Sterify® Gel
Frequently Asked Questions for Professionals

PRODUCT FEATURES

What is Sterify® Gel?
Sterify® Gel is a mucoadhesive polymeric hydrogel in a pre-filled syringe for the treatment of periodontal disease.

What is its primary function?
Sterify® Gel is a gel designed 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.

What is its composition?
Sterify® Gel is a hydrogel based on polyvinyl polymers and excipients such as Nisin, Hydroxytyrosol and Magnesium Ascorbyl Phosphate (MAP, a stable form of Vitamin C), with high plasticity and mucoadhesion.

What is the function of each component of Sterify® Gel?
In addition to the citrate-buffered saline solution, which represents the aqueous saline solution, the polyvinyl polymers perform a physical occlusive action. The excipients perform different actions, and specifically: a) Nisin is a preservative,b) hydroxytyrosol has a visco-modulating action, while c) Magnesium Ascorbyl Phosphate has a gamma-protective action during the sterilization phase of the medical device.

Does Sterify® Gel contain antibiotics?
No, Sterify® Gel does not contain antibiotics and therefore does not contribute to the creation of antibiotic resistance.

Does it contain disinfectants or antiseptics?
No, Sterify® Gel does not contain disinfectants or antiseptics.

Does it contain latex?
Sterify® Gel is biocompatible, latex-free and phthalate-free.

Does it require a prescription?
No, Sterify® Gel does not require a prescription as it is a medical device and can also be applied by non-medical personnel.

DESTINATION OF USE AND APPLICATION

When is Sterify® Gel used?
Sterify® Gel is indicated for use in cases of moderate to advanced chronic periodontal disease, as an adjunctive treatment following mechanical plaque and tartar removal procedures in the scaling and root planing (SRP) of periodontal and peri-implant pockets. It is also recommended as part of the routine periodontal and peri-implant treatment program of oral surgeons, dentists, or dental hygienists.

What is its mechanism of action?
Sterify® Gel acts as an occlusive barrier. Thanks to its specific viscoelastic and mucoadhesive properties, the gel easily penetrates the deepest and hardest-to-reach areas of periodontal and peri-implant pockets, adhering to the gingival tissue,alveolar bone, or root surface and dental implant, providing complete coverage of the pockets.

How is it applied?
After SRP and biofilm removal, the gel is applied to the gingival pocket - from the depth of the pocket to its outermost portion - where it acts as a filler to restore volume, physically preventing bacteria from entering and re-infecting the pocket itself. Sterify® Gel can thus mechanically protect the treated pockets and alveolar bone, promoting tissue healing.

How many pockets can be treated with a 0.3 ml syringe?
A 0.3 ml syringe is indicated for the treatment of 2-3 periodontal pockets, considering that the average volume of crevicular fluid (a specific fluid found in the gingival sulcus) in chronic periodontitis is around 100-150 µl. Of course, a lot will depend on the depth of the pocket, so this value may vary.

Why does the package not include a needle? And what needle is compatible with the syringe?
The syringe is deliberately supplied without a needle/cannula to allow the healthcare professional the freedom to choose the needle/cannula of the shape and material they prefer. The important thing is that the needle or cannula, screwed on after removing the cap, is sterile, preferably rounded and of a gauge suitable for the specific use (gauge 23G or higher).

What is the resorption time?
Once applied, Sterify® Gel undergoes a process of gradual imbibition in contact with biological fluids, with gradual physical removal from the implant site and degradation over a period of 14-30 days, such as to make its subsequent removal at the dental office superfluous.

After a first application, is it necessary to recall and re-apply Sterify® Gel?
As with all periodontal treatments, it is always necessary to review the patient to ensure that the healing process is proceeding properly. By customizing periodontal treatments, the practitioner is therefore free to decide whether or not to reapply the product. However, considering the product's ability to remain at the treated site, the recommendation is to wait at least 30 days before reapplying Sterify® Gel. As indicated in the IFU, in the case of treatment of periodontal pockets with a depth of more than 5 mm, a subsequent application of Sterify® Gel is suggested after 3 months from the first implantation.

Is it possible to treat multiple patients with the same syringe?
No. The syringe is single-patient and single-use.

What does it mean that Sterify® Gel does not create antibiotic resistance?
The fact that it does not contain antibiotics makes Sterify® Gel widely usable without the possibility of creating resistance by periodontal pathogens and at the same time creating a broad-spectrum antibacterial protective barrier. Once the pocket has been well instrumented and the plaque, tartar and biofilm deposits have been thoroughly removed, the operator may choose to use Sterify® Gel to guide tissue healing.

Are there cases where Sterify® Gel can be used together with a systemic antibiotic administered during periodontal treatment?
It is possible to use Sterify® Gel in conjunction with a systemic antibiotic, such as during and after surgical or non-surgical periodontal treatment in fragile patients.

If so, does the combined application of systemic antibiotic and Sterify® Gel lead to any side effects?
Absolutely not.

CLINICAL BENEFITS

What is the main clinical benefit of Sterify® Gel?
Sterify® Gel promotes tissue regeneration, with a substantial and proven constant improvement in pocket depth and a reduction in bacterial contamination.

How does the tissue regeneration process occur if Sterify® Gel does not contain drugs/antibiotics?
The most difficult task after periodontal treatment is to prevent bacterial recolonization. The physical characteristics of Sterify® Gel allow for the closure of the periodontal pocket in a way that does not favor post-treatment bacterial recolonization. Sterify® Gel, by virtue of its specific formulation combined with its three-dimensional structure, does not simply seal the gingival sulcus from which recolonization can occur, but physically occupies a volume within the pocket and subsequently promotes guided healing of the periodontal tissues post-treatment.

Regarding the improvement in pocket depth, is it possible to quantify the recovery in mm?
Treatment with Sterify® Gel in combination with SRP has consistently demonstrated a significant improvement in pocket depth (PD), exceeding twice the improvement of the control group (SRP only) at all follow-up periods. In a clinical study of 34 patients, the mean change in PD from baseline was 2.06 mm at 1 month, 2.35 mm at 2 months, and 2.21 mm at 3 months in the treatment group; conversely, the mean change in PD from baseline in the control group was 1.09 mm at 1 month, 1.36 mm at 2 months, and 1.18 mm at 3 months.

Are there also expected improvements in gingival recession and Clinical Attachment Level (CAL)?
Yes. While minimal gingival recession was observed in all patients treated in the trial, patients treated with SRP only showed significantly worse worsening than those treated with Sterify® Gel at 2 and 3 months. Furthermore, in line with pocket depth and gingival recession, significant improvements were also observed in Clinical Attachment Level (CAL),with the treatment group showing greater progress than the control group.

What does it mean that Sterify® Gel contributes to the reduction of bacterial contamination?
At the beginning of the study (baseline conditions) that led Sterify® Gel to obtain MDR certification, the frequency of bacterial contamination was similar between the treatment group and the control group, with the exception of the Prevotella Intermedia bacterial strain. At the 3-month follow-up, a “negative shift” towards lower bacterial positivity was observed in the treatment group, indicating a statistically significant trend ($p < 0.05$) towards a reduction in bacterial contamination. This trend was not observed in the control group that received SRP only, where no statistically significant differences were found ($p > 0.05$).

Is it possible to access more details on the clinical benefits?
Comprehensive data, both on bacterial contamination and on the benefits on pocket depth, gingival recession, CAL,dental stability and bleeding, are available on request.

Are there any published clinical studies in scientific journals that validate these clinical benefits?
The article on the randomized controlled split-mouth clinical trial conducted on Sterify® Gel was published in the International Journal of Dentistry on January 4, 2024. Further scientific research and clinical trials are currently underway.

STERILIZATION, SHELF-LIFE AND PACKAGING

What is the sterilization method for Sterify® Gel?
Sterify® Gel is sterilized by gamma irradiation at 25 kGy.

What is the shelf life?
If stored correctly, the integrity of the packaging and sterility of the device are guaranteed for 3 years from the date of manufacture.

What are the guidelines for storing and stocking Sterify® Gel?
To store the Sterify® Gel device, a protected environment must be guaranteed that preserves it from direct exposure to light and heat sources, clean, dry, which allows the packaging to be stored in a way to prevent its degradation and contamination of the product. To maintain sterility, it is important to store Sterify® Gel in the original, intact packaging at room temperature (15°C < T < 25°C) and prevent any damage.

What configurations are available?
At the moment, Sterify® Gel is available in a single 0.3 ml syringe, ready-to-use, single-patient and single-use.

DISPOSAL

What are the guidelines for disposing of Sterify® Gel and its packaging?
Any unused product must be disposed of as non-hazardous hospital waste, in accordance with current regulations. The materials that make up the packaging do not require special disposal conditions.