Fast-Setting Bone Graft and AutoGraft Extender.*

Ossilix is a high performance next generation calcium phosphate cement indicated for filling bony defects in cancellous bone.

This material was designed to overcome the limitations of the first generation calcium phosphate cements.

First generation cements had good compression strength, but were weak in tension, flexural strength and fracture toughness, which combined with poor handling properties, have limited their use in fracture fixation.

*Ossilix form
Advantages

- Biocompatible
- Allows for natural bone remodeling, or healing, while still maintaining the strength above that of cancellous bone
  - Immediate higher compressive strength than cancellous bone
- Easy to mix and deliver with supplied mixing system
- Fast, hard-setting; approximately 6 minutes at 37°C in wet environment*
- Can be drilled and inserted with screws
- May be implanted before or after hardware allowing surgeons to maintain their standard surgical technique and allowing precise cement and hardware placement
- Can be mixed with autograft as autograft extender*

Clinical Applications

- Simple voids in metaphyseal bone, (small tumors, cysts, defects)
- Traumatic fractures that result in bone voids in metaphyseal areas
  
  Fractures of the:
  - Distal radius (colles)
  - Proximal humerus
  - Pelvic bone
  - Proximal femur (intertroch, femoral neck)
  - Distal femur
  - Tibial plateau
  - Tibial pilon
  - Calcaneus
- Osteotomies (distal radius, tibial plateau)
- All oncological applications
- Revision total joints
- Iliac crest backfill
- Autograft extender*
DRILLABLE OSTEOCONDUCTIVE SCAFFOLD
Composition

Bone remodeling is the healing process whereby old bone is naturally removed and replaced with new bone. Ossilix is similar in composition to the mineral phase of bone.

A calcium phosphate starting powder is reacted with diluted silicate liquid, and undergoes a non-exothermic chemical reaction to form low crystalline hydroxyapatite, which hardens in vivo to create an Osteoconductive scaffold. Bony ingrowth occurs through the same cell mediated process as the patient’s natural bone remodeling.

Ossilix is optimal as a filler for metaphyseal defects due to its high immediate mechanical strength and ability to maintain that strength long term throughout the healing process.

Histology

Histology analysis demonstrated that Ossilix is highly biocompatible and osteoconductive. Histological sections were examined following four weeks and six months in vivo and showed extensive bone apposition with no adverse tissue reaction. Normal bone remodeling by localized osteoclastic, cell mediated resorption coupled with new bone formation within the implanted area was a consistent finding in areas implanted with Ossilix.

Figure 1
Femoral specimen implanted with bone cements after one month. Formation of several Haversian canals were observed in and around the implanted region. (Trichrome staining)

Figure 2
Femoral Specimen implanted with Ossilix after six months at low (left) and high (right) magnification. Mature Haversian canals were seen in areas where Ossilix was originally implanted. (HE staining)
Biomechanical Analysis

A clinically relevant understanding of long-term strength of defects treated with calcium phosphate bone void fillers (or any other bioactive material) are appropriately evaluated only \textit{in vivo}. An \textit{in vivo} biomechanical study was performed at four weeks and six months post-implantation to assess the \textit{in vivo} strength of cancellous bone defects treated with Ossilix bone void filler during replacement by native cancellous bone.

Ossilix is radiopaque and visible under fluoroscopy to allow proper placement of hardware and to ensure the cancellous defect has been completely filled.

Ossilix can be drilled and inserted with a screw to optimize use of the combination of hardware and cement, essential in treating periarticular fractures. Ossilix Form can accept hardware after a setting time of 6 minutes \textit{in vivo}, and Ossilix Fil can accept hardware after setting 10 minutes \textit{in vivo}. Ossilix should be drilled only with fluted bits or screws.

\begin{figure}[h]
\centering
\includegraphics[width=0.5\textwidth]{image1}
\caption{An \textit{in vivo} study shows Ossilix maintains strength above cancellous bone as it gets remodeled.}
\end{figure}

\begin{figure}[h]
\centering
\includegraphics[width=0.5\textwidth]{image2}
\caption{Post-op 1 year: Remodeling of Ossilix is evidenced by reduction in density of the implanted area.}
\end{figure}

\begin{figure}[h]
\centering
\includegraphics[width=0.5\textwidth]{image3}
\caption{Post-op 2 years: As material continually remolds, radiographic evidence of the implanted area returning to trabecular structure.}
\end{figure}
Indications & Case Studies

TRAUMA

Tibial Plateau Fracture

*Pre-op*
CT shows low energy Tibial Plateau fracture.

*Post-op*
X-ray shows the fixation by plating and Ossilix implantation.

Distal Radius Fracture

*Pre-op*
X-ray showing on extra-articular fracture.

*Lateral view*
shows Ossilix implantation in both dorsal and volarside of distal radius.

*Post-op*
image of implantation of Ossilix with K-wires.

Calcaneus Fracture

*Post-op*
lateral image of calcaneus shows fixation with plate and Ossilix.

*Post-op*
AP view shows the location of implanted Ossilix.
Total Joint Revision

Pre-op view shows extensive osteolysis in both compartments of tibial bone underneath the tibial tray.

Intra-op view of filling the bony voids with Ossilix.

Post-op view of Ossilix implant and new total knee joint has been inserted.

Pre-op Shoulder riding high compromised glenoid

Post-op 10cc Ossilix inject to fill voids and to Strengthen Glenoid Component

4 Months Showing significant bone remodeling and glenoid component solid

ONCOLOGY

Pre-op MRI view of atypical bone cyst.

Post-op radiograph shows complete filling of the defect in calcaneus.

Giant cell tumor of tibia.

Radiographic view shows complete filling with Ossilix. Approximately 80cc of material was used.
## Ordering Information

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
<th>Catalog</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ossilix / Form</td>
<td>Calcium Phosphate Fast Setting, 5cc</td>
<td>660-01-05</td>
</tr>
<tr>
<td>Ossilix / Form</td>
<td>Calcium Phosphate Fast Setting, 10cc</td>
<td>660-01-10</td>
</tr>
<tr>
<td>Ossilix / Fil</td>
<td>Calcium Phosphate Fast Setting, 5cc</td>
<td>660-02-05</td>
</tr>
<tr>
<td>Ossilix / Fil</td>
<td>Calcium Phosphate Fast Setting, 10cc</td>
<td>660-02-10</td>
</tr>
</tbody>
</table>

Ossilix is manufactured by Skeletal Kinetics and distributed by Exactech Inc.

## References