SUPRABONE BONE GRAFT SUBSTITUTE INSTRUCTIONS FOR USE

Classification
Suprabone-TCP is a medical device (ClassIII), not a drug.

Material
Suprabone-TCP is pure ß-tri-calcium phosphate (ß-TCP). It is an osteoconductive support matrix, which is also biocompatible and resorbable when implanted, and supports new bone formation in the defect area. Suprabone-TCP resorbs over time and ultimately replaces with natural bone. Suprabone-TCP contains no tissue of human or animal origin therefore carries no risk of disease transmission. The product contains silicate/bioglass additive for enhanced bone bonding.

Indications-For-Use
Suprabone-TCP is a synthetic osteoconductive bone substitute in the form of granules and powder. It is made to be used in non-load bearing defects in extremities, spine, pelvis, cranium, etc. as a filler.
The granules and powders may be pressed into the defect area by hand or shaped more accurately to fit the area, and may also be premixed with bone marrow aspirate and other bone grafts known clinically. Suprabone-TCP acts as a temporary scaffold, and is not intended to provide mechanical support during the healing process. The implant is biocompatible, radio-opaque and will be resorbed in a controlled way within 24 months.

Contraindications
Suprabone-TCP is not indicated for any other uses than the ones stated here. It should not be used when there is any contraindication. Suprabone-TCP is contraindicated where the device is intended to provide structural support in the skeletal system, and must not be used to gain screw fixation. Other contraindications are:

•Existing acute or chronic infections, particularly at the implantation site
•Severe vascular or neurological disease
•Poorly vascularised implantation site
•Uncontrolled diabetes
•Severe degenerative diseases
•Hypercalcemia, abnormal calcium metabolism
•Inflammatory bone disease
•Malignant tumors
•Severely impaired renal function
•Open epiphyseal plates in pediatric patients
•Uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol.

Precautions
Suprabone-TCP is only intended for the use of surgeons familiar with, and skilled in techniques of bone repair and replacement. **SUPRABONE-TCP IS NOT INTENDED FOR LOAD BEARING APPLICATIONS.** It is important to ensure that the area around the implantation site is secured mechanically with rigid fixation to provide structural support, and maintain the implant in a load free environment.

It is important to **MAXIMIZE THE CONTACT SURFACE** between existing bone and the implant to ensure proper bone regeneration.

Suprabone-TCP must not be used to gain screw fixation. The effect of Suprabone-TCP on patients with the following conditions is unknown:

•Long term infection
•Pregnancy and nursing
•Radiation bone therapy
•Cardiovascular disease
•Metabolic bone disease
•Documented renal disease

The effects of Suprabone-TCP in pediatric patients and the effects of mixing with other substances (e.g. antibiotics or serum) are also unknown. Possible Complications

Reoperation to remove or replace an implant may be required, due to specific medical conditions or device failure. Possible adverse effects may include, and are not limited to:

•Wound complications including hematoma, swelling and fluid accumulation, edema, tissue thinning, infection, bone fracture, and other complications that are possible with any surgery,
•Fracture or crushing of the implant with or without generation of particulate debris due to a load being applied,
•Bone deformity and loss of contour at the site,
•Allergic reaction to the product.

Warnings
Suprabone-TCP comes in a double sealed blister package; the product is sterile. **DO NOT USE IF THE PACKAGE INTEGRITY IS LOST.**

Read expiry date before use and **DO NOT USE IF THE EXPIRATION DATE HAS BEEN EXCEEDED.**

The inner blister must be opened just before the implantation in a sterile environment. Since Suprabone-TCP is opaque to x-rays, areas under or above the implant may be masked on the radiography. Granules and powders must be secured to prevent potential migration, and should only be used in surgical procedures where bone grafts are adequately contained.
Since both hard tissues and Suprabone have very short T2 values, it may be difficult to visualize the product with conventional MRI.

Suprabone-TCP is for single use only. **DO NOT ATTEMPT TO RE-STERILIZE OR RE-USE.**

Application
Step1: Transfer the inner blister to the sterile environment by opening the outer blister in the operating room. Open the inner blister just a few minutes before the implantation in a sterile environment.
Step2: Implant the material. Material may be gently shaped to fit the defect area, and can be mixed with bone marrow aspirate, and may be gently and carefully tamped into the place. Make sure that **SUPRABONE-TCP IS IN DIRECT CONTACT WITH ALL SURFACES OF THE DEFECT AREA.**
Step3: Secure the surgical site after implanting in order to prevent motion and implant migration. When excess fluid is present in the surgical field, the surgeon may use proper measures (i.e. cauterization, suction and application of bone wax) to reduce bleeding. If material is not positioned satisfactorily, remove the implant and start over with a new dose of Suprabone-TCP.

Storage
Store in a **DRY PLACE AT ROOM TEMPERATURE.** Optimal storage conditions: **+5ºC - +39ºC (41-102.2ºF), <70%** relative humidity. Direct contact with heating systems or storage under direct sunlight should be avoided.

Shelf Life and Disposal
The expiration date is printed on the label. **DO NOT USE AFTER THE EXPIRATION DATE.** Suprabone-TCP is environment-friendly. No special disposal is necessary. Packaging material is recyclable.

Ordering Information
Suprabone-TCP is a sterile osteoconductive bone graft substitute. It is provided with detailed instructions-for-use. The entire device is sterilized by gamma radiation. Suprabone-TCP bone graft substitute is packaged in double blisters, within an additional box for transportation and storage. In addition to this booklet, there are labels for the documentation of patients' inside the box. For further information on the product and its uses, please contact **BMT Calsis Sağlık Teknolojileri San. Tic. A.Ş.** The address is printed on this information sheet.

Symbol Key for Product Box and Label

Manufacturer
Date of Manufacture
Use-by Date
LOT Batch Code
REF Catalogue Number
STERILE R Sterilized Using Irridation
Do not Resterilize
Do not Use if Package is Damaged
Do not re-use
Keep away from sunlight
Keep dry
5°C 39°C Temperature limit
Consult instructions for use
CE symbol and Notified Body number

Please read before use.

Manufacturer
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