

Jaw's Reconstruction - Instructions

Description

The Jaw's Reconstruction System is a custom-made medical device that is used to support during the reconstruction of the jaw by autologous bone graft. The system consists of several individual aids: conceptual 3D tissue models (reconstructed jaw, the bone intended for grafting), cutting guides and spacer (sterilized model of the bone graft). The individual aids are designed for specific patient based on patient's diagnostic CT scan. The aids are made from certified material for use in medicine.

Conceptual model of bone intended for grafting is used to determine the precise location of bone graft cutting guide. Conceptual model of Jaw's reconstruction is used to preoperative shaping of fixing material. **Conceptual models are not intended for sterilization and direct use in the operating room.**

The cutting guides are used to indicate cut planes for precise bone grafting and to indicate resection cut planes on the jaw. Spacer is used to check the current situation directly in the operating room. Spacer allows you to make minor adjustments in case of unpredictable complications. **Cutting guides and spacer are supplied in a non-sterile condition and are intended for sterilization and direct use in the operating room.**

The list of supplied individual aids and the graphical representation of their use are on the opposite side of this instructions.

Indication

The Jaw Reconstruction System is used to support of primary or secondary reconstruction of the jaw by autologous bone graft.

Contraindication

No contraindication are known.

Sterilization

The individual aids **are supplied in a non-sterile condition**. The aids intended for sterilization are listed on the opposite side of this Instructions. Recommended sterilization methods are **Cold plasma and Autoclave 134 °C** including the Pre-sterilization preparation (cleaning and disinfection). The pre-sterilization preparation (cleaning and disinfection) is carried out according to the customary practice and internal regulations of applied hospital.

Storing

There are no special requirements for storing. Length guarantees of the Jaw reconstruction aids declared by the manufacturer is 24 months from date of declaration of conformity to a particular product.

Medical device classification

The Jaw's reconstruction System is a **Custom-made class IIa medical device**. It is surgically invasive, inactive and without a measurement function. It is intended for transient use (use for ~ 30 minutes). It is supplied as non-sterile.

Warning

- **Conceptual 3D tissue models** are used to only for determination of the precise location and preoperative preparation. They **do not come in contact with the patient**, his/her blood or body fluids They are not intended for sterilization and direct use in the operating room.
- Patient Identifier (PID) is created by composition of first three letters from surname and first three letters from name. Example: Surname: Novak, Name: Karel -> PID: NOVKAR
- **Before use make sure** that Case ID (JRCxyz) and Patient Identifier (PID) on the supplied aids with the data on the individual Declaration of Conformity match.
- The individual aids **are supplied in a non-sterile condition**. Aids for sterilization must be disinfected and sterilized prior to surgery as recommended in this instructions.
- The Jaw's reconstruction System is a **custom-made medical device**. The supplied aids are intended only for the specific patient.

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