



INSTRUCTION FOR USE

GDT PERIOFOCUS

BIODEGRADABLE CHIP FOR PERIODONTIC SOCKET

PURPOSE

Small orange-brown rectangular chip, rounded at one end for insertion into periodontal pockets as an adjunct to scaling and root planing procedures for reduction of pocket depth in patients with periodontitis. After insertion, the periodontal pocket fills with saliva and the chip expands before it gradually dissolves. This enables free circulation of chlorhexidine gluconate throughout the pocket.

DIRECTION FOR USE

1. Open individual foil pocket.
2. Grasp the chip at flat end with suitable forceps.
3. Insert curved end first, into the periodontal pocket.
4. Press apically to the base of the pocket.
5. After proper insertion, GDT Periofocus should rest subgingivally at the base of the pocket.
6. It does not require removal since it biodegrades completely.

A single chip GDT Periofocus contains 2.5 mg chlorhexidine gluconate. 40% of the dose is released within first 24 hours. The release of remaining 60% of the antibacterial component takes up to 10 days.

Important Notice:

GDT Periofocus should not be used if the patient has a known sensitivity to chlorhexidine. Anaphylaxis, as well as serious allergic reactions, have been reported with dental products containing chlorhexidine.

PRECAUTIONS AND WARNINGS

Despite its proven low antigenicity, hypersensitivity reactions may occur due to the xenogenous origin of the collagen. If allergic reaction, dermatitis or rash develops, consult a physician.

The GDT Periofocus chips are disposable and intended for single use.

After being removed from the protective package must not be re-sterilised and should be discarded.

Patients can immediately eat, drink and brush their teeth, and there are no dietary restrictions.

Instruct patients to avoid flossing at the site of insertion for ten days to avoid dislodging the chip. All other oral hygiene may continue as usual.

Use only dry instruments and gloves with a GDT Periofocus.

POSSIBLE SIDE EFFECTS:

Very common side effects: Toothache.

COMMON SIDE EFFECTS (probably affecting up to 1 in 10 people):

Swelling, pain or bleeding of the gums.

UNCOMMON SIDE EFFECTS (probably affecting fewer than 1 in 100 people):

- Swelling of the lymph glands.
- Dizziness.
- Enlargement, shrinkage and itching of the gums.
- Mouth ulcers.
- Teeth sensitivity.
- Neuralgia (pain from irritation of the nerve).
- General tiredness.
- Fever.

PACKAGING

Chips in foil pockets in box
Instruction for use

5 pcs
1 pcs

STORAGE

Do not store above 25° C. Protect from moisture. Keep out of the reach of children.



Caution, consult accompanying documents.



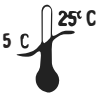
Do not re-use/for single use only.



Consult use instructions.



Do not re-sterilize.



Temperature limit.



Do not use if package is damaged.



Keep Dry



Date of manufacture.



Keep away from sunlight.



use by date Expiry Date: Month & Year.



Sterilised using irradiation.



Batch code.