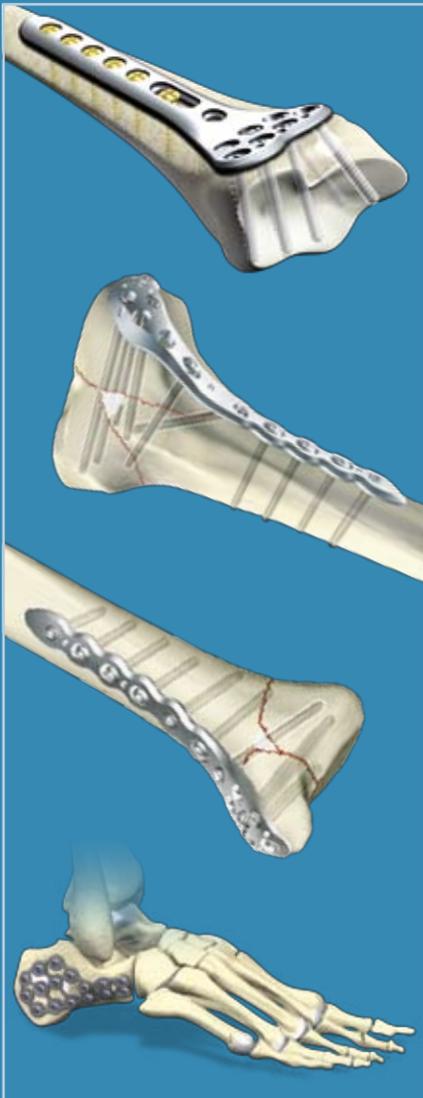


# HydroSet Injectable HA Bone Substitute

The difference in Bone Substitute  
Technology:

- Fast setting
- Excellent wet-field properties
- Osteoconductive
- Enhanced screw fixation in cancellous bone at and after surgery



# Introduction

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### Special acknowledgement is made to:

- Dr. Peter Catalano, M.D., Otolaryngology, Lahey Clinic, Burlington, MA, USA, for his valuable contribution in the development of the product and premarket testing
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- Dr. Walt Virkus, M.D., Assistant Professor of the Department of Orthopaedic Surgery at Rush University Medical Center in Chicago, Illinois, for sharing his technical know-how and surgical expertise and providing assistance in the preparation of this Operative Technique.

# Product Overview

## Packaging and Sterility

HydroSet is packaged sterile in exact, pre-measured ingredients.

**Sizes offered:** 3cc, 5cc, 10cc, 15cc

There are two separate sterile packs. (Syringe and cannula are for single use only. Do not resterilize).

### 1. Foil Pouch:

The powder is packaged in a plastic bowl. The bowl is placed in a Tyvek® container. Underneath the bowl containing the powder is a desiccant to control moisture. This should never be implanted or mixed with the powder. The Tyvek® container is placed in a foil pouch and it is sterilized via gamma irradiation.

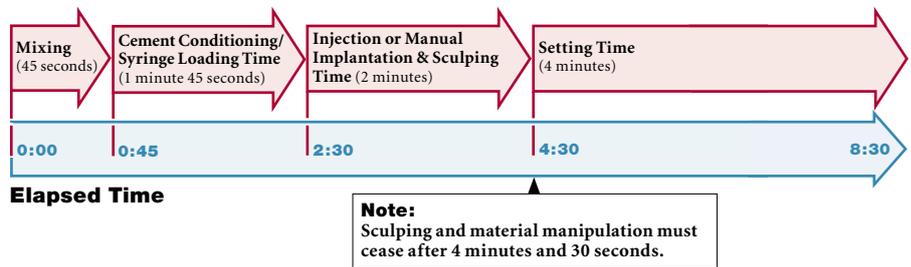
### Caution:

The product should be used within 60 minutes of opening the outer powder packaging.

### 2. Liquid Blister Kit:

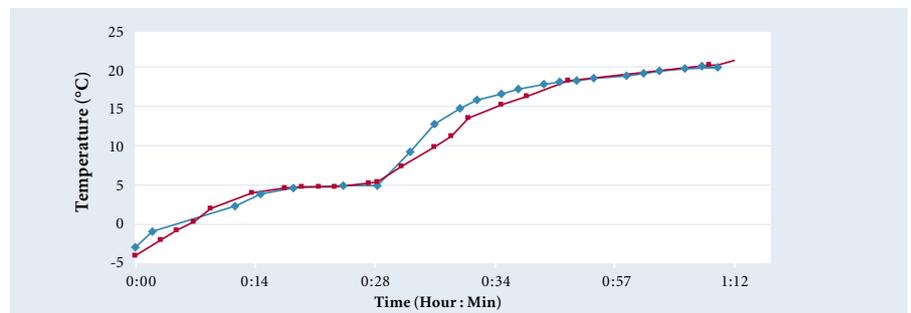
The packaging which contains the sterile, liquid filled syringe also includes the cement delivery syringe with a preattached funnel, plunger rod, 8ga cannula and mixing spatula which are sterilized via Ethylene oxide.

## INJECTION or MANUAL IMPLANTATION



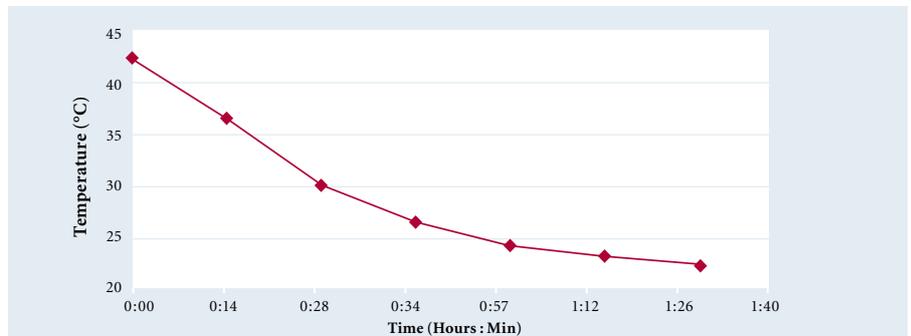
## Storage Information

Room temperature between 15 and 25°C (approx. 59-77°F).



**HydroSet Temperature Equilibrium (Liquid Syringe) - From Frozen State**

◆ Room Temp = 20°C  
■ Room Temp = 22°C



**HydroSet Temperature Equilibrium (Liquid Syringe) - From Heated State**

◆ Room Temp = 22°C

## Sterile Needles

The HydroSet package contains an 8ga cannula. 10ga and 12ga cannulas are available as single use, sterile packaged to meet a variety of surgeons needs.

- 8ga cannula OD = 4.2mm
- 10ga cannula OD = 3.4mm
- 12ga cannula OD = 2.8mm

### Note:

Always refer to the IFU as well before using HydroSet.

## Handling Characteristics

HydroSet is quick-setting and easy to mix and deliver via hand application or syringe injection.

**Mixing Time:** 45 seconds

**Transfer Time:**

1 minute 45 seconds

**Injection and Sculpting Time:**

2 minutes

**Setting Time:** 4 minutes at 32°C defect site temperature

### Caution:

HydroSet is temperature sensitive, therefore, handling times are approximate based on product and OR temperatures of 18 to 22°C (approx. 64–72°F). A higher temperature can lead to a shorter setting time and a lower temperature to a longer setting time.

Tyvek® is a DuPont registered trademark.

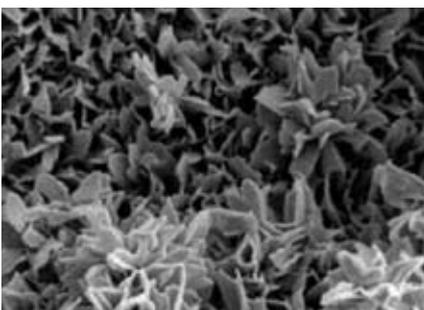
# Rationale, Features & Benefits

HydroSet is an injectable, sculptable and fast-setting bone substitute.

HydroSet is a calcium phosphate cement that converts to hydroxyapatite, the principle mineral component of bone. The crystalline structure and porosity of HydroSet makes it an effective osteoconductive material, with excellent biocompatibility and mechanical properties<sup>1</sup>. HydroSet is specifically formulated to set in a wet field environment and exhibits outstanding wet-field characteristics<sup>2</sup>. The chemical reaction that occurs as HydroSet hardens does not release heat that could be potentially damaging to the surrounding tissue. After implantation, the HydroSet is remodelled over time at a rate that is dependent on the size of the defect and the average age and general health of the patient.

## Indications

1. HydroSet is indicated to fill bone voids or gaps of the skeletal system (i.e., extremities, craniofacial, spine and pelvis). These defects may be surgically created or osseous defects created from traumatic injury to the bone. HydroSet is indicated only for bone voids or gaps that are not intrinsic to the stability of the bone structure.



**Scanning Electron Microscope image of HydroSet material crystalline microstructure at 15000x magnification**

HydroSet cured in situ provides an open void/gap filler that can augment provisional hardware (e.g., K-wires, plates, screws) to help support bone fragments during the surgical procedure.

The cured cement acts only as a temporary support media and is not intended to provide structural support during the healing process.

2. The cured cement is intended to enhance screw fixation in cancellous bone at and after the time of surgery\*. Injecting HydroSet into cancellous bone creates a composite of bone and cement; this is referred to as Bone Augmentation, and results in better fixation of screws. HydroSet is not intended for use in areas where the surrounding bone is osteoporotic, avascular or otherwise not capable of supporting or anchoring the implant.

## Contraindications

- Use in defects as a sole anchorage material for fixation of implants.
- Use in currently infected field or surgical site near an infection
- Use in patients with acute traumatic injuries with open wounds near the defect that are likely to become infected
- Use for open fractures

- Use for bone voids that link joint spaces and/articulating surfaces
- Use for load bearing applications
- Use in areas where surrounding bone is avascular or is incapable of supporting or anchoring the implant
- Use in patients who have not reached an age at which skeletal system growth is essentially complete.
- Use in patients with the following conditions: abnormal calcium metabolism, metabolic bone disease, a recent untreated infection, immunologic abnormalities and systemic disorders which result in poor wound healing or will result in tissue deterioration over the implant site.
- Use for augmenting pedicle screws.
- Use in Vertebroplasty or Kyphoplasty

### Warning:

- HydroSet should not be used in areas where the surrounding bone is osteoporotic, avascular or otherwise not capable of supporting or anchoring the implant.
- Care should be taken to avoid overpressurizing the device because this may lead to extrusion of the device beyond the site of its intended application and damage to the surrounding tissues
- Care should be taken to avoid overpressurizing the device because this may lead to fat embolization or embolization of the device material into the bloodstream.

### Note:

**Always refer to the IFU as well before using HydroSet.**

## References

1. **Chow, L, Takagi, L.** A Natural Bone Cement – A Laboratory Novelty Led to the Development of Revolutionary New Biomaterials. J. Res. Natl. Stand. Technol. 106, 1029-1033 (2001).
2. **TR-1808. E703.** Wet field set penetration (Data on file at Stryker)

\*This indication is not cleared for use in the U.S.

# Rationale, Features & Benefits

## Advantages

- Injectable or manual implantation
- Fast Setting
- Isothermic
- Excellent wet-field Characteristics
- Osteoconductive
- Augmentation of provisional hardware
- Radiopaque to allow convenient visualization of healing during follow-up
- Enhanced Screw fixation in cancellous bone at and after surgery\*

Self-curing calcium phosphate cements (CaP) are used clinically to replace, repair and augment non load bearing defects in cancellous bone voids<sup>1</sup>. Next to understanding and advancing the mechanical properties of these materials as well as the biological integration with the surrounding bony structure; the clinical ease of application and handling of CaP materials cannot be overlooked. OR and defect temperature, wet field properties and defect size play a key role.

1. TR-1808 A701 Animal Study conducted at the Ballina, Ireland Animals Testing facilities by Peter Catalano, M.D., Lahey Clinic, on canine sinus defect model in a wet environment (27°C).

- Alpha-BSM® is a registered trademark of Depuy a Johnson & Johnson Company.
- Norian® is a registered trademark of Synthes®.
- MIIG® X3 is a registered trademark of Wright.

## Application Properties

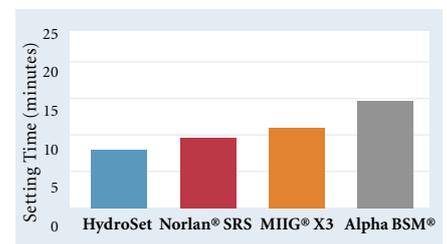
### Wet Field Setting<sup>1</sup>

HydroSet demonstrated superior cement washout resistance and setting properties when subjected to blood and/or saline during application compared to other evaluated commercially available cements.

In a wet field environment HydroSet sets significantly faster than Norian®, SRS, MIIG® and Alpha-BSM®.



**Canine sinus cavity defect, wet field with blood and saline**



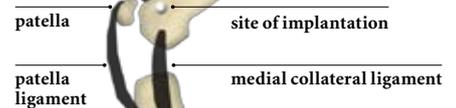
## Histological Properties

### Biological Rabbit Model<sup>1</sup>

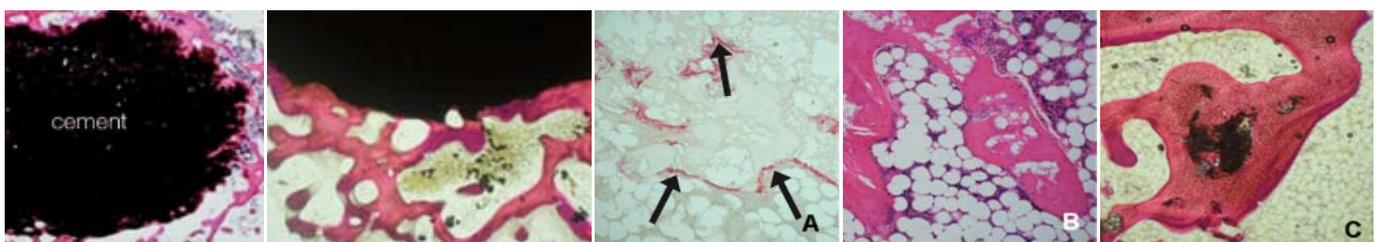
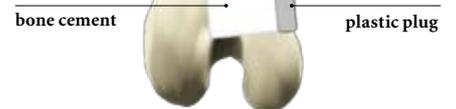
- Histology proved HydroSet to be biocompatible & osteoconductive as an effective bone void filler
- Histology results indicated good cement integration into the bony defect site for all three bone substitutes over the 1 year study window.
- All three CaP's tested (Norian, BoneSource and HydroSet) were resorbed by an osteoclastic mechanism. All cements were found to be variable with none of the CaP's fully remodelled in the one year study time period.

### Adult New Zealand Rabbit

#### medial view



#### frontal view



**A** CaP in defect after 6 weeks surrounded by newly formed vital bone (mag 12.5x).

**B** Detail of tight contact between new bone and cement surface after 52 weeks (mag 25x)

**A** TRAP-positive cells resorbing cement after 26 weeks

**B** HE stained section showing new bone formation on HydroSet after 26 weeks

**C** Non-decalcified section after 52 weeks (mag 100x)

\*This indication is not cleared for use in the U.S.

# Rationale, Features & Benefits

## Bone Augmentation Rationale\*

Calcium Phosphate based (CaP) cements resorb slowly (over years) so it can be expected that bone augmentation effects obtained at the time of surgery should be maintained for an extended period of time. This effect has been demonstrated, to a limited degree, in a study<sup>2</sup> in which screw (3.5mm dia.) pullout strength was shown to be improved at 1 week (W1), 3 months (M3) and 6 months (M6) in goat bone that was augmented with CaP cement (Fig.1).

In summary CaP cements have the following characteristics when used for bone augmentation<sup>2</sup>:

- in low density materials (bone models/animal & human cadaver bone) there is increased pullout strength when screws are augmented with calcium phosphates
- this effect is greatest in the least dense cancellous bone
- the augmentation effect is seen in diameters of orthopaedic screws 1.5mm to 8.0mm

Screw fixation failure in cancellous bone represents a surgical challenge. In these cases, augmentation of screw purchase with injectable biomaterials has been proposed to increase the strength of the fixation. An in-vitro study investigated the biomechanical conditions that improve fixation strength in an in-vitro model of cancellous bone with and without augmentation with HydroSet as well as to explore the effect of a cortical shell. It was suggested that the presence of a cortical shell is a significant factor in pullout strength of a screw<sup>3</sup>.

For this in-vitro study of screw fixation in HydroSet augmented cancellous bone models, an open pore foam model (Sawbones material 1521-59) was utilised to simulate cancellous bone.

Cancellous bone screws (Stryker 325460S A5 mm × 60mm, thread length 20 mm, pitch 2 mm), were inserted in the cancellous bone blocks to model 4 different clinical scenarios: a) screw purchase through cancellous bone only; b) screw purchase in cancellous bone traversing a cortical layer; c) screw purchase through augmented cancellous bone and, finally, d) screw purchase through augmented cancellous bone and traversing cortical layer (Fig. 2).

In each experiment the cancellous screw was inserted into the simulated bone block using the simulated bone block using the appropriate surgical tooling. The insertion depth for each screw was standardised to 20 mm through a pre drilled 3.5 mm pilot hole.

The cortical layer was simulated by application of a Perspex layer 2 mm thick to the uppermost side of each block.

The mean pullout strength and standard deviations for each of the test configurations are shown in (Fig 3).

The experimental results showed the benefits of augmentation with a four-fold increase in pullout strength in the augmented foam without a cortical layer and nearly fourteen-fold increase with the augmentation in the presence of a cortical layer. A statistically significant increase in pull-out strength in open pore foam was achieved with the augmented specimens compared to the non-augmented ones.

\*This indication is not cleared for use in the U.S.

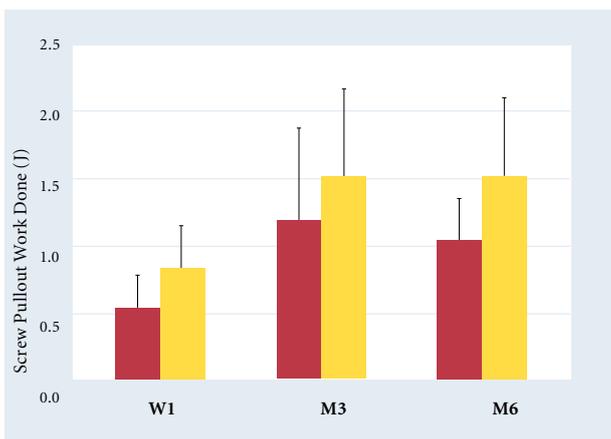


Fig. 1 Difference in Pullout Work Done ■ Control = screw alone ■ Expt = screw + BoneSource

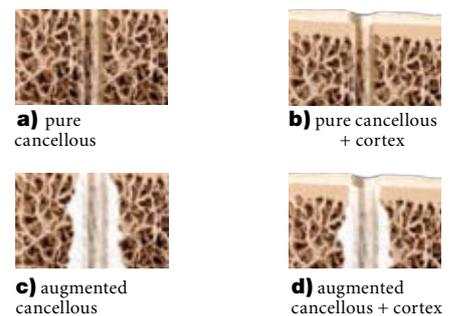


Fig. 2

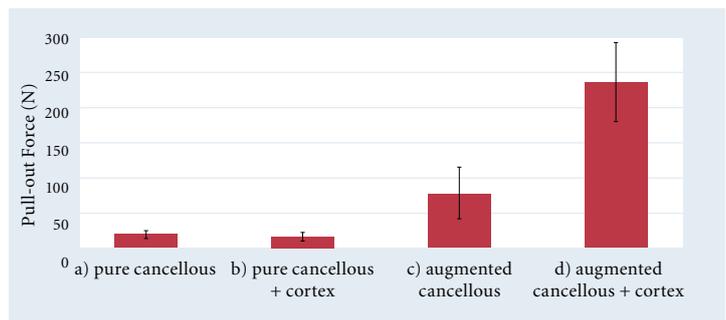


Fig. 3 Pull-out force for each test configuration

# Rationale, Features & Benefits

Another in-vitro<sup>4</sup> test was performed at the University of Bath, UK to measure the screw pull-out forces for 5mm, 4mm and 2mm cancellous bone screws in an open pore polyurethane foam, with and without HydroSet. Statistical analysis of the data clearly indicated that there was no significant difference between any augmented test groups. There was a significant difference between all the test groups and the non-augmented screws within the open pore material (Fig. 4)

**If HydroSet is used for bone augmentation, please mind the following information:**

**Warning:**

- HydroSet should not be used in areas where the surrounding bone is steoporotic, avascular or otherwise not capable of supporting or anchoring the implant.
- Care should be taken to avoid overpressurizing the device because this may lead to extrusion of the device beyond the site of its intended application and damage to the surrounding tissues
- Care should be taken to avoid overpressurizing the device because this may lead to fat embolization or embolization of the device material into the bloodstream.

**Caution:**

- Insertion of screws in hardened cement must be done in a controlled manner (slowly drilling at <1000 rpm.). Drilling of cement should begin 12 minutes after initial mixing of the cement.
- If using cement to augment screws for enhanced fixation strength, place screw into cement 2.5 to 4.5 minutes from the start of mixing.

**Contraindication:**

- HydroSet is contraindicated for use in augmenting pedicle screws.

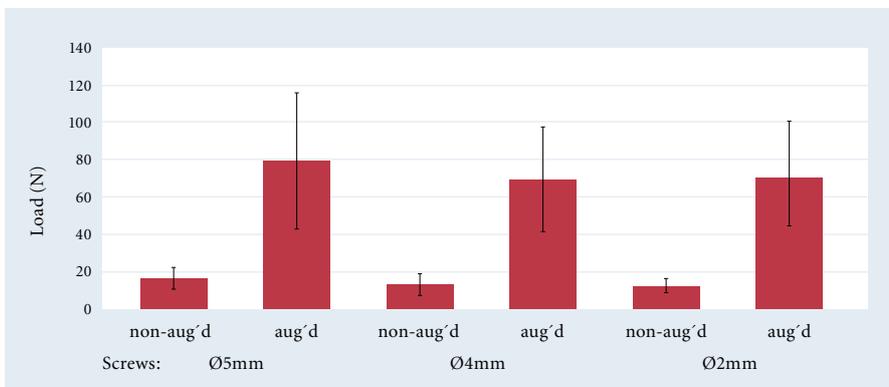


Fig. 4  
**Screw Pull-out force**

## References

- <sup>1</sup> Hess B, Insley G, Murphy M. Application properties and histological characteristics of injectable CaP bone substitutes. *Injury, Int.J.Care Injured* (2006) 37S, S3–S9
- <sup>2</sup> Leung, K S, Tam, K F, Cheung, W H. Application of injectable hydroxyapatite on implant fixation in osteoporotic goat model. ORS 2006
- <sup>3</sup> Procter P, Hess B, Murphy M, In-vitro study of screw fixation in augmented cancellous bone models. Abstract presented at ORS 2008
- <sup>4</sup> **Screw pull-out report**, Centre for Orthopaedic Biomechanics, University of Bath, UK, Dec. 2006 (T.R.1862.E503)

# Technical Details

## Steps to Implantation

### Mixing

Each kit contains one liquid-filled glass syringe and one bowl of powder.

Peel off the lid on the Liquid Blister Kit and place the inner Tyvec tray on the sterile field. Place the cement delivery syringe barrel at an angled position using the fixture aid in the blister tray to hold the syringe securely.

#### Note:

Approach the fixture aid holding the syringe at a 45 degree angle and then push the syringe onto the fixture aid to achieve a stable footing. Peel back the lid on the bowl and empty the liquid contents of the syringe into the bowl with powder (Fig. 1).

Take caution when injecting the liquid into the powder. Loss of liquid may cause a dry mixture that is difficult to inject.

#### Caution:

Ideal operating room temperatures should be between 18° and 22° C (64.4°–71.6° F).

Mix the liquid and powder thoroughly in a circular motion for 45 seconds, ensuring that all the solution has been distributed throughout the powder (Fig. 2). Compress the material against the sides of the bowl until a homogeneous, consistent paste is achieved.

#### Caution:

The cement paste may look uniformly mixed after 10–15 seconds of mixing; however, continue to mix for 45 seconds to ensure the powder is thoroughly mixed into solution. If manual implantation is desired, it is recommended to wait until 2 minutes and 30 seconds have elapsed (from the start of mixing) prior to implantation.

Transfer the paste from the mixing bowl to the delivery syringe using the supplied spatula (Fig. 3).



# Technical Details

This will allow the paste to run slowly down the syringe barrel keeping an open air pathway through the syringe assembly at all times.

The funnel comes pre-attached to the syringe barrel. Once cement transfer is complete, remove the funnel (counterclockwise direction) (Fig. 4) and attach the supplied cannula (clockwise direction) (Fig. 5).

## Caution:

If the placement of provisional hardware is required, wait until twelve minutes from the start of mixing until implantation of K-wires, plates or screws (ensuring hardware fixation is to bone).

Attach the plunger rod into the piston at the syringe barrel entrance by threading into place while keeping the syringe system vertical with the cannula pointing up (Fig. 6).

Fully load the plunger rod into the syringe barrel to remove trapped air in the syringe assembly and to accumulate the paste to the base of the syringe (Fig. 7). Removing trapped air is necessary. Trapped air will compromise injectability.

The loading process should be complete by 2 minutes and 30 seconds from the start of mixing.

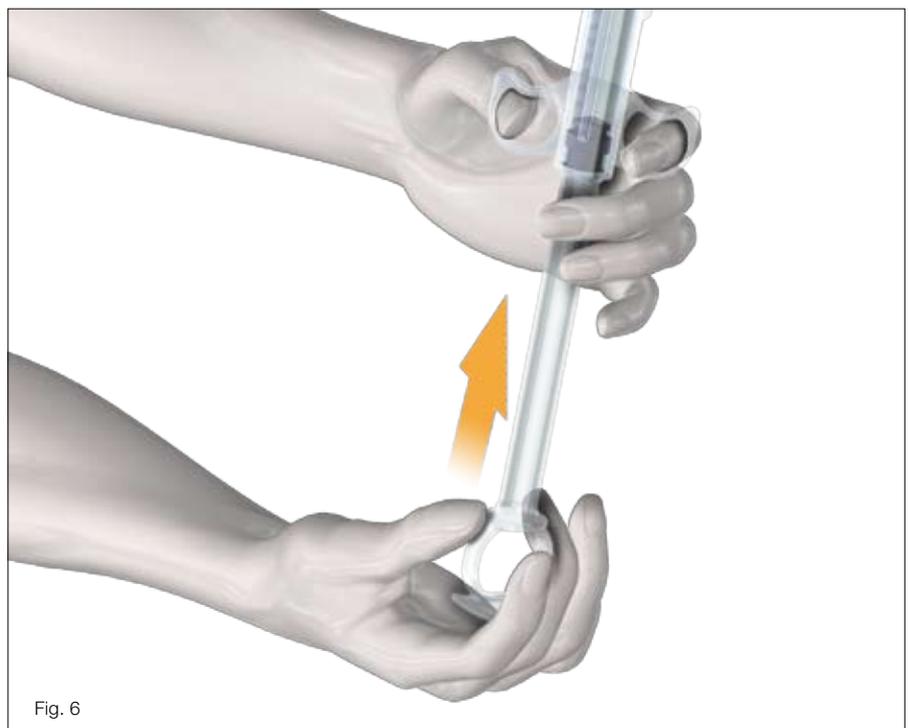
## Implantation & Sculpting

Once the syringe is fully loaded and ready to inject, there will be 2 minutes of injection time before the material begins to harden and it may become too difficult to inject.

## Caution:

Contact and heat transfer between the palm of hands and syringe barrel may decrease this injectability time window. Deliver the material to the defect site. Use the spatula to contour as desired.

**Sculpting and material manipulation must cease after 4 minutes 30 seconds from the start of mixing.**



## Set time

Allow the material to set completely before closing. Set time is 4 minutes 30 seconds to 8 minutes 30 seconds from the start of mixing (potentially longer if the defect effective temperature is less than 32° C).

**Leave the material undisturbed until it is completely set.**

# Technical Details

## Distal Radius Void Filling

### Plate Technique

**1. Perform a volar approach to the distal radius.** Additional dorsal approach may be necessary if direct visualization of the articular surface is required.

**2. Obtain preliminary reduction of the articular surface.** Temporary fixation with K-wires is helpful in stabilizing the elevated articular fragments until the HydroSet Bone Substitute or definitive hardware are placed.

**In preparation for use, thoroughly mix the liquid and HydroSet powder for 45 seconds.**

**Note:**  
Perform either Step 3 or Step 4.

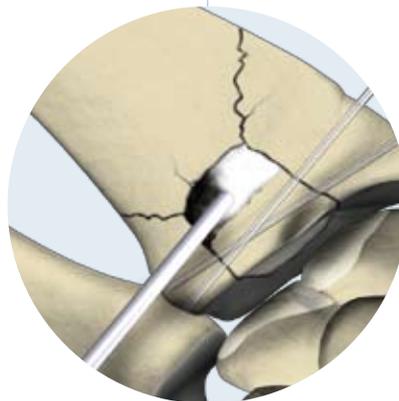
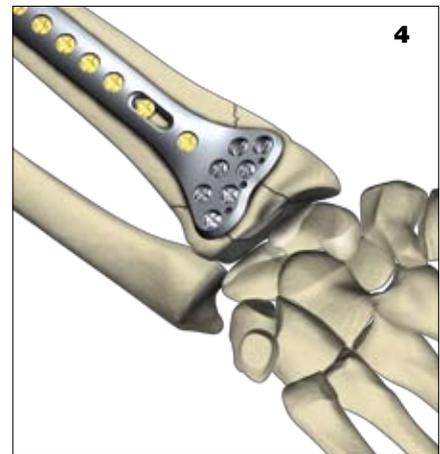
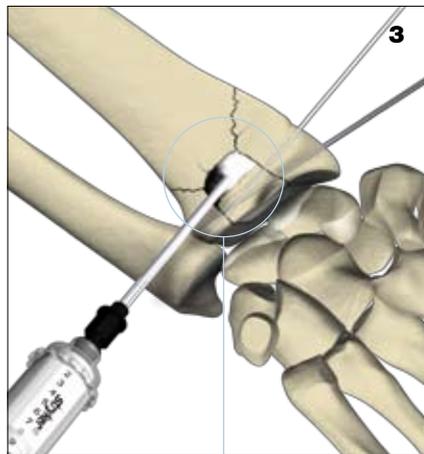
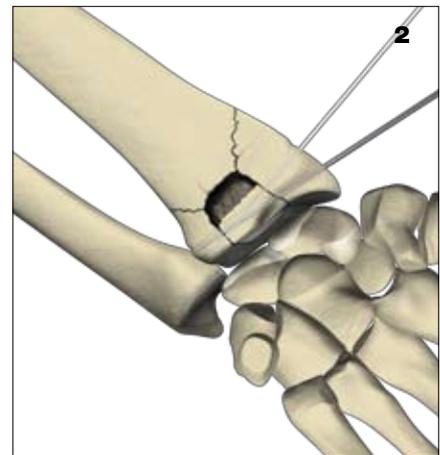
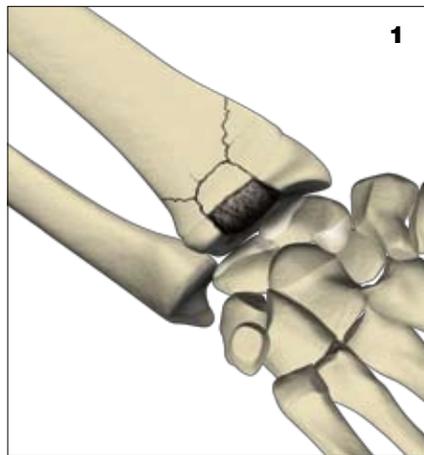
**3. Inject the HydroSet Bone Substitute** using the provided syringe and cannula directly into the residual defect. After the cement has set, follow with placement of definitive hardware. Additional fragment specific plates may be placed as necessary.

OR

**4. Place the volar plate** and inject the HydroSet Bone Substitute using the provided syringe and Cannula under fluoroscopic guidance. The cannula may be inserted through an exposed fracture line. The HydroSet is then injected under fluoroscopic control to minimize extrusion outside of the defect.

### Caution:

For VariAx Distal Radius plates\*, a 12 gauge cannula (OD 2.8mm) or smaller to pass through the hole in the plate may be required as the standard 8 gauge cannula (OD 4.2mm) provided might be too wide for this indication.



### Note:

Screw fixation must be provided by bone.

### Note:

Bone augmentation with HydroSet can be applied before insertion of the fixation/locking screws in cancellous bone. Please refer to page 14 for the instruction for use of the HydroSet for bone augmentation.

\* For more information about the VariAx Distal Radius Locking Plate System, please refer to the Literature Number: 90-07800 or 90-70801

# Technical Details

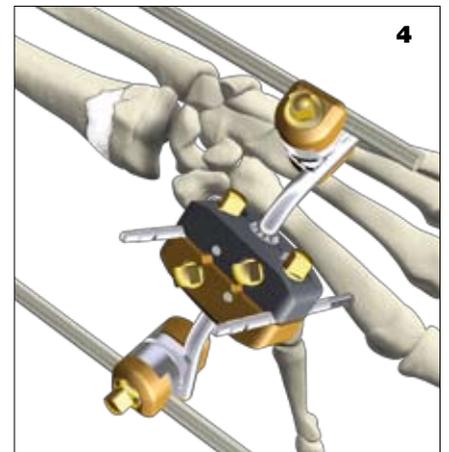
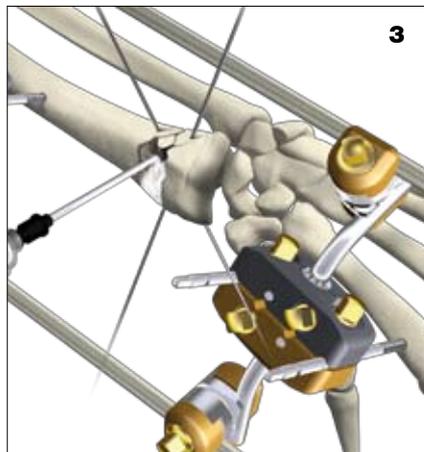
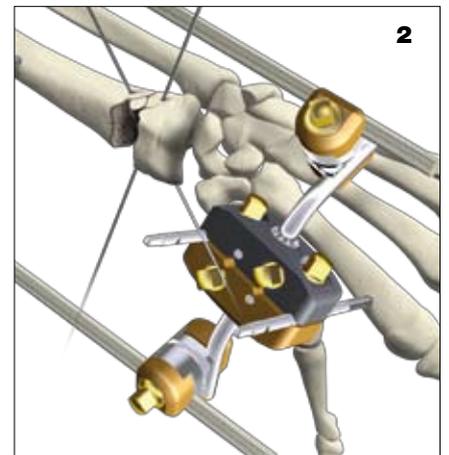
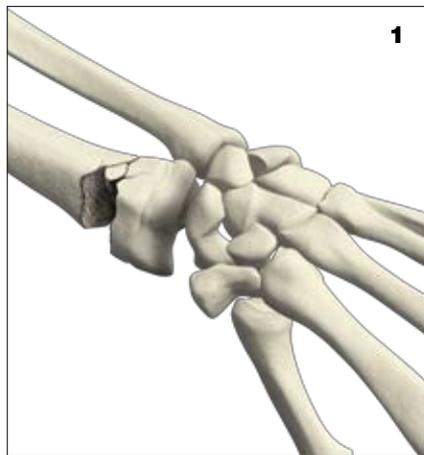
## Distal Radius Void Filling

### External Fixator Technique

- 1. Place an external fixator\*** in accordance with the manufacturer's technique.
- 2. Apply distraction** across the wrist with the external fixator.
- 3. Place K-wires** into any unreduced fragments and manipulate to adjust the reduction and maintain preliminary fixation. Additional wires are placed as needed to achieve adequate fracture stability.

**In preparation for use, thoroughly mix the liquid and HydroSet powder for 45 seconds.**

- 4. Place the HydroSet cannula** into the fracture defect through an exposed fracture line or through a cortical drill hole. The HydroSet Bone Substitute can be injected under fluoroscopic control to minimize extrusion into the soft tissues.



**Note:**  
Hardware fixation must be provided by bone.

\*For more information about Stryker External Fixation Systems please refer to following Literature Numbers:  
5075-1-500 Hoffmann II Compact Brochure  
5075-1-600 Hoffmann II Compact MRI Brochure

# Technical Details

## Tibial Plateau Void Filling

### Plate Technique

#### 1. Obtain anterolateral exposure.

Submeniscal arthrotomy may be useful for direct joint visualization of the articular surface (optional).

#### 2. Reduce the articular surface by:

**Option 1** - Direct elevation of depressed articular fragments.

**Option 2** - Indirect elevation of depressed articular fragments through cortical window (medial or lateral).

Temporary fixation with K-wires may be helpful in stabilizing the elevated articular fragments until HydroSet Bone Substitute or definitive hardware is placed.

**In preparation for use, thoroughly mix the liquid and HydroSet powder for 45 seconds.**

#### **Note:**

Perform either Step 3 or Step 4.

#### 3. Inject the HydroSet Bone

**Substitute** using the provided syringe and cannula directly into the residual defect. After the cement has set, place the definitive hardware.

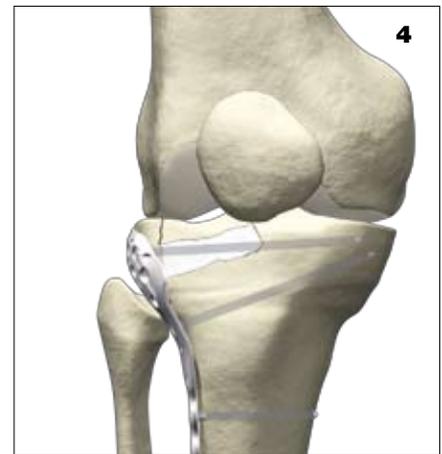
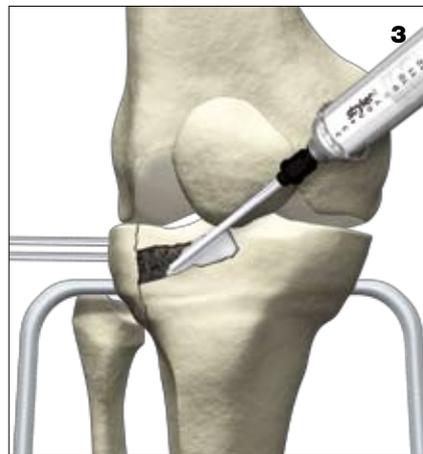
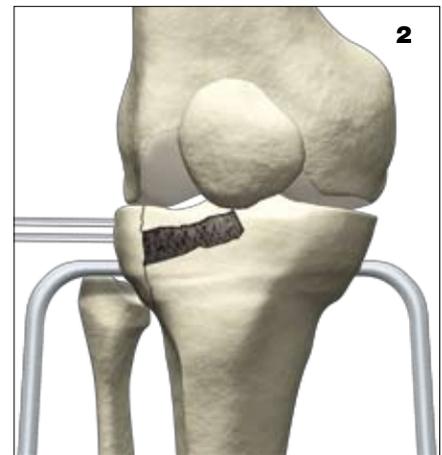
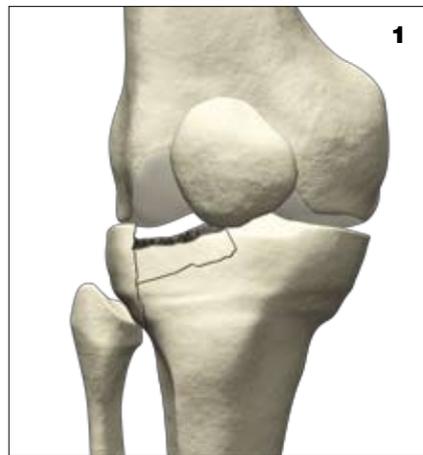
#### **Note:**

**Bone augmentation with HydroSet can be applied before insertion of the fixation/locking screws in cancellous bone. Please refer to page 14 for the instruction for use of the HydroSet for bone augmentation.**

OR

#### 4. Place the definitive hardware and inject the HydroSet Bone

**Substitute** using the provided syringe and cannula under fluoroscopic guidance. The 8ga cannula may be inserted through an exposed fracture line or a 4.2mm drill hole. The HydroSet is then injected under fluoroscopic control to minimize extrusion outside of the defect.



#### **Caution:**

For AxSOS Proximal Tibia\* plates, a 10 gauge cannula (OD 3.4mm) or smaller to pass through the hole in the plate may be required as the standard 8 gauge cannula (OD 4.2mm) provided might be too wide for this indication.

#### **Note:**

**Screw fixation must be provided by bone.**

\*For more information about the AxSOS Proximal Tibia Locking Plate System please refer to the Literature Number: 982278

# Technical Details

## Tibial Pilon Void Filling

### Plate Technique

**1. Obtain exposure of distal tibia.** Anterolateral or anteromedial exposures are standard.

**2. Obtain preliminary reduction of the articular surface.** K-wires are useful to temporarily maintain articular reduction. Reduction can be obtained by direct manipulation of the depressed fragments or indirectly by the use of tamps and elevators placed through cortical windows.

**In preparation for use, thoroughly mix the liquid and HydroSet powder for 45 seconds.**

**Note:**

Perform either Step 3 or Step 4.

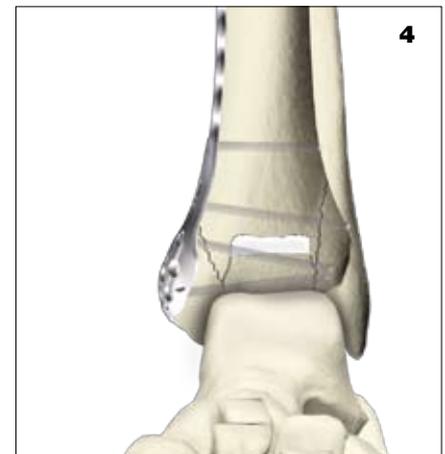
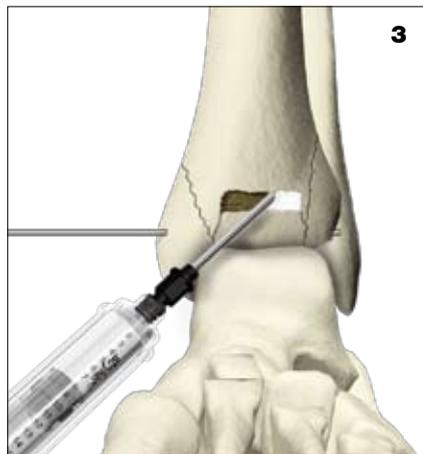
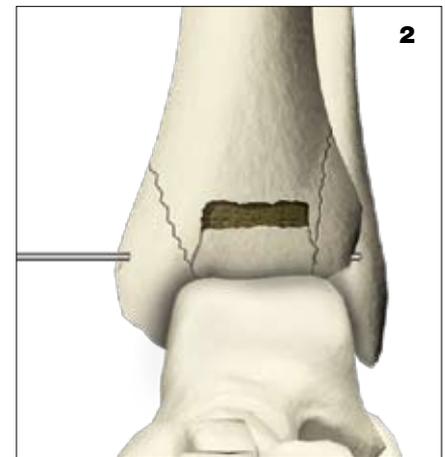
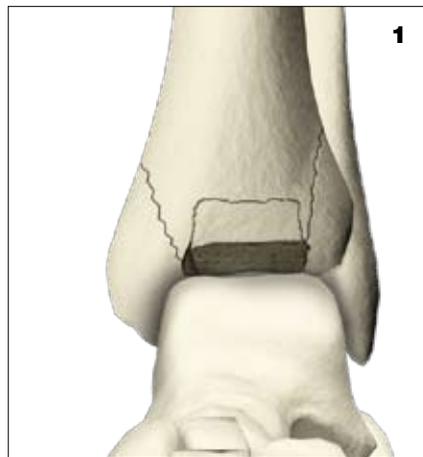
**3. Inject the HydroSet Bone Substitute** using the provided syringe and cannula directly into the residual defect. After the HydroSet has set, follow with placement of definitive hardware.

**Note:**

**Bone augmentation with HydroSet can be applied before insertion of the fixation/locking screws in cancellous bone. Please refer to page 14 for the instruction for use of the HydroSet for bone augmentation.**

OR

**4. Place the definitive hardware and inject the HydroSet Bone Substitute** using the provided syringe and cannula under fluoroscopic guidance. The 8ga cannula may be inserted through an exposed fracture line or a 4.2mm drill hole. HydroSet can be injected under fluoroscopic control to minimize extrusion outside of the defect.



**Caution:**

For AxSOS Distal Tibia\* plates, a 10 gauge cannula (OD 3.4mm) or smaller to pass through the hole in the plate may be required as the standard 8 gauge cannula (OD 4.2mm) provided might be too wide for this indication.

**Note:**

**Screw fixation must be provided by bone.**

\*For more information about the AxSOS Distal Tibia Locking Plate System please refer to the Literature Number: 982279

# Technical Details

## Bone Augmentation\*

### Plate Technique

With “locking screw-plate systems” results have improved compared with conventional plates and screws when dealing with weak bone. However, bone augmentation with calcium phosphate cement can potentially further improve the screw fixation of the “angle stable construction” in an osteoporotic bone. The cement may potentially provide a more stable surrounding around the metal that can result in a more stable construction than without augmentation. When using HydroSet for bone augmentation with a plate and screw fixation system, the following surgical steps are recommended:

**1. Obtain preliminary reduction of the articular surface.** K-wires are useful to temporarily maintain articular reduction.

Reduction can be obtained by direct manipulation of the depressed fragments or indirectly by the use of tamps and elevators placed through cortical windows.

**2. Locate the plate on bone to stabilize the fracture** (use K-wire for initial stability)

**3. Drill the holes for screws** according to the respective implant technical requirements.

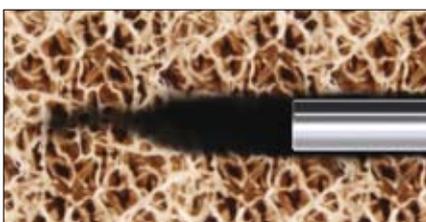


Fig. 1a



Fig. 2a

### Warning:

Use of HydroSet in defects as a sole anchorage site for fixation implants is a contraindication. Screw should rely on the surrounding cancellous bone for definitive fixation and HydroSet is used to augment the cancellous bone to enhance the screw fixation strength. Inspect and remove extra HydroSet cement debris from the defect after injection and/or drilling and tapping for screw placement to eliminate potential for defect soreness, redness, or skin irritation.

**4. Insert one or two screws** to keep the plate stable.

**5. Prepare HydroSet and inject the cement** into the drilled holes under fluoroscopic guidance.

- Use the back-fill technique (filling the screw hole in retrograde fashion) if the OD of the cannula is smaller than the drill used (Fig. 1a and 1b)

or

- Use a “pressurized” technique (filling the screw hole in antegrade fashion, with the tip of the cannula at the screw hole entrance) if the OD of the cannula is larger than the drill used (Fig. 2a and 2b).



Fig. 1b



Fig. 2b

**6. Insert the screws into the hole** while the cement is still soft (approx. 2 min after injection).

### Caution:

Do not use HydroSet for bone augmentation of lag screws. When using locking plates, always lag before you lock.

### Note:

**For VariAx Distal Radius plates, a 12 gauge cannula (OD 2.8mm) or smaller to pass through the hole in the plate may be required as the standard 8 gauge cannula (OD 4.2mm) provided might be too wide for this indication.**

**For AxSOS Proximal Humerus, Proximal and Distal Tibia plates, a 10 gauge cannula (OD 3.4mm) or smaller to pass through the hole of the plate may be required as the standard 8 gauge cannula (OD 4.2mm) provided might be too wide for this indication.**

The amount of HydroSet needed is estimated to be 3–5cc of cement for augmenting 6–10 screws. (depending on screw diameter and length)

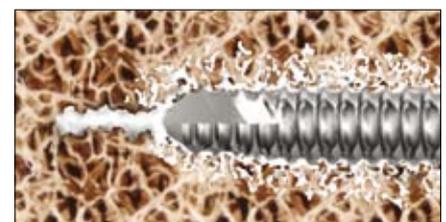


Fig. 1c



Fig. 2c

\*This indication is not cleared for use in the U.S.

# Ordering Information



REF	Description
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397003	3cc HydroSet Bone Substitute
397005	5cc HydroSet Bone Substitute
397010	10cc HydroSet Bone Substitute
397015	15cc HydroSet Bone Substitute
707010	8ga x 10cm cannula (1 carton box with 10 units )
397022	10ga x 10cm cannula (1 carton box with 10 units )
397024	12ga x 7.5cm cannula (1 carton box with 10 units )

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**Joint Replacements**

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**Trauma, Extremities & Deformities**

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**Craniomaxillofacial**

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**Spine**

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**Biologics**

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**Surgical Products**

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**Neuro & ENT**

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**Interventional Pain**

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**Navigation**

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**Endoscopy**

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**Communications**

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**Imaging**

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**Patient Handling Equipment**

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**EMS Equipment**

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