

Integrated Sterilizer & Shredder ISS 500L

Product Description

The ISS 500L Integrated Sterilizer & Shredder (hereafter ISS 500L) is a steam sterilizer with an integrated shredder, intended for treatment of biological hazardous waste.

The ISS 500L performs both shredding and waste steam sterilization in a single vessel. The vessel is fitted with a motor-driven shaft, with powerful shredding/crushing blades which can rotate in two directions inside the vessel to reduce the size and volume of the waste.

ISS 500L includes the following features:

- Large capacity sterilization chamber
- Steam generator
- Automatic door locking and door opening mechanism
- Drain box for evacuation of sterilized liquids
- Water separator system to prevent return of used water from the machine to the water source
- All the gases from the contaminated chamber (before sterilization) will be evacuated via 0.01 micron bio filter
- 2 temperature sensors, one in the bio filter and one in the chamber

Application

Celitron's compact medical hazardous waste solution, the Integrated Sterilizer & Shredder, is a steam sterilizer with an integrated shredder, designed for on-site conversion of biohazardous waste in hospitals, clinics and laboratories, complying the EU and WHO recommendations.

Dimensions

Chamber inner dia. x depth:	840 x 923 mm
Chamber volume, net.:	560 liters.
External Dim. with housing W x H x D:	2710 x 2030 x 2300
External Dim. with autoloader W x H x D:	2710 x 2900 x 2800

Configuration and Options

<u>Model</u>	<u>Heating</u>	<u>Doors</u>
ISS 500L	Electric, 380-400V, AC	Single

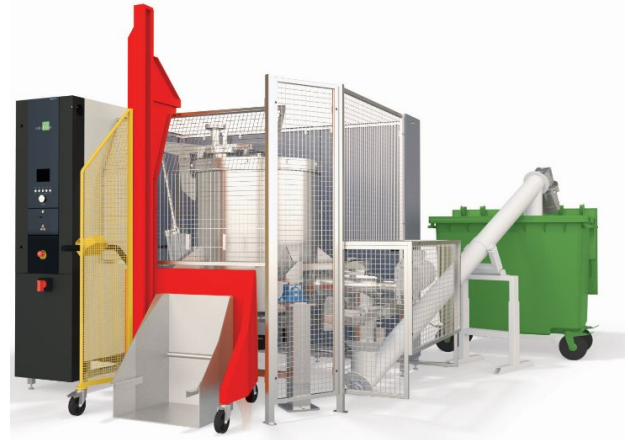
Available Accessories:

Standard:

- Steam generator (72 kW)
- RS 232 communication port
- Integrated ink printer
- Reverse-Osmosis system
- SD card slot with 2 GB SD card & reader

Optional:

- HMI PC software
- Air compressor



Languages

The operator panel is set up with following standard languages (maximum 8 languages per unit), more available upon request:

- English
- Russian
- Spanish
- French
- Arabic
- Portuguese
- Lithuanian
- Finnish

Standards

ISS 500L complies with following standards and codes:

- Machinery Directive- 2006/42/EC;
- Pressure Equipment Directive- PED 2014/68/EU;
- 2006/95/EC Low Voltage Equipment Directive;
- EMC Directive 2004/108/EC Article 7 (1)
- RoHS II Directive 2011/65/EU
- EN 60204-1:2006+A1:2009 Safety of machinery - Electrical equipment of machines - Part 1: General requirements.
- EN 61000-6-2 Electromagnetic compatibility (EMC) - Generic standards - Immunity for industrial environments.
- EN 61000-6-4 Electromagnetic compatibility (EMC) - Generic standards - Emission standard for industrial environments.
- CE mark

The company's quality management system meets the following quality standards:

- ISO 9001 – Quality Management System – Requirements.
- ISO 13485 – Quality systems – Medical devices – Particular requirements for the application of ISO 9001

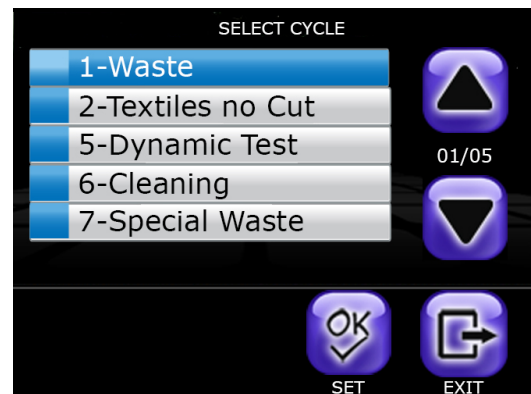
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Standard features

- MICROPROCESSOR CONTROLLED** - The control system of the sterilizer is based on state of the art microcomputer technology, ensuring a highly reliable and safe operation. The computerized control unit ensures a fully automatic operation through the entire cycle; hence after setting the pre-selected data and starting the operation, no further intervention is necessary. The selected program, the main phases of the cycle and the status of the machine are controlled and displayed on digital readouts.
- DESIGN AND CONSTRUCTION** - The ISS meets the highest standards requirements for quality, safety and operation. Stainless steel pressure vessels 316L conforms to the Pressure Equipment Directive (PED). The unit standard supplied with 316 stainless steel valves and piping components.
- CHAMBER** - The device is constructed of durable stainless steel 316L and is pre-heated. All metal parts in the inner surfaces are made of stainless steel. The chamber is constructed with an internal sprinkler for the automatic cleaning process.
- DOOR** - The sterilizer's chamber is equipped with one door, provided with an automatic locking mechanism, preventing the opening of the door by a safety lock. The door is electrical, air operated sliding door.
- BLADES** - The vessel is equipped with a multipurpose shredder/crusher blade on the bottom, to ensure use of the full volume of the vessel. It is regulated by an electric motor which drives the knife shaft through a tooth belt. The patented shaft connects the knife to the motor through the sealed bearing house. The 16,5 kW servo motor is sufficient to rotate the shaft for various operations. The blades are mounted on the shaft and are designed to shred waste such as sharps, dialyzers, syringes, papers, cloth, plastic and glass. The blade is made of non-corrosive high carbon steel with hardened cutting edges.
- GASKET** - The sealing of the chamber is made by utilizing a heat-resistant silicone rubber gasket.
- ENERGY SAVING MODE** - The ISS is equipped with an Energy Saving Mode which is activated when the unit is not used after a certain period of time. This mode saves energy and ensures safety of operation and is thus environmental friendly.



- CONTROL SYSTEM** - A microprocessor based control system, state of the art "Freescale" technology, automatically controls all programs including the sterilization cycle. The system includes a 5.7" digital touch-screen graphic display, communication, self and remote diagnosis and PC connection for external documentation and printing. It ensures a reliable, safe and user-friendly operation. The displayed information is available for users in a variety of languages. During the sterilization cycle the control system measures, controls and shows in digital display: the time, chamber temperature, chamber pressure and sterilization status. While the power is off, the non-volatile memory keeps the status of the sterilizer, and the real-time clock, driven by its own back-up battery, keeps running the date and time.



- ALARMS** - Depending on the state of the input and of the installed accessories, the controller is capable of displaying and/or printing several alarms, including:
 - Door Unlock
 - Temperature/ Pressure Error
 - Low/High Temperature
 - Low/High Pressure and more.
- CYCLE DOCUMENTATION** - For a clear and concise documentation of processes, the control unit is provided with a 24 character per line printer, connected to the processing unit. This releases a hard copy printing of the relevant information regarding operation during the cycle, such as temperature, pressure, sterilization and number of cycles, etc. In case of an uncompleted cycle, the print-out indicates the cycle failure and the cause of the failure.
- STEAM GENERATOR** - The steam generation takes place in a vessel which is completely separated from the sterilization chamber (i.e. no heating elements inside the chamber itself) and from the unit itself. The external steam generators (2*36 kW) is automatically controlled by an electronic system. The steam capacity is 101.5 kg/h.



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Options and Accessories

STANDARD

- **REVERSE-OSMOSIS (water softener)**

A Reverse-Osmosis system shall be used to improve the quality of the water used to generate steam in the electric steam generator. The use of mineral-free water will contribute to better performance and longer life of the autoclave's chamber. The water purification system uses a high quality booster pump which can provide 6.8 bar water pressure to pass through the membrane even under low water pressure area. The booster pump prevents damage, prolongs the life of the membrane and improves the TDS rejection of 26.4 or 52.8 liter per day. It is capable of removing over 96% of total dissolved solids +99% of all organics +99% of all bacteria.



- **DATA COLLECTION**

Sterilization cycles' data can be collected online on a SD card through an SD card slot, and can be downloaded into a computer equipped with proprietary PC software. 2 GB SD card collects up to 40 years logging data, including: the selected cycle, start time, cycle stages, temperature/pressure, end time, cycle graph, cycle status (pass/ fail), etc. All collected data can be printed via PC.



OPTIONAL

- **MONITORING AND DOCUMENTATION SOFTWARE (HMI SOFTWARE)**

Powerful PC Windows based software is available for monitoring, logging, control and service.



- **AIR COMPRESSOR**

Oil free direct driven air compressor. The hobby series consists of oilless air compressors designed for D.I.Y. enthusiasts. Compressor without air collection. Thanks to the compact and safe constructional design and to the reduced weight, these compressors may be easily used and transported anywhere by anybody. They are complete with a pressure reducer and electrical lead with plug ready for immediate use. The housing in shock proof material safeguards the user from exposure to the internal rotating components and hot surfaces.



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Cycle description

ISS 500L offers 3 sterilization cycles, 1 test cycle and 1 cleaning cycle.

The recommended load volume is minimum the half of the chamber's useful volume in order to reach optimized shredding result.

1. Waste Sterilization

- Sterilization temperature: 134°C (273°F), -0°C +3°C, (-0°F +5.4°F)
- Sterilization time: 5 minutes*
- Dry Time*: 5 minutes.
- Average cycle time: 25 minutes.

*Sterilization and dry time can be manually extended by the user.

Cycle Sequence

- **Loading the waste:** Waste is automatically loaded into the chamber by a lifter or a conveyor, depends on the customer's needs. The door closes and the waste cycle can be started with pressing one button on the full color touch-screen display.
- **Heating stage:** Steam is introduced into the chamber until the sterilization temperature is reached (134°C and pressure of 312kPa – *absolute pressure*).

Shredding:

The shredder starts working during the heating stage in different speeds, as required and continues working until the end of the cycle.

- **Sterilization stage:** The unit starts sterilizing at 134°C, 312 kPa (*absolute pressure*) for at least 3 minutes (can be extended in case of need).
- **Exhaust stage:** The shredder starts working in low speed. Cold water is injected to the chamber to reduce pressure down to 220 kPa (*absolute pressure*). When pressure is lower than 220 kPa, the fast exhaust valve opens.
- **Drying stage:** Pushing air into the chamber for approximately 5 seconds (till around 120 kPa (*absolute pressure*)) and releasing it through the fast exhaust valve.
- **Unloading:** The treated waste is automatically unloaded from the chamber through a 6" pipe.

2. Special Waste Cycle

Special Waste Cycle parameters might differ from the original values in the Waste Cycle, as it can be customized by a local technician, according to the type of the medical waste.

3. Glass Cycle

Glass Cycle parameters differ from the regular Waste Cycle, due to the reduced shredding time (30 sec.) and minimized water injection into the chamber. When Glass Cycle is selected, only glass waste is allowed to be loaded into the vessel.

4. Dynamic test

The purpose of this test is to detect leakages under pressure.

Operations Sequence

- The shredder is operated to create a vortex.
- Sterilization time: 3.5 minutes.
- No drying stage.
- During periodic Maintenance, or if a leak has been detected during this test, a technician may use leak detection foam to detect the source of leakages during this test.

5. Cleaning cycle

Operations Sequence



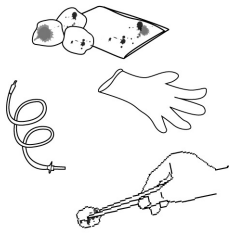

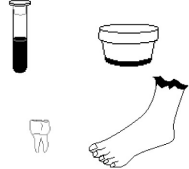

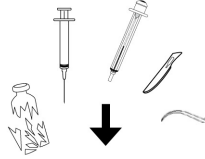

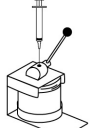
- Water and steam are introduced into the EMPTY chamber; steam is introduced to the filter to clean any remaining residues.
- The system holds a temperature of 60°C in the chamber for 5 minutes, while the shredder is working in high speed.
- Drainage of the water and residue into the drain box via the Fast Exhaust valve.
- Adding Water for 2 minutes. The shredder's motor is stopped.
- Pressurizing the chamber to 110 kPa with steam and compressed air.
- Drainage of the water into the drain box via the Fast Exhaust valve.

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Waste Collection and Segregation

The treatment in the ISS requires that different kinds of waste shall be worked upon separately. This requires responsibility of all involved employees at the hospital, so that the segregation of waste is done at the stage of waste generation. Follow the below recommendations for waste segregation:

Segregation of Medical Waste - Four Categories

Non-Infectious Waste	Infectious Waste	Highly Infectious Waste	Sharps Waste
<ul style="list-style-type: none"> • Paper/Packaging material • Food 	<ul style="list-style-type: none"> • Gauze/Dressing • Blood/IV fluid lines • Gloves 	<p>Anatomical waste</p> <ul style="list-style-type: none"> • Teeth • Placenta <p>Pathological waste</p> <ul style="list-style-type: none"> • Sputum container • Test tubes containing specimens 	<ul style="list-style-type: none"> • Infusion sets • Broken slides • Broken vial • Broken ampules • Lancet • Retractable • Scalpels • Blades • Needles
 <p style="text-align: center;">↓</p> 	 <p style="text-align: center;">↓</p> 	 <p style="text-align: center;">↓</p> 	 <p style="text-align: center;">↓</p>  <div style="border: 1px solid black; padding: 5px; width: fit-content;"> <p>If using a needle remover</p>  </div>

WARNING!

Highly Infectious Waste (RED BAGS) shall be treated in this machine according to local rules and regulations!



Note: Any segregation method to be implemented shall be in compliance with local rules and regulations. The Manufacturer's recommendations concerning the sterilization of each type of material/item shall be taken into consideration.

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THE FOLLOWING TYPES OF WASTE CAN BE PROCESSED IN THE ISS:

- Syringes
- Dialyzers
- Scalpels
- Small textiles (max. 10%/ load but not more than 7 kg)
- Test
- Complete Sharps Containers
- Food Waste from healthcare facilities*
- Other Bio-Medical Hazardous Waste

* The food waste to be sterilized and shredded by ISS shall consist of leftovers from the patients' meals, not of remaining debris from the kitchen, for what other regulations may be applicable.

RECOMMENDED WASTE SEGREGATION FOR THE ISS 500L

It is highly recommended for hospitals and clinics, producing large amount of glass to segregate at the point of generation separately from other infectious wastes. This requires responsibility of all involved employees at the hospital. The operator can use the dedicated Special Waste and Glass Cycles to treat the segregated hazardous waste.

CONDITIONS

- This device is for indoor use only!
- The sterilizer should be loaded only with the material as described above.
- The environment shall not exceed an ambient temperature of 40°C and a relative humidity of 85% respectively.
- The operation altitude shall not be over 2000 meters (ambient pressure shall not be lower than 80 kPa (11.6 psi)).

Recommended room dimensions:

height: min. 2,9 m

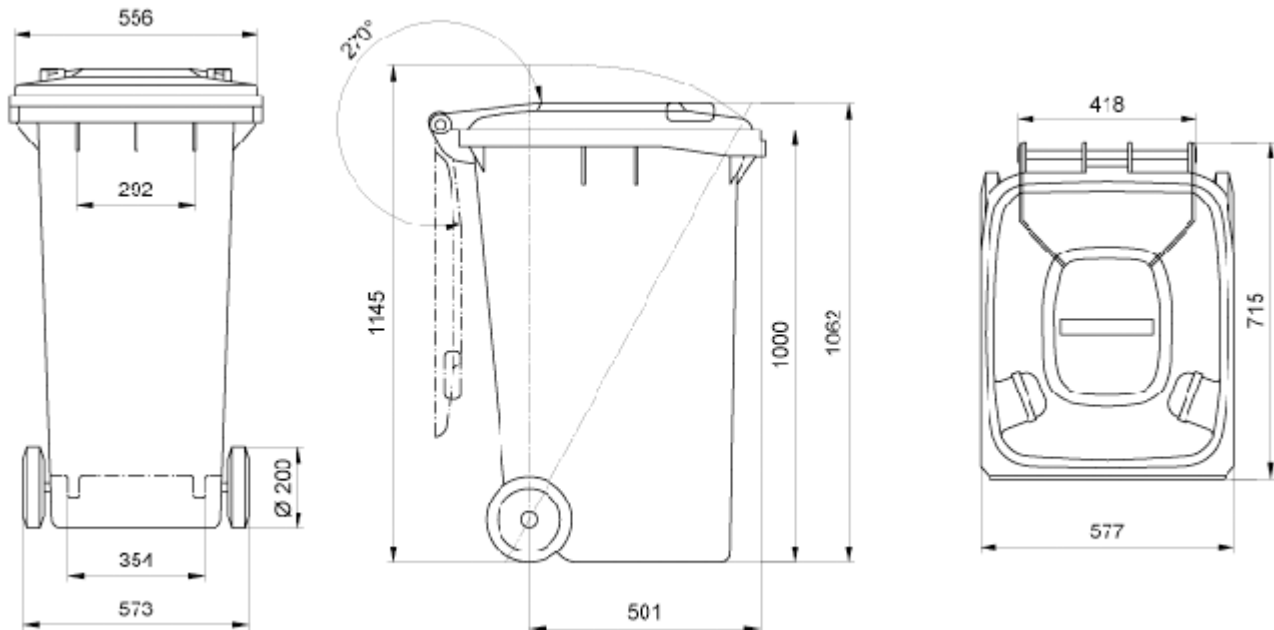
width: 3 m

length: 3 m

BIN MEASUREMENTS (IS NOT PART OF THE MACHINE)

The bin lifter is designed to the bin, with these dimensions:

Volume: 240 Liter, Wheel: Ø 250 mm



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External dim. with housing W x H x D:	2710 x 2030 x 2300
External dim. with autoloader W x H x D:	2710 x 2900 x 2800
Recommended interior high	3 m
Chamber volume, net.	560 liter
Average processable waste kg/h	100 - 150 kg/h <i>(Depends on the density of the waste)</i>
Chamber shape	Cylindrical 316L
Chamber dimensions, inner dia. x depth	840 x 923 mm
Approximate weight	2300 kg
Shipping details	1 paletta: 201 x 225 x 219 cm (L x W x H) - 1800 kg 1 paletta: 131 x 251 x 222 cm (L x W x H) - 900 kg /Frame & Electrical Box/ 1 paletta: 85 x 360 x 110 cm (L x W x H) - 300 kg /Bin Lifter + screw conveyor/
Average water consumption during the cycle	150-200 liter
Average mineral free water consumption during the cycle	8-12 liter
Max. working pressure <i>(relative pressure)</i>	2.7 bar (39 psi) <i>(According the EN13445 standard, is always in relative value.)</i>
Min. working pressure <i>(relative pressure)</i>	-0.9 bar (-13.5 psi) <i>(According the EN13445 standard, is always in relative value.)</i>
Steam source	Saturated steam – 101.5 kg/h steam capacity, built in steam gen. 2* 36 kW
Steam pressure <i>(relative pressure)</i>	3 bar (43,5 psi)
Purified water source	30 liter/h
Compressed air pressure	6.0-8.0 bar (87.0-116.0 psi)
Water source	Filtered tap water
Water pressure	1.0-6.0 bar (14.5-87 psi)
Peak sound level	86 dB
Average power consumption per cycle	40-50 kWh
Max electric power with steam gen.	110 kW, 3 phase, 380-400V – 3x150A, 50/60 Hz, 6kA
Max electric power for steam generator	72 kW
Voltage fluctuation	±10%
Operation	Electronic with microprocessor
Controls	Digital
Display	LCD color display, resistive touch screen, 5,7”
Integrated ink printer	Yes (Standard)
Connection to PC	RS232 (Standard)
Unloading accessories	Waste trolley
Maximum solid load	up to 120 kg (264.5 lb.)
Maximum textile load for waste cycle	10% of the total load but max. 7 kg (15.4 lb.)
Minimum recommended load volume	half of the chamber’s useful volume
Waste volume reduction	up to 80%

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Number of sterilization cycles	3 cycles -1 waste cycle, 1 special waste cycle, 1 glass cycle
Number of cleaning and test cycles	2 cycles - 1 dynamic test cycle and 1 cleaning cycle
Sterilization temperature	134°C- 137°C
Drying system	Compressed air
Stand-by	Yes
Automatic switch-off protections (night cycle)	Yes
Appearance of face	Painted/Glass
Automatic water filling	Standard
Automatic water draining	Standard
Automatic water draining	Standard
Manual water filling and draining	No
Drain disposal	Depends on the waste characteristics and local regulations. The ISS does not use chemicals or agents that should be neutralized, only water (steam), but if the waste includes chemical or high level organic materials, the authorities can require additional treatment.
Door locking device	Fully automatic chamber door locking device.
Characteristics	<p>The unit has 1 outlet at the drain box. Drain water temperature is approx. 65 °C. Pressure: atmospheric + max. 20kPA Other important instructions: The ambient temperature around the device must not exceed 40°C and 80% humidity. The ceiling above the device should be Waterproof and non-flammable with working temperature 150°C or higher Drain pipe has to be heat proof. Exhauster need to be high capacity. The floor construction should contain drain hole in the lowest place of floor. All device area floor construction have to provide incline toward the drain hole. The floor in the device area must be waterproof and non-flammable. The construction of the floor in the device area must be massive and thick. The room shall be well ventilated outside.</p>

