

*Instructions for use

CE 2797

Description

The **T-Gen**(Absorbable collagen membrane) is made of pure collagen, to minimize antigenicity, which is without further cross-linking or chemical additives for excellent biocompatibility. **T-Gen** is a biodegradable collagen membrane derived from porcine pericardium certified by a veterinarian and is purified to prevent immunologic reactions. **T-Gen** has a porous and fibrous microstructure that is hydrophilic and prevents the ingrowth of fibrous tissue into the bone defect. **T-Gen** is sterilized by gamma radiation.

Intended use

T-Gen is indicated for guided tissue regeneration procedures in periodontal defects.

Procedures

1. Peel off outer and inner pouches, choose **T-Gen** to fit the wound area and trim it to fit the size of the defect.
2. **The template is a convenience item to assist in shaping T-Gen and not implantable**, which is must be discarded following modification. In order to distinguish between the membrane and the template, the template is marked with the word "TEMPLATE".
3. The wound site of patient should rinse with antimicrobial agent or sterilized saline solution. The **T-Gen** can be used regardless of front and back side.
4. The **T-Gen** can be used in dry or hydrated conditions. If the clinician prefers the handling state of the hydrated condition, the membrane can be hydrated in sterile water or sterilized saline solution for at least 3 minute prior to use.
5. Fixation of the membrane is use with glue, clip and suture.

Storage conditions

1. Store at use only between 1 and 30°C.
2. Keep away from heat.
3. Keep dry.

Expiration date

36 months from manufacture date.

Contraindications

T-Gen is derived from a porcine source and should not be used in patients with sensitive reaction to porcine materials.















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Precautions

1. Device is sterile if the package is unopened and undamaged. Do not use if the package seal is broken.
2. Do not re-sterilize. Discard all open and unused portions of **T-Gen**.
3. The device must be used prior to the expiration date.
4. Discard device if mishandling has caused possible damage or contamination.
5. Do not reuse. Sterility and function no longer guaranteed in the event of reuse. Cross contamination and infection may occur if reused.
6. **T-Gen** should not be used in the presence of infected wounds.
7. **T-Gen** should only be used by trained dentists and surgeons.
8. **T-Gen** should be used with special caution in patients with acute or chronic infection at the surgical site, uncontrolled metabolic diseases, prolonged corticosteroid therapy, autoimmune diseases, radiotherapy and heavy smoking.
9. If there are any changes in the performance of the membrane (such as infection, pain, any other unusual symptoms), clinician has the responsibility to inform the patient on all proper contraindications, side effects, and precautions. When these conditions occur, clinician should be instructed to see a well trained dental specialist immediately.

Symbols on the Label

	Authorized representative in the European Community
	CE mark and identification number of Notified Body
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged
	Caution (See instructions for use)
	Manufacturer
	Sterilized using irradiation
	Temperature limit
	Batch code
	Use-by date
	Date of manufacture
	Keep away from sunlight
	Keep dry

EC REP

Emergo Europe

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T-Gen

