English : INSTRUCTIONS FOR USE

ICB® Bone Block Allograft / ICB® Cortical Bone Particulate Allograft / ICB® Cancellous Bone Particulate Allograft

DESCRIPTION: ICB® bone allograft is a 'Donated Human Tissue' derived from musculoskeletal tissue supplied by US – based tissue banks in accordance with the guidelines of the American Association of Tissue Banks (AATB) and the Food and Drug Administration's (FDA) applicable Code of Federal Regulations (12CFR1270). The musculoskeletal tissue is processed to remove cells that can solicit a potential immune reaction through a patented method while preserving the remaining bone components and structure. The bone is frozen at -70 ° C and subject to gamma sterilisation using a dose of 25 to 38 kGy, to render the allograft non-viable and sterile. Microbiological cultures are performed on each lot to assure the absence of bacterial and fungal pathogens. The bone allografts are supplied to licensed dental surgeons, implantologists and periodontists only.

Warning: DO NOT RESTERILIZE. RMTB does not recommend resterilisation of the bone allograft as resterilisation may result in structural damage and functional impairment of the allograft.

Warning: **For single patient use only in one patient.**

INDICATIONS / INTENDED USE: ICB® bone allografts are indicated for oral surgery bone grafting procedures in dental procedures where there is a need to correct, restructure, fill / support, rebuild, repair and / or replace bone due to bony defects or deficiencies or bone loss.

CONTRAINDICATIONS : ICB® bone allografts are contraindicated in patients not considered fit and suitable to undergo reconstruction of bony defects due to bone loss with bone grafting procedures.

PATIENT SELECTION: Ensure patients receiving ICB® bone allografts are evaluated in terms of medical history, medications and overall health and can meet proper hygiene and follow-up requirements.

REGULATORY STATUS: Bone grafts are regulated domestically and internationally by laws governing human tissues and cells. The allografts are processed in accordance with the prevailing (international and domestic) requirements for the procurement and processing of banked human tissues (e.g. US FDA 21 CRF 1270 and 1271; EU Directives 2004/23/EEC; other international directives) and relevant standards and guidelines on tissue banking set by the AATB and / or national regulatory agencies.

Processing of the donor tissue, laboratory testing and careful donor screening minimize the risks of the donor tissue transmitting disease to the patient. No long-term studies have been conducted to evaluate the carcinogenic or mutagenic potential or reproductive impact of the clinical application of the bone allografts.

DONOR SCREENING AND TESTING: Donor tissue undergoes detailed testing and screening to assure its safety. Blood, serum and tissue samples from donors are screened by a certified laboratory working to CLIA (42 CFR 493) and found to be negative when tested for:

- Antibody to human immunodeficiency virus (HIV) types 1 and 2;
- Hepatitis B surface antigen (HbsAg);
- Antibody to hepatitis B (HBV), hepatitis B core (HBc, total);
- Antibody to hepatitis C (HCV);
- Antibody to human T-lymphotropic virus (HTLV) type I and II;
- Syphilis (RPR or VDRL);
- HCV NAT;
- HIV NAT;
- HBV NAT

Tests used are approved by the appropriate regulatory authorities (e.g. US FDA).

Donor suitability is determined by careful donor screening including history (medical and social), physical examination, cause of death and serology and microbiology and show negative for presence of infectious diseases, malignancies and degenerative neurological diseases of unknown aetiology. RMTB upon receipt of musculoskeletal donor tissue reviews donor screening and testing records. Existing tests as conducted cannot provide absolute assurance that human source material will not transmit disease.

HOW SUPPLIED: The donor tissue is aseptically processed under controlled conditions. The bone block is double packaged in inner / outer pouches in an inert atmosphere. The cancellous and cortical bone particulates are packaged in a external vial containing an inner vial with the bone particulates. The allografts are hydrated within their packaging.

The inner packaging is sterile and can be placed in surgical field. Each allograft is labelled with size, dimensions and thickness ranges. Vials have colour coded seals corresponding to bone type and measurement in grams.

STORAGE: The allografts are shipped hydrated and at room temperature (18 ° C to 25 ° C). The allografts are to be stored at room temperature in a controlled environment. The expiry date for the allograft is found on the outer label.

WARNINGS and PRECAUTIONS

- Do NOT use the allograft if packaging is damaged, perforated or torn.

WARNINGS and PRECAUTIONS (Continued)

- Do NOT use the allograft if upon opening the allograft is no longer hydrated.
- **Do NOT rehydrate** the allograft if dried out. **Discard unused or residue allograft in accordance with institutional guidelines or national rules concerning biological waste.**
- Do NOT place the outer package in the sterile field. Only the inner pouch and vial are sterile.

POTENTIAL ADVERSE EFFECTS

- Sequelae due to surgery or surgical technique
- Opening of incision site due to suture release.

IMPLANTATION

1. Prior to surgery, standard precautions should be taken to minimize oral bacteria and potential for inflammation or infection due to migration of oral bacteria into surgical site.
2. Open the packaging.
3. Keep the outer packaging out of the sterile field placing the sterile inner packaging in the sterile field.
4. Prepare the implantation site. Ensure that the ICB® bone allografts come in contact with a well-vascularised implant bed.
5. Aseptically transfer the bone allograft to the implantation site. When implanting the ICB® bone allograft minimise soft tissue trauma.
6. Close the implantation site passively for optimal healing results.
7. Unless infection or necrosis occurs that could necessitate removal of the allograft, the implantation site should not be disturbed until it has time to heal.

TRACEABILITY: Information on implantation is required for traceability to comply with relevant regulatory requirements for human tissue and cells. Complete the tissue tracking form supplied with each ordered allograft. The information requested complies with data protection requirements as it uses anonymised patient information. Follow the instructions on the tissue tracking form and return as directed.

CUSTOMER SERVICE: For questions and concerns and to report potential incidents occurring with the bone allografts, contact your local tissue establishment or distributor who supplied the ICB® bone allografts.

Rocky Mountain Tissue Bank (RMTB)
2993 S Peoria St. Suite 390, Aurora, Colorado, 80014

DEFINITIONS SYMBOLS


Do not use if damaged


Read instruction for use / Consult instruction for use

Sterile / gamma radiation


Use by date

Lot number


Processed by


Storage temperature