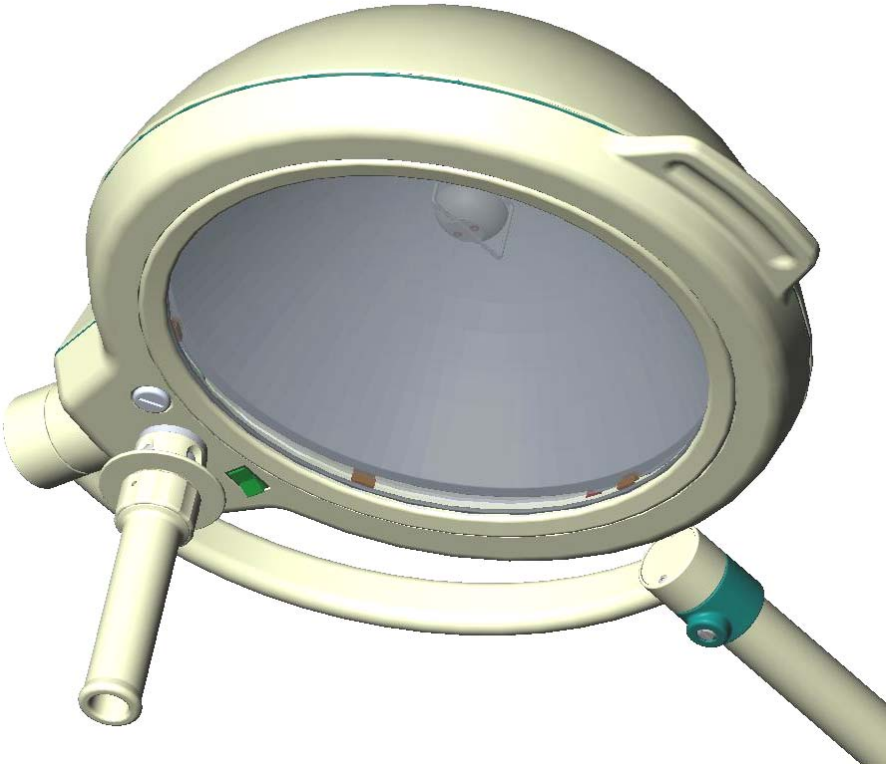
Directions for use

MACH M2



Mach M2 ceiling-, wall- and stand model
Mach M2 F ceiling-, wall- and stand model

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Dear customer!

Congratulations for acquiring our new **lamp MACH M2**.

With this lighting system you profit from a whole range of new developments, based on 50 years of experience in the production of operating and doctor lights.

The lighting system is characterised by a previously unreceivable general colour rendition value of **Ra=96**. In other words, the colours are **reproduced naturally** and in **high contrast**. The wound area is shown in a **comfortable light**.

The different reds of a wound area can now be recognised very precisely. For the doctor or surgeon this means a considerable **improvement in the recognition of details in the wound area**.

The R96 lighting system uses computer-optimised cold-light filters that reduce both **the unwanted build-up of heat in the head area and the heat radiated on the illuminated wound area to a minimum**.

All information quoted here relates only to the illuminants. Details of ceiling, wall and stand installation can be found in the mounting instructions.

1. Safety instructions

Pay attention to the directions for use when handling the lamp.

WARNING:

This device has not been designed for use in potentially explosive areas.
According to the Medical Device Regulation the lamp is classified under class I.

Store the OT-lamp in its package for at least 24 hours in the respective roombefore mounting, in order to eqal temperature differences.

Please read the instructions for use carefully to make the most of your lighting system and to avoid any damages to the device.

The lamps may only be repaired and special assembly work may only be carried out on the reflector or sockets by ourselves or a company that has been expressly authorised by us.

The manufacturer can only be made responsible for the safety of the lamp if repairs and alterations are carried out by the manufacturer himself or a company that guaranteed to observe the safety regulations.

The manufacturer cannot be made liable for personal or material damages if the lamp is operated inexpediently or incorrectly or used for purposes other than those for which it is intended.

All lamps are equipped with heat protection filter.
It is not allowed to use the lamps without this filter! Do not remove the heat protection filter, otherwise risk of burn!

The lamp is to be dismatled from the spring arm in reverse order to its assembly and is to be done only after securing the spring arm by a second person.

Make sure that the lamp is in perfect working order before every use.

Attention, external transformer!
The lamp works only with an external transformer.
The external transformer must be tested and validated according to IEC 60601-1, otherwise it is not allowed to use it with Dr. Mach lamps.

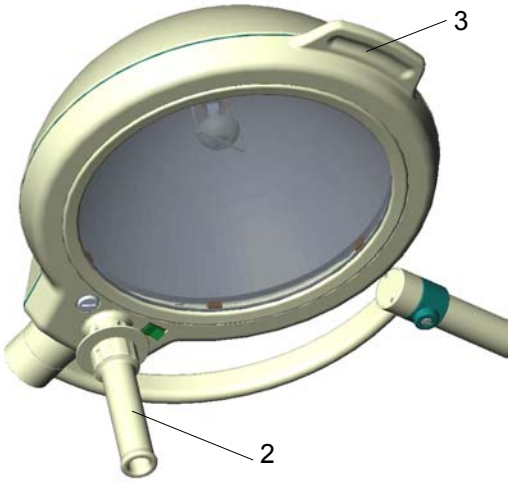
2. Operating the lamp MACH M2

2.1 Brief description of the lamp

The lamp MACH M2 is available in following versions:
- Mach M2, examination and small surgery lamp with fix-focus;
- Mach M2 F, examination and small surgery lamp with focusable light field.

2.2 Turning the lamp ON/OFF

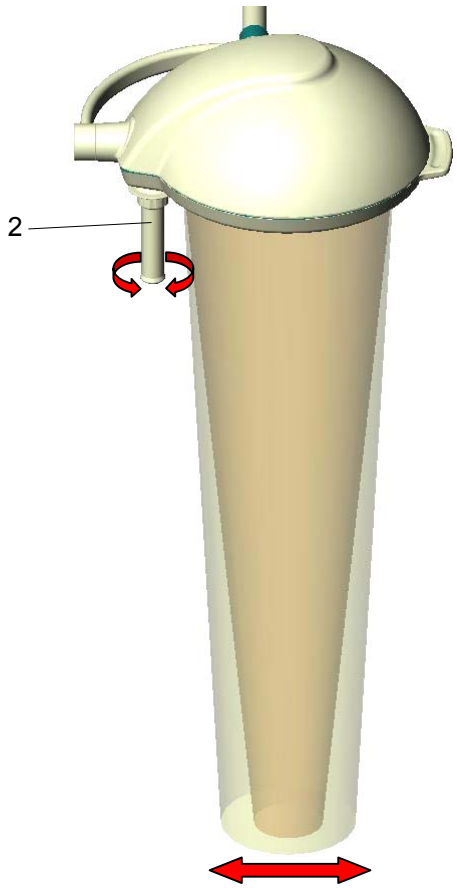
The lamp is turned ON and OFF by the **rocker switch 1**.



2.3 Positioning

Use the **sterilisable handle 2** or the **handle 3** at the lamp housing the position the lamp.

Use the **sterilisable handle 2** for positioning during treatment. This handle can be removed for sterilisation.

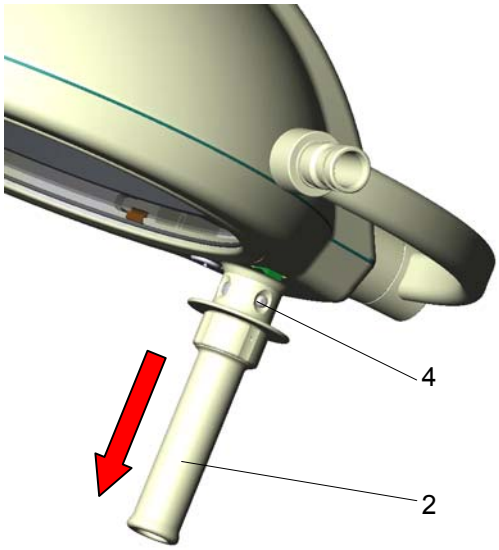


2.4 Adjusting the light field (only Mach M2 F)

The lamps Mach M2 F have a focusing function. That means, the diameter of the light field can either be enlarged or bundled to a smaller area, depending on the circumstances.

For adjusting the light field size turn the handle 2 at the lamp (see figure).

3. Cleaning



3.1 Sterilisable handle

At delivery the lamp is equipped with the **handle 2**. The handle is removable and sterilisable. Before using the first time and before every use the handle sleeve must be cleaned, disinfected and sterilised.

The handle must be removed for sterilisation:

- To remove press the **lock 4** and pull off the **sterilisable handle 2** while keeping the lock pressed.
- To attach, push on and slightly twist the handle until the **lock 4** engages securely.

Handles often become unsterile during an operation. Therefore always keep aditional handles available for exchange.

Cleaning / disinfection and sterilisation

Basics
Efficient cleaning / disinfection is an essential requirement for effective sterilisation of the handle.
Within the scope of responsibility for the sterility of the products it should be noted that only sufficiently validated equipment and product specific processes are used for cleaning / disinfection and that the validated parameters are complied with in every cycle.
In addition, the hospital / clinic hygiene regulations must be observed.

Cleaning / disinfection
Cleaning and disinfection must be carried out immediately after use.
A mechanised process (disinfector) should be used for cleaning / disinfection. The efficiency of the process used must be recognised and validated in principle (e.g. listed under disinfectants and disinfection procedures tested and recognised by Robert-Koch-Institute / DGHM).
When using other procedures (e.g. a manual procedure), proof and process efficiency in principle must be provided within the scope of validation.
Proof in principle of the suitability of the handles for efficient cleaning / disinfection was provided using a cyclic cleaning system (Netsch-Bellmed T-600-IUDT/AN, programme 2 for small parts; code B).

It is not allowed to use agents / disinfectants, which contain the following substances, as these may cause changes in the material:

- High-concentration organic and inorganic acids
- Chlorinated hydrocarbons
- 2-ethoxyethanol

When cleaning / disinfecting, the following procedures must be followed:

	Process	**Time (sec.)**
Zone 1	Pre-rinse, external, cold, 10 – 15°C Washing, acidic, external 35°C Draining time Re-rinse, external approx. 80°C Draining time Re-rinse, external approx. 80°C Draining time	45 120 10 *10 *15 *15 15
Zone 2	Washing, alkaline, external, 93°C Draining time Re-rinse, external, acidic, 90°C Draining time Re-rinse, external 90°C Draining time	135 10 10 15 15 15
Zone 3	Drying, external 100 – 120°C	200
Zone 4	Drying, external 100 – 120°C	200
	Door open / close & transport (sluice discharge)	60
	Cycle time overall ca.	290 ≈ 5 minutes

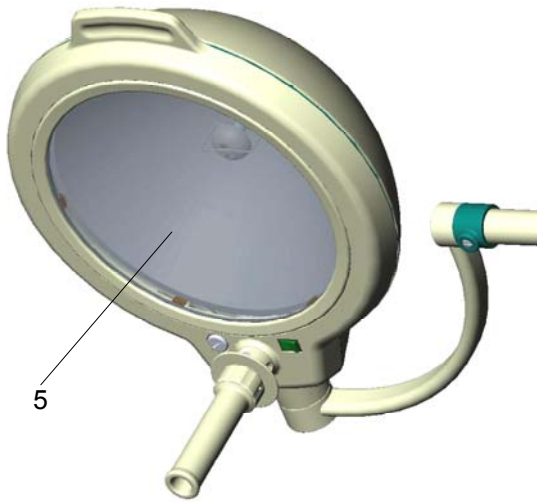
* When occupying the disinfection zone (washing zone 2), the re-rinse and draining times will depend on the respective objects being washed therein!

Sterilisation
Only previously cleaned and disinfected handles may be sterilised.
The handles are placed in a suitable sterilisation pack (one-way sterilisation pack, e.g. foil / paper sterilisation bags, single or double pack) in accordance with DIN EN 868 / ISO 11607 for steam sterilisation and then sterilised.
Use only the sterilisation procedure listed below for sterilisation. Other sterilisation procedures (e.g. ethylene oxide, formaldehyde and low-temperature plasma sterilisation) are not permissible.

Steam sterilisation procedure
Validated in accordance with DIN EN 554/ISO 11134
Maximum sterilisation temperature 134°C

Proof in principle of the handles' suitability for effective sterilisation was provided using a fractional vacuum process (Euroselectomat 666 by MMM Münchner Medizin Mechanik GmbH, sterilising temperature 134°C, holding time 7 min.)

Inspection / durability
The handles should be inspected for damage and changed before re-use, if required.
The handles may be cleaned / disinfected, sterilised and re-used for a maximum of 1000 times. If the handles are re-used more than 1000 times, then this will be the responsibility of the hospital / clinic.



3.2 Lamp head, splinter protection disk

The lamp has a high-quality surface. The surface can be cleaned with conventional cleaning agents.

The **splinter protection disk 5** is made of a high-quality plastic. Pay attention to the following during cleaning:

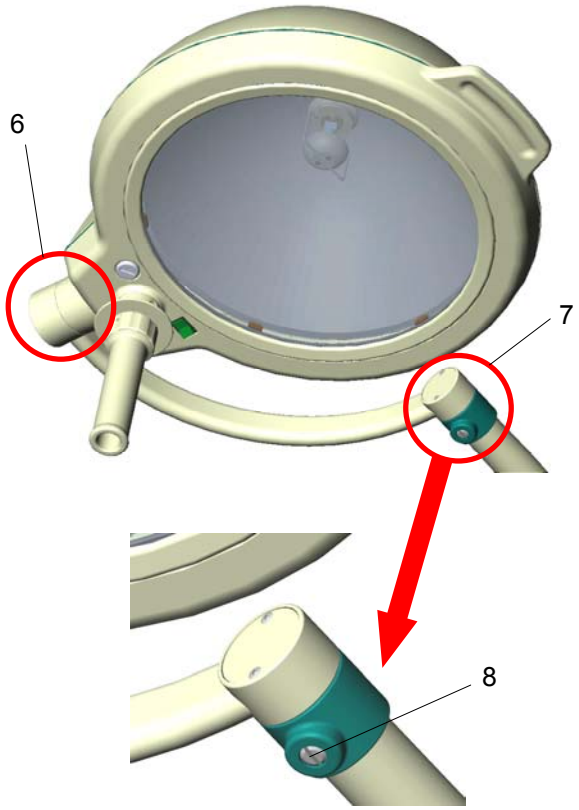
- Always clean the **splinter protection disk 5** with a wet cloth (never clean with a dry cloth!).
- Only use disinfectants with **less than 20% alcohol**.

Alc. ≤ 20 %

Wipe the **splinter protection disk 5** after cleaning with an antistatic, non-fluffy cloth.

4. Maintenance

4.1 Adjusting the mobility



The lamp MACH M2 is supplied with brakes on the suspension fixture and on the lamp housing. Adjust these brakes, if necessary, after installation.
If it is difficult to move the lamp, or if it does not keep its set position, the brake forces should be adjusted.
Service and a check of the lamp should be made every two years.
In order to keep the system easy-running throughout its life span, we recommend that the hinges should be greased avery two years with acid-free grease.
Attention: Before dismounting the lamp, set the height adjustment of the spring arm to horizontal position (see mounting instructions "Ceiling attachment – wall attchment").

4.1.1 Adjustments at the lamp head

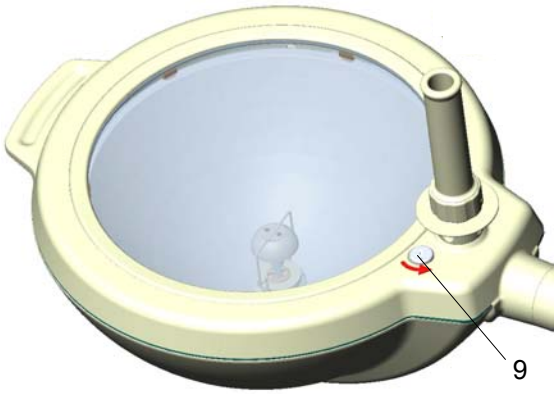
Adjusting the mobility in the **lamp joint 6** is not necessary.

In case the mobility in the **lamp joint 7** is too easy-going or too heavy-going, the **brake screw 8** must be adjusted with an appropriate screw driver.

4.2 Changing of spare parts

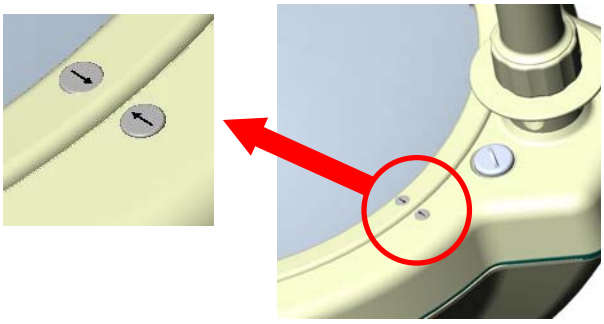
4.2.1 Changing the halogen bulbs

Dr. Mach uses special halogen bulbs as illuminants.
Only original Dr. Mach replacement bulbs may be used.
The use of other bulbs can lead to a considerable reduction of the light power and increase in the thermal load. The halogen bulbs have a service life of approx. 1200 hours.

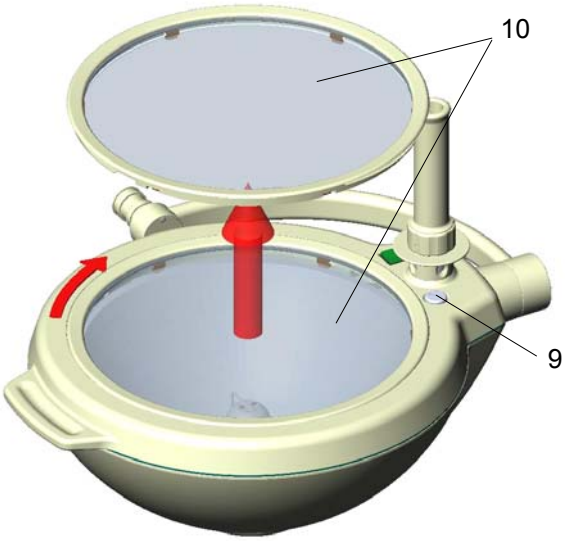


- **Turn off the lamp.**
  ATTENTION: Parts of the housing and the halogen bulb may be very hot immediately after use.
- Turn the lamp, so the light outlet points to the ceiling.
- Turn the **screw 9** anticlockwise with an appropriate screw driver.

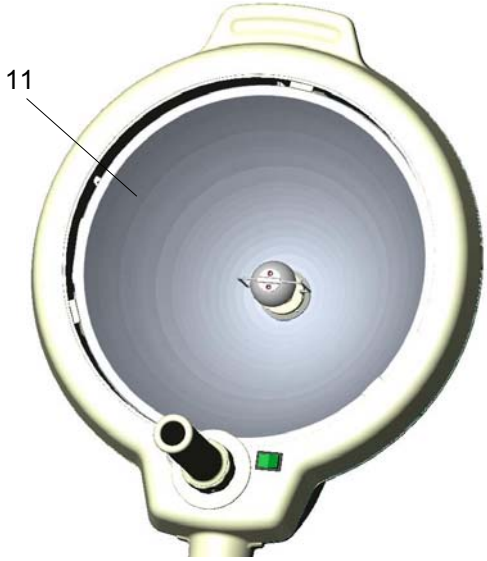
Remark:
In case there is no screw driver available, you can use a coin.



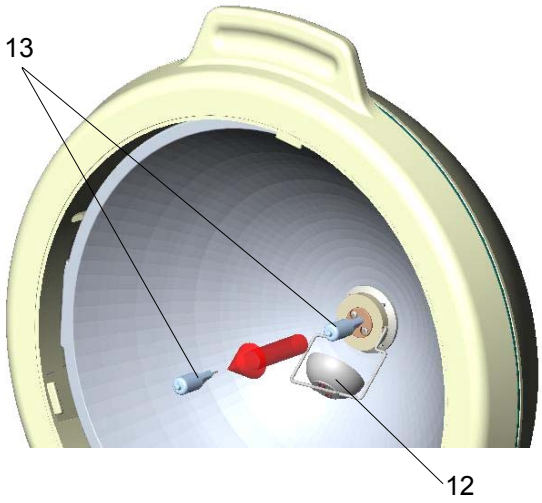
- By turning the **screw 9** anticlockwise, the **retaining ring 10** turns clockwise off the lower housing part.
- Turn the **screw 9** until the two marking arrows on the ring of the light and the lower housing part of the lamp match as shown in the figure.



- Then remove the **retaining ring 10** by pulling it upwards.



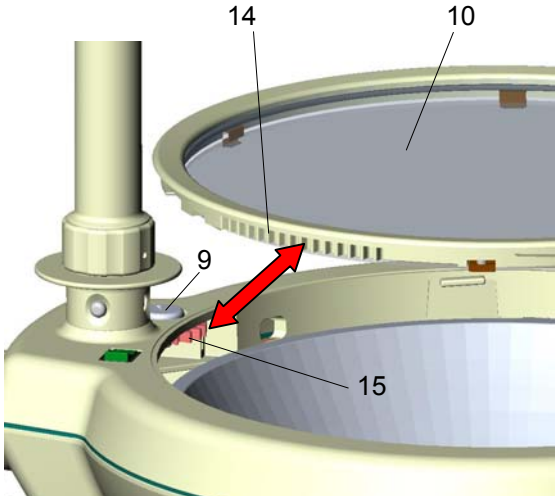
- Now you can see the open **reflector 11** in front of you.
  ATTENTION: Do not touch the inner surface of the reflector, otherwise this surface can be damaged.



- Tilt the **shadower 12** off-center as shown in the figure on the left, until it snaps in in the provided groove.
- Pull the **halogen bulb 13** carefully off its socket.

ATTENTION: Never touch new halogen bulbs with your fingers. Always use the original packaging or a clean cloth.

- Carefully insert the halogen bulb (22,8V, 77W) in the socket.
- Tilt the **shadower 12** in its original position.



- Mount the **retaining ring 10** in reverse order (anticlockwise rotation).
  For mounting position the **retaining ring 10** so that the **toothed wheel segment 14** of the ring and the **toothed wheel 7** in the lower housing part work into each other.
- Fix the retaining ring by turning the **screw 9** clockwise.
- Check the function of the new halogen bulb.

4.2.2 Changing the filter disk

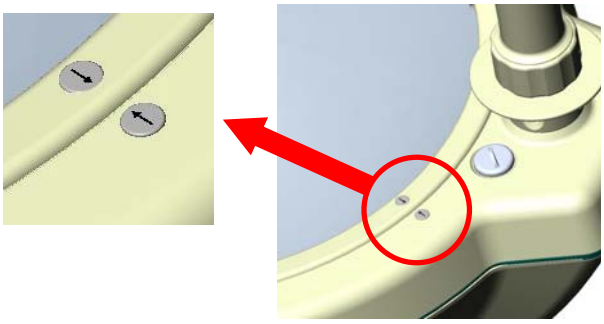
The filter disk mounted between reflector and splinter protection disk prevents a damaging heating of the illuminated area.

ATTENTION!
It is not allowed to use the lamp without this filter.

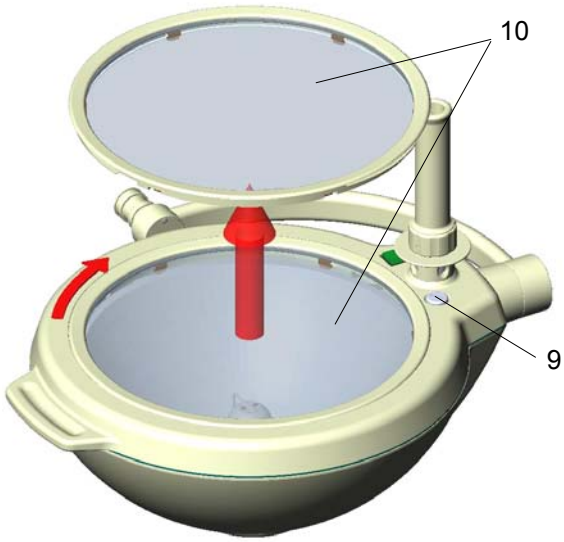
Always place the filter disk on a soft, non-scratching base to preserve its surface.

- **Turn off the lamp.**
  ATTENTION: Parts of the housing and the halogen bulb may be very hot immediately after use.
- Turn the lamp, so the light outlet points to the ceiling.
- Turn the **screw 9** anticlockwise with an appropriate screw driver.

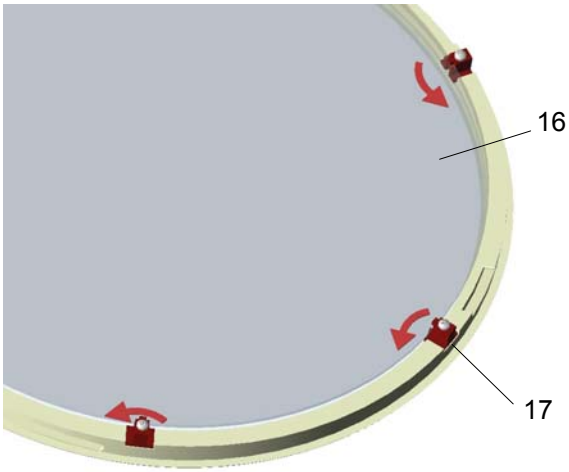
Remark:
In case there is no screw driver available, you can use a coin.



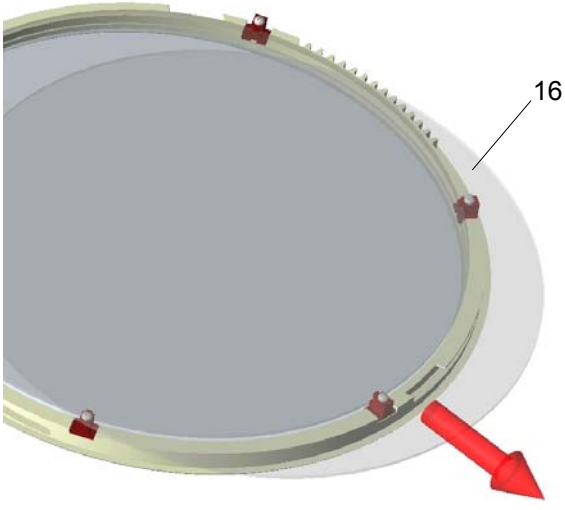
- By turning the **screw 9** anticlockwise, the **retaining ring 10** turns clockwise off the lower housing part.
- Turn the **screw 9** until the two marking arrows on the ring of the light and the lower housing part of the lamp match as shown in the figure.



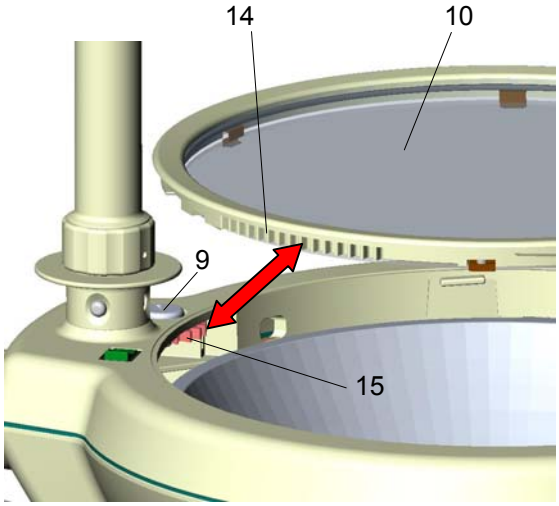
- Then remove the **retaining ring 10** by pulling it upwards.



- The **filter disk 16** is held by six **retainers 17**, which are fixed with six recessed head screws.
- Loosen the screws at three adjacent **retainers 17**.



- Lift the **filter disk 16** carefully and pull it off the other three retainers.
- Mount the new filter disk in reverse order.
  ATTENTION: Only use filter disks, that have been cleaned properly (see chapter 3.2).



- Mount the **retaining ring 10** in reverse order (anticlockwise rotation).
  For mounting position the **retaining ring 10** so that the **toothed wheel segment 14** of the ring and the **toothed wheel 7** in the lower housing part work into each other.
- Fix the retaining ring by turning the **screw 9** clockwise.

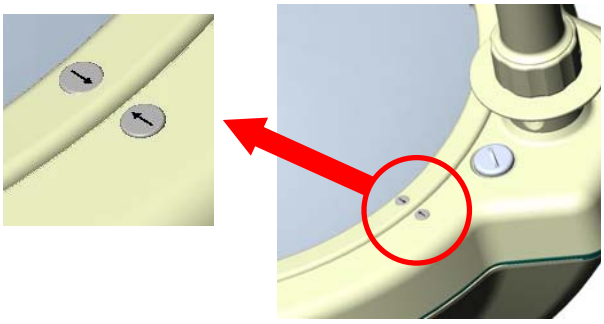
4.2.3 Changing the dispersing lens

The dispersing lens is made of a high-quality plastic. In case the dispersing lens looses its optical characteristics, this can reduce the luminous intensity and the light quality provided.
It may be necessary to exchange the dispersing lens.

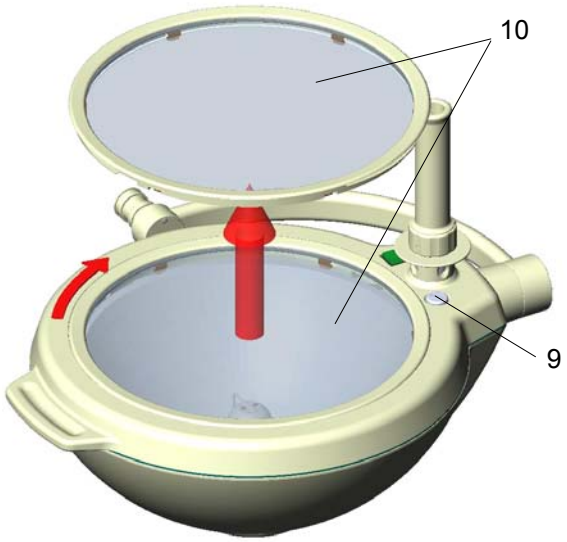
Always place the dispersing lens on a soft, non-scratching base to preserve its surface.

- **Turn off the lamp.**
  ATTENTION: Parts of the housing and the halogen bulb may be very hot immediately after use.
- Turn the lamp, so the light outlet points to the ceiling.
- Turn the **screw 9** anticlockwise with an appropriate screw driver.

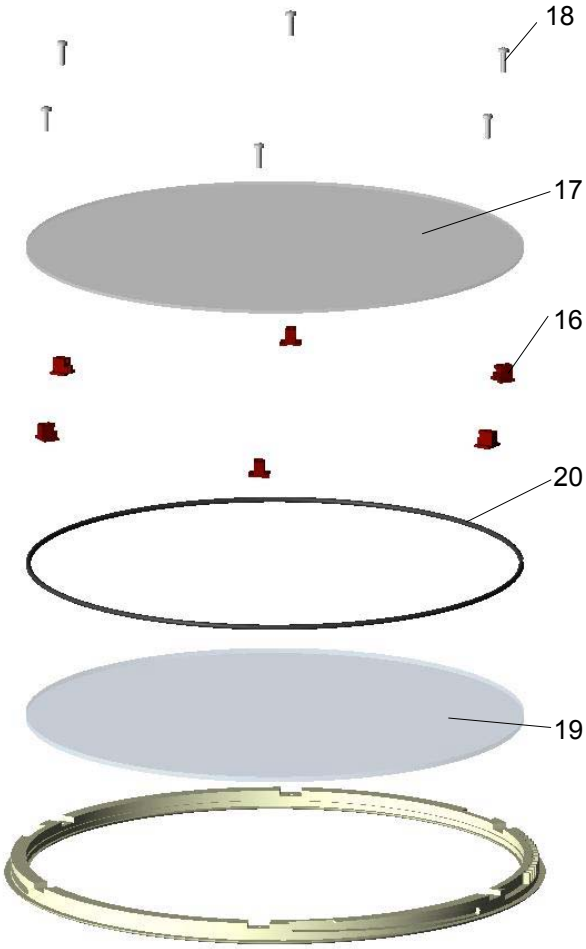
Remark:
In case there is no screw driver available, you can use a coin.



- By turning the **screw 9** anticlockwise, the **retaining ring 10** turns clockwise off the lower housing part.
- Turn the **screw 9** until the two marking arrows on the ring of the light and the lower housing part of the lamp match as shown in the figure.



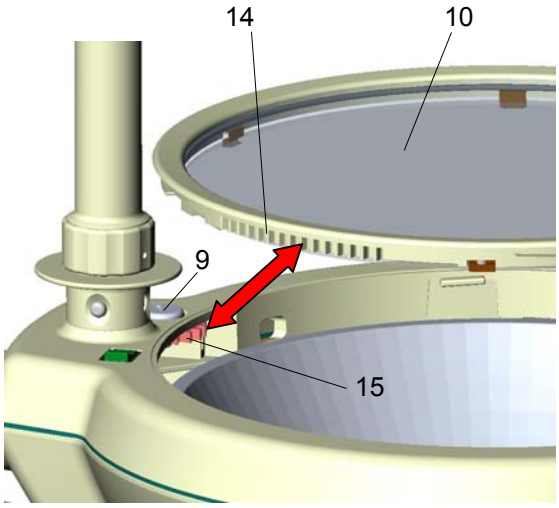
- By turning the **screw 9** anticlockwise, the **retaining ring 10** turns clockwise off the lower housing part.
- Remove the **retaining ring 10** by pulling it upwards.



- Loosen the six **screws 18** and remove them.
- Lift the **filter disk 17** off the six **retainers 16**.
  Always place the filter disk on a soft, non-scratching base to preserve its surface.

- Remove the six **retainers 16**.
- Remove the r**ing 20**.
- Remove the **splinter protection disk 19**.
  Always place the splinter protection disk on a soft, non-scratching base to preserve its surface.
- Mount the new **splinter protection disk 19**.
  ATTENTION: Only use splinter protection disks, that have been cleaned properly (see chapter 3.2).

- Mount the r**ing 20**, the **retainers 16** and the **filter disk 17** in reverse order and fix the six retainers with the **screws 18**.



- Mount the **retaining ring 10** in reverse order (anticlockwise rotation).
  For mounting position the **retaining ring 10** so that the **toothed wheel segment 14** of the ring and the **toothed wheel 7** in the lower housing part work into each other.
- Fix the retaining ring by turning the **screw 9** clockwise.

5. Data

5.1 Technical data

	Mach M2 F	Mach M2
Central light intensity at a distance of 1 meter	40.000 – 80.000 Lux	60.000 Lux
Light field diameter d_{10}	160 mm	170 mm
Light field diameter d_{50}	90 mm	110 mm
Light intensity with one shadower	125 Lux	45 Lux
Light intensity with two shadowers	47.000 Lux	35.000 Lux
Light intensity on the ground of a normed tube	79.200 Lux	59.600 Lux
Light intensity on the ground of a normed tube with one shadower	85 Lux	30 Lux
Light intensity on the ground of a normed tube with two shadowers	46.000 Lux	34.500 Lux
Illumination depth	1600 mm	1600 mm
Colour rendering index R_a at 4300 Kelvin	96	96
Colour rendering index R_9 at 4300 Kelvin	> 90	> 90
Focusable light field size	140 – 240 mm	180 mm Fixfocus
Colour temperature (Kelvin)	4300	4300
Radiation intensity in field	130 W/m^2	130 W/m^2
Temperature increase in head area	2 °C	2 °C
Total power consumption	80 VA	80 VA
Number of bulbs: Halogen 22,8/24V 80W	1	1
Working distance	700 – 1400 mm	700 – 1400 mm
Height adjustment	1300 mm	1300 mm

5.2 Electrical data

Mach M2 F / Mach M2	
Power consumption	80 W
Voltage AC/DC	22,8 V
Current	3,5 A
Halogen bulb	22,8 V / 80 W IRC
Frequency	50/60 Hz
Degree of protection	Type B
Class of protection	I.

5.3 Environmental conditions

Operation

	Min.	Max.
Temperature	+10°C	+40°C
Relative athmospheric humidity	30 %	75 %
Air pressure	700 hPa	1060 hPa

Transport / storage

	Min.	Max.
Temperature	-10°C	+50°C
Relative athmospheric humidity	20 %	90 %
Air pressure	700 hPa	1060 hPa

5.4 General remarks

When installing a lamp, its fail-safety must be guaranteed according to DIN VDE 0100-710 (former DIN VDE 0107).

Protective conductor

6. CE-mark

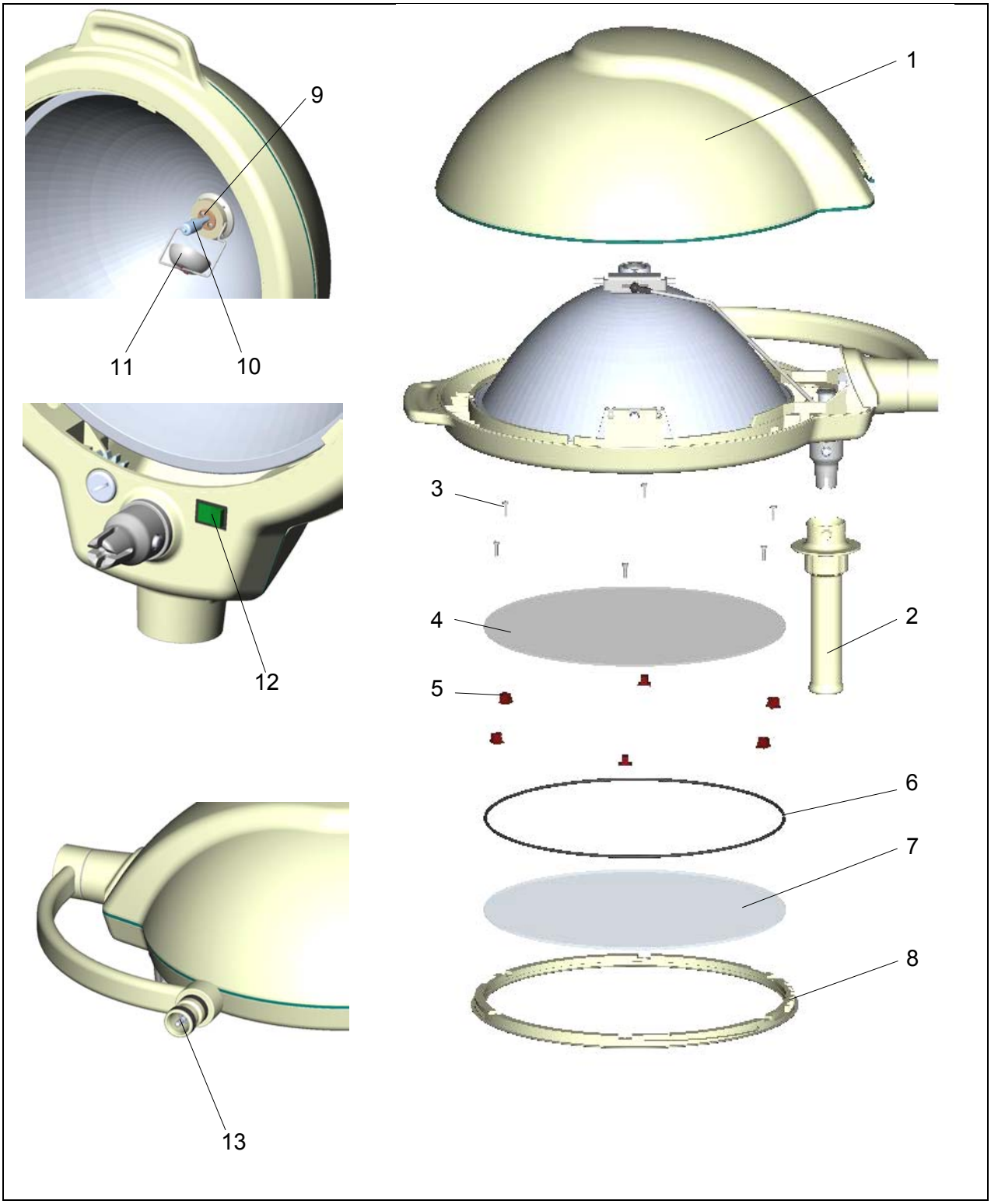
The products Mach M2 comply with the standards 93/42/EEC for medical products of the European Community's Council. Dr. Mach applies the standard EN 60601-2-41.
Dr. Mach GmbH is certified according to DIN EN 46001:1996 and DIN EN ISO 13485:2001.

7. Disposal

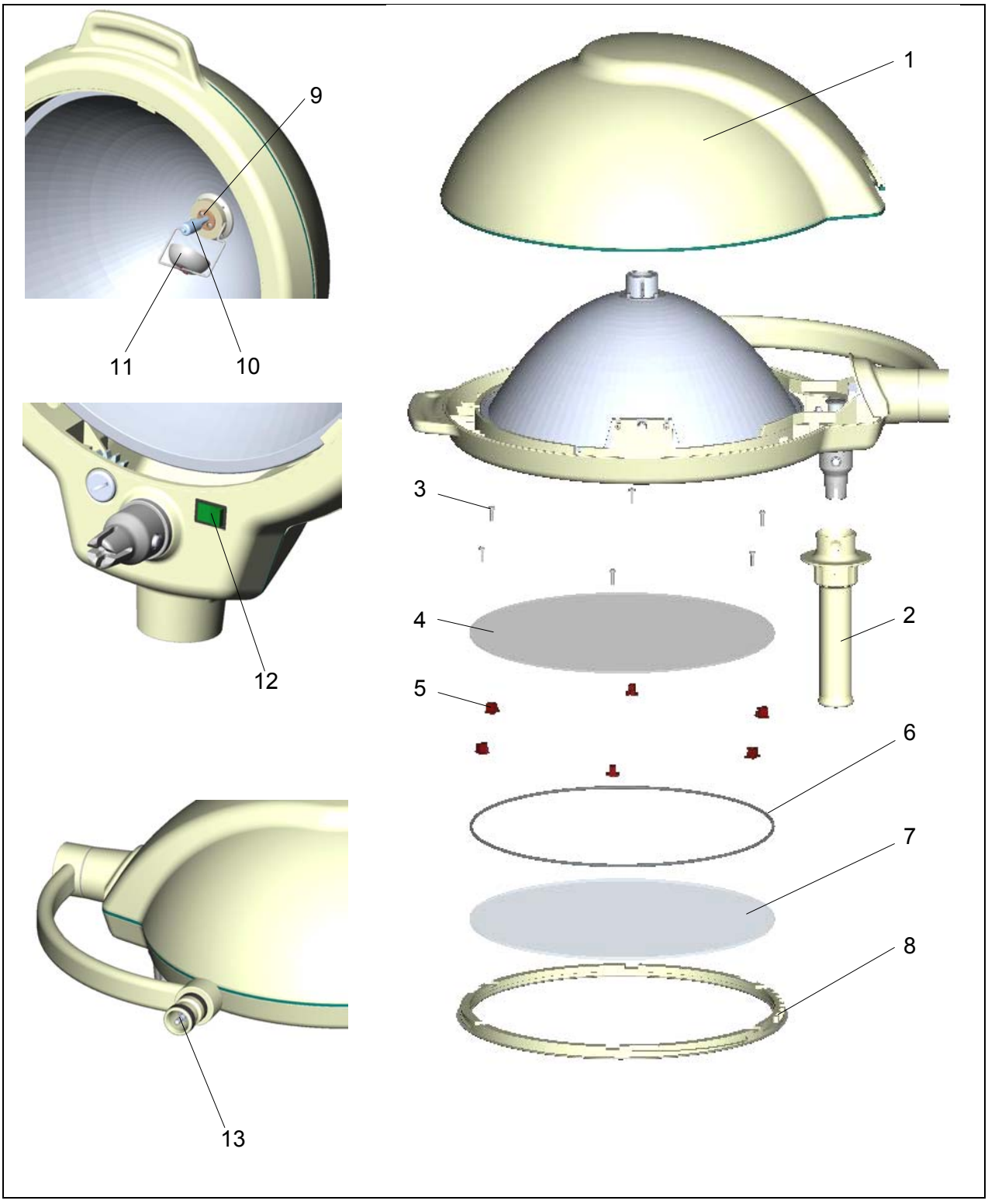
The lamp doesn’t contain any dangerous goods.
The components of the OT-lamp should be properly disposed at the end of its shelf-life.
Make sure, that the materials are carefully separated.
The components should be disposed according to the contained materials.

8. Spare parts

8.1 Mach M2 F



8.2 Mach M2



9. Spare parts list

Item	Qty.	Name	EDVNO	Remark
1	1	Upper housing part	12011001	with sealing cord
2	1	Sterilisable handle	21150002	
3	6	Screw DIN7985-HM3x12-Ni	65152037	
4	1	Conversion filter D284 Califlex Eco	67390204	
5	6	Retainer	27021206	
6	1	Ring	27021205	
7	1	Splinter protection disk	27021201	
8	1	Retaining ring	27021203	
9	1	Socket GY 6.35	67320007	
10	1	Halogen bulb 22,8V 80W IRC	67100105	
11	1	Shadower	27061001	
12	1	ON/OFF switch	67340004	
13	1	Sliding contact with cable		

Remark:
The parts 3,4,5,6,7 and 8 can also be ordered as a premounted complete unit **(No. 27021001, retainig ring)**.