LipoCollector™ II

Operating Instructions

CE 0482

ISO 13485

Operating instructions for LipoCollector™ II Item No. 650100

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General description of the LipoCollector™ II

The LipoCollector™ II (hereafter LipoCollector) is suitable for the collection of fat intended for re-injection (fat grafting/fat harvesting) or laboratory purpose. The LipoCollector collects the cell-liquid mixture suctioned off during liposuction using water-jet assisted liposuction (WAL) and separates the fat from the remaining liquid.
The LipoCollector serves to filter lipocytes and connective tissue from the aspirate which is extracted during water-jet assisted liposuction. A special filter unit, comprising a stainless steel wire fabric with a mesh/hole size from 0.2 mm to 0.315 mm, captures the appropriate particles in a sterile collection container in such a way that only the WAL rinsing solution ends up in the suction container (waste) provided.

This method of lipocyte extraction represents a refinement and makes the procedure easier when extracting larger quantities of autologous fat.

Safety instructions

Intended use

The LipoCollector is intended to be used for collecting fat during water-jet assisted liposuction. The device can be used in outpatient as well as inpatient surgeries.
The prerequisite for optimal use of the product is functioning suction equipment (body-jet®) suitable for WAL and the appropriate application system (WAL applicator).

Human Med AG does not guarantee the quality of the autologous material collected with the LipoCollector and assumes no liability for any surgical procedures undertaken using the collected material or their results.

Explanation of the safety information

WARNING! The safety information WARNING! denotes a hazard that may cause personal injury.

CAUTION! The safety information CAUTION! denotes a hazard that may cause damage to property.

ATTENTION! The safety information ATTENTION! denotes a hazard that may cause the device to malfunction.

Please pay particular attention to the safety information in each chapter.

Explanation of the operating instructions, training of medical personnel

Who must read the operating instructions?
An important component of the safety concept of the product is the operating instructions. Therefore, all those who will
• prepare,
• set up,
• operate,
• dismantle,
• clean and disinfect

the device and the instruments should read the operating instructions and usage recommendations.

WARNING!
The LipoCollector may only be used by medical specialists trained in this procedure in compliance with the current operating instructions. Human Med AG assumes no liability for any damage resulting from improper use. Please contact our customer service department if you have any questions or suggestions or require clarification.

General Safety Instructions

WARNING! The use of the LipoCollector and its accessories may only be done under environmental conditions whereby **strict adherence to surgical hygiene management** is guaranteed.

WARNING! Dropping the lid or other heavy parts of the LipoCollector may lead to **injuries**! Always handle the parts with the greatest care and minimise the height from which parts may fall.

WARNING! Before the first proper use a **test run** should be carried out during **'normal' liposuction**, for which the aspirate can be discarded, as the surgeon's technique may also affect the fat extraction and this may have to be adapted to optimise future results.

ATTENTION! Dropping or other vigorous application of force may damage the components of the LipoCollector, which may potentially impair the **functioning of the system**. Always handle the parts with care.

ATTENTION! Only original parts and accessories may be used**.**

Notes for initial operation

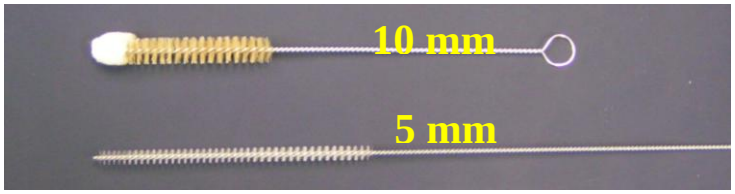
The LipoCollector is supplied as a set made up of different separate components. After checking that the packaging is undamaged and the contents are complete, the disposable components, which are marked sterile, are separated from the rest and stored.
All reusable items must be cleaned and sterilised before to the first use according to the processing guide contained in these instructions.

Disposal

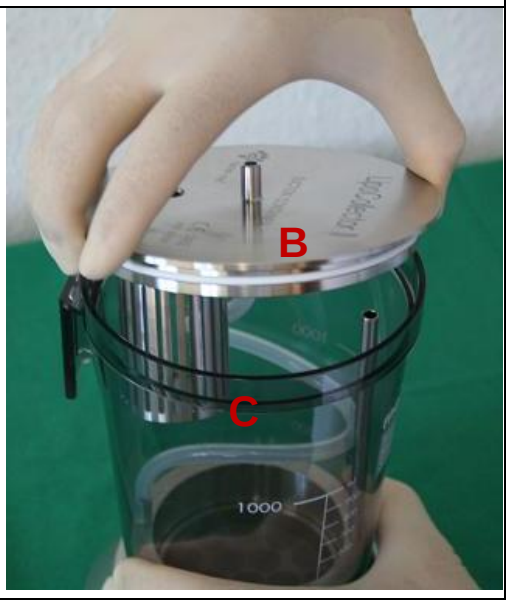
The LipoCollector can be disposed of at the end of its life according to the valid guidelines for the disposal of medical waste.

Processing and assembly of the LipoCollector

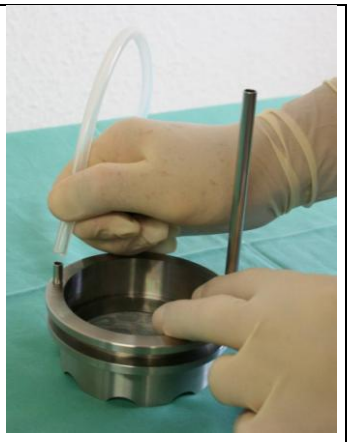
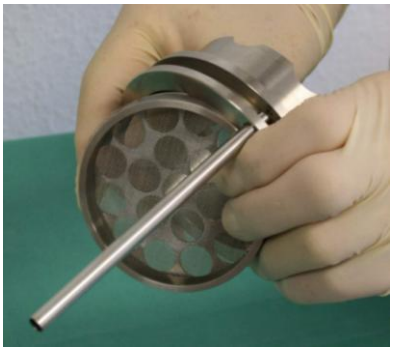
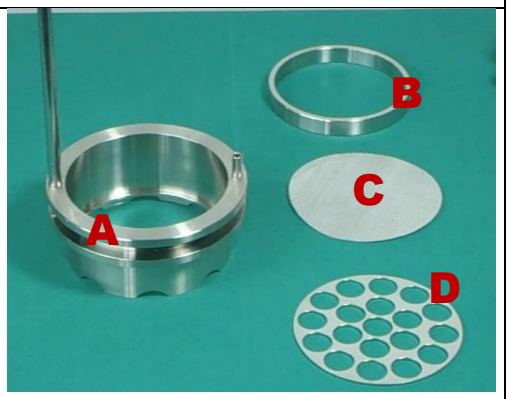
General information

Note:	Only those cleaning agents should be used which are recommended for the cleaning of plastics. Please refer to the manufacturer of the instrument cleaning or disinfecting agent.	
ATTENTION!	**Do not use cleaning or disinfecting agents that contain phenol, as these products can damage the plastic components of the LipoCollector.** **Never use rinsing agents.** Rinsing agents cause stress cracks to form in the collection container and can shorten the lifetime of this container.	
ATTENTION!	Cleaning and sterilisation must only be carried out by **trained personnel** in specifically designated rooms.	
Recommendation:	**Automated cleaning is always preferred to manual cleaning** because the processes are always consistent.	
Note:	Ensure **careful operation in accordance with local safety regulations** in the processing of medical products.	
Recommendations:	*Automatic processing*	*Manual processing*
	We recommend the use of a 'neutral enzymatic 2-component cleaning system'. We recommend the use of a cleaning and disinfection machine that has a laparoscopy basket with connections for lumens (e.g. Hamo® LS 2000 with the load carrier 247.10.0233, both from Steris). The validation of the automatic processing has been carried out using the cleaning agents and machines specified above.	We recommend either the use of an alkaline cleaning agent approved for manual processing and a disinfecting agent approved for manual disinfecting or the use of a combined cleaning and disinfecting agent. The validation of the manual processing has been carried out using Gigasept Instru AF.
Limit to re-use:	The end of the product lifetime is determined by normal wear and tear resulting from correct use. All components of the LipoCollector have been safely tested for **50 processing cycles** using validated processing procedures as well as a standard cleaning procedure with "neodisher MediClean forte". Any additional processing cycles or other type of processing becomes the responsibility of the user.	
Necessary tools:	Ultrasound cleaning bath, rinsing bath, cleaning bath and cleaning brushes 	

Disassembly

Preparation and transport	Remove surface soiling with a disposable cloth / paper towel. Avoid allowing blood and tissue residue to dry. We recommend immediate processing after use. Do not use fixing agents or hot water (> 40°C) as these denature proteins, thereby compromising the cleaning result.
	Transport should be done in a closed container to avoid contamination of the environment. It is recommended to begin reprocessing the parts of the LipoCollector immediately after use.
Dismantling	Remove the reduction connector (A) on the 'PATIENT' port from the lid of the collection container. 
	The seal must be detached from the reduction connector and disposed of. 
WARNING!	The seal is a disposable product and **must not be reprocessed**. Repeated use can lead to loss of elasticity of the material, leading to contamination of the aspirate with particles.
	The lid (B) is removed from the collection container (C). Then the inner ring/bypass is removed. 

	One end of the inner tubing is pulled out from the underside of the lid. 
	The basket (D) must be detached from the underside of the lid. 
	The seal must be removed from the lid and disposed of. 
WARNING!	The lid seal is a disposable product and must not be re-processed. Repeated use can lead to loss of elasticity of the material, leading to contamination of the aspirate with particles.
	It is recommended to strike a hand against the edge of the container to loosen the inner ring/bypass. Then the inner ring/bypass is removed. If it is difficult to remove, the release lever, Item No. 653400, may be used.  

	The inner tubing must be detached from the inner ring/bypass and disposed of. 
WARNING!	The inner tubing of the LipoCollector is a disposable product and must not be reprocessed. Processing and repeated use may lead to toxic reactions and thus to damage of the fat as it is passed down the tube.
	The fixation ring, mesh filter and foot ring plate are removed in this order from the inner ring/bypass.  
	The parts are now as shown below: A: Inner ring/bypass B: Fixation ring C: Mesh filter D: Foot ring plate **The mesh filters (C) must be disposed of.** 
WARNING!	The mesh filters are disposable products and must not be re-processed. Due to the fine mesh size of the filter, it is not possible to process the filters to ensure hygienic results free of residue.

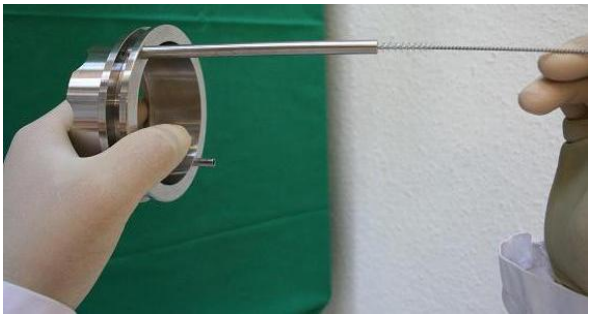
Cleaning and disinfection

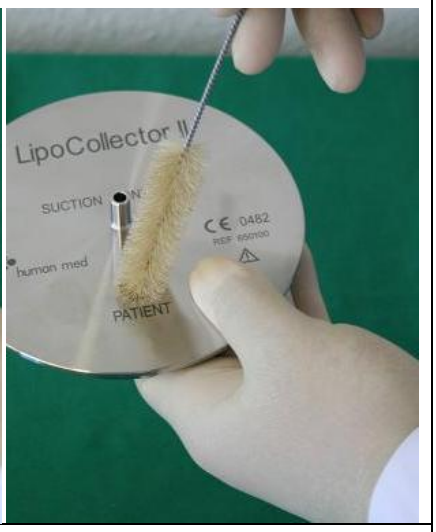
A) Automated cleaning and disinfection

Recommendation:	All individual parts required for re-use, **collection container, foot ring plate, inner ring/bypass, basket, lid, reduction connector and fixation ring**, must now be placed in the cleaning and disinfection machine.
	When cleaning the lumens of the tubular elements (A) of the inner ring/bypass, it is necessary to connect these to the hose connectors of the cleaning and disinfection machine. If possible use a machine in which the channels can be connected to the load carrier for flushing. 
	The same applies for cleaning the lumen of the reduction connector 
	and for cleaning the lumen of the tube connecting piece (B) on the lid. 
	We recommend the use of silicone hosing for the connections to the cleaning machine.
	The following steps must be carried out in a cleaning and disinfection machine: the process described here reflects the validated processing from Human Med AG.
Automatic pre-cleaning:	2 x pre-rinse with 30°C water for 5 minutes each.

Automatic cleaning:	The cleaning step is done with 55°C water, dosed with the solution according to the manufacturer's specification (we recommend deconex TWIN BASIC in combination with TWIN ZYME) with a hold time at the temperature of at least 15 minutes. Finally rinse for 3 minutes with cold water and then rinse for 3 minutes with completely deionised water at 20°C.
Blowing out	The blowing out of the cleaned products should be carried out at a temperature of 80° C with a hold time of 1 minute.
Automatic disinfection	Thermal disinfection is done using completely deionised water at a water temperature of 93°C with a hold time of 10 minutes.
Automatic drying	Drying should be done at 70°C for at least 15 minutes.
Cooling	The products are cooled off at 30°C.

B) Manual cleaning and disinfection

Insertion of the parts for manual pre-rinsing	All individual parts required for re-use, **collection container, foot ring plate, inner ring/bypass, lid, reduction connector and fixation ring**, must be immersed in the cleaning and disinfecting solution (Gigasept Instru AF, 1.5%, made up with lukewarm water, if possible, with deionised water) for at least 10 minutes or longer in cases of stubborn or dried soiling.
	All parts must be cleaned with a brush. Pre-cleaning with the brushes must be carried out using the cleaning and disinfecting solution (Gigasept Instru AF, 1.5%, made up with warm water, deionised water if possible). These steps must be repeated until the brushes and the surfaces and cavities to be cleaned are free of visible contamination. **The instrument cleaning solution must be renewed at least daily or any time there is visible contamination.**
Manual pre-cleaning	Carry out the cleaning of cavities as follows. Both tubes of the container insert must be cleaned with the 5 mm brush.  

	The cavities in the lid must be cleaned with the 5 mm and the 10 mm brushes.  
	The reduction connector must then be cleaned with a 5 mm brush. 
Manual cleaning and disinfection	All parts must now be completely immersed in an ultrasound bath with cleaning and disinfecting solution (Gigasept Instru AF, 3%, made up with lukewarm water, if possible, with deionised water). The cleaning step in the ultrasound bath must be at least 5 minutes long. Cleaning for 15 minutes in an immersion bath is also possible. The same lukewarm cleaning solution is required in this case. **Do not mix with other cleaners.**
ATTENTION!	After cleaning in the solution the parts must be thoroughly rinsed with flowing water (preferably demineralised) or in a rinsing bath for at least **one** minute. **Repeat rinse step a second time.**
3. Cleaning check:	Check all surfaces, openings and cavities for visible contamination. Any contaminated parts must go through the cleaning process again.
4. Drying	Dry all parts inside and out with sterile compressed air.
5. Maintenance:	Maintenance of the individual parts is not intended.
6. Examination and testing:	Carry out a visual inspection for wear and tear **(connectors on the lid for deformation, collection containers for cracks, all stainless steel parts for signs of rust)**. Any damaged parts must be discarded. **Note:** *If you want to return damaged parts to Human Med AG or your suppliers, they must be cleaned, disinfected and sterilised beforehand and the appropriate proof must be enclosed.*

Sterilisation

1. Packing:	The dried individual parts of the LipoCollector must be packed as follows in sterile packaging suitable for steam sterilisation as per ISO 11607. The package must be large enough that the seal is not under tension. 1. Inner ring/bypass separately 2. Lid separately 3. Fixation ring, foot ring plate, basket and reduction connector together 4. Collection container separately
2. Sterilisation	Steam sterilisation using a fractionated vacuum procedure at 121°C for at least 15 minutes and at 134°C for 3 minutes is validated. Sterilisation at 134 °C for at least 10 minutes was tested with no negative effects on the material detected. For every sterilisation check the pressure protocol for the particular steriliser to ensure compliance with the necessary parameters.
3. Storage:	The individual sterile foil bags must be stored in a closed cupboard protected from dust, moisture and large temperature fluctuations. The shelf life is determined by the specifications for the sterile packaging used.

The instructions specified above for reprocessing of the LipoCollector have been validated as suitable by Human Med AG.

Information about validation of reprocessing

The following test instructions, materials and machines were used for validation of cleaning:

Automatic cleaning agent:
deconex TWIN BASIC / TWIN ZYME, Borer Chemie AG

Automatic neutraliser:
Deconex 64 NEUTRARADRY, Borer Chemie AG

Manual cleaning agent:
Gigasept Instru AF, SCHÜLKE & MAYR

Manual disinfectant:
Gigasept Instru AF, SCHÜLKE & MAYR

Cleaning and disinfecting machine:
LS 2000, Hamo with drawer basket (laparoscopy basket with connections for Lumina)
Program NEUTRAL WASH

Details of the validation can be requested from Human Med AG.

If the chemicals and machine described above are not available, it is the responsibility of the user to validate according to his procedures.

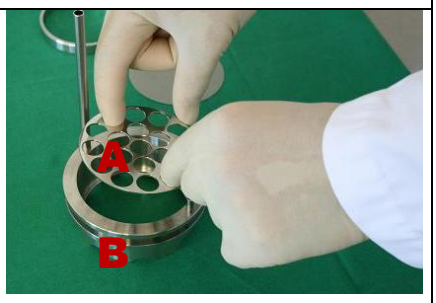
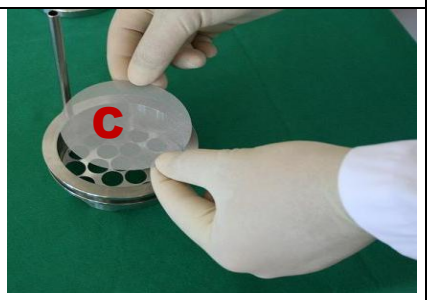
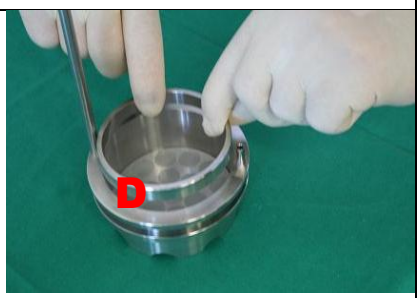
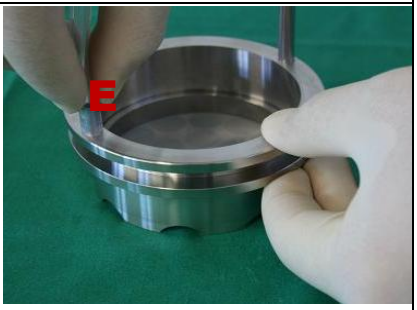
The person carrying out reprocessing is responsible for ensuring that the processing actually carried out with the equipment, material and personnel in the processing setup achieves the desired results.

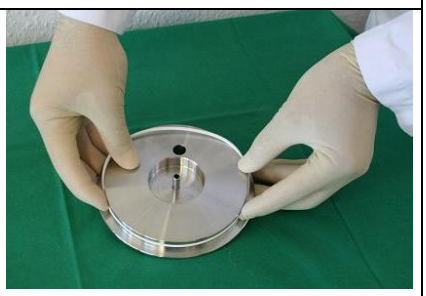
For this purpose validation and routine monitoring of the procedure are required. Likewise, any deviation from the instructions provided by the person carrying out reprocessing should be analysed carefully for its effect and possible adverse consequences.

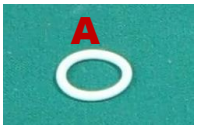
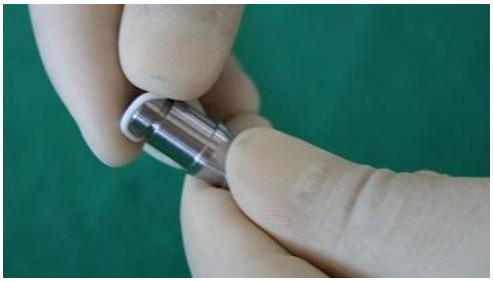
Lists of tested cleaning and disinfection agents

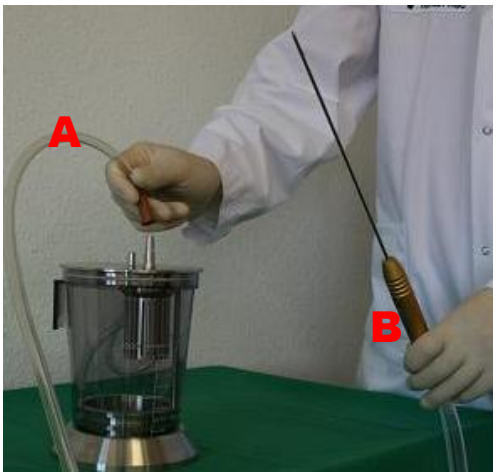
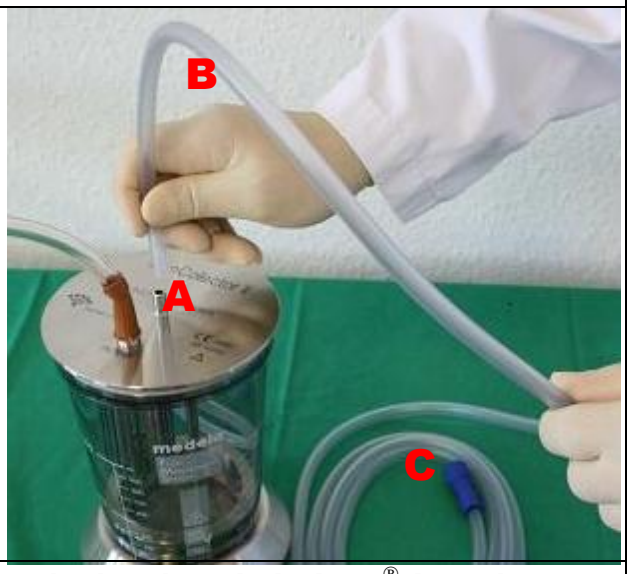
Trade name	Manufacturer	Comment
Instrument cleaning		
Thermosept RKN-zym	SCHÜLKE & MAYR	Enzymatic cleaner
Thermosept alca clean	SCHÜLKE & MAYR	Alkaline cleaner with surfactants, pH value > 10 possible
Neodisher MediClean forte	DR. WEIGERT	Alkaline cleaner with surfactants, pH value > 10 possible
Manual instrument disinfection		
Neodisher Septo 3000	DR. WEIGERT	
Disinfecting cleaner		
Gigasept Instru AF	SCHÜLKE & MAYR	Aldehyde-free
2-component cleaning system		
TWIN BASIC TWIN ZYME	Borer Chemie AG	Neutral-enzymatic and mild alkaline

Assembly prior to clinical use

ATTENTION!	Carry out a **visual inspection for damage and wear**. If there is visible damage on components do not assemble the product.
WARNING!	The assembly of the complete LipoCollector must be carried out **under aseptic conditions** using the supplied sterile single-use components (inner tubing, seals for the lid and reduction connector and mesh filter).
WARNING!	All components must be allowed to **cool down sufficiently** after sterilisation (below body temperature) before they may be used.
	The foot ring plate (A), the mesh filter (C) and the fixation ring (D) must be assembled as described below.
	The foot ring plate (A) is placed in the inner ring/bypass (B). 
	Then a new mesh filter (C) is inserted. See the guidelines on page 19 of these operating instructions for information about selecting the mesh filter. 
	The fixation ring (D) is then placed on top. 
	New inner tubing must be fitted onto the nipple (E) of the inner ring/bypass. 

	The completed inner ring/bypass is inserted into the collection container and pressed right down. Ensure that there is a firm fit. 
	The collection container must be placed on the foot ring. 
	A new seal is placed in the groove of the lid. The seal must lie completely in the groove. 
ATTENTION:	Do not stretch the seal too much; this can alter its elasticity, causing the LipoCollector to leak with a reduction in the suction.
	The basket must be placed over the nipple (B) on the inside of the lid. 
	The other end of the inner tubing must be fitted onto the connector nipple on the lid. 
ATTENTION:	Push the hose all the way in to securely fix the basket.

	Fill the collection container with sterile saline solution up to the 400 ml mark. 
	The lid with its seal is then fitted onto the collection container. The basket must sit below the opening for the reduction connector in the lid (labelled PATIENT). 
ATTENTION:	Make sure that the basket is in the correct position, otherwise there will be not prefiltering.
	A new seal (A) must be placed on the reduction connector. It must sit completely in the groove.  
ATTENTION:	Do not stretch the seal too much; this can alter its elasticity, causing the LipoCollector to leak with a reduction in the suction.
	The reduction connector is moistened with physiological saline and then inserted with a twisting movement into the opening labelled ‘PATIENT’ on the lid. 
ATTENTION!	The seal may be damaged if it is not moistened with liquid or if it is not twisted into the opening.
WARNING!	Damage to the seal may result in contamination of the aspirate with silicone particles! Therefore be absolutely diligent in avoiding any damage.

	The LipoCollector is now ready for connection of the tubing (A) from the cannula (B) to the reduction connector. 
	The connecting tube B is inserted onto the connector labelled SUCTION CONTAINER on the lid (A). The other end C of the tube leads to the suction container on the body-jet® or to another suction appliance. 
ATTENTION!	Do not connect the connecting tube directly to the body-jet® device but rather always to the suction container (waste).
ATTENTION!	Follow the instructions for use for the body-jet® or the particular suction device used!

Instructions for fat harvesting

WARNING! Lipocytes are cold sensitive! The ambient temperature for the collected fatty tissue should be at least 20°C (and 37°C at the highest).

Note: If pre-warmed (to maximum body temperature) infiltration and rinsing solution is not normally used, it should definitely be considered for procedures that include lipocyte extraction.

WARNING! The suction vacuum should not exceed -0.5 bar to minimise any damage to the fatty tissue collected.

WARNING! The composition of the anaesthetic rinsing solution may affect the vitality of the cells harvested.

Level of fluid above the mesh filter

The principle behind the LipoCollector is that there is an initial separation of liquid and lipocytes due to the physical buoyancy. The less dense fat floats on the liquid which is concurrently and continuously suctioned off. In doing so the filter is constantly rinsed with liquid which reduces blockage of the filter mesh.

ATTENTION! In order to achieve optimal filtration there should always be liquid above the mesh filter. Therefore:

- Fill the collection container before the liposuction with sterile isotonic saline up to the 400 ml mark on the container scale.
- Only switch the suction on when you begin with the liposuction itself (do not do an 'empty run'). Recommended order:
    - Insert the liposuction cannula
    - Close the bypass hole on the handle and keep it closed
    - Start the suction pump

  A closed system during the approximately first ten minutes helps to prevent clogging of the mesh filters.
- Do not shake or swing the LipoCollector.

Function of the basket

The LipoCollector is equipped with a basket that acts as a pre-filter. By turning the lid, the basket is positioned precisely beneath the opening of the PATIENT port, ensuring that incoming aspirate first runs through the basket. Larger strands of tissue are retained in the grates of the basket, which reduces blockage of the mesh filter and/or cannulae.

Selection of the mesh filter

ATTENTION: The correct filter size is determined by various factors, some of which are dependent on the surgeon's technique. Particularly for surgeons with minimal experience with the system, the filter size must first be approximately determined in a **test run** prior to the first lipocyte transplantation.

In the test run a mesh filter with a 250 µm mesh size should first be used. Filtration is optimal when no significant amount of liquid backs up above the filter while simultaneously no lipocytes are sucked past the filter. A mesh filter of the appropriate size is selected as required.

Ensure gradual pressure reduction

During operation of the LipoCollector an abrupt reduction in pressure in the system should be avoided. If the system is opened on the patient's side, the atmospheric pressure causes a large drop in pressure that leads to knocking of the suction hose and forceful injection of the aspirate, which may severely damage the filter mechanism.

Therefore please note the following points:

- Release the bypass hole of the cannula slowly (rolling movement of the thumb)
- Do not pull the cannula abruptly from the incision (with existing vacuum)
- Only use the original reduction connector ('Patient' port on the container lid)

Mode of operation to improve the quality of the aspirate

The **vacuum** should only be as high as necessary to achieve a good suction result. The recommendation is max. -0.5 bar. On one hand, this reduces excessive 'sucking in' of the aspirate on the filter, which may also lead to blockages. On the other hand, the mechanical load on the lipocytes is reduced, which is also beneficial for the quality of the lipocyte concentrate.

To ensure trouble-free collection and optimal harvesting of the fat component from the aspirate, it is advantageous to operate **with steady cannula movements**. The surgeon should rather allow the water to do the work and not extract the fat by dissection using pressure on the suction opening of the cannula. The fat should be 'rinsed free' by the gentle force of the water. Any excessively large connective tissue pieces in the aspirate can thus be avoided as far as possible.

It is recommended to work with a **3.8 mm cannula** of STS (stainless steel) type so that loosened fat particles or cell islets remain as small as possible.

The infiltration should be **RANGE 1 or 2** (body-jet® and AquaShape® mobile) in this case.

Collected quantity / liquid fraction of the aspirate

The filtering of the aspirate with the LipoCollector is done predominantly using **buoyancy and gravity**. The suction of the liposuction system bypasses the previously collected aspirate via the integrated bypass. This means the fatty tissue that has been suctioned off is handled as gently as possible.

ATTENTION! Pay attention to the level of liquid in the container during liposuction. If the aspirate collected in the container exceeds the height of the bypass tube, it can overflow, causing subsequent loss of incoming aspirate.

Based on experience, the portion of liquid remaining in the aspirate after completely passing through is **about 20–25** %, which is favourable in case of later injection/tissue infiltration through thin cannulae such as the BEAULI infiltration cannula. This means that centrifugation can generally be omitted.

The **quantity** of collected fat-liquid mixture can be **approximated** using the scale on the side of the collection container. This approximation is only for estimating the quantity of fat collected during liposuction and is no substitute for precisely recording a volume to be injected later if required.

To make the estimate, subtract 200 ml (which is the container volume beneath the filter and the volume of the unit) from the value read from the scale. To calculate the quantity of solid components, a liquid fraction of about 20–25 % must be subtracted.

Example calculation: Drain volume, read from container scale: 800 ml

./. 200 ml void volume

= about 600 ml fat-liquid mixture (ready for further use)

./. 25% liquid fraction

= approx. 450 ml fraction of solid components (‘pure’ fat)

Extraction of fat from the container

Prior to extraction of the fat from the LipoCollector, the liquid fraction in the aspirate should be reduced by allowing the suction pump to run for a short time (approx. 2 minutes) after completion of the liposuction. The flow of the liquid can be easily seen through the transparent container.

To avoid air contact as much as possible, the filtered aspirate can be withdrawn using a cannula while keeping the lid closed. To do this, the reduction connector is removed from the lid and the basket is moved to one side by twisting the lid. The opening is then used to extract the aspirate.

ATTENTION: Make sure that the Basket is in its proper position again when continuing collecting fat.

The sterile extraction cannula (Item No. 655010) – in connection with a 50 ml disposable syringe – is recommended for this extraction. The cannula is adjusted to the height of the container and does not reach too deeply when introduced through the lid opening. The winged Luer connector provides the best possible grip.

For transfer from syringe to syringe there is a Luer-to-Luer connector (female/female), Item No. 5206634, available.

Troubleshooting guide

Insufficient vacuum pressure (or no suction)

Background: Because the LipoCollector is integrated into the suction system, all necessary connections must be pressure-stable; that is, no additional air must be able to enter the system. Experience shows that faulty operation occurs often here.

ATTENTION: It takes about 10 seconds for the vacuum pressure to build up to the full level in the collection container of the LipoCollector.

Possible indications of absent or insufficient vacuum pressure: no, or only a very small quantity of, aspirate suctioned into the container, slow flow in the suction tube, low pressure reading on the manometer of the suction pump (body-jet®).

Causes: blocked suction cannula, leaks in the system (frequently in the LipoCollector), damaged collection container resulting from improper processing or handling, incorrect or clamped off tubing connections, incorrect equipment setting.

Fault isolation:

All components of the system (the applicator with cannula, the complete LipoCollector, the connecting tubes, the collection container with bag and the body-jet itself) are properly connected, and the device is switched on. The suction cannula is in the adipose tissue (suction holes and bypass hole are closed).

Begin by checking the vacuum-manometer in reference to the possible causes described in sections 1. and 2. below.

1) **The device/system is properly assembled, and the vacuum-manometer shows the appropriate reading (500mbar), but no liposuction/fat harvesting is possible.**
    a. Disconnect the suction tubing of the applicator from the tube-connecting piece on the LipoCollector (patient port).
        i. **If the manometer reading drops below 300mbar there is a blockage in the applicator/cannula.**
        ii. **If the manometer reading remains constant look for the blockage between the LipoCollector and the body-jet device.**
    b. Disconnect the connecting tube from the LipoCollector lid (SUCTION CONTAINER port).
        i. **If the manometer reading remains constant there is a blockage between the connecting tube, collection container with bag, body-jet with protective filter.**
        ii. **If the manometer reading drops below 250mbar there is a blockage in the LipoCollector.**
2) **The device/system is properly assembled, but the pressure reading on the manometer is too low; no liposuction/fat harvesting is possible.**
    a. Disconnect the suction tubing of the applicator from the tube-connecting piece of the LipoCollector (patient port), and block airflow in the tube-connecting piece of the LipoCollector by hand.
        i. **If the manometer reading increases significantly, look for a suction fault/leak between the applicator and cannula.**
        ii. **If the manometer reading remains insufficient, then look for an improper setting/suction fault/leak between the LipoCollector and the body-jet device.**
    b. Disconnect the connecting tube from the LipoCollector lid (SUCTION CONTAINER port), and block airflow in the connecting tube by hand.
        i. **If the manometer reading remains insufficient, there is an improper setting/suction fault/leak between the connecting tube, collection container with bag, body-jet with protective filter.**
        ii. **If the manometer reading increases significantly look for the suction fault/leak on the LipoCollector itself.**

Information on fault isolation and rectification:

Applicator	Is the suction cannula blocked? (This is the most common cause when the problem arises during a liposuction treatment). One indication of a blocked cannula is a sudden decrease in resistance to cannula movement in the tissue. Wipe free/rinse
	Is the suction tubing from the body-jet® applicator correctly connected to the LipoCollector?

Device, settings, filter, suction container	Is the body-jet® / the suction pump switched on? (illuminated display, pump sounds)
	Is the vacuum changeover-switch of the suction pump on the body-jet® set to the correct suction container side? (right or left)
	Is the rotary switch of the vacuum regulator set to a high enough vacuum pressure? (max. -0.5 bar)
	Is the overflow safeguard/bacteria filter on the body-jet® blocked? Follow the steps specified in the body-jet operating instructions for checking and changing the filter.
	Is the tubing between the suction container and the body-jet® correctly inserted?
	Is the disposable bag in the suction container completely unfolded?
	Is the hydrophobic filter in the suction bag blocked? (caused by contact with fluids, e.g. after emptying the aspirate) The suction bag must be changed.
	Is the tubing between the LipoCollector and the body-jet® suction container correctly attached on both sides?
LipoCollector	Is the lid of the LipoCollector correctly closed, and is the seal (O-ring) correctly and completely positioned in the respective groove? Is the lack of sufficient vacuum pressure being caused by a leak in the O-ring or lid? The vacuum pressure can be increased by pressing down the lid on the collection container (for 10 sec.) or changing the seals.
	Is the seal (O-ring) correctly positioned on the reduction connector, and is the reduction connector correctly inserted into the lid?
	Insufficient vacuum pressure may be caused by damage to the suction container from - processing errors, as indicated by cracks (see Fig. a), or container deformation (the inner ring is no longer seated correctly on the floor of the container) or - notches in the edge of the lid (see Fig. b).
	a)  b) 
	Fault rectification: Use a new collection container. ATTENTION! Never use a damaged collection container. The processing instructions must be strictly observed. Always ensure that there are no metal parts in the collection container during sterilisation. Do not attach the stainless steel components of the LipoCollector until all components are completely cooled.
	Is a kink in the inner tubing causing the absence or lack of vacuum pressure?
	  
	Fault rectification: Ensure that the tubing has been property connected and handled!

Pay special attention to the information provided in the body-jet® operating instructions or the respective operating instructions of the third-party device (if using the AquaShape® mobile).

Harvested fat is too watery

Most common causes

1. Mesh filter blocked.

A common cause for 'too watery fat' is blockage of the mesh filter in the LipoCollector, which leads to the WAL rinsing solution remaining in the container.

Blockage of the mesh filter on the other hand may be caused by the following:

- Insufficient level of liquid (saline solution) before and during the whole collection period. Also see the hints on page 18 of the operating instructions.
- Too many connective tissue strands in the aspirate that were not caught by the pre-filter (basket). Also see the hints on page 18 of the operating instructions.
- Incorrect mesh filter selected. Also see the hints on page 19 of the operating instructions.

2. Faulty extraction

- If the extraction cannula is inserted too deeply into the LipoCollector (only possible if the lid is off) or if original cannulae are not used for extraction, in some cases the extraction point is too deep in the LipoCollector and the liquid required to rinse the mesh filter can be aspirated as well. Also see the hints on page 20 of the operating instructions.

3. Inner tubing not (or incorrectly) mounted in the LipoCollector (rare)

- If the tube is not fitted or is incorrectly fitted, a vacuum can build up in the LipoCollector and still block all the fluid as it cannot be transported further into the waste container of the pump. See the guidelines on page 14 of these operating instructions for information about correct assembly prior to use.

Remedial action to be taken if there is clearly too much water in the collected aspirate

a) Still inside the container

Wait for about 10 minutes so that fluid and water can separate by buoyancy; this often clears the mesh filter, and the remaining fluid can be suctioned out, or the fat floating on the top can be easily extracted.

b) In the syringe

If the aspirate has been drawn into the syringes already (e.g. 50 cc), let the syringes rest for about 10 min in a syringe rack with the piston pointing upwards. After spontaneous fat from fluid separation it should be easy to eject the excess fluid from the syringes before the fat is transferred into smaller syringes for further use.

NOTE:

Please refer to the enclosed "Fault Isolation Guide". This guide offers a flowchart that illustrates the major causes of error described in these operating instructions as well as recommendations for their rectification.

The flowchart does not claim to be exhaustive and is not considered a part of these operating instructions.

List of LipoCollector™ II products

Item No.:	Description		PU	
650100	**LipoCollector™ II**, complete set Contains: 2 x 650021 / 2 x 650022 / 1 x 650010 / 650120 / 650050 / 650030 / 650040 / 650041 / 653200 / 651200 / 651250 / 651315 / 1306300010		1 set	
LipoCollector™ II – Disposables				
650022	LipoCollector disposable set (seals / inner tubing)	sterile	1 Set	
651200	Mesh filter 200 µm	sterile	10 pcs	
651250	Mesh filter 250 µm	sterile	10 pcs	
651315	Mesh filter 315 µm	sterile	10 pcs	
1306300010	Connection tubing to suction container Length: 3 metres	sterile	50 pcs	
LipoCollector™ II - Spare parts				
650010	Container		1 pc	
650120	Lid (LC II)		1 pc	
650050	Basket		1 pc	
650021	Reduction connector		1 pc	
650030	Inner ring / Bypass		1 pc	

650040	Foot ring plate	1 pc	
650041	Fixation ring	1 pc	
653200	Foot ring	1 pc	
653400	Release lever	1 pc	

LipoCollector™ Upgrade Kit

650101	**Upgrade Kit from LC I to LC II**	1 set	
	Contains:		
650120	Lid (LC II)	1 pc	
650050	Basket	1 pc	

BEAULI™ Set

655000	**BEAULI Set,**		1 set	
	Contains:			
655010	Extraction cannula	sterile	1 pc	single-use
655020	BEAULI infiltration cannula	sterile	1 pc	single-use
5206634	Luer-to-Luer connector (f / f)	sterile	1 pc	single-use
650022	LipoCollector disposable set	sterile	1 set	single-use

BEAULI™ - Disposables

655010	Extraction cannula	individually packed single-use	sterile	10 pcs

655020	BEAULI infiltration cannula	individually packed single-use	sterile	10 pcs

5206634	Luer-to-Luer connector (female/female)	single-use	sterile	100 pcs.