Snappy™ Abutment

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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

Snappy™ Abutments are premanufactured dental implant abutments which can be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation

The Snappy™ Abutments are intended to be used with the following implant systems:

- Snappy Abutments which feature a conical connection (CC) can be used with Nobel Biocare implants featuring a conical connection.
- Snappy Abutments which feature an Internal Tri-Channel connection can be used with Nobel Biocare implants featuring an Internal Tri-Channel connection.
- Snappy Abutments which feature an external hex connection can be used with Nobel Biocareimplants featuring an external hex connection.

Snappy™ Abutments are co-packed with a clinical screw, an impression coping, a healing cap and a temporary coping.

Refer to Nobel Biocare Instructions for Use (IFU) IFU1057 for information regarding the clinical screw.

Nobel Biocare products are intended and available to be used in a variety of configurations. For further information refer to Nobel Biocare publication Compatibility Information by navigating to ifu.nobelbiocare.com.

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 foun-dation for anchoring tooth replacements in either jaw. Restorations range from replacing one single tooth to fixed partial dentures using cement- retained supra-constructions.

Indications for Use

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

It is contraindicated to use Snappy™ abutments in:

- 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.

Materials

Snappy Abutment 5.5 NobRpl, Snappy Abutment 4.0 NobRpl, Snappy Abutment 5.5 CC NP, Snappy Abutment 5.5 NobRpl NP

Abutment and Screw:
Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Healing cap:
Polysulfone polymer.

Impression coping:
Polyamide 6.6 polymer.

Plastic coping:
Polycarbonate polymer.

Snappy Abutment 5.5 Bmk Syst, Snappy Abutment 4.0 Bmk Syst, Snappy Abutment 5.5 CC RP, Snappy Abutment 4.0 CC WP

Abutment:
Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value).

Screw:
Titanium alloy composed of Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy. Detailed chemical composition of the Titanium alloy is Titanium balanced with 5.50 - 6.50 wt.% Aluminium, 3.5-4.5 wt.% Vanadium, max. 0.25 wt.% Iron, max. 0.13 wt.% Oxygen, max. 0.08 wt.% Carbon, max. 0.05 wt.% Nitrogen, max. 0.012 wt.% Hydrogen, (max. -maximum value). Screw is partly coated by Diamond like Carbon Coating. The coating is metal containing carbon coating, containing tungsten carbide and carbon with chromium interlayer between substrate and Diamond like Carbon coating.

Healing cap:
Polysulfone polymer.

Impression coping:
Polyamide 6.6 polymer.

Plastic coping/Temporary coping:
Polycarbonate polymer.

Cautions

General

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

When using a new device/treatment method for the first time, working with a colleague who is experienced with the new device/treatment method may help avoid possible complications. Nobel Biocare has a global network of mentors available for this purpose.

Before Surgery

Special attention must 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, other parafunctional habits or unfavorable jaw relationships, reappraisal of the treatment option may be considered.

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

All components, instruments and tooling used during the clinical and/or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

At Surgery

Never exceed 35 Ncm prosthetic tightening torque for the abutment screw. Overtightening of abutment may lead to a screw fracture.

Because of the small sizes of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. gauze, dental dam, or throat shield).

Small diameter implants and angled abutments are not recommended for the posterior region.

After Surgery

To help ensure a successful long term-treatment outcome, it is advised to provide comprehensive regular patient follow up after implant treatment and to inform the patient about appropriate oral hygiene.

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 clearance.

2. Connect the abutment (Figure 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 (Figure 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 (Figure C).

Figure A

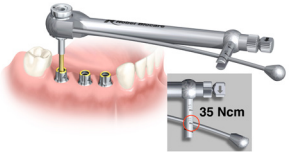

Figure B

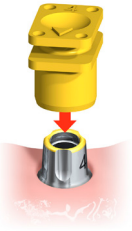

Figure C

5. Take an impression (Figure D)

6. Provisionalize using plastic temporary coping or a healing cap (Figure E).

Caution Do not use plastic temporary coping with polyurethane cements. The cement will not cure.

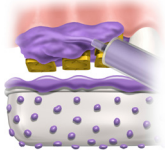

Figure D

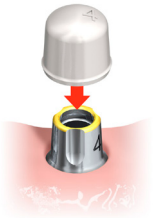

Figure E

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 (Figure F).

Caution Do not use temporary cement when cementing ceramic crowns and bridges, due to increased risk of microfractures.

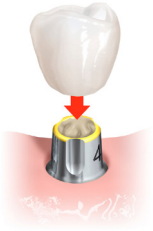

Figure F

Table 1 – 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

Sterility and Reusability Information

Snappy™ Abutments have been sterilized using irradiation and are intended for single use only. Do not use after the labeled expiration date.

Warning Do not use device if the packaging has been damaged or previously opened as the device sterility and/or integrity may be compromised.

Caution Snappy™ Abutments are single use products and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause local or systemic infection.

Magnetic Resonance (MR) Safety Information

These products are fabricated from a metal material which can be affected by MR energy. For further information refer to Nobel Biocare publication **Magnetic Resonance (MR) Safety Information** by navigating to ifu.nobelbiocare.com.

Storage, Handling and Transportation

The device must be stored and transported in dry conditions in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

Disposal

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, re-cycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Manufacturer and Distributor Information

Manufacturer	Nobel Biocare AB PO Box 5190, 402 26 Västra Hamngatan 1 Göteborg 411 17 Sweden www.nobelbiocare.com
Distributed in USA by	Nobel Biocare USA, LLC 22715 Savi Ranch Parkway Yorba Linda, CA, 92887 USA

Caution Federal law restricts this device to sale by or on the order of a licensed physician or dentist.

Legal Statements

Symbols Glossary

Please refer to the packaging label for the applicable symbols related to the product. On the packaging label you may encounter various symbols to convey a specific information about the product and/or its use. For further information refer to Nobel Biocare publication to the **Symbols Glossary** by navigating to ifu.nobelbiocare.com.