Ball Abutment
Instructions for use

Important: Please read.

Disclaimer of liability:
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Description:

A premanufactured dental implant abutment directly connected to the endosseous dental implant intended for use as an aid in prosthetic rehabilitation. An abutment together with a adjustable Goldcap to be used for full-arch restorations.

Internal tri-channel connection for: NobelReplace®, Replace Select™ and NobelSpeedy® Replace.

External hex connection for: Brånemark System® and NobelSpeedy® Groovy.

Intended use:

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.

The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw.

Indications:

For fully edentulous jaws retaining a tissue-supported overdenture.

Indicated for patient with extensive bone or soft tissue loss, with compromised manual dexterity or phonetic concerns. Also to be used when implants are placed too posterior to allow retention by means of a bar. Allows for misangulation up to 30° between implants.

Contraindications:

Ball Abutment is contraindicated for patients:

– who are medically unfit for an oral surgical procedure.

– in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.

– allergic or hypersensitiv to titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium) or gold alloy (gold, platinum, palladium, iridium).

Cautions:

Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulations.

To secure the long term treatment outcome it is advised to provide comprehensive regular patient follow up after implant treatment and to inform about appropriate oral hygiene.

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.

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.

Never exceed **15 Ncm** prosthetic tightening torque for the abutment. Overtightening of abutment may lead to a screw fracture.

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.

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

Handling procedure:

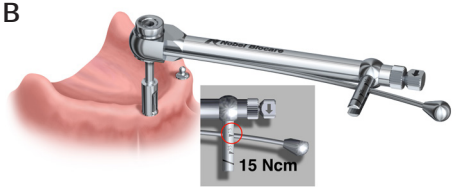
Clinical procedure

1. Choose appropriate abutment height and connect the abutments to implants (**A**).

A

2. Tighten abutments to **15 Ncm** using the Manual Torque Wrench Prosthetic and Screwdriver Machine Ball Abutment (**B**). If the Adapter for NobelReplace® WP to RP is used, push the ball abutment RP through the adapter into the implant and tighten to **15 Ncm** as described above (**C**).

B



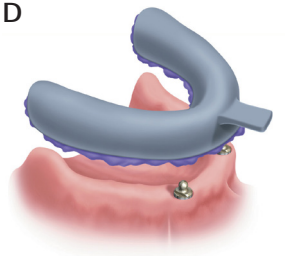
C

3. Take an impression using a custom tray (**D**).
4. Position the ball abutment replicas into the impression.

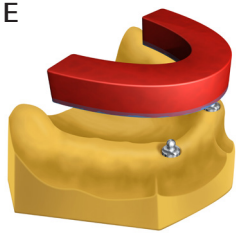
Laboratory procedure

5. Fabricate a model and produce an occlusal rim (**E**).

D



E



Clinical procedure

6. Check jaw relationship by using the occlusal rim. Make sure the rim does not make contact with ball abutments. Record the jaw relationship.

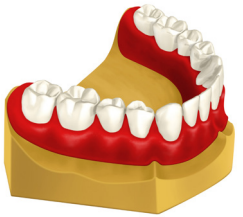
Laboratory procedure

7. Produce a tooth set-up in wax (**F**).

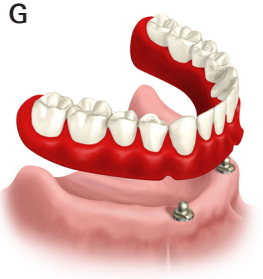
Clinical procedure

8. Evaluate wax set-up (**G**). Make sure that the rim does not make contact with the ball abutments.

F



G



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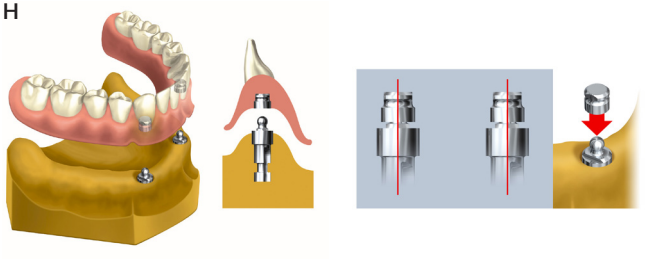
Laboratory procedure

9. Finalize the overdenture and process the gold caps into the overdenture (**H**).

H



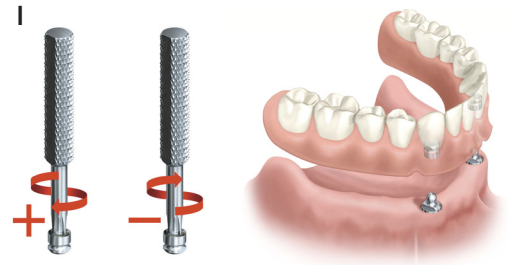
Clinical procedure

10. Use the Screwdriver Machined Ball Abutment and Manual Torque Wrench Prosthetic to verify the tightening of the abutment to **15 Ncm**.

Caution: Never exceed recommended maximum **15 Ncm** prosthetic tightening torque for the abutment screw Over tightening of abutment may lead to a screw fracture.

11. Place the overdenture and verify occlusion. If applicable, adjust the retention and confirm the hinge axis movement. Retention force of Gold Caps should be adjusted to desired retention by turning the lamellae retention insert clockwise (increasing) or counter-clockwise (decreasing) using the Screwdriver/Activator for Gold Cap (**I**).

I



Note: Do not turn the Screwdriver/Activator more than one turn.

Materials:

Ball Abutment: Titanium alloy 90% Ti 6% Al 4% V.

Gold Cap: Gold alloy 60% Au, 19% Pt, 20% Pd, 1% Ir.

Cleaning and sterilization instructions:

Ball Abutment is delivered sterile for single use only prior to the labeled expiration date.

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

Caution: Ball Abutment 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.

MRI 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.

For additional information on Magnetic Resonance Imaging, please consult the "Cleaning & Sterilization Guidelines including MRI Information of Nobel Biocare Products" available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

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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CE 2797

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.

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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

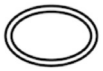
Date

Date of manufacture

Do not resterilize

Do not re-use

Do not use if package is damaged



Double sterile barrier system

Rx Only

For prescription use only

Health care centre or doctor

Keep away from sunlight

Keep dry

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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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