PRO-DENSE™

Injectable Regenerative Graft

COMPREHENSIVE
SURGICAL TECHNIQUE
BOOKLET

WRIGHT™
FOCUSED EXCELLENCE

Contents

Wright recognizes that proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience, and patient condition. Prior to use of the system, the surgeon should refer to the product Instructions For Use package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions For Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the Instructions For Use package inserts are available on wright.com under the link for Prescribing Information.

Please contact your local Wright representative for product availability.

Introduction

PRO-DENSE™ Bone Graft Substitute paste consists of pre-measured surgical grade calcium sulfate and calcium phosphate, pre-measured neutralized glycolic acid mixing solution, and the tools necessary to mix the components into a paste and inject the material into the defect site. When mixed and injected according to directions, PRO-DENSE Bone Graft Substitute paste will harden in situ and provide temporary intraoperative support. PRO-DENSE Bone Graft Substitute products are provided sterile for single patient use.

Indications

PRO-DENSE resultant paste is intended for use as a bone graft substitute to be injected or digitally packed into open bone voids gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities and pelvis) to cure in situ. These open bone voids may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥6 years old), surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process. The PRO-DENSE paste cured in situ provides an open void/gap filler that can augment provisional hardware (e.g. K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process. PRO-DENSE is provided sterile for single use only.

For the PRO-DENSE Core Decompression Procedure Kit: The PRO-DENSE Core Decompression Procedure Kit, consisting of a bone void filler and manual surgical instruments, is intended to be used during core decompression procedures. The bone void filler component resorbs and is replaced with bone during the healing process. The bone void filler included in the PRO-DENSE Core Decompression Procedure Kit is not intended to be used as a load-bearing device.

For the Mixing and Delivery System: The Mixing and Delivery syringe is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

Contraindications

The PRO-DENSE Bone Graft Substitute injectable paste is contraindicated where the device is intended as structural support in load-bearing bone and in articulating surfaces. Conditions representing relative contraindications include:

- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative bone disease
- Closed bone void/gap
- Pregnancy
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol
- Hypercalcemia
- Renal compromised patients
- Patients with a history of or active Pott's disease

CYST

TWO NEEDLE PERCUNTANEOUS SURGICAL TECHNIQUE FOR BENIGN BONE CYSTS AND TUMORS

Design Surgeon

Matthew J. Seidel, MD

Orthopaedic Surgical
Oncology of Arizona

Assistant Professor of Orthopedic Surgery,
University of Arizona

Medical Director, Orthopaedic Oncology, Piper
Cancer Center, Scottsdale Healthcare

Surgical Technique

A percutaneous technique can minimize soft tissue disruption, decrease pain and may improve postoperative rehabilitation. The following technique is most appropriate for bone cysts that are filled with fluid which usually affect the long bones.

IMPORTANT: During grafting, ensure that the cyst cavity is not pressurized.

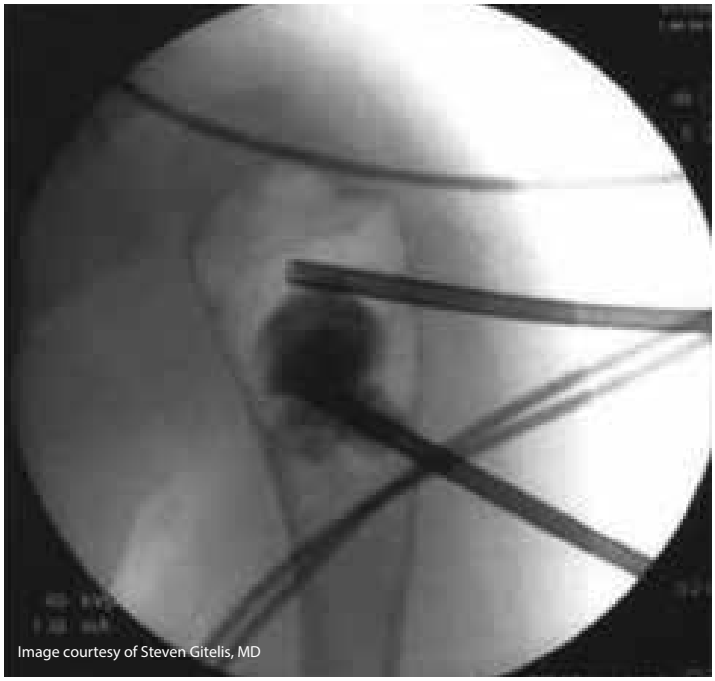
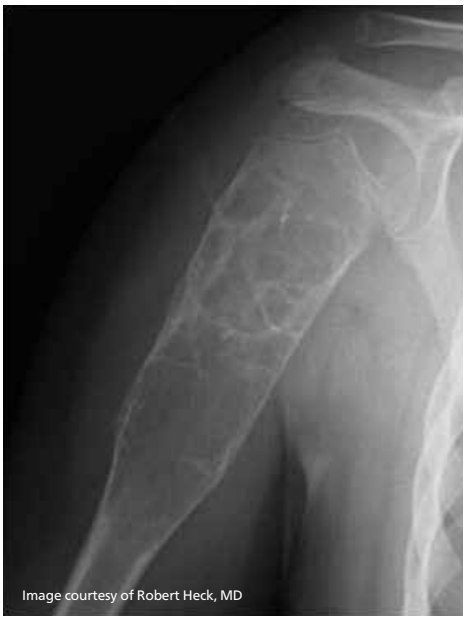


Image courtesy of Steven Gitelis, MD

After a percutaneous surgical treatment has been chosen, access the lesion taking care to avoid important neurovascular structures.



| Figure 1 - Twelve Year Old Male Pre-Op

Step 1: Setup

Patient is placed supine on a radiolucent table. The contralateral arm is tucked so that the C-Arm can be brought in from the opposite side. The entire arm is then prepped and draped in a sterile fashion so that the arm can be rotated during the procedure to allow AP and Lateral views on the C-Arm.

When accessing lower extremity cysts, a standard extremity draping technique is used and the C-Arm is again brought in from the opposite side of the table. Tourniquet is generally not necessary with the percutaneous technique but is ultimately up to the discretion of the surgeon.

Step 2: Approach

The volume of the cyst can be estimated either on pre-operative x-rays/scans or after draping by using a large (eg 60cc) syringe and placing it over the cyst. Under C-Arm guidance the plunger of the syringe can be moved so that the volume in the syringe approximates the volume of the cyst. This step is important as the appropriate volume PRO-DENSE kit will need to be opened prior to the next step. The 7cc,10cc, 12cc, and 15cc kits contain two cannulas with trocars. The cannulas are used in the aspiration and injection and the sharp end of the trocars can be used for debridement.

Access to the cyst is obtained through two small incisions. Two trocars are placed, one in the proximal most aspect of the cyst and the other in the distal most aspect. Care is taken to avoid penetrating the physis.

Step 3: Excise the lesion and irrigate

After the cyst is entered from above and below, aspiration of the cyst is performed.

Using two large syringes (e.g. 60cc not included in PRO-DENSE kit) and sterile saline, the cyst can be lavaged by injecting through one trocar and aspirating through the other. When possible, this process continues until the lavage fluid is clear.


Image courtesy of Matthew Seidel, MD

Curettage of the cyst:

» **Trocar:** Using the sharp trocar from the cannula, the trocar can be passed into the cyst cavity and used to curettage the walls of the cyst. This is usually done from both entry sites and the trocars can be bent with a standard plier to allow for access to the entire cyst. Care is taken during the bending process as the tips of the trocars are sharp.

Curettage of the cyst is continued until the surgeon feels adequate removal of the cyst lining and any internal septations has been achieved. Curettage of the area of the cyst opposed to the physis in active cysts is not recommended due to the risk of growth arrest.

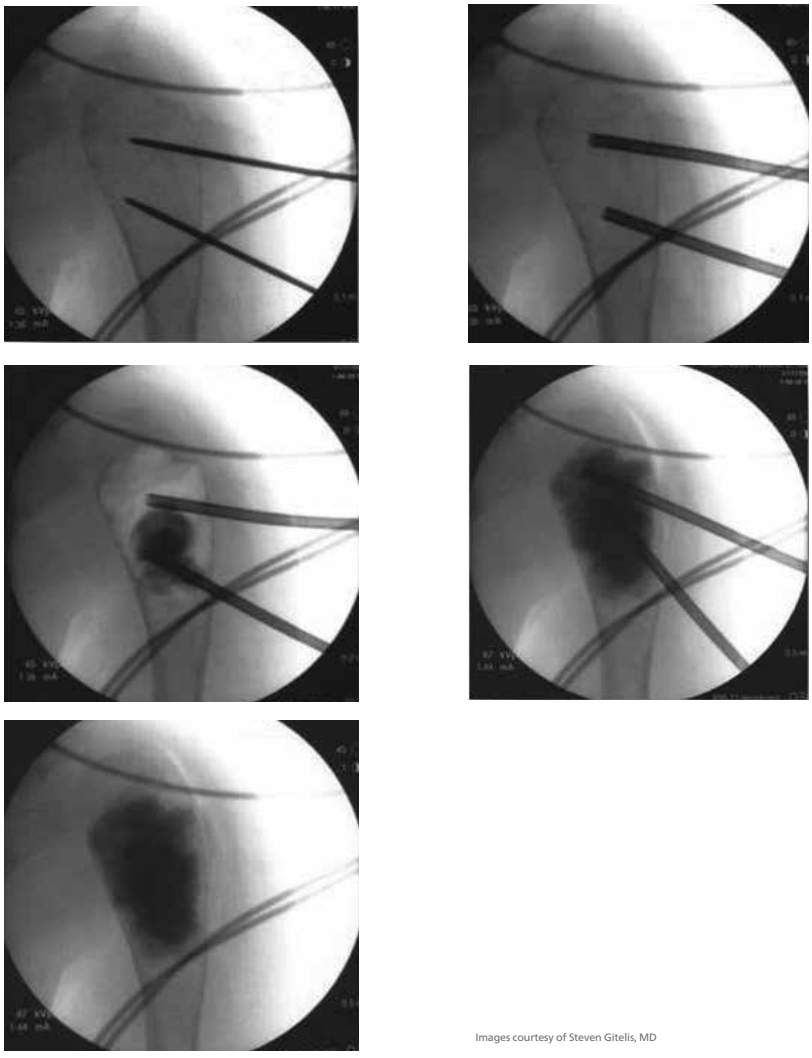
After curettage, the cavity is again lavaged with sterile saline as in the previous step to clear all debris. If the surgeon feels necessary, this debris can be collected and sent for pathology.

Step 4: Grafting with PRO-DENSE

Graft injection may be completed through either of the cannulas. In order to ensure the cavity remains free of liquid, blood or other debris during the injection process, the cannula not being used for injection is attached to suction. C-arm guidance is used to direct the grafting cannula so few or no fluid/air pockets occur within the cavity or graft.

During the injection process, some of the graft may extrude out of the bone and into the soft tissues. The excess graft can usually be irrigated and suctioned away.

IMPORTANT: During grafting, ensure that the cyst cavity is not pressurized.



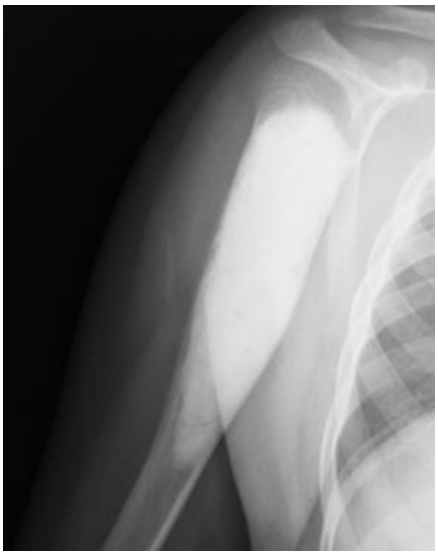
Images courtesy of Steven Gitelis, MD

Postoperative Protocol

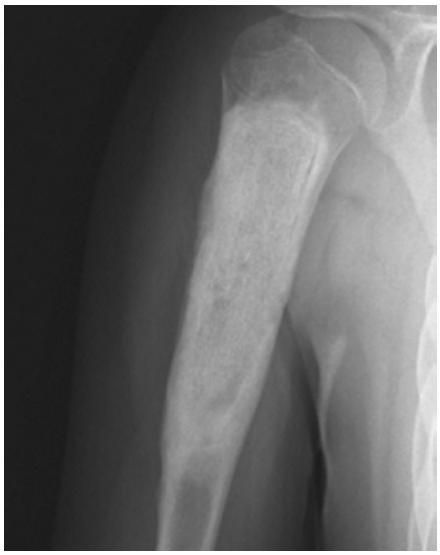
The patient is often placed in a sling for two weeks after surgery for upper extremity cysts or made non weight bearing for lower extremity lesions.

Patients are then followed as clinically appropriate and evaluated to determine level of activity, usually at 4-12 week intervals with X-RAY to ensure full incorporation of the graft.

Long term follow up is dictated by lesion type and the surgeon's clinical judgment of risk of recurrence.



2 Weeks Post Op



1 Year Post Op

Images courtesy of Robert Heck, MD

TRAUMA

Introduction

The reduction of complex fractures while maintaining a well aligned congruent joint is key to a satisfactory clinical outcome and is important for the return to activity. Stable internal or external fixation supports mobility and weight bearing. Proper fixation techniques of fractures (ORIF, CREF) is vital to the healing process, however in some situations a biologic augmentation is needed to fill a void and supplement the hardware used to repair these pathologies.

For these reasons, the use of a Bone Graft Substitute such as PRO-DENSE is suitable to provide in situ augmentation to provisional hardware to help support bone fragments during the surgical procedure.

PRO-DENSE is shown to provide the high compressive strength needed to augment traditional repairs, while also providing a reliable pathway to predictable DENSE bone regeneration.*

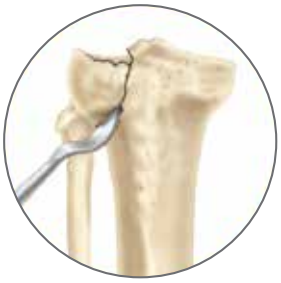
**All claims are based on a critically sized canine proximal humerus defect model. It is unknown how results from the canine model compare with clinical results in humans. Data on file at Wright.*

Surgical Technique

TRAUMA EXAMPLE 1:

TIBIAL PLATEAU FRACTURE

Presented by J. Tracy Watson, M.D., St. Louis, MO

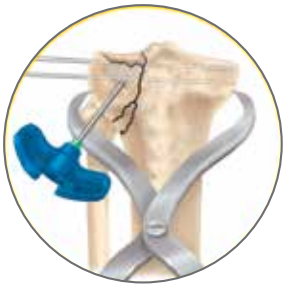


STEP 1 GAIN EXPOSURE AND DISIMPACT FRAGMENTS

Care should be taken to plan a relatively straight full-thickness incision such that wound nexrosis can be minimized; periosteal stripping should be avoided. Access to the depressed surface can be obtained directly through the fracture line at the base of the condylar fragment or a cortical window can be made utilizing numerous drill holes and an osteotome. Once adequate exposure has been obtained, place a curved elevator distal to the fragments to facilitate disimpaction under flouroscopy. Periosteal stripping should be avoided.

STEP 2 STABILIZE FRAGMENTS

Although the depressed fragments can often be elevated en masse, the reduction is often tenuous and unstable. In this case, supplemental Kirschner wires or provisional instrumentation can be utilized to stabilize reduction of the larger condylar fragments.

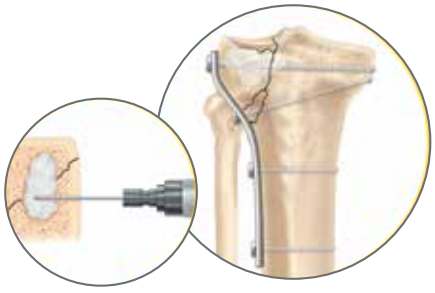


STEP 3 FINALIZE ARTICULAR REDUCTION

Once the fragments have been reduced and stabilized, insert the appropriate sized injection needle into the compression defect. Positioning of the needle and appropriate reduction of the articular surface can be confirmed via flouroscopy.

STEP 4 INJECT PRO-DENSE TO AUGMENT PROVISIONAL HARDWARE

With provisional hardware in position and the PRO-DENSE Graft delivery needle in place, prepare the PRO-DENSE Graft using the mixing instructions provided in the kit. After graft preparation, dock the syringe onto the pre-placed needle. With flouroscopy assistance, begin introduction of the PRO-DENSE Graft material into the compression defect. Injection delivery time is approximately 2 1/2 minutes.



STEP 5 PLACE FINAL HARDWARE

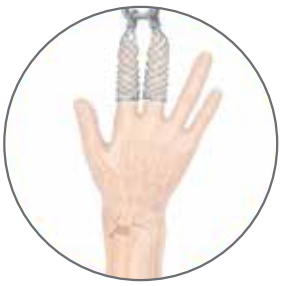
Fixation hardware may be placed with standard drilling or use of self-tapping screws before the graft is set.

NOTE: Always ensure distal screw fixation is within bone.

TRAUMA EXAMPLE 2:

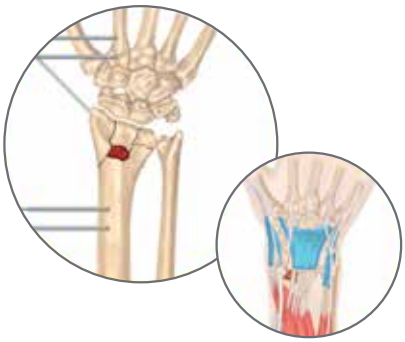
DISTAL RADIUS FRACTURE

Presented by Keith Raskin, M.D., New York, NY



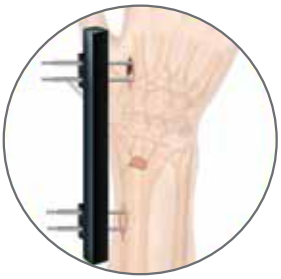
STEP 1 PERFORM CLOSED REDUCTION

After adequate regional anesthesia, the fracture is grossly realigned through closed manipulation, in preparation for external fixation.



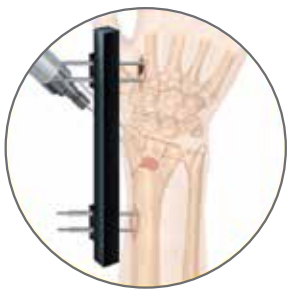
STEP 2 PLACE EXTERNAL FIXATION

The distal pin site is approached through a short longitudinal incision along the dorsoradial border of the index metacarpal. The terminalsensory radial nerve branches are well protected as the pins are inserted with bicortical purchase under direct visualization. The proximal pins are inserted in a similar fashion through a separate incision along the dorsoradial border of the radial shaft approximately 3-5cm proximal to the fracture site. The radial sensory nerve is identified and protected as the pins are inserted under direct visualization.



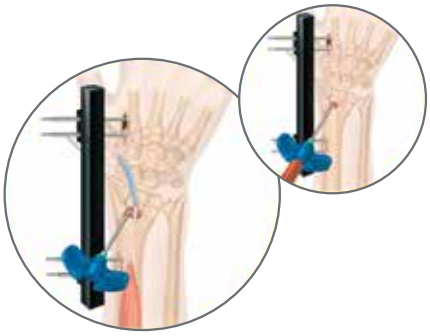
STEP 3 APPLY LIGAMENTOTAXIS

Ligamentotaxis is applied across the fracture site through the application of the external fixator of choice.



STEP 4 INSERT INTRAFOCAL PINS

Once the deforming force of the carpus has been neutralized through the external fixation, the fracture can be further manipulated with the use of smooth .045" and .062" smooth K-Wires. These wires can be safely inserted from the radial styloid region or through accepted intrafocal pinning technique.



Step 5 PLACE DELIVERY NEEDLE

Once the fracture is stabilized with external fixation and percutaneous K-Wire insertion, the metaphyseal void can be obliterated without the need for open bone grafting technique. The PRO-DENSE Graft injection cannula is inserted along the radial border of Lister's Tubercle. This avoids injury to the adjacent thumb extensor tendon and radial sensory nerve branches. Fluoroscopic assistance is recommended. Once the cannula is properly placed, the hematoma is evacuated and the PRO-DENSE Graft is prepared according to the mixing instructions provided in the kit.

STEP 6 INJECT

After graft preparation, dock the syringe onto the pre-placed needle and begin injection. A gentle windshield-wiper motion assists in the completion of filling. Injection delivery time is approximately 2 1/2 minutes.

STEP 7 APPLY ADDITIONAL PINS

Final adjustment of the fracture can be performed by adding wires inserted through the PRO-DENSE Graft before the graft has set.

NOTE: Always ensure distal wire fixation is within bone.

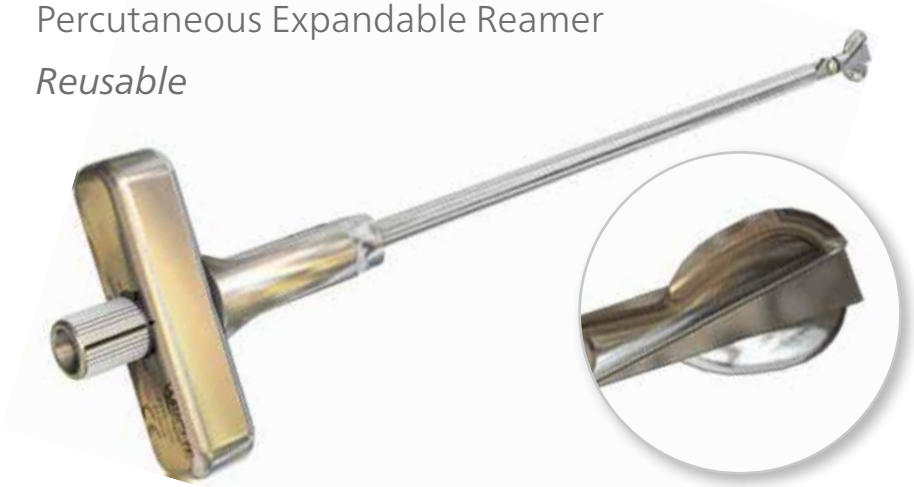
CORE DECOMPRESSION

X-REAM™ PERCUNTANEOUS EXPANDABLE REAMER & PRO-DENSE™ CORE DECOMPRESSION PROCEDURE KIT

Advanced Core Decompression System Product Introduction

X-REAM
Percutaneous Expandable Reamer

Reusable



PRO-DENSE
Core Decompression Procedure Kit

3.2mm Fluted Guidewire | Tissue Protector | 9.0mm Drill Bit | Working Cannula & Obturator | Curette | Tamp

Instrumentation and Grafting

The Advanced Core Decompression System includes the reusable X-REAM Percutaneous Expandable Reamer that allows optimized debridement when used in conjunction with the PRO-DENSE Core Decompression Procedure Kit (CDK) to prepare for a standard core decompression. The procedure kit, sold separately, includes single-use, disposable instruments that are designed to efficiently facilitate a standard core decompression, and PRO-DENSE Injectable Graft for backfilling the surgically-created defect.

NOTE: The PRO-DENSE Core Decompression Procedure Kit is designed for single site usage.

Minimally-Invasive Technique

When properly used, the expandable reamer tool allows optimal debridement of dead bone through a small incision.

Fast, Efficient Procedure

Ready-to-use disposable instruments for a standard core decompression.

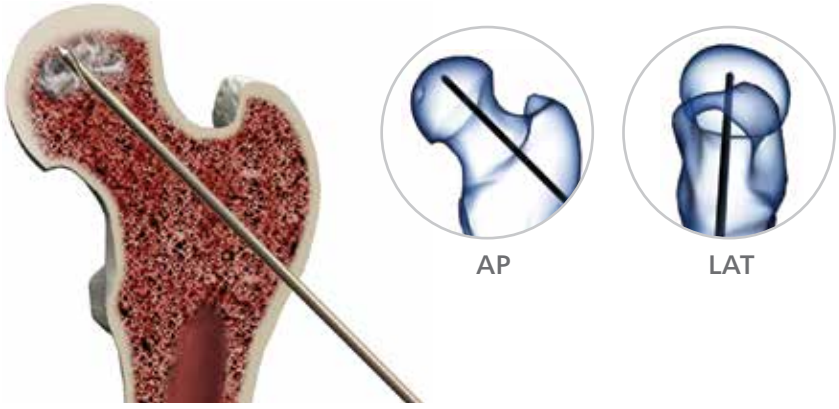
Core Decompression of the Femoral Head Surgical Technique

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting Wright Medical.

Remove all plastic caps on instruments prior to use.

Step 1 | ACCESS LESION

Use a 2cm stab incision for access. Under fluoroscopic guidance (both AP & LAT views), introduce the 3.2mm fluted guidewire into the lesion. Most lesions are anterior and superior.

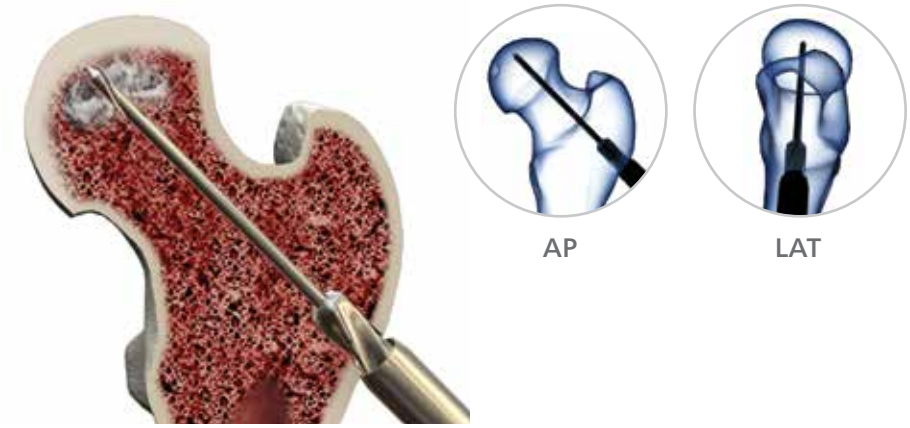


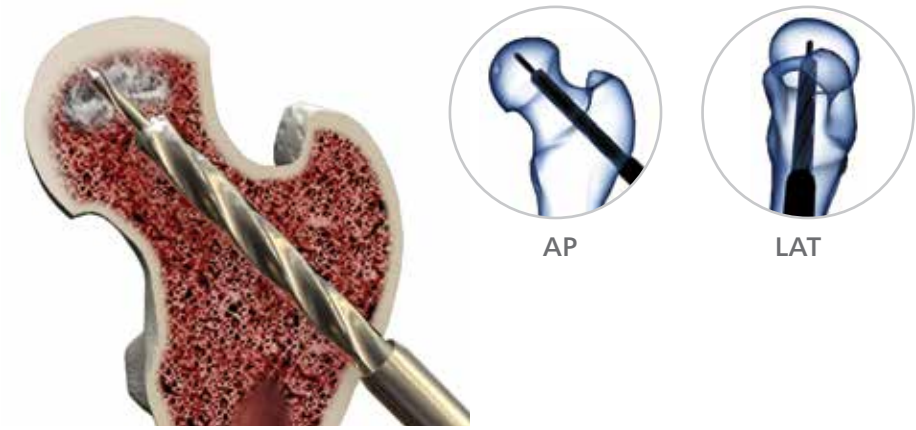
Step 2

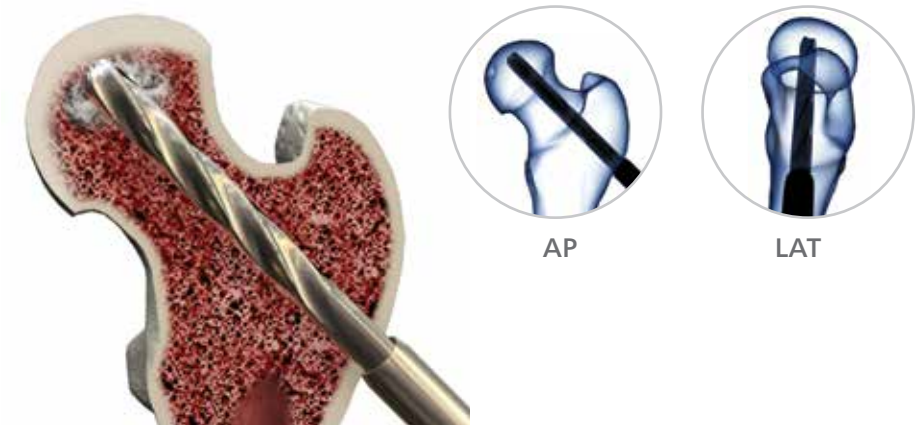
Introduce the tissue protector over the guidewire and down to the bone prior to drilling.

Step 3 | DECOMPRESS FEMORAL HEAD

Using the 9mm cannulated drill bit, decompress the femoral head by drilling a core approximately 5mm from the endosteal surface of the femoral head. AP and LAT fluoroscopic views should be used to confirm direction.

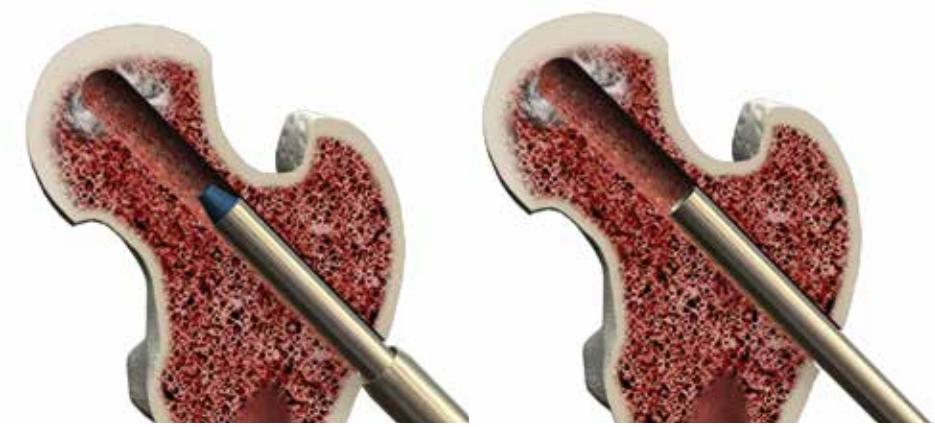






Step 4 | PLACE WORKING CANNULA

Maintain placement of the tissue protector and remove the drill bit and guidewire. Place the working cannula with obturator through the tissue protector and into the core. Position the working cannula up into the core several centimeters (fit should be snug). Remove the tissue protector and obturator.



For Standard Debridement with PRO-DENSE Core Decompression Procedure Kit

Step 5 | DEBRIDE DEAD BONE

Standard debridement can be accomplished using the curette and/or the fluted guidewire.

NOTE: If not using the X-REAM tool, go to step 9.

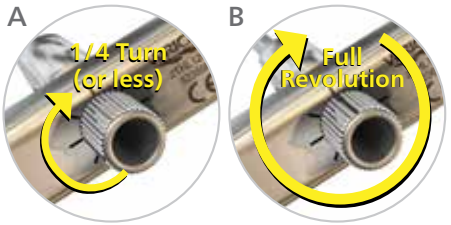
Step 6 | ADVANCED DEBRIDEMENT

Advanced debridement can be carried out using the X-REAM Percutaneous Expandable Reamer.

REAMER PLACEMENT

Introduce the Reamer through the working cannula confirming placement with fluoro (AP & LAT views).

Step 7 | DEBRIDE DEAD BONE



A) Turn the blade control knob ¼ turn (or less) clockwise.

*NOTE: It is **extremely important** not to open the blades too far prior to rotating the tool. Otherwise, blade failure will occur.*

B) Rotate the entire instrument two full revolutions.

C) Repeat steps A & B until desired expansion is achieved. Use fluoro as needed to monitor the blade expansion.

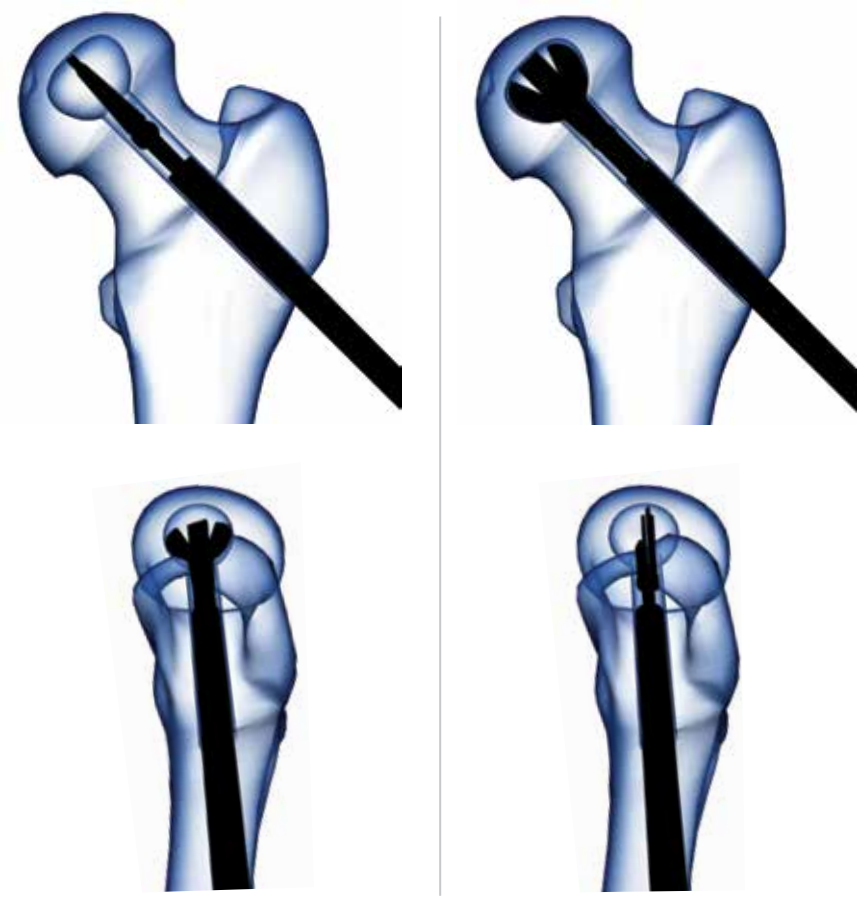
D) If the blades are opened too far prior to cutting, turn the blade control knob counterclockwise until it stops and withdraw the instrument into the working cannula to collapse the blades. Reinsert the instrument and begin again at Step 7A.

NOTE: The instrument must be withdrawn back into the working cannula in order to collapse the blade.

X-REAM Tool *in situ* Expansion

AP

LAT



WARNING: During expansion, frequently confirm blade position under fluoro (BOTH AP and LAT views). Rotate instrument so blade width can be clearly determined (i.e. blades are perpendicular to view).

CAUTION: Be sure not to violate the subchondral plate during the blade expansion.

Step 8 | REMOVE X-REAM TOOL

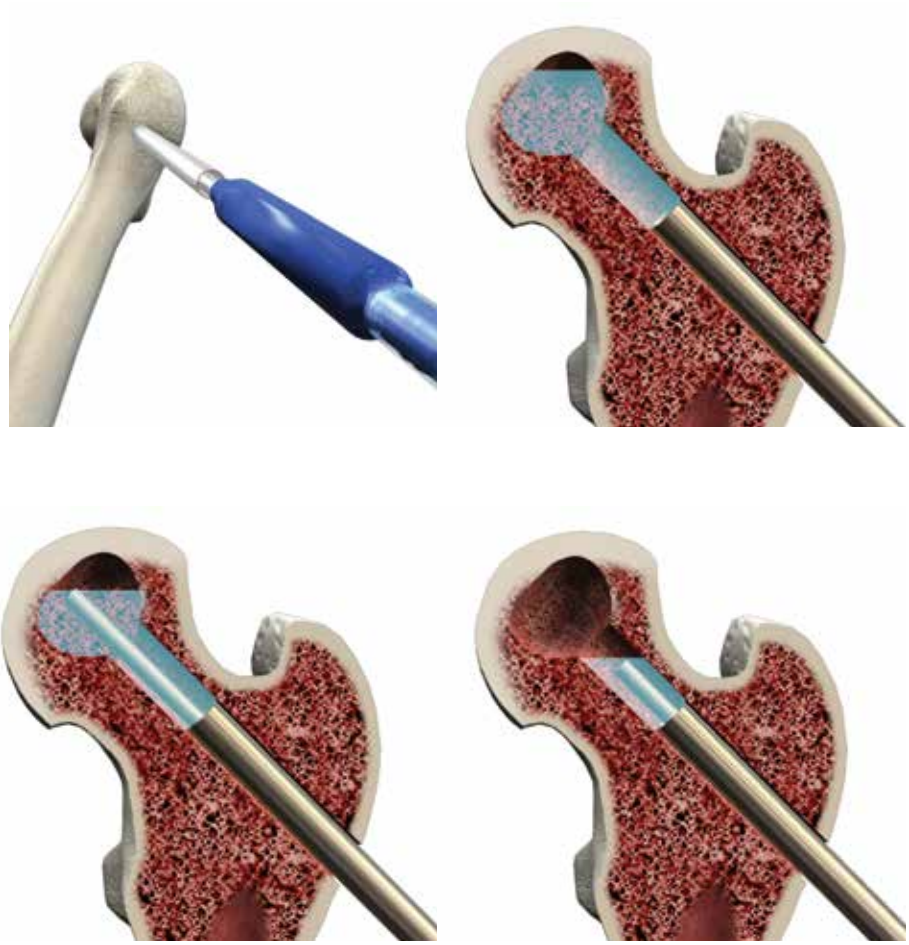
Once debridement is complete, turn the blade control knob counterclockwise until it stops.

Simply withdraw the X-REAM tool through the working cannula. The blades will self-collapse.

Step 9 | ASPIRATE CORE (RECOMMENDED)

Once debridement is complete, use the suction tip from the PRO-DENSE Core Decompression Procedure Kit to remove the debrided tissue.

Flushing with a combination of irrigation and suction works best.



Step 10 | GRAFT CORE

Prepare graft per instructions provided in the kit.

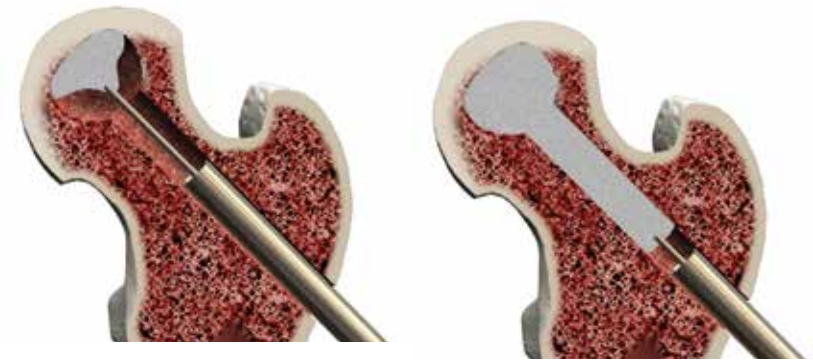
Backfill the core using the PRO-DENSE Injectable Graft (included in kit) to completely fill the surgically-created bone defect.

Begin by placing the needle at the back of the defect and injecting with thumb pressure.

Slowly inject while simultaneously withdrawing needle.

Periodically check graft placement with fluoro.

Slowly remove the working cannula while backfilling the core.



Step 11

Confirm final placement of graft under fluoroscopic guidance and close in standard fashion.

Ordering Information

87SR-0020	PRO-DENSE Injectable Regenerative Graft 2cc
87SR-0050	PRO-DENSE Injectable Regenerative Graft 5cc
87SR-0070	PRO-DENSE Injectable Regenerative Graft 7cc
87SR-0100	PRO-DENSE Injectable Regenerative Graft 10cc
87SR-0120	PRO-DENSE Injectable Regenerative Graft 12cc
87SR-0150	PRO-DENSE Injectable Regenerative Graft 15cc
87SR-CDK0	PRO-DENSE Core Decompression Kit – 15cc

Large Volume

87SR-0400	PRO-DENSE Injectable Regenerative Graft 40cc

Disposable Instrumentation

1200-SYR0	Syringe Only Kit
PSCL-0000	Extremity Procedure Kit with Targeting Guide
84LK-0000	Osteolysis Procedure Kit
20BL-1200	X- REAM™ Blade

Reusable Instrumentation

1000-KIT2	X-REAM™ Percutaneous Expandable Reamer

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