stryker

Pro-Dense LoVisc™

Injectable Regenerative Graft

Operative technique

Comprehensive operative technique

Pro-Dense LoVisc Injectable Regenerative Graft

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Introduction

Pro-Dense LoVisc Injectable Regenerative Graft 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 LoVisc will harden in situ and provide temporary intraoperative support. Pro-Dense LoVisc products are provided sterile for single patient use.

Indications

Pro-Dense LoVisc 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. Pro-Dense LoVisc 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 LoVisc is provided sterile for single use only.

Contraindications

Pro-Dense LoVisc 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 percutaneous operative technique for benign bone cysts and tumors

Design surgeon

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Operative 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.

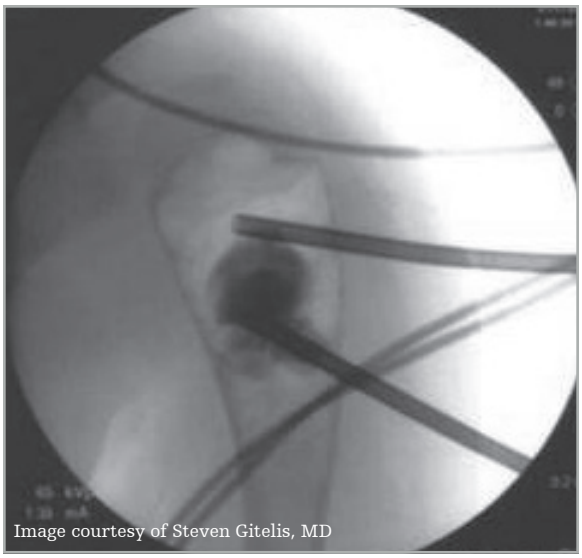


Image courtesy of Steven Gitelis, MD

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

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. A 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 preoperative x-rays/scans or after draping by using a large (e.g., 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 LoVisc Kit will need to be opened prior to the next step. The 5cc, 10cc, and 20cc 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.

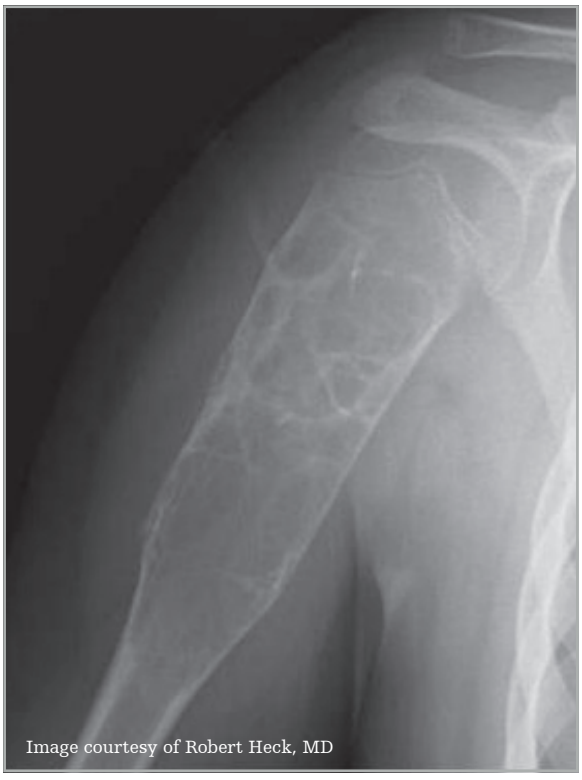


Image courtesy of Robert Heck, MD

Twelve-year-old male, preoperative

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 LoVisc 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.

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 it necessary, this debris can be collected and sent for pathology.

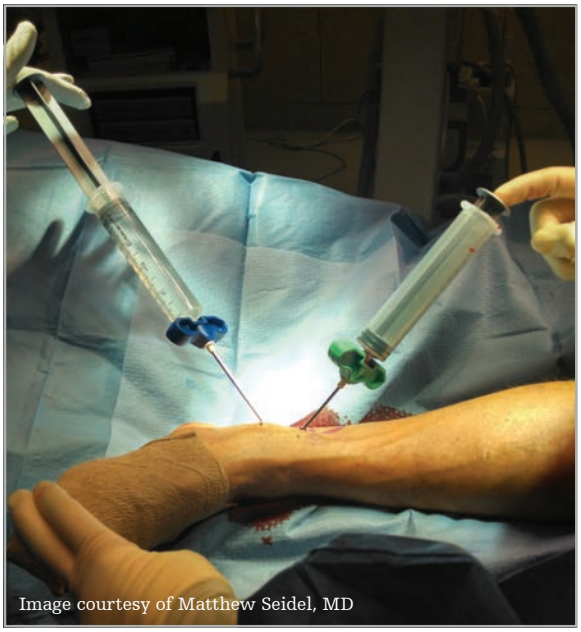


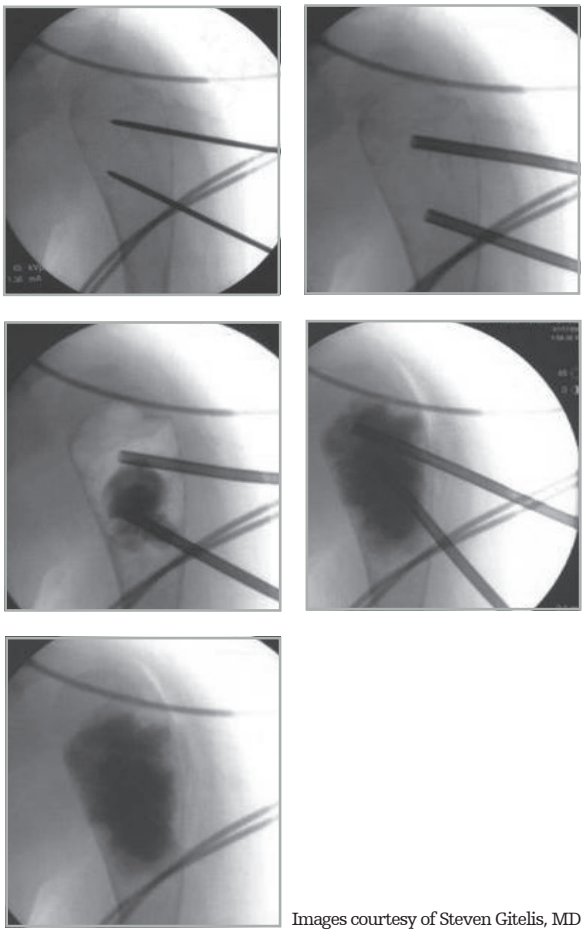
Image courtesy of Matthew Seidel, MD

Step 4: Grafting with Pro-Dense LoVisc

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.



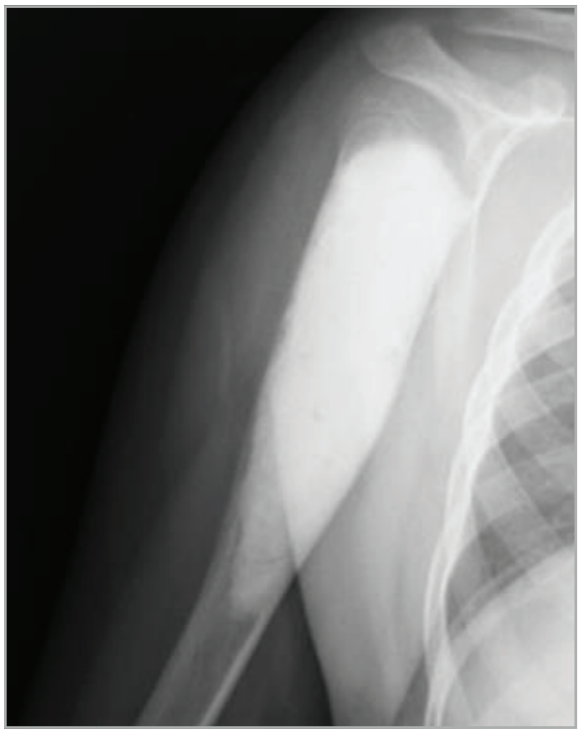
Images courtesy of Steven Gitelis, MD

Postoperative protocol

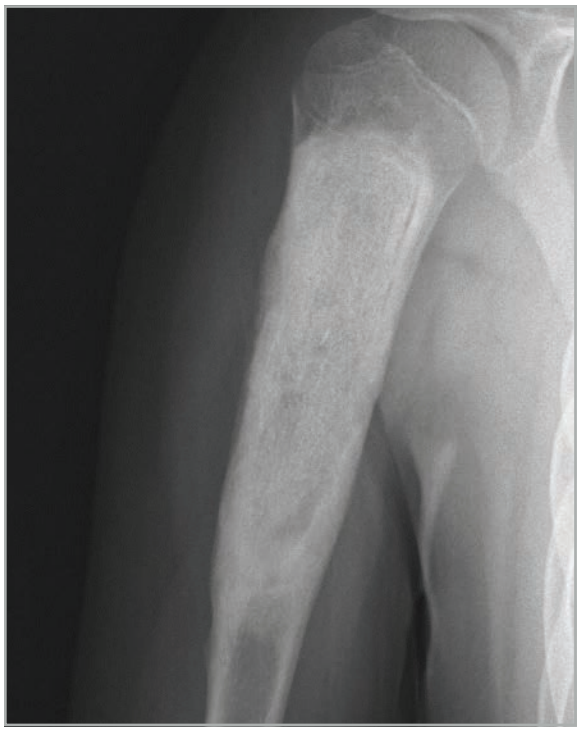
The patient is often placed in a sling for two weeks after surgery for upper extremity cysts or made non weight bearing for lower extremity lesions.

Patients are then followed as clinically appropriate and evaluated to determine level of activity, usually at 4- to 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 postoperative



1 year postoperative

EPK

Extremity Procedure Kit

Operative technique

This technique describes a method to access, debride, and graft (backfill) benign cystic bone cysts and tumors, surgically created osseous defects, and osseous defects created from traumatic injury to the bone in the extremities.

For the purposes of demonstrating utility of the surgical instrumentation, this technique guide will address an osseous defect of the lower extremity. However, the application of these instruments is inclusive to both lower and upper extremity uses to access, debride, and graft osseous defects.

The defect should not be pressurized during injection and the graft should not be used in open bone voids intrinsic to the stability of the bony structure. Take care to avoid neurovascular structures.

Pro-Dense Acessories to access and debride osseous defects (PSCL00000)

Kit components

1. Drill guide (optional)
Aids in guide wire placement

2. 2.5mm fluted guide wire
Guides drill bit to desired location

3. Tissue protector
Minimizes soft tissue interference during drill bit use

4. 5.3mm cannulated drill bit
Defect access

5. Working cannula with blunt obturator
Provides continuous access to surgical site when placed into core tunnel

6. Angled curette
Aids in debridement of bone

7. Suction tip and handle
Allows for tissue/fluid removal from the defect site during procedure

8. 10G needle with trocar
Facilitates the delivery of Pro-Dense LoVisc graft material to fill bone void

9. Tamp
Used to clear obstructions in working cannula and core tunnel

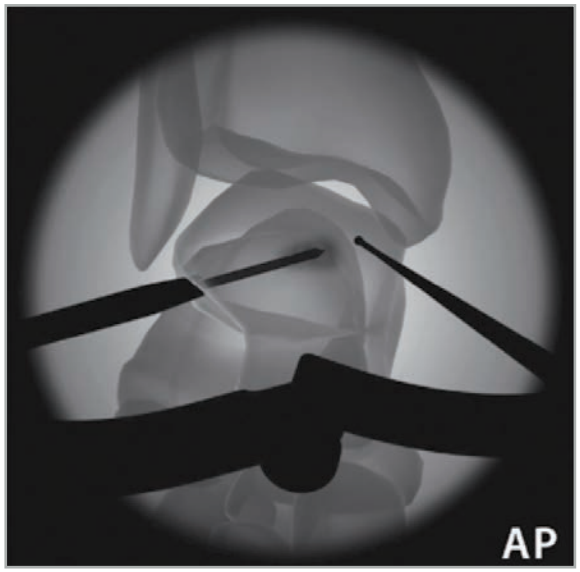
Example: Talus

Step 1: Setup

Prep limb in standard fashion and distract to enable visualization. If using diagnostic arthroscopy, establish routine anterior and posterior arthroscopic portals. If applicable, assess cartilage by probing the area to ensure that cartilage is intact.

Step 2: Approach

A small 1-2cm stab incision is made using a standard approach to access the lesion in the extremity bone. Carry out blunt dissection down to the bone.

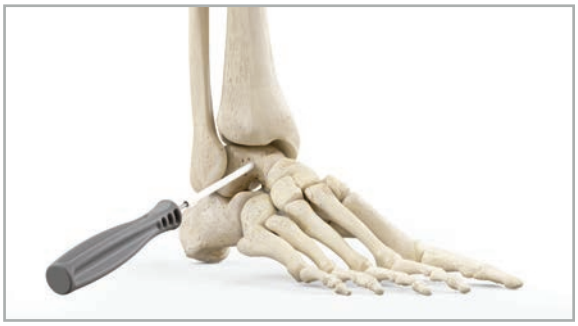


Optional: The provided targeting guide **(1)** may be used for more precise placement. Place the guide through the anterior or posterior portals, depending on defect location, and precisely localize the defect in preparation for drilling. Manipulate the angle of guide toward the defect. Once the correct entry angle is achieved, the drill targeting guide is tightened at the large, center thumb screw.

Using the 2.5mm **(2)** fluted guidewire, access the defect under fluoroscopic guidance (check both AP and LAT to ensure proper placement within the bone). Reposition as needed. If applicable, ensure the articular surface is not violated.

Once the guide wire is properly placed, remove targeting guide (if used; maintain guidewire placement). Place the tissue protector **(3)** over the guidewire and down to the bone. Place the 5.3mm cannulated drill bit **(4)** over the guidewire and through the tissue protector down to the cortex. Drill into the central aspect of the defect, using biplanar fluoroscopy in both AP and LAT to ensure proper placement.

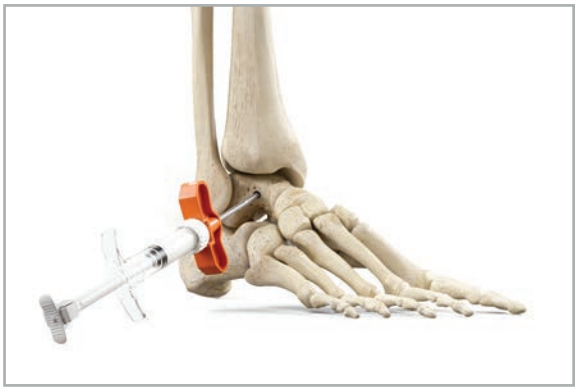
Step 3: Excise the lesion and irrigate



Remove the drill bit, tissue protector, and guidewire. Insert the working cannula **(5)** to provide continuous access to the surgical site (remove blunt obturator).

Using the angled curette **(6)**, debride the defect. If desired, a biopsy sample may be taken for further investigation. Use fluoroscopic guidance to ensure adequate debridement. A combination of suction and irrigation can be used by injecting normal saline into the surgically created defect and irrigation with the suction tip and handle **(7)**. Once debridement is complete, suction the defect to remove debrided tissue and fluid.

Step 4: Grafting with Pro-Dense LoVisc



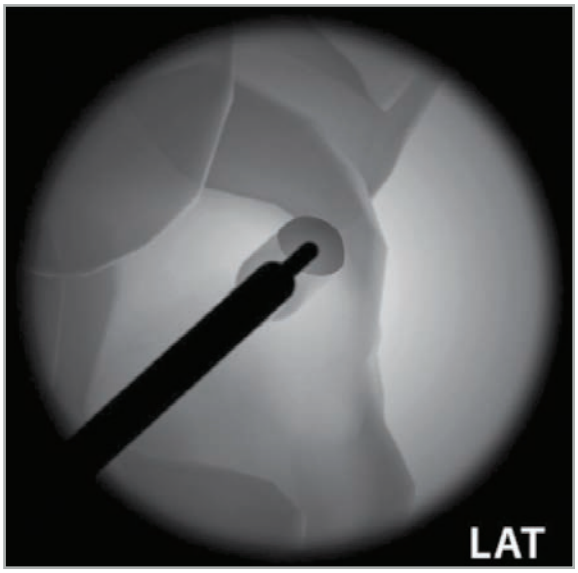
Mix Pro-Dense LoVisc according to the supplied instructions. Using the 10G delivery needle **(8)**, inject the prepared Pro-Dense LoVisc into the bone void to completely backfill the surgically created defect, taking care to avoid injection into the joint space (if applicable) or soft tissues. The defect should not be pressurized during injection and the graft should not be used in open bone voids intrinsic to the stability of the bony structure.

Begin by placing the needle at the back of the defect and injecting with thumb pressure. Slowly inject while simultaneously withdrawing needle. This will help eliminate back pressure that can make injection difficult. Periodically check graft placement with fluoro. Slowly remove the working cannula while backfilling the surgically created defect.

If graft material extravasates from the drill hole, simply use a gentle wash in the soft tissue and suction to remove.

If needed, the supplied tamp **(9)** may be used to clear the working cannula and/or pack the graft (without pressurizing) to ensure complete filling.

Once complete, confirm graft placement and close in standard fashion.



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Ordering information

87SRLV05	Pro-Dense LoVisc Injectable Regenerative Graft	5cc
87SRLV10	Pro-Dense LoVisc Injectable Regenerative Graft	10cc
87SRLV20	Pro-Dense LoVisc Injectable Regenerative Graft	20cc

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

Trauma & Extremities

Content ID: AP-016741

Manufactured by:

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