

Cristófoli, Brazilian importing company and manufacturer of health products certified by ISO 13485 - Health Products - Quality Management System - Requirements for Regulatory Purposes and compliance with RDC 665/2022 - *BPF - Boas Práticas de Fabricação - ANVISA requirements.

Cristófoli Mini-incubador

CRISTÓFOLI'S MISSION

Develop innovative solutions to protect life and promote health.

CRISTÓFOLI'S QUALITY AND ENVIRONMENTAL POLICY

Cristófoli Equipamentos de Biossegurança Ltda., established at Rua São José, 3209, Área Urbanizada II in Campo Mourão, Paraná, Brasil, manufactures biosafety equipment to assist the health field having as policy: "Develop innovative solutions for the health field by using agile, robust and objective processes to better serve its clients. Fulfill the requirements for regulatory purposes of the applicable standards, promote the continuous improvement of its quality and environmental systems, prevent pollution, reduce its environmental impacts and continuous training of its employees, achieving this way, a sustainable profitability and the maximization of the company's value". Rev. 2.

*BPF - Boas Práticas de Fabricação: Brazilian standard similar to the GMP - Good Manufacturing Practices (FDA / US).

"Cristófoli. Valuing life!"

Thanks for choosing us. You, our clients, are the reason of Cristófoli's commitment.

We put together this manual to guide you as best as possible, in the use and maintenance of your Cristófoli Mini-incubador.

We would like to thank all our customers and partners for helping us to continually improve and innovate our products and services.

Special thanks to Liliانا J. P. Donatelli, Cristófoli's Biosafety Consultant who provides us a valuable assistance in the coordination of the Cristófoli's Biosafety Project, complementary products research, our employees, representatives and technicians trainings, and as a lecturer of Biosafety Courses for professionals, academics and assistants.

For any complaints about our products, please get in touch with our CSD - Customer Service Department, through the address below.

INTRODUCTION

This equipment was developed to assist you in the important procedure of incubating the self-contained biological indicators used to monitor steam sterilization autoclave cycles. We dedicated ourselves intensively to guarantee you the highest quality and safety. We hope to obtain this way, the highest level of satisfaction from our clients.

The purpose of this manual is to familiarize you with the features and proper operation of your **Cristófoli Mini-incubator** so you know how to take good care of it, obtain the best results in the incubation process, as well as increase the equipment lifespan.

We recommend extra attention to this manual, the incubation process, although simple, requires familiarization with the procedure.

All the data on biosafety in this manual were taken, fully or partially, from publications of renowned biosafety professors based on the Brazilian Legislation or on International Standards to offer updated information about the monitoring process.

It is important to know some aspects that can void this warranty as a result of negligence, improper use, non-authorized repairs, etc.

You will find the Warranty Certificate on page 4.

Manufacturer
Cristófoli Equipamentos de Biossegurança Ltda.
Rua São José, 3209 - Campo Mourão - PR - Brasil.
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CNPJ 01.177.248/0001-95 - Inscr. Est. 90104860-65
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Responsible Technician
Eduardo Luiz Soppa
CREA-PR: 109201/D

LEGEND OF SYMBOLS



Caution, consult accompanying documents



Autoclavable



Alternate Current



Caution!
Hot Surface



Date of
Manufacture



Maximum Pile



Equipment
Class II



This Side Up



Fragile
Handle with Care



Keep Dry



Batch Number



Serial Number



Keep Away from
Sunlight



Recyclable



Manufacturer

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IMPORTANT SAFETY INFORMATION

The intended use of this equipment is to perform the incubation of the self-contained biological indicators used to monitor the sterilization cycles in steam autoclaves. It is essential that the operator reads attentively all the instructions before using the mini-incubator to make sure they are correctly understood.

SAFETY STEPS TO PROPERLY OPERATE YOUR CRISTÓFOLI MINI-INCUBATOR

WARNING! Always make sure you unplug the equipment to perform any kind of maintenance or everyday cleaning.

- **We recommend** reading this manual until it is fully understood. Keep it at hand and use it as a constant reference source;
- **Do not** allow patients or especially children to get close to the device;
- Use **only** the self-contained biological indicator described in this manual;
- **Never** touch the incubation area (Fig. 2, page 2) during or right after using the mini-incubator. **Improper use may cause burns. Cristófoli is not responsible for incorrect procedures that may cause accidents;**
- Make sure the mini-incubator's lid is properly closed before using it. **Not following this procedure will prevent its correct functioning.** See "How to Use the Cristófoli Mini-incubator" (Page 2).
- **WARNING!** Never put any kind of object inside the mini-incubator different than a self-contained biological indicator or make any use other than the one described in this manual.

PLEASE, READ ALL THE INSTRUCTIONS IN THIS MANUAL BEFORE USING YOUR CRISTÓFOLI MINI-INCUBATOR. INCORRECT USE MAY RESULT IN INCUBATION FAILURE, INCORRECT INTERPRETATION OF THE RESULTS AND/OR ACCIDENTS !

INSTALLATION INSTRUCTIONS

The storage/installation must be done in a place protected from the weather action (indoors) in normal conditions of ambient temperature.

The Cristófoli Mini-incubator can be easily installed. Check if the wiring voltage of your building is in accordance with the mini-incubator specifications consulting the "Technical Data" (Page 4) at the time of installation. See "Warranty Certificate" and "How to Proceed When Service is Needed" (Page 4).

PHYSICAL INSTALLATION

Install the mini-incubator on a flat, leveled and firm surface, at an adequate height for the operator to handle it. Leave enough room close to the mini-incubator for the proper handling of the biological indicators to be incubated. The place where the mini-incubator will be installed must be ventilated, clean and apart from the place where the patients are treated. The ideal installation should be done in a separate sterilization and/or material processing room.

Important! Install your mini-incubator where it can be easily unplugged. This is the proper way to turn the equipment off completely.

ELECTRICAL INSTALLATION

- 1► The voltage of the Cristófoli Mini-incubator is from 90V to 253V (automatic voltage selection), as informed in the identification label located under the device (Fig. 3). Make sure the wiring voltage where it will be installed is in accordance with the values marked in the field **Voltage** of the Identification Label. **ATTENTION! Non compliance with this requirement may damage your mini-incubator. Cristófoli is not responsible for damages caused by inappropriate installations and/or voltage.**
- 2► Use a common outlet to plug it in (two pins, Figs. 1 and 1A).
- 3► **Never** use extensions, voltage transformers or any kind of adapters.

The electrical installation must follow the data from the table below:

MODEL	AMPERAGE	VOLTAGE
Cristófoli Mini-incubator	0,07	90V - 253V AC automatic voltage selection

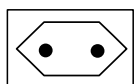


Fig. 1

Bipolar outlet and plug
(two pins) 10 A.

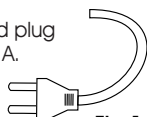


Fig. 1A

SAFETY DEVICES

Your Cristófoli Mini-incubator has the following safety devices:

- 1► **LID** - It closes the incubation area during operation, helping to maintain the temperature stable and protect the operator from accidental burns (Fig. 2).
- 2► **PRINTED FUSE** - Built into the electronic circuit, its purpose is to protect the building electrical wiring against peaks of energy.

MINI-INCUBATOR FEATURES

- **MAIN UNIT** - It is made with injected ABS plastic, white on the lower half and transparent on the top half (Fig. 2).
- **LID** - Its function is to close the incubation area during operation to maintain the temperature stable (Fig. 2).
- **POWER CABLE** - Used to connect the equipment to the electric outlet (Fig. 3).
- **INCUBATION AREA** - Screwed to main unit, it is where the indicators are inserted for incubation. It has a capacity for 4 biological indicators (Fig. 2).
- **LED** - It indicates when the mini-incubator is on, it also illuminates the incubation area, making the visualization of the results easy and clear (Fig. 2).
- **IDENTIFICATION LABEL** - Affixed under the device, its function is to identify the mini-incubator technical data (Fig. 3).

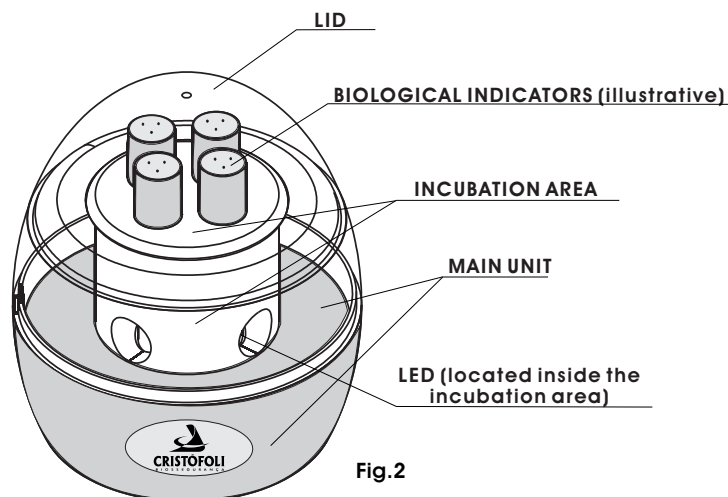


Fig. 2

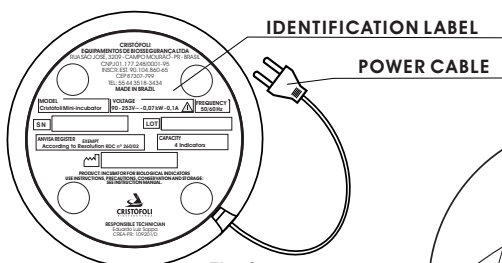


Fig. 3

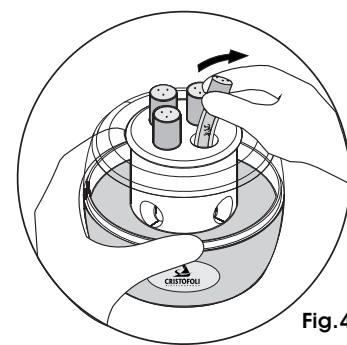


Fig. 4

HOW TO USE THE CRISTÓFOLI MINI-INCUBATOR

ATTENTION! Before starting the incubation procedures, the operator must be using latex gloves. Handle the biological indicators carefully. The mini-incubator must be installed in a proper and exclusive sterilization and/or materials processing room.

The symbol 14A appears in the identification label of the mini-incubator, that means the selected item requires special attention and that the user/operator must observe its reference in the instruction manual provided with the equipment regarding the potential hazard the device may offer and any actions to be taken should an adverse situation occur. Cristófoli Equipamentos de Biossegurança Ltda., is not responsible for any failures and/or accidents caused by the non-observance of this warning.

ATTENTION! Use only self-contained biological indicators for steam sterilization with the mini-incubator. Non-observance of this recommendation may cause incubation failure, poor interpretation of the results and/or damage to the device, as well as loss of warranty.

"Correct functioning of sterilization cycles should be verified for each sterilizer by the periodic use (at least weekly) of Bis". (Centers for Disease Control and Prevention. Guidelines for Infection Control in Dental Health-Care Settings - 2003. MMWR; 52 (No. RR-17): page 24). Each institution must also, according to the Brazilian Health Ministry, establish a monitoring routine of its autoclaves, with the objective of detecting faults in their equipment and/or process.

In hospitals, monitoring must be done on a daily basis (AORN, 1994). A biological indicator must be used for every sterilizer load that contains an implantable device. The load can only be released after the results of incubation are known.

Use only biological indicators for steam (56°C)

- 1 - Plug the mini-incubator into the outlet. The white LED will light indicating the device is on;
Note: The incubation temperature is 56°C. Wait for the temperature adjustment which will take from 40 to 60 minutes;
- 2 - After being sterilized according to its manufacturer instructions, remove the indicator from the autoclave, wait 15 minutes, activate it and insert it into the incubation area, activate also another indicator from the same batch that was not autoclaved to serve as a control;
Note: To activate the biological indicator, hold the mini-incubator firmly and insert it half way in any of the available incubation orifices (Fig. 4), press it carefully in any direction until you feel that the internal glass ampoule has broken, bring it back to its due position and slide it into the incubation area.
- 3 - Wait for the correct incubation time according to the instructions of your biological indicator manufacturer (24 or 48 hours);
Note: It is important that during the incubation period, the lid is always closed to keep the temperature steady, open it only when necessary (insert or remove the biological indicators).
- 4 - After the time needed for the incubation has elapsed, remove the biological indicator from the incubation area and check the results.
It is recommended to examine the biological indicators at regular intervals to verify the color change (example, 12, 16, 20, 24 and 48 hours). Bacterial growth is indicated by the color change of the biological indicator according to the manufacturer instructions.
Note: To cancel the incubation process, simply unplug it from the electric outlet.

VIDEO: STERILIZATION MONITORING

Watch the video "Sterilization Monitoring in table top autoclaves" (Monitorização da Esterilização em Autoclaves - Indicadores Biológicos - Parte II), which contains instructions on how to perform Sterilization monitoring with biological indicators (english subtitles available).

The video shows how to perform the test using Biological Indicators, it teaches you to read the results and to register the process correctly. This instruction shows the entire process step by step, for you to perform sterilization monitoring safely.

Point your cellphone camera to scan the code below, or access our Youtube channel: www.youtube.com/cristofoliequip.



Video: Monitoramento da Esterilização em Autoclaves
Parte II - Indicadores Biológicos

REQUIREMENTS TO BE OBSERVED FOR THE INCUBATION PROCESS

We suggest that the operator standardize the incubation process and prepare a written routine to avoid leaving any requirement behind.

INDICATORS STORAGE

The storage of the biological indicators must follow the instructions from the manufacturer, specially the temperature exposure limits. The cabinets must be easy to clean, located in a dry room with fresh air, free from odors, disinfectants and/or sterilants.

BIOLOGICAL INDICATORS SHELF LIFE

The shelf life / expiration date is generally printed on the label and/or box of the biological indicators, it is the date after which they cannot be used. We recommend the use of the "SporTest" biological indicators which have an 18-month shelf life.

INCUBATION PROCESS MONITORING

Monitoring is nothing more than controlling the incubation with self-contained control indicators. The control indicators (indicators that have not been sterilized), have the important function of evaluating the viability of the test indicators, as well as the capacity of the incubator in providing the ideal conditions to incubate them. In case the result from the control is not positive, it is possible that there is some problem with that batch of indicators, with their storage, or even with the incubator. Check if a power outage occurred during the incubation process. If that is the case, perform the whole test again. That means a new cycle must be performed in the autoclave, containing a test indicator and the incubation process must be repeated with a new control indicator.

AUTOCLAVE STERILIZATION MONITORING

The purpose of the Biological indicators is to monitor autoclave sterilization cycles, they are considered the most accepted method for monitoring the sterilization process because they assess it directly by killing known highly resistant microorganisms (e.g., *Geobacillus stearothermophilus* for steam and *Bacillus subtilis* for ethylene oxide), rather than merely testing the physical and chemical conditions necessary for sterilization. Because spores used in BIs are more resistant and present in greater numbers than the common microbial contaminants found on patient-care equipment, an inactivated* BI indicates other potential pathogens in the load have been killed. The articles must have been previously cleaned before being sterilized, since the organic matter protects the microorganisms from the action of the sterilizing agents.

"Correct functioning of sterilization cycles should be verified for each sterilizer by the periodic use (at least weekly) of Bis". (Centers for Disease Control and Prevention. Guidelines for Infection Control in Dental Health-Care Settings - 2003. MMWR:52 (No. RR-17): page 24). Each institution must also, according to the Brazilian Health Ministry, establish a monitoring routine of its autoclaves, with the objective of detecting faults in their equipment and/or process.

In hospitals, monitoring must be done on a daily basis (AORN, 1994). A biological indicator must be used for every sterilizer load that contains an implantable device. The load can only be released after the results of incubation are known.

The number of test indicators to be put in each piece of equipment must be established according to its volume. A control BI, from the same lot as the test indicator and not processed through the sterilizer, should be incubated with the test BI; the control BI should yield positive results for bacterial growth and the results from the test BI should be negative. The incubation process must begin from 15 minutes after the end of the sterilization, and no later than two hours after it.

(* inactivated = negative).

POSSIBLE INCUBATION FAILURES

- 1► Insufficient exposure time to the proper temperature;
- 2► Incorrect handling of the incubator or the biological indicators;
- 3► Inappropriate indicators for incubation (not proper for steam, incorrectly stored or overdue shelf life);
- 4► Removal of the lid, causing the incubation temperature to drop beyond the ideal level;
- 5► Lack of preventive maintenance;
- 6► Power outage;
- 7► Defective incubator.

ATTENTION! - Failures during the incubation process are detected during monitoring.

PREVENTIVE MAINTENANCE

Some preventive procedures are necessary for the best functioning and durability of your mini-incubator:

- Use **only** self-contained biological indicators, proper for steam sterilization;
- Keep the mini-incubator clean. To clean the incubation area, use a cotton swab with alcohol 70% or peracetic acid at 1% and rub inside the indicators compartments some times. The use of other materials and/or products may cause damages.
- The external cleaning must be done daily using a soft cloth and biodegradable neutral detergent, next, clean it thoroughly with a soft cloth and alcohol 70% or peracetic acid at 1%.

TROUBLESHOOTING

WARNING! For any parts replacement, contact your local dealer or the manufacturer. We listed below some possible problems and solutions you can try on your own.

THE MINI-INCUBATOR DOES NOT TURN ON

POSSIBLE CAUSES	SOLUTIONS
The energy cable is not connected to the electrical network;	Connect the cable correctly;
No power;	Check if there is a power outage in your building;
Printed fuse burned out;	See "How to Proceed when Service is Needed" (Page 4);

A MINI-INCUBADORA LIGA, MAS NÃO AQUECE

POSSIBLE CAUSES	SOLUTIONS
Defective circuit board;	See "How to Proceed when Service is Needed" (Page 4);

A MINI-INCUBADORA DEMORA PARA ATINGIR TEMPERATURA OU NÃO A MANTÉM

POSSIBLE CAUSES	SOLUTIONS
The mini-incubator lid is open;	In case the lid of the incubation area is open, close it properly;

A TEMPERATURA DA MINI-INCUBADORA SOBE EXCESSIVAMENTE

POSSIBLE CAUSES	SOLUTIONS
Defective circuit board;	See "How to Proceed when Service is Needed" (Page 4);

If the problem persists after the verification of all the items listed, contact your local dealer.

QUALITY CONTROL

All Cristófoli Mini-incubators are tested and monitored individually, according to the parameters of the table below.

Heating Time	Temperature	Incubation Time
Cold or hot Mini-incubator 60 minutes	55 °C to 60 °C	24 or 48 hours (according to the B. I.)

NOTE: Heating Time values are expressed considering the technical data chart regarding the environment conditions, (temperature / altitude). Incubation time will depend on the biological indicator used. (check the time needed for your BI by consulting its manufacturer instructions).

HOW TO IDENTIFY YOUR MINI-INCUBATOR

The metallic identification label is located underneath the equipment. Its purpose is to identify the mini-incubator technical data.

ATTENTION! - Removing the Identification Label and/or any other stickers from the product will cause automatic loss of the warranty.

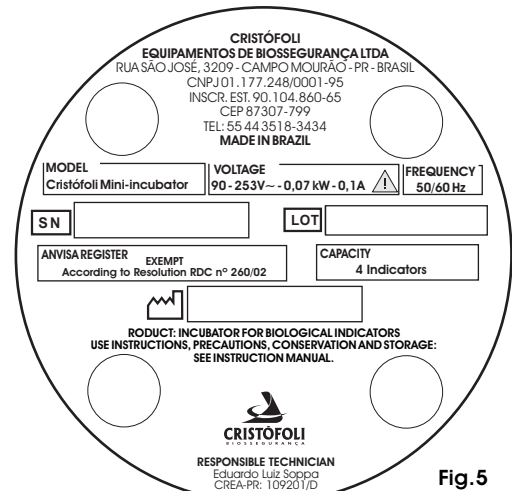


Fig.5

TECHNICAL DATA

TECHNICAL DATA CHART

CRISTÓFOLI MINI-INCUBATOR

CERTIFICATIONS	Cristófoli Mini-incubators are manufactured by Cristófoli Biossegurança, company which Quality Management System is certified by ISO 13485:2003, and in accordance with BPF - Boas Práticas de Fabricação - ANVISA (Brazilian standard similar to GMP - FDA/US).
CAPACITY	4 biological indicators
WEIGHT.....	240 g
CYCLE	24 o 48 hours (steam)
OVERALL CLEARANCE	15 cm for each side
CLEARANCE REQUIRED TO OPEN THE LID	12 cm
EXTERNAL DIMENSIONS (H x D)	8,7 x 7,6 cm
LID DIMENSIONS (H x D)	3,3 x 7 cm
VOLTAGE	90 - 253V AC single-phase
FREQUENCY	50/60 Hz
POWER	10 Watts
POWER CONSUMPTION	10 Watts hour
MAXIMUM TEMPERATURE	60 °C
*PROPER ROOM TEMPERATURE	15 °C to 40 °C
*PROPER WORKING ALTITUDE	Up to 2.000 m

* In case the altitude and/or temperature of your work place is different from the one mentioned in this manual, contact Cristófoli by the e-mail: cac@crisfoli.com.

Note: The manufacturer reserves the right to make changes and/or improvements to this product at any moment without prior notice.

WARRANTY CERTIFICATE

CRISTÓFOLI EQUIPAMENTOS DE BIOSSEGURANÇA LTDA., warranties the Cristófoli Mini-incubators for 01 (one) year against any manufacturing defect from the date of the purchase receipt (provided it contains the serial and lot numbers of the equipment), of which 03 (three) months refer to the legal warranty (established by section II, art. 26, CDC, Brasil) and nine (09) months to the contractual warranty (arranged in art. 50, CDC, Brasil). Visit our website www.crisfoli.com and register your product online.

Traveling costs (based on the distance traveled in km) and the stay of the authorized technician for installation, repair or maintenance **before or after the warranty period** will be responsibility of the buyer/owner as well as the freight charges for shipping the equipment to the authorized technical assistance office for repairs or if necessary, to the factory itself.

CRISTÓFOLI EQUIPAMENTOS DE BIOSSEGURANÇA LTDA., is not liable for damages / accidents caused by improper use, operation or installation of its products, in this case the equipment will lose its warranty and the repair will be paid by the buyer / owner.

The warranty will be voided in cases of:

- Problems arising from natural causes (such as floods, lightning, etc.).
- Sinister (theft or robbery).
- Damage caused by accidents, such as: drops, failure of the power supply and/or building wiring, short circuits, fire, etc..
- Improper installation of the equipment and/or plugging it into an incorrect voltage outlet.
- Removal and/or tempering of the serial number shown in the identification label of the product.
- Signs of tampering and/or blotted out data on the purchase or service receipt of the equipment.
- Signs of external violation of the product or broken factory seal.
- Use different from the intended purpose.
- Changes made to the equipment by the client himself/herself.
- Repairs performed by technicians who are not part of the Cristófoli Authorized Service Network.
- Noncompliance with any measure or caution recommended in the instruction manual of the product.
- Lack of periodic maintenance of the equipment or neglect regarding any item presented on the topic "Preventive Maintenance" of this instruction manual.

The printed fuse and the lid of the incubation area are not covered by this warranty.

ATTENTION! In order to validate the contractual warranty of the product it is necessary to send a copy of the purchase receipt to the following e-mail address: garantia@crisfoli.com.

HOW TO PROCEED WHEN SERVICE IS NEEDED

Before contacting **your local dealer**, please, have in hands, the model of your equipment, serial number and the date of manufacture found on the identification label located underneath the equipment (Fig. 3, page 2 and Fig. 5, page 3) and a description of the problem. It will be also necessary to have the original invoice from your dealer to confirm the date of purchase.

Always contact your local dealer. If you have problems contacting your dealer, contact us by e-mail: crc@crisfoli.com or through our website: www.crisfoli.com.

GUIDANCE FOR THE FINAL DISPOSAL OF THE EQUIPMENT

The environment is something that belongs to everyone, therefore it is up to each one of us to make the decisions that will help in its preservation and reduce the damages resulting from human activities.

All equipment has a useful lifespan, but it is not possible to determine how long, as it varies according to the intensity and how the equipment is handled.

CRISTÓFOLI EQUIPAMENTOS DE BIOSSEGURANÇA LTDA recommends users of their products to seek the best destination when disposing the Mini-incubator or its components, taking into account the materials recycling legislation effective in your country.

We advise you take your equipment to recycling specialized companies that due to the continuous and fast paced development of new recycling technologies and materials reuse, provide the best way of disposing and recycling it properly, contributing this way to reduce the consumption of non-renewable raw materials.

It is worth reminding you that your Cristófoli Mini-incubator packaging, as indicated on the box itself, is recyclable.

Other items to be observed for the preservation of our planet:

- Reduce the amount of consumption material;
- Reuse all durable goods for as long as possible;
- Properly dispose the amalgam residues, mercury contaminates the soil;
- Recycle all possible materials at the end of their useful lifespan;
- Perform the correct separation of all waste.

On behalf of users, we thank you for your concern and cooperation.

LINKS OF INTEREST

www.anbio.org.br	Biosafety National Association
www.anvisa.gov.br	ANVISA - Brazilian National Sanitation Surveillance Agency
www.ccih.med.br	Site of the book "Hospital Infections"
www.cdc.gov	Centers for Disease Control and Prevention (Atlanta-GA-USA).
www.crisfoli.com	Cristófoli's website
www.fob.usp.br	Bauru Dentistry College
www.saude.gov.br	Brazilian Health Ministry
www.saude.sp.gov.br	São Paulo Health Department

For better serving our clients, we offer our Cristófoli Biosafety Consultancy Service

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