DIRECT2 Lid

Figure 1: DIRECT2 Lid Configuration
1. Lid, Main Part
2. Drain Lever/Straw to adjust flow to the drain
3. Drain Port
4. O-Ring, Drain Lever and Drain Port
5. O-Ring, Drain Lever and Drain Port
6. O-Ring, Lid

INSTRUCTIONS FOR USE

1 General of the DIRECT2 Lid

The DIRECT2 Vacuum Lid is an autoclavable, reusable medical device, the purpose of which is to assist in the transfer of fluid and tissue into the Puregraft 850 System.
The amount of tissue and fluid that can be transferred into the Puregraft 850 System using the DIRECT2 Lid is up to 900 mL.

2 Safety Instructions

2.1 Intended Use

The DIRECT2 Vacuum Lid is intended to be used for transferring fluid and tissue into the Puregraft System during lipoplasty procedures. This device is non-surgically invasive and intended for cleaning and steam sterilization prior to use.

2.2 Significance of the Instructions For Use

The Instructions For Use is critical for product safety. Therefore, all who will prepare, set-up, operate, dismantle, clean, disinfect, sterilize, pack, or store the device must read the Instructions For Use.

Only medical staff who have been trained in this Instructions For Use shall be allowed to the use the DIRECT2 Lid.

Bimini Health Tech assumes no liability for any damage resulting from improper use. In case of uncertainty, contact the Customer Service department of Bimini Health Tech.

2.3 General Safety Instructions

The DIRECT2 Lid and its accessories are only to be used under ambient conditions that guarantee strict adherence to maintaining aseptic conditions and surgical hygiene.

Dropping the lid or other heavy parts of the DIRECT2 Lid may cause injuries. Always handle with care.

Dropping or the use of excessive force may damage the components of the DIRECT2 Lid, which may potentially impair proper functioning of the system. Always handle with care.

The DIRECT2 Lid is designed to work only with its original components.

2.4 Initial Use

The DIRECT2 Lid will only work with the Puregraft 850 System.

All components have been delivered non-sterile and must be cleaned, disinfected, and sterilized prior to their first use according to the processing instructions included in these Instructions For Use.

3 Assembly of the DIRECT2 Lid

Visually check all parts of the DIRECT2 Lid for damage, wear, and possible fouling. Do not assemble if any individual part shows signs of damage.
The complete DIRECT2 Lid is to be assembled under aseptic conditions.
After sterilization, all parts of the DIRECT2 Lid must sufficiently cool down (below body temperature) before they can be used.

Before starting the procedure, assemble the canister and lid and check that the lid seals and can hold vacuum. If vacuum is not maintained, the lid should not be used. O-Ring Replacement Kits and Port Replacement Kits may be ordered by contacting the customer service department of Bimini Health Tech.

PUREGRAFT 850 SYSTEM:

1. Remove contents from packaging
2. Assemble canister stand.
3. Insert canister into canister stand.
4. Remove DRAIN and AUX caps from Puregraft 850 bag, but leave on sterile field (do not discard).
5. Insert the metal DRAIN LEVER/STRAW into the appropriate hole on the top of the lid. Make sure to push the DRAIN LEVER/STRAW all the way in.
6. Insert the STRAW into the Puregraft 850, making sure the metal straw does not pierce the Puregraft bag/filter. After doing so, twist the metal DRAIN LEVER into the DRAIN port on the Puregraft bag (do not overtighten).
7. Securely press the TISSUE port on the Puregraft bag to the TISSUE port on the Lid.
8. Ensure Puregraft bag is not twisted or wrinkled near ports to ensure ports are not kinked or blocked.
9. Fold Puregraft bag in half length-wise with Puregraft Logo artwork facing inward (artwork folded onto itself).
10. Insert folded Puregraft bag into canister and firmly press lid onto canister.
11. Place patient liposuction tubing onto PATIENT TUBE port.
12. Place aspiration tubing onto VACUUM TUBE port.

4 Lipo Harvesting using the DIRECT2 Lid

1. Begin lipo harvest process.
2. Adjust the DRAIN LEVER to the desired level.
3. Do not fill bag with fluid and tissue past ~900 mL.
4. When ready to remove fluids, turn the DRAIN LEVER to “MAX FLUID DRAIN”.
5. When finished draining, turn off aspirator/house vacuum.

5 Disassembly of the DIRECT2 Lid

1. Remove patient liposuction tubing from PATIENT TUBE port and aspiration tubing from VACUUM TUBE port.
2. Lift the DIRECT2 Lid from the canister and disconnect the TISSUE port and unscrew the DRAIN port from the Puregraft 850 system. Once the DRAIN port is disconnected, the DIRECT2 Lid can be removed and stored in a safe place to prevent damage.
3. Unscrew cap from drain line on Puregraft drain bag and then attach this cap to the AUX port. If cap is dropped, cap originally removed from AUX cap can be used.
4. Purge air from Puregraft 850 bag.
5. Securely attach drain line to DRAIN port on Puregraft bag.
6. Remove Puregraft bag from canister, using saline or LR as lubricant if bag is difficult to remove from canister.
7. Proceed with standard Puregraft tissue purification protocol.

6. Reprocessing of the DIRECT2 Lid

6.1 General Information

6.1.1 Reprocessing Procedure

The DIRECT2 Lid is intended to be reprocessed after use. In order to prevent patient infections, all components must be reprocessed each time before use.

The design and the materials of the device only allow specific methods for reprocessing.

Disinfection

The Robert-Koch Institute (RKI) and the American Center for Disease Control and Prevention (CDC) identify the reusable medical products through which body fluids are conveyed to be critical.

In accordance with the RKI guidelines, the DIRECT2 Lid is assessed to be reprocessable without any particular requirements. Automated cleaning and disinfection of the device is preferred. After thorough cleaning, the product and its parts must be sterilized by steam sterilization prior to its usage with a patient.

New, non-sterile DIRECT2 Lid parts are to be treated like used products. They must be fully cleaned, disinfected, and sterilized prior to use.

Manual cleaning

Both manual and automated cleaning of the device leads to acceptable results. However, manual cleaning methods bear a certain risk of infection for the cleaning personnel. Automated cleaning methods minimize this risk and moreover, have the advantage of being validated by a standardized procedure for greater consistency.

Standards

Bimini Health Tech recommends adherence to the US Standard ANSI / AAMI ST 35 “Good Hospital Practice: Handling and Biological Decontamination of Reusable Medical Devices” and the RKI Instructions

“Anforderung an die Hygiene bei der Aufbereitung von Medizinprodukten“, recommendation Bundesgesundheitsblatt 44/2001 1115 – 1126.

Compatibility

Bimini Health Tech distinguishes between two types of compatibility:
1. Micro-biological compatibility
2. Material compatibility

6.1.2 Selection of the Processing Method

The appropriate processing procedure should be selected according to the national hygiene provisions and local guidelines of hospital hygiene.

Automated cleaning and disinfection

When selecting the disinfector, please check to ensure:
- it is certified and accredited (e.g. by FDA or CE marked according to DIN EN ISO 15883);
- it uses an approved program for thermal disinfection;
- the program includes a sufficient number of rinse cycles;
- only sterile or low-germ (max. 10 germs/mL) and low-endotoxin (max. 0.25 endotoxin units/mL) water is used;
- the drying air is filtered;
- the disinfection machine is maintained and inspected regularly. When selecting the cleaning agent, please check to ensure:
- it is suitable for cleaning medical products;
- the chemicals are compatible with the product;
- the concentrations indicated by the producer of the cleaning agent are strictly followed.

Manual cleaning and disinfection

When selecting the cleaning agent and disinfectant, please check to ensure:
- it is suitable for cleaning medical products;
- the disinfectant has approved efficacy (CE approved or FDA approved in the US);
- the chemicals are compatible with the product;
- the concentrations and reaction times indicated by the producer of the cleaning agents are strictly followed;
- only sterile or low-germ (max. 10 germs/mL) and low-endotoxin (max. 0.25 endotoxin units/mL) water is used;
- the drying air is filtered.

6.1.3 Control and Checking

All disinfection and sterilization procedures must be reviewed regularly. Test strips can be used for testing the concentration of the disinfectant. The concentration must be tested daily to prevent the solution from being diluted and losing its effectiveness. All sterilization procedures are to be regularly checked using biological indicators.

• Cleaning and sterilization must only be carried out by trained staff in rooms specifically designated for this purpose.

6.1.4 Recommended cleaning, disinfection, and sterilization methods
Manual cleaning and disinfection
The disinfectant CIDEX OPA is recommended for use with this product. Follow the instructions provided by the disinfectant producer. The procedures described below are based on the standard ISO 17664 "Sterilization of medical devices – information to be provided by the procedures for processing serializable medical devices."

Automated cleaning and disinfection
The recommended disinfector is the G 7836 CD (Miele Professional, with rack and mobile injector unit E429 for lumina) programmed for neutral processing with the cleaning agent Thermosept RKN- zym (Schulke, Norderstedt).

Steam sterilization on the basis of the fractionated vacuum method
The sterilization is to be performed at a sterilization temperature of minimum 132 °C (269.6 °F), maximum 138 °C (280.4 °F) and at a sterilization temperature holding time of minimum three (3) minutes and a maximum thirty (30) minutes in a steam sterilizer validated according to ISO 17665-1.

6.2 Workplace safety and health
Prevention of infections and chemical burns
Bodily particles of the patients and decontamination chemicals present a hazard. Protective equipment is required for protection against dangerous chemicals and potentially infectious materials. During cleaning, disinfection, and sterilization processes, wear protective equipment comprising of eye protection, face shield, moisture-resistant clothes, tight-fitting chemical- resistant gloves that are sufficiently long so that no skin areas remain uncovered. Always remove contaminated protective equipment before leaving the processing facilities.
Toxic chemical fumes
As protection against toxic chemical fumes, the disinfection and sterilization room must be sufficiently ventilated.

6.3 Preparation of reprocessing at the place of use
The reusable parts of the DIRECT2 Lid are to be prepared for the subsequent reprocessing immediately after they have been used, still in the operating room.

When reprocessing medical products, take care to work carefully according to the local safety regulations.

Preparation and transport
Remove the rough surface soiling using a disposable cloth or a paper towel. Transport the product components from the place of use to the reprocessing facilities. The parts can be transported either dry or immersed in fluid. Contaminated parts are to be transported in containers in order to prevent the environment and personnel from potential contamination. When transporting dry, please ensure that no soiling can dry on the instruments. Do not use fixating agents or hot water (>40 °C / 104 °F) since these promote protein coagulation and can impair the cleaning result.
• The subsequent cleaning must begin within three (3) hours after use. If this time limit is exceeded, special measures are to be taken to achieve a proper cleaning effect. It is recommended to start with the reprocessing of the DIRECT2 Lid immediately after use.
• When transporting the instruments immerse in fluid, the cleaning must begin within one (1) hour after use. Saline is not suited for immersion.
• The above indicated time limits for transport must not be exceeded. Never leave a used instrument overnight before reprocessing. If an instrument is left in dry condition for a longer period, heavy soilings may dry on, leading to encrustrations that may be difficult to remove.

Limitation of reprocessing
Provided that the product is used as intended by the producer, the end of its service life is determined by normal wear and tear.

6.4 Manual cleaning and disinfection
Infection risk by improper cleaning agents
Using improper cleaning agents can provoke an infection control risk. Only use cleaners that are approved in accordance with national hygiene-related regulations and local guidelines.

Risk of infection and damage due to residues of cleaning agents
After cleaning thoroughly rinse each component with deionized water during the last rinse cycle in order to remove all residues. Do not use tap water for the last rinse cycle.

Risk of damage due to residues of disinfectants
Disinfectant solutions can contain various aggressive chemical ingredients (e.g. chlorine) that may cause corrosion of the product. Therefore, thoroughly rinse the product with de-ionized water to remove all residues. Do not use tap water for rinsing since it could be chlorinated.

Risk of damage due to incompatible cleaning agents and disinfectants
Incompatible cleaning agents and disinfection solutions can cause considerable damages to the DIRECT2 Lid. Therefore, only use cleaners recommended by Bimini Health Tech for use with the DIRECT2 Lid.

Risk of damage by exceeding the concentration and the contract time
Strictly adhere to the instructions given by the disinfectant producer regarding the concentration and the contact time of the disinfectant solution. In order to prevent the device from damages, the indicated values must not be exceeded.

6.4.1 Manual Cleaning
Prescribed cleaning agents
When disinfecting with CIDEX OPA, use a low-foaming enzymatic detergent of a neutral pH value (6-8) for cleaning. Cidezyme GI is recommended.
• It is advised not to use strong acid or alkaline cleaning agents.

Immersion of the parts for manual pre-rinsing
All parts must be immersed in the cleaning and disinfectant solution mixed with lukewarm water (deionized if possible) for at least ten (10) minutes or longer in case of stubborn or dried on soilings. The concentration is to be selected according to the disinfectant producer's specifications

Manual pre-cleaning
All individual parts must be pre-cleaned in the cleaning solution using brushes. The work must be repeated until the brushes, the surfaces, and hollow spaces to be cleaned are free of visible contamination. After cleaning, rinse all parts with potable water.

Manual cleaning
All parts must be completely immersed in an ultrasound bath with cleaning and disinfectant solution mixed with lukewarm water (deionized if possible). They must stay in the ultrasound bath for at least five (5) minutes.
The concentration is to be selected according to the producer's specifications. Do not mix with other cleaners. After cleaning, rinse all parts with deionized water.

Cleaning check
Check all surfaces, ports, and hollow spaces for visible contamination. Return contaminated parts to the cleaning process.

6.4.2 Manual Disinfection
Prescribed cleaning agents
CIDEX OPA Ortho-phthaladehyde HL disinfectant solution
• Contact time: at least 5 min. (undiluted)
• Maximum period of use: 14 days
• In case of strong contamination, it is recommended to renew the solution earlier.

Manual disinfection
Procedure and concentration when using CIDEX OPA:

Immerse the DIRECT2 Lid parts in the prepared solution (concentration according to the producer's specification) for five (5) minutes. There must not be any air bubbles on the parts of the DIRECT2 Lid.
• In order to avoid damages to the product, only use gripping pliers with rubber jaws when handling the instruments in the disinfectant solution.

Rinsing
After disinfection, completely rinse all parts in a large volume rinse bath (at least 8 liters) for at least thirty (30) seconds. Afterwards, flush all lumens of the lid as well as the straw by hand again and use a water jet pistol for at least 15 seconds on each of the three o-rings. Dispose of the rinse water.
• Thoroughly rinse all parts with sterilized, deionized water to remove all toxic residues of the disinfectant.

Drying
Dry all parts internally and externally using sterile compressed air.

Maintenance
The individual parts are not intended for maintenance.

Check and inspection
Visually check the parts for damage and wear. Check the ports on the lid for deformation and all stainless-steel parts for corrosion. Reject any damaged part.
Note: If damaged parts shall be returned to Bimini Health Tech or an authorized distributor, they must be cleaned, disinfected, and sterilized before and be accompanied with the relevant documented evidence.

6.4.3 Sterilization after Manual Cleaning and Disinfection
Packaging
In accordance with ISO 11607, the dried DIRECT2 Lid must be packed in sterile packaging suited for steam sterilization as follows separately:
• Lid with O-ring (Items 1 and 6 in Figure 1)
• Drain Port and O-rings (Items 3, 4, and 5 in Figure 1)
• Drain Lever and O-rings (Item 2, 4 and 5 in Figure 1)

The packaging must be large enough so that the sealing is not subject to stress.

Sterilization

STERILIZER CYCLE TYPE	GRAVITY	PRE-VACUUM
Minimum Temperature	132 °C	132 °C
Cycle Time	15 minutes	3 minutes
Minimum Dry Time	3 minutes	3 minutes
Sample Configuration	Double Wrapped	Double Wrapped

Process the product with steam sterilization using a pre-vacuum process at 132 °C (269.6 °F) for at least three (3) minutes. No adverse effects on the DIRECT2 Lid are expected after sterilization at 134 °C (273 °F) for a maximum of thirty (30) minutes.

Prior to each sterilization procedure, always check the batch process record for the respective sterilizer to ensure that the cycle complies with the required parameters.

Storage
The individual sterile plastic bags have to be stored in a closed cupboard, protected from light, dust, humidity and extreme fluctuations in temperature. The shelf life is determined by the product specifications of the sterile packaging used.

Active ingredients
CIDEX OPA:
Phthaldialdehyd (synonym: benzol-1,2-dicarbaldehyd) (this information is based on the producer's specification)

6.5 Automated cleaning and disinfection
Prescribed cleaning agents
The following cleaning agents are approved by the producer:

• CIDEZYME® GI / ENZOL® enzymatic detergent (co. ADVANCED STERILIZATION PRODUCTS, Division of Ethicon Inc.)

Note: If possible, the instruments are to be transported from the place of use to the reprocessing facilities in dry condition in order to avoid the protein that can deposit due to the cleaning agent that is used.

The water inflow into the washing machines must start at lower temperatures (approx. 20 °C/ 68.0 °F) to prevent thermal coagulation of proteins.
• When cleaning the lumen of the straw, it should be connected to the hose connectors of the washing and disinfection machine (preferably on the drawer cart of the machine). The same is to be done when cleaning the ports. Silicone hoses are recommended for the connectors of the washing and disinfection machine.

6.5.1 Automated cleaning and disinfection
The following working steps are to be carried out when using a washing and disinfection machine.

Manual pre-cleaning
Disassemble the DIRECT2 Lid and soak in a cleaning solution of tap water with 0.5% Cidezyme (ASP) at temperature (20 °C ± 2 °C) for 5 minutes. At the beginning of the soak time the lumina should be flushed with 5ml of the cleaning solution using a syringe.

The outside of the DIRECT2 Lid components should be brushed under cold running tap water (14 °C - 18 °C) with a soft bristled nylon brush until all visible residues are removed.

Automated cleaning
NOTE: The Drain Port straw should be connected to the flush port of the rack.
• 2-minute pre-cleaning with cold tap water
• Drain
• 5-minute cleaning with 40 °C tap water and 0.3% cleaning solution Thermosept RKN-zym (Schulke, Norderstedt)
• 3-minute rinse with cold deionized water
• Drain
• 2-minute rinse with cold deionized water
• Drain

Blowing
The cleaned parts are to be blown out at a temperature of 80 °C (176 °F) and a hold time of one (1) minute.

Disinfection
Completely immerse the disassembled DIRECT2 Lid components in Cidex OPA® solution for 5 minutes at 20 °C ± 2 °C according to the instructions for use of the manufacturer.

Automated drying
Perform drying at 70 °C (158 °F) for at least fifteen (15) minutes

Cooling
The products cool down at 30 °C (86 °F).

Maintenance
The individual parts of the DIRECT2 Lid are not intended for maintenance.

Check and inspection
Visually check the parts for damage and wear. Check the ports on the lid for deformation; the collection container for cracks, all stainless-steel parts for corrosion. Reject any damaged part. Note: If damaged parts shall be returned to Bimini Health Tech or to an authorized supplier they must be cleaned, disinfected and sterilized before and be accompanied with the relevant documented evidence.

6.5.2 Sterilization after automated cleaning
See section "6.4.3 Sterilization after Manual Cleaning and Disinfection"

6.6 Information on validation of reprocessing
If the above described chemicals and machines are not available it is the user's responsibility to ensure validation of the reprocessing method used.

It is the reprocessor's responsibility to ensure that the reprocessing actually performed with equipment, materials and personnel in the reprocessing facility achieves the desired result. This requires validation and routine monitoring of the process.

Likewise, any deviation from the instructions provided must be properly evaluated by the reprocessor for effectiveness and potential adverse consequences.

Trade Name	Producer	Remarks
Automated Cleaning		
Thermosept RKN-zym	SCHULKE & MAYR	Enzymatic detergent
CIDEZYME® GI / ENZOL® enzymatic detergent	ADVANCED STERILIZATION PRODUCTS	Enzymatic detergent
Manual Cleaning		
CIDEZYME® GI / ENZOL® enzymatic detergent	ADVANCED STERILIZATION PRODUCTS	Enzymatic detergent
Manual Disinfection		
CIDEX® OPA	ADVANCED STERILIZATION PRODUCTS	High level disinfectant for semi-critical medical devices

7 Disposal
DIRECT2 Lid can be disposed of at the end of its service life according to the related guidelines of the disposal of medical waste.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

REF	Catalog Number, Reference Number
LOT	Lot Number
NON STERILE	Provided Non-Sterile Must Clean & Sterilize Prior to Use
	Do not use if package is damaged
	Keep package dry
	See Instructions For Use
	Manufacturer
	Date of Manufacture

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