


## 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, the respective seals are made of silicone.

Code No.	Description	Text on 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 using the implant box in conjunction with the BactoSonic, observe the instructions for use of the ultrasonic bath.

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

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

The product is delivered in non-sterile condition.

### Places of usage

For use in hospitals, doctor's surgeries and laboratories.

### Safety instructions



#### Risk of infection

As part of their intended use, the products come into contact with contaminated implants. There is a risk of infection when handling them.

- 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 120 °C.

### Preparation before cleaning

It is the responsibility of the preparer to ensure that the actual treatment carried out with the equipment, materials and personnel utilised, achieves the desired result.

To prepare the implant box, place it in the bottom part, with lid and seal. Be careful not to damage the gasket.

#### ATTENTION

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

For easier removal of the seal, lightly tap the wet lid against a hard surface until the seal loosens.

## Treatment (automatic)

### Equipment:

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

- Insert the bottom part, lid and seal into the device in such a way that full contact with the cleaning agent is guaranteed and the liquid can drain off. Ensure that the inserted parts are not subjected to mechanical stress.
- Use a validated cleaning program with thermal disinfection at a minimum of 90 °C and approx. 100 °C during the drying phase in the cleaning/disinfection device. Do not exceed 120 °C during the entire treatment process.
- When removing the bottom part, lid and seal, visually check for contamination. Repeat the cycle or clean manually if needed.

## Treatment (manual)

### Equipment:

Ultrasonic bath with sonication fluid.

A solution of water and a special ultrasound preparation is used as the sonication fluid.

We recommend the ultrasound preparation STAMMOPUR DR 8, which is a VAH-certified preparation for disinfection and cleaning. Observe the application tips in the instructions for use of the cleaning agent and disinfectant!

Other mildly alkaline preparations that allow use in the ultrasonic bath are also permitted.

Do not heat the ultrasonic bath.

Do not exceed 120 °C during the entire treatment process.

- Place parts on a basket or utensil holder.
- Insert the bottom part, lid and seal into the bath in such a way that they make complete contact with the cleaning and disinfection agent on all surfaces, i.e. that all surfaces are covered with the liquid.
- Operate ultrasonic bath: The sonication time should be selected in accordance with the instructions for use of the preparation used.
- When removing the parts, carry out a visual

inspection for contamination. Repeat sonication as required.

- Rinse the bottom part, lid and seal thoroughly under running water and dry with a lint-free, soft and absorbent cloth.

### ATTENTION

Do not use abrasives or brushes.

## Inspection and testing

Reassemble the bottom part and lid with seal. Carry out a visual inspection for wear and damage, particularly on the safety seals. It should be easy to place the lid on the base.

## Limitations of treatment

Frequent treatments only have a minor effect on the implant boxes. The lifespan is defined by wear and damage during use.

## Packaging

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

## Sterilisation

### ATTENTION

The bottom part, lid and seal must be handled separately in sterile goods packaging. The product is thermolabile. Do not exceed 120 °C.

### Procedure:

Gas plasma sterilisation, e.g. using hydrogen peroxide. Temperature below 55 °C.

Maximum duration 105 minutes.

### Alternative:

Low-temperature sterilisation using the formaldehyde water vapour process (low temperature sterilisation process) in a temperature range between 55 - 75 °C. (according to ISO 25424).

Sterilisation according to a procedure validated by the user.

## Positioning

No specific restrictions.

The regulations for storing sterile goods must be observed.

## Duty of disclosure

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

## Manufacturer contact



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For additional instructions and queries regarding this process, please send an email to [info@bactosonic.com](mailto:info@bactosonic.com).

The diagram illustrates the process of accessing user manuals. At the top, a speech bubble icon contains a document symbol and the letter 'A'. Below this, a laptop displays a globe icon, and a QR code is shown to its right. Arrows from both the laptop and the QR code point to a central circular icon depicting a person reading a document. To the right of this central icon is a PDF icon. Below the diagram, the website [www.manuals.bandelin.com](http://www.manuals.bandelin.com) is listed. At the bottom, an envelope icon is next to the email address [info@bandelin.com](mailto:info@bandelin.com), followed by the phone number +49 30 768 80-0 and the fax number +49 30 773 46 99.