

English



EASY BONE SCRAPER

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EC REP

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CE ● CE conformity marking

● Date of manufacture **LOT** ● Batch code

● Non-sterile ● Manufacturer

● Single use

● Caution, consult accompanying documents

Rx Only ● Federal law(USA) restricts this device to sale by or on
the order of a licensed dentist

● Consult instructions for use

EC REP ● Authorised representative in the european community

IFU-DSE-3500-R04/ 2024-11-06

[Product name] EASY BONE SCRAPER

[Model name] 3500SK,3500NK

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

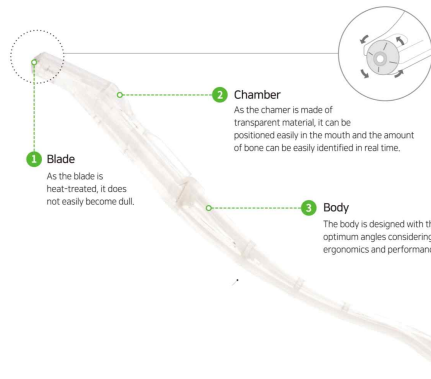
This product is an only single use medical device.

Purpose of use

Passive surgical instruments used for osteotomy, resection,
puncture, etc.

Product Features

- Blade : As the blade is heat-treated, it does not easily become dull.
- Chamber : The chamber is made of transparent material, it can be positioned easily in the mouth and the amount of bone can be easily identified in real time.
- Body : The body is designed with the optimum angles considering ergonomics and performance.



* Features *

1. The front part is bent so that the lateral access to the oral cavity is easy.
2. The blade can be rotated 360° and can be used up to 4 times in 90° increments.
3. As the product is transparent, you can see in real time the amount of autologous bone that has been taken.

Instruction for Use & Procedure

1. Preparations before use

- 1) Do not use if packaging is damaged or opened.
- 2) Check the product for deformation or foreign substances before use.
- 3) Be careful not to injure the blade and check the blade for damage.
- 4) User sterilization is carried out by the hospital itself before use
 - Sterilization method: After sterilization at 121°C for 30 minutes by high-pressure steam sterilization method, drying for 30 minutes

2. How to use

- 1) The device must be gripped with the transparent 'Chamber' always facing the bone.
- 2) With the blade of the product in contact with the bone surface, collect the bone tissue as if pulling it toward the handle.
- 3) The collected cortical bone is used by pushing up the round part at the back of the chamber.
- 4) If cortical bone collection is to continue, return the transparent chamber of the product to its original position.
- 5) If it is determined that the blade has become dull during use, the blade drive mounted on the product handle may be detached and used to rotate the blade to use the new blade.

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. As a user sterilized product, be sure to use it after sterilization.
2. The user must check the patient's condition.
3. Dental bone surgery procedures should be performed by trained professionals.
4. Wear sterile gloves when using the product and be careful not to get hurt by the blade of the product.
5. Reuse of used devices may result in deterioration of performance and functionality, and cross-contamination.

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.

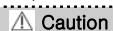
2. Warning

For safe and effective use, we strongly recommend:

- 1) The operator must be an expert with advanced treatment skills.
- 2) Before using the product, the operator must fully understand the operation method and precautions for the product.
- 3) In an operating room that can remain sterile, the procedure should be performed after wearing a sterile surgical suit.
- 4) Inappropriate patient selection and technique may cause procedure failure.

3. Side effects

Side effects such as infection, pain, and inflammation may occur.



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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