

# Leica M220 F12

**User Manual/Installation Manual** 

10 716 922 - Version 05



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

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/installation manual

In this user manual the surgical microscope Leica M220 F12 is described. In the part "Installation manual" the assembly of the Leica M220 F12 is descriped.



In addition to notes on the use of the instruments this user manual gives important safety information (see chapter 3).



 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
$\triangle$	Warning	Indicates a potentially hazardous situation or improper use that could result in serious personal injuries or death.
$\triangle$	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.
<b>&gt;</b>		Action required; this symbol indicates that you need to perform a specific action or series of actions.

## 2 Product identification

The model and serial numbers of your product are located on the identification label on the underside of the horizontal arm.

► Enter this data in your user manual and always refer to it when you contact us or the service workshop regarding any questions you may have.

Туре	Serial no.

## 2.1 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.

# 3 Safety notes

The Leica M220 F12 surgical microscope is state-of-the-art technology. Nevertheless, hazards can arise during operation.

Always follow the instructions in this user manual, and in particular the safety notes.

#### 3.1 Intended use

- The Leica M220 F12 surgical microscope is an optical instrument for improving the visibility of objects through magnification and illumination. It can be applied for observation and documentation and for human medical treatment.
- The Leica M220 F12 surgical microscope is subject to special precautionary measures for electromagnetic compatibility.
- Portable and mobile as well as stationary RF communications equipment can have a negative effect on the reliability of the Leica M220 F12 surgical microscope's functionality.
- The Leica M220 F12 is intended for professional use only.

#### 3.2 Indication for Use

- The Leica M220 F12 surgical microscope is suitable for ophthalmic application such as Retina, Cornea and Cataract surgery in hospitals, clinics or other human medical institutions.
- The Leica M220 F12 surgical microscope may only be used in closed rooms and must be placed on a solid floor or mounted to the ceiling.
- These Instructions for Use are intended for professional physicians, nurses and other medical and technical staff who prepare, operate or maintain the device. It is the duty of the device owner/operator to train and brief all the operating personnel.

#### 3.3 Contraindications

No known contraindications for Use.

# 3.4 Directions for the person responsible for the instrument

- ► Ensure that the Leica M220 F12 surgical microscope is used only by persons qualified to do so.
- ► The Leica M220 F12 surgical microscope may only be operated by professional persons.
- ► Ensure that this user manual is always available at the place where the Leica M220 F12 surgical microscope is in use.
- ► Carry out regular inspections to make certain that the authorized users are adhering to safety requirements.
- ► When instructing new users, do so thoroughly and explain the meanings of the warning signs and messages.
- Allocate responsibilities for commissioning, operation and maintenance. Monitor compliance with this.
- Only use the Leica M220 F12 surgical microscope when it is free of defects.
- Inform your Leica representative or Leica Microsystems (Schweiz) AG, Medical Division, 9435 Heerbrugg, Switzerland, immediately about any product defect that could potentially cause injury or harm.
- ▶ Report any serious incident in relation to the Leica M220 F12 surgical operating microscope system to your Leica representative or Leica Microsystems (Schweiz) AG, Medical Division, 9435 Heerbrugg, Switzerland, and to your competent authority immediately after it has occurred.
- ► If you use accessories from other manufacturers with the Leica M220 F12 surgical microscope, make sure that these manufacturers confirm that the combination is safe to use. Follow the instructions in the user manual for those accessories.
- Only the following accessories may be used with the Leica M220 F12 surgical microscopes:
  - The Leica Microsystems accessories described in chapter 9 this User Manual.
  - Other accessories, provided that these have been expressly approved by Leica as being technically safe in this context.
- Modifications to or service on the Leica M220 F12 surgical microscope may be carried out only by technicians who are explicitly authorized by Leica to do so.
- Only original Leica replacement parts may be used in servicing the product.
- After service work or technical modifications, the device must be readjusted in accordance with our technical specifications.
- If the instrument is modified or serviced by unauthorized persons, is improperly maintained (as long as maintenance was not carried out by us), or is handled improperly, Leica Microsystems will not accept any liability.
- The effect of the surgical microscope on other instruments has been tested as specified in EN 60601-1-2. The system passed the emission and immunity test. Comply with the usual pre-

- cautionary and safety measures relating to electromagnetic and other forms of radiation.
- The electric installation in the building must conform to the national standard, e.g., current-operated ground leakage protection (fault-current protection) is suggested.
- Like any other instrument in the operating theater, this system may fail. Leica Microsystem (Schweiz) AG therefore recommends that a backup system is kept available during the operation.
- Only the supplied power cord may be used.
- The power cord must have a protective conductor and must be undamaged.
- The power cord must be mechanically secured with the "Power Input" socket to prevent accidental disconnection.
- The Leica Microsystems surgical microscope may be used only by physicians and medical assistance personnel with appropriate qualifications who have been instructed in the use of the instrument. Specific training is not required.
- All parts of the Leica M220 F12 shall not be serviced or maintained while in use with a patient.
- Use of this equipment adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories and cables other than those specified or provided by the manufacturer of his equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The Leica M220 F12 surgical microscope may be used only in closed rooms and must be placed on a solid floor.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Leica M220, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

#### Note:

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

# 3.5 Directions for the operator of the instrument

- ► Follow the instructions described here.
- ► Follow the instructions given by your employer regarding the organization of work and safety at work.
- ► Check the illumination intensity before and during surgery.
- Don't move system without released brakes.
- Operate the system only with all equipment in its proper position (all covers fitted, doors closed).
- ► To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- ► All parts of the M220 shall not be serviced or maintained while in use with a patient.
- ► The LED module shall not be changed while in use with a patient.

#### Phototoxic damage to the retina during eye surgery



#### WARNING

Damage to the eyes due to prolonged exposure!
The light of the instrument may be harmful. Risk of eye damage increases with the duration of exposure.

During exposure to the light from this instrument, do not exceed the hazard reference values. If the exposure time exceeds 50 seconds with this instrument at maximum output power, the hazard reference value will be exceeded. The following table is intended to serve as a guideline and make the surgeon aware of the potential hazard. The data have been calculated for the worst-case scenario:

- · Eye with aphakia
- Completely unmoving eye (continuous irradiation of the same region)
- Uninterrupted light exposure, e.g. no surgical instruments in the eye
- Pupils dilated to 7 mm

The calculations are based on the corresponding ISO standards<sup>1) 2)</sup> and the exposure limit values recommended in them. Published literature shows that a moving eye may allow for increased time of exposure <sup>3)</sup>.

Light	Recommended maximum exposur according to 1) [min.]	•		
setting	Without filter	With GG435 filter	With GG475 filter	
25 %	2 min	4 min	25 min	
50 %	1 min	1 min	11 min	
100 %	50 s	1 min	8 min	
Wit	With retina protection filter 5× (10448676)*			
<b>100</b> % 15 min				



\*Use the protection filter  $5 \times (10448676)$  to increase the operation duration by at least a factor of 5 compared to the standard configuration without a filter.

#### Sources:

- DIN EN ISO 15004-2:2007 Ophthalmic instruments Fundamental requirements and test methods – Part 2: Light hazard protection.
- 2) ISO 10936-2:2010 Optics and photonics Operation microscopes/Part 2: Light hazard from operation microscopes used in ocular surgery.
- 3) David Sliney, Danielle Aron-Rosa, Francois DeLori, Franz Fankhauser, Robert Landry, Martin Mainster, John Marshall, Bernhard Rassow, Bruce Stuck, Stephen Trokel, Teresa Motz West and Michael Wolffe, Adjustment of guidelines for exposure of the eye to optical radiation from ocular instruments: statement from a task group of the International Commission on Non-Ionizing Radiation Protection (ICNIRP), APPLIED OPTICS Vol. 44, No 11, p2162 (10 April 2005)

Protect the patient with the following safeguards:

- Short illumination times
- Low brightness setting
- Use of protective filters
- Switching off the illumination during breaks in the operation

It is recommended to adjust the brightness to the minimum necessary for the surgery. Infants, patients with aphakia (whose eyelens has not been replaced by an artificial lens with a UV protection screen), small children and persons with diseases of the eye are at greater risk. The risk is also increased if the person being treated or operated on has, within the last 24 hours, already been exposed to illumination from the same or any other ophthalmological instrument that uses a bright visible light source. This applies especially to patients that have been examined via retinal photography.

The decision about which light intensity to use for an application must be made on a case-by-case basis. In any event, the surgeon must evaluate the risks and benefits of the used light intensity. Despite all efforts to minimize the risk of retinal injury by surgical microscopes, damage may still occur. Photochemical retinal damage is a possible complication of the necessity to use bright light to make eye structures visible during difficult ophthalmological processes.

#### Stability (floor stands only)

When moved in the operating room, the swing arm must be folded up and locked and the brakes must be applied, otherwise the swing arm could drift out of control and the stand could topple.

#### Hazards due to movable parts

This section describes uses that, inadvertently, could lead to hazardous situations.

- Add accessories and balance the stand before the operation, and never over the field of operation.
- Do not put your fingers between the microscope and the focusing drive; They could get crushed.

#### Floor stand

- Always push the instrument to move it; never pull it. Feet in lightweight shoes could become trapped beneath the casing of the base.
- The footbrakes must remain engaged throughout the operation.

#### **Electrical connections**

The control unit may be opened only by a Leica-approved service technician.

#### Accessories

Only the following accessories may be used with the Leica Leica M220 F12 surgical microscopes:

- The Leica Microsystems accessories described in this User Manual.
- Other accessories, provided that these have been expressly approved by Leica as being technically safe in this context.

### 3.6 Dangers of use



#### WARNING

#### Damage to the eyes due to prolonged exposure! The light of the instrument may be harmful. Risk of eye damage increases with the duration of exposure.

During exposure to the light from this instrument, do not exceed the hazard reference values. If the exposure time exceeds 50 seconds with this instrument at maximum output power, the hazard reference value will be exceeded.



#### WARNING

#### Danger of injury due to:

- · uncontrolled lateral movement of the arm system,
- tilting of the stand,
- trapping of feet in lightweight shoes beneath the casing of the base.
- Abrupt braking of the surgical microscope at a threshold that cannot be crossed.
- ► For transportation, always move the Leica M220 F12 surgical microscope into the transport position.
- ▶ Never move the stand while the unit is extended.
- ► Never roll the stand or OP equipment over the cables lying on the floor.
- Always push the Leica M220 F12 surgical microscope; never pull it.



#### WARNING

#### Risk of death from electrical shock!

► The surgical microscope may be connected to a grounded socket only.



#### WARNING

#### Risk of injury from parts falling down!

- Complete all preparations and adjustments on the optics carrier before the operation.
- Never rebalance or re-equip the optical components and accessories with the instrument over the operation area.
- ▶ Before re-equipping, always lock the swing arm.
- ► Check that the optical components and accessories fit well and are fastened securely before the operation.
- ► Before changing equipment during an operation, swivel the microscope away from the operation area.



#### WARNING

#### Failure of the illumination can be dangerous for the patient!

Keep a compatible replacement LED module ready.



#### WARNING

#### Light that is too intense can damage the retina!

Observe the warning messages in the chapter on "Safety Notes".



#### WARNING

#### Risk of injury from the surgical microscope swinging down!

- Do not exceed the max. load when equipping components and accessories.
- Check the total weight using the "Load table".



#### WARNING

#### Risk of death from electrical shock!

Disconnect the power cable from the instrument power socket before changing fuses.



#### WARNING

#### Risk of injury from the surgical microscope swinging down!

- Lock the swing arm.
- Never change the accessories or attempt to rebalance the microscope while it is above the field of operation.
- Balance the swing arm each time after changing accessories.



#### WARNING

#### Risk of injury to the patient.

- Don't switch on/off during surgery.
- Don't unplug systm during surgery.



#### **CAUTION**

#### Danger of infection!

Leave sufficient space around the stand to prevent contact with non-sterile components.



#### **CAUTION**

# Feet in lightweight shoes can become trapped beneath the base of the stand!

Always push the surgical microscope; never pull it.



#### **CAUTION**

#### Surgical microscope can move without warning!

Always secure the footbrakes when you are not moving the system.



#### **CAUTION**

#### **Burn hazard!**

The LED module get very hot.

► Check that the LED module have cooled before you remove it.

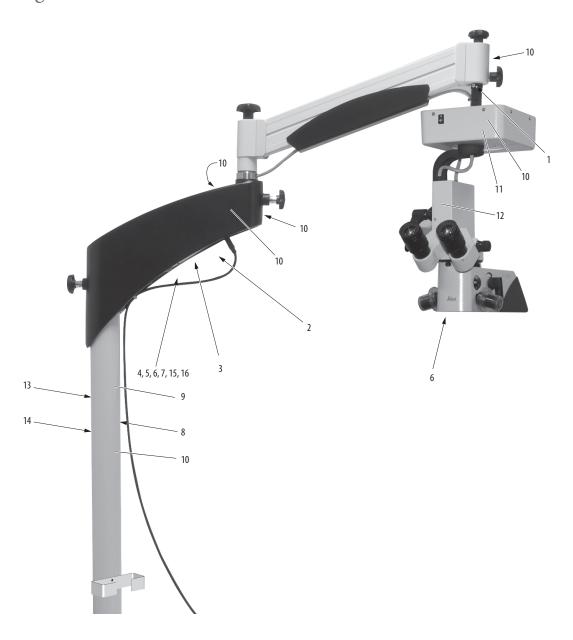


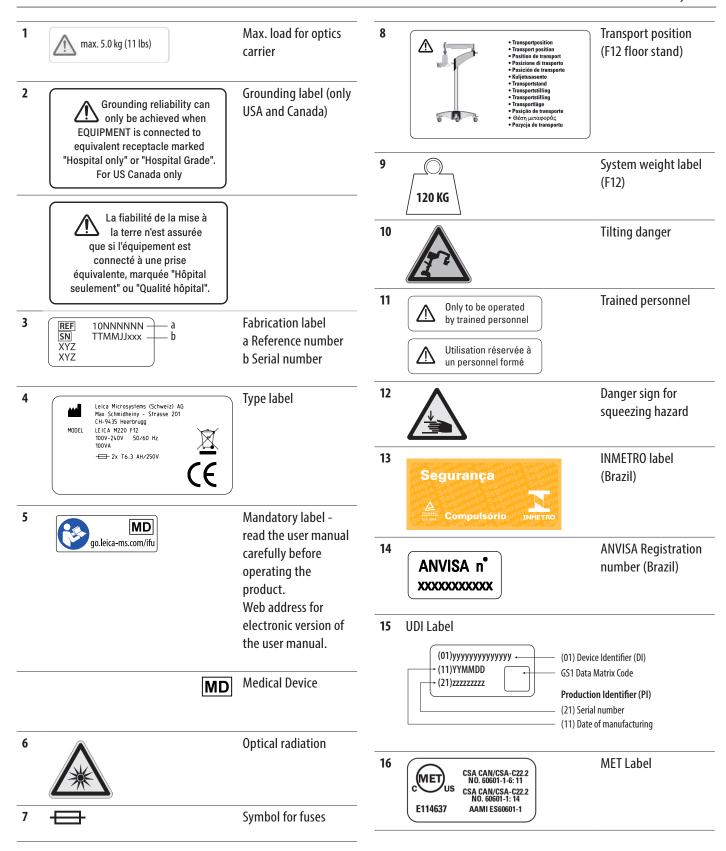
#### **CAUTION**

#### Surgical microscope can tilting without warning.

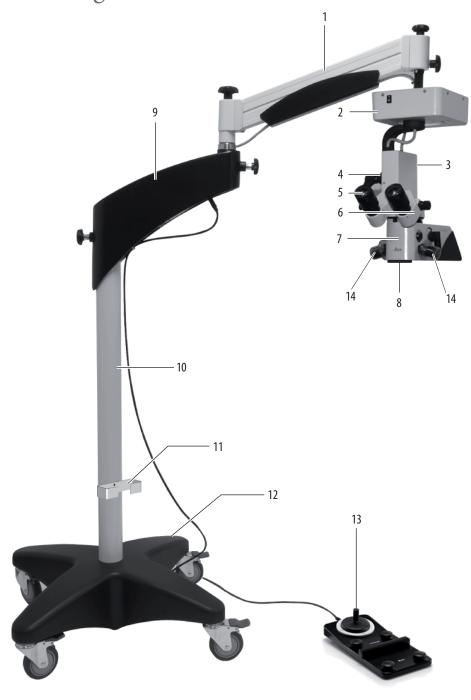
Always push the surgical microscope in park positon carefully.

# 3.7 Signs and labels





# 4 Design



- 1 Swing arm
- 2 XY-unit (optional)
- 3 Focus unit
- 4 Tilt head
- 5 Eyepieces
- 6 Binocular tube
- 7 Optics carrier

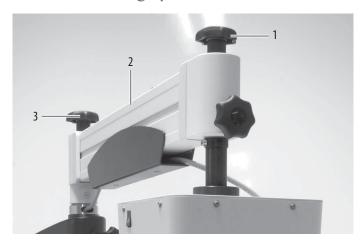
- 8 Objective
- 9 Horizontal arm
- 10 Column
- 11 Footswitch holder
- 12 Base
- 13 Footswitch
- 14 Handle

## 5 Functions

### 5.1 Illumination

The illumination of the surgical microscope Leica M220 F12 consists of a LED. It is in the optics carrier located.

### 5.2 Balancing system



With a balanced surgical microscope Leica M220 F12 you can move the optics carrier in any position without tilting or falling down. After balancing all movements during operation only need a minor force.

With the rotary knob (3) on the swing arm (2) the drifts will be adjusted.

The brake knob (1) locks the vertical position.

### 5.3 Footbrakes

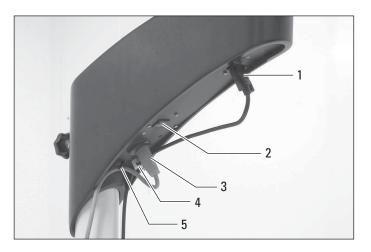


Footbrakes are attached to each of the four wheels on the stand. The wheel is engaged and released with the footbrake engage/ release lever (1).

- Press the footbrake engage/release lever down (3): The footbrake is engaged.
- Lift the footbrake engage/release lever (2): The footbrake is released.

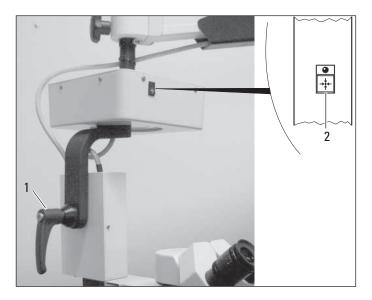
# 6 Controls

## 6.1 Horizontal arm



- Connection for footswitch
   Only connect the footswitch provided by Leica Microsystems (Schweiz) AG, Medical Division
- 2 Power switch
- 3 Power connection
- 4 Cable holder for footswitch cable
- 5 Power cable strain relief device

# 6.2 Tilt head/focusing unit



#### Tilt head

1 Clamping lever for manual tilt movement

#### **Focusing unit**

2 XY-unit reset button

# 6.3 Footswitch (standard configuration)



- 1 Focus up and down
- 2 XY adjustment
- 3 Magnification change
- !

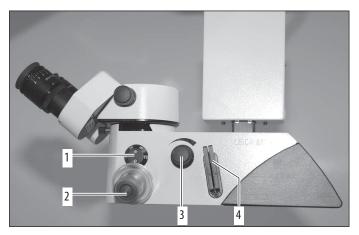
The assignment of 1 and 3 (magnification and focus control) can be switched. For additional information, refer to the service manual or ask your local after-sales service.

### 6.4 Stand

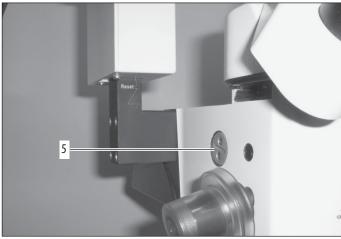


- 1 Rotary knob for joint brake
- 2 Rotary knob for balancing
- 3 Brake knob for locking the vertical position
- 4 Footbrake engage/release lever

# 6.5 Optics carrier

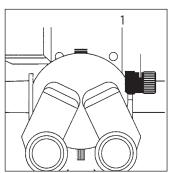


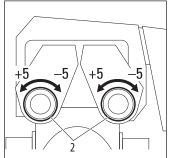
- 1 Magnification indicator
- 2 Handles
- 3 Illumination switch and control
- 4 Inserts for filter (UV protection filter GG475, GG435 and protection filter 5×)



5 Emergency drive for the magnification changer In case of emergency, the magnification can be adjusted on the emergency drive using a coin or the like.

# 6.6 Binocular tube, eyepiece, second observer tubes





- 1 Drive knob for interpupillary distance adjustment (optional)
- 2 Dioptric adjustment
- 3 Knurled ring for image correction



# 7 Preparation before surgery

### 7.1 Transportation



#### WARNING

#### Danger of injury due to:

- uncontrolled lateral movement of the arm system,
- · tilting of the stand,
- trapping of feet in lightweight shoes beneath the casing of the base.
- Abrupt braking of the surgical microscope at a threshold that cannot be crossed.
- ► For transportation, always move the Leica M220 F12 surgical microscope into the transport position.
- ▶ Never move the stand while the unit is extended.
- Never roll the stand or OP equipment over the cables lying on the floor.
- ► Always push the Leica M220 F12 surgical microscope; never pull it.



#### **CAUTION**

# Feet in lightweight shoes can become trapped beneath the base of the stand!

Always push the surgical microscope; never pull it.



#### **CAUTION**

#### Surgical microscope can move without warning!

Always secure the footbrakes when you are not moving the system.



#### **CAUTION**

#### Surgical microscope can tilting without warning.

Always push the surgical microscope in park positon carefully.

#### Locking the swing arm

- Position the swing arm (1) approximately horizontally.
- ► Tighten the brake knob for locking the vertical position (2). The swing arm is now locked.
- Release the articulation brakes (3) and fold up the swing arm. Due to the rotation stop, the swing arm can be moved in one direction only using the horizontal arm.
- Move the surgical microscope into transport position and tighten the articulation brakes.

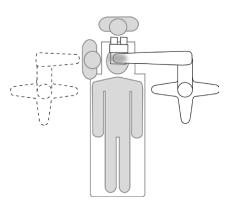


# Transporting surgical microscope and securing it in a new location

- ▶ Unplug the power plug from the instrument.
- Remove the footswitches from the instrument.
- Step on the footbrake engage/release lever (4) to release the footbrakes.
- ► Push the surgical microscope to its installation location at the column (5).
- ► Lock the footbrakes at the installation location.

# 7.2 Positioning surgical microscope over operating table

- ► Carefully move the surgical microscope at the column to the operating table and position it for the forthcoming operation.
- Tighten the footbrakes.

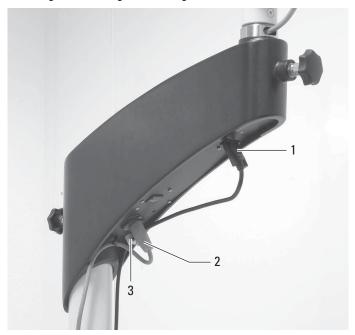




#### WARNING

#### Risk of death from electrical shock!

- The surgical microscope may be connected to a grounded socket only.
- Connect the power cable (2) to the socket.
- Connect the footswitch in the socket (1) to the horizontal arm and guide it through the cable guide (3).





#### **CAUTION**

#### Danger of infection!

- Leave sufficient space around the stand to prevent contact with non-sterile components.
- Inspect all terminals and make certain that all accessories
- ► are seated firmly.
- Release the articulation brakes and set them to a light resistance.

To make the joint easier to move:

► Release the articulation brake (5).

To make the joint more difficult to move:

- ► Tighten the articulation brake (5).
- Loosen the brake knob for locking the vertical position (4).
- Extend the swing arm.
- Check the weight setting on the swing arm by raising and lowering the microscope and correct as necessary, see chapter 7.10.



# 7.3 Installing the binocular tube, eyepiece and objective

# $\Lambda$

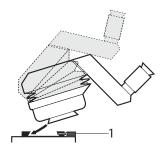
#### WARNING

#### Risk of injury from the binocular tube falling down!

► Tighten the clamping screw securely.

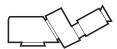
The surgical microscope can be adjusted to fit any work situation.

#### Installing the binocular tube

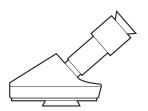


- Unscrew the clamping screw (1).
- Push binocular tube into the dovetail ring.
- Tighten the clamping screw securely.

#### Inclined binocular tube

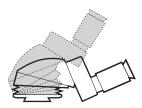


#### Inclined binocular tube 45°



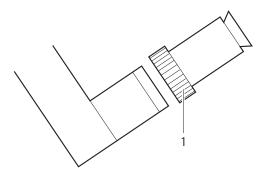
Optional for use on the assistant attachment (not a standard configuration)

#### Binocular tube 5°-25°



Optional for use on the assistant attachment (not a standard configuration)

#### Installing the eyepiece



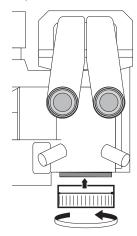
- Set the eyepiece in place.
- ► Tighten the rotary ring (1).

#### **Eyepieces**

- Eyepiece 10×, TC
- Eyepiece 10×/21B, adjustable
- Eyepiece 8.33×, adjustable
- Eyepiece 12.5×/17B, adjustable
- Leica ToricEyePiece

#### Installing the objectives

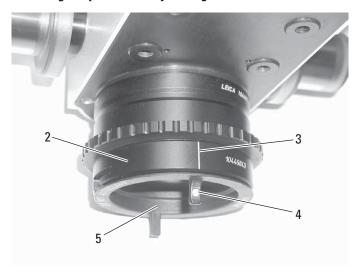
Objectives screw onto the microscope with a right-hand thread.



#### **Objectives**

- Objective WD = 175 mm APO
- Objective WD = 200 mm APO
- Objective f = 175 mm
- Objective f = 200 mm
- Objective f = 225 mm

#### Installing the protective objective glass



- ► Fit the objective protection glass holder (2) to the objective and position it so that the marking (3) faces back.
- ► Hold the objective protection glass (5) in position and turn slightly to the right.

The protective objective glass engages, the marks (3) and (4) are positioned one above the other.

!

The protective objective glass is not autoclavable.

#### **Inserting additional filters**

The Leica M220 F12 features two slots for additional filters.



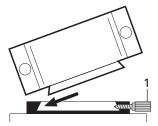
You can use temperature-resistant filters with a diameter of 32 mm. For further information, please contact your Leica Microsystems representative.



- Pull out the 2 empty filter holders (1).
- Fasten the filter in the filter holder.
- Reinsert the filter holder (1).

# 7.4 Installing the adapter for accessories

#### Installing the beam splitter/stereo adapter



- Unscrew the clamping screw (1).
- Push the beam splitter/stereo adapter into the dovetail ring.
- Tighten the clamping screw.

# Beam splitter with 50/50 % observation, alternative: beam splitter with 70/30 % observation



#### Installing the adapter



- Insert the adapter in the beam splitter.
- ► Tighten the rotary ring (1).

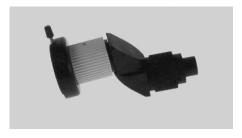
## 7.5 Adjusting second observer tube



- Insert stereo attachment/second observer tube into beam splitter.
- ► Tighten the rotary ring (1).

#### Stereo attachment for second observer

The dual stereo attachment can be attached to the left or right on the beam splitter and turned any direction.



#### Adjusting the second observer tubes



- Rotate the monocular second observer tube in the desired direction.
- Adjust the diopter setting at the eyepiece.
- Correct the image with the knurled ring (2).

#### Adjusting the stereo attachment for second observer

- Turn the attachment for second observer in the desired direction.
- ► Align the binocular tube horizontally.
- Adjust the diopter setting at the eyepiece.
- Correct the image with the knurled ring (2).

# 7.6 Installing documentation accessories

# $\Lambda$

#### WARNING

#### Risk of injury from parts falling down!

- ► Complete all preparations and adjustments on the optics carrier before the operation.
- Never rebalance or re-equip the optical components and accessories with the instrument over the operation area.
- ► Before re-equipping, always lock the swing arm.
- Check that the optical components and accessories fit well and are fastened securely before the operation.
- ► Before changing equipment during an operation, swivel the microscope away from the operation area.



- 1 Adjusting the magnification
- 2 Focusing knob

#### Fitting the phototube

- Fasten the phototube to the documentation port of the 0° assistant attachment or to the beam splitter.
- Secure the camera, complete with adapter, in the phototube. Tighten the clamping screw.

Please refer to section 9.2 for a list of video accessories.

# 7.7 Selecting documentation accessories

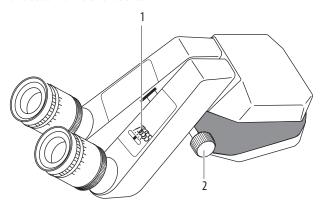
	Zoom video adapter	TV attachment	Photo/TV dual attachment	TV attachment	Photo/TV dual attachment	Zoom video adapter	TV attachment
	35 mm	55 mm	60 mm	70 mm	85 mm	100 mm	107 mm
1/4 "							
1/3 "							
1/2 "							
2/3 "							
1"							

	Photo/TV dua	al attachment	
	250 mm	350 mm	
35 mm			
Digital Photo Camera			
Field of vi	ew	Monitor/image	

# 7.8 Adjusting the eyebase and eyepoint (optional)

The distance between both pupils and the desired contact with the eyepieces are adjusted individually.

You can prepare the surgical microscope before the operation using the data from a user table.

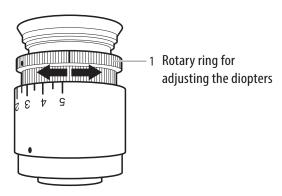


- 1 Interpupillary distance scale
- 2 Setting wheel

#### Adjusting the interpupillary distance

- ► Set the eyelenses of the eyepieces to "0" or select the required diopter value.
- ► Set the magnification changer to step 10.
- Look into the eyepieces and adjust the tubes with the setting wheel (2) or by hand (in the case of binocular tubes without a setting wheel) until a circular field of view is visible.

## 7.9 Adjusting the parfocality



#### Adjusting the diopter settings

Adjust the diopter settings accurately for each eye separately (1); only this method will ensure that the image will stay in focus throughout the entire magnification range (parfocal).

#### Prepare the microscope

- Switch on the microscope at the control unit and place a flat test object such as a piece of paper beneath the objective.
- Set the maximum brightness.
- Set the minimum magnification.
- Shift the microscope until the test object is visible in the center of the field of view and reasonably sharp.

#### Focus on the test object

- Set the maximum magnification.
- ► Focus the microscope.
- ► Set the minimum magnification.

#### Adjusting the diopter settings

- Adjust the diopter setting for each eye in turn (1), until the image is seen in sharp focus.
- Set the maximum magnification.
- Focus the microscope again.
- Set the minimum magnification.
- Inspect the diopter settings, readjusting them if necessary so that both images are sharp.

#### **Checking parfocality**

▶ Observe the test object while zooming through the whole range. The image sharpness must remain constant at all magnifications. If it does not, then repeat points 2 to 4 of this procedure.

# 7.10 Changing accessories of the surgical microscope and balancing the swing arm



#### WARNING

#### Risk of injury from the surgical microscope swinging down!

- Lock the swing arm.
- ► Never change the accessories or attempt to rebalance the microscope while it is above the field of operation.
- ▶ Before re-equipping, always lock the swing arm.
- Balance the swing arm each time after changing accessories.



#### Locking the swing arm

- Position the swing arm (1) approximately horizontally.
- ► Tighten the brake knob for locking the vertical position (2). The swing arm is now locked.

#### Cleaning the optical accessories

- ► Inspect the cleanliness of the eyepieces and objective as well as any photo or TV adapters as appropriate.
- Remove dust and dirt.

#### Installing the accessories

► Outfit the microscope with all accessories for use.

#### Balancing the swing arm

- Hold the microscope firmly.
- Loosen the brake knob for locking the vertical position (2). The swing arm is now released.
- By moving the swing arm manually, determine whether more force is required to move it upwards or downwards.

If more force is required to move it upwards:

► Turn the balancing knob (3) in the direction of the larger weight (counterclockwise).

If more force is required to move it downwards:

- Turn the balancing knob (3) in the direction of the smaller weight (clockwise).
- When adjusting the brake force, note that the upwards movement force is slightly less than the downwards force.

## 7.11 Attaching the sterile components

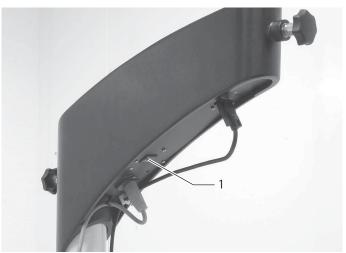
#### **Standard components**

- · 2 handles, transparent
- 1 drive knob (Illumination switch)

The handles and drive knob can be sterilized via steam or gas.

- Sterilize the handles and drive knobs.
- Attach the sterile drive knob to the rotary knob for illumination.
- Attach the sterile handles to the optics carrier.

# 7.12 Starting up the surgical microscope



- Switch on the power switch (1).
- ► The light is switched on and the XY-unit moves to the reset position.

# 7.13 Checks before operation

# 7.13.1 Checking the function of the LED illumination

## $\Lambda$

#### WARNING

### Failure of the illumination can be dangerous for the patient!

► Keep a compatible replacement LED module ready.



Switch on the microscope using the power switch.

The LED is illuminated.

► Turn the button (1) to the right.

This increases the brightness.

► Test the illumination across the entire brightness range.

#### 7.13.2 Checking the focus drive

See chapter 8.5.

#### 7.13.3 Check the fastening of the power cable

► Check if the power cable is fasten to the swing arm using cable ties (see chapter 2.4.1 in the installation manual).

# 8 Operation

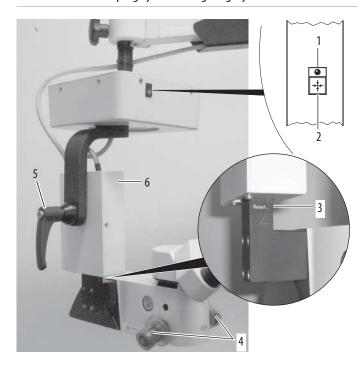
### 8.1 Positioning the microscope



#### WARNING

#### Risk of injury to the patient.

- ► Don't switch on/off during surgery.
- ► Don't unplug systm during surgery.



#### Set the middle position

► Press the "Reset XY-unit" key (2).

The XY-unit is driven to its middle position.

When the middle position is reached, the LED (1) lights up.

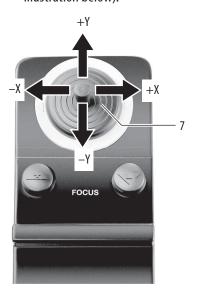
Using the footswitch, move the focus into reset position (see mark (3)).

#### **Coarse positioning**

► Hold the microscope by the two handles (4) and position it.

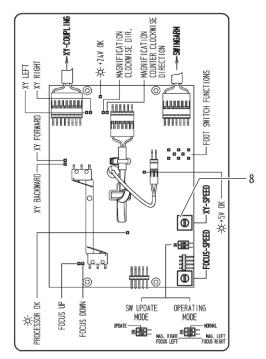
#### Fine positioning

Actuate the XY-unit using the footswitch (7) (for directions, see illustration below).



Adjusting the travel speed of the XY movement:

- Remove the focus cover (6).
- ► On the upper potentiometer (8) of the board, set the speed to the desired value.



#### Adjusting the tilt

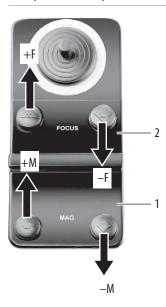
- ▶ Open the clamping lever (5).
- Adjust the tilt of the microscope.
- ► Close the clamping lever (5).

# 8.2 Adjusting the focus

#### NOTE

#### Destruction of the focus motor!

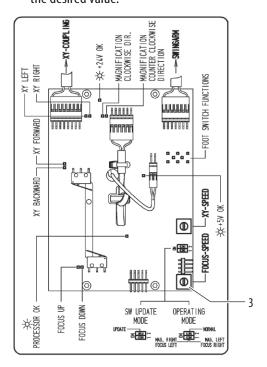
► If the focus motor fails, adjust the focus manually by moving optics carrier up or down.



Press the button (2) on the footswitch.

#### Adjusting the travel speed of the focus movement

- ► Remove the focus cover (6, chapter 8.1).
- ► On the lower potentiometer (3) of the board, set the speed to the desired value.



### 8.3 Adjusting the magnification

Set the magnification on the footswitch using button (1, chapter 8.2).

The following values will be cycled through: 6.4; 10; 16; 40; 25, 16.

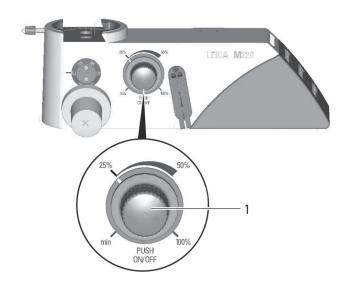
## 8.4 Adjusting the illumination

# $\Lambda$

#### WARNING

#### Light that is too intense can damage the retina!

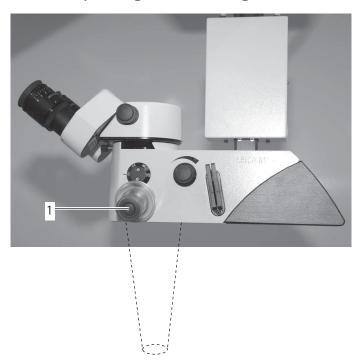
Observe the warning messages in the chapter on "Safety Notes", chapter 3.



#### Switching microscope illumination on and off

Use button (1) to switch the microscope illumination on and off and to control the brightness.

# 8.5 Adjusting the working distance



- Adjust the approximate working distance by raising or lowering the microscope using the handles (1).
- ► Set the exact working distance using the button on the footswitch for the focus drive.

# 8.6 Decomissioning

- ► End the recording procedure on the camera (loss of data).
- ► Return the Leica M220 F12 surgical microscope to the transport position (see chapter 7.1).
- ➤ Switch off the Leica M220 F12 surgical microscope at the power switch (2, chapter 6.1).

# 9 Components and accessories

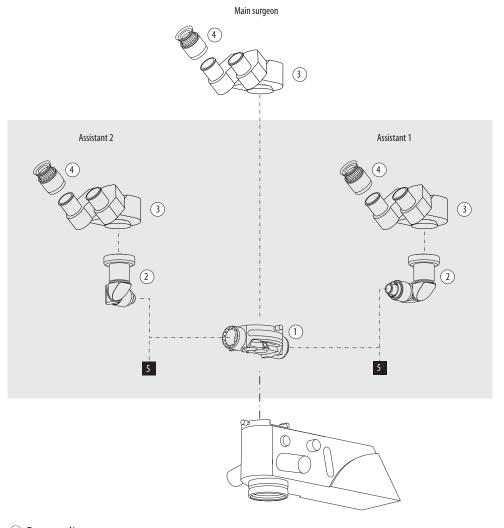


#### WARNING

#### Risk of injury from the surgical microscope swinging down!

- ► Do not exceed the max. load when equipping components and accessories.
- Check the total weight using the "Load table", chapter 9.3.

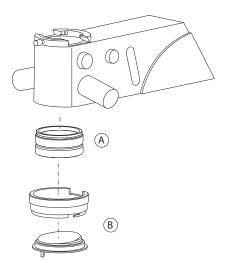
### 9.1 Observer side



- 1 Beam splitter
- 2 Second observer stereo attachment
- **3** Binocular tube
- 4 Eyepiece
- 5 Documentation port

	lmage	Component/accessory	Description
1)		Beam splitter 50/50 Beam splitter 70/30	The two interfaces can be used as assistant ports and documentation ports
2		Second observer stereo attachment	For assembling the binocular tube
3		Binocular tube, inclinable 5° to 25° with PD	<ul> <li>Adjustable viewing angle and height</li> <li>Adjustable interpupillary distance</li> </ul>
3		Binocular tube, inclined, T, type II	
3		Binocular tube, inclined, TC	
3		Binocular tube, 45°	Optional for use on the assistant attachment
4		Eyepiece 10× Eyepiece 8.33× Eyepiece 12.5×	
4		Eyepiece, 10×, TC	
(5)		Leica ToricEyePiece	<ul> <li>Facilitates adjustments to the angle of toric intraocular lenses via an integrated scale</li> <li>For further information, see the separate operating and installation instructions</li> </ul>

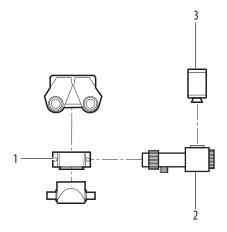
#### **Patient-side**



- (A) Lens
- B Protective glass with holder

Item No.	lmage	Component/accessory
A		<ul> <li>Objective APO WD175</li> <li>Objective APO WD200</li> <li>Objective f = 175 mm</li> <li>Objective f = 200 mm</li> <li>Objective f = 225 mm</li> </ul>
B		Holder for protective glass
B		Protective glass

# 9.2 Video accessories for Leica M220 F12



- 1 Beam splitter (50/50 % or 70/30 %), rotatable beam splitter
- 2 Video adapter (Leica ZVA / RVA / MVA)

#### Video adapter

- For commercially-available video cameras with C-mount, complete with adapter (3).
- The video adapter (2) is installed at the beam splitter.
- Zoom and fine focus function for Leica Zoom Video Adapter



- adjusted.
- Set the maximum magnification.
- ▶ Place a flat test object with sharp contours under the objective.
- Look through the eyepieces and focus the microscope.
- Set the minimum magnification.
- Set the maximum magnification (f = 100 mm) on the Leica Zoom Video Adapter.
- Focus the monitor image on the Leica Zoom Video Adapter.
- ► Set the desired magnification on the Leica Zoom Video Adapter.

### 9.3 Load table

_		_
	-	

You can find the value for the max. load in the "Technical Data", chapter 13.6.

Leica M220 F12 equipment, serial number .....

Max. load for stand from microscope interface.....kg

				Install	ation
iroup	Art. No.	Description	Weight	Quantity	Total
Assistant	10446482	Beam splitter 50/50	0.41 kg		,
	10446565	Beam splitter 70/30	0.41 kg		,
Optics	10445937	Objective APO WD200	0.41 kg		
	10445938	Objective APO WD175	— 0.41 kg		,
	10431692	Objective f = 175 mm			,
	10382162	Objective f = 200 mm	0.20 kg		,
	10457297	Objective f = 225 mm			,
	10448217	Binocular tube, inclinable 5° to 25° with PD	0.74 kg		,
	10446574	Binocular tube, inclinable, T, type II	0.74 kg		,
	10446618	Binocular tube, 45°	0.56 kg		,
	10448404	Binocular tube, inclinable, TC	0.93 kg		,
	10448028	Eyepiece, 10×			
	10448125	Eyepiece, 8.33×	0.10 kg		,
	10446739	Eyepiece, 12.5×			
	13613532	Eyepiece 10×, TC	0.07 kg		,
Accessories for front section of the eye	10448554	Leica ToricEyePiece	0.10 kg		,
Sterilizable		Clip-on handle			,
components	10428238	Binocular tube T rotary knob cover	0.01 kg		,
	10446468	Holder for protective glass	0.10 kg		,
	10446467	Protective glass	0.06 kg		,
		Dust covers			,
Documentation	10448215	Leica Zoom Video Adapter	0.76 kg		,
	10448362	Leica Manual Video Adapter f=70	0.5 kg		
	10448363	Leica Manual Video Adapter f=55	0.5 kg		,
			Complete System	Load	,

### 10 Care and maintenance

#### 10.1 Care instructions

- Put a dust cover over the instrument during breaks in work.
- Keep accessories in a dust-free place when not in use.
- · Remove dust with bellows and a soft brush.
- Clean the objectives and eyepieces with special optics cleaning cloths and pure alcohol.
- Protect the surgical microscope from moisture, vapors, acids, alkalis, and corrosive substances.
  - Do not store chemicals near the instruments.
- Protect the surgical microscope from improper handling.
   Never install any other socket or unscrew the optical systems or mechanical parts unless expressly instructed to do so in the instructions.
- Protect the surgical microscope from oil and grease.
   Never oil or grease the guide surfaces or mechanical parts.
- · Remove any dirt with a moistened disposable cloth.
- To disinfect the surgical microscope, use compounds from the surface disinfectant group based on the following active ingredients:
  - Aldehydes
  - Alcohols
  - · Quaternary ammonium compounds



Due to potential damage to the materials, never use products based on

- · halogen-splitting compounds,
- · strong organic acids,
- · oxygen-splitting compounds.
- ► Follow the disinfectant manufacturer's instructions.



It is recommended to conclude a service contract with Leica Service.

#### **Tropical environment/fungus**

Leica Microsystems employs certain safety precautions in its manufacturing techniques and materials.

Other preventive measures include:

- · Keep optical parts clean.
- Use or store the system in a clean environment only.
- Store under UV light when not in use.
- Use in continuously climate-controlled rooms only.
- Keep them away from moisture and cover the instrument with a plastic cover filled with silica gel.

#### 10.2 Maintenance

The Leica M220 F12 surgical microscope is basically maintenance-free. To ensure that it always operates safely and reliably, we recommend that you take the precaution of contacting the responsible service organization.

You can arrange for periodic inspections or, if appropriate, conclude a maintenance contract with them.



- We recommend concluding a service contract with Leica Microsystems Service.
- Use only original spare parts for servicing.

# 10.3 Care and Maintenance of the Leica Footswitch

After each operation, clean the Leica footswitch in warm or hot water (but below 60 °C). It is basically maintenance-free. In case of defects, please contact the responsible service organization.

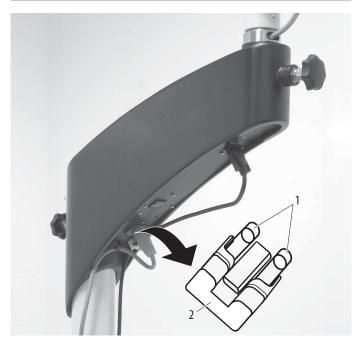
## 10.4 Changing the fuse



#### WARNING

#### Risk of death from electrical shock!

Disconnect the power cable from the instrument power socket before changing fuses.



The fuses are located in a fuse holder (2) in the instrument power socket.

- ► Using a screwdriver, pry out the fuse holder (2), then pull it all the way out by hand.
- ► Change out the fuses (1).



Use only 6.3 AH time-lag fuses.

Replace the fuse holder (2) and press it in all the way using your hand.

## 10.5 Replacing the LED module



#### **CAUTION**

#### Burn hazard!

The LED module get very hot.

Check that the LED module have cooled before you remove it.



The Leica M220 F12 does not have a built-in auxiliary lamp. A replacement LED module should always be kept at hand. If an LED burns out, another spare LED module should be purchased to be kept at hand by the user.

Use only Leica original replacement LED module.

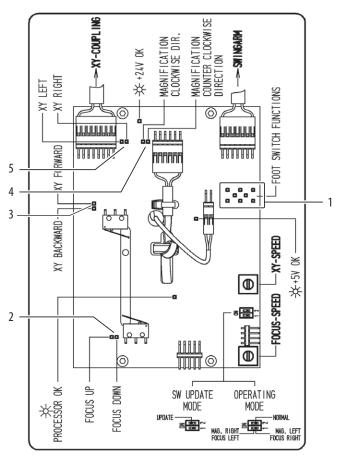


The replacement of the LED module of the illumination is described in detail in the replacement instructions that accompany the LED replacement module (10 448 374 Leica order number).

# 10.6 Checking the function of the LED illumination

See chapter 7.13.1.

# 10.7 Diagnostics in case of malfunctions



- 1 LED footswitch button
- 2 Focus up/down
- 3 XY forwards/backwards
- 4 Magnification clockwise/counterclockwise
- 5 XY left/right
- Remove the focus cover (6, chapter 8.1).

#### Testing the buttons on the footswitch

► Press the button on the footswitch.

The corresponding LED (1) on the board in the "FOOT SWITCH FUNCTIONS" area must be illuminated.

If the LED is not illuminated, the footswitch may be defective or not connected correctly.

#### **Testing the motors**

If the footswitch is working properly, the motors of the drive are tested.

▶ Press the button on the footswitch.

The corresponding motor LED must be illuminated.

If the LED illuminates but the corresponding motor does not move, the motor may be defective.

# 10.8 Notes on reprocessing of resterilizable products

#### 10.8.1 General

#### **Products**

Reusable products supplied by Leica Microsystems (Schweiz) AG such as rotary knobs, objective protective glasses and capping pieces.

#### **Limitation of reprocessing**

For the medical devices used on patients suffering from Creutzfeldt Jacob Disease (CJD) or suspected of having CJD or variant CJD, the local statutory requirements have to be met. Normally resterilizable products used on this group of patients are to be eliminated without risk by incineration.

#### Occupational safety and health protection

Particular attention must be paid to the occupational safety and health protection of the persons responsible for preparing contaminated products. Current regulations of hospital hygiene and prevention of infection must be observed in the preparation, cleaning and disinfection of the products.

#### Limitation of reprocessing

Frequent reprocessing has little effects on these products. The end of the product life cycle is usually determined by wear and tear and damage through use.

10.8.2 Instructions

#### Workplace

Remove surface contamination with a disposable cloth/paper cloth.

#### Storage and transport

- No special requirements.
- It is recommended to perform the reprocessing of a product immediately following its use.

#### Preparation for cleaning

Remove the product from the Leica M220 F12 surgical microscope.

#### Cleaning: manually

• Equipment: running water, detergent, alcohols, microfiber cloth

#### **Procedure**

- Rinse surface contamination off of the product (temp. < 40 °C). Use some rinsing agent depending upon degree of contamination.
- Alcohol may also be used to clean the optics if heavy contamination such as fingerprints, grease streaks etc. is present.

Dry off products, except for optical components, with a disposable cloth/paper cloth. Dry off optical surfaces with a micro-fiber cloth.

#### Cleaning: automatically

· Equipment: cleaning/disinfecting device

It is not recommended to clean products with optical components in a cleaning/disinfecting device. In addition, optical components must not be cleaned in ultrasonic baths in order to prevent damage.

#### Disinfection

The alcohol disinfection solution "Mikrozid. Liquid" may be used in accordance with the instructions on the label.

Please note that after disinfection, the optical surfaces must be rinsed thoroughly with fresh drinking water, followed by fresh demineralized water. The products must be dried thoroughly before the subsequent sterilization.

#### Maintenance

No special requirements.

#### **Control and functional test**

Check the snap-on behavior of rotary knobs and handles.

#### **Packaging**

Individual: A standard PE bag may be used. The bag must be large enough for the product so that the closure is not under tension.

#### Sterilization

See Sterilization table on chapter 10.8.3.

#### Storage

No special requirements.

#### **Additional information**

None

#### Contact information of manufacturer

Address of local agent

Leica Microsystems (Schweiz) AG verified that the aforementioned instructions for the preparation of a product are suitable for its reuse. The processing person is responsible for reprocessing with the equipment, materials and personnel and for achieving the desired results in the reprocessing installation. In general, this requires validations and routine monitoring of the process. Every deviation from the supplied instructions should also be examined carefully by the processing person to determine effectiveness and possible detrimental consequences.

#### 10.8.3 Sterilization table

The following table gives an overview of the available sterilizable components to the surgical microscopes of Leica Microsystems (Schweiz) AG, Medical Division.

		Permissible s	terilization :	methods			I	Produc	ts		
Article No.	Designation	Steam autoclave 134°C, t > 10 min.	Ethylene oxide max. 60°C	STERRAD® <sup>1)</sup>	M320	M220	M620	M844 M822 M820	M525	M530 ARveo	M720
10180591	Clip-on handle	✓	_	✓	_	_	✓	✓	_	_	_
10428328	Rotary knob, binocular tubes T	✓	_	_	_	✓	_	✓	✓	✓	✓
10384656	Rotary knob, transparent	✓	_	✓	_	✓	✓	_	_	_	_
10443792	Lever extension	✓	_	_	_	-	✓	✓	_	_	_
10446058	Protective glass, multifocal lense	✓	✓	✓	_	-	-	_	✓	✓	_
10448439	Protective glass	✓	✓	_	_	_	_	✓	_	_	<b>√</b>
10448440	Cover, sterilizable	✓	_	_	✓	_	_	_	_	_	_
10448431	Protective objective glass	✓	✓	✓	✓	_	_	_	_	_	_
10448296	Protective objective glass, spare part (package of 10)	✓	✓	_	_	-	-	✓	_	-	✓
10448280	Protective objective glass, complete, sterilizable	✓	✓	_	_	_	_	✓	_	_	✓
10731702	Cover, sterilizable	✓	_	✓	✓	-	_	✓	_	_	_

<sup>1)</sup> This medical device falls within the validated stertility claims of the STERRAD® 100S / STERRAD® 100NX / STERRAD® 50 / STERRAD® 200 Systems. Follow the instructions for use of your STERRAD® System User's Guide prior to sterilizing devices in STERRAD® Systems.

### 11 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.

### 12 What to do if ...?



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

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

### 12.1 General malfunctions

Malfunction	Possible cause	Remedy
The swing arm raises or lowers by itself.	The swing arm is not correctly balanced.	► Balance the swing arm (see chapter 7.10).
The swing arm lowers even when the balance scale is set to its highest level.	The total weight of the microscope and accessories is too high.	Reduce the total weight.
	Gas spring is defective.	Have the gas spring replaced by Leica Microsystems Service.
The microscope cannot be moved or moved only with a great deal of effort.	Articulation brakes set too tightly.	Loosen the articulation brakes (see chapter 7.1).
The functions cannot be actuated via the footswitch	The cable connection has loosened.	<ul><li>Check the power cable.</li><li>Check the footswitch connection.</li></ul>
	Footswitch defective	<ul> <li>Carry out diagnostics according to chapter 10.7.</li> <li>In the event of a defect, contact Leica Microsystems service.</li> </ul>

### 12.2 Microscope

Malfunction	Possible cause	Remedy
The image goes out of focus.	Eyepieces not seated properly.	► Screw the eyepieces all the way on.
	Diopters not set correctly.	Perform dioptric correction exactly as specified in the instructions.
Unwanted reflections.	The objective cover is not installed correctly on the sterile drape.	Clamp the objective cover of the sterile drape to the objective with the cover tilted slightly forwards.
Image is cut off.	The filter holder is not inserted correctly.	Press the filter holder completely into the optics carrier.
Focus movement is too slow.	Speed set too low.	Adjust the speed using the potentiometer on the footswitch (see chapter 8.1).
XY movement is too slow.	Speed set too low.	Adjust the speed using the potentiometer on the footswitch (see chapter 8.1).

Malfunction	Possible cause	Remedy
Magnification changer does not work.	Magnification changer locked.	Adjust the magnification manually on the emergency drive (see chapter 6.5).
	Motor/footswitch defective.	<ul> <li>Carry out diagnostics according to chapter 10.7.</li> <li>In the event of a defect, contact Leica Microsystems service.</li> </ul>
Focus is not working.	Motor/footswitch defective.	<ul> <li>Carry out diagnostics according to chapter 10.7.</li> <li>In the event of a defect, contact Leica Microsystems service.</li> </ul>
XY movement is not working.	Motor/footswitch defective.	<ul> <li>Carry out diagnostics according to chapter 10.7.</li> <li>In the event of a defect, contact Leica Microsystems service.</li> </ul>



If your instrument has a malfunction that is not described here, please contact your Leica representative.

### 12.3 TV, photography

Malfunction	Possible cause	Remedy	
The image on the monitor is too dark.	The video camera and/or monitor is/are not set correctly.	Optimize the settings for the camera and/or monitor (see manufacturer's operating instructions).	
	Filter/diaphragm is set incorrectly.	Adjust the brightness or change the filter/ diaphragm.	
The photos are unsharp.	The parfocality of the microscope is not set properly.	Check the parfocality of the microscope (see chapter 7.9).	
Specimen is out of focus.	The specimen is not precisely focused.	Focus accurately, insert graticule if necessary.	



If your camera or monitor has a malfunction that is described or not described here, please contact the representative from the camera or monitor provider.

### 13 Technical data

#### 13.1 Electrical data

#### **Power socket**

F12 Floor stand Centrally located on the control unit

100-240 V AC (± 10 %), 50/60 Hz

Fuse  $2 \times T 6.3 \text{ AH } 250 \text{ V}$ 

Power consumption Leica M220 F12: 100 VA

Safety class Class I

### 13.2 Surgical microscope

Magnification Motorized,

APO-chromatic, 5-step magnification

changer 6.4/10/16/25/40x

Stereo base 24 mm
Objective, standard f=200 mm

Objective, optional f=175, 225, 250 mm

WD=175 mm AP0 WD=200 mm AP0

Eyepiece, standard  $10 \times 21B$ 

Eyepiece, optional  $12.5 \times 17B$ ,  $8.33 \times 22B$ 

XY-unit  $40 \times 40$  mm, adjustable speed

Tilt ±15°

Focus range 40 mm, adjustable speed

Reset functions XY-reset

Illumination Coaxial red reflex illumination
Light source Direct and long-lasting LED

illumination.

Average service life of 60,000 h for an end-of-life criterion of 70 % of the

initial brightness

UV filter UV and IR-free LED illumination

Eye protection filter GG475 optional

Protection filter 5×

Light intensity Using a sterile drive knob on the optics

adjustment carrier

#### 13.3 Stand

#### Leica M220 F12 floor stand

Max. range 1068 mm Travel range (up/down) 540 mm

Base Footprint:  $608 \times 608$  mm

Transportation height, 1680 mm

min.

#### Assistant's microscope

Standard semi-stereo (via beam splitter)

Footswitch 8 functions, watertight

Protection class IPX8

5 different selection options

#### **Accessories**

Binocular tube with

fixed angle

Binocular tube, variable 3 different selection options

Beam splitter 50/50 % and 70/30 %

Zoom Video Adapter 35-100 mm with sterile fine focus

No

Oculus SDI/BIOM

compatible

Moeller EIBOS No

compatible

### 13.4 Optical data

Objective f = 175 mm						
Eyepiec	e	Total magnif	ication (mm)	Field of view Ø (mm)		
		min.	max.	min.	max.	
8.33×	22	3.1	19.5	59.6	9.4	
10×	21	3.7	23.4	56.9	9.0	
12.5×	17	4.6	29.2	46.0	7.3	

			Objective f = 200 mm		
Eyepiece Total magnification (mm) Field of view Ø (mm)				ew Ø (mm)	
		min.	max.	min.	max.
8.33×	22	2.7	17.0	68.1	10.8
10×	21	3.2	20.4	65.0	10.3
12.5×	17	4.0	25.5	52.6	8.3

Objective f = 225 mm					
Eyepiece	Total magnif	ication (mm)	Field of vi	ew Ø (mm)	
	min.	max.	min.	max.	
8.33× 22	2.4	15.1	76.6	12.1	
10× 21	2.9	18.2	73.1	11.6	
12.5× 17	3.6	22.7	59.2	9.4	

### 13.5 Control unit

Connection sockets for

- Power cable
- Footswitch

### 13.6 Configurations and Weights

From the interface of the microscope, the stand has a maximum load of 5.0 kg.

Determine the total weight of the load using the "Load table",chapter 9.3.

#### 13.7 Ambient conditions

Use +10 °C to +40 °C

+50 °F to +104 °F

30 % to 75 % relative humidity 780 mbar to 1013 mbar air pressure

Storage:  $-30 \,^{\circ}\text{C}$  to  $+70 \,^{\circ}\text{C}$ 

-22 °F to +158 °F

10 % to 100 % relative humidity 500 mbar to 1060 mbar air pressure

Transport:  $-30 \,^{\circ}\text{C} \text{ to } +70 \,^{\circ}\text{C}$ 

-22 °F to +158 °F

10 % to 100 % relative humidity 500 mbar to 1060 mbar air pressure

## 13.8 Electromagnetic compatibility (EMC)

#### Environment for which the instrument is suitable

Hospitals except for near active HF Surgical Equipment and the RF shielded room of an ME System for magnetic resonance imaging, where the intensity of EM Disturbances is high.

#### Compliance IEC 60601-1-2

Emissions • CISPR 11, Class A, Group 1

- Harmonic Distortion per IEC 61000-3-2 Class A
- Voltage Fluctuation and Flicker per IEC 61000-3-3 Class A, Figures 3-7

Immunity • Electrostatic discharge IEC 61000-4-2:

CD +/- 8 kV, AD +/- 15 kV

• Radiated RF EM Fields IEC 61000-4-3:

80 - 2700 MHz: 10 V/m

• Proximity Wireless fields IEC 61000-4-3:

380 — 5785 MHz: 9 V/m; 28 V/m

 Electrical Fast Transients and bursts IEC 61000-4-4:

± 2 kV: Power supply lines

- Surges IEC 61000-4-5:
  - ± 1 kV Line-to-line
  - \_ ? kV Line to me
- ± 2 kV Line-to-groundConducted disturbances, induced by RF fields

IEC 61000-4-6:

10 V rms
Rated Power-frequency Magnetic Field IEC 61000-

4-8:

30 A/m

• Voltage dips and interruptions IEC 61000-4-11: according to IEC 60601-1-2:2014

#### 13.9 Standards fulfilled

- 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; EN 61000-3-2; IEC 61000-3-2.
- Further applied harmonized standards: IEC 62366, IEC60825-1, EN60825, IEC 62471, EN62471, EN 980.
- The Medical Division, within Leica Microsystems (Schweiz) AG, holds the management system certificates for the international standard ISO 13485 relating to quality management and quality assurance.

#### 13.10 Limitations of use

The Leica M220 F12 surgical microscope may be used only in enclosed rooms and on solid, level floors and ceilings.

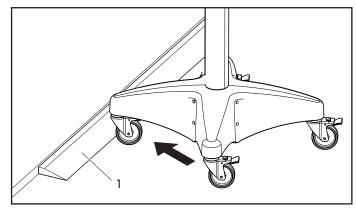


For the Leica M220 F12 drift effects must be taken into account on floors which slant >0.3°.

The Leica M220 F12 is not suitable for crossing thresholds higher than 20 mm.

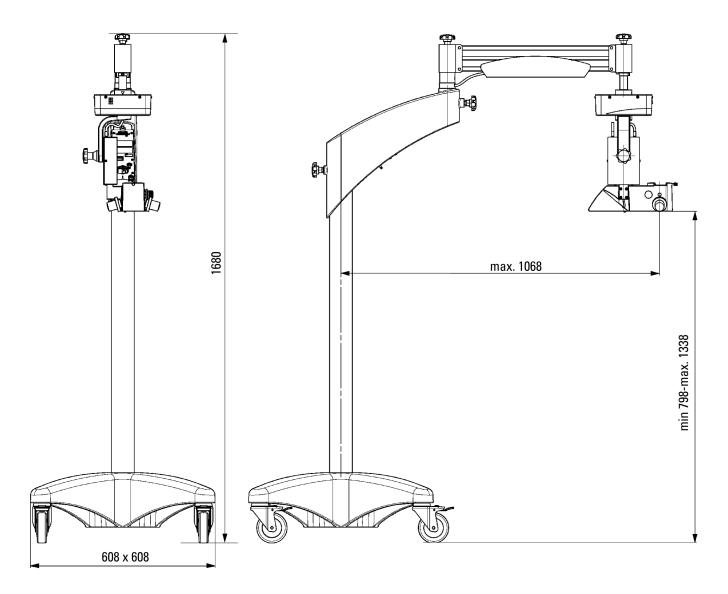
Without auxiliary equipment, the Leica M220 F12 can only be moved across thresholds up to a max. height of 5 mm.

To move the Leica M220 F12 over thresholds of 20 mm, the wedge (1) included in the packaging can be used.



- ► Place the wedge (1) in front of the threshold.
- Move the surgical microscope across the threshold in the transport position, pushing it by the handgrip.

### 13.11 Dimensions



Unit of measure mm



# Leica M220 F12

**Installation Manual** 

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### 1 Preparations



- Have the following tools and materials ready before you start assembling the Leica M220 F12 surgical microscope.
- You will need assistance for some of the work.

#### **Accessories supplied**

All screws and nuts

#### **Tools**

#### NOTE

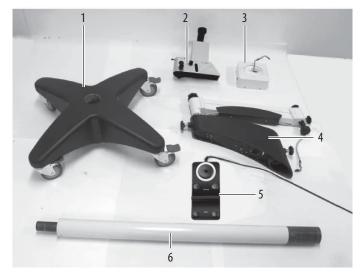
#### Screws or threads can be destroyed!

- ► Tighten all screws without using excessive force.
- Allen key (2.5 mm; 5 mm)
- Screwdrivers for Phillips head screws (Size 0)

#### **Assembly material**

Cable ties

### 1.1 Standard delivery



- 1 Base
- 2 Optics carrier and focus/tilt unit
- 3 XY-unit (optional)
- 4 Swing arm (horizontal and spring arm)
- 5 Footswitch
- 6 Stand column

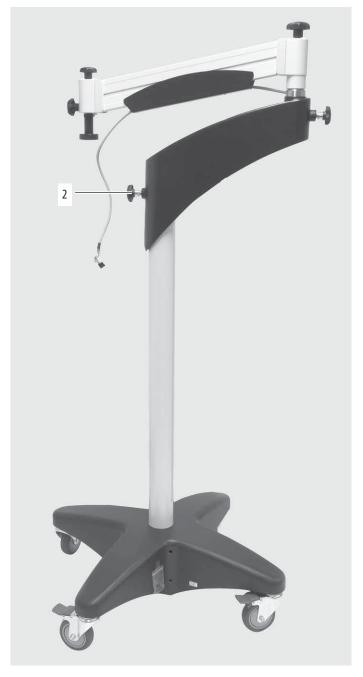
Additionally, other miscellaneous accessories according to the specific order, e.g. tubes, objectives etc.

## 2 Assembly

### 2.1 Installing the F12 floor stand

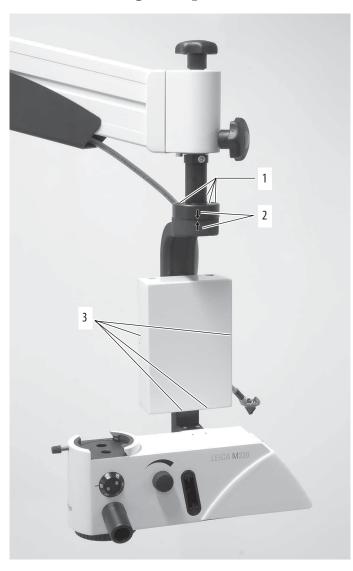


- ► Insert the column into the base
- ► Fasten it using the 2 pretreated Allen screws (1) provided.
- ► Close off the threaded holes (1) using the plastic plugs provided.

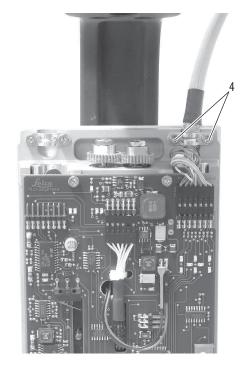


- Attach the swing arm to the column.
- ► Check the braking action using the rotary knob (2). If no braking action is identified, contact Leica Microsystems Support.

### 2.2 Mounting the optics carrier



- Use only the screws provided to fasten the optics carrier. These are pretreated with threadlocker.
- Fasten the optics carrier to the swing arm using the 4 pretreated Allen screws (1) provided.
- ► The red arrows (2) on the swing arm and optics carrier must be positioned one above the other.
- ► Unscrew the 4 Phillips head screws (3) of the focus cover.
- Remove the focus cover.



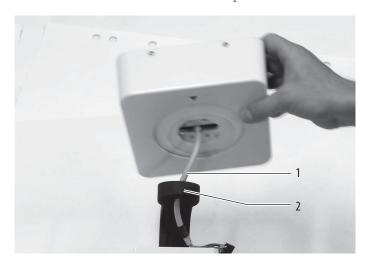
- Feed the cable from the swing arm into the right plug on the board.
- ► Secure the cable using the cable clamp and 2 Allen screws (4).
- Make sure that the wire cloth of the cable touches the cable clamp.
- ► Reinstall the focus cover using 4 Phillips head screws.



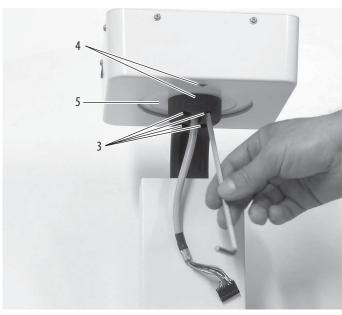
► Loosely fasten the cable on the swing arm using the cable tie (5).

# 2.3 Installing the XY-unit (optional) and optics carrier

### 2.3.1 Screw the XY-unit to the optics carrier



► Thread the cable of the XY-unit (1) through the eye of the optics carrier (2).



► Fasten the optics carrier to the XY-unit using the 4 pretreated Allen screws (3) provided.

The cover plate (5) must remain movable.

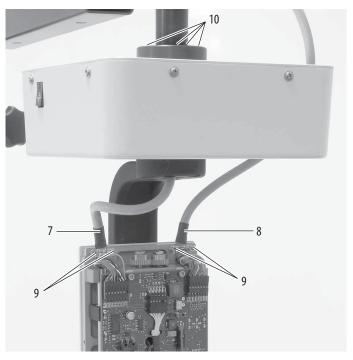
- The positions of the red arrow (4) on the swing arm and XY unit must match.
- Fasten the XY-unit to the swing arm using the 4 pretreated Allen screws (10) provided.

The red arrows on the XY-unit and the swing arm must be positioned one above the other.

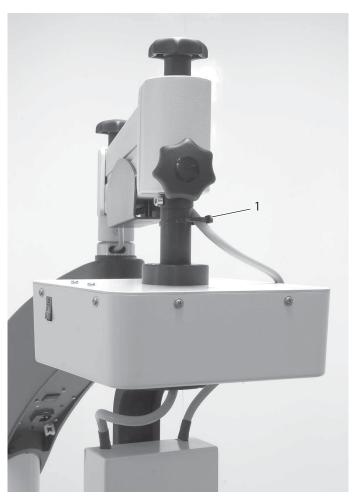
#### 2.3.2 Connecting the cables



- ▶ Unscrew the 4 Phillips head screws (6) of the focus cover.
- Remove the focus cover.



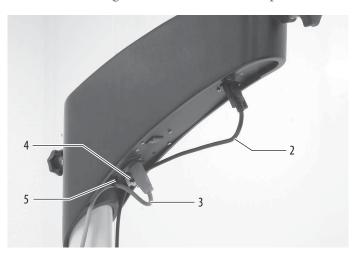
- ► Guide the cable of the XY-unit (7) at the left and the cable of the swing arm (8) at the right into the plug of the printed circuit board.
- ► Fasten both cables to the rear section of the PCB housing using cable clamps and 2 Allen screws (9) for each.
- ► Reinstall the focus cover using 4 Phillips head screws.



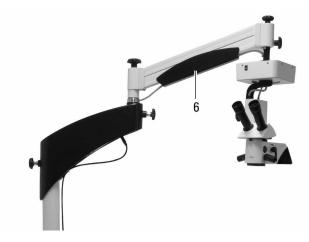
- Loosely fasten the cable on the swing arm using the cable tie (1).
- The XY-unit must be able to rotate freely.

### 2.4 Cabling

#### 2.4.1 Attaching the strain relief for the power cable



- ► Fasten the power cable (3) to the swing arm using cable ties (5).
- ► Connect the footswitch cable (2) and guide it through the cable guide (4).
- 2.4.2 Routing the video cable (optional)



- Guide the video cable through the cable duct (6) of the swing arm.
- Make sure to leave enough cable length at the articulation points so as not to restrict freedom of movement.
- ► Route the video cable alongside the existing electronics cable and fasten it using cable ties.

### 3 Checklist

Are all the cables routed correctly and not pinched?

## 4 Disassembly

▶ Disassemble the Leica M220 F12 surgical microscope in the opposite order in which it was assembled.

### 5 Instrument Setup

### 5.1 Preparatory work



- ► Make sure that all parts are seated firmly.
- Connect the Leica M220 F12 surgical microscope to the power supply and switch on the power switch (1).
- ▶ Balance the swing arm (see chapter 7.10 in the user manual).

### 5.2 Checking the functions

Check the following functions in accordance with the user manual:

► Release all brakes of the Leica M220 F12 and move the stand over the entire range of movement.

Result: The brakes disengage; the microscope can be moved over the entire range of movement freely and without noise.

► Move down the X/Y ranges and focus ranges using the footswitch.

Result: Even, quiet movement over the entire range.

Adjust the magnification across the entire range.

Result: Adjustment possible over the entire range, no unwanted noise.

Switch on the illumination and test it across the entire brightness range.

Result: The illumination functions properly and can be adjusted.

Otherwise, please contact Leica Microsystems service with regard to this matter.

# 6 Equipment Acceptance and Delivery to the Owner

After completing the assembly or maintenance work Leica Microsystems Service will start the inspection and acceptance program.

This inspection is aimed at determining whether

- the safety requirements concerning the protection of the patients and of the medical personnel have been fulfilled,
- the performance characteristics of the Leica M220 F12 surgical microscope system are being delivered.



The system as a whole should not be started up until acceptance by Leica Microsystems Service has taken place.

This is followed by the training of the personnel.

## 7 Delivery report

Assembly and functional testing of the Leica M220 F12 was carried out properly in accordance with the regulations contained in the assembly instructions.

Name and address of the custo	mer		
Department			
Representative of Leica Mici	rosystems (Schweiz) AG, Med	cal Division	
Name			
Address			
Acknowledged	Signature		
Location	Date		

This acceptance certificate must be filled out by the responsible installation engineer and a copy given to both the customer and the Leica Microsystems representative.

Must be retained for: 20 years



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CONNECT WITH US!

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