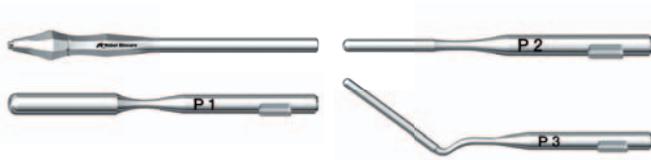


Periotome

Instructions for use



Important: Please read.

Disclaimer of liability:

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Description:

The Periotome is a reusable blade-shaped instrument to be used to facilitate removal of teeth with minimal damage to the surrounding alveolar bone. The Periotome is available in three different blade configurations, depending on the shape of the tooth (P1 to P3). The blades are to be connected to a handle.

Intended use:

The Periotome may be used in the course of non-traumatic tooth extraction especially in preparation for an immediate implant placement.

The Periotome can be used for controlled separation of the periodontal fibers around the root of the tooth to be extracted. The instrument is also indicated to reflect the marginal gingiva after tooth extraction while the implant site is being prepared.

Indications:

This instrument is to be used in teeth damaged beyond repair that need to be extracted and in cases where non-traumatic gingiva separation is indicated.

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 stainless steel.

Warning:

The Periotome should not be used on ankylosed teeth or to elevate root tips.

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.

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.

The incorrect use of the instrument can lead to blade fracture.

Handling procedure:

1. Seat the blade in the handle by rotating the handle counterclockwise while holding the handle tip. Slide the blade into the handle tip. The blade shank has a guide that engages a slot in the handle to prevent rotation. Tighten by turning the handle clockwise.
2. Gently but firmly push the blade of the Periotome deep into the periodontal space of the tooth to be extracted. "Walk" the blade in up and down movements around the root of the tooth to separate the periodontal fibers. The tooth can then be removed following standard surgical procedures.
3. To release the gingiva after extraction, insert the Periotome subperiosteally and elevate the tissue from the bone. The marginal gingiva can then be reflected while the implant site is being prepared.

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

Materials:

Blade and handle: medical grade stainless steel.

Cleaning and sterilization instructions:

The devices are delivered non-sterile, are intended for reuse and must be cleaned and sterilized prior to use. Before cleaning, disassemble the handle tip and the handle.

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.

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

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

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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