

Implant boxes – Accessories for BactoSonic

The implant boxes are sample containers and accessories for the BactoSonic. They are offered in various sizes, are waterproof and are used to hold implants. The material of the boxes is polypropylene, while the seals are made of silicone.

| Code no. | Designation | Print on the implant box |
|----------|-------------|--------------------------|
| 3280 | IB 5 | HPL 311 |
| 3281 | IB 6 | HPL 933 |
| 3282 | IB 10 | HPL 842 |
| 3283 | IB 18 | HPL 322 |
| 3284 | IB 20 | HPL 819 |

When the implant box is used in conjunction with the BactoSonic, the operating instructions for the ultrasonic bath must be followed.

The products are Class A in vitro diagnostic medical devices per Regulation (EU) 2017/746.




Cleaning, disinfection and sterilisation must be carried out before each use and before disposal.

delivered is non-sterile.

Place of use

For use in clinics, practices and laboratories.

Safety instructions

 **Risk of infection**

The products come into contact with contaminated implants as part of their intended use. There is a risk of infection when handling.

- Wear suitable protective gloves and, if necessary, other personal protective equipment.
- Do not use damaged products.

Storage and transport

Storage, transport and use between 10°C and 121°C.

Preparation before cleaning

The person performing the treatment is responsible for the treatment actually carried out with the equipment, materials and personnel used achieving the desired result.

To treat, disassemble the implant box into its lower part, lid and seal. Do not damage the seal in the process.

NOTICE

Do not use sharp or pointed objects to remove the seal.

To make it easier to remove the seal, lightly tap the wet lid against a hard surface until the seal loosens.

Treatment (mechanical)

Equipment required:

Use a cleaning/disinfection device (CDD in accordance with DIN EN ISO 15883) and a mildly alkaline detergent.

- Insert the lower part, lid and seal into the device in such a way that complete contact with the detergent is ensured and the liquid can drain away. Make sure that the inserted parts are not exposed to mechanical stress.
- Use a validated cleaning programme with thermal disinfection at at least 90 °C and approx. 100 °C in the drying phase in the cleaning-disinfection device.
- When removing the lower part, lid and seal, perform a visual inspection for impurities. If necessary, repeat the cycle or clean manually.

Treatment (manual)

Equipment required:

Ultrasonic bath with sonication liquid.

A solution made of water and a special ultrasonic preparation is used as the sonication liquid.

We recommend the ultrasonic preparation STAMMOPUR DR 8, which is a VAH-certified preparation for disinfection and cleaning. The information on use in the usage instructions of the detergent and disinfectant must be observed!

Other mildly alkaline preparations that can be used in ultrasonic baths are also permitted.

Do not heat the ultrasonic bath.

Do not exceed 121 °C during the entire treatment process.

- Place parts on the basket or utensil holder.
- Insert the lower part, lid and seal into the bath in such a way that there is complete contact with the detergent and disinfectant on all surfaces, i.e., all surfaces are covered with the liquid.
- Run the ultrasonic bath: the duration of sonication must be selected in accordance with the usage instructions of the preparation used.

- When removing the parts, perform a visual inspection for impurities. If necessary, repeat sonication.
- Rinse the lower part, lid and seal thoroughly under running water and dry with a lint-free, soft and absorbent cloth.

NOTICE

Do not use abrasives or brushes.

Control and verification

Reassemble the lower part and lid with the seal. Perform a visual inspection for wear and damage, especially on the safety closures. It should be easy to fit the lid onto the lower part.

Limitations on treatment

Frequent treatment has only a minor effect on the implant boxes. Their lifespan is determined by wear and damage during use.

Packing

Disassemble the implant boxes again. Standard packing material can be used; double sterile packing is recommended.

Sterilisation

NOTICE

The lower part, lid and seal must be handled in a dis-assembled state and in sterile packing. The product is thermolabile. Do not exceed 121 °C.

Procedure:

Steam sterilisation with fractional prevacuum (in a steam steriliser in accordance with DIN EN 13060 and/or DIN EN 285)

Temperature: 121 °C, min. duration 15 mins.

Sterilisation according to a procedure validated by the user.

Storage


No specific restrictions.

The regulations for the storage of sterile goods must be observed.

Reporting obligation

Serious incidents must be reported to BANDELIN electronic GmbH & Co. KG and the competent authority.


Contact with the manufacturer:



 **BANDELIN electronic GmbH & Co. KG**
Heinrichstrasse 3-4
12207 Berlin
Phone: + 49 30 768 80-0
Fax: + 49 30 773 46 99



For information and questions about the procedure, please send an email to info@bactosonic.com.




Spare parts

| Code no. | Designation | Silicone seal for: |
|----------|-------------|--------------------|
| 32800 | DI 5 | IB 5 |
| 32810 | DI 6 | IB 6 |
| 32820 | DI 10 | IB 10 |
| 32830 | DI 18 | IB 18 |
| 32840 | DI 20 | IB 20 |




www.manuals.bandelin.com



info@bandelin.com
 : +49 30 768 80-0
 : +49 30 773 46 99