StarDerm | 9-12

Resorbable Collagen Membrane

INSTRUCTIONS FOR USE

Intended Use:
StarDerm 9-12 Resorbable Collagen Membrane is intended for use in oral surgical procedures as a resorbable material for use in augmentation around implants placed in immediate extraction sockets; delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects; guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.

Description:
StarDerm 9-12 is a white, nonfriable membrane matrix engineered from highly purified porcine dermis. *StarDerm 9-12* is resorbable which eliminates the need for a second surgical procedure that is normally required to remove a non-resorbable membrane. *StarDerm 9-12* products are sterile, non-pyrogenic, and for single use only.

Administration:
StarDerm 9-12 is packaged in a double sterile pouch. The outer pouch should be opened carefully, allowing the inner pouch to be placed onto a sterile field. The membrane should be removed from the inner pouch with sterile gloves or instruments.

The bone defect is exposed by a mucoperiosteal flap and basic surgical procedures are performed (e.g. curettage). The space-making material such as autologous bone, demineralized bone matrix and ceramic materials may be used to fill the defect.

StarDerm 9-12 can be placed either dry or hydrated. If the clinician prefers the handling characteristics of the hydrated collagen, the membrane can be hydrated in sterile water or saline solution for approximately five minutes prior to the final placement.

StarDerm 9-12 can be trimmed to the size and shape of the defect in the dry or wet state using sharp, sterile scissors.

StarDerm 9-12 should overlap the walls of the defect by at least 2 mm to allow complete bone contact and to prevent gingival connective tissue invasion below the material.

Fixation of the membrane may be indicated to avoid displacement due to loading or mobilization. The membrane can be sutured in place using absorbable sutures and a non-cutting needle. Resorbable tacks can also be used to affix the membrane. The mucoperiosteal flap is sutured over the collagen membrane and the wound should be closed completely to avoid accelerated resorption due to membrane exposure. The membrane is expected to be essentially resorbed in approximately 9 to 12 months.

Post-operative Procedures:
StarDerm 9-12 is completely resorbable and should not be removed. Patients should rinse with an antimicrobial agent such as chlorhexidine gluconate (Peridex) twice daily for four weeks following surgery. Beginning 24 hours after surgery, the wound site may be additionally swabbed with a cotton-tipped applicator dipped in the antimicrobial agent.

The patient should refrain from brushing the treated area for two weeks following the surgery. After this period, the patient may be instructed to gently brush the area with a soft toothbrush. Dental floss should not be used prior to four weeks following surgery. Coronal scaling and prophylaxis can be performed at follow-up visits, if indicated.

The patient should be seen seven to ten days following surgery for wound evaluation and removal of any closing sutures or periodontal packing. These follow-up visits should be repeated every two weeks thereafter, up to eight weeks following surgery. The patient may return to normal oral hygiene routine.

StarDerm 9-12 should be essentially resorbed in approximately 9 to 12 months following surgery. However, probing and subgingival scaling should not be performed prior to six months following surgery to prevent damage to immature tissues. Other assessments of clinical health may be repeated, including plaque, bleeding and tooth mobility indices.

Contraindications:
StarDerm 9-12 is contraindicated in patients who have:

- acute infections or contaminated wound in the oral cavity
- known allergy to collagen of animal origin or other porcine-derived products
- clinically significant renal, hepatic, cardiac, endocrine, hematologic, autoimmune or systemic disease, which in the physician's judgment, will prevent safe implantation or likely healing.

Warning:
Clinicians should use care in screening their patients for any known allergies to collagen or porcine-derived products.

Precautions:
As with all surgical procedures, caution should be exercised when treating medically compromised patients such as patients receiving long-term steroidal therapy or currently taking anticoagulants. Patients with clinically significant systemic diseases, indicating a history of anaphylactic reactions, autoimmune diseases, uncontrolled diabetes or severe hypertension have not been implanted with the membrane; therefore, the safety and effectiveness for those patients have not been determined. The membrane has not been evaluated in pregnant women, children and/or in patients with conditions involving extremely severe defects with little peridontium or bone.

StarDerm 9-12 cannot be re-sterilized or re-used. Open, unused *StarDerm 9-12* must be discarded. In vivo stability may be adversely affected if re-sterilized. Cross-contamination and infection may occur if re-used.

Do not use if the product sterilization barrier or its packaging is compromised.

Adverse Reactions:
Possible complications that can occur with any dental surgery include infection, swelling of the intraoral tissue, thermal sensitivity, gingival recession, excessive gingival bleeding, flap sloughing, resorption or ankylosis, with loss of crestal bone height, pain, or complications associated with the use of anesthesia. Minor discomfort may occur for a few days.

Storage:
The product should be stored at room temperature (15°C to 30°C). Avoid excessive heat and humidity.

How Supplied:
One (1) membrane per package:

Catalogue Number	Size
SD1520	1.5 cm x 2.0 cm
SD2030	2.0 cm x 3.0 cm
SD3040	3.0 cm x 4.0 cm

Caution: (Rx only)
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist.

Labeling Symbols:
Symbols may be used on some international package labeling for easy identification.

⚠	See instructions for use
⌛	Expiration Date
	Do not reuse after opening
LOT	Lot number
STERILE R	Method of sterilization – gamma
	Temperature Limitation
REF	Catalog Number
Rx Only	USA law restricts this device to sale by or on the order of a physician or dentist
	Manufacturer
	Do not use if the product sterilization barrier or its packaging is compromised.

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