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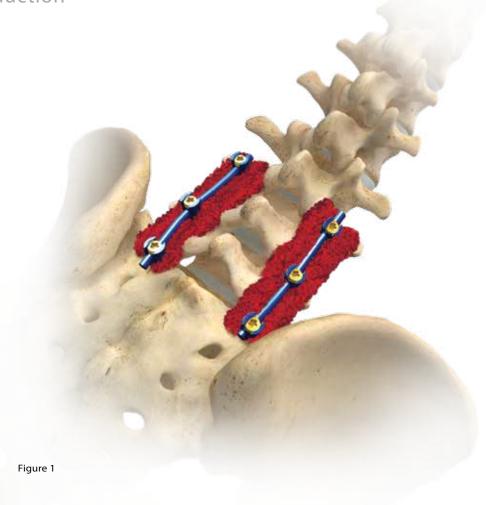
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Introduction



Thoracolumbar pedicle screw and rod systems are used to treat degenerative pathologies in the spine and for spine deformity correction. The goal of this surgical technique supplement is to educate the reader on key surgical technique steps relative to the application of bone graft material in lumbar spine fusion procedures. This surgical technique is intended to serve as a supplement to the Polaris 5.5 surgical technique.¹ For surgical technique steps involved in implanting screws and rods for spine fusion procedures, please refer to the surgical technique manuals specific to those systems.

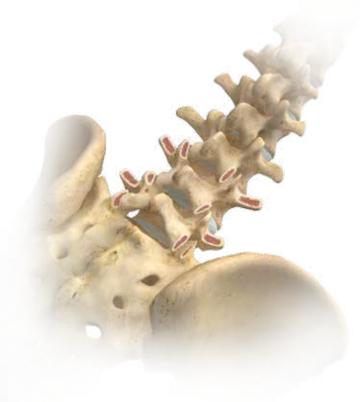


Figure 2 Decorticate to bleeding cancellous bone

Bone Grafting Surgical Technique Posterolateral Fusion:

For a posterolateral fusion, the transverse processes are exposed at each level to be fused. This exposure should also include exposing the intertransverse membrane between the transverse processes to enable bone graft to be adequately placed in this trough between the processes. The transverse processes are then decorticated with a pneumatic burr until bleeding cancellous bone is visible (Figure 2). The lateral portion of the facet joints directly adjacent to the transverse processes and the facet joints themselves are also decorticated. Bone graft material is prepared prior to application to the surgical site. Appendix A provides a brief guide to choosing a bone graft material. If hydration of bone graft material with BMA or PRP is desired, dispense the hydration fluid into a plastic cup on the sterile field. The bone graft material may be added to this cup and thoroughly mixed and saturated with the hydration fluid. Alternatively, the hydrating fluid may be taken up in a syringe and squirted directly onto the bone graft carrier. This method is particularly effective when the hydrating fluid is being used to saturate a structural corticocancellous interbody graft.

Methods for aspiration of bone marrow can be found in Appendix B. Appendices C and D provide processing steps for bone graft material and hydration fluid options, respectively.

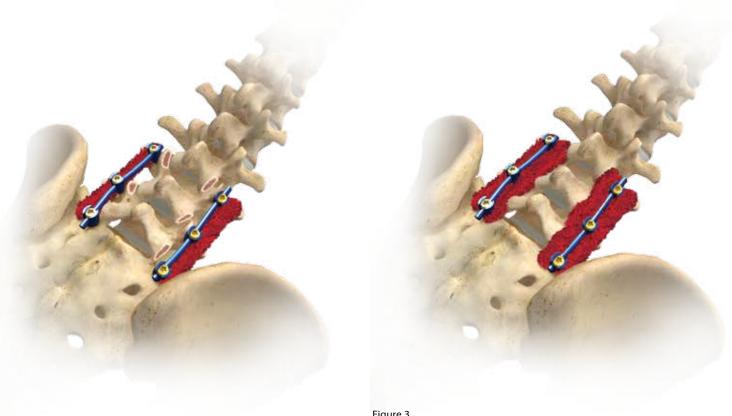


Figure 3 Bone graft placement along the lateral margins and within the facet joints

Ideally, in a lumbar fusion, the bone graft is placed posterolaterally after making the pedicle screw tracks but prior to actually placing the lumbar screws. This ensures that the instrumentation does not block effective placement of the bone graft material in the lateral gutter.

Under direct vision the bone graft is then placed between the decorticated transverse processes making sure to have a continuous bridge of bone. Bone graft can be placed along the decorticated lateral margin of the facet joints as well as within the facet joints (Figure 3). Please refer to the specific pedicle screw and rod system surgical technique manual for details on how these systems are instrumented and implanted.

Alternative Method

Bone Grafting Surgical Technique Anterior Lumbar Interbody Fusion (ALIF)

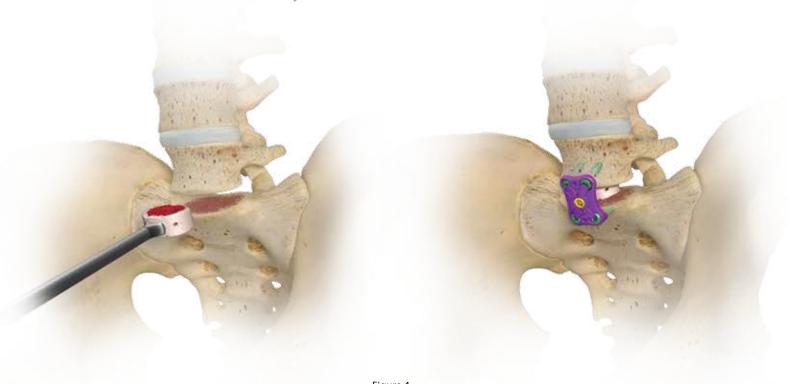


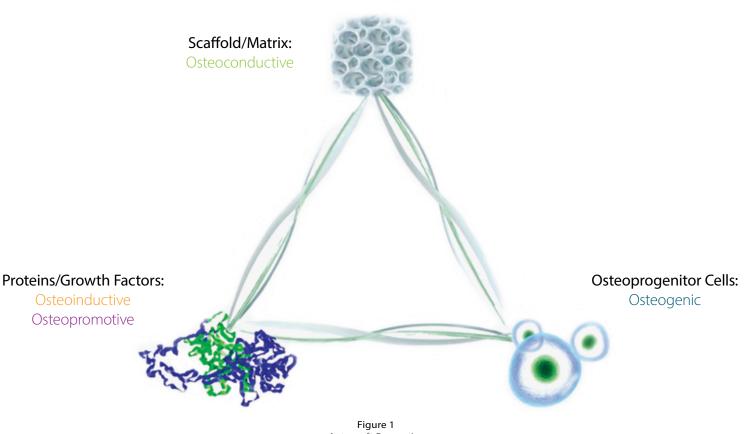
Figure 4 Bone Grafting in an anterior interbody fusion procedure

Expose the affected level via a standard incision and tissue dissection, and perform any necessary bone and tissue removal. Remove disc material and prepare endplates at the appropriate level. Use a combination of rongeurs, curettes, rasps or osteotomes to remove the disc material and cartilage from the vertebral endplates. Bone graft material is prepared as described in the Posterolateral technique.

If an allograft cage is being utilized, the center portion of the allograft cage should be tightly packed with the graft material (Figure 4). Pack the graft as tightly as possible to prevent the graft from dislodging during impaction of the cage. Carefully decorticate the adjoining vertebral endplates of the disc space. Take care to not fully violate the subchondral bone of the endplate surfaces when decorticating to prevent subsidence of the implanted cage. If doing an Anterior/Posterior Lumbar Fusion (360 degree) procedure, please refer to the specific cage and plating system surgical technique manuals for details on impacting the cage in place and instructions for appropriate use of bone graft material, instrumentation and implantation.

Appendix A

Choice of Bone Graft Material



Autograft Properties

Choice of Bone Graft Material

Autograft is the most common bone graft material of choice for spinal fusion procedures.² Autograft is the gold standard because it has all the principal elements necessary to form a solid fusion.^{3,4} Specifically, autograft not only contains the scaffolding necessary for bone healing, but it also is able to induce bone formation as it contains the pluripotential cells and signals necessary for successful bone healing³ (Figure 1). Additionally, there is no risk of disease transmission.³

The use of autograft has some downsides including the increased surgical time and prolonged pain at the donor site.⁵ Also, autograft harvest may not provide enough bone graft material to cover the required fusion area.⁴ This leads to the need for alternate solutions, such as synthetic and allograft/DBM materials.

There are numerous bone graft material choices available for spinal fusion procedures today,² and they include DBM putties/gels, synthetic HA/Collagen materials combined with BMA, allograft/autograft combined with PRP, etc. Bone marrow aspirate (BMA) or platelet-rich plasma (PRP) can be combined with DBM particles and/or cancellous chips and used as a bone graft material, because the combination graft material exhibits osteoconductive, osteoinductive and osteopromotive properties.6-8

The use of blood or bone marrow aspirate with graft materials can provide platelets or mesenchymal cells at the fusion site.⁹ Clinical evidence suggests cellular concentration may positively affect the clinical outcome of bone grafting procedures.^{10,11}

Appendix A

Choice of Bone Graft Material



Figure 2 Bonus CC Matrix combined with BMA

Bonus CC Matrix Bone Graft System¹²

Bonus CC Matrix is allograft bone. It is both osteoinductive and osteoconductive. Due to these characteristics it is an autograft alternative.

Bonus CC Matrix utilizes a unique formulation of demineralized cortical bone (DBM) and mineralized cancellous chips. This combination of optimal sizes and ratios provides a unique scaffold for bone growth while avoiding the common delivery and packing challenges associated with larger bone chips. Bonus CC Matrix offers all the benefits of allograft while providing the surgeon a consistent and efficient method of hydration with PRP or BMA (see Figure 2). Appendices C and D details steps involved in processing PRP from a mixture of blood and bone marrow and combining the concentrated output with Bonus CC Matrix.

The cortical bone (DBM) and mineralized cancellous chips used in Bonus CC Matrix come from the same donor. The tissue is processed using Allowash technology to inactivate a broad panel of viruses. Potential donors are evaluated through a multi-step process and subjected to testing that meets current AATB and FDA requirements.

Allowash is a trademark of LifeNet Health Corporation.

Bone Marrow Aspiration Techniques



into iliac crest wall

onto cannula handle and withdraw BMA

Anterior Approach Anterior Superior Iliac Spine(ASIS):

The ASIS should be palpated on the anterior iliac crest. Make a small stab incision approximately two centimeters posterior from ASIS. Use the trocar assembly to probe the iliac crest through the incision. Identify the medial and lateral edges of the iliac crest and dock the trocar assembly in the middle of the superficial cortex of the iliac crest.

While holding the trocar assembly in the palm, use gentle but firm pressure to advance the needle, rotating it in an alternating clockwise/counter clockwise motion until it advances between the cortices of the iliac crest (Figure 1). Then remove the inner trocar and lock the syringe containing anticoagulant onto the trocar handle (Figure 2).

Bone Marrow Aspiration Techniques

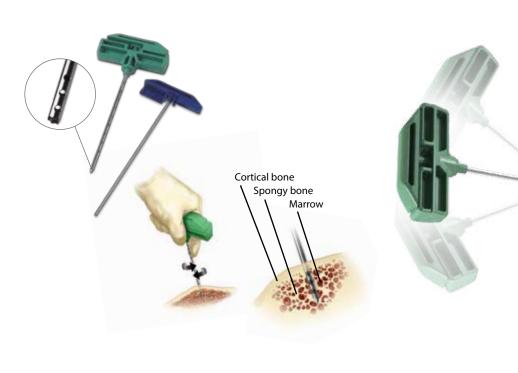


Figure 3 Ensure all distal holes of cannula are well within the cortical surface Figure 4 Use same hole in cortical wall and redirect BMA needle or start a new entry hole

Anterior Approach Anterior Superior Iliac Spine(ASIS) (cont.):

Ensure the aspiration holes in the cannula are below the cortical surface (Figure 3). Next, aspirate approximately 5 ml of bone marrow aspirate. This is the maximum amount that should be aspirated without readjusting the trocar. It is recommended not to aspirate excessive amounts of bone marrow from any one site, since larger volumes result in excessive dilution of the bone marrow with peripheral blood.¹³

To readjust and aspirate additional bone marrow, disconnect the syringe, replace the inner trocar, redirect the assembly by 15–20 degrees and advance the assembly (Figure 4). Be certain not to penetrate the medial cortex of the ilium. In general, advance the trocar no more than 5–7 cm. Aspirate approximately 5 ml of marrow. Continue this process until the desired volume of bone marrow is obtained.

Bone Marrow Aspiration Techniques

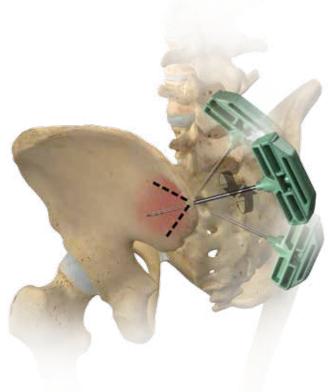


Figure 5 Placement of trocar needle for aspirating BMA using posterior approach

Posterior Approach Posterior Superior Iliac Spine (PSIS)

The posterior superior iliac spine (PSIS) is an excellent source for autograft bone as well as bone marrow aspirate (BMA). Palpate and mark the PSIS. Use a narrow scalpel to make a stab incision directly over the superficial cortex. Then insert the trocar assembly. The medial and lateral edges of the PSIS should be probed and trocar assembly docked in the middle of the superficial cortex. The trocar should be aimed 30° lateral from para-sagittal plane and 20–30° inferior from transverse plane (see Figure 5). Holding the trocar assembly in the palm, use gentle but firm pressure to advance the needle, while rotating the assembly in alternating clockwise/counter clockwise motion until it is advanced between the cortices of the iliac crest. Remove the inner trocar and lock the syringe containing the anticoagulant onto the cannula handle. Ensure the aspiration holes in the cannula are below the cortical surface. Aspirate approximately 5 ml of bone marrow. To aspirate additional bone marrow, disconnect the syringe, replace the inner trocar and reposition by redirecting the assembly 15–20 degrees and advancing the assembly. Take care not to penetrate the medial or lateral cortex of the ilium. The exact depth of optimal advancement varies somewhat, but the trocar should not be advanced more than 5–7 cm. Continue to aspirate approximately 5 ml of bone marrow until the desired volume is obtained.

Bone Marrow Aspiration Techniques

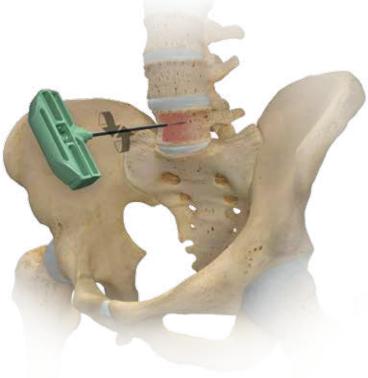


Figure 6 Bone marrow aspiration anteriorly from vertebral body

Technique for Aspirating BMA from the Vertebral Body

The paramedian, retroperitonal approach to the anterior lumbosacral spine provides direct visualization of the anterior vertebral body. This approach is routinely used for anterior access to the lower lumbar spine. The trocar assembly can be used to draw bone marrow directly from the vertebral body (Figure 6). Begin by incising the overlying periosteum with electrocautery, and then insert the trocar assembly until all the portals of the cannula are below the cortical surface. Attach the syringe containing the anticoagulant to the cannula and slowly aspirate. The needle should be repositioned after aspirating 5 ml. Continue aspirating and repositioning until the desired volume of bone marrow is obtained. After removing the trocar assembly, apply bone wax to the entry site on the vertebral body to prevent bone bleeding.

Bone Marrow Aspiration Techniques

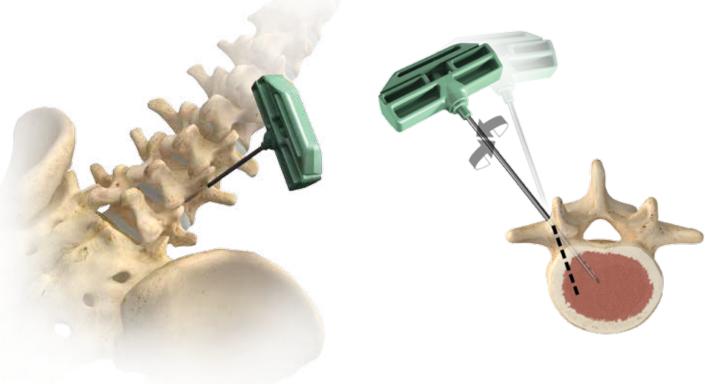


Figure 7 Bone marrow aspiration posteriorly using a transpedicular approach

Technique for Aspirating BMA Using a Transpedicular Approach

BMA can easily be aspirated posteriorly from the vertebral body by passing the trocar assembly into the vertebral body by a transpedicular approach. The starting point for the transpedicular approach is the same as that for placement of a pedicle screw (Figure 7). After identifying the starting point and marking the entry point with a burr or awl, use the trocar assembly in the same fashion as a pedicle probe. Advance the trocar assembly through the pedicle and into the vertebral body.

For most lumbar vertebral bodies, the cannula is initially advanced approximately 30 mm. The inner trocar handle is then removed and the syringe containing anticoagulant is attached. After approximately 5 ml of BMA is aspirated, replace the inner trocar and advance the cannula another 10 mm. Another 5 ml of BMA can then be aspirated. This process can be repeated for each of the exposed pedicles until the desired volume of BMA is obtained.

Appendix C

Bonus CC Matrix - Processing Steps



Figure 1



Figure 2

Vacuum Lock Attachment

Attach the 30 cc vacuum syringe to the valve fitting on the side of the graft syringe containing Bonus CC Matrix (Figure 1).

Vacuum Lock Priming

Pull on the vacuum syringe plunger until fully out, and then twist the plunger to engage the locking mechanism (Figure 2).

Appendix C

Bonus CC Matrix - Processing Steps

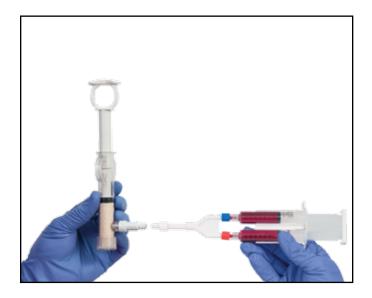


Figure 3

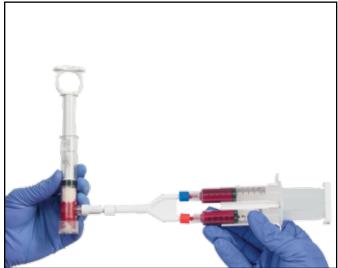


Figure 4

Hydrating Product Attachment

Holding the graft syringe at the valve, twist off the 30 cc vacuum syringe. Attach a dispensing syringe containing the liquid component onto the valve of the graft syringe with Bonus CC Matrix. Ensure there is enough hydration fluid to allow for a minimum ratio of 0.6 ml fluid to 1 cc Bonus CC Matrix prior to attaching syringe to graft syringe (Figure 3).

Vacuum Assisted Loading

The liquid component will be dispensed into the Bonus CC Matrix automatically. When utilizing a dual syringe system, be sure to use a clip plate on the plungers to ensure the hydrating medium is delivered at the same rate (Figure 4).*

*It may be necessary to manually depress the plungers simultaneously to inject additional hydration liquid.

Appendix C

Bonus CC Matrix - Processing Steps

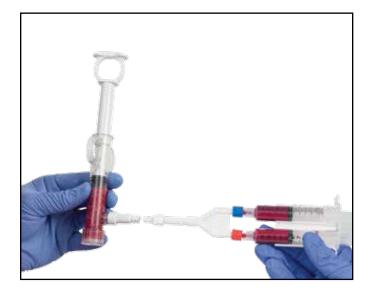




Figure 5

Figure 6

Vacuum Loaded

Detach the dispensing syringe. Piston the plunger of the graft syringe with Bonus CC Matrix for 10 seconds. This will assist with hydration of the graft material (Figure 5).

Graft Log Delivery

Remove the cap from the end of the graft syringe and depress the plunger to extract the hydrated graft material (Figure 6).

BioCUE BBMA Concentration System - Processing Steps



Figure 1 Whole blood is drawn from the patient

	Standard BioCUE Kit	Mini BioCUE Kit
Input	60 ml mixture of anticoagulated whole blood and anticoagulated BMA	30 ml mixture of anticoagulated whole blood and anticoagulated BMA
Output	6 ml of Blood and Bone Marrow Aspirate (BBMA) Output/PRP	3 ml of Blood and Bone Marrow Aspirate (BBMA) Output/PRP
Spin Time	15 minutes	15 minutes
Spin Speed	3200 RPM	3200 RPM

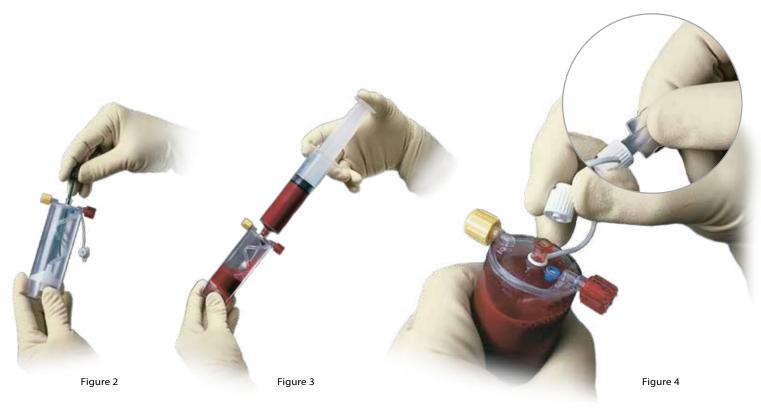
Whole Blood Draw

Draw 10 ml of ACD-A into 60 ml syringe, attach to apheresis needle and prime with ACD-A ensuring the ACD-A coats the entire inner surface of the syringe. Flush the syringe with the excess ACD-A ensuring a 1:9 ratio of ACD-A to whole blood is achieved after the blood draw. Slowly draw blood from the patient into the 60 ml syringe primed with ACD-A (Figure 1). Gently, but thoroughly, mix the blood and ACD-A upon collection to prevent coagulation. For blood draw when using a Standard BioCUE kit, use the provided 60 ml syringe and when using a Mini BioCUE kit, use the provided 30 ml syringe.

Bone Marrow Aspiration

Draw 10 ml ACD-A into a sterile 30 ml syringe; ensure the ACD-A coats the entire inner surface of the syringe. Attach 30 ml syringe to BMA needle and prime with ACD-A. Flush the syringe with the excess ACD-A ensuring a 1:5 ratio of ACD-A to BMA is achieved after aspiration. Remove BMA needle and replace the trocar. Follow the BMA needle manufacturer's package insert to obtain BMA in the 30 ml syringe primed with ACD-A. Gently, but thoroughly, mix the BMA and ACD-A upon collection to prevent coagulation.

BioCUE BBMA Concentration System - Processing Steps



Preparation of PRP

Load Blood and Bone Marrow Aspirate

Unscrew cap on center port number one and remove cap and green packaging post (Figure 2).

Slowly load blood and BMA one at a time into center port number one (Figure 3).

Remove protective cover on white tethered cap. Screw white cap onto center port number one (Figure 4).

BioCUE BBMA Concentration System - Processing Steps

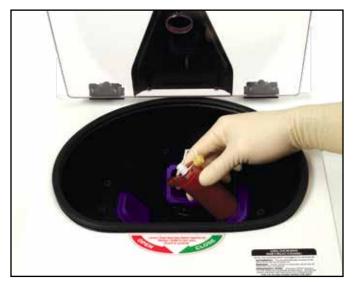


Figure 5



Figure 6

Balance Centrifuge

Press the red button to release the lid of the centrifuge and open. Place the tube into the centrifuge (Figure 5).

BioCUE Standard System: Fill blue counterbalance with 60 ml of sterile saline or water and place into opposite side of centrifuge (Figure 6).

BioCUE Mini System: If using the mini kit, the purple mini buckets must be inserted into the centrifuge. Fill the blue mini counterbalance with 30 ml of sterile saline or water and place into side opposite of the mini disposable in the centrifuge.

Process BioCUE Disposable

Close the lid by rotating the lid latch clockwise. "Latched" indicator will illuminate. Set the speed to 3200 RPM and the time to 15 minutes. Press the green button to start spin. Once the spin is complete, press the red button to illuminate the "Unlocked" indicator. Twist the latch counterclockwise to open the lid.

BioCUE BBMA Concentration System - Processing Steps

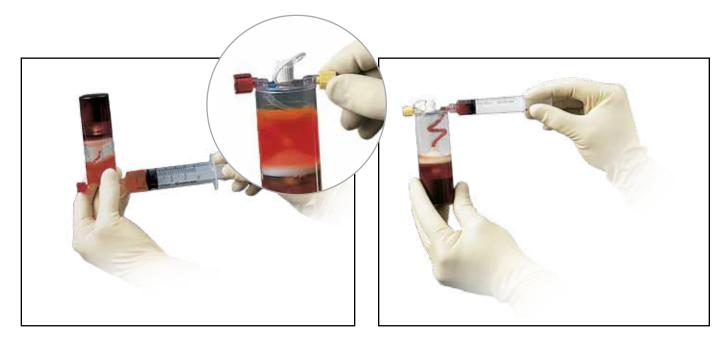


Figure 7

Figure 8

Extract Platelet-Rich Plasma (PRP)

To extract the platelet-poor plasma (PPP), remove yellow cap on side port number two and connect the 30 ml syringe. Slowly tilt the tube while withdrawing PPP (Figure 7). Replace the yellow cap.

Holding the separator in the upright position, shake vigorously for 30 seconds.

Remove the red cap on side port number three and connect the 10 ml syringe.

Extract the PRP into the attached 10 ml syringe (Figure 8).

Appendix E

Product Catalog Numbers

Autologous Product Offering

PRODUCT	DESCRIPTION	CATALOG NUMBER
	BioCUE BBMA Concentration System Kit (Standard)	800-0611A
	BioCUE <i>B</i> BMA Concentration System Kit (Mini)	800-0610A
	CDO - Curved Delivery Option	800-0526
Da	Graft Preparation System	800-0300
#	Bone Marrow Aspirate Needle	800-0705
	Bone Graft Convenience Kit with BioCUE Standard Disposable	800-0536
	Bone Graft Convenience Kit with BioCUE Mini Disposable	800-0534

Appendix E

Product Catalog Numbers

Bone Graft Products

PRODUCT	DESCRIPTION	CATALOG NUMBER
	Bonus CC Matrix – 5cc	48-1805
	Bonus CC Matrix – 10cc	48-1810
	StaGraft Cancellous DBM - 20 x 30 x 5 mm Strip	92-3230
	StaGraft Cancellous DBM - 20 x 50 x 5 mm Strip	92-3250
	StaGraft Cancellous DBM – 14 mm Cube	92-3214

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Bonus CC Matrix

INDICATIONS

Bonus CC can be used to fill bony voids or gaps that have been surgically created, or for filling osseous defects in nonweight bearing applications. Bonus CC may be used with orthopedic, spinal, reconstructive, craniofacial, maxillofacial and periodontal bone grafting procedures. It can be used alone or in combination with autologous bone, or other forms of allogeneic bone in grafting procedures of nonweight bearing value. It can be used or hydrated with autologous blood, bone marrow aspirate, or autologous blood derived products such as platelet rich plasma and platelet poor plasma. It may also be hydrated with saline or antibiotic solution.

CONTRAINDICATIONS

Infection at the surgical site and/or distant foci of infections that may spread to the surgical site is a contraindication for Bonus CC.

BioCUE Platelet Concentration System

INDICATIONS

The BioCUE Platelet Concentration System is designed to be used in the clinical laboratory or intraoperatively at the point of care for the safe and rapid preparation of platelet poor plasma (PPP) and platelet rich plasma (PRP) from a small sample of a mixture of blood and bone marrow. The plasma and concentrated platelets produced can be used for diagnostic tests. Additionally, the PRP can be mixed with autograft and/or allograft bone prior to application to an orthopedic site.

The PRP prepared by this device has not been evaluated for any clinical indications.



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