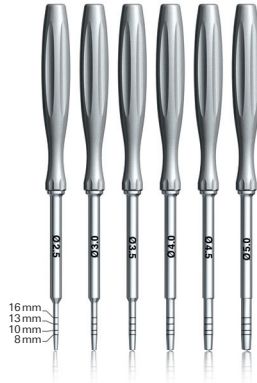


# Osteotomes

## Instructions for use



### Important: Please read.

#### Disclaimer of liability:

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of Nobel Biocare. Non-recommended use of products made by third parties in conjunction with Nobel Biocare products will void any warranty or other obligation, express or implied, of Nobel Biocare. The user of Nobel Biocare products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. Nobel Biocare disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Nobel Biocare products. The user is also obliged to study the latest developments in regard to this Nobel Biocare product and its applications regularly. In cases of doubt, the user has to contact Nobel Biocare. Since the utilization of this product is under the control of the user, they are his/her responsibility. Nobel Biocare does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

#### Description:

Osteotomes are surgical instruments that can be used to support the osteotomy preparation for implant placement. The function of the Osteotomes is to manually form the osteotomy by compressing the bone in order to improve bone quality (bone condensing) and bone quantity (ridge expansion in horizontal and vertical dimension) for sufficient primary stability of implants. They consist of an ergonomic manual handle and a working part. The Osteotomes are designed in different diameters (2.5, 3.0, 3.5, 4.0, 4.5 and 5.0mm) which are marked on the device. The working part has marked lines showing various different heights (8, 10, 13 and 16mm).

#### Intended use:

The Osteotomes are limited to use in the maxillary arch and are intended to be used in soft bone. The Intended use for this device is to create an osteotomy of compacted bone in the posterior maxilla sub-antral to the sinus for the placement of endosseous implants.

#### Indications:

The Osteotomes are used for the insertion of Nobel Biocare Implants in posterior maxillary bone.

#### 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 commercially titanium alloy grade 5 (Titanium-6Aluminium-4Vanadium).

#### Cautions:

Care and maintenance of instruments are crucial for a successful treatment. Sterilized instruments not only safeguard your patients and staff against infection but are also essential for the outcome of the total treatment.

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.

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](http://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.

#### Handling procedure:

1. Mark and drill the initial pilot hole with Twist Drill 2 mm to full depth.
2. Insert the tip of Osteotome 2.0mm into pilot hole and push the instrument into the bone while rotating it, avoiding side-to-side or off-axis leverage. Leave the Osteotome in place for about 10 seconds to allow the bone to relax. Remove the Osteotome by simultaneously rotating the tool and withdrawing it.
3. Use the same technique to progressively expand the implant site with larger Osteotomes depending on the implant diameter.

For additional information on the implant site preparation please consult the procedures manual of the respective implant system available at [www.nobelbiocare.com](http://www.nobelbiocare.com) or request latest printed version from a Nobel Biocare representative.

#### Materials:

Biocompatible surgical grade alloyed Titanium alloy 90 % Ti, 6 % Al, 4 % V.

#### Cleaning and sterilization instructions:

The devices are delivered non-sterile, are intended for reuse and must be cleaned and sterilized prior to use.

For USA: Seal single device in a pouch and steam sterilize at 270°F (132°C) for 3 minutes.

For outside USA: Seal single device in a pouch and steam sterilize at 132°C–135°C (270°F–275°F) for 3 minutes.

Alternative UK: Seal single device in a pouch and steam sterilize at 134°C–135°C (273°F–275°F) for 3 minutes.

**Warning:** Use of non-sterile components may lead to infection of tissues or infectious diseases.

Full set of recommended parameters are provided in "Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products" available at [www.nobelbiocare.com/sterilization](http://www.nobelbiocare.com/sterilization) or request latest printed version from a Nobel Biocare representative.

#### 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.



Rx Only



Non-sterile



Caution



Consult instructions  
for use



Use-by date



Batch code

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