

From Eye to Insight



MEDICAL DIVISION

# Surgical Microscope Air Removal System

User Manual

10 747 139 - Version 00

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Thank you for purchasing a Leica surgical microscope system.  
In developing our systems, we have placed great emphasis on simple, self-explanatory operation. Nevertheless, we suggest studying this user manual in detail in order to utilize all the benefits of your new surgical microscope.  
For valuable information about Leica Microsystems products and services, and the address of your nearest Leica representative, please visit our website:

[www.leica-microsystems.com](http://www.leica-microsystems.com)

Thank you for choosing our products. We hope that you will enjoy the quality and performance of your Leica Microsystems surgical microscope.



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### Legal disclaimer

All specifications are subject to change without notice.  
The information provided by this manual is directly related to the operation of the equipment. Medical decision remains the responsibility of the clinician.  
Leica Microsystems has made every effort to provide a complete and clear user manual highlighting the key areas of product use. Should additional information regarding the use of the product be required, please contact your local Leica representative.  
You should never use a medical product of Leica Microsystems without the full understanding of the use and the performance of the product.

### Liability

For our liability, please see our standard sales terms and conditions. Nothing in this disclaimer will limit any of our liabilities in any way that is not permitted under applicable law, or exclude any of our liabilities that may not be excluded under applicable law.

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# 1 Introduction

## 1.1 About this user manual

The Surgical Microscope Air Removal System is an accessory for Leica surgical microscopes.

In this user manual the functions of the

Surgical Microscope Air Removal System are described.

For information and description of the Leica surgical microscope, please refer to the user manual of the particular surgical microscope.



In addition to notes on the use of the instruments this user manual gives important safety information (see chapter "Safety notes")



► Read this user manual carefully before operating the product.

## 1.2 Symbols in this user manual

The symbols used in this user manual have the following meaning:

Symbol	Warning word	Meaning
	Warning	Indicates a potentially hazardous situation or improper use that could result in serious personal injuries or death.
	Caution	Indicates a potentially hazardous situation or improper use which, if not avoided, may result in minor or moderate injury.
	Note	Indicates a potentially hazardous situation or improper use which, if not avoided, may result in appreciable material, financial and environmental damage
		Information about use that helps the user to employ the product in a technically correct and efficient way.
		Action required; this symbol indicates that you need to perform a specific action or series of actions.

## 1.3 Optional product features

Different product features and accessories are optionally available.

The availability varies from country to country and is subject to local regulatory requirements. Please contact your local representative for availability.

## 2 Safety notes

A Leica surgical microscope with Surgical Microscope Air Removal System is state-of-the-art technology. Nevertheless, hazards can arise during operation.

- ▶ Always follow the instructions in this user manual of the Leica surgical microscope, and in particular the safety notes.

### 2.1 Intended use

- The Surgical Microscope Air Removal System is a Leica Surgical Microscope accessory to apply the sterile drape in a close-fitting manner.

### 2.2 Dangers of use



#### WARNING

Risk of infection due to an insterile drape system.

- ▶ Put on sterile gloves to apply the sterile drape.
- ▶ Always follow the instructions provided by the manufacturer of the sterile drape.



#### CAUTION

Risk of malfunction due to a blocked exhaust pipe outlet.

- ▶ Make sure the exhaust pipe outlet is not covered by the drape.



#### CAUTION

Risk of imbalance.

- ▶ Make sure to assemble the system at the correct location.

### 2.3 Information for the person responsible for the instrument

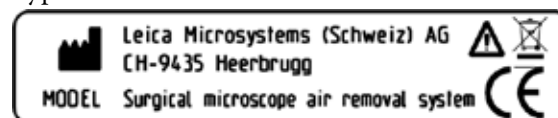


- Please refer to the user manual of the corresponding Leica surgical microscope.
- Observe all regulations on operating with sterile components.

### 2.4 Signs and labels

The following labels are located at the main body.

Type label



Read instructions



- ▶ Read this user manual carefully before operating the product.

## 3 Description

### 3.1 Function

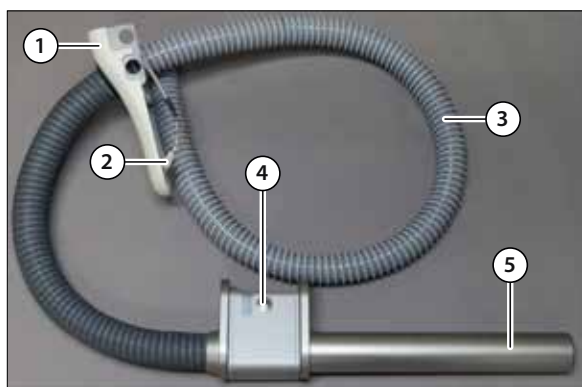
The Surgical Microscope Air Removal System is a suction system to apply the sterile drape in a close-fitting manner to the Leica surgical microscope. It is powered by the surgical microscope via an AC adapter.

### 3.2 Design

The Surgical Microscope Air Removal System is an accessory to a Leica OH surgical microscope stand.

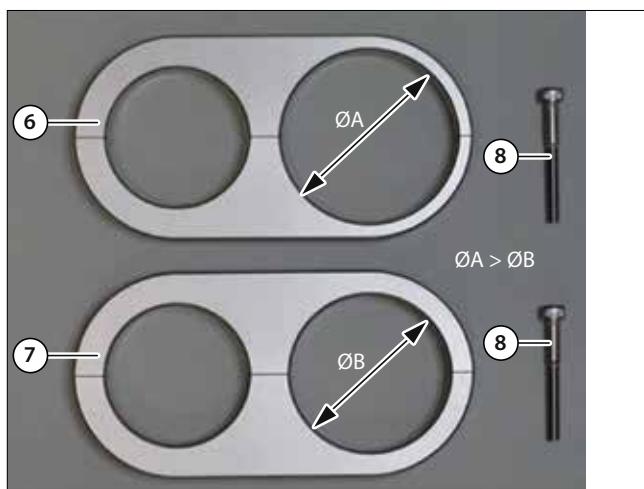
#### 3.2.1 Parts of the system

##### Suction device



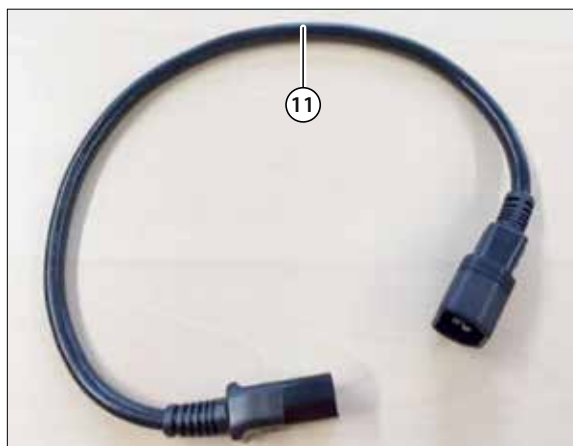
- 1 Cover
- 2 Power plug
- 3 Suction hose
- 4 Suction On/Off switch
- 5 Exhaust pipe

##### Attachments



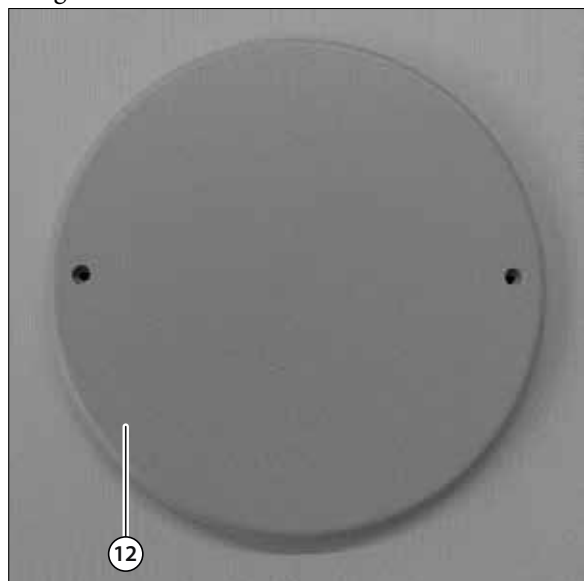
- 6 Metal part A, larger diameter
- 7 Metal part B, smaller diameter
- 8 M4 x35 cap screws

##### AC adapter



- 9 Power plug to the vacuum drape system
- 10 AC adapter
- 11 Adapter cable

Weight disc



12 Weight disc

## 4 Best practice for applying the sterile drape

- ! Only use the sterile Leica tested drapes specified in the Accessories section of the user manual of the Leica surgical microscope.
- Drape only as far as the arm system (see picture below and user manual of the Leica surgical microscope).

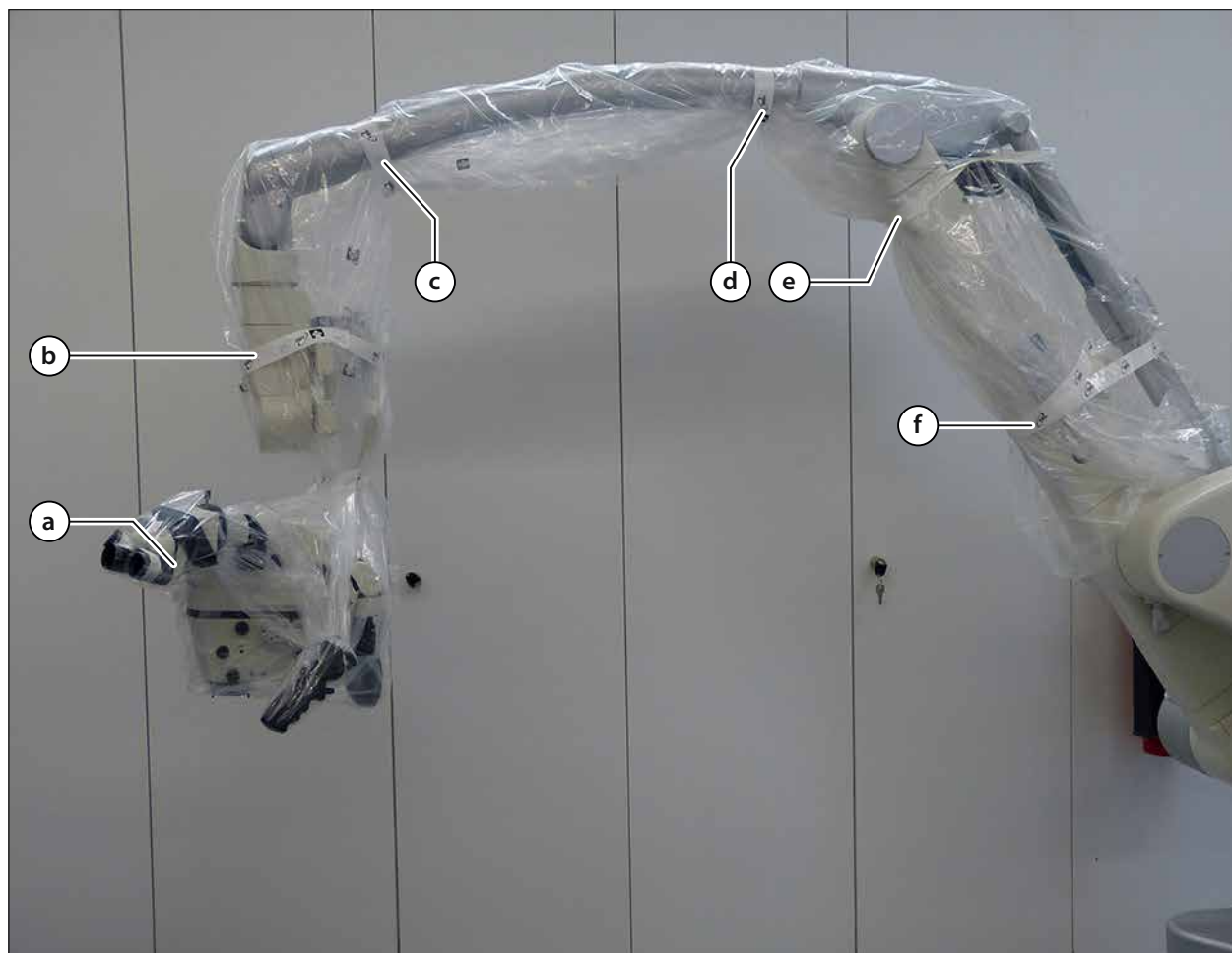


### CAUTION

Risk of infection.

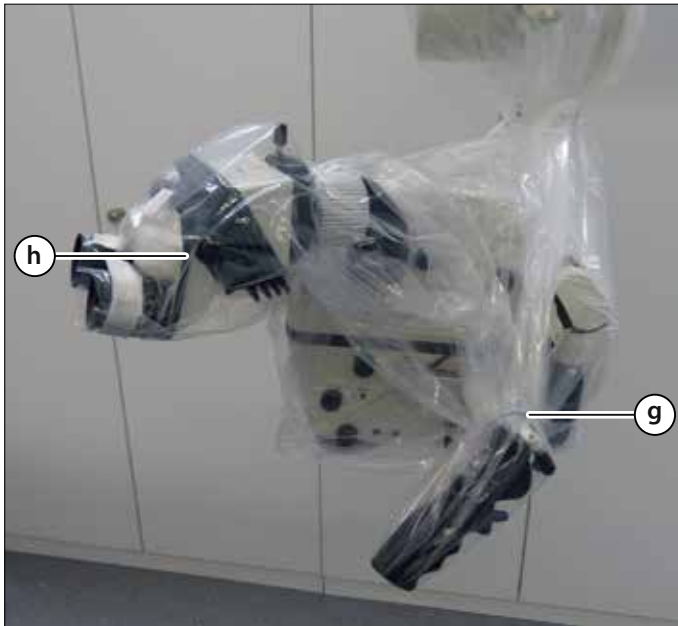
- ▶ Leave sufficient space around the stand to ensure that the sterile drape does not come into contact with non-sterile components.

- ! Follow the instructions provided by the manufacturer of the sterile drape.



- ▶ Activate the "All Brakes" function on the handle and extend the arm system.
- ▶ Put on sterile gloves.
- ▶ Attach all the sterile controls.
- ▶ Unpack the sterile drape carefully and drape it over the surgical microscope as far as the arm system, beginning at the optics carrier.
- ▶ Clamp the protective glass (optional) onto the objective.
- ▶ Apply straps (a) to (f), i.e. 2 straps on each arm segment.
- ▶ Make sure that strap (b) is positioned between the dark blue and white paint, otherwise it will be difficult to rotate.
- ▶ Do not pull the drape over the exhaust pipe outlet.





- ▶ Place a rubber band (h) at each handle.
- ▶ Place a rubber band (g) at each binocular to prevent the sterile drape from falling in the field of view or from touching the surgeon's non-sterile face mask.
- ▶ Tuck excess drape under rubber bands so it does not hang down by the lens.
- ▶ Do not attach the sterile drape too tightly with the provided ribbons. It must still be easy to move the instrument.
- ▶ Check the ease of movement of the instrument.

## 5 Preparation before surgery

- ▶ Check the cables of the vacuum drape system for any damage. If any damage has been found, stop using the device and get in contact with Leica Service.
- ▶ Check all other parts of the vacuum drape system for any abnormality.
- ▶ Test the operation of the vacuum drape system, see next chapter.

## 6 Operation



- ▶ Turn on the main power of the Leica OH stand.
- ▶ Press the suction ON/OFF switch (4).  
The ON/OFF switch (4) will start blinking in blue light.  
The vacuum drape system will start suctioning at its highest speed for 2 minutes and automatically switch to low speed.
- ▶ Press the suction ON/OFF switch (4) again to stop suctioning or in case of emergency.

## 7 Care and maintenance

**!** The Surgical Microscope Air Removal System is an accessory for a Leica surgical microscope. For care and maintenance please refer to the user manual of the Leica surgical microscope.

## 8 Disposal

The respective applicable national laws must be observed for disposal of the products, with the involvement of corresponding disposal companies. The unit packaging is to be recycled.

## 9 What to do if...?

**!** If electrically operated functions do not work properly, always check these points first:

- Is the power switch switched on?
- Are the power cables attached correctly?
- Are all connecting cables attached correctly?

**!** For malfunctions regarding the Leica surgical microscope refer to the user manual of the Leica surgical microscope.

### Malfunction

- Low speed mode does not start automatically after 2 minutes.

### Remedy

- ▶ Turn off the power and get in contact with Leica Service.

## 10 Technical data

### 10.1 Electrical data

Power supply	100 to 240 V 50/60 Hz 0.15 to 0.08 A
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### 10.2 Compatability

Leica surgical microscopes	Leica M530 OH6 Leica M525 OH4 Leica M720 OH5 ARveo
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### 10.3 Ambient conditions

In use	+15 °C to +40 °C / +59 °F to +84 °F 45 % to 95 % rel. humidity 800 mbar to 1060 mbar atmospheric pressure
Storage	At room temperature 10 % to 100 % rel. humidity 500 mbar to 1060 mbar atmospheric pressure
Transport	–30 °C to +70 °C / –86 °F to +158 °F 10 % to 100 % rel. humidity 500 mbar to 1060 mbar atmospheric pressure

### 10.4 Standards fulfilled

#### CE conformity

- Medical Devices Directive 93/42/EEC including amendments.
- Classification: Class I, in compliance with Annex IX, Rule 1 and Rule 12 of the Medical Devices Directive.
- Medical electrical equipment, Part 1: Generally defined for the security in IEC 60601-1; EN 60601-1; UL 60601-1; CAN/CSA-C22.2 NO. 601.1-M90.
- Electromagnetic compatibility: IEC 60601-1-2; EN 60601-1-2.
- The Medical Division, within Leica Microsystems (Schweiz) AG, holds the management system certificates for the international standards ISO 13485 and ISO 14001 relating to quality management, quality assurance and environmental management.

## 11 Manufacturer's declaration of electromagnetic compatibility (EMC)



The Surgical Microscope Air Removal System was tested in combination with Leica surgical microscopes. For the EMC declaration, please refer to the user manual of the Leica surgical microscope.

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The fruitful collaboration “with the user, for the user” has always been the foundation of Leica Microsystems’ innovative strength. On this basis, we have developed our five corporate values: Pioneering, High-end Quality, Team Spirit, Dedication to Science, and Continuous Improvement.

**MEDICAL DIVISION**

What does a surgeon expect from an outstanding surgical microscope? Sharp, clear images, and a modular system aligned with the surgeon and OR staff needs.

**Innovations for your practice**

From the first surgical microscope with widefield optics in the 1980s to the first microscopes with Horizontal Optics and with LED illumination, Leica Microsystems has been at the forefront of innovation in the development of surgical microscopes.

HD video, fluorescence and retinal viewing systems also demonstrate the continued innovative nature of the Leica team. We strive to provide the surgeon with leading edge technology to enhance performance, surgeon comfort, and patient outcomes.

The Medical Division, within Leica Microsystems (Schweiz) AG, holds the management system certificates for the international standards ISO 9001, ISO 13485, and ISO 14001 relating to quality management, quality assurance and environmental management.



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