Calcigen® PSI
Resorbable Bone Graft Substitute

Attention Operating Surgeon

PRODUCT DESCRIPTION
Calcigen® PSI resorbable bone graft substitute is a pre-shaped (cubes, blocks, cylinders and granules) of calcium phosphate bone graft material for the repair of bony defects. The material consists of osteoconductive and bioresorbable cubes, blocks, cylinders, and granules of approximate volume between 5 to 50 cc. When placed in contact with viable bone, new bone forms on and between the pores of Calcigen® PSI.

Calcigen® PSI, when placed into a bony site, initially occupies approximately 10 to 40% of the defect volume, leaving approximately 60 to 90% void volume for bone ingrowth. During the bone healing process, literature data suggest that the material used in Calcigen® PSI gradually resorbs and is replaced by bone through the process of cellular remodeling.

Contents may settle or fragment during shipment.

INDICATIONS FOR USE
Calcigen® PSI bone graft substitute is indicated for bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from disease or traumatic injury to the bone. Calcigen® PSI bone graft substitute can be combined with autogenous bone marrow aspirate or autogenous blood. Calcigen® PSI resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS
The use of Calcigen® PSI Resorbable Bone Graft Substitute is contraindicated for:

1. Fractures of the growth plate
2. Segmental defects
3. Indications which may be subjected to excessive impact or stresses
4. When there is significant vascular impairment proximal to the graft site
5. When there are metabolic or systemic bone disorders that affect bone or wound healing
6. Infected sites
7. When stabilization of the defect is not possible
8. Hypercalcemia, abnormal calcium metabolism

The use of Calcigen® PSI is also contraindicated in cases where intraoperative soft tissue coverage is not planned or possible.

**INSTRUCTIONS FOR USE**

These instructions are intended as guidelines for the use of Calcigen® PSI as part of a surgical technique. They are not intended to replace or change standard procedures for treatment of bone defects involving bone grafting and internal fixation.

Procedures involving bone grafting result in highly variable outcomes. Factors to be considered in selecting the bone grafting material and the surgical technique to be utilized are as follows:

1. Age of patient
2. Quality of the patient's bone
3. Location of the defect
4. Anticipated loading conditions
5. Proximity of the graft to a suitable blood supply
6. Ability to achieve direct apposition of the graft to viable host bone
7. Presence/addition of autogenous bone or bone marrow at the graft site
8. Elimination of gaps in the graft site
9. Ability to suitably stabilize the graft site
10. Complete coverage of the graft material to prevent migration

**Preoperative Preparation:** Radiographic evaluation of the defect site is essential to accurately assess the extent of the defect and to aid in the selection and placement of the Calcigen® PSI and fixation devices.

**Surgical Procedure Notes:** Calcigen® PSI does not possess sufficient mechanical strength to support the reduction of a graft site prior to soft and hard tissue ingrowth. Therefore, anatomical reduction and rigid fixation, in all planes, should be obtained independent of Calcigen® PSI.

Calcigen® PSI resorbable bone graft substitute must fill the defect and contact as much bone as possible. Calcigen® PSI can be used alone or mixed with autogenous bone marrow aspirate or autogenous blood.

Stabilization of the void site must be sufficient to prevent collapse and deformity secondary to functional loading. Calcigen® PSI cannot be used to obtain purchase for screws. Screws must gain purchase into the patient’s own bone.

Calcigen® PSI must not be used to repair bone defects where complete soft tissue coverage cannot be achieved.

Calcigen® PSI package may contain more than one porous scaffold. Though these are cubes, blocks, granules, cylinders, they may be shaped by carving, using a sharp object in the operating theater. It is advised that this be performed away from the surgical site to prevent debris falling on the surgical site. Shaped surfaces should be smooth and free from excessive loose particles prior to implantation.

**Postoperative Care:** Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices.

The complexity of the defect site and the overall physical condition of the patient determine the length of time a defect should remain in a reduced state of loading. Hardware should not be removed until the defect is healed.
WARNINGS AND PRECAUTIONS
Calcigen® PSI resorbable bone graft substitute does not possess sufficient mechanical strength to support reduction of a defect site prior to soft and hard tissue ingrowth. Fixation techniques are recommended as needed to assure stabilization of the defect in all planes. Calcigen® PSI is intended for use by surgeons familiar with bone grafting and fixation techniques. Complete postoperative wound closure is essential.

Calcigen® PSI is radiopaque until resorbed. Radiopacity may mask underlying pathological conditions. Radiopacity may also make it difficult to radiographically assess the ingrowth of new bone.

Incomplete or lack of osseous ingrowth into bone void is possible with any bone void filler material.

Complications
Potential complications using this product are identical to those encountered in autogenous bone grafting procedures and include the following: superficial wound infection; deep wound infection; deep wound infection with osteomyelitis; nonunion; wound dehiscence; delayed union; malunion; loss of reduction; refracture; cyst recurrence; hematoma; and cellulitis. Some of these conditions may result in re-operations and may also require removal of the material.

STERILITY
Calcigen® PSI is supplied sterile. The product is radiation sterilized with at least 25 kGy (2.5 Mrad).

Calcigen® PSI is supplied sterile in dated individual double sterile barrier packages. The package should be inspected prior to use to ensure the sterility barrier has not been compromised.

This product is for single use only and should not be resterilized.

Calcigen® PSI is a trademark of Biomet Inc.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed physician.

Comments regarding this product can be directed to Attn: Regulatory Department, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-1683.