OssDsign® Catalyst

SPINAL/ORTHOPEDIC APPLICATIONS

For USA Audiences only

Caution: Federal law (USA) restricts this device to sale, distribution and use by or on the order of a physician.

BONE GRAFT SUBSTITUTE INSTRUCTIONS FOR USE.
PLEASE READ BEFORE USE.
CONTAINS IMPORTANT PRODUCT INFORMATION.

PRODUCT DESCRIPTION

OssDsign Catalyst is an osteoconductive, resorbable, porous, 100 % nanosynthetic calcium phosphate bone void filler. OssDsign Catalyst contains 5.8 wt% silicon substituted calcium phosphate granules suspended in a resorbable polymer gel. The aqueous polymer gel phase binds the highly porous granules into a moldable, pliable formulation which enables OssDsign Catalyst to be used without any further gelation, mixing of components or graft setting time. OssDsign Catalyst is supplied sterile and can be combined with autograft for use as a bone graft extender. The high surface area porous granules have been designed to deliver consistent and rapid bone ingrowth, remodeling and cell-mediated resorption during the bone healing process.

INDICATIONS FOR USE

OssDsign Catalyst is indicated for filling bone voids or defects of the skeletal system (i.e., the posterolateral spine, intervertebral disc space, extremities and pelvis) that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or as a result of traumatic injury to the bone. OssDsign Catalyst is a bone graft putty that is resorbed and replaced with bone during the healing process. OssDsign Catalyst must be used with morselized autograft bone at a ratio of 1:1 by volume in the posterolateral spine. When used in intervertebral body fusion procedures, OssDsign Catalyst must be used with morselized autograft bone at a ratio of 1:1 by volume with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

CONTRAINDICATIONS

OssDsign Catalyst is not designed or sold for any use except as indicated. OssDsign Catalyst is contraindicated for the following:

- defects where primary mechanical stabilization is not possible.
- segmental defects without supporting instrumentation.
- when there is significant vascular impairment proximal to the graft site.
- when there are metabolic or systemic bone disorders that affect bone or wound healing.
- where there are serious metabolic diseases.
- use in infected sites.
- use in patients with osteomyelitis at the operative site.
- conditions in which general bone grafting is not advisable.
- situations where intraoperative soft tissue coverage is not planned or possible.
- patients whose lifestyle compliance and/or physical attributes could, in the opinion of the treating surgeon, compromise the clinical outcome of the surgery.
- pediatric or skeletally immature patients.
- hypercalcemia.
- severe vascular or neurologic disease.

WARNINGS

OssDsign Catalyst is intended for use by qualified surgeons familiar with bone grafting and rigid fixation techniques. OssDsign Catalyst does not possess sufficient mechanical strength to support reduction of a defect site prior to soft and hard tissue ingrowth. Rigid fixation techniques are recommended as needed to assure rigid stabilization of the defect in all planes. Complete postoperative wound closure is essential. OssDsign Catalyst does not set in situ following implantation. Caution must be exercised when treating individuals with bleeding diathesis of any etiology. Use of Nonsteroidal Anti-inflammatory (NSAIDS) medications may delay graft healing. Use of alternate means of pain control should be considered whenever possible.
Potential complications of surgery include wound infection, reaction to medications or anesthesia, pain, thromboembolism, cardiac or pulmonary complications and blood loss. OssDsign Catalyst should not be used to treat patients who are pregnant or nursing. Potential postoperative risks include, but are not limited to; hematoma, urinary retention, thrombophlebitis and continued pain. All patients will be exposed to the same risks associated with any bone grafting procedure such as fracture, migration, infection, resorption or rejection of the graft, delayed union, nonunion, or pseudoarthrosis. These complications may require re-grafting or revision.

PRECAUTIONS

- Do not use after expiration date printed on the label.
- Do not re-sterilize.
- FOR SINGLE USE ONLY: OssDsign Catalyst is designed for single use only and should only be removed from the packaging material immediately prior to use. Do not reuse device. Excess material opened, but unused must be discarded.
- Store in a clean, dry area at a temperature between 5°C (41°F) and 40°C (104°F).
- The delivery syringe containing the OssDsign Catalyst is not intended to be patient-contacting. Refer to the Directions for Use section below.
- The graft must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained.
- Completely fill the bony defect, ensuring maximal contact between OssDsign Catalyst and the host bone.
- Do not overfill the bony voids or gaps with the OssDsign Catalyst product, as this may lead to extrusion of the product beyond the site of its intended application and damage to the surrounding tissues.
- Remove any excess material before closure.
- Altered characteristics from not handling according to these instructions may lead to failure. An example of improper handling is mixing OssDsign Catalyst with anything other than autograft bone.

ADVERSE EVENTS

Potential adverse events that may occur relative to the placement of bone void fillers include:

- Revisions and/or removals.
- Superficial wound or deep wound infection.
- Pain/discomfort, swelling, redness, fever, inflammation.
- Fluid accumulation.
- Delayed or nonunion, lack of osseointegration, inadequate bone formation.
- Protrusion, dislodgement, migration, or extravasation (leakage).
- Allergic/immune response.
- Hematoma.
- Cyst.

STERILIZATION

OssDsign Catalyst is provided STERILE and ready to use unless the package has been opened or damaged. Do not use if the packaging has been opened or damaged. OssDsign Catalyst has been sterilized by gamma irradiation.

DIRECTIONS FOR USE

OssDsign Catalyst packaging should be inspected prior to use to ensure it is not damaged.

1. Determine the volume of the bone defect or the volume of graft required for the surgical procedure.
2. Determine if the volume of OssDsign Catalyst will be augmented with local or iliac crest harvested autograft. (For use in the posterolateral spine and intervertebral space OssDsign Catalyst must be combined with autograft).
3. Select an appropriate number of packages of OssDsign Catalyst based on product volume/size in addition to any autograft to best fill the defect providing maximum contact with the bone surface.

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4. Remove the product from the outer carton and then open the outer barrier (Tyvek - sterile barrier).
5. Transfer the inner barrier (Foil – moisture barrier) containing the delivery device to the sterile operating field.
6. Open the foil barrier and remove the syringe. Fully unscrew and remove the lid on the open bore syringe delivery device. Discard the lid.
7. Extrude OssDsign Catalyst from the syringe prior to use. The extruded putty can be molded or shaped by hand or cut to size prior to implantation. Do not attempt to extrude the OssDsign Catalyst directly into the surgical site.
8. OssDsign Catalyst must be used with autograft as a bone graft extender in the posterolateral spine and intervertebral space. Combine OssDsign Catalyst with morselized autograft bone at a ratio of 1:1 by volume.
9. Gently pack the desired amount of bone graft into the implantation site ensuring not to use excessive force as this will cause granule breakdown.
10. OssDsign Catalyst should be used in the OR in an aseptic surgical field. The bone void site should be adequately prepared to expose healthy bleeding bone to help promote future bone growth.
11. Secure filled defect with surrounding soft tissue and perform rigid fixation of bone void as needed. Optimal management of fractures or defects requires adequate alignment and stability.

ADDITIONAL LABELS

Additional labels are attached for inclusion in patient records to enable the tracking of this device.

HOW PROVIDED

OssDsign Catalyst is provided sterile in a moldable putty form. A variety of pack sizes are available (1, 2.5, 5 and 10 cc).

MANUFACTURER

Distributed by:
OssDsign USA Inc
10320 Little Patuxent Parkway
Ste 850
Columbia, MD 21044
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SYMBOLS GLOSSARY

ANSI/AAMI/ ISO 15223-1:2021 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

Symbol	Title of Symbol (Reference Number)	Description of Symbol
	Consult instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use.
	Batch Code (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue Number (5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Do not re-use (5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a procedure.
	Do not resterilize (5.2.6)	Indicates a medical device that is not to be resterilized.
	Sterilized using irradiation (5.2.4) Single sterile barrier system with protective packaging inside (5.2.13)	Indicates a medical device that has been sterilized using irradiation. Indicates a single sterile barrier system with protective packaging inside.
	Use by date (5.1.4)	Indicates the date after which the medical device is not to be used.
	Manufacturer (5.1.1)	Identifies the distributor of the medical device.
	Quantity per box	Indicates the number of medical devices per box.
	Temperature Limit (5.3.7)	Indicates the temperature limits to which the medical device can be safely exposed.
	Do not use if package is damaged (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.
	Prescription only	Caution: US Federal Law restricts this device to sale by or on the order of a physician.
	Keep dry (5.3.4)	Indicates a medical device that needs to be protected from moisture.
	Keep away from sunlight (5.3.2)	Indicates a medical device that needs protection from light sources.

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