



Biologics

The value of the NuVasive
biologics portfolio



Why biologics?

When the goal of a surgical procedure is to achieve bony fusion, a biologic is critical in supporting the bone formation process. Biologics provide the proper foundation and environment to facilitate bone growth at the surgical site. Different types of biologics are available to meet a variety of needs from both the clinical and economic value perspectives. Biologics can be derived from allograft (human cadaveric tissue), they can be synthetically developed, or they can be a combination of the two.

Autograft is considered the gold standard of biologics because it contains all three essential elements to support bone formation: osteoconductivity (a scaffold for bone growth), osteoinductivity (signaling to nearby cells to grow bone), and osteogenesis (living cells that can form bone). However, patient bone quality, volume and comorbidities may dictate an allograft or synthetic biologic solution be used instead. These biologics can mirror autograft by featuring all three of the essential elements listed above or feature one to two of these elements. Other areas to consider when evaluating a biologic may be clinical evidence, size and handling configurations, storage requirements, price and product support.

NuVasive offers a comprehensive portfolio of biologics for a broad spectrum of product categories to meet different surgeon and hospital needs. Consolidating your biologics to NuVasive means having access to a market-leading cellular allograft, a unique synthetic ceramic powered by Level I clinical evidence,¹ and a wide offering of demineralized bone matrix and traditional bone allograft products. Many of these products are available to order as case-specific loaners, consignment, or stocking, the last of which provides additional savings to the customer. **This is the value of the NuVasive biologics portfolio.**

Considerations when choosing a biologic



Allograft tissue
source



Osteogenicity,
osteoconductivity,
osteoinductivity



Clinical
evidence



Form factors/
handling



Pricing/
availability



Safety



Product
support



Cellular allografts

Cellular allografts are derived from donated human cadaveric tissue with processing methods that retain living cells in the cancellous bone, while being combined with demineralized cortical bone. A cellular allograft is osteogenic, osteoinductive, osteoconductive—a complete autograft replacement.²

Osteocel by NuVasive

- The most studied cellular allograft in the market*
- Osteocel contains an average of three million viable cells per cubic centimeter, which have an average 85% cell viability³
- Osteocel has a shelf life of five years when stored frozen at -80 C°
- Processed by AlloSource®, one of the leading tissue banks in the United States
- Available as Osteocel Plus and Osteocel Pro, in sizes 1–15 cc

Features

- Osteoconductive, osteoinductive, osteogenic²
- 30+ peer-reviewed clinical publications
- Simplified product preparation with Osteocel Pro

Key considerations of cellular allografts

How many clinical studies?

How many cells per cc?

What is the average cell viability?

Is there supporting clinical evidence?

Common cellular allografts

- Trinity Evolution® and Trinity ELITE®
- ViviGen® and ViviGen Formable®
- PrimaGen®
- Bio4®
- Via®



Osteocel Plus



Osteocel Pro



Synthetic ceramics

Synthetic ceramics are manufactured using various mineral components such as beta tricalcium phosphate or hydroxyapatite. Synthetic ceramics typically only provide a scaffold for new bone formation and are generally used as bone graft extenders.

Attrax by NuVasive

- A unique, surface-optimized synthetic ceramic, Attrax has demonstrated the ability to grow bone on its own in an intramuscular environment, making it more than just a scaffold⁴
- Attrax Putty is a rare biologic powered by Level I clinical evidence, which is data of the highest quality. The study concluded Attrax Putty alone demonstrated non-inferior fusion performance compared to autograft in posterolateral lumbar spinal fusions¹
- Available as Attrax Putty and Attrax Scaffold, in sizes 1–30 cc, as strips, blocks, morsels and cylinders
- Room temperature storage; five-year shelf life

Features

- Osteoconductive, promotes increased bone formation¹
- Level I clinical evidence

Key considerations for synthetic ceramics

Supported by Level I evidence?

Sizes and shapes?

Common synthetic ceramics

- MasterGraft®
- Vitoss®
- ActiFuse
- iFactor



Attrax Putty cylinders



Attrax Putty strips



Attrax Putty blocks



Attrax Scaffold morsels



Demineralized bone matrix (DBM)

DBM is derived from donated human cadaveric tissue and often combined with a synthetic carrier to provide different handling characteristics. The demineralization process exposes the growth factors in the bone, so it provides signaling in addition to a scaffold.⁵ It is still intended to be used as a bone graft extender.

Propel DBM by NuVasive

- Propel DBM Putties and Gels are demineralized cortical bone combined with a reverse phase medium carrier, which is designed to provide excellent moldability and graft containment
- Propel DBM Putty Plus and Gel Plus contain added cancellous bone chips for handling and additional osteoconductive properties
- Propel DBM Fibers are 100% cortical bone without a carrier, and are available in preformed boats for the posterolateral spine
- Propel DBM Sponge is 100% cancellous bone without a carrier, and becomes flexible, compressible and conformable when hydrated
- Processed by AlloSource, one of the leading tissue banks in the United States

Features

- Osteoconductive, osteoinductive



Propel DBM Putty



Propel DBM Fibers



Propel DBM Fiber Boats



Propel DBM Gel

Key considerations for DBMs

What type of carrier?

What type of lot testing?

Common DBMs

- Grafton®
- DBX®
- Optium®



Traditional bone allograft

Traditional bone allograft is derived from donated human cadaveric tissue and it serves as a scaffold for new bone formation. It is intended to be used with other biologics and primarily serves to extend volume. It is the least expensive biologic option.

Traditional bone allograft by NuVasive

- Available as cancellous chips, crushed cancellous, cortical cancellous chips and demineralized cancellous chips
- Available as freeze-dried or frozen
- Available in volumes 5–90 cc

Features

- Osteoconductive

Key considerations for traditional bone allograft

What types of chips available?

Sizes and shapes?

Common traditional bone allograft

- MTF chips
- AlloSource chips
- LifeNet chips



Cancellous chips



Cancellous crushed

Average price



Amnion

Amnion is derived from donated human placenta and it is considered an allograft; however, it is not a bone void filler like the other biologics previously discussed. Amnion is intended to be used in spine surgery as a protective barrier.

Amniotic Membrane by NuVasive

- Processed by AlloSource, one of the leading tissue banks in the United States
- Demonstrated to remain in place through the critical healing phases⁶
- Double-sided design, which can help reduce concerns about tissue orientation and maximize tissue barrier opportunities
- Packaged hydrated for improved handling characteristics
- Room temperature storage; two-year shelf life

Features

- Protective barrier

Key considerations for amnion

How many layers?

Tissue source?

Common amnion

- EpiFix
- AmnioFix
- VersaShield



Amniotic
Membrane DS

Additional offerings*

*Contact your local NuVasive sales representative for details

Ambient Biologics Cabinet Program



Osteoecel Discount Freezer Program



MDF-DU302VX-PA

MDF-C8V1

Additional information

Product codes and sizes



For the NuVasive biologics portfolio, visit [nuvasive.com](https://www.nuvasive.com) for additional information.

Instructions for use



For product indications, contraindications, storage requirements, and other information, please reference the IFU webpage.

References

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3. NuVasive White Paper. Osteogenic and Osteoinductive Potential of Osteoecel® Pro after Cryopreservation. March 2014. 9501251 A.
4. Yuan H, Fernandes H, Habibovic P, et al. Osteoinductive ceramics as a synthetic alternative to autologous bone grafting. *Proc Natl Acad Sci* 2010;107(31):13614-9.
5. Tilkeridis K, Touzopoulos P, Ververidis A, et al. Use of demineralized bone matrix in spinal fusion. *World J Orthop* 2014;5(1):30-7.
6. Samaniego AC, Ronholdt CJ, Ryan S, et al. Human amniotic tissue as an anti-adhesion, anti-inflammatory barrier in an ovine spinal laminectomy model. *AlloSource White Paper*, 2009.

*Based on review of publicly available materials at the time of this release (9/1/2020).

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