

genex®

Bone Graft Substitute



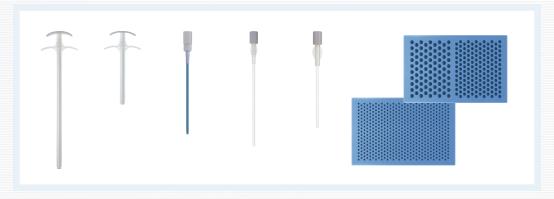
Simple to use synthetic absorbable material designed to promote regeneration of bone in osseous defects

Your choice of synthetic bone graft not only influences the efficiency of each surgical procedure, it has considerable impact on the long-term outcome.

gene**x** is a catalyst for bone healing. It complements the body's natural healing processes, enabling the optimal remodeling of bone architecture to that of native trabecular bone. In 12 months, gene**x** is completely absorbed and remodeled while leaving no foreign artifacts after resorption.^{1,2}

Closed-mixing system increases surgical case efficiency by shortening preparation time and extending workability

Options



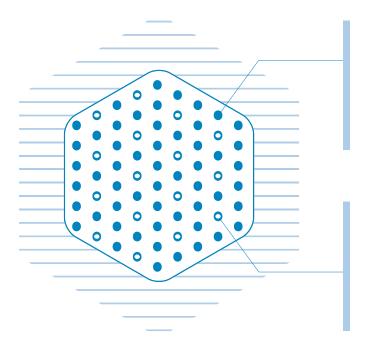
Biphasic composite of purity, balance and characteristics

gene**x** is specifically formulated to provide a balance of osteoconductive scaffold strength and persistence in the body with optimum handling, workability and remodeling.

Our proprietary recrystallization and purification methods removes impurities from genex, such as:⁶

No inflammatory pyrophosphates

No slow and non-absorbing compounds such as hydroxyapatite



50% calcium sulfate osteoconductive carrier

- ▶ Provides early structure
- ► Absorbs quickly and completely to create pores for early bone ingrowth
- ► Proprietary DRy26" recrystallization method

50% ß-tricalcium phosphate osteoconductive scaffold

- ► Facilitates bone healing and remodeling
- ► Fully absorbs at a rate that complements bone healing
- ▶ Proprietary 15 step purification method

Complements the body's natural healing processes and encourages normal bone structure⁶

STRENGTH similar to trabecular bone³⁻⁵ genex PERSISTENCE 50:50 biphasic absorption supports early bone formation and provides a longer term osteoconductive scaffold to complement bone healing and remodeling

CONSISTENCY and





Tibial plateau fracture⁷

Patient presented with: Comminuted Schatzker type II fracture of right leg. X-ray examination revealed 2 large fragments and several small fragments.

Outcome: At 15 months' follow-up the fracture had healed and knee was stable, with a range of motion of 0–130. gene**x** had completely absorbed.



Proximal femur fracture²

Patient presented with: Failed intramedullary nailing of an extracapsular neck of femur fracture. Patient complained of prominent metalwork and pain.

Outcome: At 12 months' follow-up the fracture had healed with complete absorption of gene**x**. Patient had a good range of hip motion and was able to walk and manage stairs.



Distal tibia non-union8

Patient presented with: Healed fibula with a non-union of the distal tibia and a fracture through the nail, 19 months after the initial operation.

Outcome: At 10 months' follow-up the non-union had healed completely, patient had fully recovered and was scheduled to have the intramedullary nail removed.



Single stage revision ACL reconstruction⁹

Patient presented with: Malposition of the femoral tunnels following failed ACL reconstruction.

Outcome: At 7 months' follow-up bone reformation was seen with gene**x**. At 2 years' follow-up the patient had a normal ACL examination and returned to day-to-day activities and some active sports.

Completely absorbs to leave no trace

gene**x** is a precisely balanced β-tricalcium phosphate and calcium sulfate hemihydrate compound with distinct design properties:

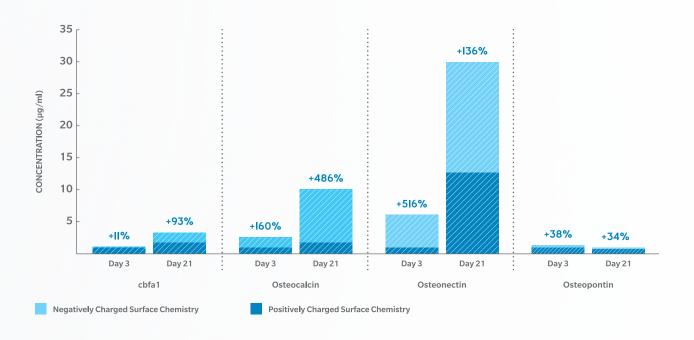
- ► Contains no hydroxyapatite (HA)
- ► Negatively charged surface chemistry
- ► Compressive strength similar to trabecular bone³⁻⁵

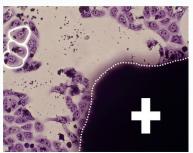
gene**x** provides a powerful scaffold for accelerated bone restoration and helps to hinder soft tissue ingrowth:

- ► Enhances osteogenic response¹⁰
- ▶ Completely absorbed within 12 months¹
- Several studies have concluded healthy bone is restored in a clinically relevant timeframe⁷⁻⁹

Negatively charged genex enhances the osteogenic response to accelerate bone growth 10,14

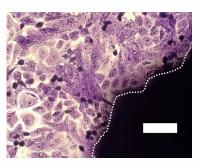
▶ UP TO **5X** NORMAL LEVELS





Positive surface charge

In-vitro human osteoblast culture, 3 days¹¹



Negative surface charge

Completely absorbed within 12 months^{1,2}

gene ${\bf x}$ contains no hydroxyapatite. HA can only be absorbed at 1–2% per year 12

	IMPLANTATION	8 WEEKS	16 WEEKS	36 WEEKS
Decalcified histology	TIME		4 3 7 7 8 7 7 8 7	POSTEIN
H&E stain				
Micro-CT				
Sham control Micro-CT				

Several studies have concluded healthy bone is restored in a clinically relevant timeframe⁷⁻⁹

gene**x** restores bone to normal trabecular structure.¹







Post-operative



15 months

Unrivaled flexibility for delivery and application

With one of the most comprehensive bone graft substitute systems at your fingertips, genex equips you with everything you need to adapt to the wide ranging and sometimes unpredictable demands of trauma surgery. From difficult-to-reach sites or minimally invasive procedures, genex enables you to inject, mold or prepare beads according to your chosen technique. The genex closed-mixing system maximizes efficiency and provides the assurances of:

- ► Fully supported aseptic technique
- ► Injectable up to 3 minutes
- ▶ Moldable 3 to 5 minutes
- ► Hardens in 15 minutes at room temperature

Fewer steps and significantly less time to prepare than before¹³

- ► Closed-mixing system is **2X** faster to prepare than open mixing system
- ▶ **Longer** working time
- ▶ Drillable after 15 minutes

Closed-mixing for large or small volumes

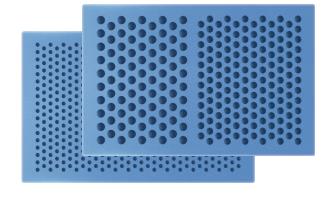


Choose your cannula for injection



Mold beads for digital placement into voids





Mr. Hemant K. Sharma

Consultant Orthopaedic Surgeon, Hull, UK

Clinical particulars

22-year-old male presented with a comminuted Schatzker type II fracture of right leg. X-ray examination revealed 2 large fragments and several small fragments.

Treatment

Using an anterolateral approach, the lateral fragment was rotated to open the fracture, fragments elevated and held with temporary K-wires. The joint was visualized through submeniscal approach. 7cc of genex paste was implanted and the lateral fragment closed with a clamp. 2 partially threaded 6.5mm cancellous screws were placed subchondrally just below the elevated intra-articular segment. Locking plate and a combination of locking and non-locking screws were placed.

Outcome

At 15 months' follow-up, the fracture had healed with complete absorption and remodeling of genex. The knee was stable, with a range of motion of 0–130. Patient reported normal function with occasional clicking and aching at the end of the day, with some discomfort at lateral joint line.



Presentation - CT Scan



Post-operative



6 Months



15 Months

Mr. Aamer Nisar and Mr. Shiva Gopal

Consultant Orthopaedic Surgeons, Hull, UK

Clinical particulars

86-year-old male sustained a comminuted extracapsular fracture of left proximal femur following a fall. This was nailed, however, subsequently at 4 months the screw backed out and patient complained of prominent metalwork and pain.

Treatment

CT suggested partial union. Following Multidisciplinary Team discussion, revision of the fixation was planned. Nail was removed and examination suggested the fracture site was still mobile. Bone grafts were harvested using a reamer system. The autologous grafts and gene**x** paste were then implanted at the fracture site, and the fracture was plated with a combination of locking and non-locking screws. Patient was instructed to be touch weight-bearing for 6 weeks.

Outcome

At 12 months' follow-up, the fracture had healed with complete absorption and remodeling of genex. Patient had a good range of hip motion and was able to walk independently and manage stairs.



Presentation - CT Scan



Post-operative



4 Months Screw backing out



4 Months



◀ 1 Year post-revision

Professor James B. Richardson

Consultant Orthopaedic Surgeon/Professor of Orthopaedics, Oswestry, Shropshire, UK

Clinical particulars

34-year-old male initially treated for right tibia and fibula fracture with a bilateral intramedullary nail, presented 19 months after the initial operation with acute pain around the fracture site. X-ray examination revealed a healed fibula with a non-union of the distal tibia and a fracture through the nail.

Treatment

The broken nail was extracted and a new nail inserted and locked distally with 2 locking bolts. The fracture site was decorticated and packed with genex paste. Closure was achieved with suture and a drain was placed over the proximal wound. The patient demonstrated good movement of toes and right ankle. Mobilization to partial and full weight-bearing was recommended as soon as the patient was comfortable to do so.

Outcome

At 3 months' follow-up the wound was clean and the bone appeared to be healing satisfactorily. The patient had mobilized fully and was extremely pleased with the outcome.

At 10 months' follow-up the non-union had healed completely. The patient had fully recovered and was scheduled to have the intramedullary nail removed.

Case study continued





Presentation - CT Scan





Post-operative





3 Months



10 Months

Mr. Peter Thompson

Consultant Orthopaedic Surgeon, Coventry & Warwickshire, UK

Clinical particulars

24-year-old female had a hamstring ACL reconstruction in 2006, revision in 2009 and graft failure in 2016. Revision surgery was planned using a graft from the opposite leg.

CT scan confirmed malposition of the femoral tunnels: one was very anterior (type III) and the other (type II) would breakthrough upon drilling an anatomical femoral socket. The double tibial tunnel also caused a 1.7cm diameter cavity (Fig. 3).

Treatment

Single-stage revision ACL reconstruction was possible by filling the type II femoral tunnel and tibial cavity with genex paste before drilling tunnels in an anatomical position. The new femoral socket partly overlaps the previous tunnel filled with genex (Fig. 4).

Outcome

Post-operative x-rays (Fig. 5, 6) show graft fixation with a suspensory button on the femur, a bioabsorbable interference screw and soft tissue staple on the tibia. gene**x** can be seen in the tunnels of the distal femur and proximal tibia (arrows). Bone reformation is seen at 7 months (Fig. 7, 8).

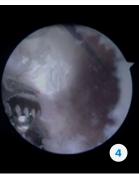
Normal ACL examination with return to day-to-day activity and some active sports 2 years post-operatively.

Case study continued

















Ordering information

Part Number	910-010Z	910-005Z	910-003Z
In the pack	10cc	5cc	Зсс
Mixing syringe with powder	•	•	•
Dispensing syringe	•	•	
Mixing solution	•	•	•
Bead mat	•	•	
Paste applicator	•	•	
Choice of cannulas	•	•	•
Cannula sizes included			
2.1mm inner diameter, 3.0mm outer diameter, insertion length 79mm, tapered, radiopaque (blue) cannula (12G)	•	•	
2.5mm inner diameter, 3.5mm outer diameter, insertion length 100mm, plastic cannula (11G)	•	•	•
3.15mm inner diameter, 3.75mm outer diameter, insertion length 70mm, plastic cannula (9G)	•	•	•
6mm inner diameter, 8mm outer diameter, insertion length 72mm, open bore plastic cannula with handle and obturator	•	•	
6mm inner diameter, 8mm outer diameter, insertion length 157mm, open bore plastic cannula with handle and obturator	•		

References

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- Biocomposites internal testing: Biomaterials Compressive strength; Applicable methodology ISO/DIS 18531:2015(E) Implant for surgery – Calcium phosphate bioceramics – Characterization of hardening bone paste materials. 2015, MA0390R1.
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- 6. Biocomposites internal and external testing: gene**x** Bone Graft Substitute technical file: Section 3.1.7 (Rev1) Final product specification, 2022.
- 7. Clinical case study: Mr HK Sharma; Tibial plateau fracture: Data on file.
- 8. Clinical case study: Prof JB Richardson; Distal tibia non-union: Data on file.

- Clinical case study: Mr P Thompson; Single stage revision ACL reconstruction: Data on file.
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Power To Restore Without Leaving a Trace

- ▶ Optimized to be **completely** absorbed and remodeled 1,2
- ▶ **Closed-mixing system** with comprehensive delivery options
- ▶ Similar strength to trabecular bone³⁻⁵

The Zimmer Biomet Biologics product portfolio represents the passionate pursuit of the most innovative and clinically relevant solutions addressing the needs of surgeons and their patients.



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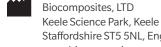
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For complete product information, including indications, contraindications, warnings, precautions, and potential adverse effects, see the package insert and www.zimmerbiomet.com or contact your local Zimmer Biomet sales representative; for additional product information, visit www.zimmerbiomet.com.

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Responsible Manufacturer

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