INFUSE®
BONE GRAFT

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SUMMARY OF INDICATIONS

SPINE

ALIF - with Medtronic titanium threaded interbody device.

OLIF - with Medtronic PERIMETER™ or CLYDESDALE™ interbody device.

TRAUMA

Acute open tibial fractures with IM nail fixation.

DENTAL

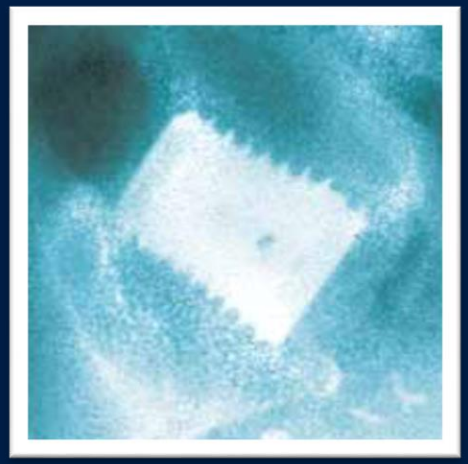
Sinus augmentation and localized alveolar ridge augmentation for defects associated with extraction sockets.

PRODUCT COMPOSITION, HANDLING & STERILITY

1	▪ 1.5mg/cc rhBMP-2 ▪ 98% pure, freeze dried ▪ Type I bovine collagen sponge (ACS) ▪ Sterile water
2	▪ Absorbable collagen sponge (ACS) provides localized protein delivery ▪ ACS provides scaffold for new bone ingrowth
3	▪ rhBMP-2: Filter sterilization, maintains bioactivity level ▪ ACS: Device-level sterility (SAL 10^{-6})

PERFORMANCE

SPINE



- 94.5% fusion rate at 24 months, compared to 88.7% with autograft alone[1]
- 55% improved in Oswestry scores on average[1]
- Reduced hospital stay, less blood loss and less OR time[1]
- 98% fusion success at 6 year follow-up[2]

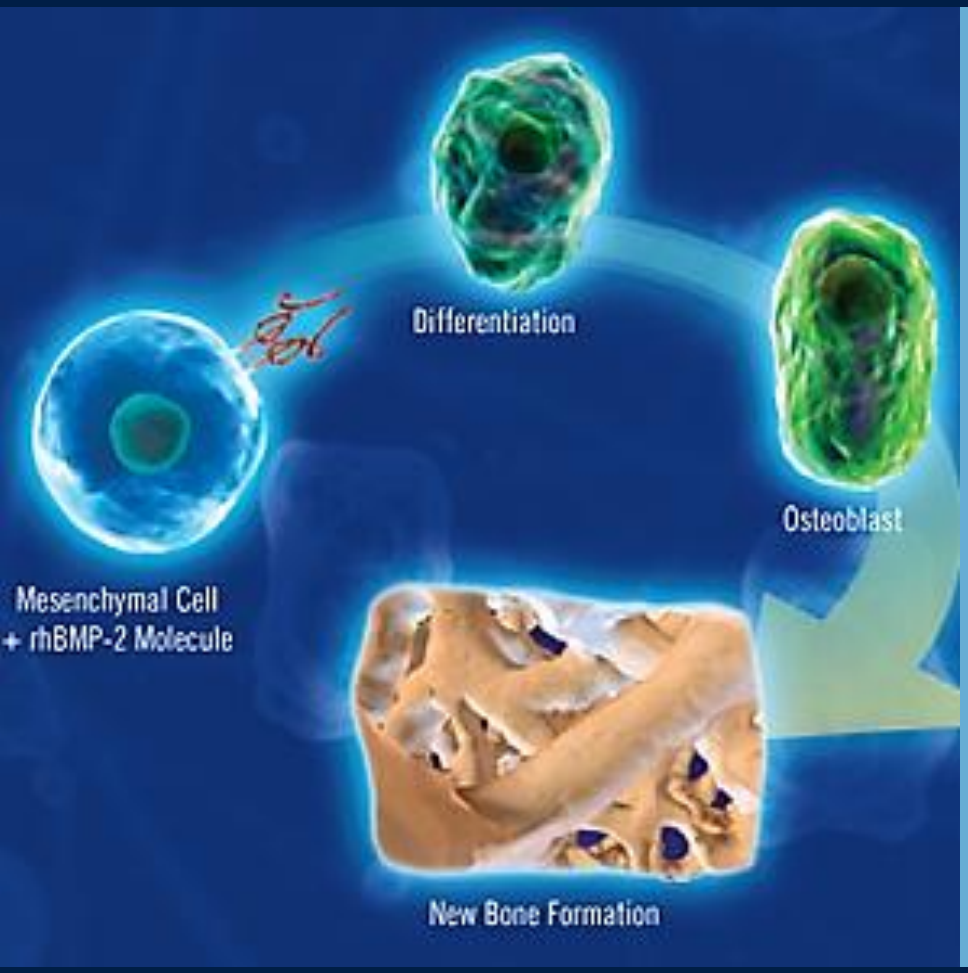
TRAUMA

- Significantly reduced secondary surgical interventions by 41%[3]
- Significantly reduced non-union rate by 29%[3]
- Significantly reduced infection rate in severe fractures by 44%[3]

DENTAL

- Average of 10.41mm of new bone generated in implant sites with less than 4mm native bone[5]
- Histology demonstrates normal mature 100% viable bone[5]
- Equivalent implant survival rates vs. autogenous bone graft[4]

MODE OF ACTION



INFUSE® rhBMP-2 is an **osteoinductive** protein that results in the induction of new bone tissue at the site of implantation.

Surgical implantation and retention of rhBMP-2 at the treatment site is facilitated by the ACS matrix.

rhBMP-2 binds to receptors on the surface of mesenchymal stem cells (MSCs) and **causes cells to differentiate into bone forming cells** (osteoblasts).

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PRODUCTS

XX Small 1.05mg Vial rhBMP-2 0.7ml (cc) Graft Volume	**X Small** 2x 1.05mg Vials rhBMP-2 1.4ml (cc) Graft Volume	**Small** 4.2mg Vial rhBMP-2 2.8ml (cc) Graft Volume
Medium 2x 4.2mg Vials rhBMP-2 5.6ml (cc) Graft Volume	**Large** 12mg Vial rhBMP-2 8.0ml (cc) Graft Volume	**Large II** 12mg Vial rhBMP-2 8.0ml (cc) Graft Volume

REFERENCES

1. Burkus et al. Anterior Lumbar Interbody Fusion Using rhBMP-2 With Tapered Interbody Cages. Journal of Spinal Disorders and Techniques. 2002, Vol. 15, no 5. pp. 337-349.
2. Burkus JK, Gornet MF, et al. Six-Year Outcomes of Anterior Lumbar Interbody Arthrodesis with Use of Interbody Fusion Cages and Recombinant Human Bone Morphogenetic Protein-2. J Bone Joint Surg Am. 2009; 91:1181-9
3. US Food and Drug Administration. Summary of Safety and Effectiveness – INFUSE Bone Graft (P000054) http://www.fda.gov/cdrh/pdf/p000054b.pdf
4. US Food and Drug Administration. Summary of Safety and Effectiveness – INFUSE Bone Graft (P000053) http://www.fda.gov/cdrh/pdf/p000053b.pdf
5. Triplett, et al. Pivotal, Randomized, Parrallel Evaluation of Recombinant Human Bone Morphogenetic Protein-2/ Absorbable Collagen Sponge and Autgenous Bone Graft for Maxillary Sinus Floor Augmentation. J Oral Maxillofac Surg. 67:1947-60, 2009

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The product systems referenced in this presentation may incorporate technology developed by Gary K. Michelson, M.D.

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THANK YOU