

# Preloaded Injectable Bone Graft with **ZPC**™







Activated graft with Negative Surface Charge

Rapid bone formation

Fully resorbed

The premium synthetic putty





 $\textit{geneX}^{\otimes}$  is a unique synthetic bone graft in the form of an easy to use putty.

**geneX**® putty possesses a consistent controlled negative surface charge. This initiates reproducible cell activity, driving endochondral ossification as the putty is fully resorbed and replaced by bone.

**geneX**<sup>®</sup> has been designed with an optimised composition of β-tricalcium phosphate and an ultra pure calcium sulphate component, produced by a patented manufacturing process.

#### **Product Features**

- >>> Negative Surface Charge for rapid bone formation
- >>> Fully resorbed and replaced by bone
- >>> Superior handling capabilities, and conforms to the surgical site
- >>> Resists migration at operative site
- >>> Synthetic eliminating the risk of disease transmission





# Engineered to Drive Bone Healing through three key stages of

Biocomposites has developed a unique patented process,  $ZPC^{TM}$  making  $geneX^{@}$  the only graft with a reproducible Negative Surface Charge.

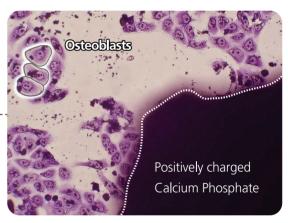
This process controls the graft surface properties initiating reproducible cell activity and accelerating bone formation<sup>1,2</sup>. Key proteins are harnessed at the graft surface,<sup>3,4</sup> directing bone cell adhesion and proliferation for rapid osteogenesis and bone formation.<sup>5</sup>

# Stage 1

**ZPC**<sup>TM</sup> Graft Surface activation

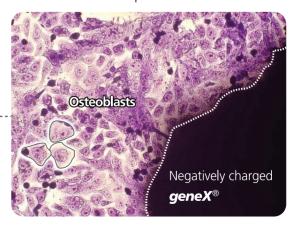
- Negatively charged matrix
- Promotes the cellular cascade protein / cell attachment

Surface of positively charged calcium phosphate - limited cell attachment



Positive surface charge, *In-vitro* osteoblast culture, 3 days, (Toluidine Blue stain).

Surface of negatively charged **geneX**® - prolific cell attachment and proliferation



**ZPC**<sup>TM</sup> Negative surface charge, *In-vitro* osteoblast culture, 3 days, (Toluidine Blue stain).

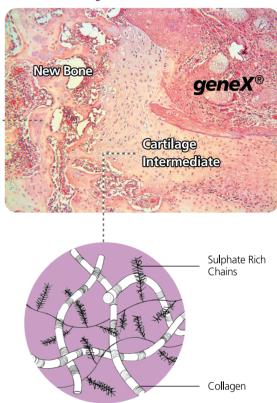


# bone growth

# Stage 2

The sulphate phase in **geneX**® stimulates the formation of the cartilage intermediate phase - Endochondral ossification

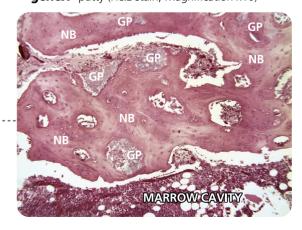
*In-vivo*, 4 weeks post implantation. (H&E stain, Magnification x10)



# Stage 3

Surface charge facilitates the transition from cartilage to new bone

*In-vivo*, 8 weeks post implantation. NB-New Bone, GP-**geneX**® putty (H&E stain, Magnification x10)



Residual **geneX**® putty is fully incorporated into new bone formation, to be naturally resorbed through remodelling processes.



# Convincing fusion: From the laboratory...

## Animal Data - The Boden Model for Spinal Fusion

**geneX**® was applied alone to the Boden rabbit model for posterolateral fusion. This challenging application duplicates the surgical technique, environment, and the biology associated with fusion in humans and is recognised as an accurate animal model for spinal fusion research.<sup>6</sup>

The results show that **geneX**® putty achieves spinal fusion, forming bone as a stand alone synthetic bone graft, without the need for autograft, blood, or bone marrow aspirate.<sup>7</sup>

**geneX**® putty placed adjacent to the vertebral body and between the transverse processes.



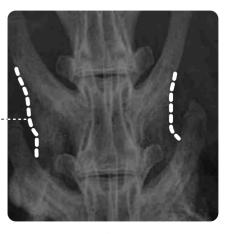
Immediately Post-op

Sulphate phase is resorbed and incorporated into a cartilage intermediate phase.



4 weeks Post-op

Robust bridging trabecular bone between the transverse processes. Effective posterolateral fusion proven by distraction testing.<sup>7</sup>



12 weeks Post-op



#### ...to the operating room

## Case History

A male patient aged 35;

- Transforaminal lumbar interbody fusion at L4-5 and L5-S1 with PEEK cages.
- Bone graft with an intertransverse fusion was performed from L4 to the ala of the sacrum.
- Local autograft was placed on the left and 10 cc of geneX<sup>®</sup> alone was placed on the right.

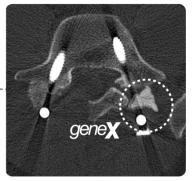
L5, Axial CT scan showing **geneX**® placement on the right side of the spine.

At the **geneX**® site, early decrease in radiodensity is observed as the calcium sulphate phase is gradually resorbed.

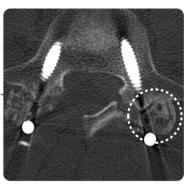
Evidence also shows robust bone formation.

Appositional growth of new bone is convincingly demonstrated around the 'outside' of the graft bed, suggesting promotion of bone formation by **geneX**®. The β-tricalcium phosphate phase is resorbing and undergoing replacement by bone. Early remodelling is evident.

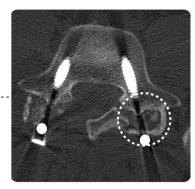
9 months post-operative scan clearly shows induction of bone, and a convincing fusion at L4-5.



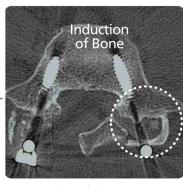
Immediately Post-op



3 months Post-op



6 months Post-op



9 months Post-op





ITEM

geneX® putty 2.5cc

geneX® putty 5cc

geneX® putty 10cc

#### References

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- 6. Glazer P, et al. Use of electromagnetic fields in a spinal fusion. A rabbit model. Spine 1997; 20 22: 2351-6.
- 7. Data on file at Biocomposites.

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