



- Method of use -

A. Matters to prepare before use

- 1) The operator should be acquainted with the operation method using this product, clinical indications, and taboos.
- 2) Check whether the product corresponds to the specification on the label before using the product.
- 3) All the apparatuses used for an operation should be prepared by being cleaned and sterilized.
- 4) Check the condition of the product and whether there is any external deformation, damage or foreign material before use.
- 5) Check whether there is any biological or biodynamic factor that may affect the operation result of the patient.
- 6) The product should be cleaned using a brush without fail to prevent adulteration of foreign materials in the process of moving the product to the dedicated sterilization tray before sterilization. Use of a steel brush or steel wool is prohibited, and a soft brush should be used at all times.
- 7) As this product is supplied in a state not sterilized, it should be sterilized by the following method before use at all times:

* Sterilization method: Steam sterilization (ISO17665-1, 2)
Sterilization condition: 15 minutes at 132°C

B. Instructions for Use and Operating Sequence

- 1) Cleanly remove the tissues and the coagulated blood remaining around the fracture line generated by osteotomy or fracture.
- 2) Temporarily reduce the fracture part using an apparatus such as a pair of fracture reduction forceps, etc.
- 3) Determine the form and the size of the plate to be used for the operation after checking the fracture line and taking into account the conditions such as the anatomical and physical conditions and the location of the screw.
- 4) Transform the plate to make it be well seated on the part to be operated to the maximum using a surgical apparatus or hands.
- 5) Put the oral and maxillofacial fixing plate transformed to fit the surgical part on the part.
- 6) If a guide hole is required, drill it by a method suitable for the oral and maxillofacial fixing plate to be used.
- 7) Fix the Titanium Mesh (the oral and maxillofacial fixing plate) with the oral and maxillofacial fixing screw.

C. Methods of Storage and Management after Use

- 1) Being a disposable product, it is prohibited to be reused and should be discarded without fail after use.
- 2) Unused products shall be stored in accordance with the method of storage before use.

- Matters that require Attention during Use -

A. Taboos

- 1) Active infection or potential infections
- 2) Osteoporosis
- 3) Hypersensitivity to the graft
- 4) Patients mentally or physically difficult to be treated after an operation
- 5) It should not be used for any other purpose than as originally intended.
- 6) Besides, it should not be used for the disabled patients who have a limit in the fastening force of plate and screw.

B. Side Effects

- 1) If an operation is done for a patient who lacks ossification due to osteoporosis or because vascular transplantation is suppressed, the product may become loose, be bent, broken or ruptured.
- 2) An early removal operation after the transplantation may cause failure in fixing the product inside the bone resulting in imperfect osteosynthesis
- 3) Inappropriate alignment or arrangement may cause delay or failure in articulation of the cut bone part
- 4) It should not be used for the patients who are sensitive to a metallic material such as titanium.

C. Warnings and Cautions

- 1) The forms and sizes of Titanium Mesh (oral and maxillofacial fixing plate) and maxillofacial fixing screw should be selected by the operator taking into account osseous, bone geometry, functional load, post-operation adaptability of the patient, and so on.
- 2) For efficient and safe use this product, the operator should be sufficiently trained and have enough experience in the operating method related to this product.
- 3) The operator should be able to make a reasonable judgment when determining the shape of the oral and maxillofacial fixing screw and Titanium Mesh (oral and maxillofacial fixing plate) to use them for a special purpose.
- 4) No excessive force should be applied to the product, if possible.
- 5) Using this product for a part on which a high load is functionally expected may cause rupture of the product or a failure in operation.
- 6) Besides, it should not be used together or in vicinity of other medical instrument such as metal plate, screw, wire, etc.
- 7) Imperfect fixing of the product may cause damage or rupture of this product.
- 8) The operator should be well acquainted with suitable precautions against problems that may occur during an operation.
- 9) An oral and maxillofacial fixing screw and Titanium Mesh (oral and maxillofacial fixing plate) suitable for the patient should be selected through a test before transplanting the product.
- 10) Selection of the product and the operation method suitable for the patient and the judgment on the removal time are the responsibilities of the operator.
- 11) Being a disposable medical instrument, this product should not be reused.
- 12) Delay in coagulation, non-coagulation, incidental bone resorption, or an external injury may cause rupture or loosening of the product by applying excessive stress to the product.

Storage Method: Room Temperature Storage (1°C ~ 35°C)
Expiry date: None

