Fortera®

Fortifying Osteoconductive Biocement

INSTRUCTIONS FOR USE

DESCRIPTION

Fortera® is a biocompatible calcium phosphate cement which is combined with a setting solution to form a moldable putty/paste that sets in the body to form a composite. It is supplied sterile in single use kits having volumes appropriate to the surgical site.

INDICATIONS FOR USE

Fortera is a moldable, self-setting, gradually resorbable, calcium phosphate bone void filler. Fortera is indicated for use to fill bony voids or defects of the skeletal system (i.e., extremities, pelvis) that may be surgically created or osseous defects created from traumatic injury to the bone and only for bony voids or defects that are not intrinsic to the stability of the bony structure. Fortera may be manually applied to the bony defect or applied to the defect through a cannula. Fortera is gradually resorbed and remodeled by the body as new bone formation occurs during the healing process.

PRODUCT STORAGE

Store Fortera at controlled room temperature between 15 and 25°C (59 to 77°F). The expiration date is printed on the outer package label and on the outer tray label. Do not use expired product.

STERILIZATION

Fortera is supplied sterile and non-pyrogenic. Fortera is sterilized by gamma radiation to a Sterility Assurance Level (SAL) of 10^{-6}. Contents are sterile unless the sterile barrier has been compromised. Do not use if the package is open or damaged.

IMPORTANT INFORMATION

Read and understand all the information in these instructions. If you have any questions, contact Vivorté® Customer Service in the USA at +1 (502) 714-7234.

WARNINGS AND PRECAUTIONS

GENERAL

Fortera is a single use device. Do not attempt to re-sterilize. Discard any unused material. Do not expose to temperatures greater than 122°F (50°C). Exposure to excessive humidity prior to mixing may compromise results.

PRE-OPERATIVE

Fortera should be used only by trained and skilled healthcare professionals familiar with the use of bone void fillers.

- Not intended for use for stress or weight bearing applications.
- Not intended for use in vertebroplasty or kyphoplasty, or similar load bearing indications.
- Not intended for use in open fractures.
- Adequate fixation should be provided for unstable defects by other means.

The safety and effectiveness of Fortera is not known:

- In patients who have undergone or who are to undergo radiation therapy at or near the implant site.
- When combining the device with other implantable biomaterials, autograft, or other legally marketed medical devices for similar indications.
- In defects that would result in intradural placement.
- In patients with delayed or non-unions.

The safety and effectiveness of Fortera on patients with the following conditions or diseases is not known:

- Documented renal disease.
- Altered calcium metabolism.
- Metabolic bone disease.
- Pregnancy/nursing.
- Defects due to disease or congenital malformation.
- Cardiovascular disease precluding elective surgery.
- Infection during the last three months and/or a history of chronic infection.

INTRAOPERATIVE

- Aseptic handling techniques are required during all phases of device handling. The device should be implanted only in a sterile field.
- The device should be prepared using the specified setting solution only. The effect of preparing the device for implantation with other substances, including antibiotics and blood, is not known and may affect device performance.
- Care should be taken when handling and mixing the powder in the bowl. Losing powder could cause an overly wet cement mixture that may exhibit undesirable handling and setting characteristics.
- Dispense the entire setting solution from the dispensing container into the powder; caution should be taken when dispensing so as to not lose liquid. Not dispensing all liquid solution into the powder could cause a dry mixture that may exhibit undesirable handling and setting characteristics.
- Mix materials into a consistent, homogeneous paste prior to implantation, strictly avoiding implantation of unmixed or dry cement particles.
- The spatula is intended for mixing device components only.
- Fortera is capable of flowing through a 16 gauge cannula. Fortera should only be used with delivery systems that have been validated for use with the device.
- Care should be taken if irrigating the defect site to keep clean; over irrigating could cause the cement to washout or lose dimensional stability during the setting period.
- Avoid extended working time outside of the defect site as setting of the cement could impact shaping or filling of defect.
- Care should be taken to not disrupt the cement setting and stability of the implant. Do not manipulate surgical site during intraoperative set time. The cement should be allowed to set at the defect site before wound closure.
- Care should be taken to contain the device in the intended treatment area. Do not overfill. Excess material should be removed prior to initiation of cement setting.
- The effect of layering Fortera is not known. Placement over non-vascularized tissue is not recommended.
- The safety and efficacy of using Fortera in conjunction with reinforcement metal mesh or implants is not known.
- Care should be taken to avoid over pressurizing the device. This may lead to extrusion of the device beyond the site of its intended application and damage to the surrounding tissues. Or may lead to fat embolization or embolization of the device material into the bloodstream.

POST OPERATIVE

Successful results may not be achieved in every surgical case. If additional surgery is required, the device should be re-evaluated and possibly removed and the surrounding bone re-evaluated to ensure that it is still viable and treated appropriately.

CONTRAINDICATIONS

Fortera is not designed or sold for any use except as indicated. Do not use Fortera in the presence of any contraindication. These conditions include but are not limited to:

- Use in a currently infected field or surgical site near an infection.
- Use in patients with acute traumatic injuries with open wounds near the defect that are likely to become infected.
- Use in areas where surrounding bone is non-viable or is incapable of supporting or anchoring Fortera.
- Use in patients with abnormal calcium metabolism, metabolic bone disease, a recent untreated infection, immunologic abnormalities, inflammatory bone disease, and/or systemic disorders which result in poor wound healing or which result in tissue deterioration over the implant site.
- Use in patients who have not reached skeletal maturity.
- Use in vertebroplasty or kyphoplasty procedures.
- Use in patients with fractures or voids that violate the intra-articular space.

POSSIBLE COMPLICATIONS

The occurrence of complications is possible occasionally and may require reoperation and/or removal of the implant. Complications may include but are not limited to:

- Tissue thinning over implant site.
- Tenderness, redness, swelling and/or edema.
- Seroma and/or hematoma.
- Acute or late infection.
- Loss of contour of the operated area.
- Pain at the operative site.
- Swelling, fluid collection.
- Neurovascular injuries due to surgical trauma.
- Implant fracture and/or migration requiring further surgery.
- Bone formation outside the defect site.
- Lack of healing or delayed healing of the bone or surrounding tissue.

Please report any unanticipated or adverse events related to the device to Vivorté, Inc. at +1 (502) 714-7234.

TRACEABILITY

Affix the patient labels provided inside the product carton to the patient record.

RISK FACTORS

The following risk factors may result in poor results in the treatment of bone defects with Fortera:

- Patient refusal to modify physical activities that can detrimentally affect healing or strenuous physical activities.
- Medical disabilities which can lead to an unnatural gait and/or loading of the affected bone.
- Muscular deficiencies.
- Local or disseminated neoplastic disease.
- Drug therapies and/or systemic or metabolic diseases that adversely affect bone healing, bone quality, or resistance to infection.
- Drug use or alcoholism.
- History of infections.
- Marked osteoporosis or osteomalacia.
- Severe deformity leading to impaired defect filler anchorage or improper positioning of the bone void filler.

RETURNS

Contact the Vivorté customer service facility where the product was shipped. All returns require a returned material authorization (RMA) number. Open products cannot be returned for credit.

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician.

WARRANTY

Suitability of the use of this medical device for any surgical procedure shall be determined by the health care provider. Vivorté shall not be liable for incidental or consequential damages of any kind.

DIRECTIONS

Fortera is optimized for use at an ambient temperature of 18-25° C. Multiple Fortera devices may be implanted.

1. Peel the Tyvek® lid from the outer tray and transfer the inner trays to a sterile field.

2. Prior to placing the paste, control active bleeding at the implant site. Suction, cautery, bone wax, and gel foam may be used.

3. Carefully dispense all of the setting liquid from the dispensing tube into the mixing bowl with the calcium phosphate (CaP) powder. Care should be taken to not dispense too quickly and cause powder to blow out of the bowl. Use of any other liquids, not provided within the product kit, to wet the powder may adversely affect the device's properties.

4. Mix the liquid and calcium phosphate mixture thoroughly using the provided mixing spatula while ensuring an even distribution of liquid until a consistent paste is formed. Continue to mix for 1 minute. Do not under-mix.

5. Once the paste is formed, it is now moldable and can be transferred into the defect. Prior to placing the paste, care should be taken to control active bleeding at the implant site.

6. If delivery through a cannula is desired, the paste should first be placed in the 14ml barrel provided. The barrel should be filled while the piston is retracted. After the barrel has been filled, remove and discard the clear sleeve on the cannula. Attach the screw-on cannula tip provided. Empty contents of the 14ml barrel through the cannula with the barrel's piston. Once the barrel's piston stops, the usable implant has been delivered. The amount of material delivered in this manner is consistent with product kit size labeling. Any material remaining in the barrel and cannula of the delivery system should be discarded and not implanted. Use of material remaining in the barrel or cannula may adversely affect the device's properties. Use of any other delivery system with Fortera may adversely affect the device's properties.

7. Timing is important. Depending on room temperature, the cement begins to set starting at 7 minutes after the setting solution is added to the powder in the mixing bowl. All the material must be transferred to the defect site before hardening commences. Any additional handling, molding or sculpting of the cement material after this time may impair proper setting.

8. Material will set between 7 minutes and 15 minutes after initial mixing. Do not manipulate surgical site during intraoperative set time. Complete setting of the material should be confirmed prior to closure of the surgical site.

Summary of Steps

Step No.	Key Steps	Total Elapsed Time	Duration Time for Step
1.	Add liquid to bowl with CaP powder	0	0
2.	Mix liquid and powder	1 min	1 min
3.	Transfer material to defect, mold and shape	1 min to 7 min	6 min
4.	Set Time	7 min to 15 min*	8 min

*Device setting times listed are based on implantation at 37°C. Lower temperatures at the implant site may increase timing.

STERILE R	Sterilized using Irradiation	LOT	Lot Number
	Warning/Caution		Date of Manufacture
	Do not use if package is damaged		Do Not Resterilize
	Consult instructions for use		Manufactured by
	Store at: 15-25°C or (59-77°F)	REF	Catalogue Number
	Single Use/ Do not Reuse/ Use only once		Non-pyrogenic
	Expiry Date		Single Sterile Barrier

Manufactured by:
Vivorté, Inc.
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Vivorté®
Performance Biologics