CELLPLEX® TCP SYNTHETIC CANCELLOUS BONE

129257-9

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For additional information and translations please contact the manufacturer or local distributor.

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*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**

℞ ONLY

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EN

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL
CELLPLEX® TCP SYNTHETIC CANCELLOUS BONE
(129257-9)

OUTLINE:

I. GENERAL PRODUCT INFORMATION

CELLPLEX® TCP Synthetic Cancellous Bone is a porous calcium phosphate bone void filler made from tricalcium phosphate for the repair of bony defects. It is osteoconductive with a trabecular structure that resembles the multidirectional interconnected porosity of human

cancellous bone. The implant is provided sterile for single patient use. CELLPLEX® TCP Synthetic Cancellous Bone guides the three-dimensional regeneration of bone in the defect site into which it is implanted. Pores in the device range from 100 to 400 µm nominally. When CELLPLEX® TCP Synthetic Cancellous Bone is placed in direct contact with viable host bone, new bone grows in apposition to the calcium phosphate surfaces of the implant, filling the pores with new bone. As the implant is bioabsorbed, bone grows into the space previously occupied by the bone graft substitute.

A. INDICATIONS

CELLPLEX® TCP Synthetic Cancellous Bone can be combined with autogenous bone marrow aspirate and/ or blood and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. The CELLPLEX® TCP Synthetic Cancellous Bone is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product resorbs and is replaced with bone during the healing process.

B. CONTRAINDICATIONS

CELLPLEX® TCP Synthetic Cancellous Bone is contraindicated for use under the following conditions:

- Fractures of the growth plate
- Segmental defects
- Indications that may be subjected to excessive impact or stress
- Significant vascular impairment proximal to the graft site

- Metabolic or systemic bone disorders that affect bone or wound healing
- Where stabilization of the defect is not possible
- Direct contact with the articular space
- Where intraoperative soft tissue coverage is not planned or possible
- Immunosuppressive therapy
- Open fractures
- Pregnancy
- Existing acute or chronic infections
- Heavily impaired renal function

C. POTENTIAL COMPLICATIONS

Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure used based on personal medical training and experience. Although Wright Medical cannot recommend a particular surgical technique suitable for all patients, a detailed surgical technique is available for surgeon reference.

Potential complications using this device 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, loss of reduction, refracture, cyst recurrence, hematoma, rejection reactions, swelling, seroma formation, pain, and cellulitis. Some of these conditions may result in reoperation and may also require removal of the implant.

D. PRECAUTIONS

CELLPLEX® TCP Synthetic Cancellous Bone does not posses sufficient mechanical strength to support reduction of a defect site prior to soft and hard ingrowth. Rigid fixation techniques are recommended as needed to secure rigid stabilization of the defect in all places. CELLPLEX® TCP Synthetic Cancellous Bone is intended for use by surgeons familiar with bone grafting and rigid fixation techniques. Complete postoperative wound closure is essential.

CELLPLEX® TCP Synthetic Cancellous Bone is radiopaque until bioabsorbed. Radiopacity may mask underlying pathological conditions. Radiopacity may also make it difficult to radiographically assess the ingrowth of new bone.

This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

Warning: Do not use kit if glass vial is cracked or broken.

<u>Intra-Operative Precautions</u>

Use medical devices in accordance with their labeled indications and Wright Medical Technology's instructions for use, especially during insertion and removal.

- Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with Wright Medical Technology's analysis of the event.

- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
  a. The material composition of the fragment (if known);
  b. The size of the fragment (if known);
  c. The location of the fragment;
  d. The potential mechanisms for injury, e.g., migration, infection;
  e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

E. ADVERSE EFFECTS

Possible adverse effects include but are not limited to:

- Wound complications including hematoma, site drainage, bone fracture, infection, and other complications that are possible with any surgery
- Fracture or extrusion of the bone void filler, with or without particulate debris generation
- Deformity of the bone at the site
- Incomplete, or lack of, osseous ingrowth into bone void, as is possible with any bone void filler.
- Transient hypercalcemia

F. HANDLING AND STERILIZATION

CELLPLEX® TCP is provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. This product should not be resterilized. The kits are for single patient use and should never be reused. Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

G. STORAGE CONDITIONS

All kits must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature. CELLPLEX® TCP Products should be stored at 15-30°C or 59-86°F.

H. DIRECTIONS FOR USE/MIXING INSTRUCTIONS

These instructions are intended as guidelines for the use of CELLPLEX® TCP Synthetic Cancellous Bone as part of established surgical techniques. They are not intended to replace or change standard procedures for treatment of bone defects involving bone grafting and internal fixation.

For best results, extreme care should be exercised to assure the correct graft material is selected for the intended application.

Preoperative preparation: Radiographic evaluation of the defect site is essential to assure the extent of the defect and to aid in the selection and placement of the CELLPLEX® TCP Synthetic Cancellous Bone and fixation devices.

For best results, CELLPLEX® TCP Synthetic Cancellous Bone must fill the defect and contact as much viable bone as possible. CELLPLEX® TCP Synthetic Cancellous Bone can be used as a carrier for bone marrow aspirate and/or blood.

Fixation of the CELLPLEX® TCP Synthetic Cancellous Bone implant site must be sufficient to prevent collapses and deformity secondary to functional loading.

Postoperative care: Postoperative patient management should follow the same plan 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 patient should be cautioned against early weight bearing, which could lead to loosening and/or failure of the fixation or loss of reduction.

The length of time a defect should remain in a reduced state of loading is determined by the complexity of the defect site and the overall physical condition of the patient. Hardware should not be removed until this defect is healed.

Patents:

One or more of the following patents may apply to Wright Medical Technology products:

United States Patents

6,136,029, 6,527,810, and 6,296,667

Additional patents pending.