Veterinary Bone Graft – Package Insert & Instructions for Use

GEM Vet™

PDGF Growth-Factor Enhanced Bone Graft

Freeze-Dried Storage & Handling

Storage: Refrigerated (at 2°-8°C), do not freeze, protect from light
Expiration: 1 year (see exp. date on package label)

How Supplied

The GEM Vet™ kit is a bone grafting system composed of one jar containing 0.5 cc **Osteoallograft®** (Ultra Fine Canine Bone Graft) and one syringe containing 0.5 mL of **rhPDGF-BB** (purified recombinant human platelet-derived growth factor-BB (PDGF)) in solution (0.3mg/ml); intended to be combined then applied to the bone defect site.

Instructions for Use

Circulator:

1. Remove the Transplant Record, the clear pouch containing the syringe with rhPDGF-BB, and the peel pouch containing the bone graft from the outer box.
   a) *Syringe component:* The exterior surface of the syringe is NOT sterile (it is in a clear **tear** pouch). *Do NOT place the syringe on the sterile field.*
   b) *Jar component:* Everything inside the white **peel** pouch is considered sterile and should be placed on the sterile field.
2. Inspect each individual component of the kit for structural integrity prior to use. If the seal of any inner or outer container is open, broken or otherwise damaged, the product should be assumed to be non-sterile and consequently, must not be used.
3. *Using sterile technique*, peel the white pouch open and present the sterile innermost vacuum-sealed pouch containing the bone graft to the sterile field.
4. When the surgeon is ready to add the rhPDGF-BB liquid component, tear open the non-sterile clear pouch containing the syringe of rhPDGF-BB. Remove the cap from the syringe and using a sterile transfer technique, squeeze the plunger handle to dispense the liquid into the sterile jar containing the bone graft.
5. Complete the **Transplant Record,** then email, fax, or mail a return copy to VTS and retain a copy for your patient records.

Sterile Team Member or Surgeon:

1. To prepare the graft, open the jar containing the freeze-dried bone graft and rehydrate by having the circulator dispense the rhPDGF-BB into the jar.
2. Mix the liquid rhPDGF-BB and particulate bone graft using a sterile instrument. Let the particles sit fully saturated with the rhPDGF-BB solution for approximately ten (10) minutes.
3. Optional Addition: Obtain a few milliliters of blood to use in addition to the rhPDGF-BB during rehydration step.
4. GEM Vet™ should be placed in direct contact with well-vascularized bone using moderate pressure, taking care not to crush the particles. GEM Vet™ should completely fill the defect to the level of the surrounding bone.

Graft Description

Each GEM Vet™ kit consists of two sterile components:

- **Osteoallograft®** which is a combination of freeze-dried canine demineralized bone matrix (DBM) and mineralized cancellous bone particles, packaged in doses measured in cubic centimeters (*e.g.*, 0.5 cc). There are no other carrier additives.
- **rhPDGF-BB** which is a highly purified recombinant human platelet-derived growth factor-BB. PDGF is a native protein constituent of blood platelets. It is a tissue growth factor that is released at sites of injury during blood clotting. Extensive in vitro and animal studies have demonstrated its potent mitogenic (proliferative) and chemotactic (directed cell migration) effects on bone and periodontal ligament derived cells. Animal studies have shown PDGF to promote bone healing in orthopedic sites and in dentistry the regeneration of periodontal tissues including bone, cementum, and periodontal ligament (PDL).

Specific applicable information about GEM Vet™ (*e.g.,* graft type and preservation method, dose, species of the donor, *etc.*) is found on the label(s) affixed to the GEM Vet™ packaging. The VTS particulate bone graft jar is packaged in a sealed moisture vapor barrier pouch and protected by an outer peel pouch layer.

Indications & Uses

GEM Vet™ may be used wherever a bone graft is needed. Bone graft is used in a wide variety of periodontic, orthopedic, neurosurgical, and other reconstructive surgeries. It may be used by itself, or in combination with autograft, additives (such as bone marrow or antibiotics), bone graft substitutes, or other implants.

The saturated GEM Vet™ graft is intended to be placed into a well- stabilized defect site. Excessive bleeding should be controlled prior to placing grafting materials.

The packaging and dosages are intended for use in one patient on a single occasion only. The volume of graft necessary for any surgical procedure depends on surgeon preference and varies with the size & type of defect. Any unopened unused material must be discarded, and components of this system should not be used separately.

Contraindications and Precautions

Caution: Federal law restricts this device to sale by or on the order of a licensed veterinarian; it is not for use in human patients.

The GEM Vet™ kit and its components may not be re-sterilized by any method or reused.

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Contraindications and Precautions (continued)

GEM Vet™ is contraindicated in the presence of untreated malignant neoplasm(s) at the surgical site. Also, as with bone autograft, allograft when applied in a site with active or latent infection may be resorbed because of the infection, unless augmented with suitable antimicrobial agents.

Although GEM Vet™ is a liquid, it must not be injected systemically.

Tissue processing procedures, donor screening and tissue testing procedures are all designed to reduce the risk of infection or disease transmission. Even though rigorous quality controls are in place to minimize the risk, as with all transplants or transfusions there may be some small risk of disease transmission. Adverse outcomes potentially attributable to the tissue must be reported promptly to VTS.

Please retain a copy of the Transplant Record for your patient files to facilitate contacting us and to enable tracing of tissues. If you have any comments or if there is any dissatisfaction with the graft or packaging at the time of implant, please notify us using the Comment section of the Transplant Record or by calling or reporting by e-mail through our website (see below).

Records, such as a logbook, should be maintained for the purpose of tracing tissues to patients (*e.g.*, date of receipt, date of transplant, recipient identification, *etc.*).

Donor/Graft Suitability

Regarding the bone graft component of this kit: the bone graft has been determined to be suitable for implantation by Veterinary Transplant Services. All required infectious disease testing and screening has been completed, reviewed, and found to be acceptable, negative, or non-reactive. Owners and medical staff knowledgeable about the donor are interviewed about the donor's medical history. Additionally, all donors are screened for infectious diseases with nucleic acid tests (aka. PCR). These are extremely sensitive assays designed to identify the presence of infectious agents by amplification of their DNA or RNA.

Canine donors should have been vaccinated for at least for rabies, canine distemper, parvovirus, and hepatitis (adenovirus 2). If no record of vaccination, appropriate tissue samples must have been tested and the results found to be non-detectable with nucleic acid tests (*e.g.,* PCR) for these typical vaccine agents. Additionally, blood or tissue samples are also tested using PCR and must be negative for *A. platys, A. phagocytophilium, E. canis, M. haemocanis, M. haematoparvum, Rickettsia spp., Leishmania spp., Babesia spp.,* and *Bartonella spp*.

Microbial assessments are performed at procurement, during processing and at packaging. All cultures are 14-day cultures for aerobes, anaerobes, and yeast. Additionally, final-packaged bone grafts are gamma irradiated. The bone graft is not released unless the final packaging irradiation documentation is acceptable.

Processing

The sterile rhPDGF-BB is aseptically processed and filled into the syringe in which it is supplied, sealed within a non-sterile tear pouch. All particulate bone grafts are collected aseptically and processed in a sterile, laminar airflow environment using procedures that are rigorously quality-controlled and designed to prevent contamination and cross-contamination. Grafts are processed with proprietary solutions that may include antibiotics, alcohols, hydrogen peroxide, acids, buffers, enzymes, and/or surfactants. Processing steps are designed to remove cellular elements and reduce immunogenicity while preserving osteoinductive proteins. Traces of processing agents may remain. Freeze-dried grafts are preserved using lyophilization to reduce the water content of the tissues and minimize structural changes to proteins. The grafts are packaged to prevent protein degradation from oxidation, and then gamma irradiated. Each irradiated graft receives an acceptable low dose of gamma radiation, which has been shown to reduce bioburden while retaining protein activity. There is an indicator label on the product packaging that turns from orange to red upon exposure to irradiation.

Storage & Handling

The GEM Vet™ kit must be refrigerated at 2-8°C (36°-46°F). Do not freeze. The rhPDGF-BB component should be protected from light prior to use; do not remove from outer covering until ready to use. Do not use after the expiration date.

The packaging is designed to remain intact during the stated shelf life, and if unopened and undamaged will maintain the aseptic condition of the graft. Care should be taken to ensure that the packaging is not damaged prior to use. It is the responsibility of the clinician to maintain appropriate storage conditions prior to implant. After the peel pouch has been opened, the graft should be maintained in aseptic conditions and the tissue should be implanted or otherwise discarded. If the graft has been opened for more than 2 hours, it should be refrigerated in a sealed container to minimize the risk of inadvertent contamination. If it is not used within 6 hours it should be discarded.

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