LOOCIDBCP™
BONE CELL PROTECTION AT ITS BEST

INSTRUCTIONS FOR USE

Date: October 2023

UNIVERSAL SURGICAL IMPLANT DRILL BITS: LOOCID BCP™ BONEBLADE LOOCID BCP™ STANDARD

INDICATION:

The Loocid BCP™ surgical implant drill bits and instruments are used for bone preparation/conditioning in the maxilla and mandible prior to implant placement. The drill bits are compatible with most implant systems.

CONTRAINDICATIONS:

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

SAFETY NOTICE:

Cutting instruments

All Loocid BCP™ drill bits are made of metal. Each product has the lot number engraved on the shank and a color ring indicating the drill bit 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:

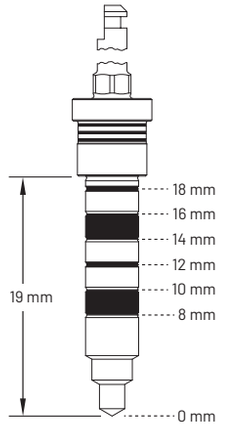
Treatment procedure/proper use

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 spaced 2 mm apart on each drill bit. Loocid BCP™ BoneBlade and Standard universal drill bit with diameter 2.0 mm has one depth mark corresponding to a depth of 6 and 8 mm. All other diameter drill bits have depth marks corresponding to depts of 8, 10, 12, 14, 16 and 18 mm.

The instrument has a working length of 19 mm. Please see image to right for visual.

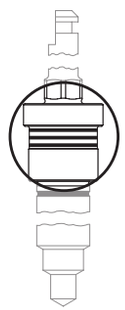


⚠ *Warning: Failure to recognize actual lengths of drill bits relative to radiographic and clinical measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended can result in permanent numbness, hemorrhage, and/or other surgical complications.*

Each Loocid BCP™ BoneBlade is color coded according to the drill bit diameter:

- White: Ø 2.0 mm
- Apricot: Ø 3.2 mm
- Blue: Ø 4.2 mm
- Grey: Ø 2.8 mm
- Green: Ø 3.5 mm
- Red: Ø 4.7 mm
- Light blue: Ø 3.0 mm
- Yellow: Ø 3.7 mm
- Purple: Ø 5.2 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. For clinical workflows, see "IFU Clinical Workflow for Universal Surgical Implant Drill Bits" page.



Example of three thin black rings on the Ø 4.2 mm drill bit.

Alternatively, a depth stop (Loocid BCP™ Depth Control) can be pushed over the drill bit to limit the drilling depth. Each Loocid BCP™ 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 BCP™ Depth Control for further information. Loocid BCP™ Standard surgical drill bits are not compatible with the Depth Control system.

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

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 before 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™ 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™ drill bits and auxiliary components. Loocid BCP™ 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:

Loocid LLC
4300 Biscayne Blvd., Suite 203
Miami, Florida 33137

E-mail: info@loocid.com
Internet: www.loocid.com

For more information please check the Loocid BCP™ workflows for specific implant systems on our website: 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	℞ only Notification required by FDA for United States markets

V.01 - 10/23

DB-UNI-IFU-EN V1

IFU CLINICAL WORKFLOW FOR UNIVERSAL SURGICAL IMPLANT DRILL BITS:
LOOCID BCP™ BONEBLADE
LOOCID BCP™ STANDARD

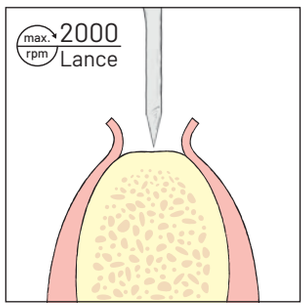
Date: October 2023

UNIVERSAL SURGICAL TRAY

Loocid BCP™ BoneBlade drill bits are designated for the Loocid BCP™ BoneBlade surgical tray. Only Loocid BCP™ drill bits should occupy the designated spaces on the surgical tray. All other instruments, provided by the clinican, should occupy the other designated spaces on the tray.

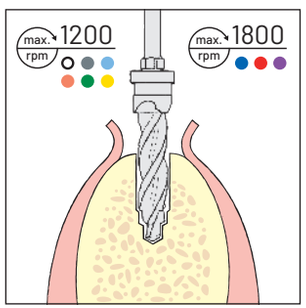
⚠ *Please note: Universal drill bits are not designed to accommodate any specific implant dimension/design.*

1-DRILL PROTOCOL



Optional

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



Step 1

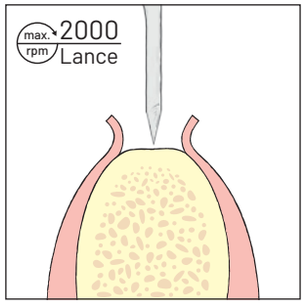
- Prepare the implant bed with the correct Loocid BCP™ drill bit to full depth corresponding to the implant diameter and length chosen.
- Drilling should be intermittent or continuous with ample external cooling with pre-cooled (5 °C, 41 °F) sterile saline solution. Ensure the drill is locked in position 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 2.0, 2.8, 3.0, 3.2, 3.5 and 3.7 mm) or 1800 rpm (Ø 4.2, 4.7 and 5.2 mm).
- Check the implant osteotomy.

⚠ *Warning: Instruments cut quickly. Reduce rpm as needed to maintain drilling control and use corresponding Loocid BCP™ Depth Control system.*

Step 2

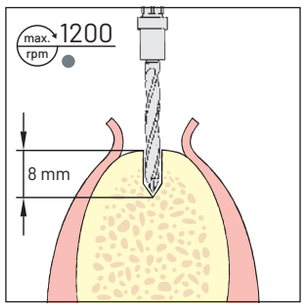
Now follow your implant company's manual in regard to the specific thread tapping and implant insertion.

2 (OR MORE)-DRILL PROTOCOL



Optional

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

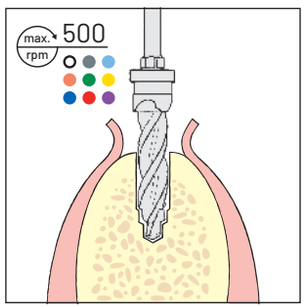


Step 1

- Prepare the implant bed with the Loocid BCP™ drill bit Ø 2.8 up to 8 mm depth.
- Check the implant axis. A parallel pin Ø 2.8 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 parallel 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.



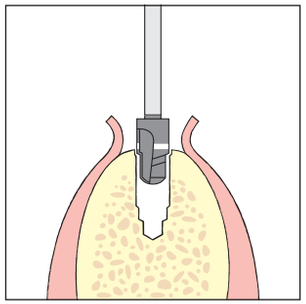
Step 2

- Widen the implant bed with the final Loocid BCP™ 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.

OR

- Widen the implant bed with a Loocid BCP™ drill bit diameter smaller than the implant being placed. Check the osteotomy, then widen implant bed to final Loocid BCP™ 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 Loocid BCP™ Depth Control system.*

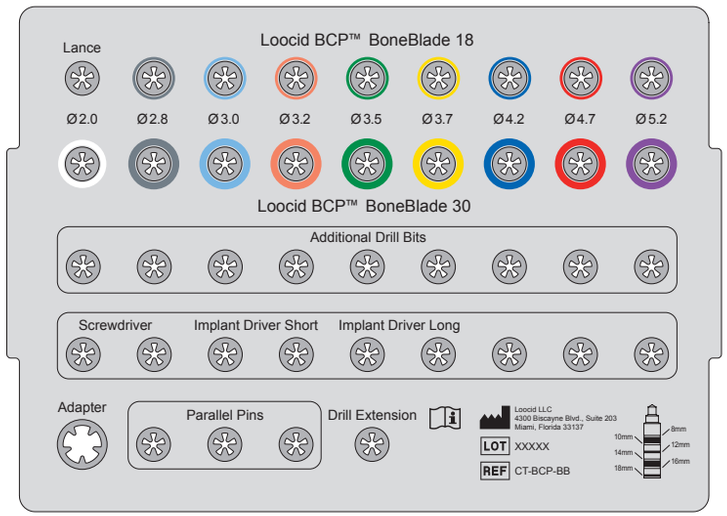


Step 3

Use the final drill bit recommended by the implant company of choice to shape the osteotomy to the implant system.

Step 4

Now follow your implant company's manual.



MANUFACTURER:

Loocid LLC
4300 Biscayne Blvd., Suite 203
Miami, Florida 33137

E-mail: info@loocid.com
Internet: www.loocid.com

EXPLANATION OF SYMBOLS:

Manufacturer

Consult instructions for use

Batch code

Catalogue number

Caution

Non-sterile

Product quantity