Abutment Retrieval Instrument Titanium Conical Connection Instructions for use





Important: Please read.

Disclaimer of liability:

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Description:

The Abutment Retrieval Instrument Titanium is reusable and made of titanium. Two versions of the instrument are available, one for NP internal conical connection, colorcoded magenta, and one for RP/WP internal conical connection, color-coded yellow.

Intended use:

The instrument may be used to remove a titanium abutment if the abutment is stuck in the implant connection due to the tight conical seal.

Indication:

The instrument is indicated for Nobel Biocare implants with a conical connection.

Contraindication:

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 (Ti 6AI-4V).

Warnings:

Do not use the abutment retrieval instrument for the removal of zirconia abutments. It is strongly recommended that the abutment retrieval instrument is used only with Nobel Biocare titanium abutments for conical connection as combining components with different dimensions can lead to mechanical and/or instrumental failure or damage the tissue.

Do not use the abutment retrieval instrument for other purposes then removal of titanium abutments for implant with internal conical connection with NP, RP or WP prosthetic interface.

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 <u>www.nobelbiocare.com</u>.

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 instructions:

Procedure:

Situation:

Abutment/clinical screw has been removed using the Screwdriver Unigrip^M and abutment/restoration is stuck due to the tight conical seal.

Note: The abutment/clincial screw must be unthreaded from both the internal threads of the implant and the abutment. In case the loose abutment/clinical screw is difficult to remove, use a small amount of sticky wax on the tip of the Screwdriver Unigrip™, which will aid in retention of the abutment screw head.

 Insert the Abutment Retrieval Instrument Titanium into the abutment and screw into place using the Screwdriver Unigrip™ until the tip of the screw touches the bottom of the hole inside the implant.

2. Apply torque to the Screwdriver Unigrip[™] to release the abutment from the implant.



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 <u>www.nobelbiocare.com/sterilization</u> 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.

Manufacturer: Nobel Biocare AB, Box 5190, 402 26 Västra Hamngatan 1, 411 17 Göteborg, Sweden. Phone: +46 31 81 88 00. Fax: +46 31 16 31 52. www.nobelbiocare.com

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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.

For additional information on surgical procedures please consult the "Procedures & products" treatment guidelines available at <u>www.nobelbiocare.com</u> or request latest printed version from a Nobel Biocare representative.

Material:

Titanium alloy grade 5 (Ti 6AI-4V).

Cleaning and sterilization instructions:

The devices are delivered non-sterile 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.

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.





L01

REF Catalogue number

Authorized Batch code representative in the European Community



CE marking





Consult instructions for use







manufacture



Do not resterilize



Date



is damaged





IFU Portal

Double sterile For prescription barrier system use only



Keep away from sunlight

Do not use if package





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Patient

identification

Keep dry



symbol.glossary.nobelbiocare.com Link to Online Symbols Glossary and

Magnetic resonance Manufacturer conditional

Medical device



Non-sterile

MR

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website

Patient information Patient number







Single sterile barrier system

Single sterile barrier system with protective



Caution

DEHP

Contains or

presence of

phthalate

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X

• +

or doctor

Health care centre

141

Do not re-use



Upper limit of temperature

STERILE EO

Sterilized using

ethylene oxide



Sterilized using Identifier steam or dry heat

STERILE R

Sterilized using

irradiation

STERILE

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Single sterile

packaging inside



barrier system with protective packaging outside











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