Essential Biologics

NeoForm® MOLDABLE

Indications for Use

NeoForm Moldable is indicated for use in voids or gaps of the skeletal system, i.e., the extremities, pelvis, and posterolateral spine, that are not intrinsic to the stability of the bony structure. These osseous defects may be created surgically or from traumatic injury. The product may be used alone in the extremities and pelvis but must be mixed with autograft when used in the posterolateral spine. NeoForm Moldable resorbs and is replaced with bone during the healing process.

Product Description

NeoForm Moldable collagen enhanced bone graft substitute is a moldable, resorbable osteoconductive bone graft substitute composed of 1-2mm NeoCor™ granules suspended in a biocompatible organic binder to facilitate shaping and containment of the implant.

The NeoCor granules in NeoForm Moldable are approximately 65% porous, biphasic calcium salts with interconnected pores having a nominal cross-section of 500 microns. The primary composition of each granule is calcium carbonate with a thin layer of calcium phosphate throughout its entire porosity.

The organic binder in NeoForm Moldable is a combination of a biocompatible polymer and Type I collagen fibers. The polymer is rapidly absorbed in-situ, leaving behind NeoCor granules and collagen fibers as an osteoconductive scaffold. The collagen in NeoForm Moldable provides a site for cell attachment, migration, proliferation, and differentiation.

After NeoForm Moldable is implanted next to viable bone and stabilized, connective tissue and bone grow into the porosity. The calcium carbonate and calcium phosphate components are biocompatible, osteoconductive, resorbable and radiographically dense. Within months, osteoclasts resorb the calcium phosphate layer, exposing the more rapidly resorbable calcium carbonate, increasing the bone density and decreasing the radio-density of the scaffold.

Contraindications

NeoForm Moldable is not designed or sold for any use except as indicated.

NeoForm Moldable is contraindicated as structural support in the skeletal system. Other conditions representing relative contraindication include:

- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative disease
- Uncooperative patients who cannot or will not follow post-operative instructions, including individuals who abuse drugs and/or alcohol
- Hypercalcemia, abnormal calcium metabolism
- Existing acute or chronic infection, especially in the site of the operation
- Inflammatory bone disease such as osteomyelitis
- Malignant tumors
- Severely impaired renal function

Precautions

NeoForm Moldable is not intended for use as a primary load-bearing implant. It is important to ensure that the area where the product has been implanted is biomechanically stable. Do not modify the size or shape of the granules. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration. Once removed from its packaging, NeoForm Moldable can become dry and crumbly when exposure time exceeds three hours.

The effect of NeoForm Moldable on patients with the following conditions is unknown:

- Documented renal disease
- Metabolic bone disease
- Pregnancy and nursing
- Radiation bone therapy
- Long-term infection
- Cardiovascular disease

The effect of NeoForm Moldable in pediatric patients is unknown.

The effect of mixing NeoForm Moldable with other substances (e.g., antibiotics or serum) is unknown.

Adverse Reactions

The following complications have been reported to result from bone grafting procedures and are considered to be potential complications for NeoForm Moldable: superficial wound infection, deep wound infection, delayed union, malunion, loss of reduction, refracture, cyst recurrence, hematoma, and cellulitis.

Warnings

- The content of the package is sterile unless opened or damaged. Read the expiration date before use. Do not use if the expiration date has passed.
- The dose is SINGLE USE ONLY. Do not attempt to re-sterilize or re-use.
- NeoCor granules are relatively opaque to x-rays. This effect may radiographically mask superimposed bony structures.

Administration

These instructions are intended as guidelines for the use of NeoForm Moldable 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.

1. Open outer (non-sterile) and inner pouches (sterile) to remove the syringe.
2. Remove cap from syringe and extrude contents.
3. Shape implant by hand as needed. When used in posterolateral spinal fusion procedures, mix thoroughly with morselized autograft in a 1:1 mix ratio.
4. Implant the device and secure the surgical site to prevent micro-motion and implant migration. When excess fluid is present in the surgical field, the surgeon may use cauterization, suction, and application of bone wax (if needed) to reduce bleeding. If the material is not positioned satisfactorily, remove the implant and start over with a new package of NeoForm Moldable.

Storage

NeoForm Moldable should be stored out of direct sunlight, between 40-90° F (5-32° C).

Caution

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

Manufactured for:

Essential Biologics, Inc.
Moorpark, CA 93021
www.EssentialBiologics.com

Explanation of Symbols Utilized

Use By Date YYYY-MM-DD	Do Not Use if Package is Damaged
Consult Instructions for Use	Store out of direct sunlight
Do Not Re-use	Store between 40°F - 90°F
Sterilized Using Irradiation	Caution, Consult Accompanying Documents
Lot Number	Non-Pyrogenic
Do Not Re-sterilize	Caution, Prescription Device
Manufacturer	