

# iFACTOR®

THE ONLY BONE GRAFT POWERED BY

**P15™** osteogenic cell binding peptide

## Attract. Attach. Activate.

The precise way to build bone.

### Mechanism of action

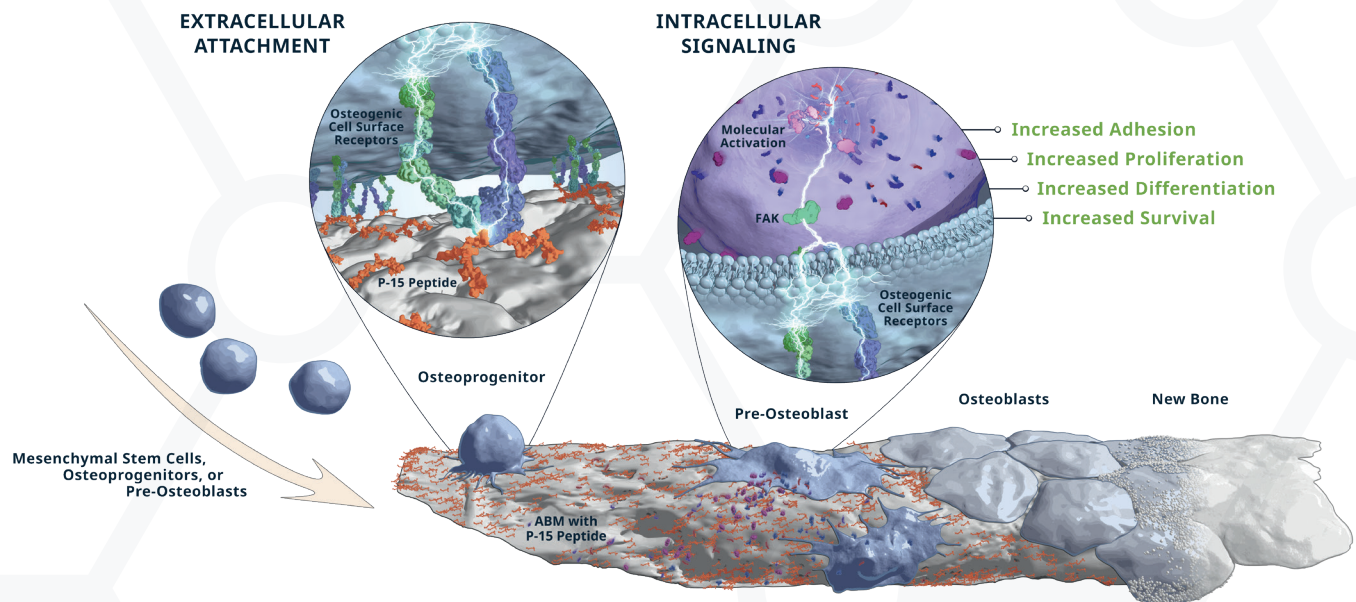
i-FACTOR is the first and only bone graft powered by P-15 Osteogenic Cell Binding Peptide™, a powerful cellular attachment factor that Attracts, Attaches and Activates bone forming cells directly at the fusion site – nowhere else.

### Efficacy

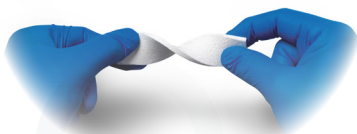
In the Level 1 Investigational Device Exemption (IDE) human clinical study, i-FACTOR achieved a fusion rate of 97.3% at 24 months, demonstrating statistical superiority vs. autograft in overall clinical success.

### Safety

P-15 Osteogenic Cell Binding Peptide™ activity is restricted to the implant surface, eliminating ectopic bone formation, and was demonstrated to be as safe as autograft in a Level 1 Investigational Device Exemption (IDE) study.



i-FACTOR Bone Graft is ready to use and thus requires no mixing or other preparation prior to use



### i-FACTOR Flex

This robust and flexible strip can be cut or shaped to fit the particular dimensions of an osseous defect or interbody fusion device.

i-FACTOR Flex FR, with purified silk, retains the safety and biocompatibility of P-15 while providing superior handling.



### i-FACTOR Putty

i-FACTOR Putty is ideal for contained areas such as interbody fusion devices.

i-FACTOR Putty is a dense, paste-like hydrogel carrier. The thick structure enables greater control during use. i-FACTOR Putty can be used standalone or mixed with autograft (recommended ratio 30:70).



## Spine

### 1 ACDF (n = 319)<sup>1,2</sup>

- 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)<sup>3</sup>

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

### 3 ALIF (n = 110)<sup>4</sup>

- 110 patients
- “...high fusion rate and clinical improvements comparable to the published results for ALIF using autograft or BMP”

### 4 PLIF (n = 40)<sup>5</sup>

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

## Orthopedics

### NON-UNION<sup>6</sup>

#### 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



#### 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       |



#### 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 |

1. Arnold PM, Sasso RC, Janssen ME, Fehlings MG, Smucker JD, Vaccaro AR, Heary RF, Patel AL, Goulet B, Kalfas IH, Kopjar B. Efficacy of i-FACTOR™ Bone Graft versus Autograft in Anterior Cervical Discectomy and Fusion. Results of the Prospective Randomized Single-blinded Food and Drug Administration Investigational Device Exemption Study. *Spine*. 2016; 41(13): 1075-1083
2. Arnold PM, Sasso RC, Janssen ME, Fehlings MG, Heary RF, Vaccaro AR, Kopjar B. i-FACTOR™ Bone Graft vs Autograft in Anterior Cervical Discectomy and Fusion: 2-Year Follow-up of the Randomized Single-Blinded Food and Drug Administration Investigational Device Exemption Study. *Neurosurgery*. 2018 Sep 1; 83(3):377-384. doi: 10.1093/neuros/nyx432. PubMed PMID: 28945914
3. Jacobsen MK, Andresen AK, Jespersen AB, Støttrup C, Carreon LY, Overgaard S, Andersen MØ. *Spine J*. 2020 Jan 28. pii: S1529-9430(20)30021-8. doi: 10.1016/j.spinee.2020.01.009
4. Mobbs RJ, Maharaj M, Rao PJ. Clinical outcomes and fusion rates following anterior lumbar interbody fusion with bone graft substitute i-FACTOR, an anorganic bone matrix/P-15 composite. *J Neurosurg Spine*. 2014 Dec; 21(6):867-76
5. Lauweryns P, Raskin Y. Prospective analysis of a new bone graft in lumbar interbody fusion: results of a 2-year prospective clinical and radiological study. *Int J Spine Surg*. 2015 Feb 3; 9
6. Gomar F, Orozco R, Villar JL, Arrizabalaga F. P-15 small peptide bone graft substitute in the treatment of non-unions and delayed union. A pilot clinical trial. *Int Orthop*. 2007 Feb; 31(1):939. Epub 2006 Jun 8