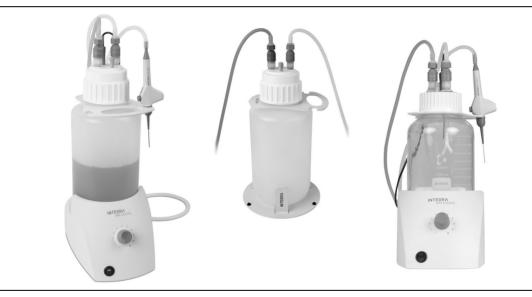
INTEGR



VACUSAFE Operating instructions

CEUR Declaration of conformity INTEGRA Biosciences AG – 7205 Zizers, Switzerland declares on its own responsibility it user

Description	Models	
VACUSAFE	158300, 158310, 158320	
comply with:		
EU Directives	Scope	Date effective
2014/35/EU	Low voltage directive (LVD)	20.04.2016
2014/30/EU	Electromagnetic compatibility (EMC)	20.04.2016
2012/19/EC	Waste electrical and electronic equipment (WEEE)	14.02.2014
2011/65/EC	Restriction of hazardous substances (RoHS)	03.01.2013
EU Regulations	Scope	Date effective
1907/2006	Registration, evaluation, authorisation and restriction of chemicals (REACH)	01.06.2007
2019/1782	External power supply efficiency	01.04.2020
EU Standards	Scope	
EN 9001:2015	Quality Management	
EN 61010-1:2010	Safety general laboratory equipment	
EN 61326-1:2013	Electromagnetic compatibility laboratory equipn	nent

Scope	Date effective
Electrical equipment safety	08.12.2016
Electromagnetic compatibility (EMC)	08.12.2016
Waste electrical and electronic equipment (WEEE)	01.01.2019
Restriction of hazardous substances (RoHS)	02.01.2013
Scope	
Safety general laboratory equipment	
Restriction of hazardous substances (RoHS)	
	Electrical equipment safety Electromagnetic compatibility (EMC) Waste electrical and electronic equipment (WEEE) Restriction of hazardous substances (RoHS) Scope Safety general laboratory equipment

USA Regulations	Scope							
47 CFR Part 15 (FCC) Electromagnetic compatibility (EMC)								
10 CFR Part 430 External power supply efficiency (CEC VI)								
17 CFR Parts 240 & 249b Dodd frank "Conflict minerals"								
27 CCR Parts 25102- 27001	Proposition 65: The safe drinking water and toxic enforcement act							
USA Standards	Scope							
UL 61010-1:2012	Safety general laboratory equipment							

CAN Standards	Scope
CSA-C22.2 No. 61010-1	Safety general laboratory equipment

CHN Regulations	Scope	Date effective		
Order 32/2016) 01.07.2016			
CHN Standards	Scope			
SJ/T 11364-2014	Restriction of hazardous substances (RoHS)			

JPN Regulations	Scope	Date effective
PSE (Denan) Law	Electrical appliance and material safety law	01.01.2014

ЕАС Технический регламент Таможенного союза						
ТР ТС 004/2011 О безопасности низковольтного оборудования						
TP TC 020/2011	Электромагнитная совместимость технических средств					

Zizers, March 29, 2021

Urs Hartmann CEO

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Table of Contents

Chapter 1	Introduction												
	1.1 1.2	Intended use											
Chapter 2	Des	cription of the device											
	2.1 2.2	Scope of delivery											
Chapter 3	Inst	Installation											
	3.1 3.2 3.3	Operating environment7Power supply7Set-up73.3.1Connecting the filter73.3.2Air outlet connection for total containment83.3.3Connection of the bottle and hand operator93.3.4Connection and calibration of the level sensor10											
Chapter 4	Оре	ration											
		Vacuum activation and notes on use											
Chapter 5	Maiı	ntenance											
	1.1 Intended use 1.2 Safety notes 2 Description of the device 2.1 Scope of delivery 2.2 Overview of the VACUSAFE 3 Installation 3.1 Operating environment 3.2 Power supply 3.3.1 Connecting the filter 3.3.2 Air outlet connection for total containment 3.3.1 Connection of the bottle and hand operator 3.3.4 Connection and calibration of the level sensor 3.3.4 Connection and calibration of the level sensor 4.1 Vacuum activation and notes on use 4.2 Use of the level sensor 4.3 Troubleshooting 5 Maintenance 5.1 Cleaning 5.2.2 Chemical decontamination 5.3 Replacement of quick coupling sockets 5.4 Replacement of liquid level sensor 5.5 Equipment disposal 6 Technical data 6.1 Specifications 6.2 Chemical compatibility												
Chapter 6	Tec	hnical data											
		Specifications											
Chapter 7	Acc	essories and consumables18											

1 Introduction

1.1 Intended use

This is a general-purpose laboratory instrument. Any use of this instrument in a medical or IVD setting is under the sole responsibility of the user.

VACUSAFE is a vacuum-based system for aspiration of non explosive aqueous solutions, such as biological buffers and media.

If the VACUSAFE is used in a manner not specified by INTEGRA Biosciences, the protection provided by the VACUSAFE may be impaired.

1.2 Safety notes



WARNING

Read these operating instructions carefully before use and pay particular attention to sections containing this symbol.

- 1) Do not carry out any conversions and alterations on the device.
- 2) Defective parts may only be replaced with original INTEGRA Biosciences spare parts according to the INTEGRA Biosciences operating or service instructions.
- 3) Do not use VACUSAFE in an atmosphere with danger of explosion. Also, do not aspirate highly flammable liquids such as acetone or ether.
- 4) When handling dangerous substances, comply with the material safety data sheet (MSDS) and with all safety guidelines such as the use of protective clothing and safety goggles.
- 5) Prolonged exposure of VACUSAFE to UV-light can cause discoloration and/or yellowing of the plastic housing. However, this will not affect the performance of the device in any way.
- 6) Excess spare parts, accessories and consumables (e.g. tubings, lids, plastic parts, rubber products, O-rings, filter) should be stored in a light protected place at ambient temperature to prevent premature material aging caused by prolonged exposure to UV-light.

Regardless of the listed safety notes, additionally applicable regulations and guidelines of trade associations, health authorities, trade supervisory offices, etc. must be observed. Please visit our website <u>www.integra-biosciences.com</u> on a regular basis for up to date information regarding REACH classified chemicals contained in our products.

2 Description of the device

Please determine which VACUSAFE model you have purchased as it will simplify the reading of these operating instructions. Find the part number of your model on the main packaging label and note it here: 158_____.

2.1 Scope of delivery

- · Base (housing with integrated bottle stand)
- Bottle with closed lid
- Bottle handle
- Lid with openings for tubing
- Tubing and filter 0.45 µm
- Cable for level sensor (models 158300, 158310)
- · Mains adapter
- VACUBOY hand operator

2.2 Overview of the VACUSAFE



- 1 On/off switch with indicator lamp
- 2 Housing
- 3 Bottle for liquid collection (either 4 L polypropylene or 2 L safety coated glass)
- 4 Bottle handle
- 5 Lid with openings for tubing
- 6 Tubing for connection of base to bottle
- 7 Tubing for connection of hand operator to bottle
- 8 Level sensor (models 158300 and 158310)
- 9 Atmospheric pressure return valve
- 10 VACUBOY hand operator
- 11 Knob for vacuum regulation



Rear view

- 12 2 L glass bottle adapter for VACUSAFE base unit (model 158300 only)
- 13 Button for calibration of level sensor
- 14 Socket for level sensor cable
- 15 Mains connection socket
- 16 Filter port (air inlet)
- 17 Air outlet with screwed connector

3 Installation

3.1 Operating environment

VACUSAFE has been designed for use in a laboratory. It shall be installed in a level, dry and dust-free location with a temperature of 5–40°C and a maximal (non-condensing) relative humidity of 80%.

3.2 Power supply

Insert the mains adapter cable into the VACUSAFE mains connection socket $(\underline{15})$ and plug it into the power source.



WARNING

Use an original INTEGRA Biosciences mains adapter only (see <u>"6.1</u> <u>Specifications" on page 16</u> for voltage requirements)

3.3 Set-up

3.3.1 Connecting the filter



Green dot towards instrument!

Insert the hydrophobic filter into the filter port with the green dot of the 0.45 μ m filter or the red dot of the 0.2 μ m filter pointing towards the instrument (see <u>"Rear view" on page 7</u>) in order to guarantee that the hydrophobic side of the filter is facing the liquid collection bottle.



WARNING

The VACUSAFE should never be used without a filter.

A standard 0.45 μm hydrophobic filter is delivered with each VACUSAFE aspiration system. 0.2 μm PTFE filters are available as accessories. The choice of the right pore size depends on the nature of your biological liquid waste and on your biosafety risk assessment.

Application	Protection							
Working with yeast, fungi, fungal spores and large bacteria	0.45 μm PTFE filter							
Working with small bacteria	0.45 µm PTFE filter (min. protection)	0.2 µm PTFE filter (max. protection)						
Working with viruses	0.2 µm PTFE filter (min. protection)	Air outlet connection, 0.2 μm PTFE filter (max. protection)						
Working with small molecules and chemicals	Air outlet connection and 0.2 / 0.45 µm PTFE filter (see 3.3.2)							

General recommendation depending on some standard applications:

These data are provided for informative purposes only and should be verified with your biosafety manager or by consulting the latest biosafety guidelines in force.

3.3.2 Air outlet connection for total containment

For total containment when your VACUSAFE cannot be placed in a biosafety cabinet, you can close the aspiration system by connecting the air outlet connector of the pump ($\underline{17}$) to the HEPA filtration system of the biosafety cabinet. To upgrade your VACUSAFE system:



- 1) If not installed, screw the air outlet connector (#158427) on the air outlet of the pump (<u>17</u>).
- 2) Fix a silicon tubing, ID 4 mm (e.g. #158332, length 180 cm), on the screwed air outlet connector.
- Fix the other end of the silicone tubing on an entry port of your biosafety cabinet. Alternatively bring the other end of the tubing under the biosafety cabinet.

Recommendation: combine the set-up with a 0.2 μm filter and self closing quick couplings.

3.3.3 Connection of the bottle and hand operator



 Place the bottle without lid in the base of the instrument. When using the 2 L glass bottle, first insert the 2 L glass bottle adapter on the back side of the VACUSAFE base unit.



 Insert the bottle handle into the neck of the bottle by screwing it in place. Close the bottle with the lid fitted with tubing openings and make sure that the lid is screwed on tightly.



- Connect one end of the blue tubing to the filter and the other end either to the fitting on the lid marked "PUMP" (model 158 320) or to the blue tubing coupling (models 158 300, 158 310).
- 4) Connect the long transparent tubing to the fitting on the lid marked "HAND" (model 158320) or to the red tubing coupling (models 158300, 158310). Insert the VACUBOY hand operator into the other end of the long tubing.

3.3.4 Connection and calibration of the level sensor



- Plug the level sensor cable into its socket at the back of the instrument and connect it to the bottle lid (models 158300, 158310). Make sure that the sensor pins inside the lid are dry and unsoiled.
- 2) Switch on the VACUSAFE. A double beep confirms correct connection of the level sensor.
- 3) Press the "CALIBRATION" button on the back of the VACUSAFE base until a short beep is emitted.

In case of failed calibration (indicated by continuous beeping and blinking of the switch indicator lamp), repeat the calibration after cleaning the sensor pins inside the lid and checking that the level sensor cable is fully inserted in the lid and base.

4 Operation

4.1 Vacuum activation and notes on use

Switch on the VACUSAFE to start the vacuum pump (the switch indicator lamp lights). Wait a few seconds until the air from the collection bottle is evacuated. To increase or decrease aspiration speed, turn the knob for vacuum regulation to the right or left, respectively (see <u>"2.2 Overview of the VACUSAFE" on page 6</u>).

Aspirate liquid by pressing the green button of the VACUBOY hand operator fitted with a suitable tip. Check the level of liquid in the bottle frequently, especially when working without level sensor, and make sure that there is enough space left for the liquid that needs to be aspirated. General recommendation: fill in the bottle up to max. 75% in case you have to subsequently add a disinfectant or autoclave the liquid waste in the bottle.

To open the bottle, first release the vacuum by opening the venting port on the lid (open the sealing screw or remove the sealing cap). Alternatively you can aspirate air with the VACUBOY. When closing the bottle for use, screw the lid on tightly. The seal in the lid needs to be adequately compressed in order to function. Also make sure the venting port is closed.

Prevent liquid or foam overflow from the collection bottle into the filter. In case the filter gets accidentally wetted or soiled, exchange it immediately or otherwise the retention of further liquid cannot be guaranteed. Note that the hydrophobic filter holds back aqueous solutions, whereas retention of apolar liquids is limited. To prevent the build-up of foam, we recommend the use of an anti-foaming agent (e.g. Antifoam A from Sigma).



WARNING

When working with dangerous substances, you must comply with the material safety data sheet (MSDS) and the additionally applicable regulations of trade associations, health authorities, supervisory offices, etc. In addition, when working with hazardous volatile substances or biohazardous agents, either place the VACUSAFE inside a biosafety cabinet or connect the instrument's air outlet (<u>17</u>) to a safety ventilation by means of a tube and of a connector (Part No. 158427), see 3.3.2.

4.2 Use of the level sensor

When the VACUSAFE bottle is full, the level sensor prevents foam or liquid from overflowing and accidentally soaking filter and instrument. As soon as foam or liquid is detected, the pump switches off to avoid overfilling of the bottle. Additionally, an audible alarm is activated and the switch indicator lamp starts blinking.

It is possible to deactivate the level sensor by simply disconnecting the sensor cable (confirmed by a double beep).

Instrument, sensor cable and bottle lid constitute an assembly that should be checked to ensure that each part matches each other (see <u>"3.3.4 Connection and calibration of the level sensor" on page 10</u>). If you have several lids, sensor cables and instruments and swap them, you have to verify the newly formed assemblies. Depending on the degree of soiling of the sensor pins inside the lid, it may be necessary to clean them and to verify the level sensor periodically.

4.3 Troubleshooting

Problem	Probable cause	Remedy					
Device not running.	Level sensor has been activated.	Empty the bottle.					
	No electrical power.	Plug the mains adapter in the power source and in the device.					
	Device is switched off.	Switch on the device (switch indicator lamp must light).					
Aspiration is very low	Aspiration speed is set to minimum.	Turn the knob for vacuum control clockwise to increase speed.					
and/or pump never stops running.	Leak in the vac- uum system.	Close the venting port by closing the sealing screw or sealing cap. Close the bottle lid tightly. Check tubing and filter for leaks. Reduce the residual flow of the VACUBOY hand operator by closing the screw opposite the operator button (see the VACUBOY operating instructions).					
	Liquid overflowed thereby blocking fil- ter.	Empty the bottle and exchange the filter.					
	Tubing is blocked.	Clean or exchange the tubing.					
Level sen- sor acti- vated	Sensor cable is connected incor- rectly.	Fully insert the sensor cable with the correct orien- tation in the lid and base sockets.					
erroneously (bottle is not	Foam activates the level sensor.	Use an anti-foaming agent (e.g. Antifoam A from Sigma)					
full).	No or incorrect veri- fication.	Verify following the instructions (see <u>"3.3.4</u> Connection and calibration of the level sensor" on page 10).					
	Soiled sensor pins.	Clean pins inside the lid and recalibrate.					
	Electromagnetic interferences dis- turb level sensor.	Eliminate or inactivate the source of electromag- netic interference.					

5 Maintenance

WARNING

5.1 Cleaning



Always switch off the VACUSAFE and disconnect it from the mains when carrying out maintenance work.

Clean the VACUSAFE housing with a lint-free cloth lightly soaked with mild soap solution in distilled water or with a 70% solution of isopropanol or ethanol. Never use bleach (sodium hypochlorite) or other solvents.

It is recommended to change the hydrophobic filter regularly, at least every three months. Exchange the filter immediately if liquid has entered.

When working with solvents and other hazardous materials always rinse the hand operator and tubing with water followed by 70% ethanol.

5.2 Autoclaving and chemical decontamination

5.2.1 Autoclaving

All parts contacting the liquid can be autoclaved: waste collection bottle, lid with tube fittings, silicone tubing and hand operator VACUBOY. When working with biohazardous material, disinfect the VACUBOY with a 70% solution of isopropanol or ethanol or a suitable disinfectant before disassembling for autoclaving. For disassembly please refer to the operating instructions of VACUBOY.

Standard autoclaving conditions: 121°C for at least 15 minutes under 1.03 bars overpressure. The autoclaving conditions depend on the autoclave, the size and the type of the load (dry or liquid), the contents and the biological agents to be deactivated. The heat conductivity is reduced when the containers are made out of plastic in comparison with glass or metal or when large volumes of liquids should be autoclaved. Adapt your autoclaving conditions accordingly.

General recommendation for standard autoclaving conditions:

- Empty glass bottle and disassembled VACUBOY: at least 20 min.
- Empty polypropylene bottle: at least 60 min.
- The bottle lid has to be always unscrewed and kept loosely on the bottle (empty or full) during autoclaving to prevent bottle from shattering.
- The tubing couplings made of PVDF have to be always disconnected during autoclaving.
- Silicone may become brittle after extensive autoclaving. Replace the tubings if they are damaged.

When autoclaving liquids:

- Do not overfill the bottle (50-75% max.) to avoid spill and boil over.
- Use a temperature probe in a reference bottle filled in with water to monitor the autoclaving process. The volume of reference should correspond to the largest liquid waste volume and the bottle material should correspond to the lowest heat conductivity material.



WARNING

Too frequent autoclaving of the VACUBOY may lead to premature material aging. The filter, the cables and the base unit itself cannot be autoclaved.

5.2.2 Chemical decontamination

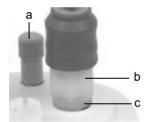
Two methods for chemical inactivation of biohazardous agents are commonly used:

- A suitable disinfectant is added to the full collection bottle and left to react for the recommended time. Any disinfectant can be used, provided that it is compatible with the bottle material (glass or polypropylene).
- The disinfectant is added to the empty bottle so that the aspirated liquid gets sterilized as it accumulates in the bottle. Use disinfectants that are free of chlorine or other corrosive agents, especially when corrosive vapors are generated and aspirated.

VACUSAFE and VACUBOY may be decontaminated with $\rm H_2O_2$ gas (maximal concentration 35 %) for 60 minutes.

5.3 Replacement of quick coupling sockets

Removal of a quick coupling socket from the lid:

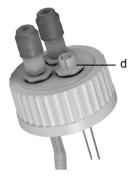


- 1) Unscrew and remove the pressure return valve (a, 9).
- Unscrew the upper part of the quick coupling (b) slightly so that the nut (c) underneath becomes accessible. Use a 17 mm flat spanner, if necessary.
- 3) Unscrew the nut (c) with a 14 mm flat spanner (the black O-ring is pointing to the lid).

Screw a new quick coupling socket on the lid. The blue socket is placed above the hole, the orange socket is placed on the port with silicone tubing and Y-connector inside the lid. The tubing with Y-connector is driving the aspirated liquid inside the bottle, while avoiding splashes on the liquid level sensor pins resulting in a false alarm signal.

5.4 Replacement of liquid level sensor

Replacement of the liquid level sensor on 2 L glass bottle lids (158402):



- 1) Unscrew the liquid level sensor (d) slightly. Use a 24 mm flat spanner, if necessary.
- 2) Screw a new liquid level sensor on the lid.

Make sure that the gasket is correctly inserted into the lid.

5.5 Equipment disposal



The VACUSAFE device must not be disposed of with unsorted municipal waste.

Dispose the VACUSAFE device in accordance with the laws and regulations in your area governing disposal of devices.

In certain regions and countries, e.g. in all EU member states, the distributor is obliged to take back this product free of charge at the end of life. Please contact distributor for more details

your local distributor for more details.

6 Technical data

6.1 Specifications

Vacuum range	-300 to -600 mbar, continuously adjustable							
Flow rate	Pump: 8 l/min (air); Aspiration: 17 ml/s (liquid, aspiration pipette)							
Dimensions (H x W x D)	530 x 180 x 320 mm							
Weight	3.4 kg							
Electricity supply	Mains adapter input: 100–240 VAC, 50/60 Hz Device input: 17–19 VDC, 15 W							
Degree of protection	IP21							
Ambient conditions	Operation: 5 to 40°C, max. 80% RH (non-condensing) Storage: -10 to 40°C, max. 95% RH (non-condensing)							

6.2 Chemical compatibility

The table below lists VACUSAFE parts that come into contact with the aspirated liquid or its aerosols and vapors, and rates the compatibility of these parts to a few of the chemicals commonly used in laboratories. To determine the compatibility of a component to a chemical not listed in the table, please consult one of the several tables available on the internet.

Note that the rating refers to soaking in the concentrated chemical; however, more relevant here is the attenuated effect resulting from indirect contact with the diluted chemical. It is recommended to test the compatibility of relevant components to a specific chemical prior to extensive use.

INTEGRA Biosciences AG does not warrant that the information in the table is accurate or complete and that any material is suitable for any purpose.

Sodium carbo Na2	nate CO3	A	A	۷	A	۷	A	A	N/A	в	A	A	A	A	A	A	A	A	N/A	۷	A
Acetic acid A	cOH	۲	A	С	В	A	A	A	V/A	A	A	в	A	A	A	A	A	ပ	A	A	A
Phenol P	hOH	c	A	A	С	A	A	A	N/A	N/A	С	A	A	A	C	A	A	С	A	A	C
Dimethyl sulfo	oxide MSO	N/A	В	A	A	A	A	A	A	N/A	N/A	С	В	A	N/A	A	A	A	A	В	N/A
Ace	tone	A	υ	A	c	A	A	A	A	с	A	U	υ	A	A	A	A	A	A	ပ	A
Sodium hydro	oxide aOH	ш	с	В	С	A	A	A	A	A	в	U	с	в	в	A	A	в	A	С	В
Hydrochloric	acid HCl	ပ	A	С	С	A	A	A	A	A	ပ	A	A	ပ	ပ	A	A	ပ	ပ	A	c
Ethanol E	tOH	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
JAVEL (e.g. NaClO)		∢	A	В	A	A	A	A	A	N/A	A	A	A	ш	A	A	A	ပ	A	A	A
vailable): ttion or slight corrosion). velling and loss of ntinuous use.	Materials	POM-C/-H	FPM (Viton)	Stainless steel	Silicone	Polypropylene	Safety glass	Polypropylene	TPE	PSU	POM-C	PVDF	FPM (Viton)	Stainless steel	POM-C	PTFE	Polypropylene	PA	PPS	FPM (Viton)	POM-C
Compatibility ratings (N/A = info not available): A = good, no or minor effects (discoloration or slight corrosion). B = fair, moderate effects (softening, swelling and loss of strength), not recommended for continuous use. C = critical, not recommended.)Y Plastic parts	O-rings	Valve spring	2 L lid gasket	4 L	2 L	4 L lid	4 L lid seal	2 L outer lid	2 L inner lid	Quick couplings	Coupling's o-ring	Level detection pins	Y-connector	Membrane	Housing	FE Housing	Pump head housing	Pump head membrane	2 L bottle adapter
Compatil A = good B = fair, r stren C = critics	Parts	VACUBOY			Tubings, 3	Bottle		Lid								Filter		VACUSAFE	base		

7 Accessories and consumables

Accessories		Part No.
Bottle	4 L, polypropylene	158370
	2 L, safety coated glass	158483
Lid for 4 L bottle	with quick couplings (PVDF) + level detection	158401
	with tubing fittings	158372
Lid for 2 L bottle	with quick couplings (PVDF) + level detection	158484
4 L bottle and lid	comprises part no. 158370 and 158401	158431
	comprises part no. 158370 and 158372	158432
2 L bottle and lid	comprises part no. 158 483 and 158 484	158485
Level sensor cable		158403
Bottle handle	for carrying polypropylene bottle (see <u>"2.2 Overview of the VACUSAFE" on page 6</u>)	158625
Bottle stand	for 4L polypropylene bottle	158630
2 L glass bottle adapter	for VACUSAFE base unit	158631
Stand	for PIPETBOY and VACUBOY	155065
Mains adapter	100–240 VAC, 50/60 Hz	158395
Y-connector	for connection of second VACUBOY hand operator	158354
Air outlet connector	for connection of tubing to the air outlet of the pump	158427

Accessories		Part No.
VACUBOY	 VACUBOY hand operator with: 1-channel stainless steel adapter 40 mm 1-channel adapter with ejector for disposable tips (with locking) Rubber adapter for Pasteur pipettes 	155510
VACUBOY set	 consists of: VACUBOY hand operator Stand for hand operator 1-channel stainless steel adapter 40 mm 1-channel adapter for disposable tips/GripTips (with locking) 1-channel adapter with ejector for disposable tips (with locking) Rubber adapter for Pasteur pipettes 8-channel stainless steel adapter 40 mm 8-channel adapter with ejector for disposable tips (with locking) 	155500
VACUBOY	Rubber adapter for Pasteur pipettes	155505
aspiration adapters	1-channel stainless steel adapter 40 mm	155502
	1-channel stainless steel adapter 150 mm	155522
	1-channel stainless steel adapter 280 mm	155525
	1-channel adapter for disposable tips (with locking)	155504
	1-channel adapter for disposable tips/GripTips (pack of 5)	159023
	1-channel adapter with ejector for disposable tips (with locking)	155526
	1-channel adapter with ejector for disposable tips	159026
	1-channel adapter with ejector for GripTips	159027
	4-channel stainless steel adapter 40 mm	155524
	8-channel stainless steel adapter 40 mm	155503
ě Ť	8-channel adapter with ejector for disposable tips (with locking)	155520
	8-channel adapter with ejector for disposable tips	159024
	8-channel adapter with ejector for GripTips	159025
TO	Stand for VACUBOY hand operator	155501

Consumables		Part No.
Tubing	for connection of hand operator to bottle, 1.8 m, silicone	158332
	for connection of base to bottle, 0.7 m, silicone, blue	158 331
Filter	for protection of vacuum source, 0.45 µm, hydrophobic	158015
	for protection of vacuum source, 0.2 µm, hydrophobic	158 020
Tubing set + 0.45 µm filter	comprises part no. 158 331, 158 332, 158 015	158 342
Y-connector with tubing	for bottle lid	158921
Gasket	for 2 L glas bottle lid	158 409

Quick tubing couplings		Material	Part No.
Coupling plug	self-closing, with barbed fitting, white/blue	PVDF	158416
(linked to tubing)	self-closing, with barbed fitting, white/orange	PVDF	158417
Coupling socket	self-closing, with O-ring, white/blue	PVDF	158423
(mounted on lid)	self-closing, with O-ring, white/orange	PVDF	158424

Daut Na
Part No.
158 402

Imprint

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