ADVANCED CORE DECOMPRESSION SYSTEM

X-REAM™

Percutaneous Expandable Reamer

PRO-DENSE®

Core Decompression Procedure Kit

WRIGHT.

Advanced Core Decompression System

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

Advanced Core Decompression

Instrumentation and Grafting

Treatment of Avascular Necrosis (AVN) of the hip can be a life-altering event, particularly for younger, active patients that may face a prosthetic joint arthroplasty. Core decompressions have been used with success in ficat stage I and II AVN.[1,2,4,6]

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

These instruments have been carefully selected and tested to simplify the technique for efficiency and consistency and to possibly provide a more cost effective outcome.[5]

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

CAUTION: Published data suggests that core decompressions in later stage AVN (Stage IIB, III or IV) may result in poorer outcomes.[3] The included PRO-DENSE® graft should not be used in late stage AVN where the graft may be subject to loading.

Minimally-Invasive Technique

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

Fast, Efficient Procedure

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

Cost Effective[5]

Published data demonstrates that successful core decompressions can possibly save money and potentially enhance the quality of life.

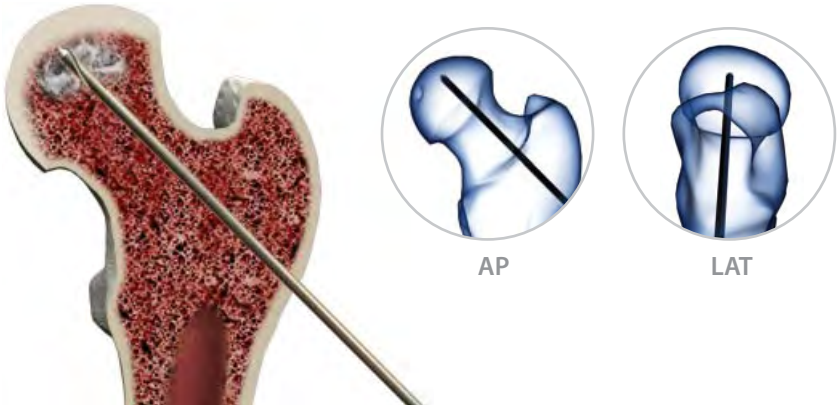
Advanced Surgical Technique - Core Decompression of the Femoral Head

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 Technology, Inc.

Remove all plastic caps on instruments prior to use.

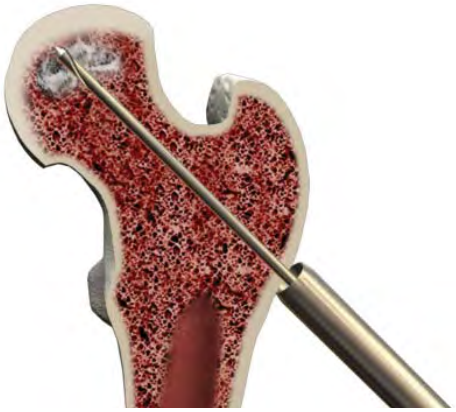
Step 1 | ACCESS LESION

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



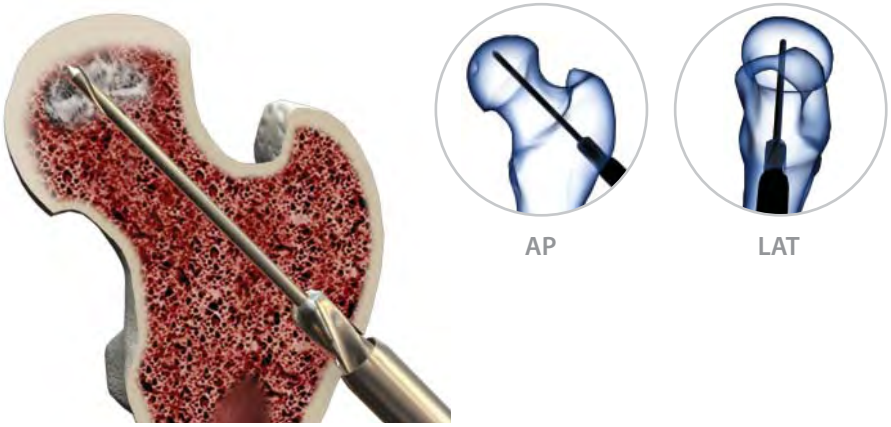
Step 2

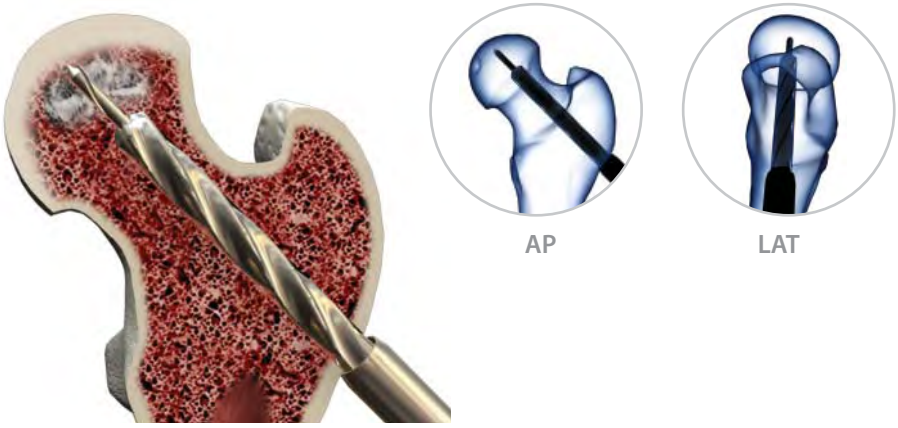
Introduce the tissue protector over the guide-wire and down to the bone prior to drilling.

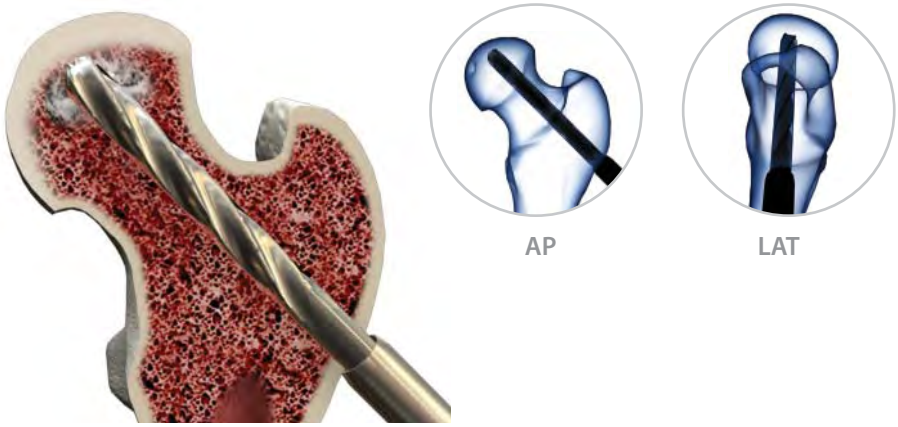


Step 3 | DECOMPRESS FEMORAL HEAD

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.

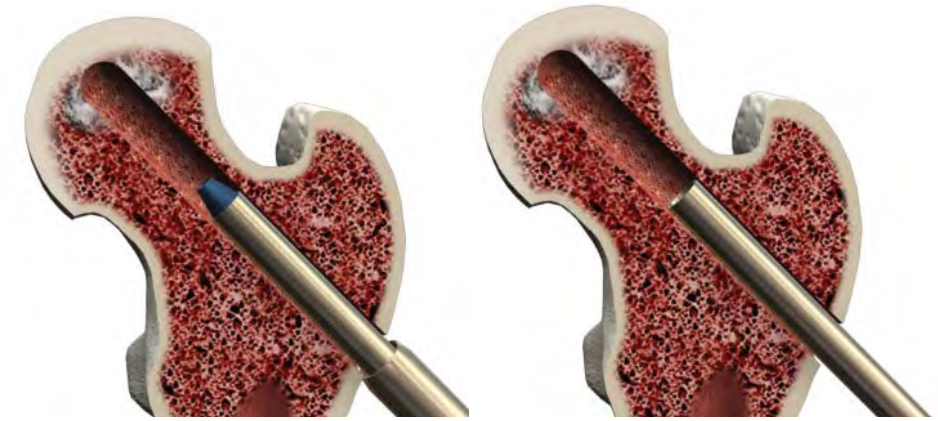






Step 4 | PLACE WORKING CANNULA

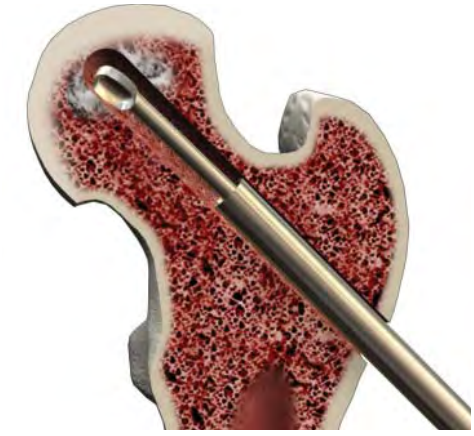
Maintain placement of the tissue protector and remove the drill bit and guide-wire. Place the working cannula with obdurator through the tissue protector and into the core. Position the working cannula up into the core several centimeters (fit should be snug). Remove the tissue protector and obdurator.



For Standard Debridement with PRO-DENSE® Core Decompression Prodedure Kit

Step 5 | DEBRIDE DEAD BONE

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



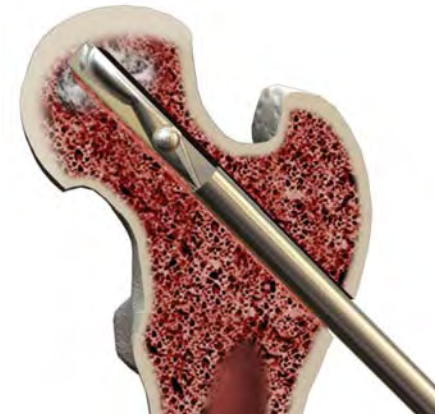
Note: If not using the X-REAM™ tool, go to step 9.

Advanced Core Decompression X-REAM™ Percutaneous Expandable Reamer

Complete Steps 1 - 4 with the PRO-DENSE® Core Decompression Procedure Kit Instruments prior to debridement.

Step 6 | ADVANCED DEBRIDEMENT

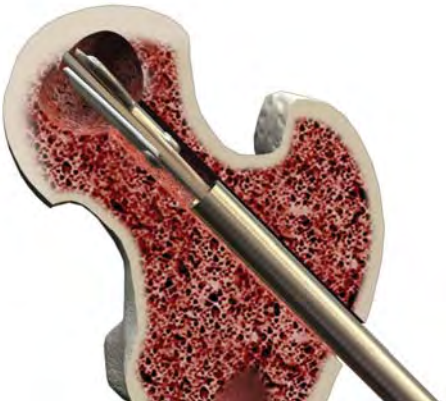
Advanced debridement can be carried out using the X-REAM™ Percutaneous Expandable Reamer.

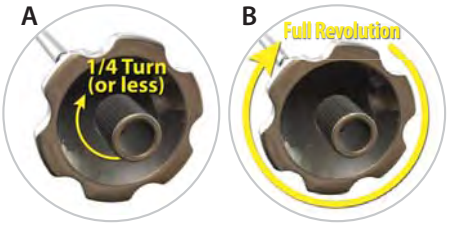


REAMER PLACEMENT

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.

B) Rotate the entire instrument at least one full revolution.

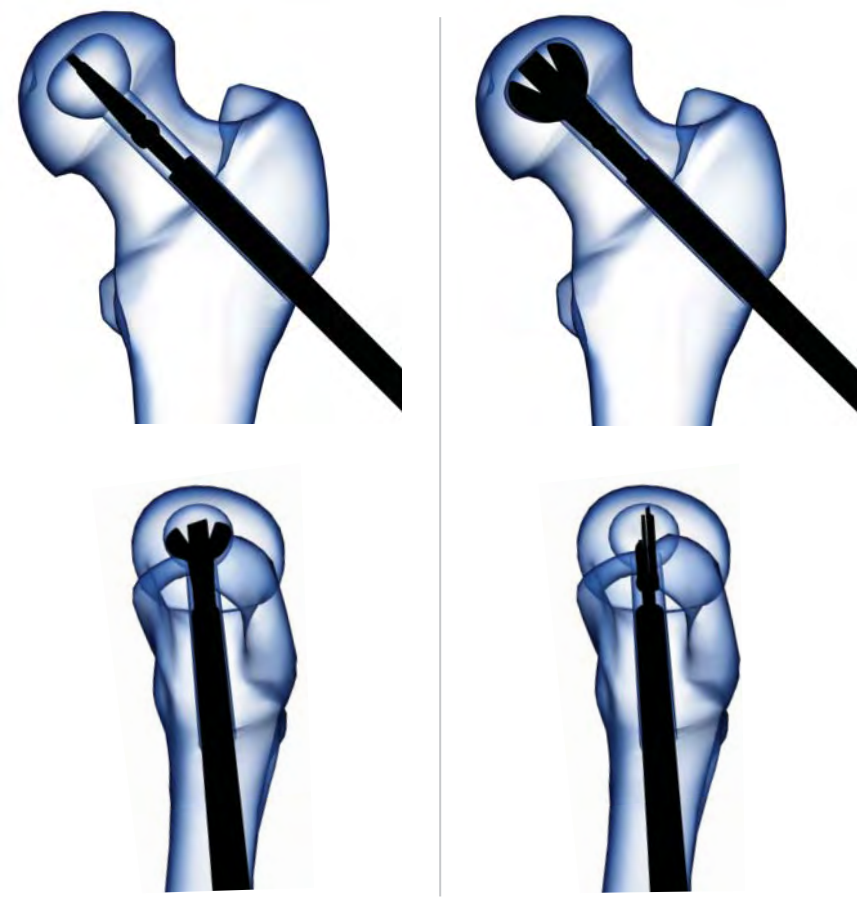
C) Repeat steps A & B until desired expansion is achieved. Use fluoro as needed to monitor the blade expansion

NOTE: It is <u>extremely</u> important not to open the blades too far prior to rotating the tool.

X-REAM™ Tool
in situ Expansion

AP

LAT



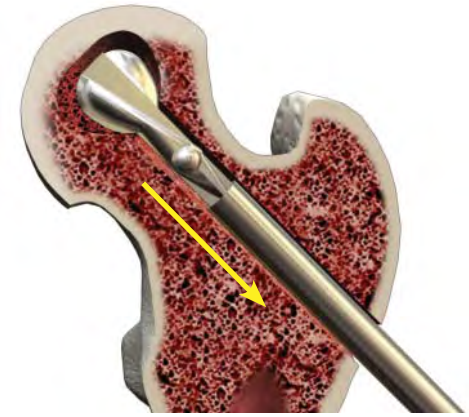
WARNING: *During expansion, frequently confirm blade position under fluoro (BOTH A/P and LAT views). Rotate instrument so blade width can be clearly determined (i.e. blades are perpendicular to view).*

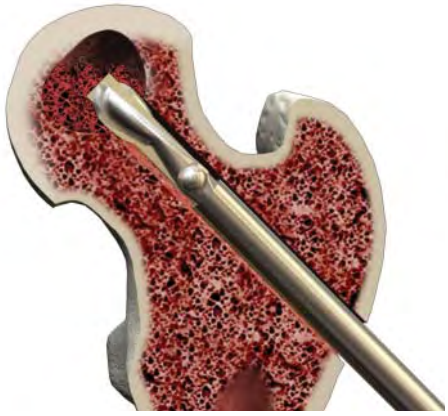
CAUTION: *Be sure not to violate the subchondral plate during the blade expansion.*

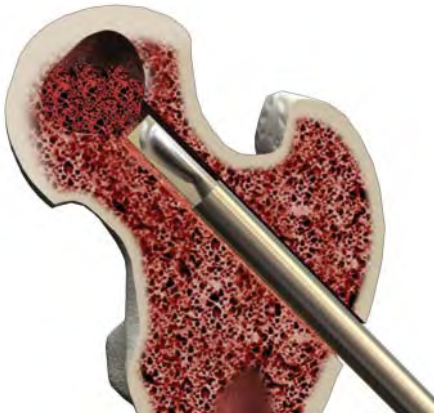
Step 8 | REMOVE X-REAM™ TOOL

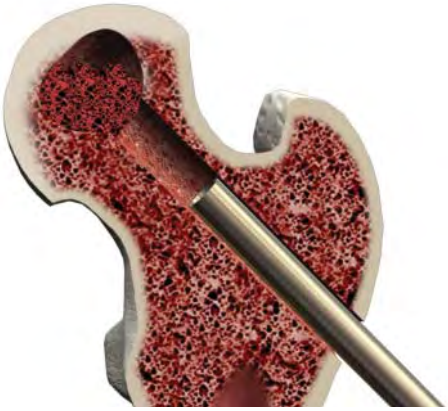
Once debridement is complete, turn the blade control knob counterclockwise until it stops.

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





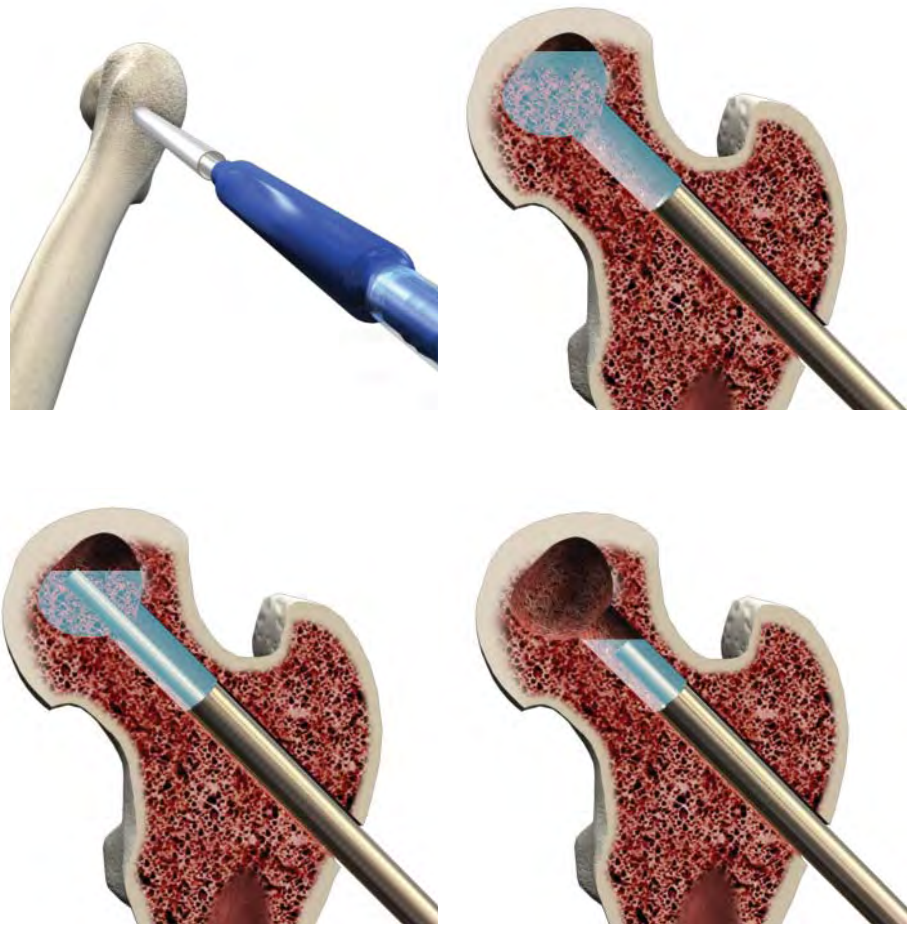




Step 9 | ASPIRATE CORE (RECOMMENDED)

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.

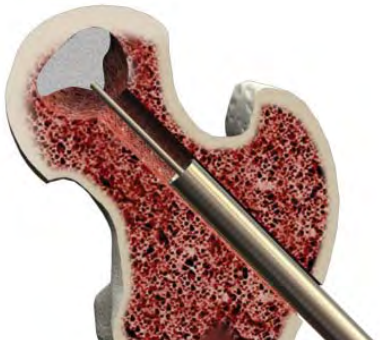
Backfill the core using the PRO-DENSE® Injectable Graft (included in kit) to completely fill the surgically-created bone defect.

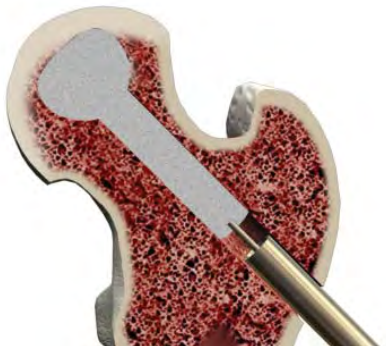
Begin by placing the needle at the back of the defect and injecting with thumb pressure.

Slowly inject while simultaneously withdrawing needle.

Periodically check graft placement with fluoro.

Slowly remove the working cannula while backfilling the core.





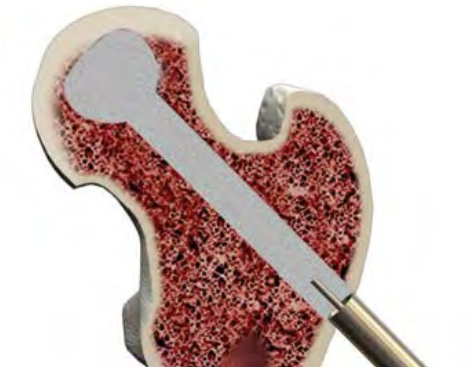
PRO-DENSE® resultant paste is intended for use as a bone graft substitute to be injected or digitally packed into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities, spine, and pelvis) to cure in situ. These open bone voids may be 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.

Step 11

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



ORDERING information

X-REAM™ Percutaneous Expandable Reamer

1000-KIT1	WRIGHT EXPRESS® Kit
1000-1200	X-REAM™ Body
10BL-1200	X-REAM™ Blade

PRO-DENSE® Injectable Regenerative Graft

87SR-CK15	PRO-DENSE® Core Decompression Procedure Kit 15cc

87SR-0410	PRO-DENSE® Injectable Regenerative Graft 10cc
87SR-0420	PRO-DENSE® Injectable Regenerative Graft 20cc

REFERENCES

1. Bozic KJ, *et al*. Survivorship analysis of hips treated with core decompression for nontraumatic osteonecrosis of the femoral head. *J. Bone Joint Surg. Am.* 1999; 81-A(2): 200-209.
2. Lavernia CJ, *et al*. Core decompression in atraumatic osteonecrosis of the hip. *J. Arthroplasty* 2000; 15(2): 171-178.
3. Hernigou, P., and Beaujean, F.: Treatment of osteonecrosis with autologous bone marrow grafting. *Clin Orthop Relat Res*, (405): 14-23, 2002.
4. Simank HG, *et al*. Comparison of results of core decompression on intertrochanteric osteotomy for nontraumatic osteonecrosis of the femoral head using cox regression and survivorship analysis. *J. Arthoplasty* 2001; 16(6): 790-794.
5. SooHoo NF, *et al*. Cost-effectiveness analysis of core decompression. *J Arthroplasty* 2006; 21(5):670-681.
6. Steinberg ME, *et al*. Core decompression with bone grafting for osteonecrosis of the femoral head. *Clin. Orthop*. 2001; 386: 71-78.

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