

## INSTRUCTIONS FOR USE

Date: September 2023

## LOOCID BCP™ NBR SURGICAL IMPLANT DRILL BITS

### INDICATION:

The Loocid BCP™ NBR surgical implant drill bits and instruments are used for bone preparation/conditioning in maxilla and mandible prior to implant placement. The drill bits are compatible with the Nobel Biocare® NobelReplace® Tapered, Nobel Biocare® NobelReplace® Select Tapered and Nobel Biocare® NobelReplace® Conical Connection implant system (<https://www.nobelbiocare.com/en-us/manuals>).

### CONTRAINDICATIONS:

- Risk of damage to anatomical structures in the region of planned treatment.
- Use in patients who are medically unfit for an oral surgery procedure.
- Use in patients allergic or hypersensitive to stainless steel or TiN (titanium nitride) coating.
- Use in patients with inadequate bone volume who might need additional bone graft procedures prior implant surgery.
- Lack of surgical planning/experience causing poor implant placement compromising patient safety and function.

### SAFETY NOTICE:

#### Cutting instruments

All Loocid BCP™ NBR drill bits are made of metal. Each product has the lot number engraved on the shank and a color ring indicating the matching implant diameter. If appropriately cared for, provided they are not damaged and not contaminated, the cutting instruments can be reused up to a maximum of 10 times (1 time = 1 implant) or when cutting efficiency declines. Further use extending beyond this number, or the use of damaged and/or contaminated instruments is not allowed. Maintain a checklist for these instruments recording the number of uses. Any worn or damaged instruments must be immediately removed and replaced with new products. The user information on handling must be followed. The instruments may only be used for the defined purpose. Failure to comply with these safety instructions may lead to injury. All components that are used intraorally must be secured to prevent aspiration or swallowing.

### APPLICATION:

#### Treatment procedure/proper use

General instructions for various surgical techniques are described in specialist literature. Patients must be informed of the generally applicable safety measures and what is expected of them prior to the surgical procedure. It is recommended that 3D Cone Beam Computer Tomography (CBCT) imaging is used in addition to regular radiograph techniques and orthopantomograms to establish the precise position and depth of the drilling. To rule out the risk of damage to adjacent structures, it is essential to evaluate the region of treatment/surgical interest.

**Note: For clinical workflows please turn the page.**

The depth of the drill hole can be determined using the marker rings/depth markings on each drill bit. Loocid BCP™ NBR short implant ( $\leq 11.5$ ) drill bits are used for implant lengths of 8, 10 and 11.5 mm and have the following depth marks: 8, 10 and 11.5 – 13 mm (the lower edge of the mark corresponds to 11.5 mm and the upper edge to 13 mm). Loocid BCP™ NBR long implant ( $\geq 13$ ) drill bits are used for implant lengths of 13 and 16 mm and have the following depth marks: 11.5 – 13 mm (the lower edge of the mark corresponds to 11.5 mm and the upper edge to 13 mm) and 16 mm.

**Warning: Failure to recognize actual lengths of drill bits relative to radiographic and clinical measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended can result in permanent numbness, hemorrhage, and/or other surgical complications.**

**Due to the function and design of the drill bits, the tip of the Loocid BCP™ NBR drill bits extend longer than the implant length when seated. Allow for this additional length when drilling near vital anatomical structures. The drill tip of the Loocid BCP™ 3.5, 4.3 and 5.0 mm is up to 1.0 mm longer than the insertion depth of the implant. The tip of the Loocid BCP™ NBR drill bits  $\varnothing 6.0$  (optional) is 1.5 mm longer than the insertion depth of the implant (see Table 1). The  $\varnothing 2.4$  mm drill bit is true to size. The subsequent drill bits are smaller in diameter than the corresponding implant (see Table 2).**

Table 1: Drill bit lengths

| Implant diameter                | $\varnothing 2.4$ mm | $\varnothing 3.5$ mm | $\varnothing 4.3$ mm | $\varnothing 5.0$ mm | $\varnothing 6.0$ mm |
|---------------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| Additional length drill bit tip | 0.0 mm               | 0.5 mm               | 0.3 mm               | 0.3 mm               | 1.0 mm               |

Table 2: True drill bit diameters

|                       |     |     |     |     |
|-----------------------|-----|-----|-----|-----|
| Implant $\varnothing$ | 3.5 | 4.3 | 5.0 | 6.0 |
| Drill $\varnothing$   | 3.4 | 4.2 | 4.8 | 5.8 |

The Loocid BCP™ NBR cortical reamers only have one depth mark at the shank: 1 – 2 mm (reference for subcrestal placement).

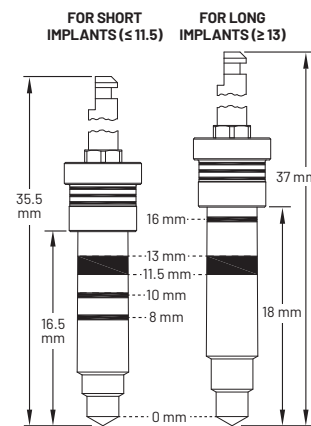
Each Loocid BCP™ NBR drill bit and cortical reamer diameter is color coded according to the NobelReplace® implant system:

- White:  $\varnothing 2.4$  mm
- Yellow:  $\varnothing 4.3$  mm
- Green:  $\varnothing 6.0$  mm
- Purple:  $\varnothing 3.5$  mm
- Blue:  $\varnothing 5.0$  mm

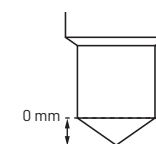
Drilling should be intermittent or continuous with ample external cooling with pre-cooled (5 °C, 41 °F) sterile saline solution. External cooling reduces chances of bone tissue from overheating while providing a clear osteotomy site. Ensure the drill is locked in position prior to use and not tilted. Preparation is carried out with low weight (2.3 kg) down to the desired depth at different speeds depending on clinical workflow. See 1-drill protocol or 2 (or more)-drill protocol on Clinical Workflow BCP™ NBR page.

Alternatively, a depth stop (Loocid BCP™ NBR Depth Control) can be pushed over the drill bit to limit the drilling depth. Each Loocid BCP™ NBR drill bit has a marking at the depth stop connection (one, two or three thin black rings or one wide black ring). See IFU Loocid Depth Control for further information.

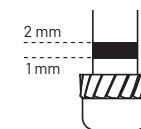
The clinical workflow of Loocid BCP™ NBR drill bits depend on the implant length, the endosteal implant diameter, and the bone class. For more information, please check the clinical workflow on the reverse side.



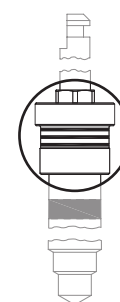
Depth markings on Loocid BCP™ NBR drill bits for short  $\leq 11.5$  (left) and long implants  $\geq 13$  (right).



Additional length of drill bit tip, Table 1.



Cortical reamer with depth mark.



Example of three thin black rings on the  $\varnothing 4.3$  mm drill bit.

### CARE AND MAINTENANCE:

All surgical residues that stick to and dry on the instruments (incrustations) lead to corrosion. Exposing instruments to moisture for longer time also leads to damage and corrosion! Always keep drill bits dry and remove moisture as soon as possible. All system components mentioned in these instructions are supplied non-sterile. Therefore, they must be disinfected and sterilized prior to each use. Prior to first use and after each use, prepare the instruments as described in the IFU Loocid Surgical Tray.

### LIABILITY INFORMATION:

Since the utilization of the product is under the control of the user, the user of Loocid BCP™ NBR drill bits is responsible for their patients and must determine whether this product and protocol is suitable for their patient and clinical circumstance. Loocid LLC 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 judgement or practice in the use of Loocid products. By using Loocid products, the user agrees to these terms described here.

The instructions for use must be read before using the Loocid BCP™ NBR drill bits and auxiliary components. Loocid BCP™ NBR drill bits and instruments are only to be used for dental applications. The following descriptions are not sufficient for ensuring proper use if the user lacks experience in surgical implant treatment. The user must be familiar with dental implant surgery and prosthetics, including diagnostic and preoperative planning. It is strongly recommended that the user, new as well as experienced dental surgeons, go through special training before undertaking any new treatment method. Loocid LLC has a network of mentors available for these purposes. The user is obliged to ensure that the product is suitable for the intended use prior to treatment. In case of doubt, the user must contact Loocid LLC.










### MANUFACTURER:

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For more information please check the Loocid BCP™ workflows for specific implant systems on our website: [www.loocid.com](http://www.loocid.com)

### EXPLANATION OF SYMBOLS:

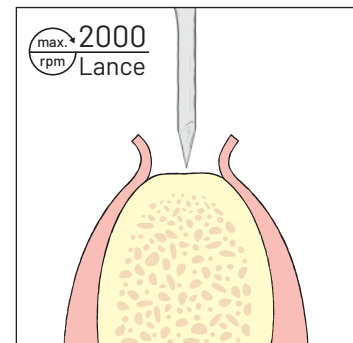
|   |   |   |   |
|---|---|---|---|
|  |  |  |  |
| Manufacturer  | Consult instructions for use  | Batch code  | Catalogue number  |
|  |  |  |  |
| Caution   | Non-sterile   | Do not use if package is damaged  | Product quantity  |
|  |   |   |   |
| Notification required by FDA for United States markets                                |   |   |   |

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NBR SURGICAL TRAY

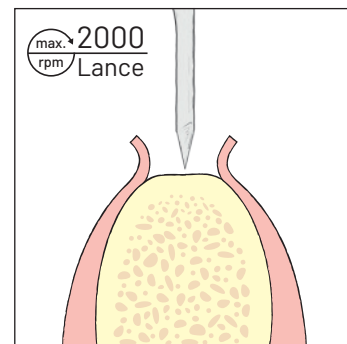
Loocid BCP™ NBR drill bits (compatible with the Nobel Biocare® NobelReplace® Tapered, Nobel Biocare® NobelReplace® Select Tapered and Nobel Biocare® NobelReplace® Conical Connection implant system) are designated for the NBR surgical tray. Only Loocid BCP™ drill bits and cortical reamers should occupy designated spaces on the surgical tray. All other Nobel Biocare® instruments, provided by the clinician, should occupy the other designated spaces on the tray.

1-DRILL PROTOCOL



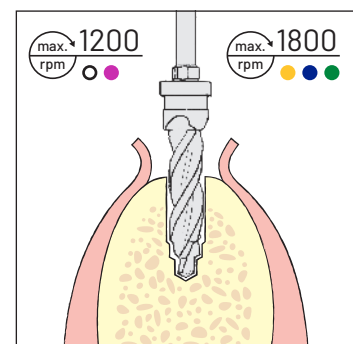
Optional

- Prepare alveolar ridge and mark implant position.
- If using lance instrument, only mark entrance point for osteotomy.
- Carefully reduce and smooth a narrow tapering ridge as needed.



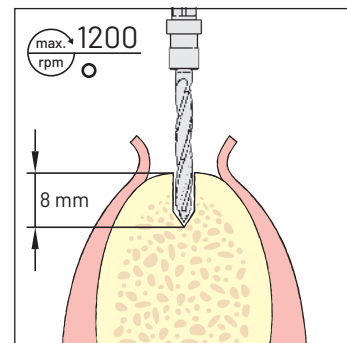
Optional

- Prepare alveolar ridge and mark implant position.
- If using lance instrument, only mark entrance point for osteotomy.
- Carefully reduce and smooth a narrow tapering ridge as needed.



Step 1

- Prepare the implant bed with the correct Loocid BCP™ NBR drill bit to full depth corresponding to the implant diameter and length chosen.
- Drilling should be intermittent or continuous with ample external cooling with pre-cooled (5 °C, 41 °F) sterile saline solution. Ensure the drill is locked in position during use and not tilted. Preparation is carried out with low weight (2.3 kg) down to the desired depth at a speed of 1200 rpm (Ø 2.4 and 3.5 mm) or 1800 rpm (Ø 4.3, 5.0 and 6.0 mm).

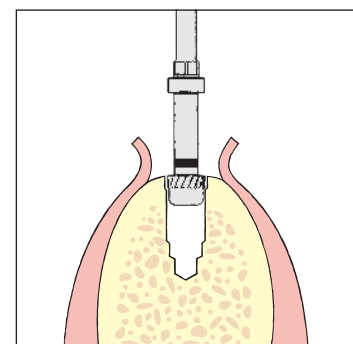


Step 1

- Prepare the implant bed with the Loocid BCP™ NBR drill bit Ø 2.4 up to 8 mm depth.
- Check the implant axis. A parallel pin Ø 2.4 mm can be used to check for correct implant axis orientation and preparation depth.

**Caution:** At this point take an x-ray, particularly in cases of reduced vertical bone availability. The alignment pin is inserted into the drilled area, allowing for a comparative visualization of the drill hole in relation to the anatomical structures.

- Correct the implant bed position, if necessary.

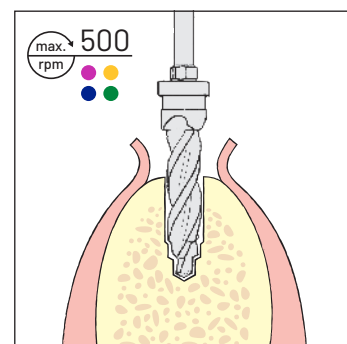


Step 2

In case of denser bone (D1-D2) and medium density bone (D3), the cortical reamer with the corresponding color ring can be used to widen the osteotomy coronally as the implant itself is the widest in the area at the top/platform of the implant. In soft bone quality (D4) the cortical reamer may be not necessary.

Step 3

Now follow your implant company's manual, IFU Nobel Biocare® NobelReplace®, in regard to the specific shaping of the osteotomy, thread tapping and implant insertion.



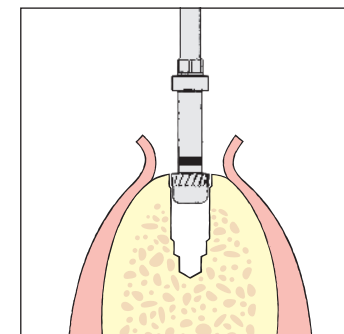
Step 2

- Widen the implant bed with the final Loocid BCP™ NBR drill bit diameter corresponding to the implant being placed.
- Drilling should be intermittent or continuous with ample external cooling with pre-cooled (5 °C, 41 °F) sterile saline solution. Ensure the drill is locked in position during use and not tilted. Preparation is carried out with low weight (2.3 kg) down to the desired depth at a speed of 500 rpm for all diameters.

OR

- Widen the implant bed with a Loocid BCP™ NBR drill bit diameter smaller than the implant being placed. Check the osteotomy, then widen implant bed to final Loocid BCP™ NBR drill bit diameter corresponding to the implant being placed.
- Drilling should be intermittent or continuous with ample external cooling with pre-cooled (5 °C, 41 °F) sterile saline solution. Ensure the drill is locked in position during use and not tilted. Preparation is carried out with low weight (2.3 kg) down to the desired depth at a speed of 500 rpm for all diameters.
- Check the implant osteotomy.

**Warning:** Instruments cut quickly. Reduce rpm as needed to maintain drilling control and use Depth Control.



Step 3

In case of denser bone (D1-D2) and medium density bone (D3), the cortical reamer with the corresponding color ring can be used to widen the osteotomy coronally as the implant itself is the widest in the area at the top/platform of the implant. In soft bone quality (D4) the cortical reamer may be not necessary.

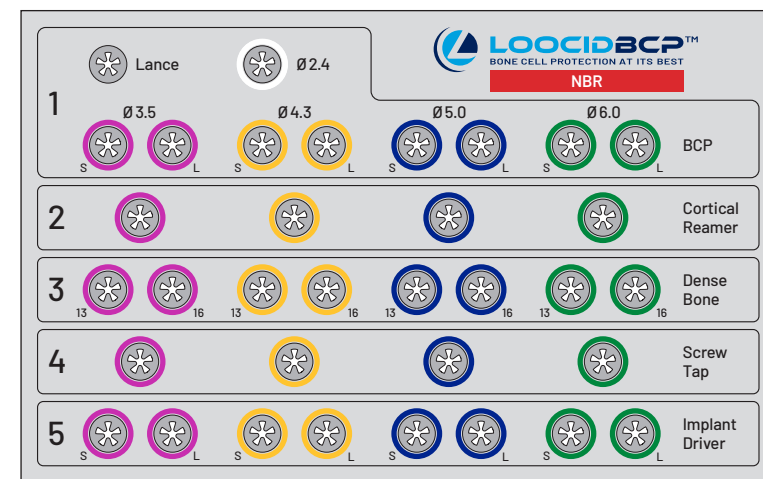
Step 4

Now follow your implant company's manual, IFU Nobel Biocare® NobelReplace® in regard to specific shaping of osteotomy, thread tapping and implant insertion.

EXAMPLE FOR LOOCID BCP™ NBR DRILL BITS:

- Ø 3.5 mm implant corresponds to purple ring drill bit for final osteotomy size.
- Ø 4.3 mm implant corresponds to yellow ring drill bit for final osteotomy size.
- Ø 5.0 mm implant corresponds to blue ring drill bit for final osteotomy size.
- Ø 6.0 mm implant corresponds to green ring drill bit for final osteotomy size.

Please note that there are long and short versions of the drill bits that can vary in their measures.

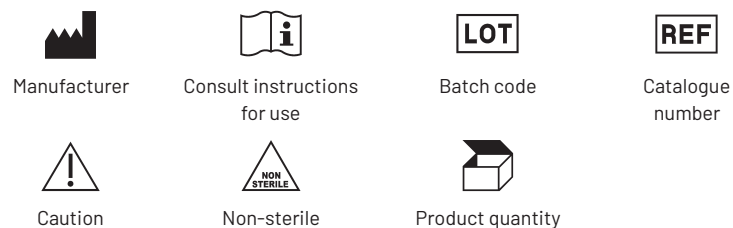


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EXPLANATION OF SYMBOLS:



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