Ostevoke Bone Graft

DESCRIPTION:

Ostevoke Bone Graft is a dual-phase bioabsorbable copolymer that appears in liquid form in <25°C and alter to gel form in body temperature. At the site of implantation, Ostevoke Bone Graft provides a sustained microenvironment to prolong the osteoinduction effect for new bone formation.

INTENDED USE:

Ostevoke Bone Graft is indicated for treatment of arthrodesis and bone fractures in dogs and cats.

CONTRAINDICATIONS:

- Do not use Ostevoke Bone Graft in cases that are pregnant, skeletally immature, have an active infection, pathological fracture, or any active malignancy.
- Do not use Ostevoke Bone Graft in cases with a known hypersensitivity to the active substance or excipients.
- Do not use Ostevoke Bone Graft in cases with an inadequate neurovascular status, e.g., high risk of amputation.
- Does not use in cases without providing mechanical stability.

WARNINGS:

- To be used only by properly trained veterinarians.
- Do not mix with other agents.
- Do not inject intravenously.
- Mechanical stability should be achieved before implanting Ostevoke Bone Graft.
- Long-bone fracture & soft-tissue management procedures should be based on standard practice, including control of infection.
- Failure to follow instructions for preparation and usage may compromise safety and effectiveness.
- Used in concentrations or dosage greater than those recommended will increase risks of excessive bone formation and generation of fluid-filled void spaces within the induced bone.
- Ostevoke Bone Graft may elicit an immune response in dogs; although no clear association with clinical outcome or undesirable effects could be observed in clinical/safety studies, the possibility of developing neutralizing antibodies or hypersensitivity-type reactions cannot be excluded.
- The possibility of an immune response should be evaluated in cases where an undesirable effect with immunological background is suspected.
- The safety and effectiveness of Ostevoke Bone Graft in nursing mothers has not been established.
- It is advised that female animal should not be pregnant for one year following treatment with Ostevoke Bone Graft.

PRECAUTIONS:

- Do not use beyond the expiry date.
- Prior to use, inspect the packaging and syringe (including barrel and plunger) for visible damage. If damage is visible, do not use the product. Retain the packaging and syringe and contact Expercy representative.
- Ostevoke Bone Graft must not be sterilized by the hospital.
- Safety and efficacy of Ostevoke Bone Graft have not been studied under conditions of reuse of device and/or applicator. Reuse may lead to immunological response and/or infection due to cross contamination, improper storage and/or handling.
- Ostevoke Bone Graft has not been studied in combination with other agents.
- Ostevoke Bone Graft has not been evaluated in skeletally immature or pregnant cases.
- No studies have been performed in dogs with known autoimmune disease, metabolic bone diseases, or in presence of malignancies.
- The safety and effectiveness of Ostevoke Bone Graft in cases with hepatic or renal impairment has not been established.
- As with any implanted material, foreign body reactions may occur with Ostevoke Bone Graft.
- While not specifically observed in the clinical study, the potential for ectopic, heterotopic or undesirable exuberant bone formation exists.
- Excessive bone and fluid filled cysts remodel into normal bone over time. Biomechanical data suggest these voids had little influence on the biomechanical properties of the induced bone or its integration with the abutting cortices.
- In cases that receiving concentrations or amounts greater than those recommended, treatment of adverse effects, where required, should be symptomatic.

ADVERSE EVENTS:

No device-related adverse reactions were reported in clinical studies. Although not necessarily attributable to the use of Ostevoke Bone Graft, the following adverse events have been reported in the postmarketed phase following the use of similar product that is intended for the treatment of bone fractures:

- Very common (more than 1 in 10 animals): mild to moderate
  lameness, firm swelling within the first 3 weeks postoperatively which recedes gradually over several months, soft swelling which recedes within 3 weeks.
- Common (more than 1 but less than 10 animals in 100 animals): mild to moderate
  seroma, excessive licking of incision area, joint stiffness, local swelling, skin ulcer, incisional discharge, incisional dehiscence, soft swelling generally resolved by week 6 postoperatively.
- Uncommon (more than 1 but less than 10 animals in 1000 animals): mild to moderate
  exuberant bony callus associated with persistent (>10 weeks) moderate soft tissue swelling and excessive licking of the incision area.
- Severe
  lameness.

PACKAGE SUPPLIED:

Ostevoke Bone Graft is supplied sterile and contain in 1ml syringe. The exterior of the package and outer contents are not sterile. Self-adhesive labels are provided for documentation purposes. The labels identify the product and production lot.

STORAGE CONDITIONS:

Store at -20 °C (-4 °F)

DOSAGE AND ADMINISTRATION:

- It's recommended that only a single Ostevoke Bone Graft kit should be used for each surgical site, the response to the use of more than one kit is unknown.
- If the bone healing does not progress properly based on the experience of veterinarian, an additional injection could be arranged one month after the first implantation.

PRE-PROCEDURE:

- Ostevoke Bone Graft is to be used by veterinarian only.
- Ostevoke Bone Graft is for single use only. Do not reuse/re-sterilize.
- Use Ostevoke Bone Graft according to the instructions for use.
- Risk is inherent in the use of all medical devices. To minimize residual risk associated with the use of this device, it is recommended that the information for use be read by the veterinarian and discussed with the owner prior to use of the device.
- Animal known to have a history of hypersensitivity to Ostevoke Bone Graft or its components should not be treated with Ostevoke Bone Graft.
- Ostevoke Bone Graft are stable for 24hr when stored at room temperature. Please discard the product that stay at room temperature longer than 24hr.
- Avoid freeze-thaw cycles of Ostevoke Bone Graft.

DIRECTIONS FOR USE:

USE IN SURGERY	USE IN **CLINIC**
1. Thaw the Ostevoke Bone Graft at 20-25° C (68-77 ° F) for at least 30 minutes before use. Please leave the syringe in the package while thawing.	1. Before use, thaw the Ostevoke Bone Graft at 2-8°C (35.6-46.4°F) for at least 2hrs or at 20-25°C (68-77 °F) for 20 minutes. Please leave the syringe in the package while thawing.
2. Check the indicator on the product package. A color change of the indicator from yellow toward red confirms that the product has been sterilized. Do not use if indicator didn't show red.	2. After thawing, please use it **immediately** or keep it at 2-8°C (35.6-46.4°F). Do not use the thawing Ostevoke Bone Graft (2-8°C (35.6-46.4°F)) after 3 days.
3. Remove the syringe containing the Ostevoke Bone Graft from package.	3. Check the indicator on the product package. A color change of the indicator from yellow toward red confirms that the product has been sterilized. Do not use if indicator didn't show red.
4. Inspect syringe for any damage. Do not use if damaged.	4. Remove the syringe containing the Ostevoke Bone Graft from package.
5. Remove the cap at the tip of the syringe and assemble with the appropriate size of needle that fits for the intended way of use.	5. Inspect syringe for any damage. Do not use if damaged.
6. It can be applied directly onto the bone fracture site or mixed with other bone substitute followed by implantation.	6. Remove the cap at the tip of the syringe, assemble with the appropriate size of needle which fits for the intended way of use.
7. After use, discard syringe and any remaining gel. The used Ostevoke Bone Graft device may be a biohazard. Follow national, local, or institutional guidelines for disposal of biohazard material.	7. Use ultrasound or X-ray to locate bone fracture site.
8. Conclude the procedure according to the standard technique of the surgeon.	8. Inject Ostevoke Bone Graft directly into the fracture site.
	9. After use, discard syringe and any remaining gel. The used Ostevoke Bone Graft device may be a biohazard. Follow national, local, or institutional guidelines for disposal of biohazard material.

CONTENTS:

1 - Syringe 1m

For further information, please contact Expercy Medical Ltd. (info@expercy.com)
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Manufactured by Industrial Technology Research Institute - Biomaterial Products Plant

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