

genex[®] Bone Graft Substitute Competitive Environment

In-person training for Distributor Sales Representatives



Training objectives

At the end of this 30 minute training session you will:

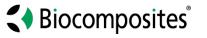
- Know who the key competitors are for genex Bone Graft Substitute
- Understand the key characteristics of their products and positioning
- Be aware of their strengths and weaknesses relative to genex Bone Graft Substitute
- Know which differentiating factors to focus on in conversations with your surgeons
- Have an action plan for protecting and increasing genex Bone Graft Substitute sales



Agenda

- Bone graft substitute market
- Competitor differentiation summary
- Product profiles:
 - Cerament[®]
 - Hydroset[®], Hydroset[®] XT
 - Pro-Dense™
 - Norian[®] Drillable Products
 - OsteoCrete[®]
 - βBeta-bsm®, γGamma-bsm®
 - Quickset™
 - Montage[®]
 - genex® Bone Graft Substitute
- Protect and increase genex sales





Bone graft substitute market

Many medical device suppliers focus on bone graft substitutes as a growth opportunity

- There are numerous synthetic bone graft substitutes available for surgeons to choose from
- Many bone graft substitutes appear to be similar, however several contain hydroxyapatite (HA) or insoluble impurities
- Your surgeon's choice of synthetic bone graft substitute influences the efficacy of each surgical procedure and has considerable impact on the long-term outcome
- When choosing a synthetic bone graft substitute, it is important to consider the following:
 - Indications of use
 - Composition
 - Absorption rate and complete absorption potential
 - Versatility
 - Setting time
 - Temperature sensitivity



Competitor differentiation summary



Product Name	Indicated Areas of Use	Contains HA or Insoluble Impurities	Claimed Absorption Rate	Fully Absorbs	Versatility	Setting Time	Temperature Sensitive	genex Key Points of Differentiation
genex® Bone Graft Substitute Biocomposites®	Long bones, extremities, spine, pelvis	No	Up to 12 months	Yes	Moldable, packable, injectable	15 minutes	No	
Cerament [®] Bonesupport [®] AB	Long bones, spine, pelvis	Yes	6-12 months	No	Moldable, injectable, beads	15 minutes	No	Indicated to fill bone voids in
Hydroset [®] , Hydroset [®] XT Stryker [®]	Long bones, craniofacial, spine, pelvis	Yes	Expected to be >6 months	No	Moldable, injectable	Within 8 minutes	Yes	 Indicated to fill bolle voids in long bones, extremities, spine and pelvis Precisely balanced β-
Pro-Dense™ Wright Medical Group	Long bones, pelvis	Yes	6-12 months	May not fully absorb	Packable, injectable	20-30 minutes	No	tricalcium phosphate/calcium sulfate hemihydrate Contains no hydroxyapatite
Norian [®] Drillable Products DePuy Synthes	Long bones, pelvis	Yes	Over a period of years	May not fully absorb	Moldable, packable, injectable	Putty: 9 min 30 sec Inject: 16 min 10 sec	Yes	(HA) or insoluble impuritiesFully absorbed within 12 months
OsteoCrete [®] Bone Solutions Inc.	Long bones, pelvis	Unknown	Not specified	Unknown	Moldable, injectable	10-12 minutes	Yes	Moldable, packable and injectableNot temperature sensitive
βBeta-bsm [®] Injectable γGamma-bsm [®] Moldable Putty Zimmer Biomet	Long bones, spine, pelvis	Yes	Expected to be >6 months	May not fully absorb	Beta-bsm: injectable, Gamma-bsm: moldable	3-5 minutes	Yes	Negatively charged surface chemistryEnhances osteogenic
Quickset™ Arthrex®	Long bones, pelvis	Yes	Expected to be ≥8 months	May not fully absorb	Injectable	Initial setting: 8 min Hardened: 24 hours	Yes	Restores strong healthy bone
Montage® ABYRX® *Indicated as a bone wax and not a bone void filler	Long bones, pelvis, cranial, maxillofacial, cardiothoracic, spine*	Yes	Expected to be >6 months	May not fully absorb	Manually applied, spreadable	Within minutes	No	

Product profiles



Cerament – Bonesupport AB

Indication & absorption rate²⁻⁴

- Bone graft substitute indicated to fill bone voids and gaps
- Contraindicated for local infection at the site of implantation
- Remodels within 6-12 months

Composition²⁻⁴

- Powder: 40% hydroxyapatite (HA) and 60% calcium sulfate
- Liquid: lohexol (180mg iodine/ml)
 - Water-soluble radio-opacification enhancer
 - Iohexol is contraindicated for significant bacterial infection





Cerament

Formats, sizing and setting times²⁻⁶

- 3 bead sizes, injectable, moldable
- 5cc, 10cc, 18cc sizes
- Bead tray available for order
 - 3.0mm, 4.7mm, 6.0mm beads
 - Bead tray requires creation of all three bead sizes if using a 10cc pack or greater
 - 18cc pack requires two trays
- Sets within 15 minutes of mixing
 - Optimum injectability at 3 minutes
 - Must be applied to a mold 3-5 minutes after mixing





Cerament

Takeaway points¹⁻⁶

- Contraindicated for infected sites
- Contraindicated for patients with a history of serious reaction to iodine based radio contrast agents
- HA has a slow/incomplete absorption rate
- HA can cause a long-term nidus for infection
- Precaution to avoid intra-articular use
- Wait time of 3 minutes required prior to injection
- Must be applied to a mold within 3-5 minutes after mixing
- Bead tray(s) must be purchased separately





Cerament¹⁻⁶

Product comparison	Cerament	genex
Composition	40% Hydroxyapatite 60% Calcium sulfate hemihydrate Iohexol	50% β – Tricalcium phosphate 50% Calcium sulfate hemihydrate Sterile water
Claimed absorption rate	6-12 months	Up to 12 months
Fully absorbs	No – HA may cause a long-term nidus for infection if not absorbed	Yes – Does not contain HA
Available sizes	5cc, 10cc, 18cc	5cc, 10cc
Versatility	3 bead sizes*, injectable, moldable	Injectable, digitally packed, moldable
Wait time before injection	3 minute wait time required after mixing for product to become viscous	None
Setting time	15 minutes	15 minutes
Drillable when fully set	Yes	Yes



Hydroset, Hydroset XT – Stryker

Indication & absorption rate^{1,7-8}

- Bone substitutes indicated to fill bone voids and gaps
- Contraindicated for infected sites
- Absorption rate not specified

Composition^{1,7-9}

- Powder:
 - Dicalcium phosphate dihydrate
 - Tetracalcium phosphate
 - Tri-sodium citrate
- Liquid:
 - Sodium phosphate
 - Polyvinylpyrrolidone
 - Water





Hydroset, Hydroset XT

Formats, sizing and setting times^{7,9-12}

- Moldable, injectable
- 3cc, 5cc, 10cc, 15cc sizes
- Injection flexibility
 - Hydroset includes standard delivery syringe and cannula
 - Hydroset XT features a self-contained mixing and delivery system with cannula
- Temperature sensitive
 - Contact and heat transfer may decrease injection time
- Sets within 8 minutes
 - Shown to extend up to 19 minutes
 - Drillable





Hydroset, Hydroset XT

Takeaway points^{1,7-13}

- Contraindicated for infected sites
- Contraindicated for bone voids that link joint spaces and articulating surfaces
- Calcium phosphate converts to hydroxyapatite (HA) after implantation
- HA has a slow and incomplete absorption rate
- HA can cause a long-term nidus for infection
- Temperature sensitive
- Variable setting times
- Hardens in a wet environment
- Drillable





Hydroset, Hydroset XT^{1,7-12}

Product comparison	Hydroset & Hydroset XT	genex
Composition	Powder: Dicalcium phosphate dihydrate, Tetracalcium phosphate, Tri-sodium citrate	Powder: 50% β – Tricalcium phosphate, 50% Calcium sulfate hemihydrate
	Mixing solution: Sodium phosphate, Polyvinylpyrrolidone and water	Mixing solution: Sterile water
Claimed absorption rate	>6 months	Up to 12 months
Fully absorbs	No – Calcium phosphate converts to HA after implantation. HA may cause a long-term nidus for infection if not absorbed	Yes – Does not contain HA
Available sizes	3cc, 5cc, 10cc, 15cc	5cc, 10cc
Versatility	Injectable, moldable	Injectable, digitally packed, moldable
Temperature sensitive	Yes	No
Setting time	8 minutes (Setting time shown to extend up to 19 minutes)	15 minutes
Drillable when fully set	Yes	Yes



Pro-Dense – Wright Medical Group

Indication & absorption rate¹⁴⁻¹⁶

- Bone graft substitute indicated to fill bone voids and gaps
- Indicated for use in benign bone cysts and tumors in children ages 6+
- Claimed absorption rate is 6-12 months

Composition^{15,17}

- Powder:
 - 75% Calcium sulfate hemihydrate
 - 25% brushite & granular β-tricalcium phosphate
- Liquid:
 - Neutralized glycolic acid





Pro-Dense

Formats, sizing and setting times¹⁴⁻¹⁵

- Packable, injectable
- 2cc, 5cc, 7cc, 10cc, 12cc, 15cc and 40cc sizes
- 15cc Core Decompression Kit
- Injection flexibility:
 - Delivery syringe with two cannula sizes included
 - Disposable syringe only kit available
- Sets within 20-30 minutes
 - Drillable

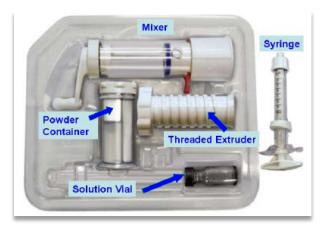




Pro-Dense

Takeaway points¹⁴⁻¹⁷

- Brushite converts to hydroxyapatite (HA) after implantation
- HA has a slow/incomplete absorption rate
- HA and non-absorbable impurities can cause a long-term nidus for infection
- Contraindicated in articulating surfaces
- Acidic pH
- Hydrophobic
- Long setting time





Pro-Dense¹⁴⁻¹⁷

Product comparison	Pro-Dense	genex
Composition	Powder: 75% Calcium sulfate hemihydrate, 25% brushite + granular β – Tricalcium phosphate	Powder: 50% β – Tricalcium phosphate, 50% Calcium sulfate hemihydrate
	Mixing solution: Neutralized glycolic acid	Mixing solution: Sterile water
Claimed absorption rate	6 - 12 months	Up to 12 months
Impurities	Unknown	No
Fully absorbs	No – Brushite converts to HA after implantation. HA can cause a long-term nidus for infection	Yes – Does not contain HA
Available sizes	2cc, 5cc, 7cc, 10cc, 12cc, 15cc, 40cc 15cc Core Decompression Kit	5cc, 10cc
Versatility	Packable, injectable	Injectable, digitally packed, moldable
Setting time	20 - 30 minutes	15 minutes
рН	Acidic	Physiologic
Drillable when fully set	Yes	Yes



Norian Drillable products – DePuy Synthes

Indication & absorption rate¹⁸⁻²⁰

- Bone graft substitutes indicated to fill bony voids and defects
- Norian Drillable Fast Set Putty and Norian Drillable Inject are contraindicated for infected sites
- Slowly absorbed over a period of years

Composition^{18,19}

- Powder:
 - Calcium phosphate with polylactide/glycolide copolymer fibers
- Liquid:
 - Dilute sodium phosphate with sodium hyaluronate





Norian Drillable products

Formats, sizing and setting times^{18,19}

- Moldable, packable, injectable
- 3cc, 5cc, 10cc
- Injection flexibility:
 - Putty: graft delivery device available
 - Inject: delivery syringe included
 - Variety of delivery needles available
- Temperature sensitive setting
 - Putty: sets within 9 min 3 sec of adding mixing solution
 - Inject: sets within 16 min 10 sec of adding mixing solution
- Drillable during or after setting





Norian Drillable products

Takeaway points¹⁸⁻²⁰

- Contraindicated for use in infected sites, articulating surfaces and the spine
- Calcium phosphate converts to a carbonated apatite after implantation
- HA has a slow and incomplete absorption rate
- HA can cause a long-term nidus for infection
- Temperature sensitive
- Norian Drillable Inject has complex preparation technique
- Drillable during and after setting





Norian Drillable products¹⁸⁻²⁰

Product comparison	Norian Drillable Fast Set Putty Norian Drillable Inject	genex
Composition	Powder: Calcium phosphate with polylactide/glycolide copolymer fibers	Powder: 50% β – Tricalcium phosphate, 50% Calcium sulfate hemihydrate
	Mixing solution: Dilute sodium phosphate with sodium hyaluronate	Mixing solution: Sterile water
Claimed absorption rate	Slowly absorbed over a period of years	Up to 12 months
Fully absorbs	May not fully absorb – Calcium phosphate converts to carbonated apatite after implantation (Similar to HA)	Yes – Does not contain HA
Available sizes	3cc, 5cc, 10cc	5cc, 10cc
Versatility	Moldable, packable, injectable	Injectable, digitally packed, moldable
Setting time	Putty: Within 9 min 30 sec of adding mixing solution Inject: Within 16 min 10 sec of adding mixing solution	15 minutes
Temperature sensitive	Yes	No
Drillable when fully set	Yes – during or after setting	Yes

OsteoCrete – Bone Solutions Inc.

Indication & absorption rate^{1,21-23}

- Bone void filler indicated to fill bony voids and defects
- Warning against use in infected sites
- Not cleared for use in the spine
- Not intended to treat large defects that would fail to heal spontaneously
- Absorption rate not specified

Composition^{1,21-22}

- Powder:
 - Magnesium oxide, monopotassium phosphate, monosodium phosphate, β-tricalcium phosphate
- Liquid:
 - Buffered saline





OsteoCrete

Formats, sizing and setting time^{1,21-25}

- Moldable, injectable
- 5cc, 10cc, 15cc
- Injection flexibility
 - Mixing & delivery syringe and cannula included in full kit only
 - Optional mixing & delivery system, mechanical advantage pack, cannula pack and bead mat available
- Setting characteristics
 - 10-12 minutes
 - Temperature sensitive
 - Exothermic reaction
 - Materials expand by 0.15 0.2%
- Not marketed as a drillable product





OsteoCrete

Takeaway points^{1,21-25}

- Warning against use in infected sites
- Not cleared for use in the spine
- Not intended to treat large defects that would fail to heal spontaneously
- Temperature sensitive
- Exothermic
- Materials slightly expand during setting by 0.15 0.2%
- Mixing & delivery syringe and cannula not included in basic kit
- Not marketed as a drillable product





OsteoCrete^{1,21-25}

Product comparison	OsteoCrete	genex
Composition	Powder: Magnesium oxide, monopotassium phosphate, monosodium Phosphate, β – Tricalcium phosphate	Powder: 50% β – Tricalcium phosphate, 50% Calcium sulfate hemihydrate
	Mixing solution: Buffered saline	Mixing solution: Sterile water
Claimed absorption rate	Not specified	Up to 12 months
Fully absorbs	Unknown	Yes
Available sizes	5cc, 10cc, 15cc	5cc, 10cc
Versatility	Moldable, injectable	Injectable, digitally packed, moldable
Setting time	10-12 minutes	15 minutes
Temperature sensitive	Yes	No
Expands during setting	Yes	No
Drillable when fully set	No – not marketed for this purpose	Yes



^βBeta-bsm Injectable & ^γGamma-bsm Moldable Putty – Zimmer Biomet

Indication & absorption rate^{1,26-27}

- Bone graft substitutes indicated to fill bony voids and defects
- Beta-bsm Injectable and Gamma-bsm Moldable Putty are contraindicated for infected sites
- Absorption rate expected to be >6 months

Composition²⁸⁻³³

- Powder:
 - 50% α-tricalcium phosphate, 50% Dicalcium phosphate dihydrate
- Liquid:
 - 0.9% Sodium chloride solution





^βBeta-bsm Injectable & ^γGamma-bsm Moldable Putty

Formats, sizing and setting times²⁸⁻³³

Beta-bsm: Injectable

Gamma-bsm: Moldable

- 2.5cc, 5cc, 10cc
- Injection flexibility:
 - Beta-bsm: Syringe with 16g needle included
 - Gamma-bsm: Not injectable
- Temperature sensitive setting
 - Isothermally sets hard in 3-5 minutes
- Gamma-bsm hardens in a wet environment
- Drillable during or after setting





^βBeta-bsm Injectable & ^γGamma-bsm Moldable Putty

Takeaway points^{1,26-33}

- Contraindicated for use in infected sites
- Calcium phosphate component converts to a poorly crystalline hydroxyapatite (HA) during setting
- HA has a slow and incomplete absorption rate
- HA can cause a long-term nidus for infection
- Temperature sensitive
- Gamma-bsm hardens in a wet environment
- Must use different products when injecting or molding
- Drillable during and after setting





^βBeta-bsm Injectable & ^γGamma-bsm Moldable Putty^{1,26-33}

Product comparison	Beta-bsm Injectable Gamma-bsm Moldable Putty	genex
Composition	Powder: 50% α-tricalcium phosphate, 50% Dicalcium phosphate dihydrate	Powder: 50% β – Tricalcium phosphate, 50% Calcium sulfate hemihydrate
Composition	Mixing solution: 0.9% Sodium chloride solution	Mixing solution: Sterile water
Claimed absorption rate	Expected to be >6 months	Up to 12 months
Fully absorbs	May not fully absorb – Calcium phosphate converts to a poorly crystalline HA during setting	Yes – Does not contain HA
Available sizes	2.5cc, 5cc, 10cc	5cc, 10cc
Versatility	Beta-bsm: Injectable Gamma-bsm: Moldable	Injectable, digitally packed, moldable
Temperature sensitive	Yes	No
Setting time	Isothermally sets hard in 3-5 minutes	15 minutes
Drillable when fully set	Yes – during or after setting	Yes



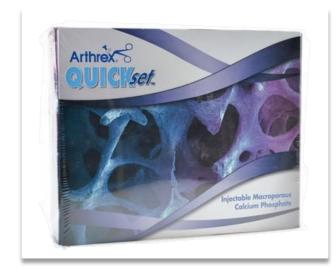
Quickset – Arthrex

Indication & absorption rate^{1,34-35}

- Bone graft substitute indicated to fill bony voids and defects
- Contraindicated for infected sites
- Not indicated for use in the spine
- Absorption rate expected to be ≥ 8 months

Composition³⁴⁻³⁷

- Powder:
 - Calcium phosphate salts with polysaccharide polymer
- Liquid:
 - Sodium phosphate solution

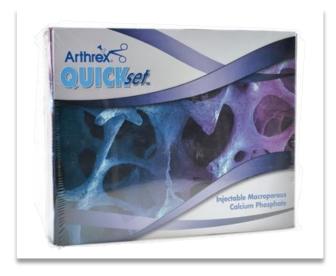




Quickset

Formats, sizing and setting times³⁴⁻³⁷

- Injectable
- 5cc, 8cc, 16cc
- Injection flexibility
 - Syringe, cannula and delivery gun included
- Setting characteristics
 - Initial setting at 8 minutes
 - Complete hardening at 24 hours
 - Temperature sensitive
- Not marketed as a drillable product





Quickset

Takeaway points^{1,34-37}

- Calcium phosphate converts to calcium-deficient apatite after crystallization
- HA has a slow and incomplete absorption rate
- HA can cause a long-term nidus for infection
- Contraindicated for infected sites and not indicated for use in the spine
- Temperature sensitive
- Not marketed as a drillable product





Quickset^{1,34-37}

Product comparison	Quickset	genex
Composition	Powder: Calcium phosphate salts with polysaccharide polymer	Powder: 50% β – Tricalcium phosphate, 50% Calcium sulfate hemihydrate
	Mixing solution: Sodium phosphate solution	Mixing solution: Sterile water
Claimed absorption rate	Expected to be ≥8 months	Up to 12 months
Fully absorbs	May not fully absorb - Calcium phosphate converts to a calcium-deficient apatite after crystallization (similar to HA)	Yes
Available sizes	5cc, 8cc, 16cc	5cc, 10cc
Versatility	Injectable	Injectable, digitally packed, moldable
Setting time	Initial setting at 8 minutes Complete hardening at 24 hours	15 minutes
Temperature sensitive	Yes	No
Drillable when fully set	No – not marketed for this purpose	Yes



Montage – ABYRX

Indication & absorption rate^{1,38}

- Resorbable hemostatic bone putty
- Indicated for the control of bleeding from cut or damaged bone
 - Categorized as a bone wax (MTJ device code)
 - Not indicated as a bone void filler
- Absorption rate not specified

Composition³⁸

- Two putty-like components comprised of:
 - Granular calcium phosphate (hydroxyapatite & β-tricalcium phosphate)
 - calcium stearate
 - vitamin E acetate
 - triacetin, 1,4-butanediol
 - lactide-diester
 - caprolactone polymers





Montage

Formats, sizing and setting times^{1,38}

- Manually applied, spreadable onto bleeding bone surfaces
- 2cc and 5cc sizes
- Instantly shapeable and spreadable
- Not injectable
- Sets within minutes
 - Adheres to bleeding bone surfaces
 - Drillable





Montage

Takeaway points^{1,38-39}

- Not indicated for use as a bone void filler
 - Categorized as a bone wax
- Adheres to bleeding bone surfaces
- No active hemostatic properties
 - Does not activate the blood clotting cascade
- Not injectable
- Contains hydroxyapatite (HA), which has a slow/incomplete absorption rate
- HA can cause a long-term nidus for infection
- Expands up to 10% due to porosity that develops during hardening phase
- Sets within minutes





Montage^{1,38-39}

Product comparison	MONTAGE	genex
Composition	Granular calcium phosphate (hydroxyapatite & β-tricalcium phosphate), calcium stearate, vitamin E acetate, triacetin, 1,4-butanediol, lactide-diester, and caprolactone polymers	Powder: 50% β – Tricalcium phosphate, 50% Calcium sulfate hemihydrate Mixing solution: Sterile water
Device type & code	Bone wax (MTJ)	Bone void filler (MQV)
Intended use	Bone hemostasis	Bone void filler
Claimed absorption rate	>6 months	Up to 12 months
Fully absorbs	No – HA may cause a long-term nidus for infection if not absorbed	Yes – Does not contain HA
Available sizes	2cc, 5cc	5cc, 10cc
Versatility	Manually applied, spreadable	Moldable, packable, injectable
Setting time	Within minutes	15 minutes
Product expansion	Up to 10% during hardening phase	None
Drillable when fully set	Yes	Yes



genex - Biocomposites

Indication & absorption rate^{1,40}

- Cleared for bony voids and defects that are not intrinsic to the stability of the bony structure
- Fully absorbed within 12 months

Composition¹

- Powder: 50% β-tricalcium phosphate and 50% calcium sulfate hemihydrate
- Liquid: Sterile water
 - 5cc paste: 4.1ml mixing liquid
 - 10cc paste: 7.6ml mixing liquid

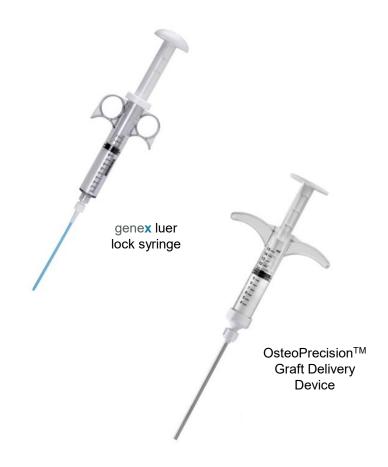






Formats, sizing and setting times¹

- Moldable, packable, injectable
- 5cc & 10cc sizes
- Injection device options
 - genex luer lock syringe
 - OsteoPrecision™ Graft Delivery Device
- Sets within 15 minutes of mixing
 - Drillable after 15 minutes





What makes <code>Genex</code> different

Designed to be completely absorbed and leave no trace

- ✓ Fully absorbed within 12 months⁴⁰
 - Contains no hydroxyapatite (HA)
 - HA can only be absorbed at 1-2% per year^{41,42}
- ✓ Enhances osteogenic response⁴³
 - Negatively charged surface chemistry accelerates bone growth up to 5x normal levels⁴³
- ✓ Restores strong healthy bone⁴⁴
 - Restores bone to normal trabecular structure in 36 weeks (critical size defect in an animal model)⁴⁵



What makes <code>Genex</code> different

Why do we use β -TCP rather than hydroxyapatite (HA)?

- ✓ Bioceramics made of more soluble forms of calcium phosphate are preferable for biomedical purposes⁴⁵
- √ β-TCP has superior osteoconductivity over HA⁴⁶
- \checkmark Osseointegration of β-TCP is faster than HA (6 weeks vs 4 months)⁴⁷
- \checkmark The full absorption of β-TCP allows for the restoration of the original bone architecture^{47,48}
- ✓ Hydroxyapatite (HA) is hardly absorbed, which blocks the formation of new bone and remodeling, and results in poor local stability or permanent stress concentration^{44,46}
- ✓ Only β-TCP is relatively balanced between scaffold absorption and bone formation⁴⁴





Takeaway points⁴⁰⁻⁴⁵

- Does not contain hydroxyapatite or insoluble impurities
- Completely absorbs within 12 months
- Fully absorbs at an optimal rate
- Available in 5cc, 10cc sizes
- Can be molded, digitally implanted or injected in difficult-to-reach sites or minimally invasive procedures
- Sets consistently within 15 minutes
- Not temperature sensitive
- Drillable after fully set





Protect & Increase genex sales

Strategies and resources



How do we protect our accounts?

Key strategies to protect accounts

- Understand what makes genex Bone Graft Substitute different
- Establish genex Bone Graft Substitute as a benchmark product
- Educate surgeons that competitor products are not equal substitutes
- Emphasize the importance of results over low prices
- React quickly
- Perform in-services
- Know what resources to draw on to help you sell genex
 Bone Graft Substitute





Resources to help you sell **Genex**®

Distributor Hub

- Training materials
- Biocomposites and genex collateral
- Sales tools
- Case studies



Distributor Hub app

- Order form
- Unsolicited requests
- genex content

Biocomposites website

- Product information specific to clinical specialties
- Biocomposites overview
- Surgeon testimonial videos
- Education



Genex[®] competitive environment

Find out more at biocomposites.com

For indications, contraindications, warnings and precautions see Instructions for Use.

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Patents granted: EP 1390086 B1, US 8632796, CN ZL02809194.9, US 8496955



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