ViviGen® and ViviGen Formable®

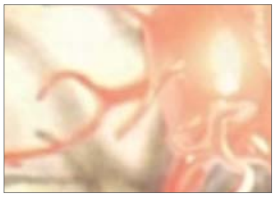
Cellular Bone Matrix

The right cells.
The right time. The right forms.

What is ViviGen?

ViviGen® is a cellular allograft intended for repair or reconstruction of musculoskeletal defects. ViviGen is being used in facial trauma and reconstruction procedures. It is comprised of three unique components that work in tandem to deliver superior healing potential compared to MSCs.[1]

Osteogenic
Lineage Committed Bone Cells



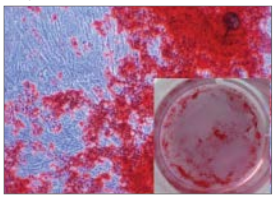
Osteoconductive
Corticocancellous Chips

Osteoinductive
Demineralized Bone

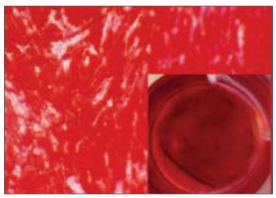
What is the ViviGen advantage?

ViviGen is different than other biologics on the market, as it is the only cellular allograft that contains lineage-committed bone cells, allowing ViviGen to directly participate in bone formation as early as day 7.[2] Pre-clinical studies suggest bone cells remain in the defect site longer and deposit a higher quality of bone than MSCs.[1]

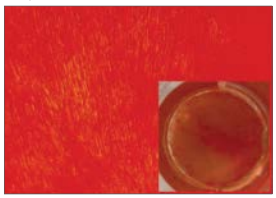
Day 7



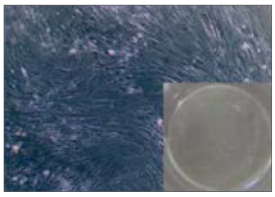
Day 14



Day 21



Day 7



Day 14

Day 21

Osteogenic capacity of ViviGen derived cells from two donors post processing, cryopreservation and thawing. Cells were allowed to grow until 75-85% confluent and then exposed to osteogenic media. Cells were then fixed at 7, 14, or 21 days and stained for calcium deposits with alizarin red. Human bone marrow mesenchymal stem cells (hMSCs, Lonza) were used as a comparative control.

What forms of ViviGen are available?

ViviGen® and ViviGen Formable® provide the same advantages with alternative formulations to meet surgeons' clinical needs.

ViviGen contains osteoinductive, demineralized bone particulate.

This particulate allows the graft to be placed into a contained void.

ViviGen Formable contains osteoinductive, precision-machined, demineralized fibers.

These demineralized fibers provide a putty-like consistency, allowing the graft to be shaped and molded.

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What are the advantages of the ViviGen packaging?

- Optimized packaging allows all ViviGen sizes to thaw in 5 minutes or less[3]
  - The rapid thaw prevents ice crystals from forming within the cell, which maintains viability.[3]
  - Competitive products can take up to 30 minutes to thaw depending on size.[4,5,6]
- ViviGen has 96% cell viability post cryopreservation and thaw[3]
  - LifeNet Health's optimized process and packaging protects bone cell viability from donor recovery to clinical use in the OR.
  - ViviGen reaches cryopreservation before the competitors start processing.[4]

How is ViviGen ordered?

	ITEM NUMBER	DESCRIPTION
ViviGen	BL-1500-001	1cc
	BL-1500-002	5cc
	BL-1500-003	10cc
	BL-1500-004	15cc
ViviGen Formable	BL-1600-001	Small
	BL-1600-002	Medium
	BL-1600-003	Large
	BL-1600-004	X-Large

All ViviGen orders are placed with LifeNet Health directly by phone: 1-888-847-7831, fax:1-888-847-7832 or email: orders@lifenethealth.org. Business hours are Monday through Friday, from 7am to 7pm EST.

How is ViviGen shipped?

Free Next-Day Delivery

ViviGen is shipped for next day delivery by 10:30am free of charge. Next day early AM is also available upon request.

Product Description – ViviGen is a HCT/P (Human Cells, Tissues, and Cellular and Tissue-based Product) comprised of cryopreserved, live, viable bone cells within a corticocancellous bone matrix and demineralized bone.
Indications for Use: ViviGen is intended for repair or reconstruction of musculoskeletal defects.

References: 1. Tortelli, et al. Biomaterials 31 (2010) 242-249 **2.** Data on file at LifeNet Health DHF 12-008
3. Trinity Evolution Thawing Guide **4.** ViviGen IFU, LifeNet Health **5.** Osteocel IFU

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