Symbios®
Allograft Particulates

INSTRUCTIONS FOR USE

THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES. IT IS INTENDED FOR SINGLE PATIENT, SINGLE USE ONLY. All tissue has been sourced by Surgenex of 1544 N 76th Street, C110, Scottsdale, AZ 85260, an American Association of Tissue Banks (AATB) accredited Tissue Bank, in accordance with Food and Drug Administration (FDA) Regulations.

USE/DESCRIPTION:
Symbios® Allograft Particulates are used in situations where a human allograft is appropriate, such as dental bone grafting procedures. Symbios® Allograft Particulates are, low-dose, gamma-irradiated particles of allogeneic human bone.

Procurement: Symbios® Allograft Particulates are declared acceptable for transplant. All tissue meets stringent donor screening and laboratory testing to reduce the risk of transmitting infectious disease.

Processing: The processing of Symbios® Allograft Particulates consists of a strict, quality-controlled procedure that involves thorough cleaning and gentle preservation of the tissue.

CONTRAINDICATIONS:
The presence of infection at the transplantation site is a contraindication for use of musculoskeletal allografts. Contraindications customary to the use of bone grafts should be observed. In addition, Symbios® Allograft Particulates should not be used in patients with:

- Osteomyelitis at the surgical site
- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Severe renal dysfunction
- Severe liver disease
- High-dose therapy with corticosteroids
- Vascular impairment at the implant site

WARNINGS:
- Discard grafts when mishandled, or when possible contamination of the graft has occurred.
- Return to the supplier, any package in which the sterile barrier has been compromised.
- Do not re-sterilize.
- Unused bone should be properly discarded.
- Single patient use only.

PRECAUTIONS:
- Federal law (USA) restricts use to licensed clinicians
- Trace amounts of Povidone Iodine, Physiological Buffers, Alcohols and Saline Solutions may be present and caution should be exercised if the recipient is allergic to these processing agents.
- Use in immunocompromized patients.

HANDLING AND PREPARATION:
Graft preparation instructions are intended as guidelines as part of established surgical techniques.

They are not intended to replace or change standard procedures or institutional protocols.

CAUTION:
All preparation should be performed using aseptic technique. In order to obtain the Symbios® Allograft Particulates, peel the outer tyvec lid back, twist off the plastic lid from the plastic vial and remove the graft onto a sterile field. Once the packaging has been opened, the tissue must either be transplanted or discarded. It is recommended that Symbios® Allograft Particulates be reconstituted prior to use by covering with sterile isotonic solution for approximately 15 minutes, (30 minutes maximum) using aseptic/sterile technique. Rehydration can also be achieved by mixing Symbios® Allograft Particulates with the patient's blood. Reconstituted grafts must be used for the surgical event for which they were reconstituted or otherwise DISCARDED.

DONOR ELIGIBILITY:
Donor eligibility (screening and testing) is performed in accordance with AATB Standards and FDA regulations. Donor screening includes assessment of the medical and social history as well as physician assessment of the donor to assure that no conditions exist that may make the tissue unacceptable for transplantation. Donor has been determined to be eligible by a Surgenex Medical Director (1544 N 76th Street, C110, Scottsdale, AZ 85260)

SEROLOGICAL TESTING:
Communicable disease testing was performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493. The testing was conducted using FDA licensed, approved, or cleared donor screening tests for cadaveric specimens where applicable. The records of this testing are maintained at Surgenex. The following required testing was performed and found to be negative or non-reactive:

- Antibody to Human Immunodeficiency Virus 1 & 2 (HIV 1 & 2)
- Human Immunodeficiency Virus Type 1 (HIV-1 NAT)
- Antibody to Hepatitis C (HCV)
- Hepatitis C Virus (HCV NAT)
- Hepatitis B Core IgG/IgM Antibody (HBcAb)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Virus (HBV NAT)
- Rapid Plasma Reagin or Serologic Test for Syphilis (RPR or STS)

Additional tests including, but not limited to, Human T-Cell Lymphotropic Virus Type I & II (HTLV I & II) may have been performed at the time of donor screening, and were found to be negative or non-reactive. A list of additional communicable disease test(s) performed will be provided upon written request to RegenX at the address provided.

MICROBIAL TESTING:
Tissue is subjected to microbiological testing at recovery and in the course of processing, and must be free of specific aerobic/anaerobic microorganisms and fungal contaminants whose presence would preclude tissue from processing or transplantation.

MEDICAL DIRECTOR ASSESSMENT:
Donor eligibility determination is made by a Medical Director who reviews and approves each donor for processing. Pertinent records may be made available upon written request to RegenX at the address provided.

POTENTIAL COMPLICATIONS / ADVERSE REACTIONS:
As with any surgical procedure, the possibility of infection exists. Although the bone processing is designed to eliminate antigenic properties of the graft, the possibility of such rejection is present in any allograft procedure. Re-operation could be necessary to correct adverse effects. Symbios® Allograft Particulates products remain sterile as long as the package is not opened and/or damaged. The graft must be used before the expiration date. Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the graft. Patients should be instructed in the limitations of the graft and should be taught to govern their activities appropriately. Appropriate placement and retention are critical factors in the avoidance of potentially adverse effect on graft performance.

Adverse reactions should be immediately reported to RegenX
As with any human tissue products, it is not possible to give an absolute guarantee that no infectious disease will be transmitted. However, this risk is greatly reduced by using processing treatments shown to be capable of reducing this risk as well as the use of strict donor screening and laboratory testing. It is the responsibility of the hospital or clinician to maintain tissue for transplantation according to recommended storage conditions. Do not use if tissue has not been stored according to the recommended storage instructions.

STORAGE REQUIREMENTS:
- Store at ambient temperature
- Do not freeze

DOCUMENTATION:
A distinct identification lot code has been associated with Symbios® Allograft Particulates that relates the product to associated records. The consignee is responsible to maintain recipient records for the purpose of tracking tissues post-transplantation. If you, the consignee, assigns a new code to an HCT/P (Human Cells, Tissues/Products), you must establish and maintain procedures for relating the new code to the identifier designated by RegenX.

Please contact RegenX to report any unexpected or adverse events, or for any additional product related information.

LABELING SYMBOLS:

	Use-by date
	Do not re-use
STERILE	Do not resterilize
	Do not use if the product sterilization barrier or its packaging is compromised
Ambient	Temperature
	See instructions for use
STERILE R	Sterilized using irradiation
ID	Batch code
	Manufacturer
Rx only	For sale by or on the order of a physician or dentist
REF	Catalog Number
QTY	Quantity

Distributor:

Dentsply Sirona

www.dentsplysirona.com

Manufacturer:
RegenX,
1034 Pearl Street
Brockton, MA 02301, USA
855-647-2651

REGENX (ACE Surgical Supply Company Inc.)
Health Canada CTO Registration Certificate
Number 100235

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