**PACKAGE INSERT**

**PREPARATION INSTRUCTIONS**

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**DirectGen™ Mineralized Allograft**

**DirectGen™ Demineralized Allograft**

All tissue has been collected, processed, stored and distributed according to the Standards for Tissue Banking of the American Association of Tissue Banks (AATB), the US Food and Drug Administration (FDA) regulations, and the Health Canada Cells, Tissues and Organs for Transplantation (CTO) Regulations (when applicable).

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<table>
<thead>
<tr>
<th>THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES. IT IS INTENDED FOR SINGLE PATIENT, SINGLE USE ONLY.</th>
</tr>
</thead>
</table>

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**DESCRIPTION / USE:**

DirectGen™ Mineralized Allograft products consist of cortical and/or cancellous bone matrix and may be used in a variety of orthopedic, neurosurgical, reconstructive, periodontal, and oral maxillofacial procedures. DirectGen™ Mineralized Allograft is supplied in a range of sizes and formats (Ground Cortical Bone, Ground Cancellous Bone, and Ground Cortical/Cancellous Bone).

DirectGen™ Demineralized Allograft products consist of a cortical bone matrix and may be used in a variety of orthopedic, neurosurgical, reconstructive, periodontal, and oral maxillofacial procedures. DirectGen™ Demineralized Allograft is supplied in a range of sizes (0.5cc, 1.0cc, and 2.0cc of Ground Cortical Bone). DirectGen™ Demineralized Allograft is analyzed for BMP-2 post terminal sterilization.

DirectGen™ Allografts are aseptically processed and packed, preserved by freeze drying, terminally sterilized by gamma irradiation and are for surgical use by licensed clinicians (i.e., physicians, dentists, oral surgeons, physician’s assistants, nurse practitioners).

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**CONTRAINDICATIONS:**

The presence of infection at the transplantation site is a contraindication for use of musculoskeletal allografts.

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**WARNINGS:**

- **Human tissue has the potential to transmit infectious agents.** Donor screening, processing treatments and laboratory testing follow stringent specifications to reduce the risk of infectious agent transmission.
- Do not use if the expiration date has been exceeded or if there is evidence of defects in package or label integrity.
- Do not re-sterilize.
- 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.

**Attention:** Patients receiving any allografts in a surgical procedure should be appropriately informed of the risk associated with these grafts.

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**PRECAUTIONS:**

Restricted to use by a licensed clinician. Trace amounts of Polymyxin B sulfate and/or Bacitracin may be present and caution should be exercised if the recipient is allergic to these antibiotics.

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**DONOR ELIGIBILITY:**

Donor eligibility (screening and testing) is performed in accordance with AATB Standards, FDA regulations, and Health Canada CTO regulations (when applicable). 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 eligibility has been determined by an AlloSource® Medical Director.

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**SEROLOGICAL TESTING:**

Communicable disease testing was performed by a laboratory registered with 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 AlloSource at the address listed at the bottom of this document. 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)
- 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 acceptable for transplantation. A list of additional communicable disease test(s) performed will be provided upon request.

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**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.

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**MEDICAL DIRECTOR ASSESSMENT:**

Donor eligibility determination is made by the AlloSource Medical Director who reviews and approves each donor for processing. Pertinent records may be made available upon written request.

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**POTENTIAL COMPLICATIONS / ADVERSE REACTIONS:**

Inherent uncertainty exists in medical and social histories and laboratory testing which may not detect known or unknown pathogens. Therefore, the following complications may occur with tissue transplantation.

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Retain this information for hospital records.

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• Loss of function or integrity of transplanted tissue with resorption, fragmentation, disintegration, and associated loss of continuity, displacement, bending or fracture.
• Immune response to transplanted tissue.
• Transmission of known pathogens including Hepatitis B or C, Human T-cell Leukemia / Lymphotropic Virus, Human Immunodeficiency Virus 1&2, syphilis or bacteria.
• Transmission or causation of diseases of unknown etiology and characteristics.

**HANDLING & PREPARATION:**

**CAUTION:** All preparation should be performed using aseptic technique. Once the packaging has been opened, the tissue must either be transplanted or discarded. Tissue is packaged in a vacuum bottle: DO NOT USE IF VACUUM IS NOT PRESENT. Carefully remove the rubber top without touching the sterile inside of the bottle. Wipe bottle rim with a sterile alcohol swab. Transfer tissue onto sterile field.

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.

<table>
<thead>
<tr>
<th>GRAFT TYPE</th>
<th>GRAFT STORAGE</th>
<th>RECOMMENDED GRAFT PREPARATION *</th>
</tr>
</thead>
<tbody>
<tr>
<td>FREEZE DRIED</td>
<td>Ground Cancellous products</td>
<td>To reconstitute, place graft in sterile basin and cover with sterile isotonic solution for a maximum of 30 minutes.</td>
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<tr>
<td></td>
<td>Ground Cortical products</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ground Cortical/Cancellous products</td>
<td></td>
</tr>
</tbody>
</table>

* Reconstituted grafts must be used for the surgical event for which they were reconstituted or otherwise DISCARDED.

**RECORD KEEPING:**

Regulatory bodies such as the FDA and Health Canada require that allograft tissue be traceable from the donor to the recipient. The transplantation facility (clinician or hospital) is responsible for traceability of the tissue post transplantation. A Transplantation Record & Feedback Form and preprinted peel-off labels are included with each package of tissue. Record the patient name or ID number, the transplantation facility name and address, the allograft tissue identification information (using the peel-off stickers) and comments regarding the use of the tissue on the Transplantation Record & Feedback Form. Return the completed form to AlloSource and retain a copy in the patient medical record. If the tissue has been discarded, please return the Transplantation Record & Feedback Form to AlloSource with the graft identification information and reason for discard.

**CONTACT INFORMATION**

Please contact Implant Direct at 888-649-6425 to promptly report any unanticipated or adverse events or should you require further information.

**PROCESSED BY:**

AlloSource
6278 South Troy Circle
Centennial, CO 80111 USA
800-557-3587 (Toll free)
Health Canada CTO Registration Number 100134

**DISTRIBUTED BY:**

Implant Direct LLC
11780 Hammarsmith Way, Unit 110
Richmond, British Columbia
Canada V7A 5E9
1-888-730-1337
Health Canada CTO Registration Number 100217

**IMPORTED/DISTRIBUTED IN CANADA BY:**

Implant Direct LLC
11780 Hammarsmith Way, Unit 110
Richmond, British Columbia
Canada V7A 5E9
1-888-730-1337
Health Canada CTO Registration Number 100217

For end users in Canada
Affix chart label here for Donor Identification Code and Expiration Date per CTO regulations 31.3 and 31.20

Retain this information for hospital records.

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