XTANT
MEDICAL

INSTRUCTIONS FOR USE
Matriform® Si Strip

℞ only **Caution: Federal law restricts this device to sale by or on the order of a physician.**

DESCRIPTION:
Matriform® Si Strip is resorbable, osteoconductive and cancellous bone-like bone regeneration material prepared from β-tricalcium phosphate (β-TCP) and porcine collagen for filling and bridging degenerative or traumatic bone defects.

The matrix structure supports the three-dimensional regeneration of bone tissue. In contact with vital bone, the synthetic ceramic material is resorbed by the body over a period of months and is simultaneously replaced by local, autologous bone.

Matriform® Si Strip is radiopaque.

INDICATIONS FOR USE:
Matriform® Si Strip is intended to fill bony voids or gaps of the skeletal system (posterolateral spine). These osseous defects may be surgically created or from traumatic injury to the bone and are not intrinsic to the stability of the bony structure. In the posterolateral spine Matriform® Si Strip is to be mixed with autograft bone. The device resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS:
- Acute and chronic infections in the operative field (soft tissue infections; inflammatory, bacterial bone diseases; osteomyelitis). For patients receiving antibiotic therapy, it is at the user's discretion whether to employ Matriform® Si Strip based on a benefit/risk analysis.
- Severe metabolic disorders, such as severe, uncontrolled or poorly controlled diabetes
- Metabolic or systemic bone diseases which impact bone or wound healing
- Disorders of calcium metabolism
- Steroid treatment
- Drugs that interfere with calcium metabolism
- Immunosuppressive therapy
- Endocrine bone diseases
- Radiation therapy in the surgical region
- Nicotine abuse
- Use in the region of an active epiphyseal plate
- Significant vascular damage in the region of the implantation site
- Insufficient soft tissue coverage
- Direct contact with the articular cavity
- Known allergies to porcine collagen or other protein allergies

WARNING:
Matriform® Si Strip cannot assume a load-bearing function. Additional osteosynthetic measures may be required depending on the nature and localization of the bone defect to be treated.

The radiopacity of Matriform® Si Strip is similar to that of cancellous bone and decreases as resorption increases. This moderate radiopacity may mask pathological conditions.

PRECAUTIONS:
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 Matriform® Si Strip and the host bone. Do not over fill the bony voids or gaps with Matriform® Si Strip 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.

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
- Altered handling characteristics leading to failure
- Protrusion, dislodgement, migration, or extravasation (leakage)
- Allergic/immune response
- Hematoma
- Cyst

SIDE EFFECTS:
None known to date.

INTERACTIONS:
No interactions between Matriform® Si Strip and medicinal products or other medical devices have been reported to date.

METHOD OF APPLICATION:
- Matriform® Si Strip may only be used by or under the supervision of medical professionals with experience in the necessary surgical techniques and the use of biomaterials. The choice of formulation and the exact surgical procedure depend on the localization, nature, and extent of the defect.
- Before implanting the bone regeneration material, bone remnants, connective and necrotic tissue must be carefully removed. Matriform® Si Strip requires direct contact with bleeding vital bone and thorough debridement of the bone is essential before implantation.
- Matriform® Si Strip can be cut to the required size with a scalpel or scissors if necessary.
  Matriform® Si Strip must be hydrated with sterile saline before implantation.
- Matriform® Si Strip must be used with autograft as a bone graft extender in the posterolateral spine. Combine Matriform® Si Strip with morselized autograft bone at a ratio of 1:1 by volume.

Matriform® Si Strip is characterized by high density and high elasticity. Due to this elasticity, the product regains its original shape after deformation.

SHELF LIFE AND STORAGE:
Matriform® Si Strip is intended for single use only, packaged gamma-sterilized, and must not be re-sterilized. Leftover material and opened, unused material must be discarded. The product must not be used if the sterile pack is visibly damaged.
Matriform® Si Strip should be kept in the outer carton in a dry place at room temperature and should not be used after the expiry date.

INQUIRIES:
For additional information, to place an order or to report complaint, contact Xtant Medical. If for any reason the graft must be returned, a return authorization is required from Xtant Medical prior to shipping.
Tel: (888) 886-9354, Email: CS@xtantmedical.com

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SYMBOLS LEGEND:

Symbol	Title of Symbol (Reference Number)	Meaning of Symbol
	Use-by date (5.1.4)	Indicates the date after which the medical device is not to be used.
LOT	Batch code (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	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 single procedure.
	Do not resterilize (5.2.6)	Indicates a medical device that is not to be resterilized.
STERILE R	Sterilized using irradiation (5.2.4)	Indicates a medical device that has been sterilized using irradiation.
	Consult instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use.
	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.
	Manufacturing date (5.1.3.)	Indicates the date on which the medical device was manufactured.
℞ only	n.a.	Prescription use only: US Federal law restricts this device to sale by or on the order of a physician.
HIBC	n.a.	QR-Code (Barcode), for the identification and traceability of a medical device.

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