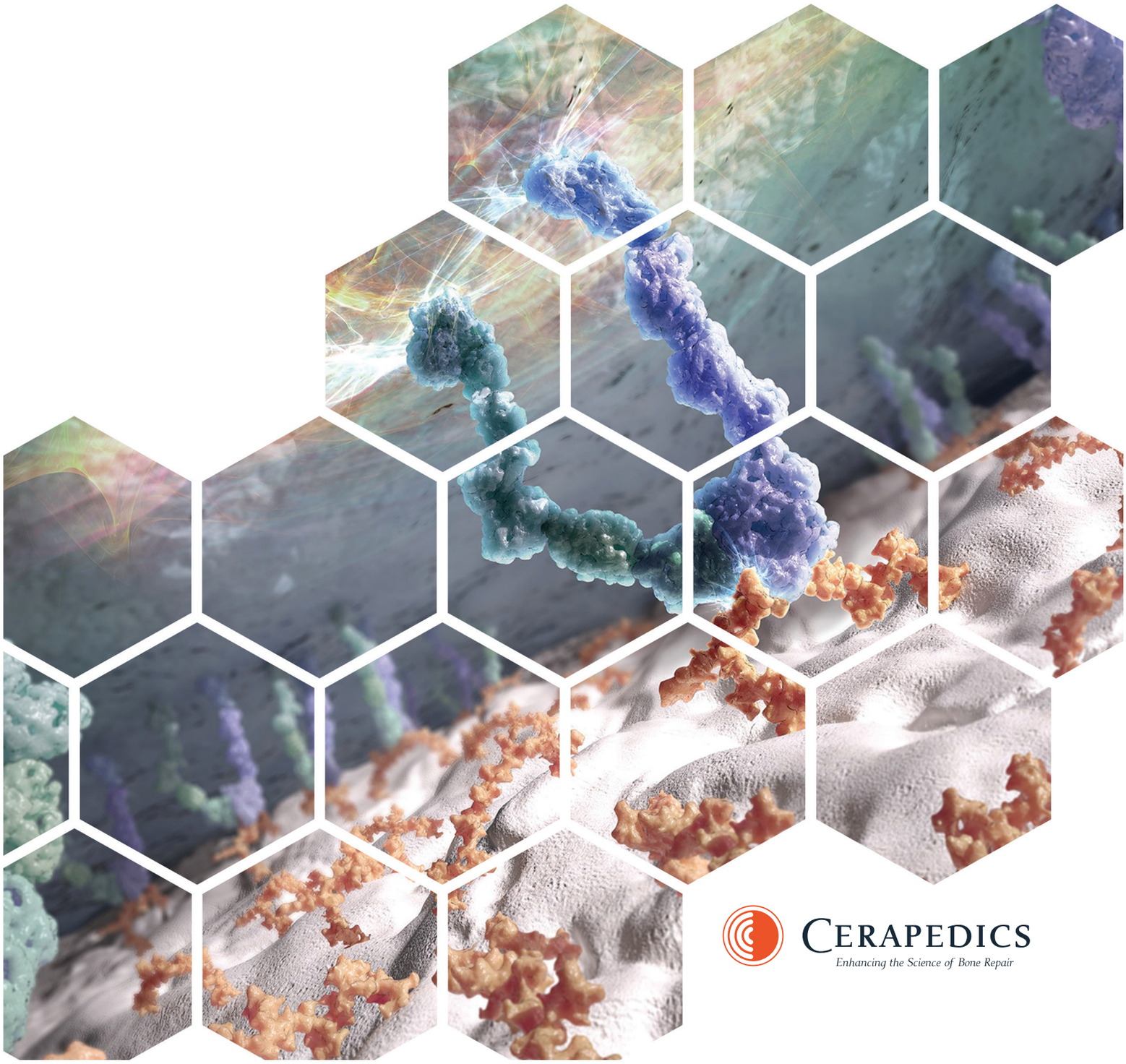
i=FACTOR®

THE **ONLY** BONE GRAFT POWERED BY

P15™ osteogenic cell binding peptide

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

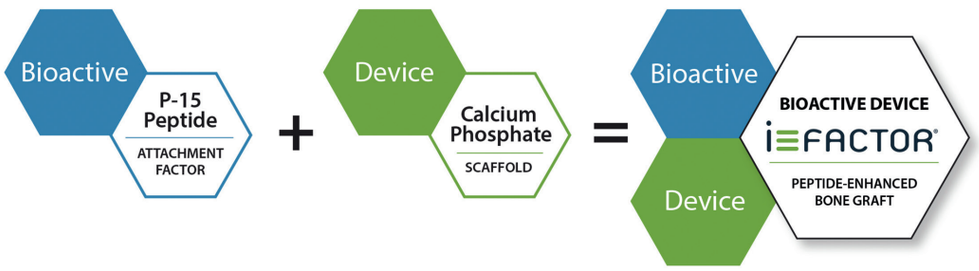
A Powerful Cell Attachment Factor Backed by Level 1 Human Clinical Evidence



CERAPEDICS

Enhancing the Science of Bone Repair

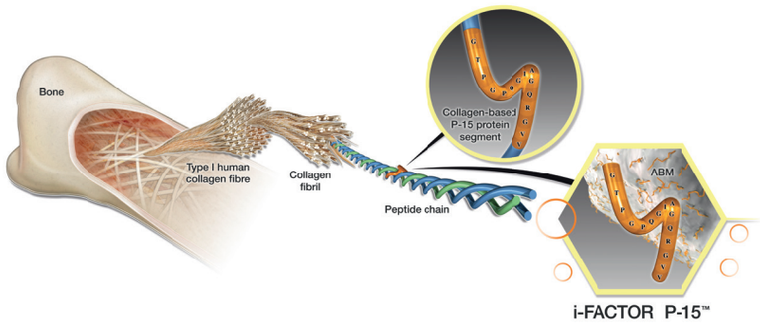
An Active Biologic which Utilizes P-15 Osteogenic Cell Binding Peptide



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

i-FACTOR technology is based on the biological activity of a 15 amino acid peptide naturally found in Type I human collagen.

This protein segment (P-15) is responsible for the attachment and proliferation of osteogenic cells. These cells bind to the synthetic P-15 found in i-FACTOR.



i-FACTOR has a unique Mechanism of Action

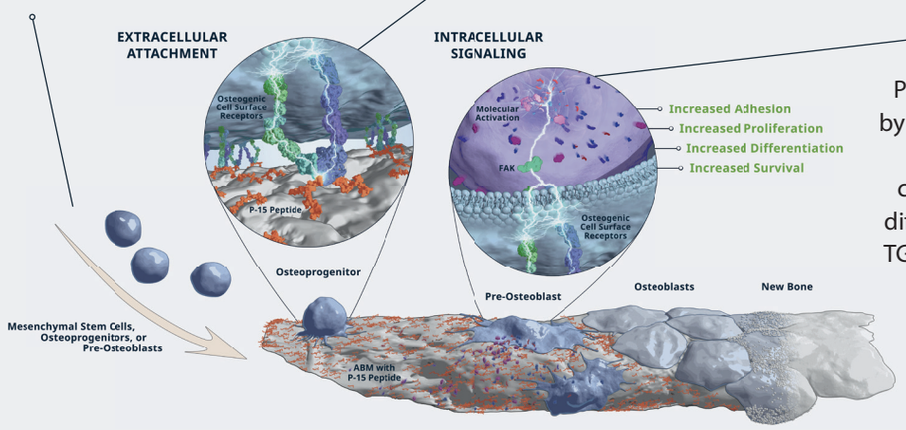
i-FACTOR increases the opportunity for cell binding in the fusion site by making an abundance of P-15 available to osteogenic cells. The ability of P-15 to enhance cell binding hastens the process of new bone formation and closely resembles the natural process of bone regeneration.[1,2,3,4]

ATTRACT

P-15 facilitates and expedites ingrowth of bone by promoting the movement of reparative cells from the surrounding tissues.[2]

ATTACH

Cells have a high affinity for P-15. Once attached cells continue to organize the matrix via tractional forces. Cell attachment is facilitated by a natural haptotactic mechanism. [2,3,4]



ACTIVATE

P-15 enhances bone formation by facilitating cellular attachment with subsequent increase in cell binding, proliferation, and differentiation of cells increasing TGFβ-1, BMP-2, and BMP-7 levels that positively influence all processes of new bone formation.[5]

✓ i-FACTOR has Level 1 Human Clinical Evidence

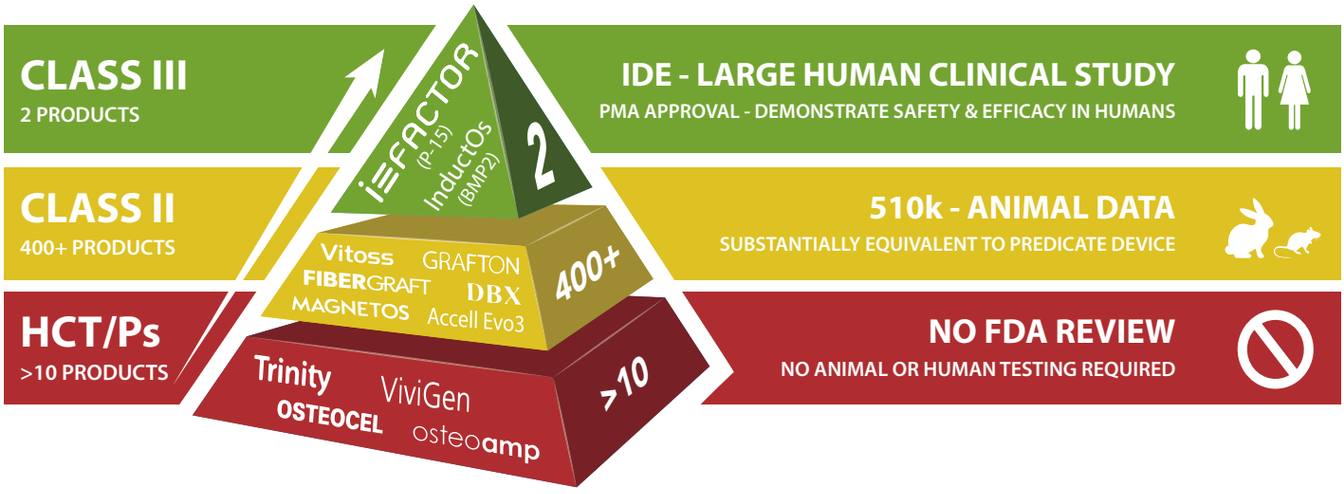
Physicians are encouraged to find the highest level of evidence to support the safe and effective use of a product in a clinical setting. i-FACTOR, which contains P-15, has published Level 1 human clinical evidence whereas the majority of bone grafts on the market have lower levels of evidence.

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

FDA guidance is globally recognised by physicians due to its clear classification systems and stringent demand for quality data to support product claims. 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.

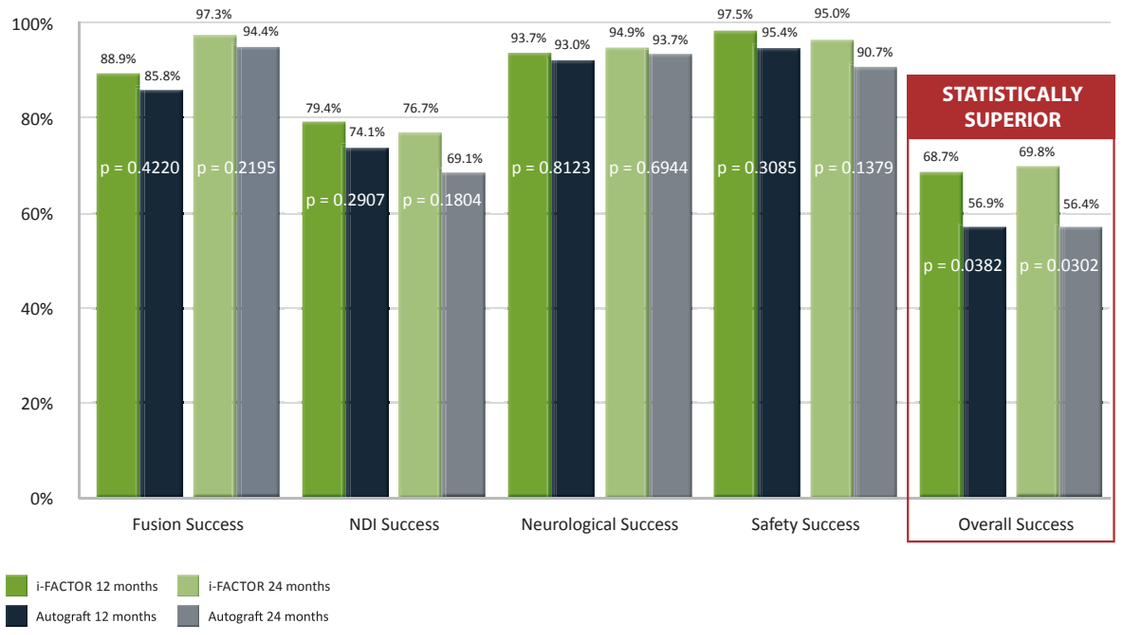
i-FACTOR has met the most robust FDA study requirements and is one of only two Class III bone grafts approved for the US spine market. The only other spinal bone graft in this category is Medtronic's InductOs™ (BMP-2). The majority of bone grafts on the market are cleared via the 510k pathway.



✓ i-FACTOR has a PMA Approval based on an IDE Human Clinical Study[6,7]

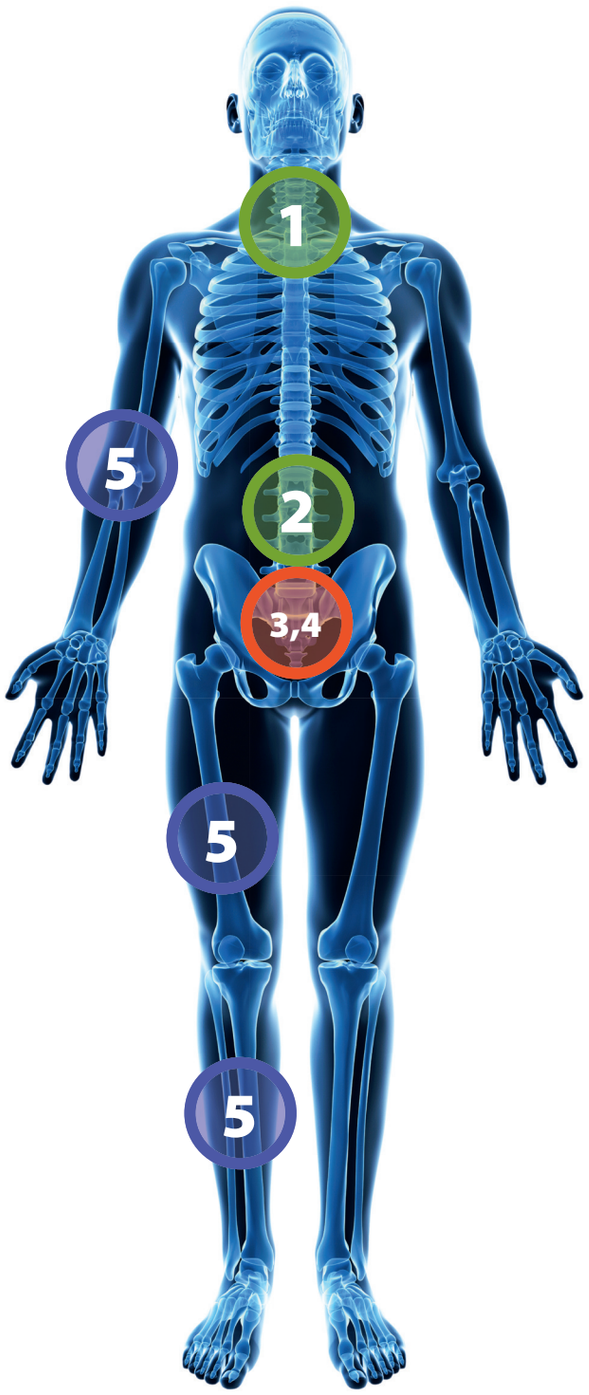
- Prospective, randomized, controlled, statistically powered, multicenter trial
- Level 1 human clinical data from 319 patients
- FDA approval based on IDE study (Investigational Device Exemption)
- One year data published 2016 in *Spine* demonstrating a fusion rate of 89.0%
- Two year data published 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[6,7]



i-FACTOR which contains P-15 was demonstrated to be statistically superior to autograft in overall clinical success at one year and two years.[6,7]

The Clinically Proven power of P-15: Osteogenic Cell Binding Peptide



Spine

1 ACDF (n = 319)[6,7]

ACDF

- 319 patients
- *"i-FACTOR subjects demonstrated higher overall success rate than control (autograft) subjects (68.75% and 56.94% respectively, p = 0.0382)"*

2 PLF (n = 98)[8]

PLF

- *"This RCT indicates i-FACTOR being significantly superior to allografted bone in enhancing intertransverse fusion (p = 0.000)"*

3 ALIF (n = 110)[9]

ALIF

- 110 patients
- *"…high fusion rate and clinical improvements comparable to the published results for ALIF using autograft or BMP"*

4 PLIF (n = 40)[10]

PLIF

- 40 patients
- *"i-FACTOR is associated with faster formation of bridging bone when compared to autologous bone in patients undergoing PLIF"*

Orthopedics

NON-UNION[11]

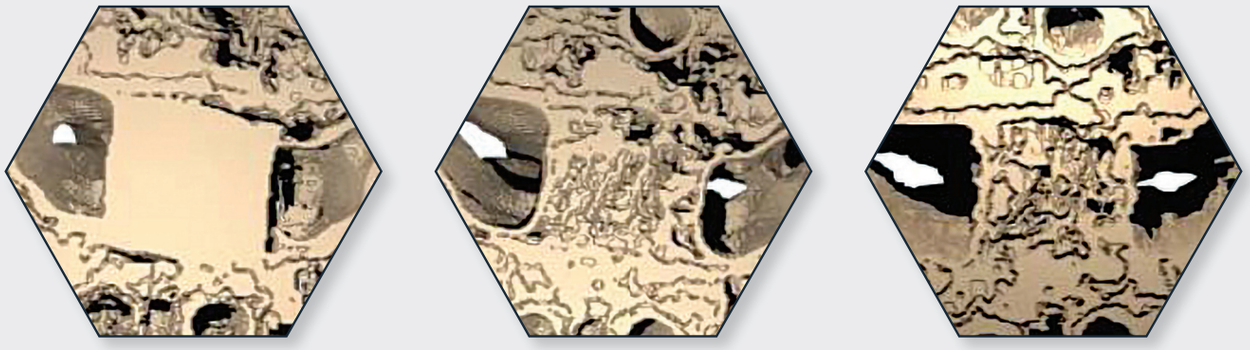
5 Treatment of non-union and delayed union (n = 22)

- *"P-15 appears to offer a safe, economical, and clinically useful alternative to autograft in the repair of ununited fractures"*

Level 1 Prospective Study Published Case Series

Fusion Characteristics Similar to Mature and Healthy Bone

To evaluate the quality of bone within the interbody space, 3D CT imaging technology was taken from a patient following a single level ACDF. Detailed analysis determined that the porosity, trabecular orientation, and structure of new bone that P-15 developed was characteristic of mature and healthy normal bone within six months.[12]



Post-op **3 Months** **6 Months**

Why choose i-FACTOR?

- ✓ Safe, predictable, proven technology
- ✓ Surface-bound with no ectopic bone growth
- ✓ Clinical superiority to autograft in single-level ACDF

- ✓ Subject to highest regulatory scrutiny (US FDA approved)
- ✓ Room temperature storage, 3-year shelf life
- ✓ Superior clinical safety profile with long and broad experience

Indication

Indication for Putty

i-FACTOR Bone Graft is a bone graft substitute material for use in the repair of bony voids or defects in orthopaedic applications throughout the skeletal system (i.e. the spine and extremities). The bony voids may be surgically created defects or may result from traumatic injury to the bone.

Indication for Flex FR

i-FACTOR Flex FR is a bone graft substitute material for use in the repair of bony voids or defects in orthopedic applications throughout the skeletal system (i.e. the spine and extremities). The bony voids may be surgically created defects or may result from traumatic injury to the bone.

putty i-FACTOR® Peptide Enhanced Bone Graft

Available Sizes

900-010	i-FACTOR Putty	1.0cc
900-025	i-FACTOR Putty	2.5cc
900-050	i-FACTOR Putty	5.0cc
900-100	i-FACTOR Putty	10.0cc

flex FR i-FACTOR® Peptide Enhanced Bone Graft

Available Sizes

		LENGTH		WIDTH		THICKNESS
950-012	i-FACTOR Flex FR	12mm	x	25mm	x	4mm
950-025	i-FACTOR Flex FR	25mm	x	25mm	x	4mm
950-050	i-FACTOR Flex FR	50mm	x	25mm	x	4mm
950-100	i-FACTOR Flex FR	100mm	x	25mm	x	4mm

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

CE 2797 Internationally available

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

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