DirectCell™

ADVANCED BONE GRAFTING SYSTEM

The Power of
Advanced Bone Grafting

Conveniently In One System

BIOGENNIX®

The DirectCell System provides **spin-free live cell harvesting**, plus a premium **bioactive[1] synthetic** - all in one advanced system. Improve clinical outcomes by combining the **osteogenic power** within your patients' own stem cells with a next-generation bone graft that **actively promotes cellular healing.** The DirectCell System streamlines your procedures by **saving OR time** and **optimizing workflow**, all while providing an ideal combination of graft materials to **improve patient outcomes**.

Some cases may not require all components of the DirectCell System

- Next-Generation TrelCor® Technology
- Marrow Rich Autograft
- High Stem Cell Counts

ADVANCED BONE GRAFT

- Next-generation bone graft products containing TrelCor granules that are actively involved in the bone formation process[2-5]
- Best-in-class handling allows for easy intra-operative placement
- Designed to be blended with autograft[a]

AUTOGRAFT HARVESTING

- Percutaneously harvests cancellous bone cores rich with bone marrow stem cells
- Microvasculature is preserved, leading to faster healing[6-8]
- Easily combines with bone graft products

STEM CELL ASPIRATE (SCA)[b,c]

- One of the highest live stem cell counts (CFU-f*) compared to standard BMA (bone marrow aspirate) harvesting methods[9-12]
- No need to centrifuge
- Patented tip design maximizes collection of stem cells, while minimizing dilution with peripheral blood

**Peer reviewed literature routinely cites CFU-f, or Fibroblast Colony-Forming Units, as the clinically relevant measure of regenerative potential.[12]*

Always refer to product Instructions for Use for bone graft materials to verify compatibility with BMA and autograft.

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Cellular Healing With the DirectCell System

The DirectCell System allows the surgeon to efficiently combine an advanced bone graft material that actively promotes cellular healing with highly active stem cell tissue to create an optimal bone graft.

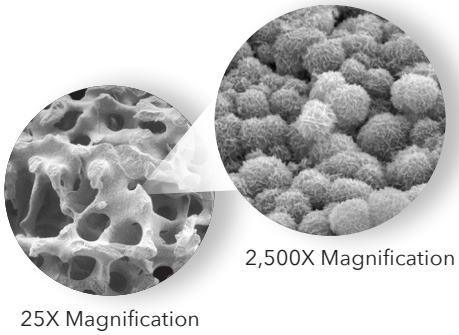


Figure 1. TrelCor granules contain a nanocrystalline HCA surface that is actively involved in the cellular healing process and a biomimetic pore architecture that promotes bone formation throughout the entire graft.[2-5]

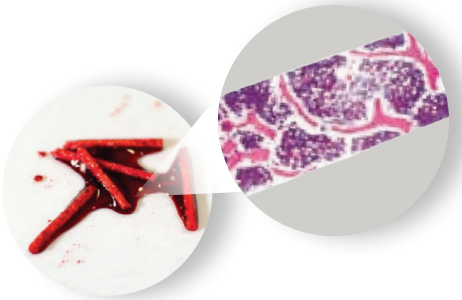


Figure 2. Autologous, vascularized living tissue with osteoconductive, osteoinductive, and osteogenic properties.

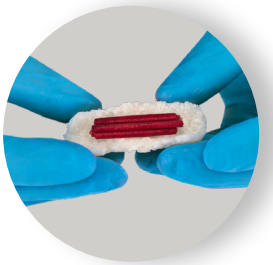


Figure 3. Harvested autograft dowels may be blended with bone graft product.[a]

Traditional BMA is primarily composed of peripheral blood with low stem cell counts.[12] By optimizing the harvesting system design, peripheral blood dilution can be minimized, creating a marrow aspirate system capable of achieving significantly higher stem cell counts (stem cell aspirate, *SCA*).

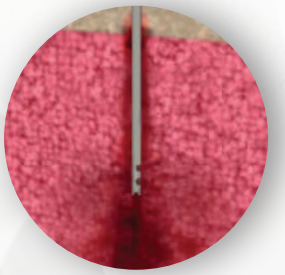


Figure 4. Traditional BMA harvesting needles are prone to blood dilution due to primary flow from the needle tip.

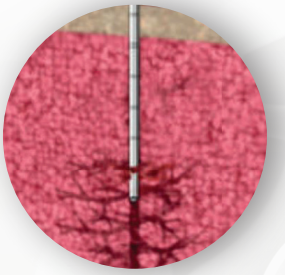


Figure 5. The DirectCell System contains a multi-level SCA harvesting system that blocks the distal tip, only pulls from lateral holes, and is easily repositioned.

Figure 6. Harvested SCA is used to hydrate bone graft strips.[a-c]

Scientific Data Supporting DirectCell Technologies

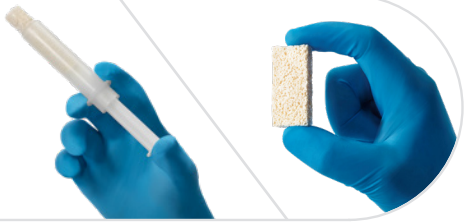
Each component of the DirectCell System is backed by scientific evidence.

- Data shows that the nanostructure and composition of bone graft materials can positively impact the healing process, and improve bone regeneration.[2-5]
- Research has demonstrated the enhanced survival of a bone graft and shorter time to a bony union when its primary blood supply is preserved.[6-8]
- Multiple clinical studies have shown that multi-level SCA harvesting systems consistently achieved the highest stem cell counts (CFU-f) versus alternative methods.[9-12]

Refer to product literature for more information.

DirectCell System Components

1



Advanced Bone Graft Product

Each DirectCell System comes packaged with one of the below bone grafting products

- Agilon® Moldable
  Available in 1.5cc, 3cc, 6cc, and 12cc volume
- Agilon Strip
  Available in Medium and Large sizes

2

Autograft Harvesting System

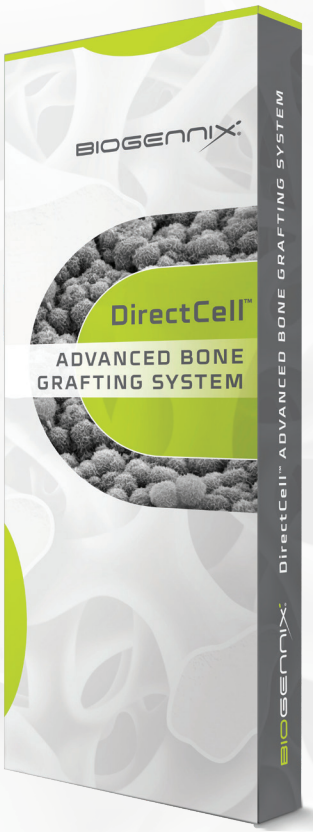
- 8G trephine needle
- Sharp stylet
- Cancellous bone extraction tool
- Core measurement tool

3

Stem Cell Aspiration System

- 11G introducer needle (9cm length)
- Sharp and blunt stylets
- Aspiration cannula
- 10cc luer lock syringe

Catalog Number	Included Bone Graft Product
BGS-8C-001-AGL	1.5cc Agilon Moldable Bone Grafting Product
BGS-8C-003-AGL	3cc Agilon Moldable Bone Grafting Product
BGS-8C-006- AGL	6cc Agilon Moldable Bone Grafting Product
BGS-8C-012- AGL	12cc Agilon Moldable Bone Grafting Product
BGS-8C-010-AGS	Medium Agilon Strip Bone Grafting Product
BGS-8C-020-AGS	Large Agilon Strip Bone Grafting Product



Notes

a. Agilon Moldable Bone Graft Substitute is intended to be mixed with autograft when used in the posterolateral spine. Agilon Strip Bone Graft Substitute is intended to be hydrated with bone marrow aspirate (BMA) and mixed with autograft when used in the posterolateral spine. Always refer to product Instructions for Use for full indications and use instructions.
b. Agilon Strip is intended to be hydrated with BMA. Agilon Moldable is not cleared for use with BMA. Always refer to product Instructions for Use for full indications and use instructions.
c. Stem cell aspirate (SCA) is a type of BMA with higher stem cell counts and is referenced as "BMA" in FDA clearances.

References

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BIOGENNIX
1641 McGaw Avenue, Irvine, CA, 92614
T 949-253-0994 F 949-266-5800 biogennix.com