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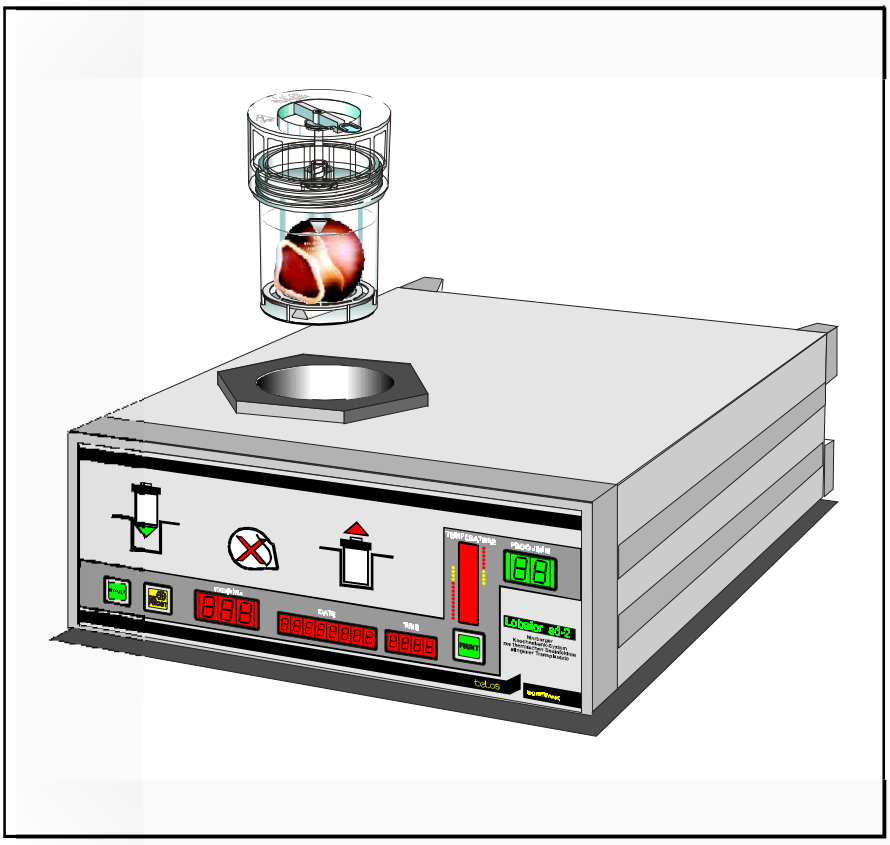
The Marburg Bonebank-System

for thermal disinfection of allogenic femoral allografts from surgical (living) donors

by Prof. Dr. Knaepler and Dr. von Garrel

Lobator sd-2 / Disinfection-Set



Instructions for Use

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Herstellung und Vertrieb
med. technischer Geräte GmbH

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Contents

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Introduction

The introduction of modern deep-freezing techniques has made allogenic bone graft a well-established therapy concept in traumatology and orthopaedic surgery

In 1993, the Marburg Bonebank-System was introduced for thermal disinfection of allogenic heads. The system comprises an electronic control unit, the Lobator sd-2, and the sterile disinfection set. This compact system inactivates HIV 1, HIV 1/0, HIV 2, HTLV, CMV, Hepatitis B and C viruses as well as Treponema Pallidum (syphilis) and vegetative bacteria while maintaining the biomechanical and biological valence of the graft

Characteristics of the Marburg Bonebank-System:

- BfArM (German Federal Institute for Drugs and Medical Devices) - validated procedure (for femoral heads up to 56 mm in diameter)
- No quarantine storage required
- No second testing of the donor required
- The graft is taken from waste tissue harvested during primary hip arthroplasty procedures
- Extraction, processing and storage of the grafts in in-house bonebanks
- Safe and cost-saving grafts

Advices on the Explant

Donor selection

For selection of appropriate donors please refer to section 3 “Criteria for the selection of living donors of allogenic bone explants” of the “bone banking guidelines”. (Deutsches Ärzteblatt, vol 98, issue 15, April 13th, 2001)

Maximum size of femoral heads

The thermal disinfection process is validated for femoral heads with a diameter of up to 56 mm. Therefore the inner dimensions of the disinfection container will not accept any larger femoral heads. We recommend to divide very large femoral heads and disinfect them in 2 containers. Such cases require a particularly precise documentation, however, indicating that 2 different graft identification numbers belong to one and the same donor

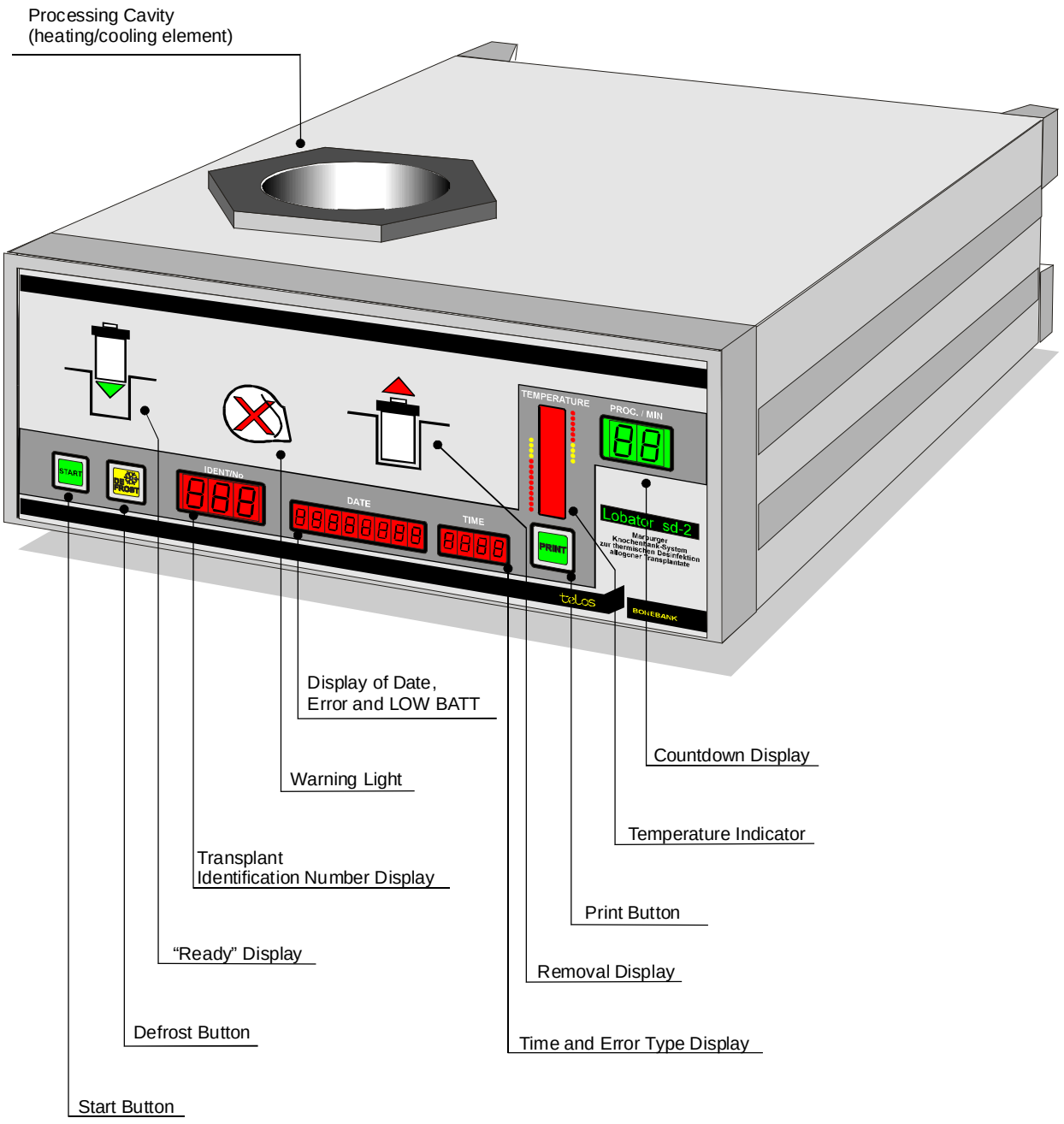
Thermal disinfection at a later time

The femoral head is placed into the disinfection container without fluid. The container is closed firmly, marked with a transplant identification number and stored in the deep freezer. It must not be filled with Ringer's solution, since the formation of ice crystals would destroy the bone structure. Moreover, a spatial separation of approved and unapproved bones in the deep freezer is required to prevent any possible confusion. The bone may remain in the deep freezer until thermal disinfection can be carried out. Then the Ringer's solution is filled in under sterile conditions and the closed container with the femoral head is exposed to room temperature for 3 hours (-45°C deep freezing storage) respectively for 5 hours (-80°C deep freezing storage) prior to thermal disinfection

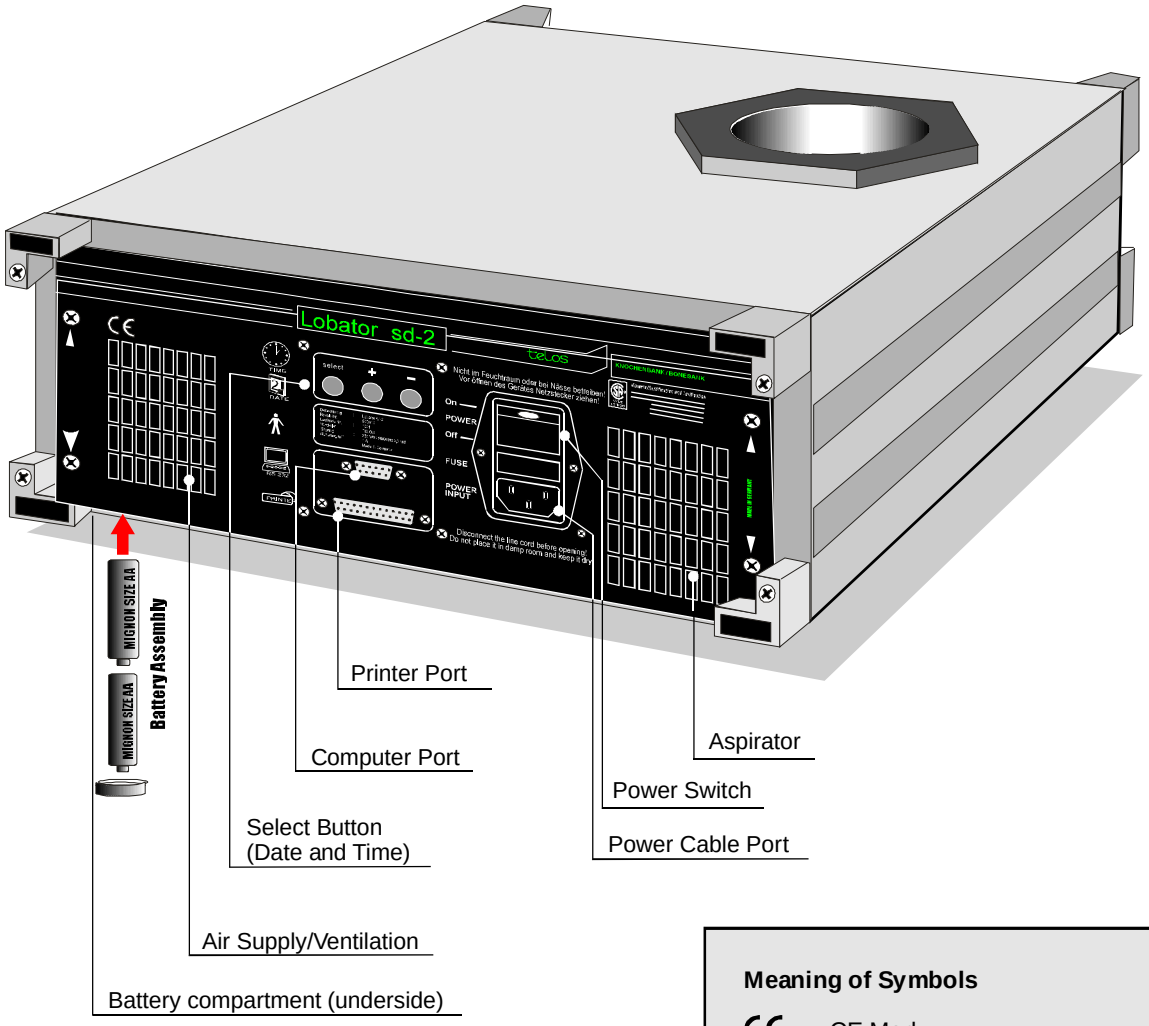
Documentation

The German bone banking guidelines (“Richtlinien zum Führen einer Knochenbank” of 13/04/2001) require a complete documentation set for each single explant. The full documentation set of the Marburg Bonebank-System comprises documents for both, the donor and the recipient, including the informed consent, donor history and examination report as well as the laboratory parameters of the serological and microbiological tests

Operating Elements and Display



Operating Elements and Display



Meaning of Symbols

CE Mark:
The product is certified in accordance with the EC regulation 93/42/EEC

Waste of electric and electronic equipment:
At the end of its lifetime, the device needs to be disposed via the return system

Symbol for protection against electric shock of type B

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Lobator sd-2

Technical Data

Manufacturer	telos Herstellung und Vertrieb med. technischer Geräte GmbH Bismarckstraße 18 D-35037 Marburg Germany Tel.: (+49) 6421/1717-17 Fax: (+49) 6421/1717-20 E-Mail: telos-marburg@t-online.de Internet: www.telos-marburg.de
Product	Lobator sd-2
Dimensions (height x width x depth)	14,0 cm x 34,5 cm x 32,5 cm
Weight	7,5 kg
REF (Article No.)	8800000 (Japan) / 8900000 (USA)
Supply Voltage	100 VAC 50/60 Hz (Japan) / 115 VAC 50/60 Hz (USA)
Power Input	250 W (Japan) / 250 W (USA)
PC Interface	IBM compatible PC with a free serial port
Available Readout Software	Version 4.1 for Windows
Printer Port	Parallel printer port CENTRONICS
Ambient Conditions Storage	Temperature: min. -40°C, max. +70°C Air humidity: min. 10%, max. 95% not condensed Air pressure: min. 500 hPa, max. 1060 hPa
Ambient Conditions Operation	Temperature: +10°C to +40°C Air humidity: 30% to 75% Air pressure: 700 hPa to 1060 hPa
Approved Accessories/REF	Disinfection-Set / 8300000
Classification	Shock Protection Class I, Type B
As per Appendix IV of Guideline 93/42/EEC	Activ, Class I
Approvals as per	DIN EN 60601-1 / DIN EN 60601-1-2
Recommended Control Period for Technical Safety	every 2 years
Warranty Period	2 years
Availability of Spare Parts	10 years
Notified Body	DEKRA Certification GmbH
Identification Number	CE 0124

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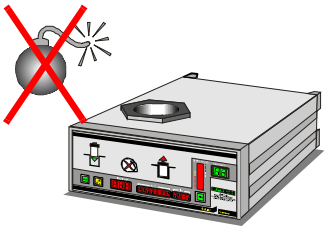
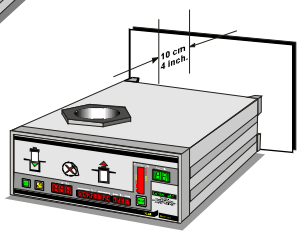
Safety Instructions

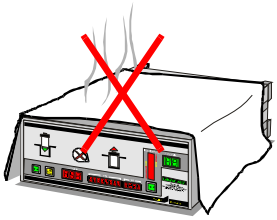
The device must not be used in explosion prone areas



The device must be positioned such that there is a minimum clear space of 10 cm between the back of the device and whatever is behind it

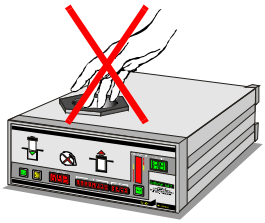


When switched on, the device must not be covered

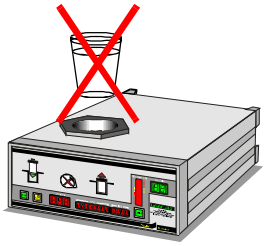


Do not handle liquids over the device

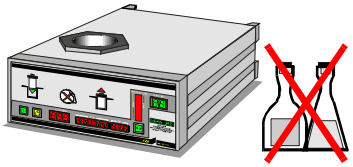
Beware of the heat generated in the heating/cooling cavity during the thermal disinfection process



For thermal disinfection and defrost processes only use the disinfection containers



Do not clean the device with strong detergents

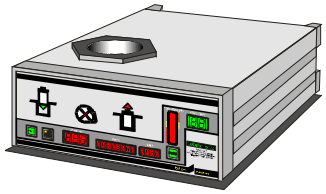


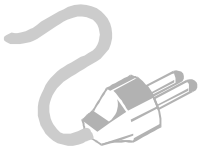
Telos will not assume any liability for damages or consequential damages arising from the inappropriate set-up, use or maintenance of the device, especially in the event of disregarded instructions for use or improper operation

Set-Up

Check the supply voltage and connect the device using the attached cable

The supply voltage is directly proportional to the heating output. To avoid any risk of undervoltage please make sure that the device is not connected to a distribution outlet. If the voltage goes below 207V the process will be aborted (**error 85**)





Thermal Disinfection Program

1. The Lobator is switched on at its back side (fig. 1)


fig. 1

2. A blinking green arrow prompts you to insert the disinfection container into the heating cavity (fig. 2)

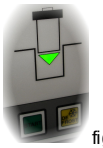


fig. 2

3. After insertion of the disinfection container the visual display will cease. Press the green START button (fig. 3) to start the disinfection process (duration: 94 minutes) (fig. 4)

fig. 3


fig. 4

4. The red LED now displays the three-digit transplant identification number (fig. 5), which is to be indicated on the disinfection set using a waterproof marker. The timer counts down, indicating the remaining time until completion of the disinfection process

fig. 5

5. A continuous sound and a red cross in the error display indicate an error and the abortion of the disinfection process (fig. 6)

fig. 6

6. A continuous sound and a red blinking arrow indicate the end of the disinfection process. The disinfection container can now be removed

7. To complete the disinfection process properly, press the blinking print button at the front panel of the device (fig. 7). If connected, the printer will then print the protocol. The device is only ready for a new process after pressing the print button

fig. 7

8. The Lobator is switched off at its back side

Errors / Malfunction Messages

During the thermal disinfection process, microprocessors are constantly controlling the supply voltage, the heating curve, the time lapse and the drive of the magnetic agitator.

In the event of failure during the thermal disinfection process, a warning signal will be audible and a cross symbol displayed, indicating the abortion of the process. In this case the device has to be switched off for a few seconds. After restarting the device, the Time and Error Type Display will show Error as well as the corresponding error number, providing information on the cause of failure and the resulting process abortion.

By pressing the PRINT button the process is saved and the Lobator sd-2 returns to its initial settings. The device is not until ready for use the temperature in the heating cavity has not decreased below 35°C. This shall prevent an excessive heating of the Ringer's solution in the preheated cavity

1. 1. Potential error sources which are checked automatically when switching on the device

Error No.	Error
0	Temperature glass too small
1	LED voltage too low
2	Charging voltage too low
3	Hardware revision too small
4	Heating pot too small
5	5 V voltage too low
6	15 V voltage too low
7	Power too low for LED display X
8	Temperature glass too big
9	LED voltage too high
10	Charging voltage too high
11	Hardware revision too high
12	Heating pot too large
13	5 V voltage too high
14	15 V voltage too low
15	Power too high for LED display X
16	Buzzer activation not L
17	Buzzer activation not H

Error No.	Error
18	LED display activation not H
19	LED display activation not L
20	LED display X off, voltage too high
21	160° control responded
22	IIC bus error - IC32 (port element for sensor) not responding to iic bus
23	Port element IC32 (sensor LED) not H
24	Port element IC32 cannot be deleted
25	Interrupt RTCC not working
26	Interrupt zero crossing circuit not working
27	Hardware failure IIC bus, FRAM or IC32
28	Timer not reporting to IIC bus
29	Port element LPT IC1 not reporting to IIC bus
30	Port element LPT IC2 not reporting to IIC bus
31	Port element LPT IC3 not reporting to IIC bus
32	Timer sensor not open
33	FRAM IC26 not reporting to IIC bus
34	FRAM checknumber failure FRAM variables
36	FRAM constant data checksum incorrect

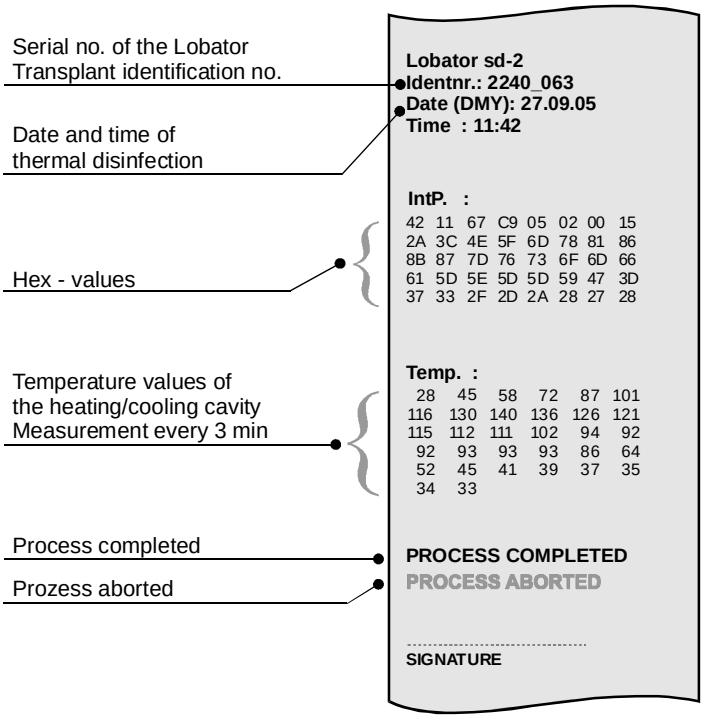
2. Potential errors occurring during thermal disinfection, which can cause abortion

Error No.	Error
80	Agitator failure
81	Failure of control processor
82	Watchdog main processor triggered
83	Power failure of more than 30 sec Please check whether the plug is connected firmly with the power supply
84	Container was taken out of the heating cavity for more than 30 sec The disinfection process will be continued, if the container is placed back into the cavity within 30 seconds. The time of removal is controlled by the microprocessor
85	Values of AD converter beyond the permitted range (207 volt or below) Please make sure that the device has not been plugged into a distribution outlet
86	Control error, no deactivation for more than 5 min. Switch off the device and restart as described above
87	After 19 min. the glass temperature has not exceeded 70°C
88	Agitator failure from AD converter

Whenever an error number is displayed and you cannot solve the problem yourself, please contact your sales representative or address to telos directly

Protocol Printout

After termination of the thermal disinfection process - whether completed or aborted - the PRINT button needs to be pressed to reset the device. If connected, the printer will then print the following protocol



The automatic disinfection process comprises three phases: The heat-up phase, the steady-state temperature phase and the cool-down phase. The electronic control system guarantee for a temperature of 82.5°C within the center of any femoral head up to 56mm for a period of 15 minutes

In order to expose the femoral head center to a minimum 82,5°C for a minimum of 15 minutes, the heating/cooling element has to be heated up to a much higher temperature (up to 140°C degrees)

Due to steriliiy reasons,, the temperature of the Ringer's lactacte solution in the closed disinfection container cannot be measured directly. This is why the temperature sensor is located on the outer surface of the container

Therefore the temperature displayed during the process is the temperature measured between the disinfection container and the heating/cooling element in °C. Each segment corresponds to 5°C. The display will start at 35°C

A microprocessor constantly compares the temperatures measured at the bottom of the heating/cooling element with those measured between the heating/cooling element and the disinfection container. Both values are compared with the programmed normative temperature curve

If the disinfection process has run through undisturbed, the annotation “Process Completed” appears at the end of the protocol. A disturbance or an interruption of the process is documented as “Process Aborted”

With the supplied cables, the Lobator sd-2 can be connected to a PC, the provided software allowes an uncomplicated communication between the device and the PC. The last 200 data sets are being saved in the device and can be selected and displayed in a chart. Via a respective button the desired protocol can be accessed and reprinted for filing

DEFROST - Program

The DEFROST program is used, whenever disinfected bone material is to be defrosted or warmed up. The DEFROST period is approx. 8 minutes and the process can be repeated several times or terminated prematurely by remeining the container out of the heating cavity. There are no transplant identification numbers being issued for this process and no protocols are printed

1. Push the power switch at the rear of the Lobator sd-2, to set the device in standby mode
2. A blinking green arrow prompts the operator to insert the transplant container completely into the heating cavity
3. After inserting the container, the blinking display ceases and the defrost process can be activated by pressing the yellow DEFROST button (fig. 1)
4. The termination of the process is indicated by an audible signal and a red blinking arrow. The transplant container can now be removed by the operator from the lobator
5. The unit is turned off by pushing the power switch at the rear of the Lobator sd-2

fig. 1

The external packaging has to be removed from the disinfection container before inserting the container into the heating/cooling cavity for defrosting

LOW BATT - Battery change

The batteries are required for the date and time display. Before they get empty, the date and time display indicates “LOW BATT”

To avoid having to reset date and time, leave the device plugged into an electrical outlet and turned on, while changing the batteries

Tilt the device laterally to open the battery compartment at the bottom of the device using a coin or similar tool. Exchange the batteries

2 Mignons size AA are required. Please make sure their poles are positioned correctly

Close the battery compartment and reposition the device in the home position

Date and time setting

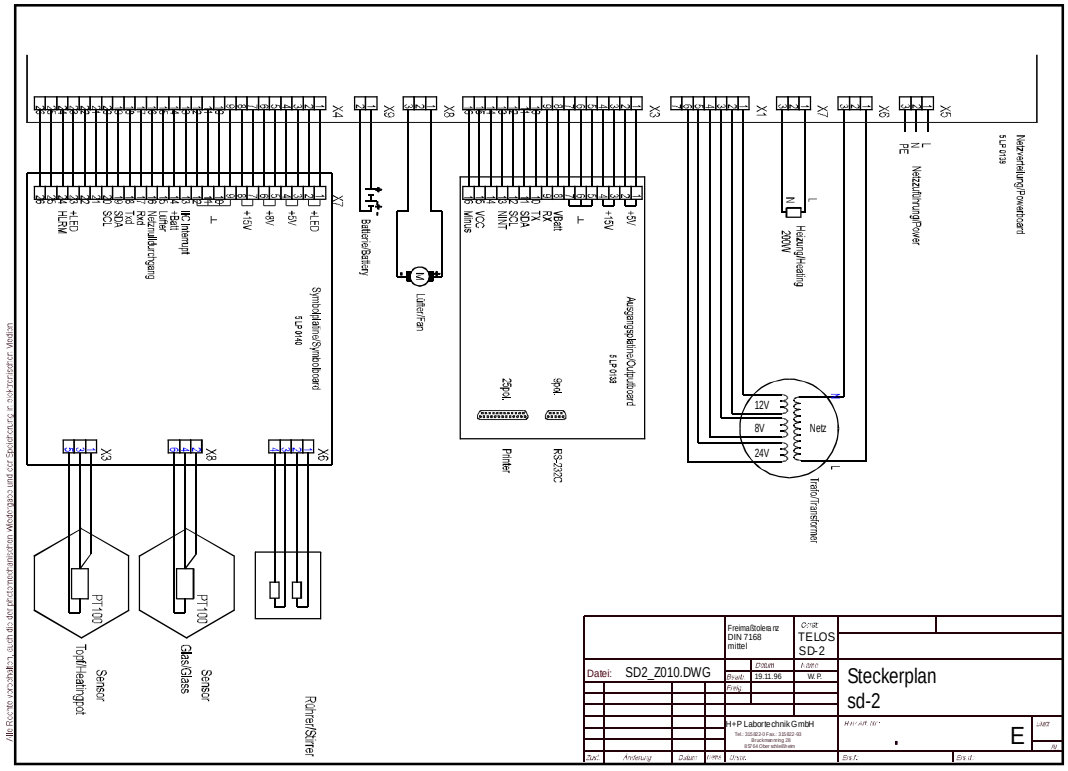
The device has to be switched on for setting date and time but it must not be running a thermal disinfection or defrost process

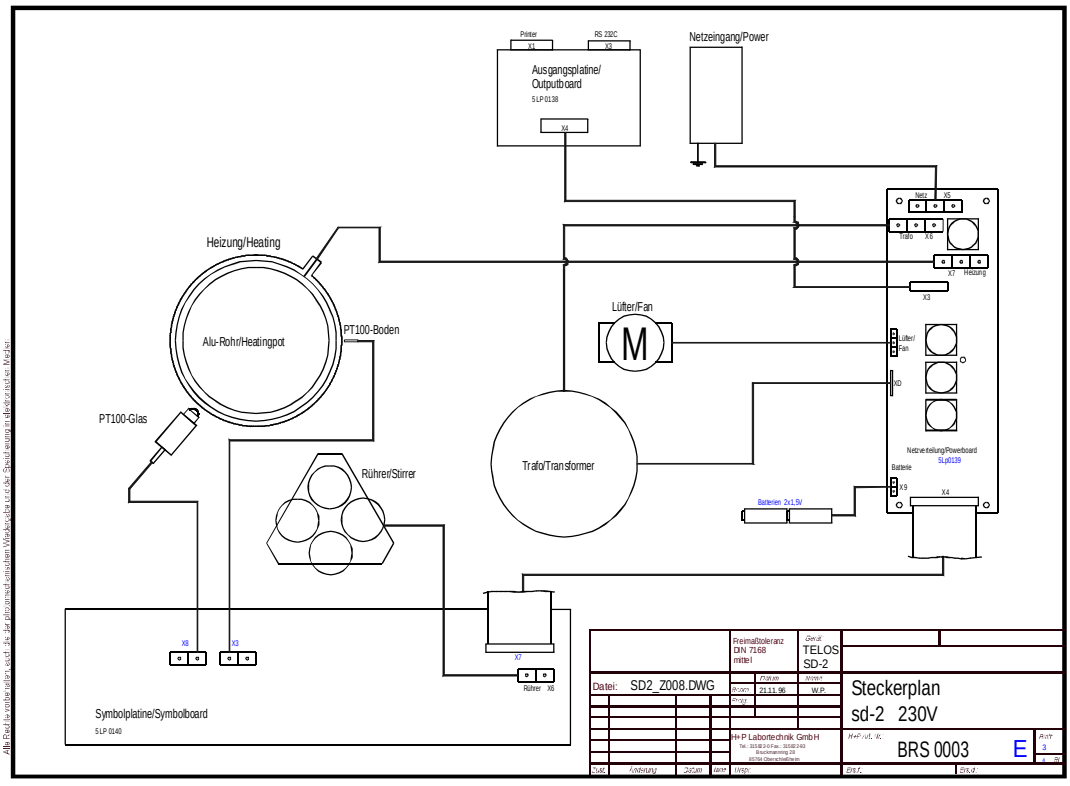
Use the “select” button at the rear of the device to select the display which shall to be changed

The blinking display can now be changed using the “+” or “-“ buttons

Having run through all front displays, the device is ready for use again

Circuit Diagrams





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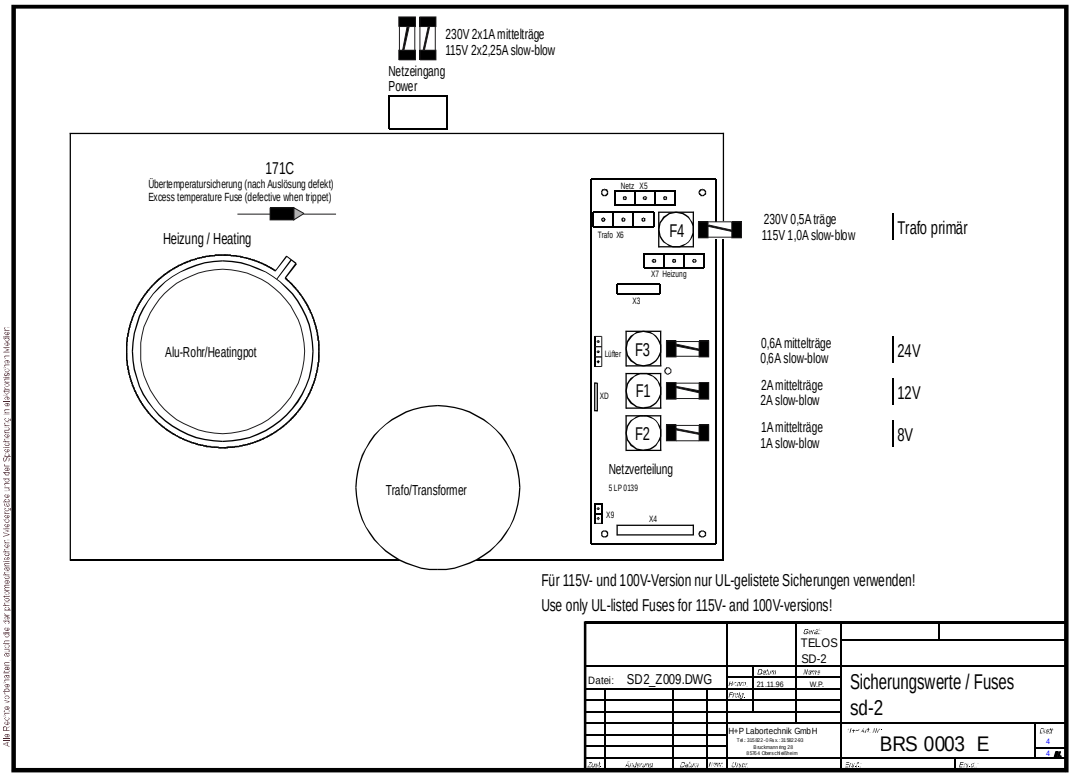
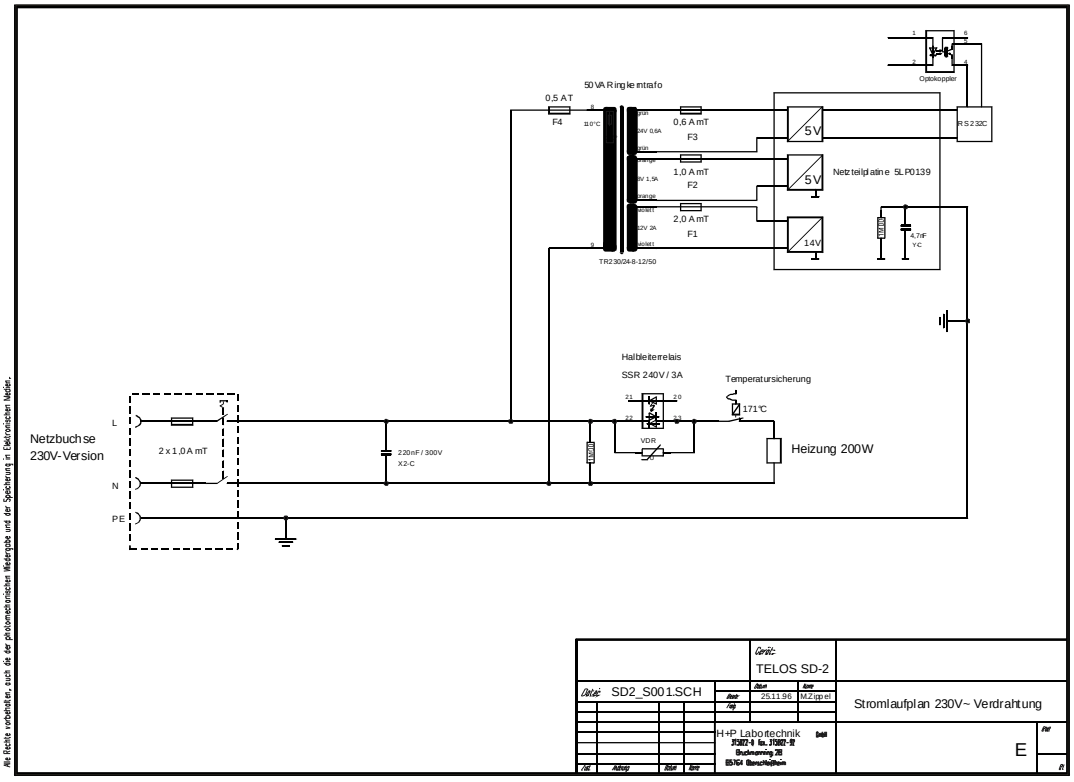
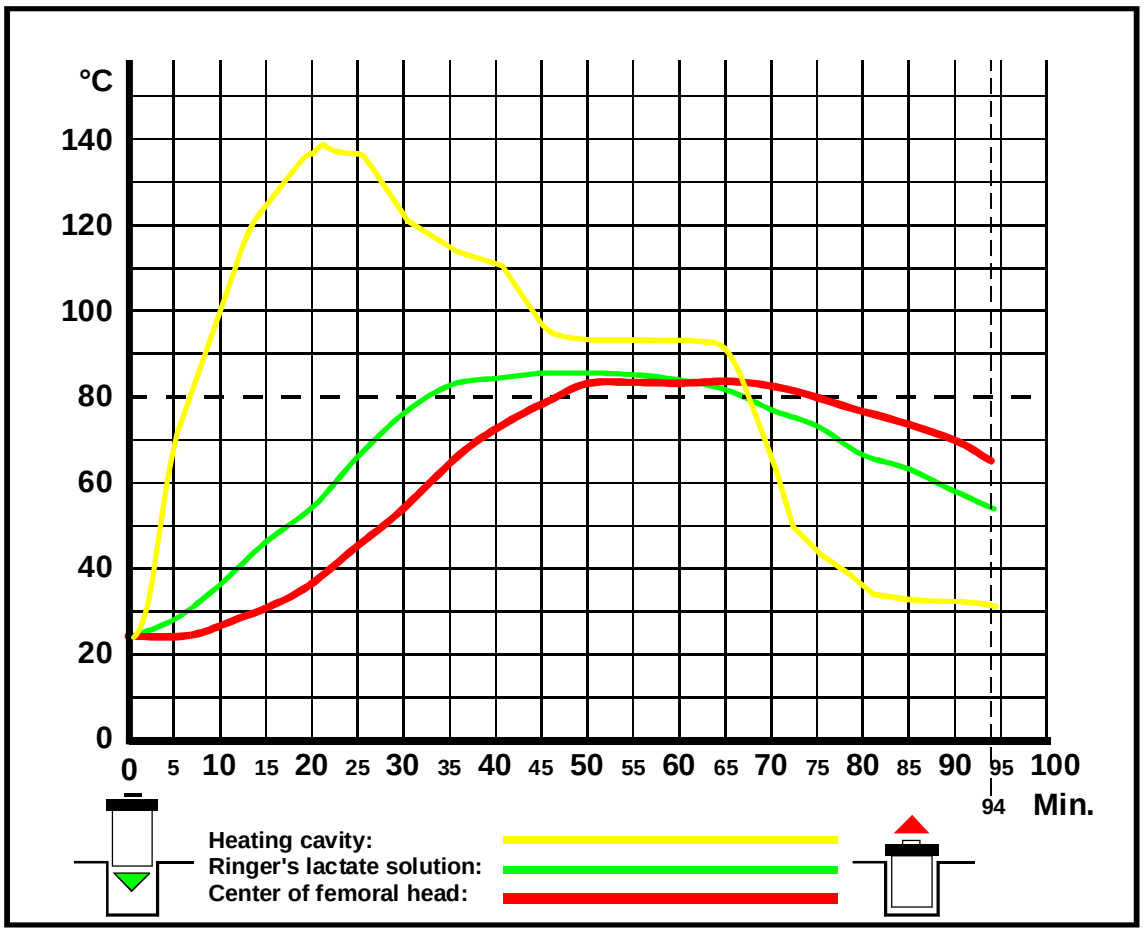
Circuit Diagrams





Example of a Disinfection Process



Example of a heating curve for the disinfection process of a large femoral head with a diameter of 52 mm after cartilage removal

Based on the heat transfer measurement results obtained from 200 tested femoral heads we determined a standardized disinfection process with respect to large femoral heads and to those with a high density of the cancellous bone in order to safely provide for a temperature of at least 82.5° C within the center of any femoral head over a period of 15 minutes

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Disinfection Set

Instructions for Use

Description

The disinfection set complies with the high quality and safety standards of the EC tissue guideline 2004/23/EC of 03/31/2004, the commission guideline 2006/17/EC as per 02/08/2006, the commission guideline 2006/86/EC as per 10/24/2006 and the German AMWHV (German regulation for the manufacture of pharmaceuticals and active ingredients) of 11/03/2006

The disinfection set comprises an external packaging and a disinfection container

The two-piece packaging is made of polystyrol and closes sterilely by means of a thread mechanism with an Evoprene seal

The disinfection container is made of Makrolon and consists of two chambers, thus complying with the A standards for clean rooms. The bottom part of the container accommodates the femoral head and is filled with the disinfection medium up to the marking line. The lid or transfer container is used for sterile closure of the bottom chamber and for taking up the disinfection liquid at the end of the process

Indication

The disinfection container is used for thermal disinfection of allogenic femoral heads from living donors in the Lobator sd-2 device and for subsequent sterile storage in the deep freezer

Contraindications

Not applicable

Handling

Prior to the first use of the system the operator should be thoroughly trained by a telos representative or an experienced colleague. Please also refer to handling notes on page 19.

After use, the disinfection containers need to be discarded in accordance with category B of the hospital waste regulation

Warnings / Precautions

The red sterility seal on the external packaging needs to be fully intact

The valve of the transfer container must only be closed (turned by 360°) after complete drainage of the liquid, otherwise the correct function of the disinfection container is not guaranteed

Adverse Effects

Not applicable

Manufacturer Warranty

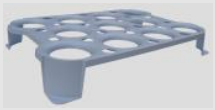
The disinfection sets are manufactured in lots. Each lot is only released for sale after hygienic testing of the manufacturing conditions by a ZLG accredited laboratory, confirming that the germ contamination on the disinfection sets before sterilization (bioburden) does not exceed the prescriptive limits and provided the submission of a sterility certificate issued by a certified contract sterilization laboratory

As the manufacturer of this device, telos will not assume any liability for damages or consequential damages arising from the inappropriate set-up, use or maintenance of the device, especially in the event of disregarded instructions for use or improper operation

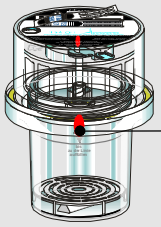
Disinfection-Set

REF 8300000
Packing unit: 11 pieces

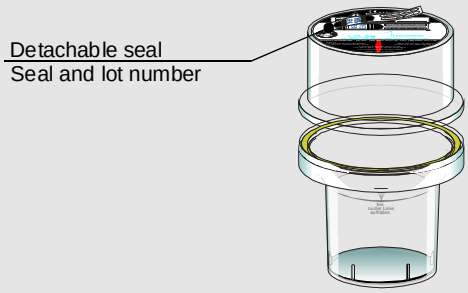
Delivery tray for 11 disinfection-Sets



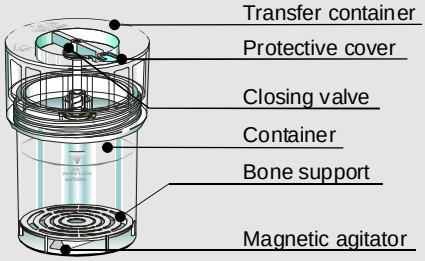
Disinfection-Set (external packaging and disinfection container)



External packaging

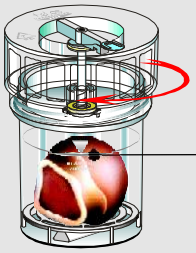


Disinfection container



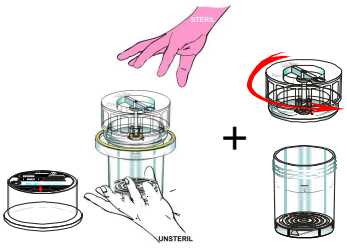
Femoral head

Filled disinfection container



Instructions for Use

Prior to the first use of the system the operator should be thoroughly trained by a telos representative or an experienced colleague



The disinfection set is handed in by a non-sterile OR assistant.

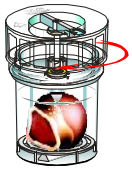
Open the external packaging, thus destroying the red sterility safety seal.

Take out the disinfection container under sterile conditions.

Open the disinfection container

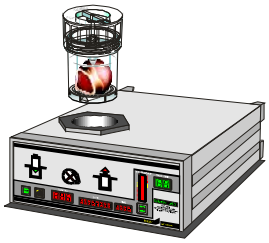
Position the measured explant in the container.

Fill the container with Ringer's lactate solution or saline up to the upper line

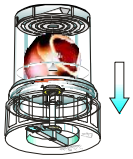


Close the disinfection container by firmly threading the transfer container onto its top

Place the disinfection container into the heating/ cooling element of the Lobator sd-2



Start the thermal disinfection program (see page 8)



After thermal disinfection the disinfection container is turned upside down such that the liquid drains into the transfer container through the open valve

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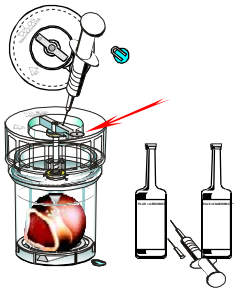
Disinfection-Set

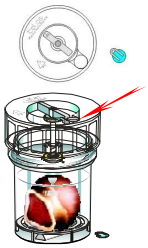
In order to prevent from backflow and provide for clean room conditions of class A within the container, the transfer container needs to be closed in its position after draining. For this purpose turn the closing valve to its stop (rotation by 360°).

After final closure of the transfer container turn the disinfection container upright again



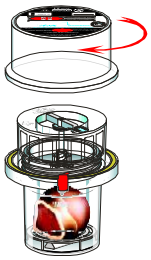
Remove the small blue closure lid on top of the transfer container as well as the blood culture lids and spray them twice with a disinfectant solution.

Withdraw a 20 ml sample from the transfer container and after exchanging the needles apply respectively 10 ml into the 2 blood culture bottles (1 aerobic, 1 anaerobic) which are then passed on to the laboratory



Press the rubber stopper into the transfer container and drain the liquid through this opening into a kidney dish

Close the opening with the small blue protective cover

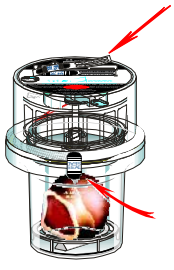


Indicate the transplant identification number of the conducted disinfection process on the transfer container using a waterproof marker.

If more than one Lobator is used, the device serial number must also be indicated on the transfer container to allow for subsequent assignment.

Put the disinfection container back into the external packaging, close it and seal it with the detachable SEAL sticker.

The two LOT numbers are sticked onto the documentation form



If no external packaging is used, note the LOT number of the disinfection set on the transfer container and position the SEAL sticker laterally on the disinfection container

Put the disinfection container into the deep freezer and store it in accordance with the management guidelines for bonebanks (Deutsches Ärzteblatt 04/13/2001), at 70°C or below. A reliable control of permanent freezing must be guaranteed. Therefore the system should be equipped with an alarm and a digital temperature record to provide for a consistent documentation of the cooling process.

The graft/transplant must not be stored for more than 5 years

Storage in the deep freezer is subject to a strict spatial separation of approved and unapproved femoral heads

Symbols on the packaging

	“Not to be reused”
	“Caution! Refer to attached documents.”
LOT	“Lot description”
	“Date of expiry”
STERILE R	“Sterilization by radiation”
CE 0124	CE marking and identification number of the notified body. The product meets all requirements of the Council Directive 93/42/EEC for medicinal products

Sterility

The product was sterilized by gamma radiation

The red marking on the external packaging indicates the sterility of the disinfection container. A further visible sign of sterility is the colour of the container, which is as clear as glass before sterilisation and which turns slightly yellow after gamma-sterilization

Storage

No special requirements.

The expiry date is indicated on the packaging. Do not use after the expiry date

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