

Trephine Drill

Instructions for use



Important: Please read.

Disclaimer of liability:

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Description:

Single use Trephine Drills are made of stainless steel and are delivered sterile. The single use Trephine Drill is for one patient and for one surgical treatment only.

Intended use:

Trephine Drills may be used to remove bone around Nobel Biocare implants with internal conical connection, tri-channel connection or external hex connection in order to remove a damaged implant. The Trephine Drills are designed for drilling bone outside an implant in order to remove the implant.

Indication:

Trephine Drills are indicated to remove damaged implants if they cannot be removed with the Implant Retrieval Tool.

Contraindications:

In general, contraindications are applicable for implant surgery related procedures in patients:

- who are medically unfit for an oral surgical procedure.
- who are allergic or hypersensitive to medical grade stainless steel or any of its alloying components.

Warnings:

Do not use the Trephine Drill for any purpose other than the removal of Nobel Biocare implants with internal conical connection, tri-channel connection or external hex connection.

Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended from lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to a hemorrhage in the floor of the mouth.

Besides the mandatory precautions for any surgery such as asepsis, during drilling in the jaw bone, one must avoid damage the nerves and vessels by referring to anatomical knowledge and preoperative radiographs.

Cautions:

Location of vital anatomical structures should be verified with X-ray images before implant retrieval.

All instruments and tooling used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient.

Careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical status of the patient.

Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone). Special caution is advised in patients who receive bisphosphonate therapy. In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

It may not be possible to immediately place an implant after using a Trephine Drill due to the size of the resulting hole and/or other factors.

It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method. Nobel Biocare offers a wide range of courses for various levels of knowledge and experience. For more info please visit www.nobelbiocare.com.

Working the first time with a colleague, experienced with the new device/treatment method, avoids eventual complications. Nobel Biocare has a global network of mentors available for this purpose.

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for a successful implant treatment.

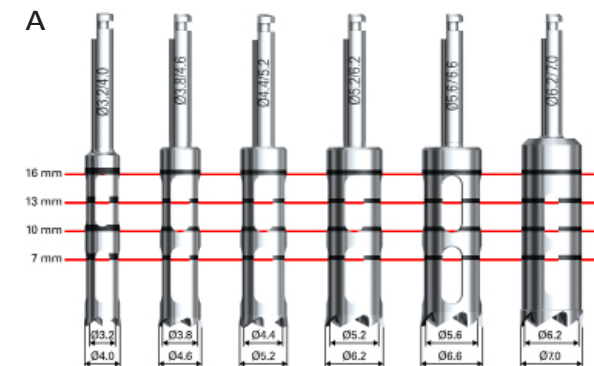
Surgical procedure:

Procedure:

1. Select appropriate Trephine Drill based on implant diameter according to laser-marking (see A). The Trephine Drill should be selected on basis of the inner diameter slightly exceeding the outer diameter of the implant. Image A shows Trephine Drill depth markings.

Note: The depth markings are in true millimeters.

Warning: Do not use an oversized Trephine Drill to avoid oversized osteotomies.



2. Remove abutment/prosthetics.

3. Place the Trephine Drill over the implant (B). Optionally, a straight Multi-unit abutment may be used to guide the Trephine Drill into proper position.



4. Start the drilling procedure using low speed (60–100 rpm) and copious irrigation. When the Trephine Drill grips into the bone, the optional straight Multi-unit abutment can be removed and the speed can be increased (1200–1500 rpm).

Warning: Do not apply excessive pressure as breakage can occur.

Warning: Instruments can wear out during use. If poor cutting, replace the Trephine Drill with a new one.

Warning: During the drilling procedure care must be taken to prevent adjacent vital structure being damaged as a result of increased width of the implant which is being removed.

It is recommended to use the depth markings on the Trephine Drills as landmarks in order to ensure that the drill does not progress deeper than planned with the subsequent risk of damaging vital structures.

Caution: Steady handling is strongly recommended as a Trephine Drill may jump side-ways abruptly before fully surrounding the implant.

Caution: Generous cooling is important when using the Trephine Drill to avoid overheating.

5. Stop drilling before full depth of implant is reached. Wiggle back and forth to remove implant and Trephine Drill.

For additional information on surgical procedures please consult the “Retrieval instrumentation” procedures manual available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Materials:

Medical grade stainless steel.

Cleaning and sterilization instructions:

The Trephine Drill is delivered sterile. The Trephine Drill is a single use product that must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

Warning: Do not use if package is damaged or previously opened.

MR safety information:

Please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.

Storage and handling:

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

Disposal:

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

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Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.

Prescription device: Rx only

Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

Symbols Glossary:

The following symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.



Authorized representative in the European Community



Batch code



Catalogue number



Caution



CE marking



Consult instructions for use



Contains hazardous substances



Contains or presence of phthalate



Date



Date of manufacture



Do not re-sterilize



Do not re-use



Do not use if package is damaged



Double sterile barrier system



For prescription use only



Health care centre or doctor



Keep away from sunlight



Keep dry

symbol.glossary.nobelbiocare.com
ifu.nobelbiocare.com

Link to Online Symbols Glossary and IFU Portal



Magnetic resonance conditional



Manufacturer



Medical device



Non-pyrogenic



Non-sterile



Patient identification



Patient information website



Patient number



Serial number



Single sterile barrier system



Single sterile barrier system with protective packaging inside



Single sterile barrier system with protective packaging outside



Sterilized using ethylene oxide



Sterilized using irradiation



Temperature limit



Tooth number



Upper limit of temperature



Sterilized using steam or dry heat



Unique Device Identifier



Use-by date

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