Snappy™ Abutment
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:

A premanufactured dental implant abutment directly connected to the endosseous dental implant intended for use as an aid in prosthetic rehabilitation.

Internal conical connection for NobelActive® CC, NobelReplace® CC and NobelParallel™ CC.

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 two-stage endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. Restorations range from replacing one single tooth to fixed partial dentures using cement- retained supra-constructions.

Indications:

Snappy™ abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended to as an aid in temporary and permanent prosthetic rehabilitation.

Contraindications:

Snappy™ abutment is contraindicated in 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 commercially pure titanium, titanium alloy Ti-6Al-4V (titanium, aluminum, vanadium), polycarbonate and polysulfone.

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 **35 Ncm** prosthetic tightening torque for the abutment screw. 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:

Modifications of abutments could be performed using copious water irrigation using high-speed drilling device and a fine diamond drill.

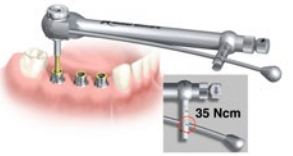
Note: Occlusal reduction of the Snappy™ Abutment should not be performed when planning to use Snappy™ impression coping as retention may be compromised.

Clinical procedure:

1. Select appropriate abutment and check occlusal clearence.
2. Connect the abutment **(A)**. It is recommended to verify the final abutment seating using radiographic imaging.
3. Tighten the abutment to **35 Ncm** using Unigrip™ Screwdriver and Manual Torque Wrench prosthetic **(B)**.
   Caution: Never exceed recommended maximum **35 Ncm** prosthetic tightening torque for the abutment screw. Over tightening of abutment may lead to a screw fracture.
4. Press the impression coping onto the abutment. A "snap" indicates that the impression coping is in place **(C)**.

A

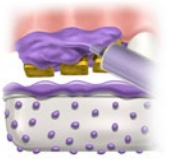
B



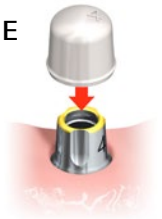
C

5. Take an impression **(D)**
6. Provisionalize using plastic temporary coping or a healing cap **(E)**.
   Caution: Do not use plastic temporary coping with polyurethane cements. The cement will not cure.

D



E



Laboratory procedure:

7. Produce a working model with removable gingival material.
   Caution: When fabricating the model, use only Snappy™ Abutment 4.0 Abutment Replica in corresponding 4.0 Impression Coping and Snappy™ Abutment 5.5 Abutment Replica in corresponding 5.5 Impression Coping. Verify correct fit before casting the model.
8. Fabricate a crown or bridge with NobelProcera® or with conventional casting technique using the plastic copings as burn-out patterns.
9. Complete the restoration with ceramic if applicable.

Clinical procedure:

10. Remove temporary restoration if applicable.
11. Use the Unigrip™ Screwdriver and Manual Torque Wrench prosthetic to verify the tightening of the abutment to **35 Ncm**.
    Caution: Never exceed recommended maximum **35 Ncm** prosthetic tightening torque for the abutment screw. Over tightening of abutment may lead to a screw fracture.
12. Cement the final restoration using conventional procedures after sealing of access hole **(F)**.
    Caution: Do not use temporary cement when cementing ceramic crowns and bridges, due to increased risk of microfractures.

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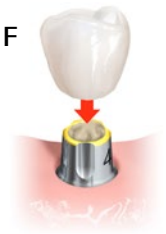
F



Snappy™ Abutment screw chart

	Abutment screw (clinical)	Lab screw
Internal tri-channel connection NP	36818	31170
Internal tri-channel connection RP, WP, 6.0	29475	29293
External hex connection NP	29282	31168
External hex connection RP	29283	29290
External hex connection WP	29284	31169
Internal conical connection NP	37891	37894
Internal conical connection RP/WP	37892	37895

For additional information on restorative and dental laboratory procedures please consult treatment guidelines available at www.nobelbiocare.com or request latest printed version from a Nobel Biocare representative.

Materials:

Abutments with internal conical and tri-channel connection: Titaniumalloy 90% Ti, 6% Al, 4% V.

Abutments with external hex connection: commercially pure titanium.

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

Temporary Coping: Polycarbonate (PC).

Healing Cap: Polysulfone (PS).

Cleaning and sterilization instructions:

Snappy™ 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: Snappy™ 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.

MR safety information:

Note: Only the Conical Connection Wide Platform has been assessed as MR Conditional. The other NobelActive® platform sizes have not been evaluated for safety and compatibility in the MR environment and have not been tested for heating or migration in the MR environment

Non-clinical testing has demonstrated that the device is MR conditional. A patient with this device can be safely scanned in a MR system meeting the following conditions:

– Static magnetic field of 1.5-Tesla and 3.0-Tesla only.

– Maximum spatial gradient magnetic field of 4000 Gauss/cm (40 T/m).

– Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) or 4 W/kg (First Level Controlled Mode).

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of 4.1°C after 15 minutes of continous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 30 mm from the product when imaged with a gradient echo pulse sequence and a 3 Tesla MRI system.

Removable restorations should be taken out prior to scanning, as is done for watches, jewelry etc.

Should there be no MR symbol on the product label, 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/sterilization 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 licenced 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 resterilize


Do not re-use


Do not use if package is damaged

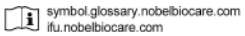

Double sterile barrier system

For prescription use only


Health care centre or doctor


Keep away from sunlight


Keep dry



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

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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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