Synthetic Osteoconductive Scaffold

Technical Monograph
Introduction

GenOS TCP

The result of extensive research, GenOS TCP synthetic osteoconductive scaffold is a three-dimensional ultra-porous structure, constructed of highly pure particles of resorbable β-tri calcium phosphate.

GenOS TCP is osteoconductive

The interconnected porous geometry of GenOS TCP is controlled to allow rapid vascularisation. The material surface is optimised for cell attachment and to function as a template to guide bone regeneration.

GenOS TCP is resorbed physiologically

The microporous surface of GenOS TCP is optimised for early cell attachment. The highly pure β-tricalcium phosphate responds to osteoblast-mediated resorption at a physiological rate.

GenOS TCP is totally synthetic

GenOS TCP is manufactured using pharmaceutical grade elements to exclude any possibility of allogenic/xenogenic contamination.

A proprietary manufacturing process, strictly controlled by an ISO 13485 quality assurance system, ensures a highly pure and reproducible material.
Porosity

Porosity is a fundamental property of any synthetic implant. Pore size has to be sufficient to allow revascularisation and the pore structure has to be interconnected to allow fluid communication so that cells can pass throughout the material.

Porosity has an important and direct relationship to the material volume and surface area, both components directly influence a material’s rate of resorption.

The surface of GenOS TCP has been optimised for cell attachment.

The porosity, surface area and material volume have been calculated, balanced and carefully controlled to provide a physiological response.

Under Remodelling

Once osteoclasts arrive within enter into the GenOS TCP structure, they begin to form lacunae in on the surface just as they would in autogenous bone.

Once attached to the surface, the osteoclasts change the local pH which causes calcium and phosphorous ions release from the GenOS TCP.

Once the local phosphorous level reaches a certain concentration, the body responds by sending osteoblasts, which settle in the newly formed lacunae and release osteoid which attaches the released calcium ions and starts to create the next bone layer.

Bone replaces the GenOS TCP at a rate dictated by the physiology, not the material.
The Case for Synthetic Scaffolds

The case for synthetic osteoconductive scaffolds

In the ninety years since Hibbs and Albee first described the effects of autogenous cancellous bone as a graft material, it has been widely regarded as the ideal substrate. However, the increasing sophistication of orthopaedic techniques places far greater demand on what can now be considered the ideal graft material.

Morbidity related to the harvest of autograft is well documented, and a high percentage of patients undergoing bone grafting have to endure long periods of painful side effects resulting from the harvest.

In many spinal procedures the volume of autograft required to achieve a successful fusion is far greater than the volume which can be safely harvested.

All the cellular potential for regenerating bone lies within a patient’s bone marrow which can be easily collected without morbidity. When marrow is combined with a synthetic osteoconductor, the resulting composite material functions equally to autograft but without the negative side effects.

GenOS TCP eliminates the risks of bone harvest by providing a readily available source of a consistent osteoconductive material in unlimited volume, which has been shown to function equally to the autograft when combined with the patient’s bone marrow.

- GenOS TCP is a proven osteoconductor
- GenOS TCP is available in unlimited volume
- GenOS TCP is the ideal carrier for the osteoinductive potential of bone marrow

Indications for using GenOS TCP

GenOS TCP synthetic osteoconductive scaffold is intended to be used as a bone void filler in the treatment of osseous defects which occur as a result of trauma or in surgically created defects.

GenOS TCP has been successfully used to treat bone loss resulting from trauma to resolve conduction defects in non-unions and to restore conduction across osteotomy sites.

In spinal fusion, GenOS TCP has proved extremely effective at expanding the volume of available fusion material by combining with any autograft produced as a result of the surgical approach.

<table>
<thead>
<tr>
<th>Spinal Fusion</th>
<th>Osteotomies</th>
<th>Trauma</th>
<th>Bone tumour or cyst</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scoliosis</td>
<td>High tibial</td>
<td>Fracture of the femoral head</td>
<td></td>
</tr>
<tr>
<td>Lumbar Fusion</td>
<td>Hallux Valgus</td>
<td>Scaphoid fractures</td>
<td></td>
</tr>
<tr>
<td>Cervical Fusion</td>
<td></td>
<td>Poor fracture-healing</td>
<td></td>
</tr>
<tr>
<td>PLIF/ALIF</td>
<td></td>
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</tbody>
</table>
Chemical Properties
The chemical composition of GenOS TCP is consistent with the specification of the International Standard ASTM F-1088:87.
Traces metal impurities are evaluated using inductively coupled plasma emission spectroscopy (ICP) or cold vapor atomic absorption.
The chemical and structural purity of GenOS TCP synthetic osteoconductive scaffold have been characterised by element analysis, infrared (IR) spectroscopy and X-ray diffraction (XRD).
Every production batch is tested to ensure quality and consistency.

Biocompatibility
The biocompatibility of β-tricalcium phosphate has been clearly established through 25 years’ use in vivo with no adverse events being reported in any of the indexed literature.
Every batch of GenOS TCP undergoes full profile testing for compliance with the Standard specifications of ASTM F-1088:87. GenOS TCP has been thoroughly evaluated and complies with the International Standard for biological evaluation of medical devices ISO 10993:2003.

Physical Properties
GenOS TCP is supplied as an irregular shaped granule in three sizes.
When mixed with blood or bone marrow the granules combine to form a cohesive matrix.
The granular geometry provides easy handling; packing of the granules into a defect is simple and precise.

Granule sizes
Fine granules: 1–2 mm
Standard granules: 2–4 mm
Large granules: 4–6 mm
Physical form: irregular granules
Purity: >99%
Crystallinity: >95% β-tricalcium phosphate

Porosity/Volume
The interconnected porosity of GenOS TCP has been calculated and is controlled during manufacture to produce a balance between optimal pore size, surface area and material volume, which results in a physiological response.
Porosity: 70% by volume
Pore geometry: macropores > 200 μm
Micropores: < 1 μm

Sterility
GenOS TCP is supplied sterile for single patient use.
Sterility is achieved by gamma irradiation and guaranteed to a sterility assurance level of 10^-6 (SAL = 10^-6).

Regulatory Status
GenOS TCP complies with the requirements of the European Medical Device Directive (93/42/EEC) and has been issued Certificate No. 0088/LROA-4001401/00232.
In the United States, GenOS TCP received pre-market approval in August 2004 (Reg No. K041616).
The GenOS Boost-BMA kit provides the surgeon with a convenient method of harvesting autologous bone marrow, and combining it with their choice of osteoconductive material such as autogenous bone or a synthetic bone void filler like GenOS Boost synthetic osteoconductive scaffold.

**GenOS Boost-BMA surgical technique**

Familiarisation with current bone marrow aspiration techniques is extremely important.

1. Position the syringe plunger within the barrel so that the black ring of the syringe plunger aligns with the line printed around the barrel of the syringe.

2. Remove the end cap.

3. Fill the space above the plunger with GenOS Boost and replace the cap.

4. Connect the extension tube to the syringe cap.

5. Place the needle
   a) Using the surgeon’s preferred bone marrow aspiration technique, insert the needle into the site from which bone marrow will be harvested.
   b) The needle should be inserted approximately 3 to 4 cm.

6. Remove trocar and connect extension tube to the luer-lock connector on the needle.
Start aspiration

- Draw the plunger back in the syringe to create a vacuum in the syringe barrel.
- Hold the plunger in position for approximately 20–30 seconds to maintain the vacuum.
- The holes in the distal wall of the cannula are positioned such that cells are drawn from 90° quadrant 1 cm high. Reposition the needle by rotating the handle through 90° changes turns the quadrant from which cells are being collected.
- Once cells have been collected from the first level, i.e. after 3 × 90° turns, withdraw the needle from the site by 1 cm to a second level and repeat the aspiration.
- Continue aspirating until all of the granules and the contents of the barrel have turned red.

Disconnect and set the syringe aside for 20 minutes to allow the blood in the marrow surrounding the granules to form a fibrin clot combining the granules into a cohesive plug.

Remove the cap and extrude the plug either directly into the defect or if being used as a graft extender, mix well with autograft chips in a container before implanting.
GenOS TCP Presentation

GenOS TCP is available in three granule sizes, packed in secure tamper-evident containers and sealed in a double blister pack system to aid sterile handling techniques.

<table>
<thead>
<tr>
<th>Granule Size</th>
<th>Pack Volume</th>
<th>Catalogue No</th>
</tr>
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<tbody>
<tr>
<td>Fine Grain</td>
<td>5 cc</td>
<td>7500 4049</td>
</tr>
<tr>
<td></td>
<td>10 cc</td>
<td>7500 4050</td>
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<tr>
<td>Standard Grain</td>
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<tr>
<td></td>
<td>10 cc</td>
<td>7500 4052</td>
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<tr>
<td></td>
<td>15 cc</td>
<td>7500 4053</td>
</tr>
<tr>
<td></td>
<td>30 cc</td>
<td>7500 4054</td>
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<tr>
<td>Large Grain</td>
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<td>7500 4055</td>
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<tr>
<td></td>
<td>30 cc</td>
<td>7500 4056</td>
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<tr>
<td>Aspiration Set</td>
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</tr>
<tr>
<td></td>
<td>30 ml</td>
<td>7500 4059</td>
</tr>
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