

# Abutment Screw Retrieval Instruments

## 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:

Single use Abutment Screw Removers, Abutment Screw Retrieval Instruments, Abutment Screw Retrieval Reverse Drills and the Screw Tap Repairs are delivered sterile. The single use instruments are for one patient and for one surgical treatment only. Please note that the Rescue Drill Guide, the Handle for Implant Rescue Collar & Drill Guide and the Handle for Machine Instruments are not delivered sterile and are reusable.

#### Intended use:

The instruments for abutment screw retrieval can be used if an abutment screw is broken and a part of the screw is left inside the implant screw channel. If the implant thread needs to be cleaned before placing a new screw, a screw tap repair can be used. The instruments are intended for both simple and advanced treatments.

#### Indication:

The instruments for abutment screw retrieval are indicated to remove broken screws for all types of Nobel Biocare connections (i.e. tri-channel, external hex, conical connection).

#### 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 medical grade stainless steel, high speed steel or any of their alloying components.

#### Warnings:

Do not use the instruments for abutment screw retrieval for any purpose other than the retrieval of a broken abutment screws and for implant thread cleaning.

Generous cooling is important when using the Abutment Screw Retrieval Reverse Drill to avoid overheating.

It is strongly recommended that the Abutment Retrieval Instruments are used only with Nobel Biocare related prosthetic components and surgical instruments as combining components with different dimensions can lead to mechanical and/or instrumental failure or damage the tissue.

#### 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.

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

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](http://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 Rescue Drill Guides should be used when drilling to prevent damage of implant internal threads.

The Abutment Screw Retrieval Reverse Drill may damage the implant internal threads and make the implant useless.

#### Surgical procedure:

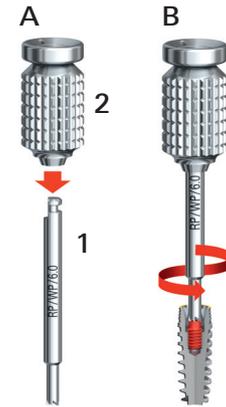
##### Procedure:

**Simple cases/step 1 – abutment/clinical screw broken at head and fragment rotatable.**

In this case, usually no drilling is needed. Abutment/clinical screw can be removed as follows:

**Instruments needed:** Abutment Screw Remover (1), Handle for Machine Instruments (2)

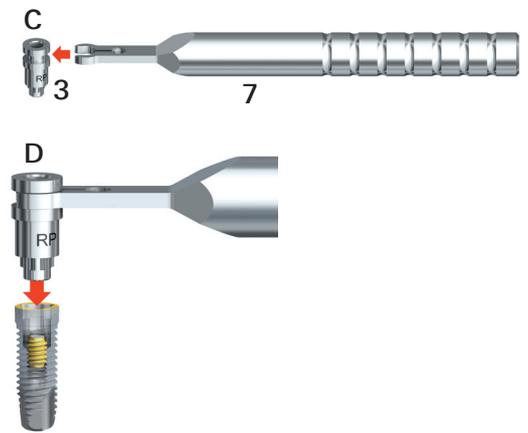
1. Select appropriate Abutment Screw Remover according to laser marking and attach to either a handpiece or a Handle for Machined Instrument (A).
2. To remove the screw shaft from the implant, place the end of the Abutment Screw Remover onto the fractured screw and rotate counter clockwise applying light pressure (B). The slow speed handpiece shall be operating in reverse mode 50 rpm maximum speed. The teeth on the end of the Abutment Screw Remover are designed to grab the screw and back it out.



**Advanced cases/step 2 – remaining abutment/clinical screw fragment not rotatable and either worn out head or broken at thread level.**

**Instruments needed:** Rescue Drill Guide (3), Abutment Screw Retrieval Reverse Drill (4), Abutment Screw Retrieval Instrument (5), Screw Tap Repair (6), Handle for Machine Instruments (2), Handle for Implant Rescue Collar & Drill Guide (7).

1. Select appropriate Rescue Drill Guide based on the implant connection type and size according to laser-marking.
2. Attach the Rescue Drill Guide to the Handle for Implant Rescue Collar & Drill Guide (C) and then connect the Rescue Drill Guide to the interface of the implant (D). The Rescue Drill Guide will support the Abutment Screw Retrieval Reverse Drill to be centered on the screw and allow a secure support when drilling.



3. Select appropriate Abutment Screw Retrieval Reverse Drill according to laser-marking and connect to the handpiece (E).

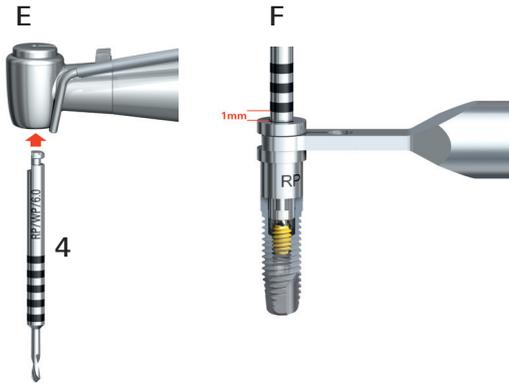
Ensure the drill unit is in reverse mode. Recommended speed is 2000 rpm. Perform the drilling in intervals using copious of irrigation to avoid heating the bone. During the procedure the Rescue Drill Guide can be heated by the drill so always hold the Rescue Drill Guide with the handle. To avoid shavings clogging the guide channel, release the Rescue Drill Guide and air-blast during procedure.

4A. Situation with worn out head: drill a hole to the depth of the screw head, without using the Rescue Drill Guide and the handle. Continue with step 6.

4B. Situation with broken abutment/clinical screw at thread level: drill a hole to a depth of ~1 mm into the fractured screw. Marking on the drill can be used as a support to define the depth. Image shows drill markings of 1 mm (F).

**Warning:** The Abutment Screw Retrieval Reverse Drill may damage the implant's internal threads and make the implant no longer usable. This can be avoided by using the Rescue Drill Guide and not exceeding a depth of 1 mm.

**Warning:** Generous cooling is important when using the Abutment Screw Retrieval Reverse Drill to avoid overheating.



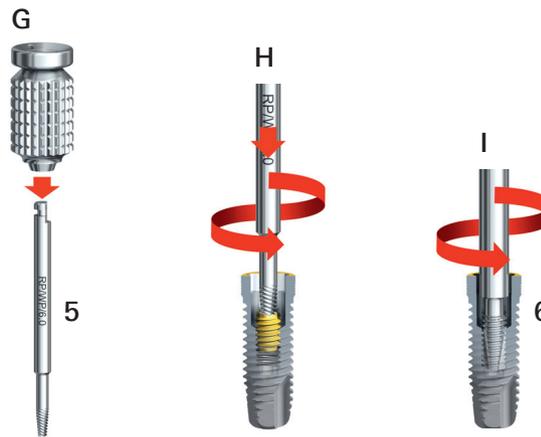
5. During the drilling sequence the fractured abutment/clinical screw might come loose.

6. If the fractured screw is still stuck, remove the Rescue Drill Guide and connect the Abutment Screw Retrieval Instrument to the Handle for Machine Instruments (G). Place the tip of the instrument into the hole in the screw and rotate the handle in counter-clockwise direction (H). Add light pressure until the instrument grip the screw and the screw can be removed.

If the fractured screw cannot be removed with the Handle for Machine Instruments, connect the Abutment Screw Retrieval Instrument to the Manual Torque Wrench Adapter and Manual Torque Wrench Surgical in order to generate more torque. If the Abutment Screw Retrieval Instrument cannot grab the screw, do some further drilling and try again (see step 4).

7. Before a new screw is placed, it is recommended to evaluate the threads inside the implant for damage. This can be done with a guide pin, screw from an impression coping, or healing abutment. If resistance is encountered, a Screw Tap Repair may be used to re-establish the thread design (I). In this case, select the appropriate Screw Tap Repair from the instrument selection guide according to laser-marking. Connect the Screw Tap Repair to the Handle for Machine Instruments or to the hand-piece. Recommended speed is 50 rpm.

8. After successful screw removal, a new screw can be inserted.



For additional information on surgical procedures please consult the "Retrieval instrumentation" procedures manual available at [www.nobelbiocare.com](http://www.nobelbiocare.com) or request latest printed version from a Nobel Biocare representative.

#### **Materials:**

Abutment Screw Removers, Abutment Screw Retrieval Instruments, Screw Tap Repairs, Rescue Drill Guides, Handle for Implant Rescue Collar & Drill Guide, Handle for Machine Instruments: medical grade stainless steel.

Abutment Screw Retrieval Reverse Drills: high speed steel.

#### **Cleaning and sterilization instructions:**

The Abutment Screw Removers, Abutment Screw Retrieval Instruments, Abutment Screw Retrieval Reverse Drills and the Screw Tap Repairs are delivered sterile and are single use only products.

**Caution:** This 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.

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

The Rescue Drill Guide, the Handle for Implant Rescue Collar & Drill Guide and the Handle for Machine Instruments 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.

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](http://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.

CE 0086

CE

Rx Only

STERILE R

NON STERILE

Sterile using irradiation

Non-sterile



Caution



Consult instructions for use



Use-by date



Do not re-use



Batch code



Do not use if package is damaged

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