PerioStōm®

Deacetylated Chitosan Microspheres - *1mg*

Distributed by: premier®

1mg powder per cartridge tip

www.PerioStom.com

INSTRUCTIONS FOR USE

READ CAREFULLY BEFORE USE

CAUTIONS

PerioStōm® is intended for application by licensed dental professionals only.

Contraindications: The administration of PerioStōm® is contraindicated in any patient with a known or suspected hypersensitivity to shellfish.

Do not suture PerioStōm®; only use on an open wound.

Ingredients: Chitosan

INSTRUCTIONS FOR USE

1. Prior to first use, autoclave the FS Dispenser™ for a minimum of 121ºC for 30 minutes. Operate the autoclave in accordance with the autoclave manufacturer's instructions.
2. Remove the cartridge from the packaging and tray.
3. Twist the cartridge into the FS Dispenser™ until the tabs seat into the recesses of the FS Dispenser™. (**Figure 1**, Step 1)
   Note: *Please keep thumb out of the thumb ring when attaching the cartridge to avoid accidentally dispensing product.*
4. Remove the silicone cap from the cartridge. Please note some powder may be retained in the cap. This has been accounted and the patient will still recieve a full dose.
5. Subgingival administration after scaling and root planing is accomplished by placing the cartridge tip into the base of the periodontal pocket and pressing down on the thumb ring to expel the powder. (**Figure 1**, Step 2)
6. After administration, remove the cartridge from the pocket, unscrew and dispose of it. (**Figure 1**, Step 3)
7. Only one cartridge should be applied per periodontal pocket.
8. After administration, if there are any unused cartridges remaining, reinsert the tray into the foil packaging and reseal.

Cartridge is single use only.

9. The FS Dispenser™ must be thoroughly cleaned and autoclaved after each patient use.
10. Remove all visible blood, saliva, powder, and other debris from the FS Dispenser™.
11. Soak the dispenser in an ultrasonic bath for 10 minutes using an aqueous instrument-cleaning detergent compatible with stainless steel, or according to the ultrasonic cleaner/detergent manufacturer's instructions. Following ultrasonic bath, rinse thoroughly with water, dry completely, and visually inspect for residual debris or damage.
12. If visible soil remains, repeat steps 10 and 11. Do not use a damaged dispenser.
13. Autoclave the dispenser for a minimum of 121 °C for 30 minutes. Operate the autoclave in accordance with the autoclave manufacturer's instructions.
14. Allow the dispenser to completely dry and cool before use.

INDICATIONS

PerioStōm® is an oral wound dressing intended as a physical barrier for temporary protection of oral mucosal tissue.

INTENDED USE

PerioStōm® can be utilized for protection of oral mucosa due to irritation, trauma, or following iatrogenic procedures such as scaling and root planing (SRP).

HOW SUPPLIED

PerioStōm® is supplied as 1mg of powder in a unit dose cartridge. Store at room temperature conditions 15°C to 30°C (59° to 86°F). Do not refrigerate. Store in dry conditions. The cartridges have an 18-month shelf life from the date of manufacture.

After opening pouch, leave desiccant in pouch and reseal.

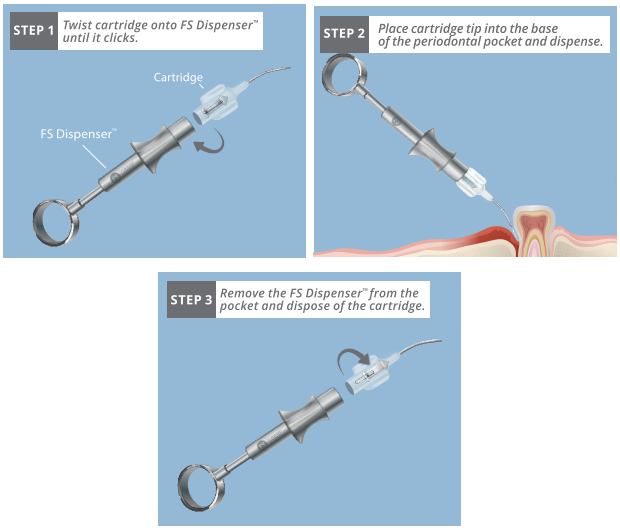


Figure 1

DESCRIPTION

PerioStōm® is packaged in a prefilled unit dose cartridge for precise application as a wound dressing and is provided non-sterile and is not intended to be sterilized before use.

The FS Dispenser™ is made of stainless steel and is a hand-held device that holds and assists in dispensing a cartridge containing PerioStom. The FS Dispenser™ is reusable and autoclavable. It will be provided non-sterile and is intended to be sterilized before use.

PATIENT INSTRUCTIONS

After treatment, patients should avoid manipulating or touching the treatment areas. For the first 48 hours after treatment, patients should avoid interproximal cleaning devices and chewing sticky, hard, or crunchy foods such as gum, taffy, apples, raw carrots, etc. Avoid oral irrigation devices for 10 days.

PerioStōm® does not have to be removed. It will slowly dissolve and be washed away by the saliva. An adhesive or dressing is not required.

Noting that SRP does cause iatrogenic trauma causing tenderness and sensitivity for approximately one week, the patient should contact their dentist if pain persists. Patients should also notify their dentist if symptoms of an allergic reaction occur such as difficulty breathing,

APPLICATION VOLUME

The volume of PerioStōm® dispensed from the tip is smaller than that used in other adjunct products. Please note some powder may be reatined in the cap when removed. This has been accounted for and the patient will still recieve a full dose. Successful administration of PerioStōm® occurs once the thumb ring has been completely depressed. This can be visualized by looking at the window in the cartridge as pictured in **Figure 2**.

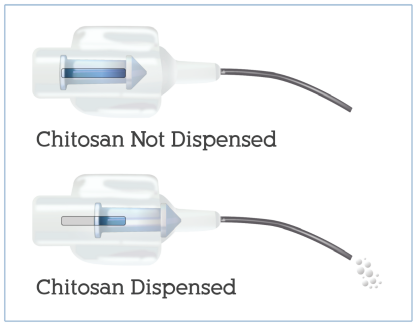


Figure 2

SYMBOLS GLOSSARY

Symbol	Description
REF	Catalog reorder number
	Expiration date of cartridge
LOT	Batch code
Rx Only	Perscription use only
	Date of manufacture
MD	Medical device
	Cartridge storage temperatures of 15°C – 30°C
	Cartridge is single use only
	Keep away from rain and in dry conditions
NON STERILE	The medical device is nonsterile
	Manufacturer
	Distributor

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