Alphatec Neocore™
Osteoconductive Matrix

Package Insert

Alphatec Neocore™ Osteoconductive Matrix

Prior to using this system, read this package insert in its entirety. These instructions are intended to provide important information for system usage.

Attention: Product is provided sterile. Do not use if the package is opened, damaged, or the expiration date on the package label has passed.

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

Description
Alphatec Neocore Osteoconductive Matrix (Neocore) is a resorbable bone void filler made from a matrix of highly purified collagen (ASTM F2212) that has high porosity beta tricalcium phosphate (TCP) granules (ASTM F1088) dispersed throughout. The implant is provided as sterile, non-pyrogenic, and for single use in double peel packages.

Indications for Use
Neocore is intended for use as a bone void filler to fill voids or gaps of the skeletal system not intrinsic to the stability of the bony structure (extremities, pelvis, posterior lateral spine). Neocore is also indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. Neocore must be wetted with bone marrow aspirate or, when used in the posterolateral spine, autologous bone must also be added (50/50 ratio by volume). Following placement in the bony void or gap (defect), Neocore is resorbed and replaced with bone during the healing process.

Contraindications
Use of Neocore is contraindicated in the presence of any of the following:
- Growth plate fractures
- Segmental defects
- Conditions where the surgical site may be subjected to excessive impact or stresses, including those beyond the load strength of fixation hardware
- Significant vascular impairment proximal to the graft site
- Metabolic or systemic bone disorders that affect bone or wound healing
- Infected sites
- Osteomyelitis at the graft site
- Defect site stabilization is not possible
- Intraoperative soft tissue coverage is not planned or possible
- Direct contact with the articular space
- Large defects that in the surgeon's opinion would fail to heal spontaneously
- Conditions in which general bone grafting is not advisable

Neocore should not be used in patients with known history of hypersensitivity to bovine derived materials.

Warnings
- Do not use if package is opened or damaged, or if expiration date has passed as this may indicate that product has become non-sterile
- Do not re-use or re-sterilize remnants of the device as the mechanical properties or performance cannot be guaranteed
- Do not use in infected sites
- The device does not possess sufficient mechanical strength to support reduction of a defect site. Rigid fixation techniques are recommended as needed to assure stabilization of the defect in all planes. The device cannot be used to obtain purchase for screws; purchase must be gained in the host bone.
- Complete postoperative wound closure is essential. Do not use the device to repair bone defects where soft tissue coverage cannot be achieved.

Precautions
- Neocore should only be used by licensed physicians trained in the use of bone graft substitutes
- Do not implant the device in a patient with a pre-existing calcium metabolic disorder (e.g. hypercalcemia)
- The device should not be used in applications other than those indicated and is not indicated to be used in immediate load bearing applications. Do not use in patients with systemic disorders resulting in poor wound healing
- If cutting the device to size, ensure surfaces are smooth and free from excessive loose particles
- Do not over-fill the defect site
- Do not use in a site during or after irradiation
- Do not use in the presence of acute or chronic inflammation
- Do not use in infected or compromised tissue sites
- Do not use where mucosal and bone healing are impaired
- Do not use in immunosuppressed patients
- Do not use in patients on medication inhibiting healing processes
- Do not leave the defect open
- Radiopacity of the device is comparable to that of bone and diminishes as it is resorbed; this may mask underlying pathological conditions and should be considered when evaluating x- rays
- Safety in pregnancy and pediatrics has not been established
- Devices are for single use only and must not be reused under any circumstances.

Potential Adverse Effects
Possible adverse reactions are similar to those for other bone void filler devices and include, but are not limited to: superficial would infection, deep wound infection, deep wound infection with osteomyelitis, adverse tissue reaction, transient hypercalcemia, nonunion, wound dehiscence, delayed union, malunion (including incomplete bone formation or lack of bone formation), loss of reduction, refracture (and fracture of newly formed bone), fracture of the bone void filler with or without particulate formation, cyst recurrence, hematoma, cellulitis, and device migration or extrusion. Immunological reactions consisting of transient localized edema, swelling, and rash have been reported to occur with bone void fillers containing collagen. The manufacturer is not aware of any evidence that the device will be unsafe or ineffective in such patients; the safety and effectiveness of the device in these patients has not been established. Occurrence of one or more of these conditions may require an additional surgical procedure and may also require removal of the bone void filler.

Storage

Store at Ambient Temperature (15-30°C). Avoid excessive heat or humidity. Do not refrigerate or freeze.

Directions for Use

Prior to using Neocore, the surgeon should evaluate radiographs of the bony defect to assess the extent of the defect. This assessment should be used to guide the surgeon in his or her selection and placement of the bone void filler and fixation devices. Rinse surgical gloves to remove any glove powder prior to handling the device.

Neocore may be used in its given form or cut to a desirable size with a scalpel or scissors at the time of use. After cutting, insert the material into the surgical site. Smaller pieces that have been cut from the scaffold may be used to fill in irregularly shaped voids in the site. Neocore is to be wetted with bone marrow aspirate until the graft material becomes saturated.To maximize bone formation the device should fill the defect and be in contact with as much viable host bone as possible.

To prevent collapse and deformity secondary to functional loading, the implant site should be sufficiently stabilized by adequate fixation. To ensure that the graft is not supporting load, anatomical reduction and rigid fixation in all planes must be obtained.

As with other bone defect repairs, typical postoperative patient management should follow along with the use of fixation devices.

Symbol Translation

REF Catalog Number

LOT Lot Number (Batch Code)

Use By

Manufacturer

Do Not Reuse

Consult Instructions for Use

STERILE R Sterilization by Irradiation

Rx only Caution: Federal law restricts this device to sale by or on the order of a licensed physician

Caution, consult documents

Not to be used in case package is damaged

Do not resterilize

15°C 30°C Store at Ambient Temperature (15°C - 30°C). Avoid excessive heat or humidity. Do not refrigerate or freeze

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