

**STERIFY**

STERIFY GEL

Sterify Gel - polymer hydrogel for the treatment of periodontal disease

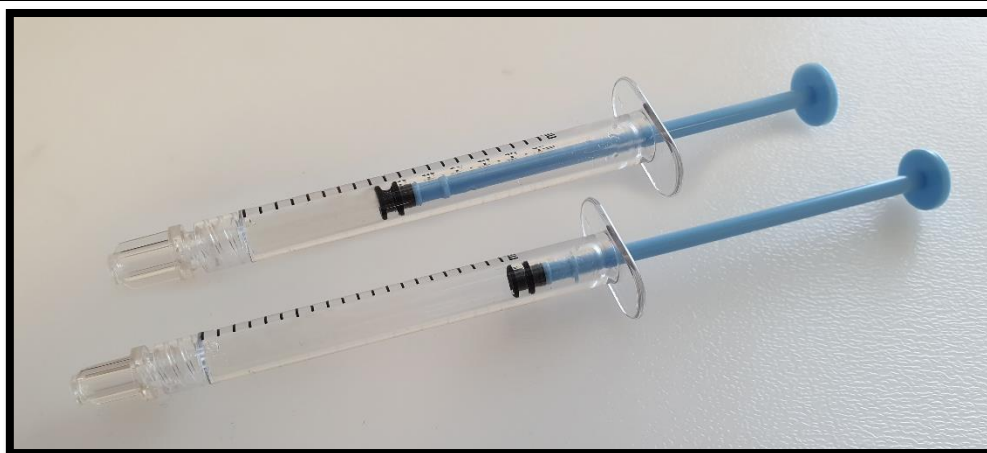


PRODUCT DATA SHEET

Rev 03
01/06/2023

INTENDED USE

Sterify Gel is a mucoadhesive polymer hydrogel in a pre-filled syringe for the treatment of periodontal disease.



MEDICAL DEVICE CLASSIFICATION

Annex VIII - MDR 2017/745	Class III, Rule 8
EMDN	P900402 - Resorbable devices for filling and reconstruction
MDS	1105 - Devices in sterile condition
RDM	Pending registration
Basic UDI-DI	80593888501W4

MANUFACTURER'S DATA

NAME AND BUSINESS NAME	Sterify S.r.l.
ADDRESS	Via Nizza, 262/1 - 10126 Torino (TO), Italy
TELEPHONE	+39 011 2173 3224
EMAIL	m.fiorini@sterify.it ; p.fattori@sterify.it
INTERNET SITE	www.sterify.it

MAIN TECHNICAL FEATURES

Pre-filled ready-to-use syringe.	
Polyvinyl polymer-based gel with high plasticity and mucoadhesivity.	
Excipients:	Nisin (preservative).
	Hydroxytyrosol (visco-modulating agent).
	Magnesium ascorbyl phosphate (gamma-protector).
Gel with occluding action of periodontal and peri-implant gingival pockets, it creates an environment unsuitable for bacterial growth and promotes subsequent tissue regeneration.	
Combined with grafts, it promotes healing of gingival mucosa and bone tissue.	
High mucoadhesive format available for periodontal and peri-implant lesions with lower containment capacity.	

STERILIZATION

Device sterilized by gamma irradiation at 25 kGy.

SHELF LIFE

The hydrogel based on polyvinyl polymers, nisin, hydroxytyrosol and magnesium ascorbyl phosphate of the Sterify line has a Shelf Life of 3 years from the date of sterilization. Shelf Life is guaranteed only if the devices are in original and undamaged packaging and stored according to the directions provided by Sterify S.r.l.

Sterify S.r.l.**Registered Office: Via Nizza, 262/1 - 10126 Torino (TO), Italy****Tel: +39 011 2173 3224 - www.sterify.it****1**

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RESORPTION TIMES

Sterify Gel is a resorbable injectable device; its degradation and resorption, in the absence of external factors contributing to its acceleration or delay, depends on the time it takes to be physically removed from the periodontal and peri-implant pockets, on average over 14 to 30 days, so that its subsequent removal at the dental office is unnecessary.

PACKING

Primary	Aluminum/Coupled Envelope (ALU/PE)
Outer packaging	Cardboard box

MAIN COMPONENTS

Polyvinyl polymers	Polyvinyl Alcohol (PVA), Polyvinyl Pyrrolidone (PVP)
Nisin	Preservative, bacteriocin
Hydroxytyrosol	Visco-modulator, anti-oxidant
Magnesium ascorbyl phosphate	Gamma-protector, stabilized vitamin C
Saline solution	Citrate buffered saline solution (CBS)

DIRECTIONS FOR STORAGE

Device should be stored in a cool, dry place at a temperature between 15° and 25°C (room temperature), avoiding exposure to direct sunlight. If stored properly and in intact packaging, the sterility of the device is guaranteed for 3 years from the date of manufacture (see expiration date on the outer label).

DIRECTIONS FOR DISPOSAL

Unused product	Dispose of as non-hazardous hospital waste according to current laws.
Product used	Dispose of as hazardous hospital waste according to current laws.
Packaging materials	The materials that make up the packaging do not require special disposal conditions.

FORMATS AND CODES

Code (REF)	Formulation	Format	Pieces
STY-GEL0301	Sterify Gel	0.3 ml	1pcs
STY-GEL0303	Sterify Gel	0.3 ml	3pcs
STY-GEL0501	Sterify Gel	0.5 ml	1pcs
STY-GEL0503	Sterify Gel	0.5 ml	3pcs
STY-GEL1001	Sterify Gel	1.0 ml	1pcs
STY-GEL1003	Sterify Gel	1.0 ml	3pcs
STY-GEL0301HM	Sterify Gel HM	0.3 ml	1pcs
STY-GEL0303HM	Sterify Gel HM	0.3 ml	3pcs
STY-GEL0501HM	Sterify Gel HM	0.5 ml	1pcs
STY-GEL0503HM	Sterify Gel HM	0.5 ml	3pcs
STY-GEL1001HM	Sterify Gel HM	1.0 ml	1pcs
STY-GEL1003HM	Sterify Gel HM	1.0 ml	3pcs

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