

English



EASY TISSUE SCRAPER

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EC REP

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| | ● CE conformity marking |
| | ● Date of manufacture |
| | ● Batch code |
| | ● Non-sterile |
| | ● Manufacturer |
| | ● Single use |
| | ● Caution, consult accompanying documents |
| | ● Federal law(USA) restricts this device to sale by or on the order of a licensed dentist |
| | ● Consult instructions for use |
| | ● Authorised representative in the european community |

IFU-DS-I-3500T-R00/ 2025-12-06

[Product name] EASY TISSUE SCRAPER

[Model name] 3500T15, 3500T25

[Weight or packaging unit] 1pack (2ea in a case)

~~This product is an only single use medical device~~

Purpose of use

A manual instrument intended to scrape and collect autologous bone or soft tissue during oral surgical procedures.

Instruction for Use & Procedure

1. Preparations before use

- 1) This product is intended for professional use only by professional training providing medical devices.
- 2) The practitioner must fully understand the product's usage instructions and precautions before using it.
- 3) Before the procedure, prepare by selecting a product appropriate for the surgical area and purpose.
- 4) Before performing the procedure, check the condition of the product, including whether it is damaged, cleaned, and sterilized.
- 5) Since this is a disposable non-sterilized product, please follow the hospital's own cleaning and sterilization methods, or follow the cleaning and sterilization conditions below. Sterilize and prepare accordingly.
 - Washing method: Before use, disinfect and clean the equipment with distilled water and alcohol, then dry it completely.
 - Sterilization method: After sterilization at 121°C for 15 minutes by high-pressure steam sterilization method, drying for 30 minutes

2. How to use

- 1) Anesthesia: Administer local anesthesia to the donor site on the maxillary palate aspect.
- 2) Positioning: Place the tissue scraper against the vertical wall of the maxillary posterior palatal region.
- 3) Elevation: While applying gentle pressure, translate the instrument in a posterior-to-anterior direction.
This action elevates the palatal epithelium while maintaining a consistent thickness of 1.0–2.0mm.
- 4) Harvesting: Depending on the clinical objective (FGG or CTG),

proceed to harvest either the epithelial layer or the underlying connective tissue

3. How to store and manage before use

This product should be stored at room temperature and away from direct sunlight and high temperatures.

Precautions for use

1. This product is a medical device and can only be used by those who have received professional training.
2. Practitioners must be fully familiar with the product's usage instructions and precautions before using it, and only sufficiently trained or skilled practitioners should use it.
3. It must not be used for purposes other than its intended use.
4. Since this product is non-sterilized, it must be sterilized before use.
5. Wear sterile gloves when using the product and be careful not to get hurt by the blade of the product.
6. The manufacturer is not responsible for any damage to the product caused by sterilization using a method other than the sterilization conditions suggested by our company or improper handling.

Warnings, side effects and contraindications

1. Contraindication

- 1) This product is a disposable medical device product and can be used only once.
- 2) Re-sterilization or washing after use is not allowed.
- 3) We do not repair products damaged by users.

2. Warning

For safe and effective use, we strongly recommend:

- 1) Do not use the product for purposes other than its intended use or modify the product.
- 2) It is not used in patients unsuitable for other surgeries.
- 3) The product must be handled with care to avoid damage or deformation.

3. Side effects

Careless use and storage of the product may cause reactions such as infection or metal allergy.

Caution

- 1) Use for purposes other than the intended use is prohibited.
- 2) Do not use products contaminated by surgeon's mistake during surgery.
- 3) The manufacturer is not responsible for any damage to the product caused by sterilization or improper handling of the product other than the sterilization conditions provided by the company.
- 4) Thorough pre-diagnosis and product inspection must be performed on the patient before the procedure.
- 5) This product is a non-sterilized product and must be used after sterilization.

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