i-FACTOR®

Peptide Enhanced Bone Graft

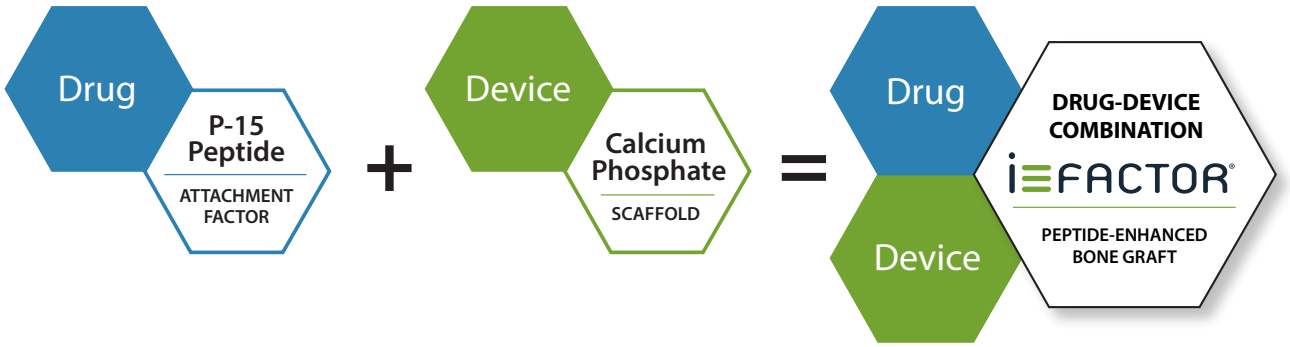
Discover the Bone Healing Power of P-15 Osteogenic Cell Binding Peptide

A Powerful Cell Attachment Factor Backed by Level 1 Human Clinical Data

CERAPEDICS

Enhancing the Science of Bone Repair

i-FACTOR is a Drug-Device Combination Bone Graft

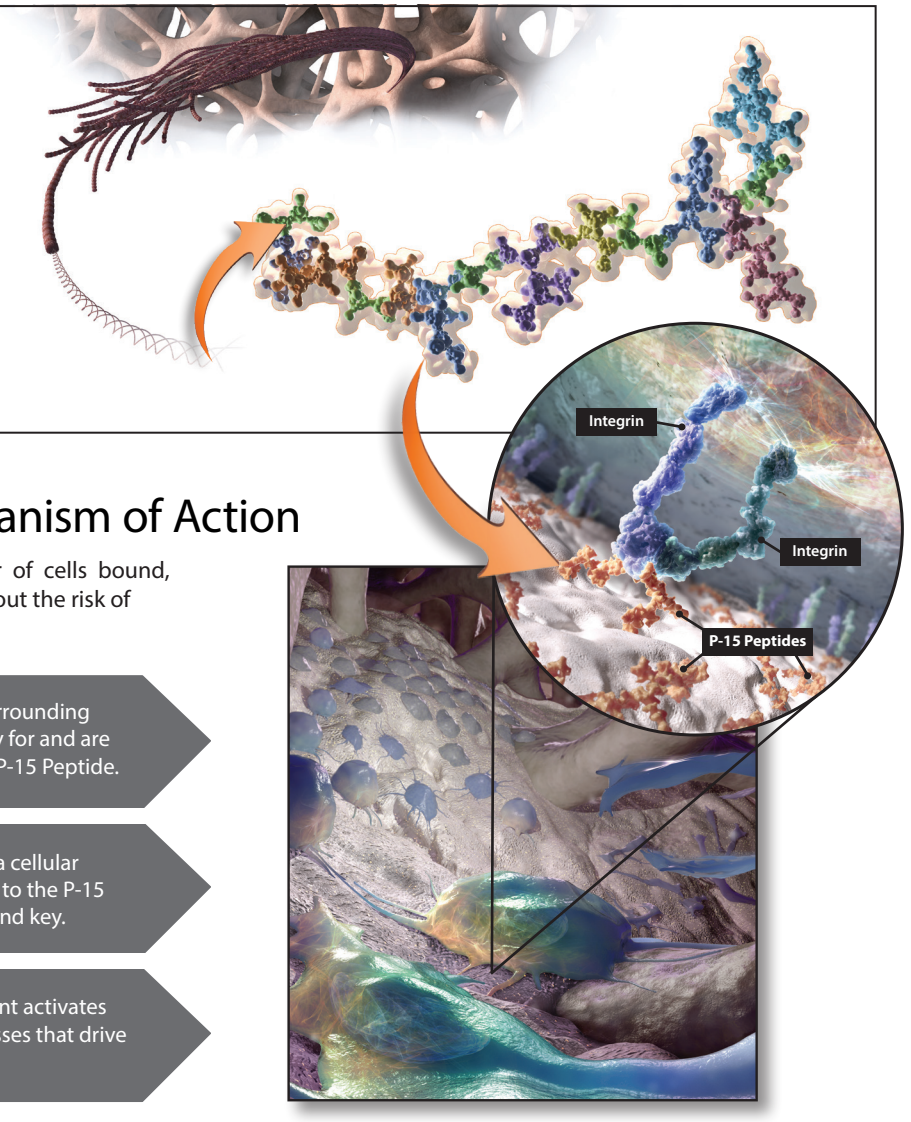


i-FACTOR's Powerful Cell Attachment Capability: The P-15 Peptide

P-15 Peptide is a naturally occurring chain of 15 amino acids found on Type I collagen and is a critical cell binding domain for bone-forming cells.

The P-15 Peptide (Drug) is pharmacologically manufactured and bound to calcium phosphate (Device) delivery particles.

This yields a high concentration of the peptide on the graft and creates an abundance of P-15 Peptide binding and anchoring surface receptor sites.



i-FACTOR has a Unique Mechanism of Action

i-FACTOR's mechanism of action increases the number of cells bound, cellular proliferation and protein/matrix production, without the risk of ectopic bone formation.[1,2,3,4,16]

ATTRACT — Osteogenic cells in the surrounding tissues have a high affinity for and are naturally attracted to the P-15 Peptide.

ATTACH — Osteogenic cells attach via cellular surface receptor integrins to the P-15 Peptide, similar to a lock and key.

ACTIVATE — The mechanical attachment activates multiple molecular processes that drive bone formation.

i-FACTOR has Level 1 Human Clinical Evidence

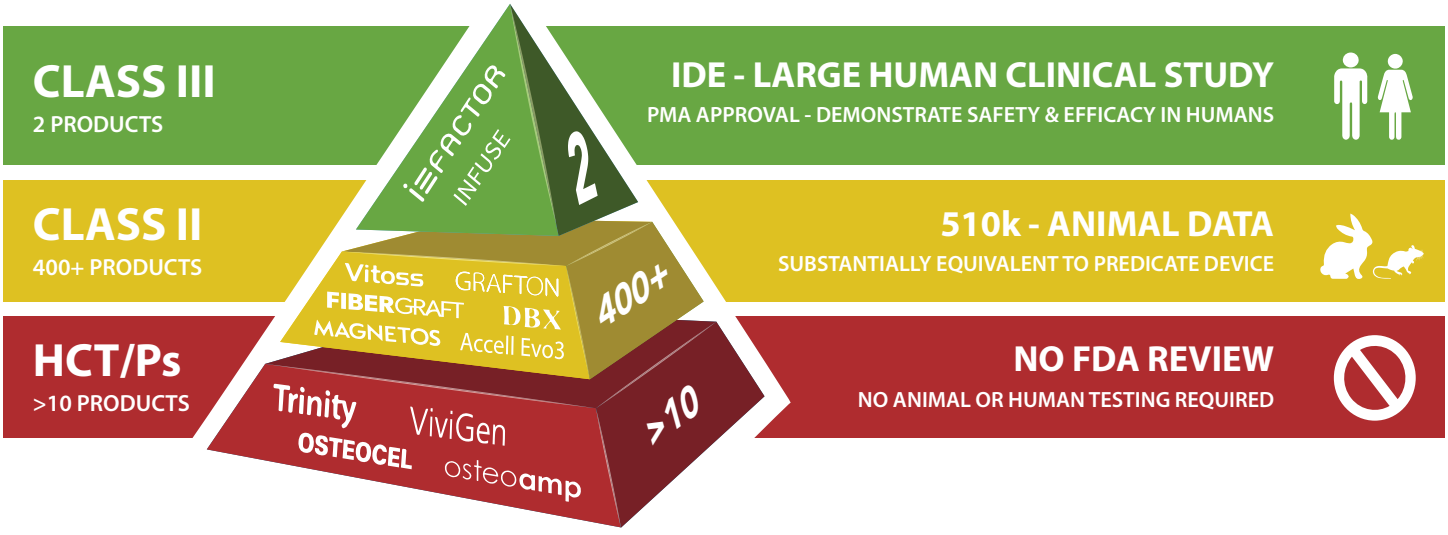
Physicians are encouraged to find the highest level of evidence to support the safe and effective use of a product in a clinical setting. Evidence-based research studies can range anywhere between Level 1 to Level 6. i-FACTOR has published Level 1 human clinical evidence whereas the majority of 510k bone grafts on the market have lower level studies.

Level 1	Randomized controlled human clinical trial	Fewer High Level Studies (Increased Cost and Quality)
Level 2	Prospective cohort study	Number of Studies
Level 3	Retrospective cohort study	
Level 4	Case studies	
Level 5	Mechanism-based reasoning	
Level 6	Animal studies, in vitro studies	Many Low Level Studies (Lower Cost and Quality)

Only 2 FDA Class III PMA Approved Spinal Bone Grafts

There are three FDA regulatory pathways for orthobiologics: Class III, Class II 510k, and HCT/P (tissue based products). Class III devices have the most rigorous pathway requiring a PMA Approved Level 1 Investigational Device Exemption (IDE) human clinical trial to bring the products to market.

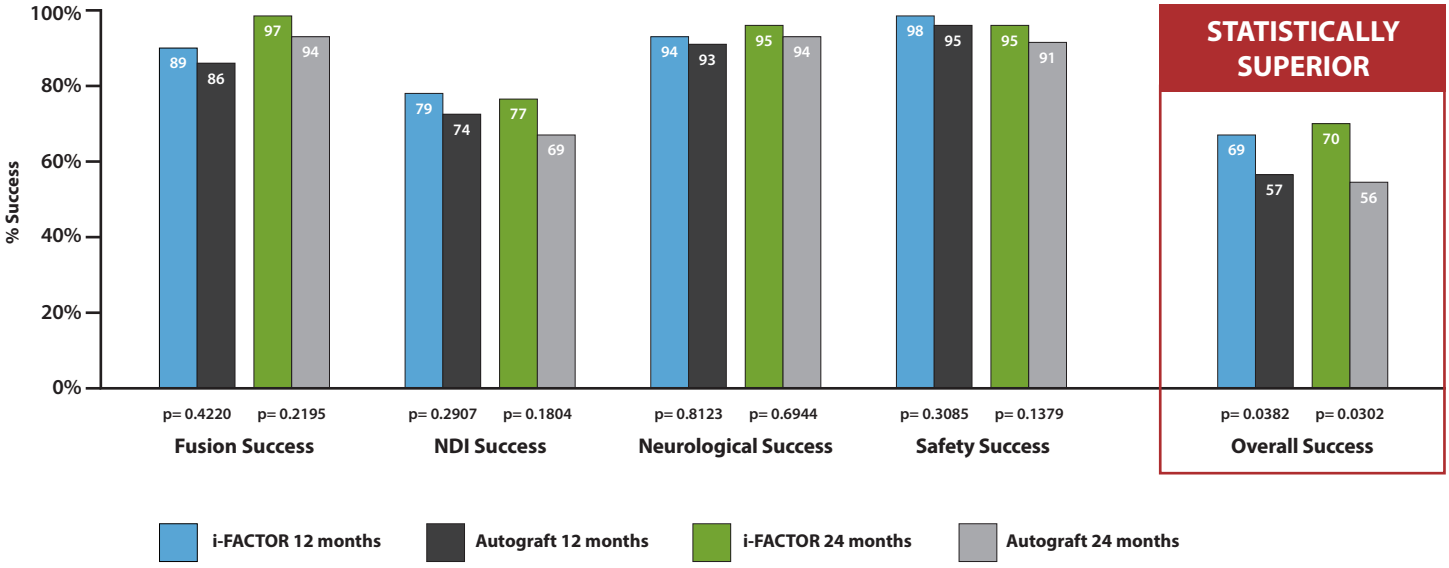
i-FACTOR has met the most robust FDA study requirements and is only the second Class III Drug-Device Combination bone graft approved for the US Spine market. The only other spinal bone graft in this category is Medtronic's Infuse™ (BMP-2). The majority of bone grafts on the market are cleared via the 510k pathway.



i-FACTOR has a PMA Approval based on an IDE Human Clinical Study[5,6]

- Prospective, randomized, controlled, statistically powered, multicenter trial
- Level 1 human clinical data from 319 patients
- FDA approval based on IDE study (Investigational Device Exemption)
- One year data published 2016 in *Spine* demonstrating a fusion rate of 89.0%
- Two year data published 2018 in *Neurosurgery* demonstrating a fusion rate of 97.3%
- Statistical superiority vs. autograft in overall clinical success at one and two years

i-FACTOR has Proven Clinical Superiority vs. Autograft[5,6]



i-FACTOR was demonstrated to be **statistically superior to autograft** in overall clinical success at one year and two years.[5,6]

i-FACTOR is the **only spinal bone graft** on the market that can make this claim.

Misconceptions of ACDF Fusion Rates

ACDF fusion rates are commonly over reported in the literature whereas studies with more stringent fusion criteria reveal lower fusion rates.[7] This is clearly demonstrated in the published ACDF fusion rates in the control arms of Cervical Total Disc Replacement (TDR) FDA mandated studies that are Level 1, prospective, randomized, controlled and blinded.

ACDF fusion rates are often over reported in the literature in comparison to IDE Study ACDF fusion rates.

i-FACTOR ACDF Fusion Rates are Higher than the ACDF Control Arms in All Cervical TDR IDE Studies[5,6]

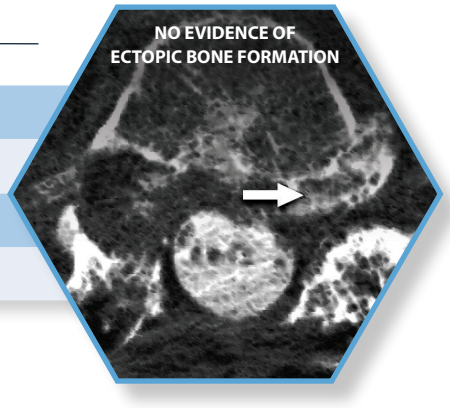
- In all Cervical TDR IDE studies, the control arms were single level ACDFs with allografts, there was no artificial disc.
- A fair comparison of fusion rates is to assess those control arm fusion rates with i-FACTOR's IDE study fusion rates because the i-FACTOR IDE Study design was also a single level ACDF with i-FACTOR in a cortical allograft ring.
- As shown in the chart below, these TDR study control arm ACDF fusion rates are as low as 78.6% and up to 94.3% which are all consistently lower than i-FACTOR's 24 month fusion rate of 97.3%.

i-FACTOR Level 1 IDE Study	i-FACTOR Test Arm Fusion Rate 24 mos	Test Arm Design
i-FACTOR[5,6]	97.3%	i-FACTOR with Allograft Ring
TDR Level 1 IDE Study	**Allograft Control Arm Fusion Rate 24 mos**	**Control Arm Design**
Bryan Cervical Disc[8]	94.3%	Allograft
PCM Cervical Disc[9]	92.1%	Tricortical Allograft
Pro-Disc C[10]	90.2%	Allograft and Local Bone
MOBI-C/TBI Study[11,12]	89.3%	Corticocancellous Allograft
Globus Secure-C[13]	89.1%	Structural Allograft
Kineflex|C Artificial Disc[14]	82.0%	Corticocancellous Allograft
M6-C[15]	78.6%	Corticocancellous Allograft and Local Bone

i=FACTOR® LEVEL 1 IDE STUDY FUSION RATE OF 97.3%[5,6]

i-FACTOR is Safe

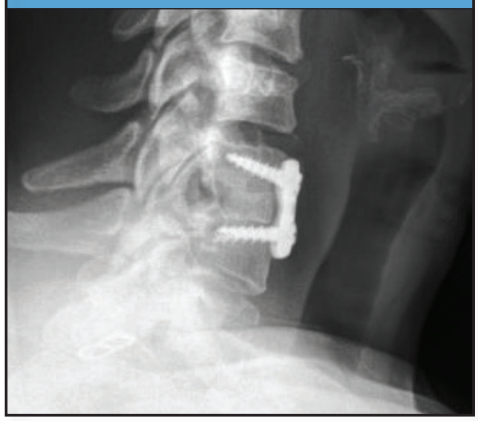
- Only grows bone in a bony environment, no evidence of ectopic bone formation[16]
- Over 100k procedures worldwide since 2008
- Clinical experience outside US since 2008, in US since 2015
- IDE Study demonstrated no difference in adverse events vs. autograft[5,6]



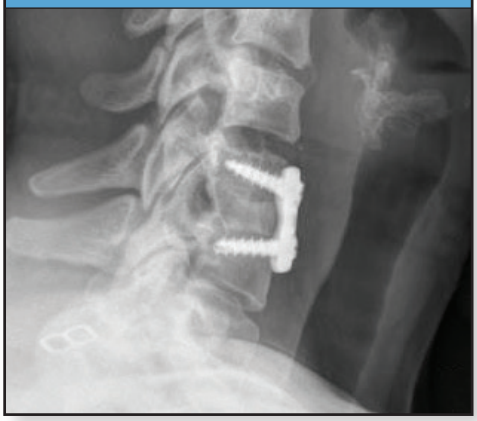
i-FACTOR is Predictable

High Fusion Rates	12 months	24 months
	89.0%	**97.3%**

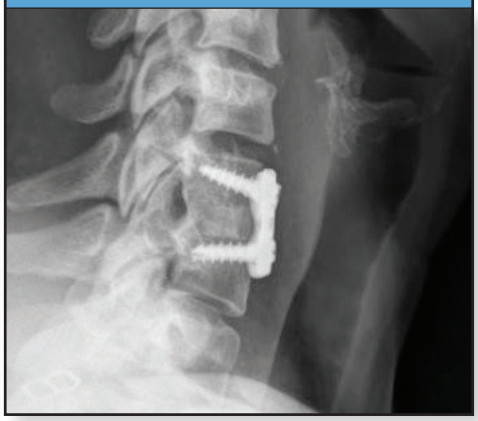
IDE Study: **3 months**



IDE Study: **6 months**



IDE Study: **12 months**

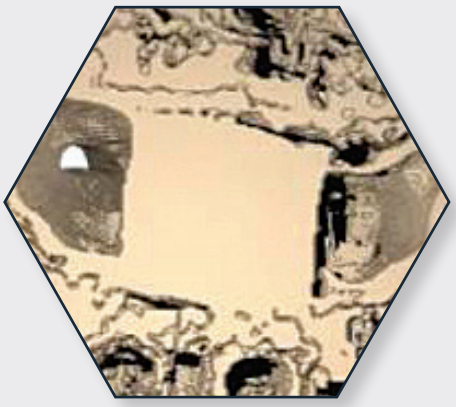


i-FACTOR has a proven **safety profile equivalent to autograft.**[5,6]

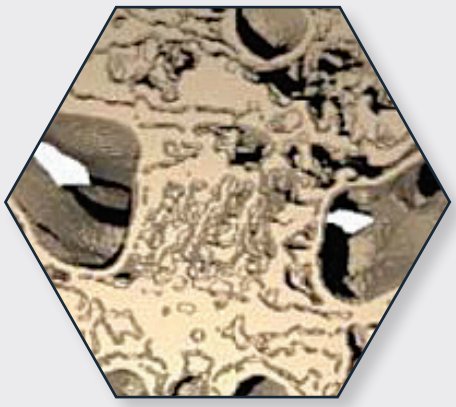
i-FACTOR **only grows bone** in the presence of **bone forming cells.**

Fusion Characteristics Similar to Mature and Healthy Bone

To evaluate the quality of bone within the interbody space, 3D CT imaging technology from a patient in the IDE study determined that the porosity, trabecular orientation and structure of the bone that i-FACTOR developed was characteristic of mature and healthy normal bone within six months.[17]



Post-op



3 Months

6 Months

Indication

i-FACTOR Peptide Enhanced Bone Graft is indicated for use in skeletally mature patients for reconstruction of a degenerated cervical disc at one level from C3-C4 to C6-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit), with or without neck pain, or myelopathy due to a single-level abnormality localized to the disc space, and corresponding to at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels, after failure of at least 6 weeks of conservative treatment. i-FACTOR Peptide Enhanced Bone Graft must be used inside an allograft bone ring and with supplemental anterior plate fixation.

Available Sizes

700-010	i-FACTOR Putty	1.0cc
700-025	i-FACTOR Putty	2.5cc
700-050	i-FACTOR Putty	5.0cc

Cerapedics is an advanced orthobiologics company focused on developing and commercializing its proprietary small peptide (P-15) technology platform. i-FACTOR® Peptide Enhanced Bone Graft is the only biologic bone graft in orthopaedics that incorporates P-15 osteogenic cell binding peptide to stimulate the natural bone healing process. This novel mechanism of action is designed to support safer and more predictable bone formation compared to commercially available bone growth factors.

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Corporate Headquarters
11025 Dover Street, Suite 1600
Westminster, CO 80021 USA
P: (303) 974-6275
E: customerservice@cerapedics.com

www.cerapedics.com

Europe, Middle East, Africa, Asia Pacific and Canada
London, England
E: emea@cerapedics.com

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