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Labrida BioClean®

EN

User's manual for Labrida BioClean®

Read carefully before use.

Product description

Labrida BioClean® is a dental device with a working end of fast-degrading chitosan attached to a stainless steel stem covered with polypropylene.

Labrida BioClean® is a disposable device for mechanical cleaning of dental implants/teeth with inflammation in the surrounding soft tissue. The Labrida BioClean® should be replaced when obvious wear is visible. To remove debris from the bristles, the brush may be rinsed in sterile saline during treatment. Labrida BioClean® cannot be re-sterilised and used a second time.

Properties/functions

Labrida BioClean® is used for gentle debridement of the implant/tooth without damaging the implant/tooth surface. The Labrida BioClean® chitosan product is gentle on soft tissues and any residues left after use dissolve and do not induce foreign body inflammatory reactions. The polypropylene tube, covering the stem, protects against damage or discoloration of prosthetics retained on the dental implant/tooth.

Labrida BioClean® reduces treatment time and allows for gentle and effective mechanical cleaning of dental implants and teeth with inflammation in the surrounding soft tissue.

Indications

Labrida BioClean® is designed for cleaning of osseointegrated dental implants and/or teeth (pocket depths \geq 4mm).

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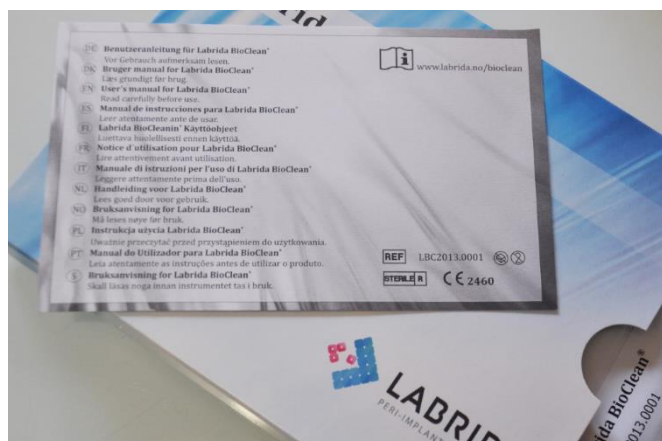
Instructions for use

The Labrida BioClean® is for professional use only. Access to dental unit and proper lighting is needed.

1. Open the box frontside up by sliding the inner box sideways.



2. Read the IFU card which refers to the webpage with the Instructions for Use in your own language. Study the IFU carefully.



3. Tear open one (1) pouch.



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- Drop the holder with Labrida BioClean® carefully into sterile saline.



- Leave it to soak for at least 2 minutes. The chitosan fibers swell, become soft and flexible, and reach optimal strength.
- Remove Labrida BioClean® from the holder. Avoid touching the blue brush bristles with fingers or instruments, since this could damage the chitosan-filaments.

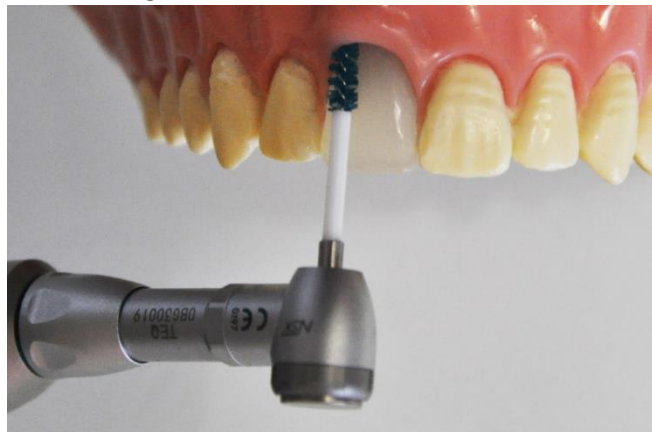


- Mount the brush in an oscillating dental handpiece. Oscillation improves usability and durability of Labrida BioClean®.



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- Place the brush carefully into the pocket around the implant or tooth before starting the handpiece. Oscillate using probing movements, without using pressure or force. Keep contact with the implant or tooth during the full treatment.



- Rinse the peri-implant and/or dental-pocket with sterile saline solution after the treatment with Labrida BioClean®.

Rotational handpieces are not advised.

The product is not designed for rotation speeds above 2000 rpm. When rotation speed is too high, the working end of the product will be destroyed, the stem may break and the brush could detach from the metal mandrel.

Make certain that the product does not wedge itself between the implant/tooth and the surrounding tissue since this could harm the patient or damage the implant/tooth or lead to detachment of the stem from the mandrel. Rinse the implant surface thoroughly with sterile saline solution after finished debridement.


Contraindications

Labrida BioClean® should not be used:

- On patients with an ASA-score ≥ 3 .
- On patients that have reported a reaction to or incompatibility with chitosan, stainless steel, glue or polypropylene.
- On clinically mobile implants.
- On newly seated and not osseointegrated implants.
- Near large nerves and blood vessels if there is a risk for structural damage.

Side effects

Labrida BioClean® is made of chitosan (the working end), surgical steel and propylene (the stem). Chitosan seldom causes side effects, but Labrida BioClean® must not be used on patients who report to have allergy, hypersensitivity or negative reactions against or incompatibility to chitosan, steel or polypropylene.

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Careless use of the product can injure the patient and damage the implant or equipment. Read the instructions in this User's manual for Labrida BioClean® carefully, and do not misuse the product.

Warnings and precautions

- Labrida BioClean® is no replacement for surgery.
- Labrida BioClean® is a disposable product for one-time use only.
- Due to the risk of infection the product must be discarded after use.
- The product cannot and must not be re-sterilised.
- The product must not be used if the inner package is no longer sealed, if it is damaged, or visually contaminated.
- The product must not be used if it is damaged.
- The product must not be used if the expiration date has passed.

The risk of complications can be minimised by correct patient selection, using good operating routines and through the correct use of Labrida BioClean® (Including compliance with the instructions in the paragraphs on contraindications, warnings and precautions listed above). In case of inhalation or swallowing of the brush or parts of it (except chitosan fibres), refer the patient to adequate medical care immediately.

Additional information

Please visit our website (www.labrida.no) for additional and updated information on Labrida BioClean®.

Validity

The validity of all previous versions of the user's manual expire upon the publication of any new version.

Ordering information

REF LBC2013.0001

Labrida BioClean®

Labrida BioClean® is manufactured by LABRIDA AS

€ 2460

LABRIDA AS

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