PearlMatrix™

P-15 Peptide Enhanced Bone Graft

Fusion takes time. **ACCELERATE IT.**

*Close the surgery-to-fusion time gap with the first and only **bone growth accelerator.**[*1,2]*

*Demonstrated statistially superior time to fusion in a single-level TLIF PMA IDE study vs. local autograft.

Cerapedics®

Repairing bones. Healing lives.

Spinal fusion is a race against time...

What if you could accelerate lumbar fusion?+

- After the patient leaves surgery, it's a waiting game.
- A longer time to fusion leaves more time for risk.
- Without biological fusion, symptomatic motion can occur.[4]
- High-risk patients face biological challenges that can make fusion even more complex.^[5]

Despite over 350+ spinal bone grafts, **only three** have met robust **Class III** FDA evidence requirements.**[3,6]

And **only one** has demonstrated **statistically superior** fusion speed.*[1,2]

You don't need just another bone graft.
You need a **bone growth accelerator.**

- Proven to accelerate lumbar fusion.+
- Class III drug-device with P-15 Peptide.
- Rigorously tested in a Level 1 PMA IDE study.
- Evaluated in high-risk patient populations.^

350+	Spinal bone grafts
3	Class-III spinal bone grafts
2	Cerapedics owned
1	**Bone growth accelerator**

^ High-risk includes nicotine use, BMI ≥ 30 and/or Type 2 diabetes.
+ In single-level TLIF procedures.
* Demonstrated statistically superior time-to-fusion in a single-level TLIF PMA IDE study vs. local autograft.
** Three drug-device combination products with spinal indications, i-FACTOR, Infuse™ and PearlMatrix as of May 2025.

PearlMatrix, powered by P-15 Peptide is the first and only **bone growth accelerator** proven to **accelerate fusion** in the lumbar spine.*[1,2]

Accelerated Fusion

Achieved statistically superior fusion speed
in a Level 1, PMA, IDE study with ~60% high-risk patients.^†[1]

Shown to accelerate lumbar fusion
with over 2x more patients fused at 6-months.†[1]

Meaningful Outcomes

Proven safety and efficacy
demonstrating statistically superior overall clinical success at 2-years.§†[1]

Achieved substantially higher fusion rates
at 6, 12 and 24 months in both the overall and higher-risk patient populations.^†,[1]

Ease-of-Use

Designed to stay where you put it
with a fibrous and moldable collagen matrix to aid in retention at the fusion site.

Formulated to optimize handling and efficiency in the operating room.

Rigorously Tested in a 293-patient pivotal, Level 1, PMA, IDE study with ~60% high-risk patients.^[1]

PearlMatrix was shown to be **as safe as local autograft.**†[3]

NO Meaningful differences in device related or serious device-related adverse events.†[1]

NO Observation of **ectopic bone formation.**†[1]

NO Incidents of osteolysis.†[1]

NO Meaningful differences in reported seroma formation.†[1]

NO Meaningful differences in reported radiculopathy.†[1]

Potential adverse events specific to PearlMatrix include allergic reaction to components of PearlMatrix Bone Graft. Please see the PearlMatrix Instructions for Use for complete safety and risk information.

^ High-risk includes nicotine use, BMI ≥ 30 and/or Type 2 diabetes. † As demonstrated in a single-level TLIF PMA IDE study vs. local autograft.
§ Overall clinical success is defined by a composite score including fusion, function (ODI), neurological, no serious device related adverse events and no index level secondary surgical interventions. * Demonstrated statistically superior time-to-fusion in a single-level TLIF PMA IDE study vs. local autograft.

PearlMatrix is a Class III drug-device powered by P-15 Peptide.

Purpose-built for enhanced performance in the lumbar spine.+[1,3]

P-15 Peptide (Drug)	Calcium Phosphate (Device)	Collagen Matrix (Carrier)
Provides a proven mechanism of action to attach and activate osteogenic cells to accelerate new bone formation.[7-9]	A porous osteoconductive scaffold coated with P-15 Peptide to provide an abundance of attachment sites for osteogenic cells.[1,3,7-9]	A fibrous and moldable carrier aids in handling, placement and retention of the P-15 coated particles at the fusion site.[1,3]

PearlMatrix is powered by P-15 Osteogenic Cell Binding Peptide.

P-15 Peptide provides a proven mechanism of action to **attach** and **activate** osteogenic cells to **accelerate** new bone formation.[7-11]

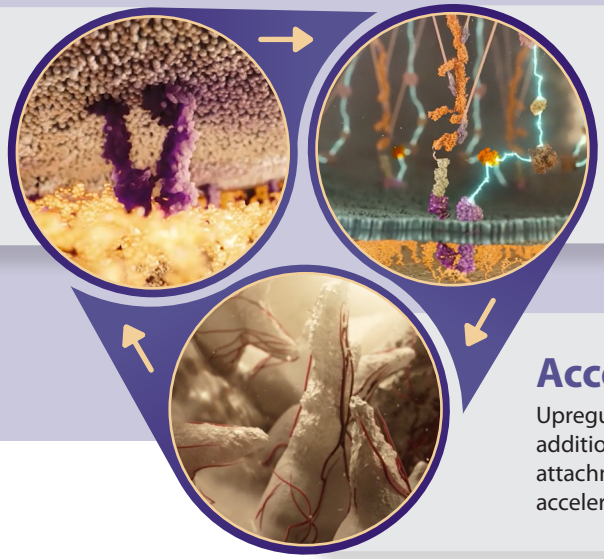
P15 | osteogenic cell binding peptide

P-15 is a naturally occurring 15-amino acid sequence found in type-1 collagen and serves as a powerful cell attachment factor. [7-9,12]

In PearlMatrix, pharmaceutically manufactured P-15 Peptide is bound onto calcium phosphate particles creating a P-15 enhanced scaffold that provides an abundance of attachment sites for osteogenic cells.[1,7-9]

Attach

Osteogenic cells **attach** to P-15 via specific surface receptors enhancing cell retention, spreading and survival.[7-9,12]



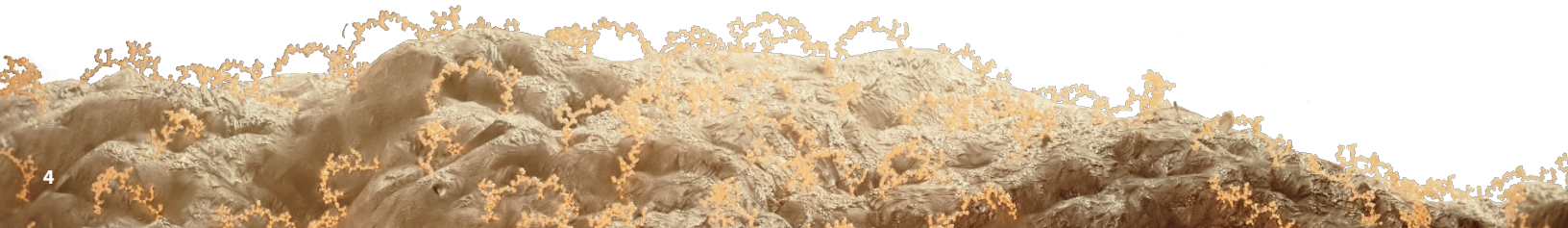
Activate

Once attached, cellular pathways are **activated** that enhance osteogenic activity by releasing growth factors and other important signaling molecules.[7-9,13]

Accelerate

Upregulation of growth factors recruit additional osteogenic cells, creating a cyclical attachment and activation process that accelerates new bone formation.[7-11,13-15]

+ In single-level TLIF procedures.



PearlMatrix was **rigorously tested** through the ASPIRE PMA IDE Study

A 293 patient, pivotal, Level 1, PMA, IDE study inclusive of ~60% high-risk patients.^[1]

Prospective, randomized, controlled, statistically-powered, IDE Study
- PearlMatrix vs. local autograft in single-level TLIF (L2-S1).
- Graft was placed both in and around a static PEEK TLIF cage.
- There was no grafting permitted in the facets or posterolateral gutters.

Study inclusion reflected a real-world patient population
- 293 patients, 33 US clinical sites, ~60% high-risk patients.
- High risk = nicotine use, BMI ≥ 30 and/or Type 2 diabetes

Primary Endpoint: 24 Month Composite Clinical Success (CCS)
- Five components: fusion, function (ODI), neurological, no serious device related adverse events and no index-level secondary surgical interventions.
- CT Follow-up: 6, 12 and 24 months.

Rigorous fusion assessment criteria
- High-resolution, thin-cut CT.
- Multiple independent reviewers.

TLIF
single-level

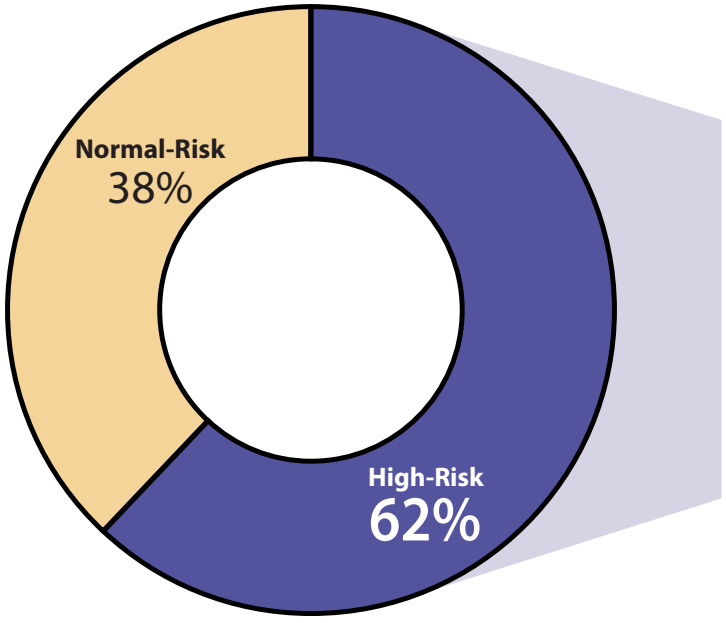
293
patients

~60%
high-risk patients

CT
Fusion assessment

~60% of the enrolled ASPIRE IDE study population were considered **high-risk**.^[1]

High-risk comorbidities can complicate bone healing and **put fusion outcomes at risk**.^[5]



High-risk comorbidities include one or more of the following:

- Nicotine Use
- Type 2 Diabetes
- BMI ≥ 30

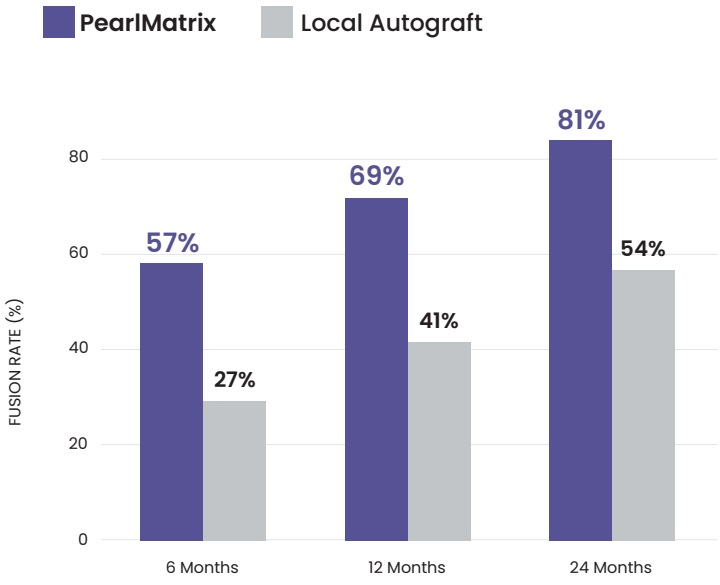
^ High-risk includes nicotine use, BMI ≥ 30 and/or Type 2 diabetes.

Fusion Rates

PearlMatrix **demonstrated substantially higher fusion rates** vs. local autograft at 6, 12 and 24 months in both the overall and higher-risk patient populations.[^†1]

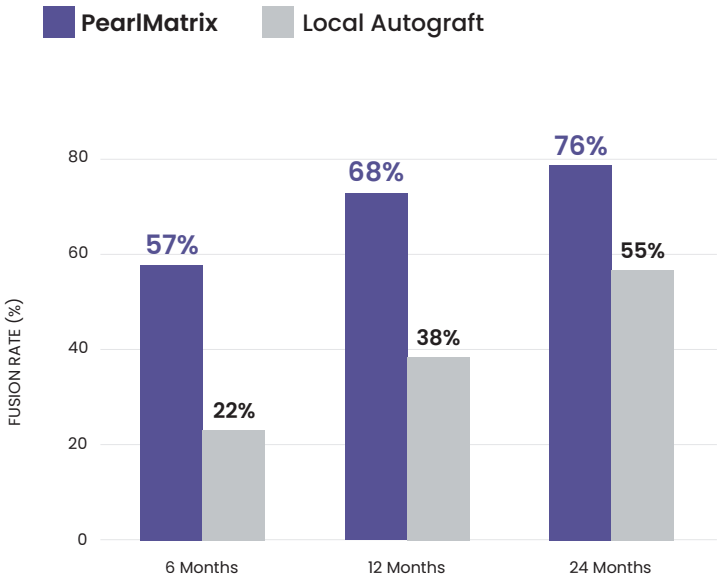
Overall Patient Population

Fusion Rates



High-Risk Patient Population[^]

High Risk Fusion Rates

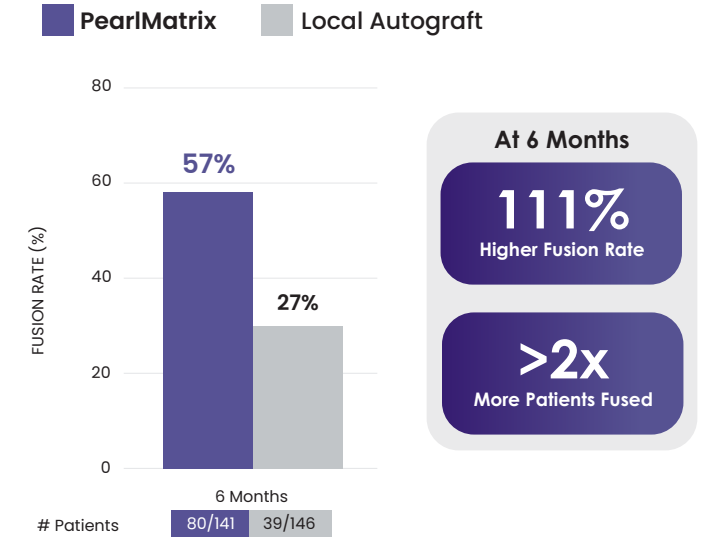


Fusion Speed

PearlMatrix demonstrated substantially faster fusion in both the overall and higher-risk patient populations achieving **statistically superior fusion speed** at 24 months in the overall population with over 2x more patients fused at 6-months.[^†]

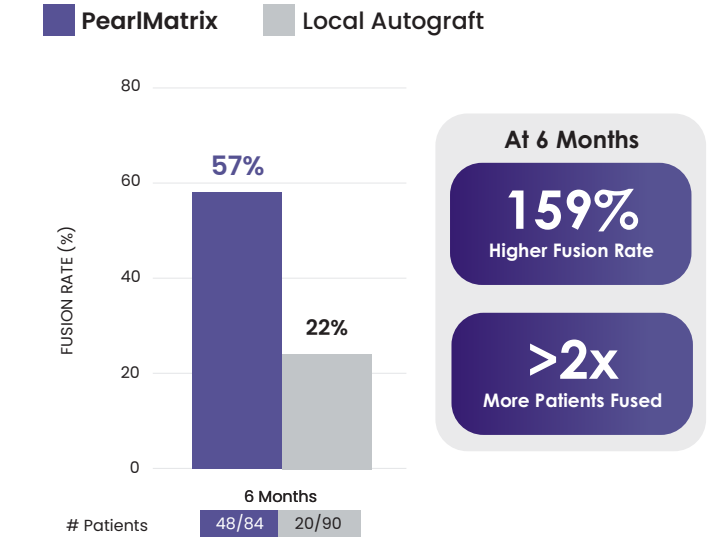
Overall Patient Population

Fusion at 6-Months



High-Risk Patient Population[^]

High-Risk Fusion at 6-Months



[^] High-risk includes nicotine use, BMI ≥ 30 and/or Type 2 diabetes.
† As demonstrated in a single-level TLIF IDE study vs. local autograft.

Overall Clinical Success

Primary Endpoint: Composite Clinical Success (overall clinical success) at 24-months.
To be considered an **overall clinical success**, a patient must achieve success in all **5 out of 5 components**.

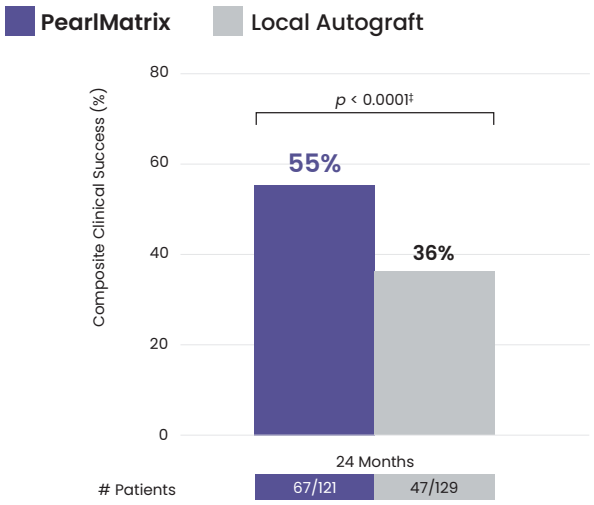
Overall Clinical Success is determined by a composite of 5 components:

- Achievement of fusion.
- At least 15-point improvement in ODI.
- No new or worsening persistent neurological deficit.
- No serious device-related adverse events.
- No secondary surgical interventions at the index level.

PearlMatrix demonstrated **substantially higher overall clinical success** at 24-months in both the overall and **higher-risk patient populations** achieving statistical superiority for the primary endpoint.^†[1]

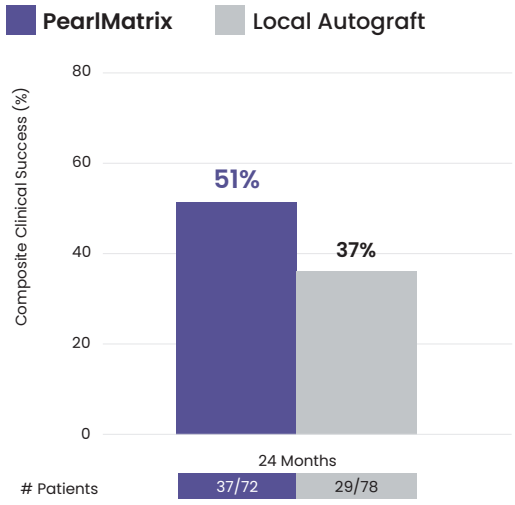
Overall Patient Population

Composite Clinical Success



High-Risk Patient Population^

High-Risk Composite Clinical Success



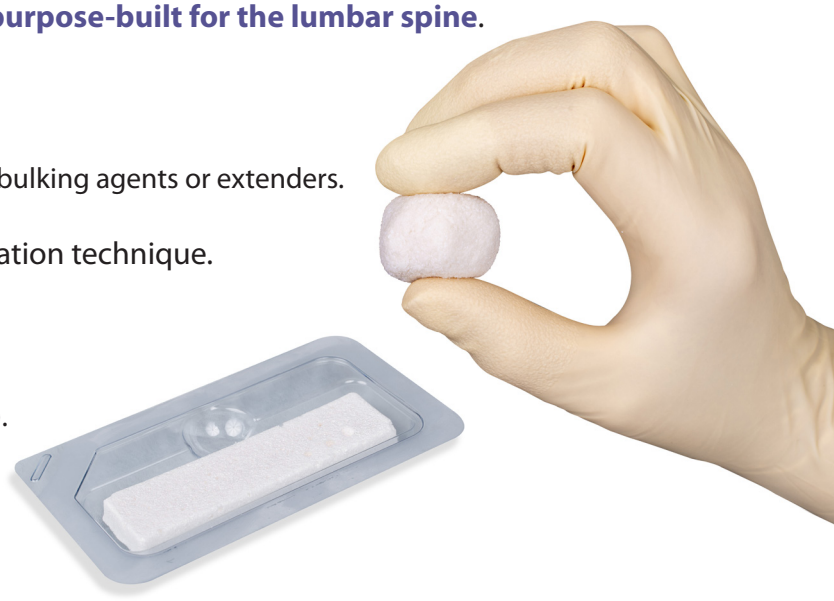
Ease-of-Use

PearlMatrix provides optimized handling properties **purpose-built for the lumbar spine**.

- Fibrous, cohesive and moldable.
- Naturally resists migration and separation.
- Adaptable to open or MIS TLIF procedures.
- All-in-one bone graft replacement that doesn't require bulking agents or extenders.

PearlMatrix is **quickly hydrated** with a simple preparation technique.

- Hydrated with sterile surgical solution (i.e., saline).
- Conveniently pre-packaged in a sterile hydration tray.
- No activation time or waiting for binding.
- Can be separated and molded into the desired shape(s).



^ High-risk includes nicotine use, BMI ≥ 30 and/or Type 2 diabetes.
† As demonstrated in a single-level TLIF IDE study vs. local autograft.
‡ Statistical significance.

PearlMatrix™

P-15 Peptide Enhanced Bone Graft

Ordering Information

Description	Size	Catalog Number
PearlMatrix™ Bone Graft, 1.0cc	1.0cc	730-010
PearlMatrix™ Bone Graft, 2.5cc	2.5cc	730-025
PearlMatrix™ Bone Graft, 5.0cc	5.0cc	730-050
PearlMatrix™ Bone Graft, 10.0cc	10.0cc	730-100

PearlMatrix is packaged as a freeze-dried material that does not require freezing or thawing.

- Three-year shelf life.
- Stored at room temperature.
- Provided sterile and intended for single-use only.

About Cerapedics Inc.

Cerapedics is committed to Repairing Bones and Healing Lives.

Cerapedics is a global, commercial-stage orthopedics company that is dedicated to redefining the path to bone repair by healing bones faster and at higher rates, so all patients can get back to living their fullest lives.

Indications and Important Safety Information

PearlMatrix™ Bone Graft is indicated for intervertebral body fusion of the spine in skeletally mature patients. PearlMatrix is intended to be used in conjunction with a PEEK TLIF Fusion Device and supplemental internal spinal fixation systems cleared by the FDA for use in the lumbosacral spine. The system is to be used in patients who have had at least six months of non-operative treatment. PearlMatrix is intended for use at one level in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back and/or radicular pain of discogenic origin with degeneration of the disc confirmed by history, physical exam, and radiographic studies.PearlMatrix is contraindicated in situations where there is an absence of load-bearing structural support at the graft site, sensitivity to components or the product, active infection at the operative site, or operative site subject to excessive impact or stress.

The effect of PearlMatrix on pregnant or nursing patients has not been evaluated. Care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure such as individuals with bleeding disorders of any etiology, long-term steroidal therapy, immunosuppressive therapy or high dosage radiation therapy. PearlMatrix in a TLIF procedure was associated with a higher rate of secondary surgical interventions compared to local autograft.

PearlMatrix should only be used by physicians who are experienced with TLIF procedure and in surgical procedures where it can be adequately contained at the bony void or defect.

To learn more about PearlMatrix, its indications, contraindications, warnings, precautions and potential adverse events, visit our website at www.Cerapedics.com or refer to the PearlMatrix Instructions for Use for complete safety and risk information.

Definitions

CCS, composite clinical success
DBM, demineralized bone matrix
FDA, Food and Drug Administration
HCT/P, human cell or tissue product
IDE, investigational device exemption
ODI, Oswestry disability index
PMA, premarket approval
CCS, composite clinical success
TLIF, transforaminal interbody fusion

Footnotes and Disclaimers

* Demonstrated statistically superior time-to-fusion in a single-level TLIF PMA IDE study vs. local autograft.
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‡ Statistical significance.
+ In single-level TLIF procedures.

References

1. PearlMatrix Instructions for Use. Cerapedics. **2.** Data on File as of 9/9/24 **3.** Internal Data on File. **4.** Bono CM, et al. Spine. 2007 Feb 15;32(4):417-22 **5.** Mariscal, et al. in preparation. **6.** Abjornson, C. et al. Int J Spine Surg. 2018;12(6):757–771. **7.** Nguyen H, et al. Biochem Biophys Res Commun. 2003;311(1):179–86. **8.** Yang XB, et al. Tissue Eng. 2004;10(7–8):1148–59. **9.** Liu Q, et al. J Orthop Res. 2012;10:1526. **10.** Thorwarth M, et al. Biomaterials. 2005;26(28):5648-57. **11.** Lindley EM, et al. J BioMed Mater Res B Appl Biomater. 2010;94(2):463-8. **12.** Hanks T and Atkinson BL. Biomaterials. 2004;25:4832-36. **13.** Emecen P, et al. Acata Odontol Scand. 2009;67(2):65-73. **14.** Lind M, et al. Bone. 1996;18(1):53-57. **15.** Lee DH, et al. Tissue Eng. 2006;12(6):1577-1586.

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