Application and safety instructions for the MEISINGER

Trephine Ejection Kit

Trephine System for Extraction of Cylindrical Bone Grafts Developed by Prof. Dr. Fouad Khoury

Art.-No.: BTE00

The Trephine Ejection Kit was developer together with Prof. Dr. Fouad Khoury. It countains several unique ideas which turn this kit into somethign special: Two- part, internally cooled trephines allow for a sale and minial invasive extraction of local bone cylinders. The inner cooling helps to prevent a damage of the bone tissue due to overheating, while the removable trephine working parts allow for an especially easy sampling of the cut out bone cylinders. Either with the aid of the ejection needle ort he ejection instruments, which perfectly mathc with the diameter of the trephine working parts, the bone cylinders can be pushed aout of the rephines. Furthermore, the included predrilling trephines allow for a safe application of the trephines.

Due to the two-part traphines, the variety of different diameteers and the optimal matching of the instruments, the Trephine Ejection Kit offers highest efficiendy, flexibility and precision to the user for the extraction of bone cylinders.

Indications

The Bone Management systém Trephine Ejection Kit is indicated for the intraoral extraction of bone cylinders for augmentation of bone deficits in the upper and lower jaw.

Instruction

The recommended speeds for the application adn the maximum speeds are summarized in the instrument overview under“Content“. For proper, safe use, these must be observed.

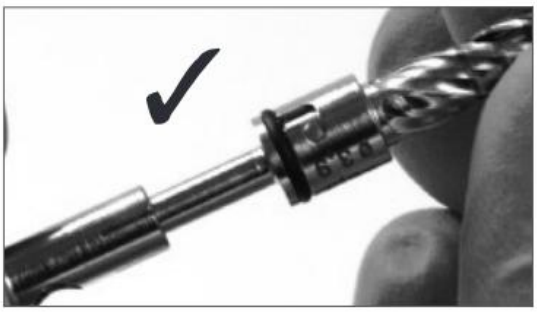
Before application

The instruments are suplied non – sterile, so they need to be cleaned, disifected and sterilized prio to use, this applies in particular to the first-time use. For cleaning and disinfection the products are dissassembled as far as possible. For that the shank of the trephine is attached to the hand wheel, so the trephine working part can be released and removed by a left-hand turn. The rubber ring remains on the shand during the first processing. After cleaning and disinfection have benn completed, the traphine working part is attached again to the shank and fixed by a richt-hand turn. The sucure fit of the working part has to be checked. Subsequently, the instruments can be sterilized according to the instructions for processing. Since the trephines have an internal cooling, these are instruments with increased processing requirements. According to the RKI guideline, mechanical cleaning and disifection in disinfection devices and sterilization with moist heat is recommended. For proper processing of the articles, please note the instructions for processing (cleaning, disinfection and sterilization) of medical devices produced by Hager Meisinger GmbH.

Initial Drilling

According to the planned diameter of the bone cylinder the appropriate initial dril is selected. With this dril the bone at the donor site is punch-marked in order to avoid slippage of the trephine.

Extraction of the bone cylinder from the donor site

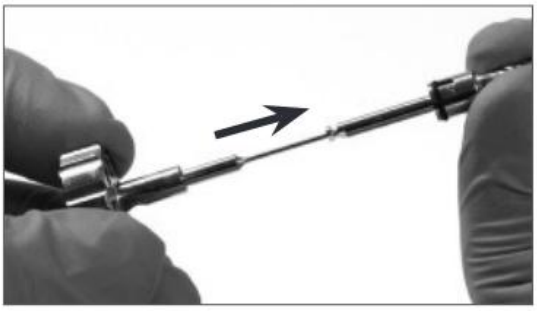


According to the planned diameter of the done cylinder the appropriate trepine is selected. Before use, the fixed position of the trephine working part on the shank has to be chcecked.

Coution: Depending odn the construction, the trephinesmay not be used counterclockwise.

At the punch-marked donor site the bone cylinder of the planned length can now be extracted with the aid of the trephine. For this purpose, the trephine is places on the cortical bone and intermittently inserted into the bone. It is recommended to support the working hand to control the trephine optimally. The speed shhould not be too low to avoid tilting of the trephine in the depth of the bone. Please note

the recommended and masimum speeds. The depth marks on the trepine working parts serve for length oriantion.

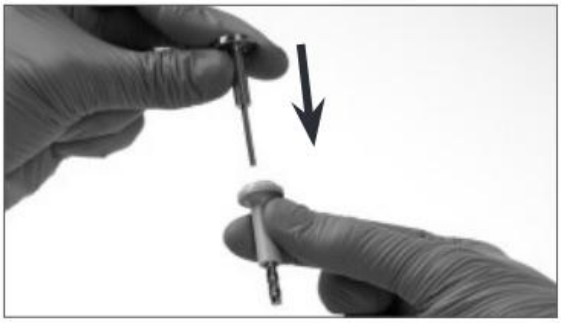


Extraction of the bone cylinder from the trephine

To extract the bone cylinder from the trephine working part, the trephine is removed from the handpiece. To achieve a better handling, the ejection needle is attached to the hand wheel. Then, it can be led through the lumen of the trephines Internal cooling from the shank end in the direction of the trephine working part, so the bone cylinder is pushed out.

Countion: In the case of soft bone, the application of the jection deedle is contraindicated due to its samml diameter. In this case, proceed according to step „Alternative Extraction of the bone cylinder from the trephine in case of soft bone“.

Alternative Exttraction of the bone cylinder from the traphine in case of soft bone



In case of soft bone, the extraction of the bone cylinder is pefromed with the aid of the ejection instruments. For that, the shank of the trephine is attached to the hand wheel, so that the trephine working part can be released and removed by a left-hand turn. Then, the trephine working part in inserted into the ejection sleeve. With the aid of the appropirate ejection instrument the bone cylinder is pushed out.

The 2.1. mm and 2.5. mm diameter trephines go with the 2.1. mm diameter ejection instrument.

The 2.9. mm and 3.1. mm diameter trephines go with the 2.9. mm diameter jection instrument.

After use

The instruments need to be cleanded, disinfected and sterilized after every application. For cleaning and disinfection the products are disassembled as far as possible. With the aid of a twwzer the rubber tings on the shank are now removed and disposed. Then, the instrument can be reprocessed.

Agter completed cleaning and disinfection, preferably completely mechanical, a new rubber ring (art- No. 2151) is mounted on the shank and the trephine working part is again attached and fised to the shand by a richt- hand turn. Than, the instruments can be sterrilized according to the instructions for processing. For a proper processing of the articles please note hte instructions for processing (cleaning, desinfection and sterilization) of medical devices from Hager Meisinger GmbH.

Contraindications

Pasically, general medical as well as local, absolute and relative contraindications for dental surgical prodedures must be considered.

Absolute contraindications

- Dentoalveolar growth which has not come to an end (expception: cases in which no dentoalveolar growth can be expected, e.g. ectodermal dysplasia)
- Active infections as well as pathological processes
- Insuffcient bone supply (quality/quantity) of the donor site as well as insuffcient bone quality of the donor region

Relative contraindications

- Diseases that affect bone metabolism
- Drug and alcohol abuse
- Lacko f cooperation of the pationt
- Poor circulation
- Hard work or active sports
- Mental condition, which can lead to disregard of the medical order
- Highly atrophic jaw

IMPORTATNT: Attention must be paid to protecting anatomical structures (safety clearance at least 2 mm) as weel as the gradient of the adjacent teeth/ tooth roots (risk of damage, infection / dehiscences).

COUNTION: For all cutting and drilling procedures (transplant removal/ other work). The following applieas: In order to reduce the risk of overheating the bone and necrosis

formation along with it, hte respektive instrument has to be used intermittently using little pressure and continuous cooling, using a sterile physiological saline solution.

It should be avoided to trepan the lingual cortical bone as demage to the soft tissue and vessels of the mouth base can lead to serious complications. The extracted bone graft should be used as quickly as possible in the recipient site or stored in blood or isotonic saline solution. It is recommended to fill larger defects agter bone extraction. In the donor site, a tencion – free and complete wound closure must follow quickly.

General instructions

Please follow general application and safety instructions for Meisenger products in the medical area and also the advice for processing (cleaning, disinfection and sterilisation) of medical devices from Hager Meisinger GmbH.

Meisinger since 1888 CE 0044

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