PerFuse Percutaneous Core Decompression Instrument

Femoral Head Surgical Technique
Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it’s meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally invasive surgical technique, advanced biomaterials or a patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.
Avascular Necrosis (AVN)

Avascular necrosis (AVN) of the femoral head is a disease commonly associated with corticosteroid use, alcohol abuse, trauma, and sickle cell disease.

The young to middle-aged patient population necessitates a joint-preserving procedure that prevents or postpones an unadvisable total joint arthroplasty. This is especially critical for patients with sickle cell disease, as 90% of those with AVN experience femoral head collapse within two years of diagnosis and also tend to have higher failure rates and more complications with arthroplasty. Avascular necrosis is the result of disruption of the vascular supply to the bone tissue.

Core Decompression

Core Decompression is a surgical technique to treat early detected Avascular Necrosis involving drilling one or more channels into the dead bone (necrotic lesion). Creating a channel into the necrotic lesion is intended to relieve intraosseous pressure within the bone and provide a channel to restore blood flow to the diseased bone. Often, core decompression involves the removal of a plug of bone out of a necrotic lesion.

Alternatively, bone decompression can be performed without the removal of a plug of necrotic tissue. An internal support scaffold is preserved by leaving the bone structure intact.

Core decompression has been demonstrated to lower pressure in the affected bone. This step can decrease pain in some patients presenting with Stage 1 or Stage 2 AVN. Unfortunately, historically this procedure has been shown to be successful in only 50% of the patients. Many of these patients progress to femoral head collapse, fracture, or THA.

Biologically-Assisted Treatments

Multiple approaches have been employed to augment core decompression with various biological materials. Autologous bone marrow aspirate, synthetic bone graft substitutes, and allograft products including milled trabecular bone and vascularized fibular grafts have demonstrated clinical benefits to patients diagnosed with early stage AVN (Table 1).

The PerFuse Approach

Recently though, a new emerging technique is increasingly used during core decompression. This technique utilizes a 6 mm cannula which allows for easy backfilling while remaining small enough to allow immediate post-op weight-bearing. This is achieved without creating heat like a reamer, which could negatively impact the clinical result.
Instrumentation

The PerFuse Percutaneous Decompression System is designed for femoral head decompression. The PerFuse cannula creates a 6 mm bore diameter channel into the necrotic tissue. This small diameter allows the PerFuse System to be used in small joints as well.

The instrument set is comprised of a single-use disposable kit containing:

- the cannula
- trocar rod
- plunger

and a reusable set containing:

- the reusable handle
- slide hammer
- slide hammer adapter
- strike cap

All components are made from ASTM F899 stainless steel.

The large (295 mm length) cannula, trocar rod, and plunger rod are designed to access and decompress necrotic tissue within the femoral head.

The shorter instrumentation (161 mm length) is designed to access and decompress necrotic tissue within the humeral head or other small joints.

Each cannula has lines etched onto the surface to indicate the instrument depth to the operating surgeon.
Assembly

**Step 1:** Fully seat the disposable PerFuse cannula into the PerFuse handle’s quick connect.

**Step 2:** Introduce the PerFuse disposable trocar through the PerFuse handle and cannula (Figure 2).

**Step 3:** Tighten the screw cap on the back of the handle to lock the trocar in place. The PerFuse instrument is now fully assembled (Figure 3).
**PerFuse Percutaneous Decompression System**

**Patient Preparation**

Prep OR with a fracture table. At times a fracture table maximizes imaging consistency and options. A second option is to place the patient in supine position on a radiolucent table.

Drape the patient in a manner that allows anterior-posterior (AP) and frog-leg radiographic images for instrument orientation. With the assistance of imaging, the PerFuse cannula is placed over the skin to determine the AP skin markings. A lateral image is also obtained by referencing the PerFuse cannula radiographically. This will provide landmarks for the lateral skin mark. The intersection of these skin markings is the incision location (Figure 4).

The hip (or hips) and the iliac crest (or crests for bilateral treatment) are prepped and draped following appropriate sterile field protocols.

**Biologics Preparation**

After the patient is positioned, draw 60cc of a whole blood and bone marrow aspirate mixture. The whole blood and bone marrow aspirate are injected into a BioCUE BMA Concentration System* tube. This tube is then processed for 15 minutes in a centrifuge. The BioCUE tube produces a 6cc PRP output, which should be mixed with the allograft or autograft bone of choice on the sterile field. At that time the bone graft mixture can be prepped for delivery into the PerFuse cannula.

**Note:** The graft material must be sized to fit through the cannula’s 3.9 mm internal diameter.

*The BioCUE BMA Concentration System is an accessory device. Please see the BioCUE package insert (also available at www.biomet.com) for complete instructions for use.
Incision
The position should be confirmed by fluoroscopy. Instrument orientation should be marked on the patient’s skin. This marking will act as a visual guide during the PerFuse Instrument insertion (Figure 4).

A 1 cm incision is made over the lateral aspect of the femur just below the vastus ridge of the trochanter. The starting point is maintained proximal to the level of the lesser trochanter and distal to the vastus ridge.

Note: Typically power instruments are not necessary except if entry into the lateral cortex is difficult.

Core Decompression Orientation
When the ideal starting point has been obtained the trocar is advanced from lateral to medial under biplanar fluoroscopy. Take care to verify the trocar position as the tip needs to be positioned parallel with the neck while stopping in the necrotic tissue (Figure 6). Altering the orientation of the PerFuse should be done prior to the cannula reaching 1 cm in depth. Also, if excessive force is needed to advance the trocar through the cortical bone the orientation of the instrument should be reassessed.
Advancing Instrument into Femur

Advance the instrument into the necrotic lesion by malleting the PerFuse Instrument Strike Cap. Typically, a change in mallet ping pitch is noted when the trocar has reached the area of necrosis. The areas of necrosis can be entered with the trocar, but should not be advanced within 5 mm of subchondral bone cortex to avoid collapse (Figure 7, 7a, and 7b). More caution should be taken when approaching an eccentric lesion.

This position is confirmed under biplanar fluoroscopy.

Remove Instrument Handle and Prep for Graft Delivery

Separate the handle and trocar from the cannula by engaging the quick release. Keep the 6 mm cannula in the necrotic portion of the femoral head.
Bone Graft Delivery

Use the luer-lock to attach the 30cc syringe containing the bone graft mixture to the PerFuse disposable cannula. Inject the contents into the necrotic tissue. Due to the sclerotic nature of the lesions, it may require significant pressure to complete this injection. If excessive resistance is met, the cannula can be retracted to a more lateral aspect of the necrotic tissue. This will increase the space for the injection and lower the pressure needed.

Remove syringe and advance the tamp until fully seated against the back of the cannula to express any remaining bone graft from the cannula.

Instrument Removal

If possible, manually remove the cannula. If a mechanical advantage is needed, the PerFuse Slide Hammer can be used to aid removal. To assemble, thread the Slide Hammer into the screw cap of the reusable handle.

The Slide Hammer assembly can also be attached directly to the cannula after the reusable handle has been removed via the Slide Hammer Adapter.

Please note, when the Slide Hammer is attached to the Slide Hammer Adapter, ensure the bell end of the Hammer faces away from the Slide Hammer Adapter to prevent interference from the adapter.
Final Look
The bone graft mixed with the output from the BioCUE sBMA Concentration System immediately perfuses the femoral head and other necrotic tissues.

Indications & Contraindications

INDICATIONS
The PerFuse Percutaneous Decompression System is intended to be used for the delivery of allograft, autograft, or synthentic bone graft material to an orthopedic surgical site. In addition, it is designed to facilitate mixing and pre-mixing of bone graft material with I.V. fluids, blood, plasma concentrate, platelet-rich plasma, bone marrow or other specified blood components deemed necessary by the clinical use requirements.

CONTRAINDICATIONS
The PerFuse Percutaneous Decompression System should not be used for vertebroplasty or kyphoplasty procedures.
PerFuse Part Numbers

800-0541 Hip Disposable Instrument Set
800-0542 Shoulder Disposable Instrument Set
800-0543 Slide Hammer Adapter
800-0544 Handle Strike
800-0545 Cap Handle
800-0546 PerFuse Instrument Case
31-473621 Slide Hammer

Accessory Part Numbers

800-0611A BioCUE aBMA
(Blood and Bone Marrow Aspirate) Concentration System

800-0610A BioCUE Mini aBMA
(Blood and Bone Marrow Aspirate) Concentration System
References

27. Steinberg ME. Core decompression of the femoral head for avascular necrosis [in German]. Orthopade. 2007; 36(5):451-457.