



USER MANUAL

UM 01 Rev.1.2 FROM 05/10/23

OLV Series Autoclavable Box User Manual

Storage

After using the tools, the autoclavable box must be placed in a protected place to avoid unnecessary contamination until re-use.

Disposal

Once the boxes can no longer be used, they can be sent back to Ippi S.r.l. for proper disposal. The silicone grommets made of VMQ 60 by TSF S.r.l. are classified by the manufacturer as EWC 07 02 17 (non-hazardous waste containing silicones). Please remember that the correct application of the EWC code depends on the transformation process performed by the consumer and must be determined by the consumer in agreement with the waste disposal company. The box and tray are made of Radel®. For disposal, Solvay requires the product to be incinerated at a suitable incineration facility with authorization by the proper authorities. Where local regulations allow, it can be disposed of in a landfill.

Maintenance

Apart from the pre-treatment procedure described above, no other maintenance is required.

Technical Information

The autoclavable box and tray are made of Radel® by Solvay Advanced Polymers Llc; the silicon supports are made of VMQ silicone compounds by TSF S.r.l. (compound made of R 401 60 rubber). Upon request, Ippi S.r.l. can supply material safety data sheets and food certifications of the materials used.

Any serious incident occurring in relation to the device must be reported to the manufacturer and the competent authority of the user’s home country.
Manufacturer: info@ippi.it

Competent authority in Italy – Ministry of Health:
<http://www.salute.gov.it/portale/home.html>



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Product Identification
Product: *This manual refers to the OLV Series.*
Product Type: *Autoclavable boxes for the autoclave sterilization of surgical tools.*
Manufacturer: *Ippi S.r.l. – Via Brodolini, 22-24-26 – 40056 Valsamoggia, loc. Crespellano (Bologna, Italy) – VAT no. 00305440372 – REA 203807*
CE marking: *Class 1 medical device (accessory for a medical device), in accordance with (EU) Regulation 2017/745. The intervention of a notified body is not required for Class 1 Medical Devices. T*

- Package Contents**
The package contains:
- Autoclavable box, complete with base and pre-assembled cover;
 - Perforated tray;
 - Silicon supports for surgical tools and/or laboratory instruments to be mounted on the tray;
 - “Product details” and “User manual”.



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Warning!!

The customer may request that the OLV box be supplied:

- With an unperforated tray;
- Without the silicone supports.

In these circumstances, the OLV series boxes cannot perform their intended use because they are not able to hold instruments or tools in the correct position. If the customer decides to create its own perforations and choose its own supports, the customer then assumes all responsibility for the purchase of any non-original parts.

Ippi S.r.l. declines all responsibility for any risks or hazards derived from the use of non-original material.

The silicone supports may be purchased separately in order to change color or to replace lost or worn-out components.

Ippi S.r.l. offers supports for cylindrical tools of various diameters and silicone supports for a variety of different tools.

Upon request, Ippi S.r.l. can send samples to assist customers in their choice of the best support for the instrument to be sterilized.

Intended use and performance characteristics

IPPI S.r.l.'s OLV Series of autoclavable boxes are conceived and designed to contain and hold surgical instruments and tools in the proper position during transport and autoclave sterilization.

The autoclavable boxes have been designed for the sterilization cycles of small steam sterilizers used for medical purposes or for material contaminated with blood or bodily fluids.

The product is intended for outpatient use.

The product is intended for use by medical or paramedical personnel familiar with the autoclave sterilization process.

The OLV Series autoclavable boxes are designed to:

- keep tools in the correct position for transport and storage as well as during and after the autoclave sterilization cycle;
- enable the correct performance of the sterilization process, allowing steam to penetrate inside the box;
- keep the utensils it holds uncontaminated during and after the autoclave sterilization process; the boxes can therefore be sterilized together with the surgical tools.

The cleaning, disinfecting and sterilization processes have been validated by the manufacturer through laboratory tests which confirm their effectiveness

Contraindications/risks/side-effects

There are no known contraindications, residual risks or side-effects.



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Cleaning and disinfection (method validated by the manufacturer)

Pre-treatment

Pre-treatment is only necessary in cases of suspected contamination with biological material or in cases of prolonged periods of inactivity. If the autoclavable boxes are suspected of being contaminated with biological material and/or after a prolonged period of inactivity, it is recommended that the silicon pads and supports be removed from the tray and to deep clean the box and its parts, removing the most significant impurities from the plastic with a jet of room-temperature water and a brush. Make sure the box is completely dry before reassembly. A visual inspection can verify the intactness of the box and the tray.

Manual cleaning

Immerse in a HI CARE 2.0 PERACETIX DROX detergent solution at a concentration of 5 g/l. There is no need to disassemble the silicon pads and tray supports. Place the box in an ultrasonic bath for 10 min. Rinse all devices with room temperature tap water for 1 minute to eliminate any remaining traces of detergent. Pay close attention to the dosages of the products used and the treatment times indicated by the manufacturer.

Manual disinfection

Immerse in a HI CARE 2.0 PERACETIX DROX detergent solution at a concentration of 20 g/l. There is no need to disassemble the silicon pads and tray supports. Place the box in an ultrasonic bath for 10 min. Rinse all devices with room temperature tap water for 1 minute to eliminate any remaining traces of detergent. Pay close attention to the dosages of the products used and the treatment times indicated by the manufacturer. Dry the devices with a clean, soft cloth.

Directions for use

Box sterilization (process validated by the manufacturer in accordance with ISO 17665-1:2006 and ISO / TS 17665-2:2009).

Place the tools to be sterilized in their proper supports which will immobilize them during handling and the sterilization cycle. Laboratory tools should be inserted into the silicon support by their shanks, leaving the area to be sterilized uncovered. Surgical tools should be inserted handle first and not by their working end. The tray with utensils should be placed inside the box, which can then be closed.

The autoclavable boxes cannot keep the contents sterile; to obtain this result, the autoclavable boxes with their contents must be placed in bags capable of maintaining their state of sterility.

Sterilize instruments in a steam autoclave at a temperature of 134°C for 4 minutes.



Consult the respective user manuals to verify the compatibility of the sterilization cycles indicated for the autoclave, tools, and the autoclavable box.