Instructions for Use

CoreLink
The Source for Spine™

EndOss™ Bone Graft Extender and Substitute

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INSTRUCTIONS FOR USE

EndOss™ Bone Graft Extender and Substitute

The Inner Package Contents are Sterile

For Single Patient Use on a Single Occasion Only

INDICATIONS FOR USE

EndOss™ is a resorbable bone void filler intended to fill bony gaps or voids that are not intrinsic to the stability of the bony structure. **EndOss™** is intended for use as a bone graft substitute in the skeletal system (extremities and pelvis). **EndOss™** is indicated for use as a bone graft extender in the spine when combined with bone autograft. These defects may be surgically created osseous defects, or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

DEVICE DESCRIPTION

EndOss™ includes a plastic tray containing the white granular material. The sterile container is in a single patient use clear plastic pouch. More information is available in the Composition section below.

INSTRUCTIONS FOR USE

These instructions are intended as guidelines for the use of **EndOss™** as a part of established surgical techniques. They are not intended to replace or change standard procedures for treatment of bone defects involving bone grafting and internal fixation. Procedures involving bone grafting can experience highly variable results. Factors to be considered in selecting the bone grafting material and the surgical technique to be utilized are as follows:

- Age of the patient
- Quality of the patient's bone
- Location of the defect
- Anticipated loading conditions
- Proximity of the graft to a suitable blood supply
- Ability to achieve direct apposition of the graft to viable host bone
- Presence/addition of autogenous bone or bone marrow at the graft site
- Elimination of gaps in the graft site
- Ability to suitably stabilize the graft site
- Complete coverage of the graft material to prevent migration

For best results, extreme care should be exercised to assure the correct graft material is selected for the intended application.

Product Handling Procedure

To Prepare **EndOss™**

1. Remove clear pouch from individual carton.
2. Peel open the clear plastic pouch.
3. Using sterile technique, transfer contents to a sterile field.
4. When ready for use, peel lid off of inner package thereby exposing product in remaining clear rigid plastic tray.
5. Autogenous bone, blood or saline may be mixed with product in tray. For use as a bone graft extender in the spine, **EndOss™** should be mixed 50/50 by volume with autograft.

Preoperative Preparation

Sterile technique must be maintained to minimize the risk of postoperative complications. The amount of **EndOss™** needed is based on the type of procedure and size of the defect being treated.
Radiographic evaluation of the defect site is essential to accurately assess the extent of the defect and to aid in the selection and placement of **EndOss™** and fixation devices.

Surgical Procedure Notes

EndOss™ does not possess sufficient mechanical strength to support the reduction of a graft site prior to tissue in-growth. Therefore, anatomical reduction and rigid fixation, in all planes, should be obtained independent of **EndOss™.**
For best results, **EndOss™** must fill the defect and contact as much viable bone as possible.
EndOss™ must not be used to repair bone defects where complete soft tissue coverage cannot be achieved.

Postoperative Care

Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Standard postoperative practices should be followed, particularly as applicable to defect repairs involving the use of fixation devices. The patient should be cautioned against early weight-bearing and premature ambulation which could lead to loosening and/or failure of the fixators or loss of reduction. The length of time a defect should remain in a reduced state of loading is determined by the complexity of the defect site and the overall physical condition of the patient. Hardware should not be removed until the defect is healed.

CONTRAINDICATIONS

EndOss™ is contraindicated where the device is intended as structural support in load-bearing bone and in articulating surfaces. Conditions representing relative contraindications include:

- Severe vascular or neurological disease
- Uncontrolled diabetes
- Metabolic Bone Disease (MBD)
- Patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol.
- Renal impairment
- Active or latent infection in or around the surgical site
- Sensitivity to ethyl acetate

WARNINGS AND PRECAUTIONS

EndOss™ is sterile during the stated shelf life in an unopened and undamaged package. The product must be used on or before the expiration date.
Do not use if the packaging has been damaged and/or the product has been contaminated. In the event of contamination, discard the product. Damaged packaging should be returned to CoreLink, LLC.
Device is intended for single patient use only. Retention or reuse of device could lead to a loss of sterility or subsequent increase risk of infection or cross-contamination.
Appropriate placement and/or fixation are critical factors in the avoidance of potentially adverse effects. **EndOss™** without autograft should not be used as a bone graft substitute in the spine.
As with any surgical procedure, the possibility of infection exists.
Adverse outcomes potentially attributable to the product must be reported promptly to manufacturer. If any dissatisfaction with the product performance or packaging occurs, notify CoreLink, LLC immediately and promptly return product and/or packaging.

STERILIZATION & ENDOTOXIN

EndOss™ has been sterilized by e-beam irradiation. The contents of the pouch, the inner package and its contents, are sterile. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. This product is for single use only and should not be re-sterilized. The product must not be used beyond the stated expiration date.

DO NOT RE-STERILIZE

Endotoxin levels of **EndOss™** are below the stated allowable limits for medical devices.

STORAGE

EndOss™ should be stored at 2°C – 27° C in a controlled environment.

COMPOSITION

EndOss™ is composed of white granules of poly (D,L-lactide-co-glycolide) (PLGA) and hyaluronic acid. **EndOss™** includes a Handling Agent composed of carboxymethylcellulose (CMC).

CAUTION

Federal (U.S.) Law restricts the use of this device to sale by, or on the order of, a physician.

Explanation of symbols on package labeling

	Caution, Consult Accompanying Documents
	Consult Instructions for Use
	Use by
	Sterilization: Radiation
	Store: 2°C – 27° C
	Do Not Reuse
	Reference Number
	Lot Number
	CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician.
	Manufactured by