# OssiVet

EN

## Synthetic, Adhesive Bone Substitute

Veterinary Medical Device [sterile 3cc single use product]

### Instruction for Use – OssiVet® – 3cc

For use in domestic companion animals - dogs, cats and *horses. (*USA and Australia only).

Not for use in humans or for animals intended for human consumption.

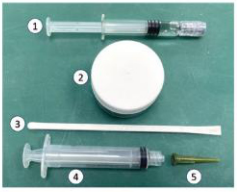
### Description of OssiVet® – 3cc:

OssiVet® is a sterile, mechanically enhanced, synthetic, self-setting calcium phosphate-based bioadhesive bone substitute for use in dogs, cats and *horses (*USA and Australia only). After mixing, the OssiVet® material can be implanted into bone defects in a low viscosity form, a high viscosity paste or as a putty (refer to Instruction for Use). OssiVet® should be implanted within 6 minutes of mixing as it will harden within 10-15 minutes to form a solid material. OssiVet® is supplied as a sterilized kit containing two sterilized pouches. The sterilized pouches contain a prefilled mixing container of calcium phosphate-based powder, a pre-filled syringe containing hydration solution, a mixing spatula, a delivery syringe and a 14-gauge transfer cannula (refer to Components and Composition of Kit).

### Components and Composition of Kit (Figure 1):

One sterilized foil pouch containing

- a prefilled mixing container with 4.5g of calcium phosphate- based powder (# 2); and




One sterilized Tyvek pouch containing:

- a prefilled glass syringe containing 1.35 mL of hydration solution (# 1);
- a mixing spatula (#3);
- a plastic delivery syringe (#4); and
- a 14G transfer cannula (#5)

### Intended Use/ Indications

OssiVet® is a self-setting, synthetic, adhesive bone substitute for use in dogs, cats and *horses. (*USA and Australia only)

OssiVet® is a structural, mechanically enhanced bone adhesive suitable for reduction, provisional fixation, or void filling of bone fractures or defects in order to enhance structural stability where standard fixation alone cannot provide sufficient support for functional mobilization.

OssiVet® is intended for:

- Osteosynthesis procedures to augment the stability of orthopedic implants (e.g., bone screws);
- Filling bone defects after removal of orthopedic implants such as bone screws;
- Arthrodesis (e.g., carpal or tarsal joint);
- Bone fractures with bone defects (e.g., fractures of the tibia, ulna, or femur in conjunction with appropriate stabilization hardware); and/or
- Bone defects following resection of benign bone tumors or bone cysts.

OssiVet® is designed and intended to be implanted into well vascularized and non-infected bone defects.

OssiVet® should not be considered a replacement for appropriate fracture reduction or orthopedic stabilization (e.g., orthopedic plates, pins, screws, external fixation).

### Instruction for Use.

| | Steps | Description |
|---|---|---|
| **Preparation** | **Step 1.** Surgical Preparation. | Prepare the surgical site according to veterinary surgical guidelines. OssiVet® should be implanted after appropriate debridement and using sterile technique. |
| | **Step 2.** Inspect the packaging. | Inspect OssiVet® packaging. Do not use if the packaging is compromised or after the product's expiration date.<br>Pre-condition the OssiVet® Kit to ambient room temperature for at least 1 hour prior to use. |
| | **Step 3.** Transfer of Sterile components to Surgical field | Open the outer carton and remove the outer pouch. Open each pouch and transfer sterile components to sterile field.<br>• The foil pouch contains one prefilled mixing container with OssiVet® powder.<br>• The Tyvek pouch contains 1 prefilled glass syringe with hydration solution, 1 mixing spatula, 1 plastic delivery syringe and short transfer cannula. |
| **Mixing Phase** | **Step 4.** Mix hydration solution and OssiVet® powder. | Remove the screw cap from the glass syringe and inject the entire volume of hydration solution into the powder container.<br>Using the spatula, mix the powder and hydration solution into a consistent, homogenous paste using circular movement for 20-30 seconds.<br>Ensure that all powder is mixed. |
| **Types of Application** | **Step 5.** Depending on the clinical need, OssiVet® can be applied in different forms described below: | |
| | **Low viscosity form** (<2 minutes mixing time) | Once the powder and hydration solution has been mixed to homogenous mixture (20-30 seconds), the OssiVet® mixture will remain in a low viscosity state for approximately 2 minutes. Within this 2-minute window, OssiVet® can be transferred into the supplied plastic delivery syringe and implanted using the supplied cannula, if required. Accounting for residual material in the cannula, the delivered volume will be approx. 2.5cc.<br>Note: The flowable consistency of the material is particularly suited for minimally invasive procedures and hard-to-access sites, enabling effective cavity filling with minimal back pressure and promoting uniform defect coverage. |
| | **High viscosity paste** (~2-4 minutes mixing time) | After 2 minutes of continued mixing the hydration solution and powder, OssiVet® will start to form a highly viscous paste that can be applied to the defect site with the spatula.<br>Place OssiVet® on the target site, pressing gently to ensure proper implantation.<br>Note: The enhanced adhesive properties make the material well suited for applications requiring reliable bone adhesion and stabilization of fracture fragments and orthopaedic hardware. |
| | **Putty** (~4-6 minutes mixing time) | After 4 minutes of continued mixing the hydration solution and powder, OssiVet® will form into a putty that can be manually manipulated and implanted into the desired location by hand or using surgical tools.<br>Note: The material is most appropriate for filling cavities or contained defects where manual shaping and maintenance of volume are required, rather than adhesive properties. |
| **Hardware Placement** | **Step 6.** Curing period. | From 6 minutes after mixing, the material should be held in a stable position within the defect and not subjected to movement or manipulation.<br>OssiVet® can be drilled with a surgical bit from 8 minutes onwards to allow placement of surgical screws. OssiVet® is radio-opaque; radiographic imaging (X-ray) can be used to verify placement.<br>OssiVet® hardens within 10-15 minutes from the start of mixing. Do not subject OssiVet® to compression, bending, or tensile forces during the curing period. |
| | **Step 7.** Hardware fixation. | OssiVet® should not be considered a replacement for bone stabilization or fixation techniques (e.g., plates, screws, pins, external fixation). OssiVet® should be used in conjunction with standard veterinary fixation methods to augment and stabilize hardware and provide mechanical stability. OssiVet® is Radio-opaque, use X-Ray as a product placement verification method. |
| **Closure** | **Step 8.** Closure of implanted site. | After implanting OssiVet®, the surgical site can be closed per standard of care surgical techniques. |
| **Post-Op Care** | **Step 9.** Post operative monitoring. | Follow postoperative care procedures as recommended for the specific surgical procedure. Monitor the patient for any signs of infection, inflammation, or adverse event |
| **Disposal** | **Step 10.** Disposal. | Dispose of packaging and materials according to applicable regulations. |

### Contraindications/Restriction for Use

**OssiVet® is contraindicated in the following conditions or procedures.**

- Patients with known intolerances/allergy to any ingredient of OssiVet® or its delivery system.
- Pregnant or nursing animals.
- Implantation into infected bone or tissue.
- In bone defects on/near the area of open epiphyseal gaps or an immature epiphyseal plate.
- In avascular tissue or areas with vascular insufficiency.
- Cranioplasty.
- Bone defects resulting from neoplastic tissue.

**OssiVet® is not intended to be placed directly into the joint space.**

**OssiVet® should only be used after carefully weighing the risk and benefits in veterinary patients with metabolic bone disorders or endocrinopathies or in patients that are immunocompromised.**

## Precautions and Warnings

| Number | Precautions and Warning |
|---|---|
| 1 | Single use only. Do not re-sterilize. Do not store and reuse contents. |
| 2 | Do not use if package is opened or damaged.<br><br>Do not use if expiration date has been exceeded or cannot be determined |
| 3 | Aseptic handling techniques are required during all phases of device handling. |
| 4 | OssiVet® should only be prepared with the provided hydration solution. |
| 5 | Mix the materials into a consistent, homogenous paste prior to implantation, strictly avoiding implantation of unmixed dry particles. |
| 6 | Transfer the entire volume of hydration solution into the powder. Inadequate transfer of all hydration solution into the powder may alter the expected setting profile. |
| 7 | Avoid extended working time outside the defect site as the fast-setting nature of OssiVet® could impart undesirable shaping or filling of the defect. |
| 8 | Care should be taken if irrigating the defect site to keep clean; over irrigating could cause OssiVet® to wash out during the setting period. |
| 9 | Do not over fill the defect site. Excess OssiVet® needs to be removed by means of a spatula or a comparable instrument before closing. |
| 10 | Placement over inadequate vascularized tissues or allograft material or other bone graft substitutes is not recommended. |
| 11 | The impact of OssiVet® within synovial joint space has not been studied. "Overflow" or remnant product in the joint space should be avoided and removed as much as possible. |
| 12 | The wound must not be left open i.e., complete postoperative wound closure is essential. OssiVet® must not be used to repair bone defects where soft tissue coverage cannot be achieved. |
| 13 | OssiVet® should be set at the defect site before closing. |
| 14 | Do not mix with additional substances other than those provided. The curing properties of OssiVet® when combined with other materials has not been evaluated. |
| 15 | Do not over-pressurize OssiVet® into tissue because this may lead to extrusion of the device beyond the site of its intended application, cause damage to the surrounding tissues, and/or may result in embolization of fat or OssiVet® into the bloodstream. |
| 16 | Ensure continuity of supply (back-up kit always available) |
| 17 | OssiVet® should be used precisely as directed. OssiVet® has radiopacity as a feature. Do not overfill the defect site with OssiVet®. The volume of device used should approximate the size of the defect since over-filling the defect site may create a risk of device migration. On application, ensure that OssiVet® cannot extrude or migrate into another soft tissue environment. |
| 18 | Do not freeze the product. If stored cold, allow OssiVet® to reach ambient room temperature (approx. 15°C to 25°C) before use. Keep the pouch sealed while equilibrating. Do not apply external heat (e.g., warmers/ microwave) to accelerate conditioning. |

## Side Effects and Adverse Events

No side effects directly attributable to the use of OssiVet® are known.
Adverse Event None reported.

## Interactions

None known.

## Storage Instructions

All components of the OssiVet® kit must be stored in dry conditions at room temperature between 0°C to 30°C.

## Sterility

The OssiVet® is supplied as a sterile product, with the contents of each kit being sterilized by irradiation. Do not resterilize. This product and its packaging are intended for Single Use Only, and product should not be stored for reuse after opening. Sterile product packaging should be inspected and if compromised, the product must be assumed non-sterile and appropriately discarded.

## Disclaimer

The use of OssiVet® remains the decision of the veterinarian. Specific factors should be considered including but not limited to the complexity of the clinical presentation, the age and physical condition of the patient and owner compliance. Veterinarians are encouraged to review or discuss the use of OssiVet® with PBC BioVet Ltd.'s clinical experts by contacting us by email at info@pbcbiovet.com or by phone at +353 61529557 for EU and +1 888 580 0399 for USA.

## Manufactured by

Biomimetic Innovations Ltd
4D Western Business Park,
Shannon, Co Clare, V14RW92,
Ireland

## Distributed by

PBC BioVet Ltd
4D Western Business Park,
Shannon, Co Clare, V14RW92,
Ireland

PBC Biomed Inc.
150 Peabody Pl Ste L1007
Memphis, TN 38103
United States

Customer service: info@pbcbiovet.com
EU Phone Number: +353 61529557
USA Phone Number: +1 888 580 0399
Australian Phone Number: +61 1 800 649 331

**CAUTION: THIS PRODUCT IS FOR USE BY LICENSED VETERINARIANS IN COMPANION ANIMALS ONLY. NOT FOR HUMAN USE OR USE IN ANIMALS INTENDED FOR HUMAN CONSUMPTION.**

## Glossary of Symbols

| | | | |
|---|---|---|---|
| STERILE R | Sterilization by irradiation | REF | Catalogue number |
| | Do not re-sterilize | | Expiration date |
| | Do not re-use. For single use only | | Manufacturer |
| | Do not use if pack is damaged | | Manufacturing date |
| | Refer to the instruction for use | | Keep dry |
| LOT | Batch number | 0°C 30°C | Store between 0°C and +30°C |
| | Distributor | MR | MR safe |
| | Double sterile barrier system | | |