STERIFY GEL – INSTRUCTIONS FOR USE

INTENDED USE:

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

DESCRIPTION:

Sterify Gel is a gel intended to promote tissue healing of the gingival and alveolar wound after mechanical removal of bacterial plaque and tartar from supragingival and subgingival dental and implant surfaces. The occluding action at the level of the periodontal and peri-implant gingival pockets creates an environment unsuitable for bacterial growth and promotes subsequent tissue regeneration.

INDICATIONS:

Sterify Gel can find useful application in cases of stage III and IV periodontal disease as an adjunctive treatment following mechanical plaque removal and root smoothing operations in periodontal and peri-implant pockets (scaling and root planing). Associated with grafts, Sterify Gel promotes healing of the gingival mucosa adjacent to the treated bone defect. It is also recommended as part of the routine periodontal and peri-implant treatment program of oral surgeons, dentists or dental hygienists. Sterify Gel HM can be used in the treatment of periodontal and peri-implant lesions with less restraining capacity, including open surgery (e.g., furcation lesions).

TARGET POPULATION:

Adult population of both sexes, except as excluded in contraindications.

CONTRAINDICATIONS:

Sterify Gel should not be used in patients with established hypersensitivity to polyvinyl polymers or any of the other materials that compose the device.

POTENTIAL ADVERSE EFFECTS:

Transient pain, dental/implant discomfort, or local hypersensitivity reactions, such as gingival swelling, may appear, in which case usual oral hygiene procedures should be treated in consultation with the specialist.

USER PROFILE:

Sterify Gel should be used only by qualified health care professionals (oral surgeons, dentists, dental hygienists), following strictly aseptic procedures.

CONTEXT OF USE:

The device must be applied with an aseptic procedure, so it is used in dental and dental offices suitable for this procedure.

MATERIALS THAT COMPOSE THE DEVICE:

The composition of the device is shown in the following table:

Components	Functional description
Polyvinyl polymers (10%):	
PVA (Poly Vinyl Alcohol), PVP (Poly Vinyl Pyrrolidone)	Physical occluding action
Excipients (0.3%):	
NIS (Nisin)	Preservative
HT (Hydroxytyrosol)	Visco-modulator
MAP (Magnesium ascorbyl phosphate)	Gamma-protector
Aqueous Solution (89.7%):	
CBS (Citrate buffered saline solution)	Saline solution

AVAILABLE FORMATS:
Sterify Gel: 0.3 ml, 0.5 ml or 1 ml pre-filled syringe of polymer hydrogel, in single or multi-pack.

Sterify Gel HM (High Mucoadhesivity): 0.3 ml, 0.5 ml or 1 ml pre-filled syringe of high mucoadhesivity polymeric hydrogel, in single or multi-pack.

WARNINGS:
Sterify Gel is biocompatible, phthalates and latex free.
Hydrogel based on polyvinyl polymers, nisin, hydroxytyrosol and magnesium ascorbyl phosphate from the Sterify line has a shelf life of 3 years from the date of sterilization. The shelf life is guaranteed only if the devices are in original and undamaged packaging and stored according to the instructions provided by Sterify S.r.l.
If the package is found to be open or damaged, do not use the device but return the package to the manufacturer. Do not use Sterify Gel after the expiration date. The expiration date refers to the product in unopened packaging and properly stored.
The materials constituting the package do not require special disposal conditions.
The use of the product mixed directly with drugs (e.g., antibiotics) has not been tested.
Sterify Gel has not been tested on pregnant patients.
Any serious incidents occurring in connection with the Sterify Gel device should be reported to the manufacturer and the appropriate authorities.

The manufacturer disclaims any liability in relation to damage caused by use of the device outside its intended purpose and on patients who are not indicated for treatment.

LIMITATIONS AND ATTENTIONS:

Read the instructions carefully before use.
Sterify Gel is a Class III sterile, single-use, single-patient medical device; it can neither be reused nor resterilized. Any residual unused product should not be stored and used in other surgeries or for other patients and should be disposed of as contaminated hospital waste according to the regulations in effect at the dental office. In the event that the disposable device is mistakenly reused, in addition to affecting its performance, possible patient infections could occur due to lost sterility and/or possible contamination of the device itself. Failure to do so implies a different use than that intended by the manufacturer, which can no longer guarantee the conditions of hygiene, functionality and safety once the package has been opened.
Sterify Gel is intended for topical gingival and bone use only. Do not use systemically.

Instructions for patients:
It is recommended not to eat, rinse or gargle with mouthwash for two hours after treatment. Follow the oral hygiene instructions provided for two days after treatment and do not use interdental cleaning aids such as dental floss or pipe cleaners. Patients should be advised to continue necessary oral hygiene practices designed to control reinfection. No restrictions on eating habits are necessary.

MECHANISM OF ACTION:

Due to its specific visco-elastic and mucoadhesive properties, Sterify Gel easily penetrates into the deepest and hard-to-reach areas of periodontal and peri-implant pockets, adhering to the gingival tissue, alveolar bone or root and dental implant surfaces, providing complete coverage of the pockets. The effect of Sterify Gel is promoted by a physical mechanism of action. After scaling or root planing and biofilm removal, the gel is applied to the gingival pocket, where it acts primarily as a filler to restore volume, physically preventing bacteria from entering and reinfecting the pocket. Sterify Gel can thus mechanically protect the treated pockets and alveolar bone, promoting tissue healing.

EXPECTED CLINICAL BENEFITS:

Although scaling and root planing is considered a gold standard treatment for periodontitis and peri-implantitis, exposure of the gingival pockets can allow bacteria to recolonize the tissues promoting new inflammation that can worsen the clinical picture. Sterify Gel may find useful application in cases of stage III and IV periodontal disease as an adjunctive treatment following scaling and root planing to improve and accelerate healing parameters and prevent inflammation and recurrent infection. In addition, antimicrobial control action prevents the use of antibiotics and the risk associated with antibiotic resistance. Such control of periodontal disease also allows the retention of patients who cannot undergo surgical treatment.

The expected clinical benefits are as follows:

- Improved outcome of the nonsurgical procedure of plaque removal and root planing in stage III and IV periodontal disease in terms of increased success of the deep hygiene procedure and limitation of disease recurrence;
- Mechanical protection of the periodontal pocket to prevent bacterial recolonization after deep hygiene procedure;
- Mechanical protection of the periodontal pocket to promote healing of gingival and alveolar tissues after deep hygiene procedure;
- Reduction or elimination of surgical procedures for the treatment of stage III and IV periodontal disease, especially in the maintenance of patients who cannot undergo surgery (e.g., patients on bisphosphonate therapy, defected, etc.);
- Reduction or elimination of local and/or systemic antibiotic therapies in individuals with periodontal disease undergoing a deep hygiene procedure;
- Non-invasive treatment of periodontal pockets without the use of disinfectants that can cause staining of dental elements and mucosal irritation or hypersensitivity.

INSTRUCTIONS FOR USE:

The product is ready to use. After the mechanical instrumentation procedure on the root surface and after washing and drying the site, Sterify Gel should be applied directly inside the periodontal or peri-implant pocket, from the depth of the pocket to the gingival margin. After removing the cap, screw a sterile cannula or needle with luer lock attachment preferably with a rounded tip of a caliber appropriate for the specific use (diameter 0.6 mm or greater, not included in the sales package) to the Sterify Gel syringe. Proceed with implantation aseptically: gently press the syringe plunger so that the gel is applied to the bottom of the pocket; press until the gel emerges or becomes visible at the gingival margin. Once implanted, Sterify Gel undergoes a process of progressive imbibition upon contact with biological fluids, with gradual physical removal from the implant site and degradation over 14 to 30 days, such that its subsequent removal at the dental office is unnecessary.

The volume of Sterify Gel is sufficient for filling several pockets, so that it can be applied simultaneously in all periodontal and peri-implant pockets to be treated. If the depth of the gingival pocket is greater than 5 mm, a subsequent application of Sterify Gel after 3 months may be indicated.

PACKAGING:

Sterify Gel is supplied sterile, in copolyester (CPE) syringe with polycarbonate (PC) cap, in aluminum/coupled (ALU/PE) pouch, single. Instructions and card(s) for the patient.

The product label is placed on the outer box (final packaging case), and the outside of each sterile package contained in the box is affixed with the sterile packaging label.

STERILIZATION:

Sterify Gel is sterilized by gamma irradiation at 25 kGy.

STORAGE:

For the storage of the Sterify Gel device, a protected environment that preserves it from direct exposure to light and heat sources, clean, dry, and allows the packages to be stored in a way that prevents the degradation and contamination of the product must be ensured. To maintain sterility, it is important to store it in its original packaging at room temperature (15°C<T<25°C) and prevent damage; if stored properly, the integrity of the packaging and sterility of the device is guaranteed for 3 years from the date of manufacture.

DISPOSAL:

Any unused product residue should not be stored and used in other surgeries or for other patients, but should be disposed of as contaminated hospital waste according to the regulations in place at the dental office.

Consumable components associated with device application, such as the syringe and needle, should be disposed of.

The materials constituting the package do not require special disposal conditions.

INFORMATION PROVIDED TO PATIENTS

The device is accompanied in each package by a patient information sheet, which contains clear and easily understood basic information about the implanted device, which also allows for its identification. This information sheet is accompanied by a card that contains the main information about the device and the patient identification data.

Health care institutions must make available to the patient to whom the device has been implanted the information sheet and the implant card, to which the label containing the device traceability data is to be attached and to be filled out indicating the patient's name, date and place of surgery, before being handed over to the patient.

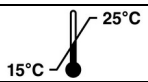
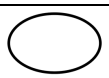
SUMMARY RELATED TO SAFETY AND CLINICAL PERFORMANCE

Sterify has prepared, in accordance with Article 32 of MDR 2017/745, a summary regarding the safety and clinical performance (SSCP) of the Sterify Gel device, which can be found on the European Eudamed database at https://ec.europa.eu/tools/eudamed, where it is linked to the product's Basic UDI-DI (80593888501W4).

PRODUCT CODES:

REF. STY-GEL0301, Sterify Gel - 0.3 ml, 1 syringe.
REF. STY-GEL0303, Sterify Gel - 0.3 ml, 3 syringes.
REF. STY-GEL0501, Sterify Gel - 0.5 ml, 1 syringe.
REF. STY-GEL0503, Sterify Gel - 0.5 ml, 3 syringes.
REF. STY-GEL1001, Sterify Gel - 1 ml, 1 syringe.
REF. STY-GEL1003, Sterify Gel - 1 ml, 3 syringes.
REF. STY-GEL0301HM, Sterify Gel HM - 0.3 ml, 1 syringe.
REF. STY-GEL0303HM, Sterify Gel HM - 0.3 ml, 3 syringes.
REF. STY-GEL0501HM, Sterify Gel HM - 0.5 ml, 1 syringe.
REF. STY-GEL0503HM, Sterify Gel HM - 0.5 ml, 3 syringes.
REF. STY-GEL1001HM, Sterify Gel HM - 1 ml, 1 syringe.
REF. STY-GEL1003HM, Sterify Gel HM - 1 ml, 3 syringes.

SYMBOLS:

	Manufacturer
	Date of manufacture
	Disposable product
	Expiration date
	Product Code
	Lot number
	Medical Device
	Do not expose to the sun
	Attention
	Refer to the operating instructions
	Gamma sterilized
	Store at room temperature (15°C<T<25°C)
	Latex-free product
	Do not use if the packaging is damaged
	Do not re-sterilize the product
	Keep dry
	CE Mark
	Sterile barrier system
	Date of implantation
	Patient Identification
	Health center or physician holding patient information
	Patient information website
	UDI as AIDC format