



D^{med}® **Triango** 80 C

D^{med}® **Triango** 80 W

D^{med}® **Triango** 80 F



IMPORTANT!
THIS OPERATING MANUAL MUST BE THOROUGHLY READ BEFORE
USING THE PRODUCT!

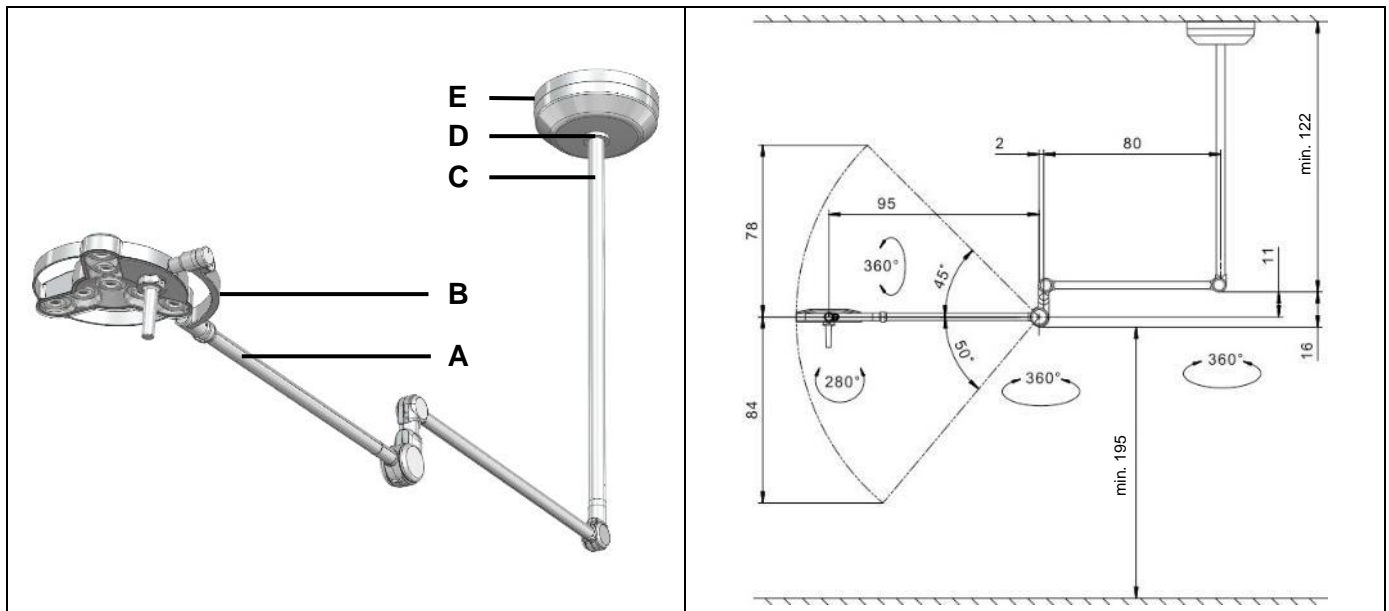
→ **STORE FOR LATER USE!**

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1. VERSIONS AND DELIVERY CONTENT

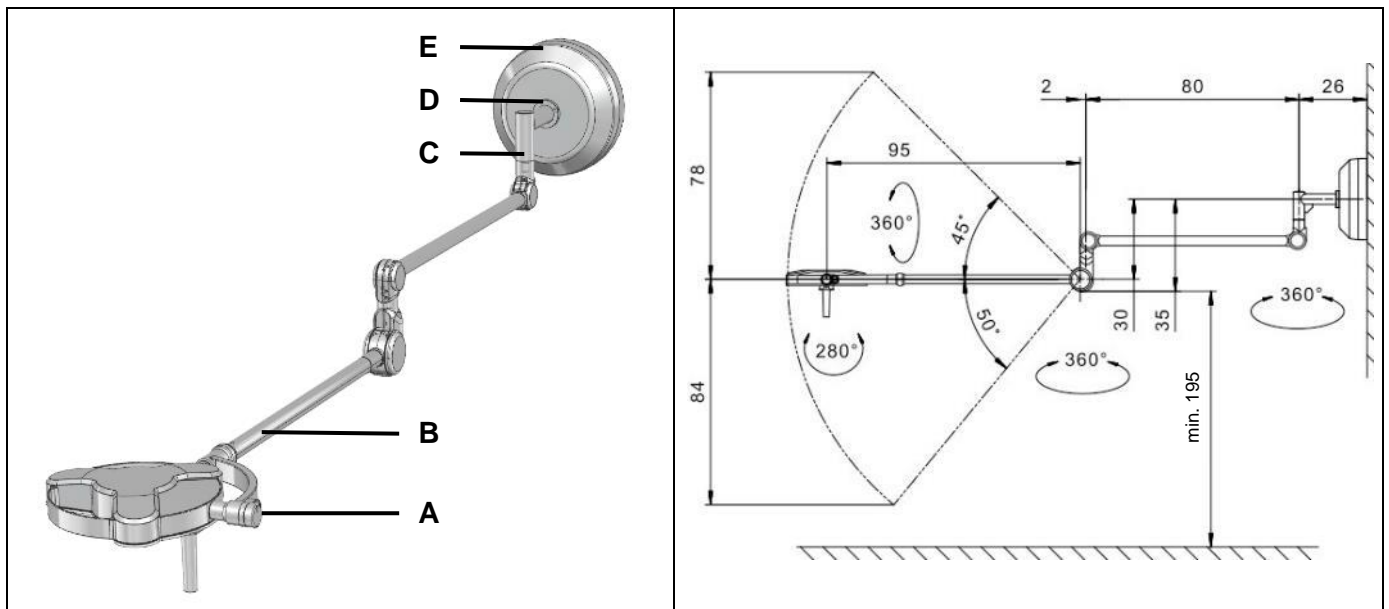
1.1 Triango 80 C



- A: Ceiling arm
- B: Luminaire head with sterilizable hand grip
- C: Ceiling tube

- D: Retaining ring
- E: Ceiling plate and cover

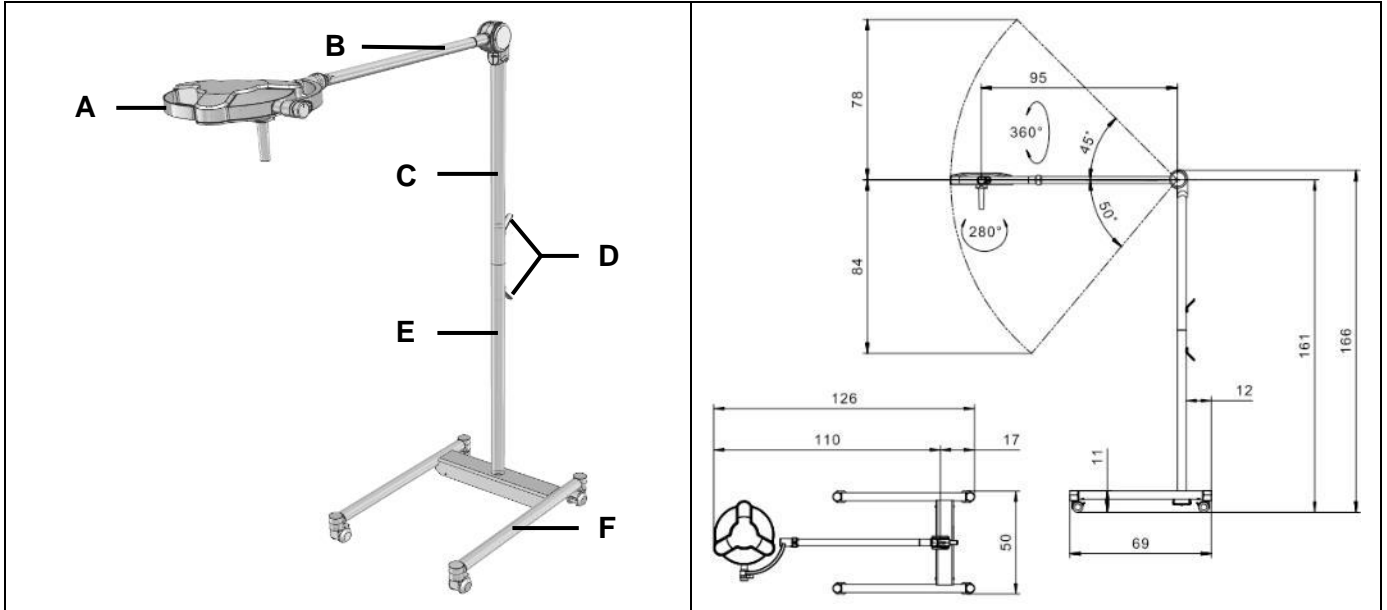
1.2 Triango 80 W



- A: Luminaire head with sterilizable hand grip
- B: Arm for wall mounting
- C: Wall bracket

- D: Retaining ring
- E: Wall holder and cover

1.3 Triango 80 F



- A: Luminaire head with sterilizable hand grip
- B: Spring balanced arm
- C: Upper support tube

- D: Lower support tube
- E: Cable holder
- F: Roller stand

2. SAFETY INSTRUCTIONS

2.1 Intended use

The Triango 80 luminaire is a treatment lamp (small surgical lamp). It is an individual lamp for use in treatment rooms that is used near the patient to assist in diagnosis or treatment. It poses no risk to the patient if a light failure causes interruption. It is intended for continuous operation and is not to be combined with other medical devices.

2.2 User profiles

Health Professional

All individuals who have completed medical training and work in the professional field they trained for.

Cleaning specialist

Trained in national and workplace hygiene regulations.

Qualified electrician

Trained in electronics and electrical technology and knows the relevant standards and regulations.

Qualified specialist

Qualified due to his technical training, knowledge and experience and knowledge of the rules, to perform assembly/dismantling.

2.3 Safety instructions

- ▶ Operation by health professionals
- ▶ This manual is part of the product and must be stored and made available to all future users.
- ▶ All work on the luminaire (including repairs) may only be performed by a qualified electrician. Assembly may only be done by a qualified specialist.
- ▶ The luminaire may not be altered or tampered with. Only approved original parts may be used. Any use other than that intended, using original parts, can change technical parameters and pose a death hazard.
- ▶ Do not exceed the maximum weight and do not hang, lean or climb on the arm, because this may cause the device to tip over, which could result in serious injury.
- ▶ Operation in potentially explosive areas is prohibited. The luminaire's current supply is a potential ignition source.
- ▶ The luminaire must be used only in dry, dust-free rooms.
- ▶ The light must not be left switched on unattended.
- ▶ Only connect the luminaire to the supply network with a protective ground conductor (PE), to prevent electrical shock.
- ▶ In the case of luminaires of protection class I, the protective ground conductor (PE) must be connected to luminaires housing.
- ▶ Do not use a damaged luminaire. Defective cables and a defective hand grip also pose a potential hazard. Do not place a cord near heat sources or sharp edges.

- ▶ Do not place extra loads on the luminaire head and arm system.
- ▶ The luminaire must not be covered with a cloth or similar item during operation.
- ▶ The ventilation openings (if present) must always be kept clear during operation!
- ▶ The luminaire must not be operated near external heat sources that exceed the luminaire's maximum ambient temperature.
- ▶ The luminaire must not be used outside the specified ambient conditions.
- ▶ Do not use with medical devices that may react sensitively to a light spectrum within the visible range (such as pulsating light and/or light with high illumination intensity).
- ▶ The luminaire may only be used for the intended use described here.
- ▶ The manufacturer cannot be held responsible for any damages resulting from use deviating from the intended use, or failure to observe the safety instructions and warnings.
- ▶ When using more than one luminaire at the same time, the total illumination intensity must not exceed $E_e 1000\text{W/m}^2$.
- ▶ Before connecting to the power grid, it is essential to check that the grid data match the device data.
- ▶ **Triango 80 F**
The luminaire must be secured during transport within the clinic.

2.4 Warning levels



DANGER

Warning of hazards that can result in **death or serious injury** if instructions are not followed.



WARNING

Warning of hazards that can result in **injury** if instructions are not followed.

CAUTION

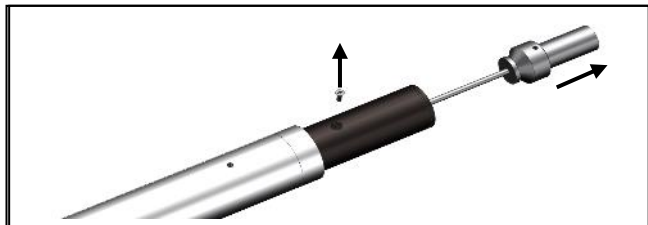
Warning of hazards that can cause **material damage** if instructions are not followed.

3. INSTALLATION: Triango 80 C

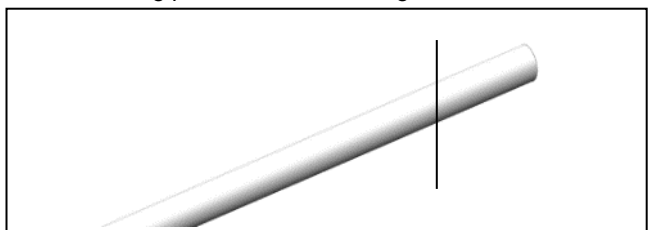
3.1 Workload data

Bending moment M_B	135 Nm
Vertical weight F_G	140 N

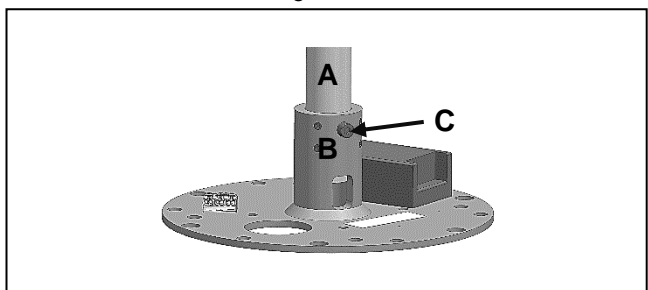
3.2 Shortening the ceiling tube



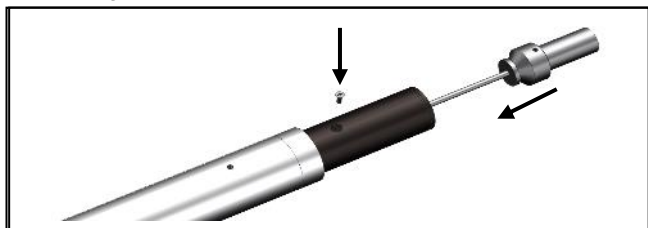
- ▶ Loosen the socket's fastening screws.
- ▶ Pull the socket, complete with cable, out of the ceiling tube using pliers on the inner ring.



- ▶ Before shortening the ceiling tube, remove the cable from the ceiling tube.
- ▶ Use a hack saw to shorten the upper end of the ceiling tube to the desired length, and then deburr it.



- ▶ Remove the fastening screw "C".
- ▶ Insert the ceiling tube "A" into the ceiling bracket "B" and drill the ceiling holder's existing hole to 9 mm in diameter. Drill the opposite hole separately.
- ▶ Note: Pull the cable through from the lower side to the upper pipe side (the 3-pin plug first) after sawing and drilling.



- ▶ Insert the cable with the socket back into the ceiling tube.
- ▶ Align the threaded hole in the socket precisely with the existing hole in the ceiling tube and install the fastening screw.

3.3. Installing the ceiling holder

DANGER

Assembly by qualified personnel

- ▶ Assembly must be done by qualified personnel only. Lack of appropriate knowledge may pose a death hazard.
- ▶ Two people are needed for assembly.

DANGER

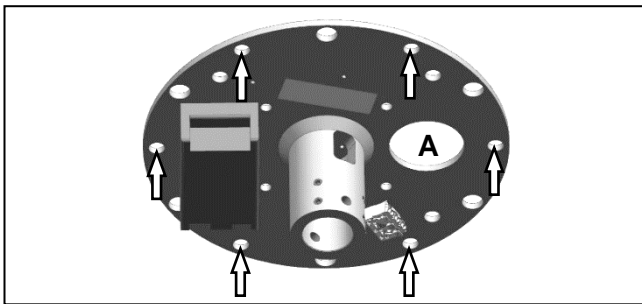
Death hazard from falling luminaire.

- ▶ The ceiling mount must only be mounted on ceilings with a concrete stability class of B25 (C20/25) or higher.
- ▶ There should be no contact with reinforcement parts of the solid ceiling during mounting. When in doubt, a licensed technician must approve installation on the specific installation surface. The load bearing capacity of the ceiling structure must be planned, checked and confirmed by a structural engineer beforehand.
- ▶ The holes must be drilled by a professional and in compliance with the drilling tolerances permitted by the manufacturer of the fastening anchor. If a drilling error occurs, such as drilling into a reinforcement bar, a structural engineer must be consulted.
- ▶ Install the luminaire such that the vertical stops are not continuously stressed during operation.
- ▶ With plaster or cladding in front of concrete, the fastening anchor must be driven completely into the concrete.
- ▶ The screws must be tightened carefully using a torque wrench according to the specifications of the fastening anchor manufacturer.

DANGER

Death hazard from electric shock.

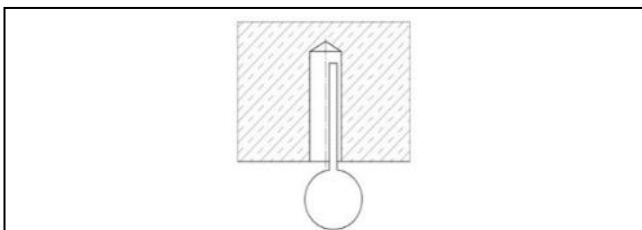
- ▶ All poles of the power cable must be disconnected from the power grid from an external lockable switch.



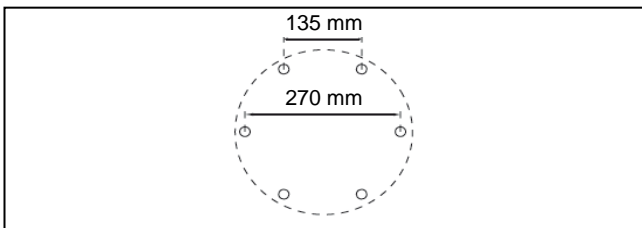
- ▶ Draw 6 drill marks.
- ▶ Observe the position of opening "A" for connecting the current.

WARNING

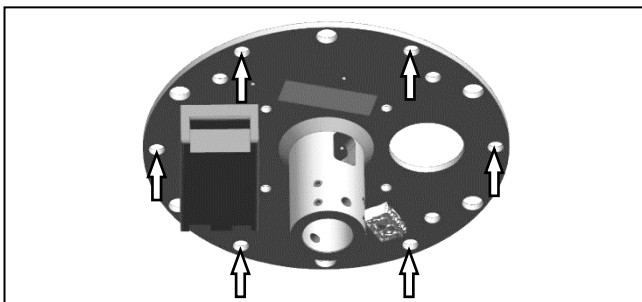
Wear safety equipment according to the tool manufacturer's instructions.



- ▶ Drill holes and blow out with a bellows.



- ▶ Check the hole distances.

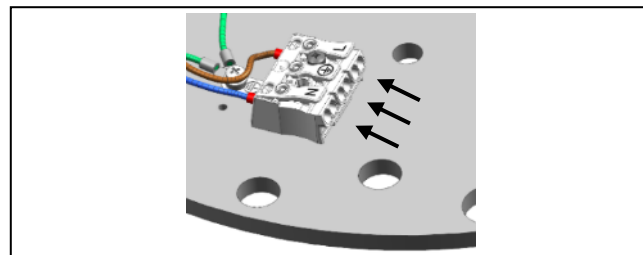


- ▶ Hold the ceiling bracket to the ceiling and hammer in the fastening anchor.
- ▶ Tighten the fastener according to manufacturer's instructions.

DANGER

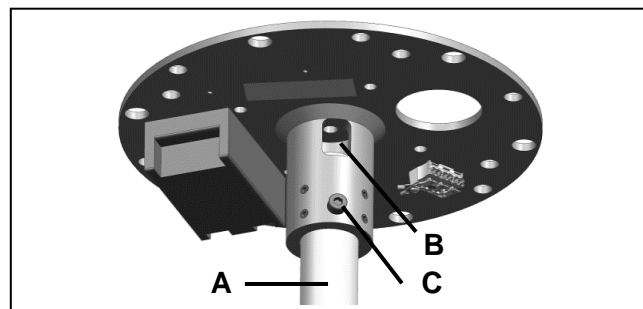
Death hazard from electric shock.

- ▶ Do not turn on the power supply before the luminaire head has been installed.
- ▶ This device must only be connected to a power grid with a protective ground conductor (PE) to prevent risk of electric shock

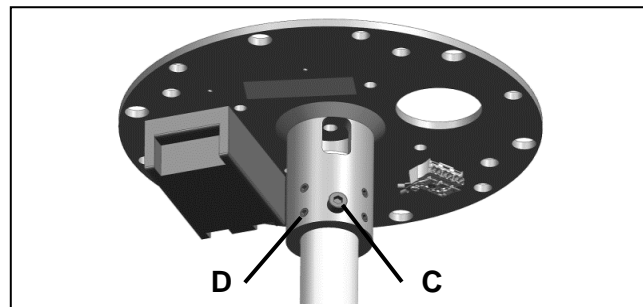


- ▶ Connect the power.

3.4. Installing the ceiling tube



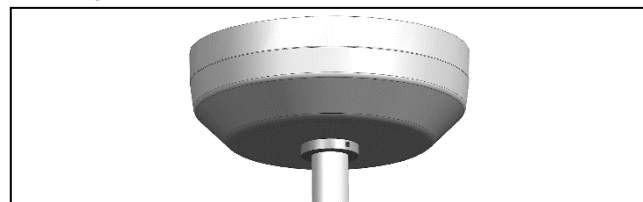
- ▶ Pull the ceiling tube cable through the opening "B" of the ceiling holder.
- ▶ Insert the ceiling tube "A" into the ceiling holder.
- ▶ Secure the safety screw "C" and the M8 nut.



- ▶ Tighten the M8 safety screw "C" and the nut (20 Nm).
- ▶ Tighten all 4 grub screws "D" (5 Nm).



- ▶ Connect the ceiling tube plug with the power supply plug.

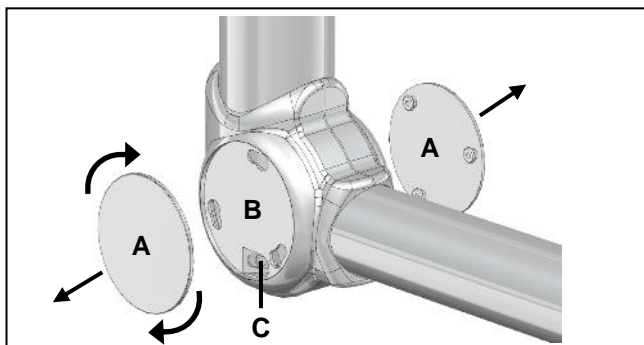


- ▶ Slide the ceiling cover and ring over the ceiling bracket and screw them tight.

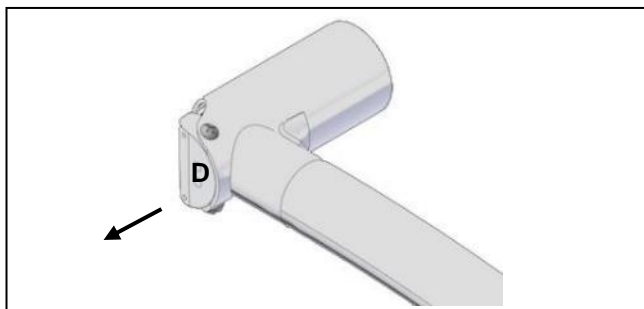
3.5 Installing the ceiling arm

⚠ WARNING

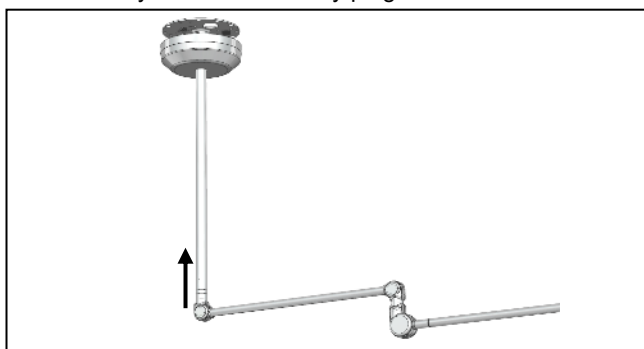
- ▶ **Injury hazard** from spring balanced arm jumping
- ▶ The spring arm can open suddenly when the binding agent is removed and cause injuries. Please remove the binder very carefully.



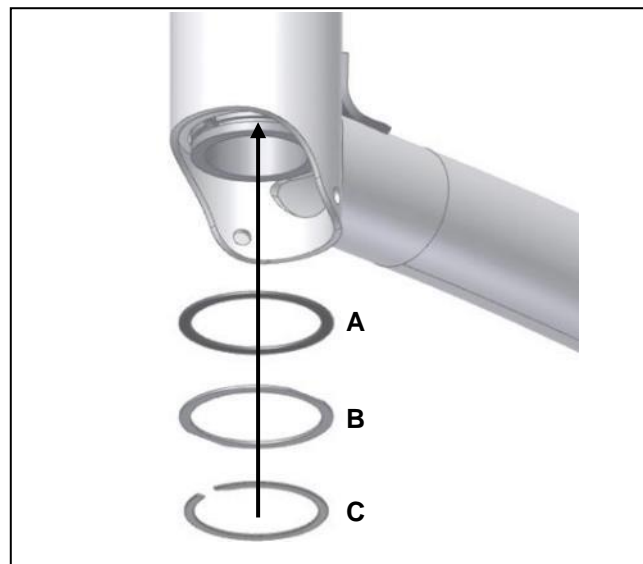
- ▶ Carefully turn the covers "A" and remove them from the joint cover "B".
- ▶ Loosen the screws "C" and remove the joint covers "B" from the transverse boom.



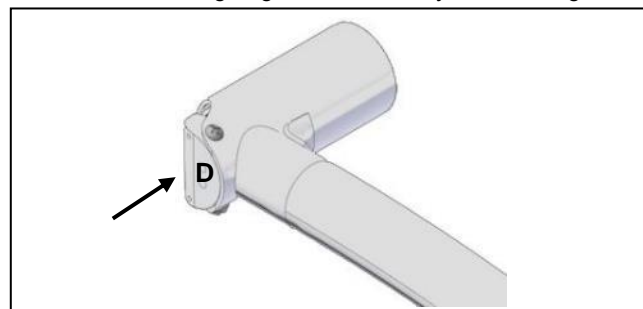
- ▶ Carefully remove the rotary plug "D".



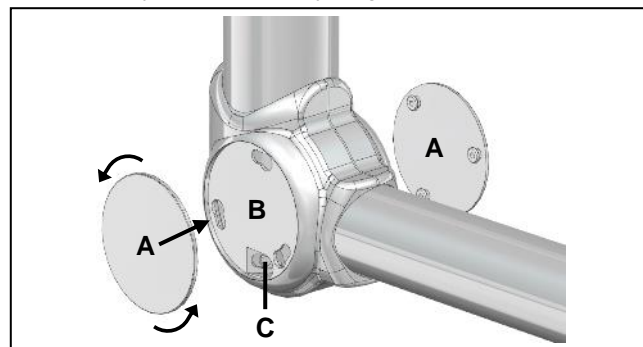
- ▶ Insert the ceiling arm into the ceiling tube.



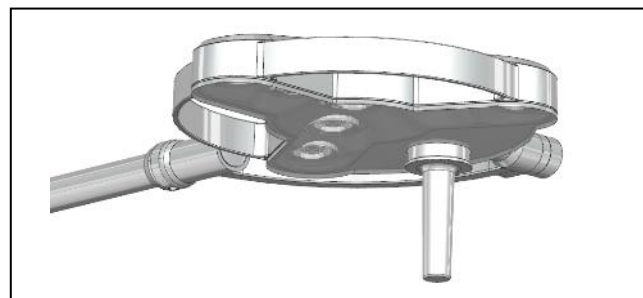
- ▶ After inserting the ceiling arm, first install the ring "A", then the locking ring "B", followed by the end rings "C".



- ▶ Carefully insert the rotary plug "D".



- ▶ Attach the joint covers "B" and install the screws "C".
- ▶ Insert the covers "A" and turn to secure.



- ▶ To proceed with installation of the **luminaire head**, see **Chapter 6**.

4. INSTALLATION: Triango 80 W

4.1 Workload data

Bending moment M_B	275 Nm
Vertical weight F_G	135 N

4.2. Installing the wall holder

- ▶ Fastening hardware does **not** come with delivery.

⚠ DANGER

Assembly by qualified personnel

- ▶ Assembly must be done by qualified personnel only. Lack of appropriate knowledge may pose a death hazard.
- ▶ Two people are needed for assembly.

CAUTION

Determine the fasteners to use from the workload data table

- ▶ Before assembly, make sure the rod dimensions are correct.

CAUTION

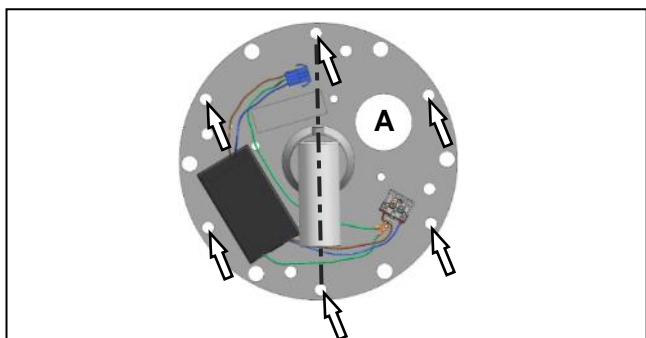
Make sure the wall holder is in the correct position.

- ▶ The wall holder must be aligned according to the axis in the image.
- ▶ Misalignment will compromise mechanical safety.
- ▶ We recommend using a counterplate on lightweight construction walls (not included with delivery).

⚠ DANGER

Death hazard from electric shock.

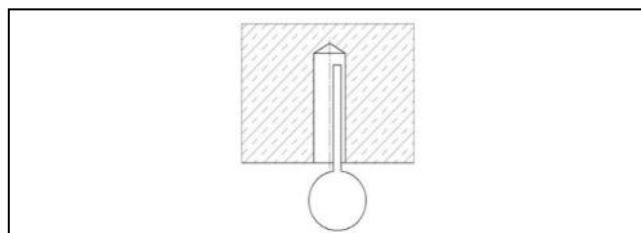
- ▶ All poles of the luminaire must be disconnected from the power supply by an external lockable switch.



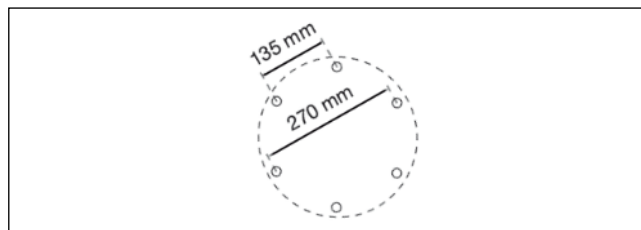
- ▶ Draw 6 drill marks.
- ▶ Observe the position of opening "A" for connecting the current.

⚠ WARNING

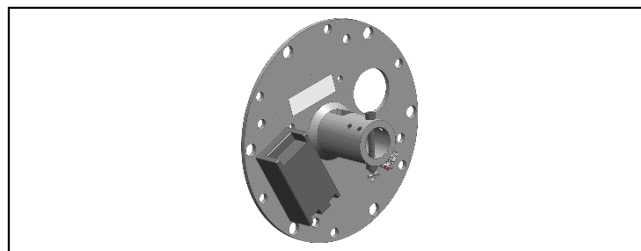
Wear safety equipment according to the tool manufacturer's instructions.



- ▶ Drill holes and blow out with a bellows.



- ▶ Check the hole distances.

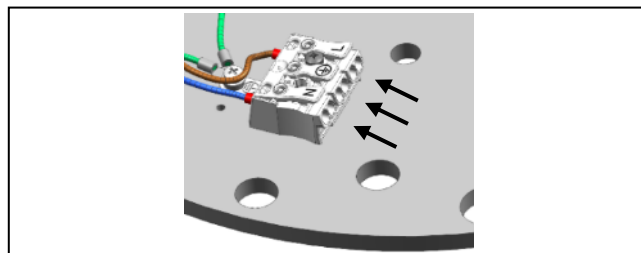


- ▶ Position the wall bracket on the wall and hammer in the fastening anchor.
- ▶ Tighten the fastener according to manufacturer's instructions.

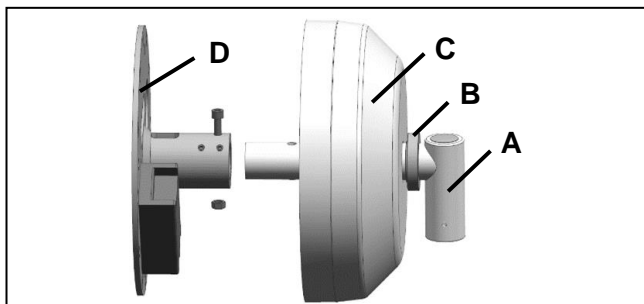
⚠ DANGER

Death hazard from electric shock.

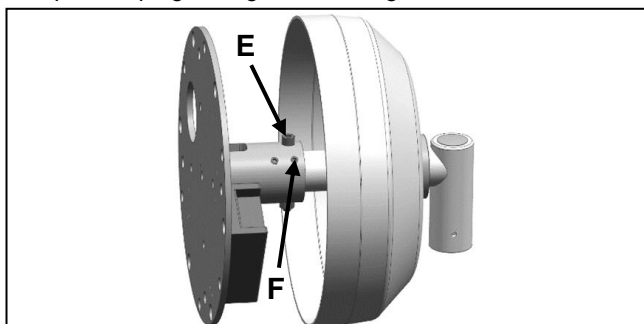
- ▶ Do not turn on the power supply before the luminaire head has been installed.
- ▶ This device must only be connected to a power grid with a protective ground conductor (PE) to prevent risk of electric shock



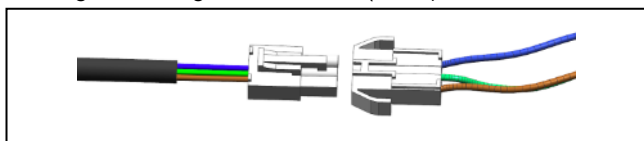
- ▶ Connect the power.



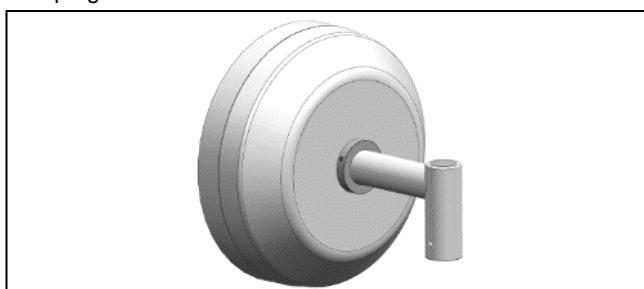
- ▶ Insert wall bracket "A" (with end ring "C" and cover "B" in position) into the wall holder "D" and simultaneously pull the plug through the rectangular cutout.



- ▶ When the wall bracket is vertically aligned, install it with the M8 locking screw and nut "E" and tighten (20 Nm).
- ▶ Tighten all 4 grub screws "F" (5 Nm).



- ▶ Connect the ceiling tube plug with the power supply plug.

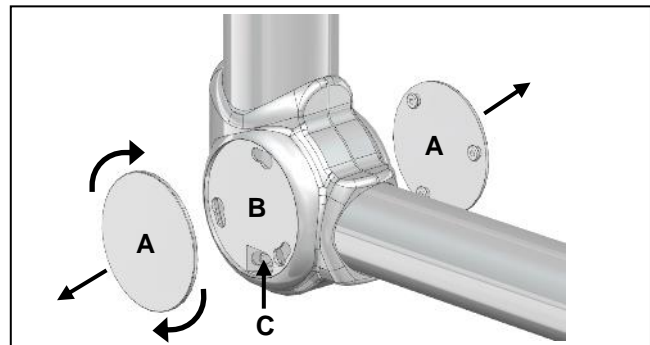


- ▶ Push the cover against the wall and screw tight with the ring (0.5 Nm)

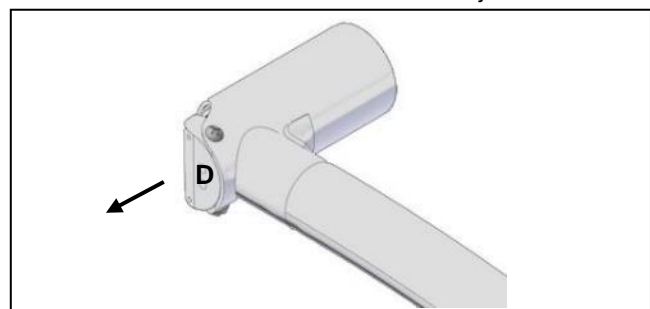
4.3 Installing the wall mounting arm

⚠ WARNING

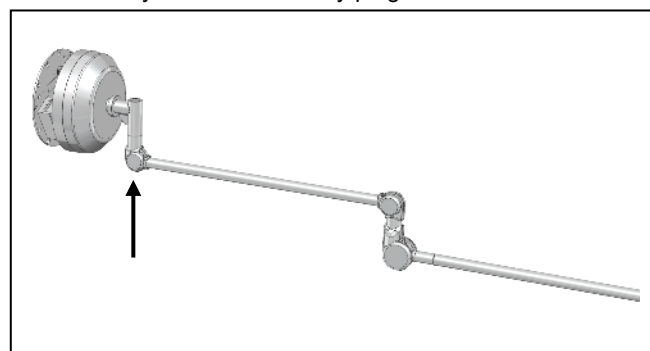
- ▶ **Injury hazard** from spring balanced arm jumping
- ▶ The spring arm can open suddenly when the binding agent is removed and cause injuries. Please remove the binder very carefully.



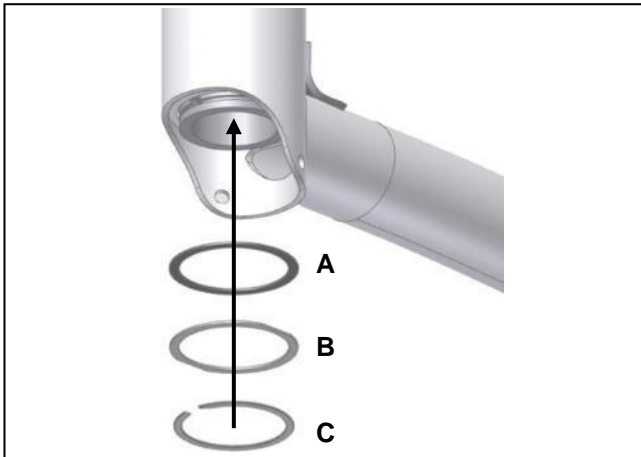
- ▶ Carefully loosen the cover "A".
- ▶ Loosen the screws "C" and remove the joint covers "B".



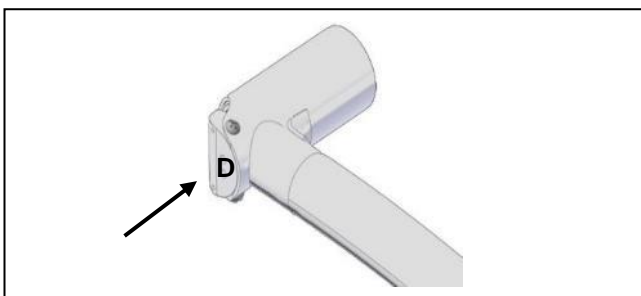
- ▶ Carefully remove the rotary plug "D".



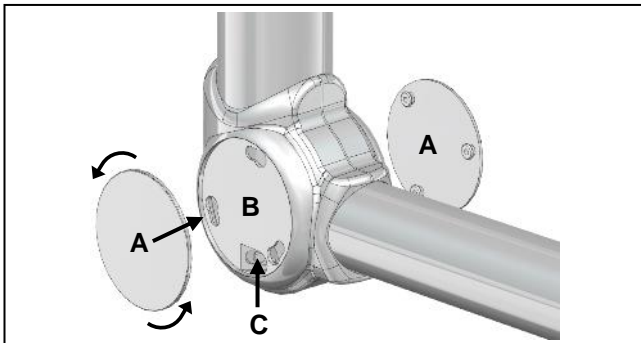
- ▶ Install the wall mounting arm.



- ▶ After inserting the wall mounting arm, first install the ring "A", then the locking ring "B", followed by the end rings "C".



- ▶ Carefully insert the rotary plug "D".

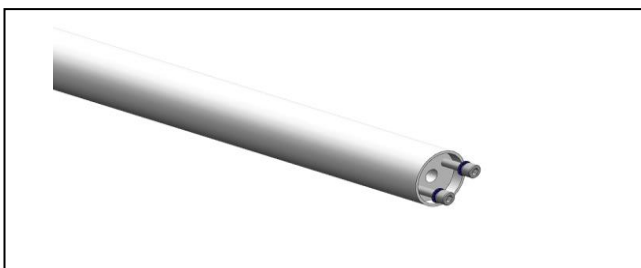


- ▶ Attach the joint covers "B" and install the screws "C".
- ▶ Attach the covers "A".

⚠ DANGER

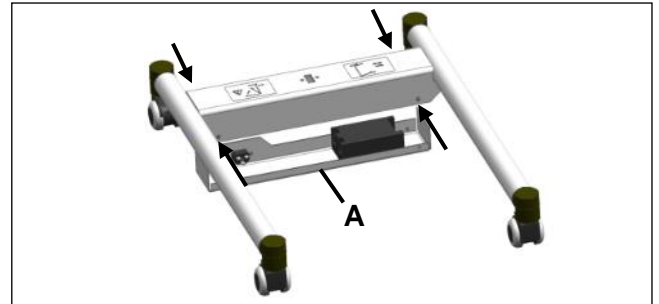
Death hazard from electric shock.

- ▶ Do not turn on the power supply before the luminaire head has been installed.

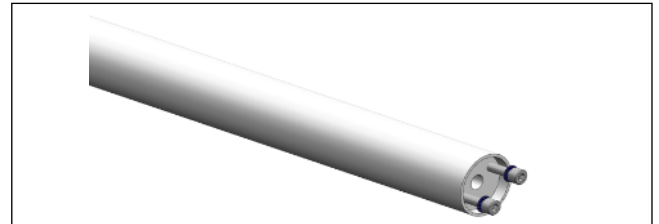


- ▶ To proceed with installation of the **luminaire head**, see **Chapter 6**.

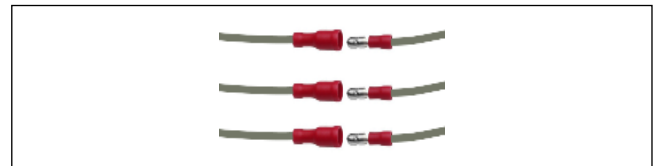
5. INSTALLATION: Triango 80 F



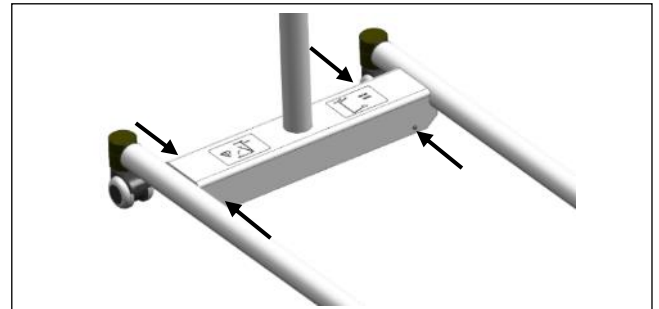
- ▶ Remove the M3 screws at the sides and then remove the power supply unit tub "A".



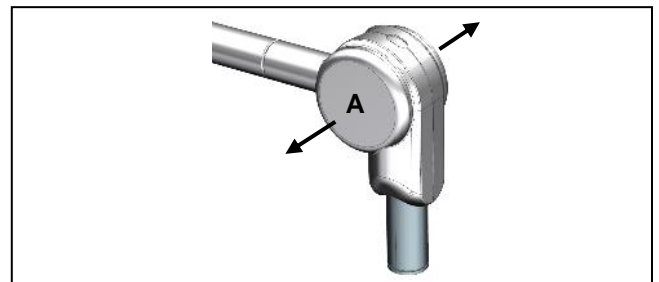
- ▶ Unfasten the two screws on the lower standpipe.
- ▶ Feed the support tube cable through the roller stand.
- ▶ Attach the support tube to the roller stand using the two Allen screws and serrated washers (10 Nm).
- ▶ The cable holder must be aligned rearward.



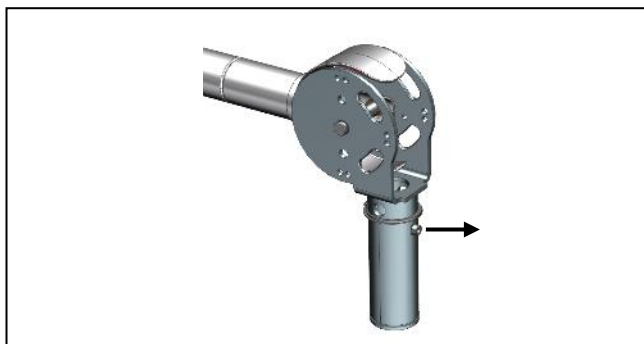
- ▶ Connect the same-colored stranded wires of the lower support tube and of the power supply.



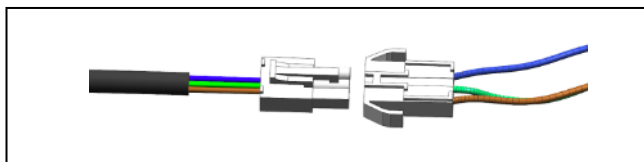
- ▶ Mount the power supply unit tub again using M3 screws and serrated washers.



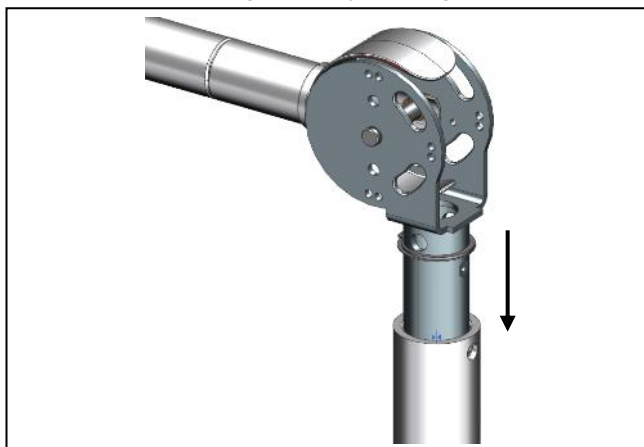
- ▶ Carefully pull off the covers "A".



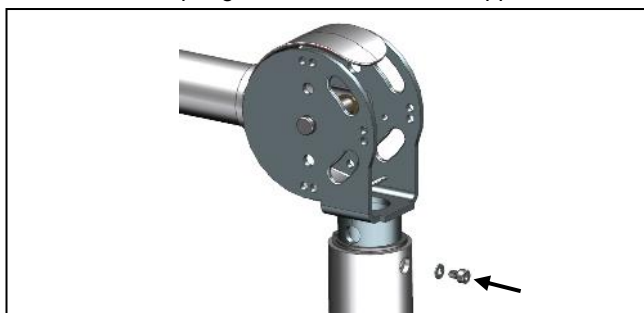
- ▶ Remove the M4 Allen screw with the washer.



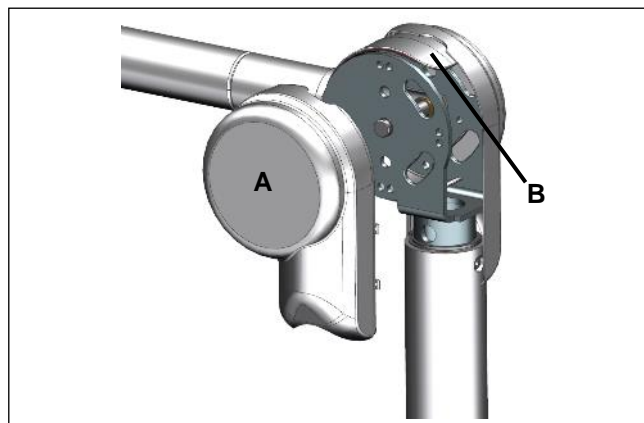
- ▶ Push the spring balanced arm's plug against the upper support tube's plug until they click together.



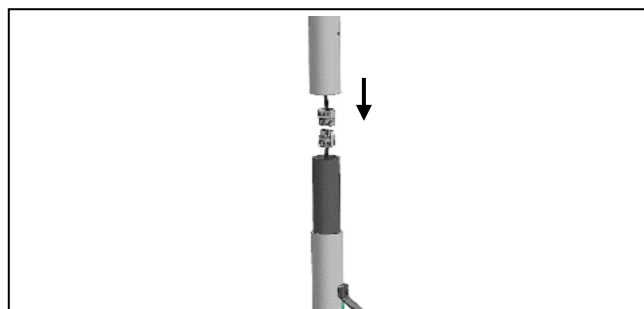
- ▶ Attach the spring balanced arm to the support tube.



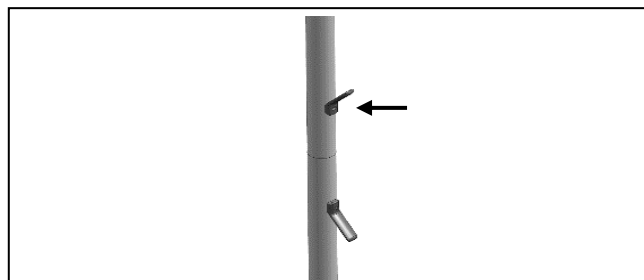
- ▶ Align the thread in the spring balanced arm according to the opening in the support tube, insert the M4 Allen screw and washer, and then tighten.



- ▶ Reattach the covers "A" one after the other. Make sure that the cover "B" is positioned in the groove of both covers "A".



- ▶ Push together the plugs on the upper and lower support tube until they click.
- ▶ Place the upper support tube on the lower one.



- ▶ Tighten the cable holder using a type 3 Allen screw on the upper support tube (2.4 Nm).

⚠ WARNING

Never unscrew the upper cable holder — injury hazard.

- ▶ If both cable holders are unscrewed, the connecting piece will come loose and fall down, which can cause personal injury and damage to the cable and device.

⚠ DANGER

Death hazard from electric shock.

- ▶ Do not turn on the power supply before the luminaire head has been installed.

6. INSTALLATION: Triango 80 luminaire head

DANGER

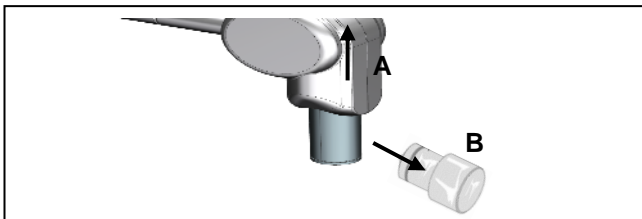
Death hazard from electric shock.

- ▶ When performing any work on the device, disconnect it from the power supply or pull the plug out of the socket and secure the device from being switched on again

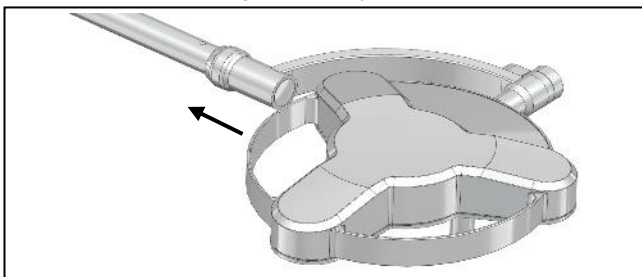
WARNING

Injury hazard

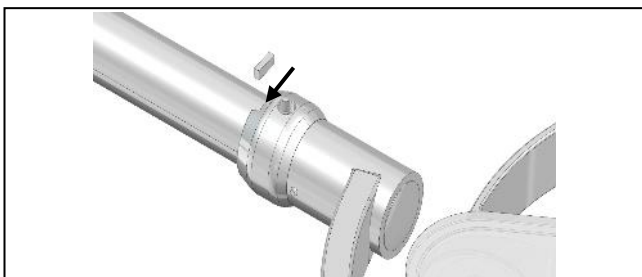
- ▶ The spring balanced arm is under high spring stress. If the boom is lowered without the installed device, it **MUST** be held firmly.
- ▶ If it is let go, it springs upward and can cause severe injury.
- ▶ Never remove the luminaire body unless the boom is in the upper position or is held securely in low position by a second person.
- ▶ To prevent severe injury or damage, always get the help of a second person when installing and removing the luminaire body.



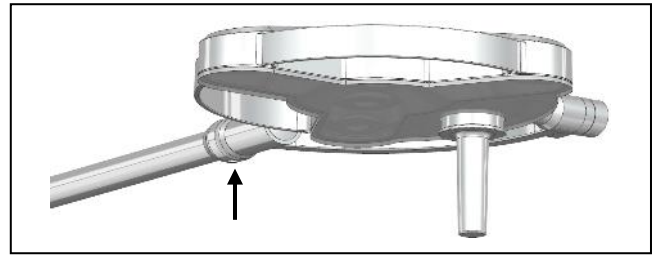
- ▶ Remove screw "A" and pull off the yellow protection cap "B" from the spring arm safety device.



- ▶ Attach the luminaire head.



- ▶ Turn the sleeve to insert the locking device.

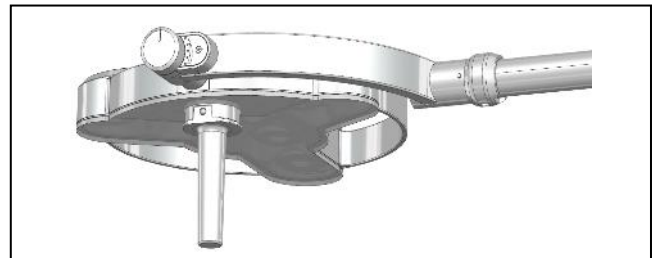


- ▶ Turn the sleeve back the other way and secure with a screw.

WARNING

Injury hazard from falling luminaire head.

- ▶ Make sure the locking device is properly installed.
- ▶ Damage to due to a poorly mounted luminaire head.
- ▶ Tighten the screw as the luminaire head's friction requires.



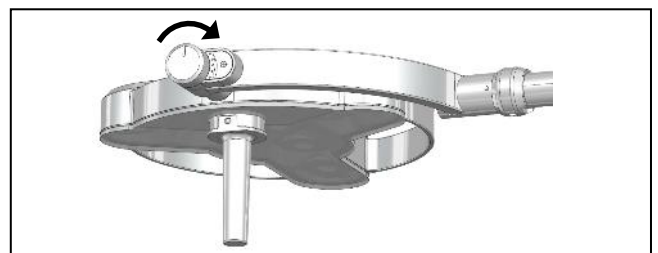
- ▶ Attach the hand grip.

7. OPERATION

Triango 80 C, W, F

CAUTION

- ▶ This product emits potentially hazardous optical radiation. Do not stare directly into the light cone. Eye irritation may occur.
- ▶ The radiation emitted by this product complies with the exposure limits for reducing the risk of photobiological hazards based on IEC 62471: RG 2 (medium risk).



- ▶ Turn the luminaire on with the rotary knob.
- ▶ The luminaire can be dimmed by turning the head.
- ▶ Before each use, perform a functional test: All LEDs in the light cone must come on.

CAUTION

- ▶ The rotary knob is not removable.

Triango 80 F

⚠ DANGER

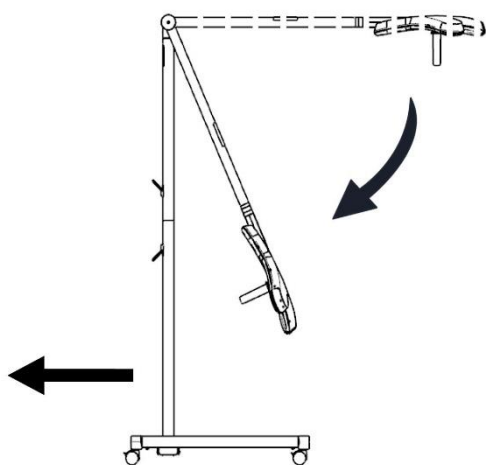
Death hazard from electric shock.

- ▶ Do not plug in any damaged power cables.
- ▶ If the power cable shows damage, immediately replace it with a new one.
- ▶ The connection voltage and frequency must match the data on the type plate.
- ▶ Only connect to power grid with protective ground conductor (PE)

CAUTION

When changing locations

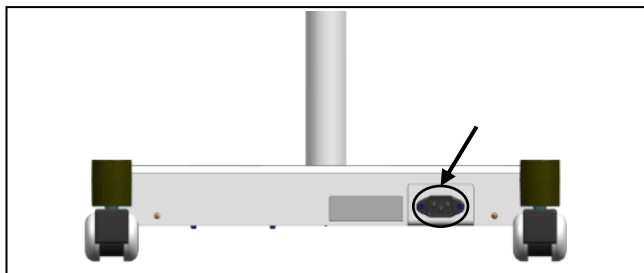
- ▶ Put the terminal into its lowest position.



- ▶ Unlock the casters.
- ▶ Take care not to run over anything, including the connection cable.
- ▶ Hold firmly during transport within the clinic.
- ▶ Be particularly cautious of slopes, thresholds, bumps and other obstacles.

CAUTION

- ▶ When it is not in use, wind the power cable onto the cable holder.



- ▶ Insert the power cable.
- ▶ Connect cable to the power grid.

8. CLEANING AND DISINFECTION

⚠ DANGER

Death hazard from electric shock

- ▶ Before performing disinfection cleaning, pull the plug out of the socket and secure the device against unintended switching on again.

CAUTION

Material damage due to incorrect cleaning

- ▶ For cleaning, use only products that do not impair operation of the luminaire.
- ▶ For cleaning, do not use solvent-based, chlorine-based or abrasive detergents, because they can crack plastic parts and cause other damage.
- ▶ The cleaning agents must be approved for use on plastics such as PC, PMMA, PA and ABS.
- ▶ Concentrated disinfectant can damage the luminaire.
- ▶ For concentration and application times, check the information provided with the product used.
- ▶ The wrong cloth may cause scratches.

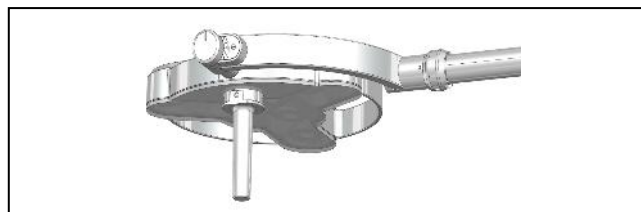
RECOMMENDED DISINFECTANTS

- ▶ Dismozon Plus
- ▶ Kohrsolin Extra
- ▶ Lysoformin
- ▶ Microbac Tissues
- ▶ Mikrozyd Sensitive Liquid

CAUTION

Dirt reduces the light strength

- ▶ Keep cover clear through regular cleaning.
- ▶ Only wipe cleaning allowed.



- ▶ Clean the PMMA clear cover with a chamois soaked in windshield wiper fluid.

CAUTION

To minimize the risk of disease transmission, applicable health and safety regulations and the requirements of the national hygiene and disinfection authorities must be observed in addition to these instructions.

8.1 Sterilizing the hand grip

- ▶ Sterilization must be done according to **ISO 17665-1** (Sterilization of health care products in moist heat).

CAUTION

Damage to the hand grip

- ▶ Do not sterilize with hot air
- ▶ Package the hand grip in a sterile bag before sterilization.
- ▶ The hand grip is designed exclusively for damp sterilization with 3 times fractioned pre-vacuum and saturated steam with the following parameters:

Temperature	134°C
Overpressure	2.0 bar
Dwell time	6 min
Vacuum drying	20 min

- ▶ After sterilization, check the hand grip for mechanical integrity.
- ▶ Do not use damaged hand grips.

9. SAFETY INSPECTIONS

⚠ DANGER

Death hazard from electric shock.

- ▶ Unplug from the grid and turn switch to off position.
- ▶ The power supply cable must be checked at least once a year for damage.

CAUTION

- ▶ Maintenance and repairs can be performed only by qualified electricians.
- ▶ The corresponding user profile is in Chapter 2 Safety instructions.

EVERY YEAR:

- ▶ Check the power supply cable for damage and replace if necessary.
- ▶ Check for deformations and cracks in the plastic parts.
- ▶ Check the load bearing system for distortion or damage.
- ▶ Check for loose parts.

9.1 SETTING THE SPRING FORCE

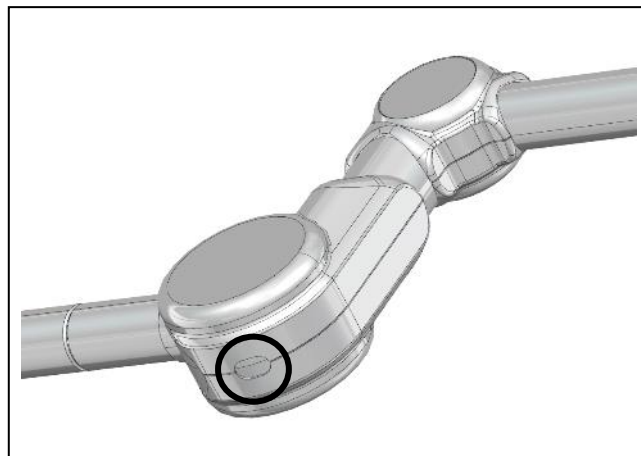
CAUTION

- ▶ The ideal spring force is set at the factory.

Triango 80 C / Triango 80 W

CAUTION

- ▶ The luminaire head **must** be installed before the spring force is adjusted.

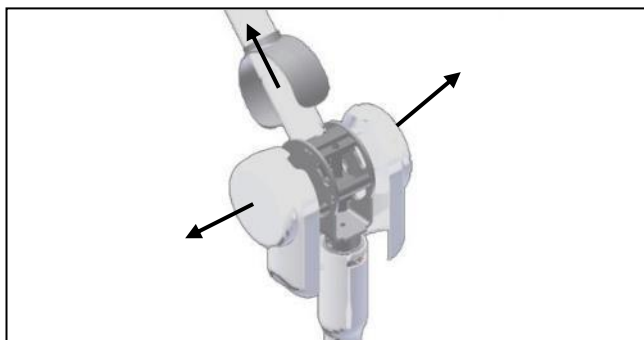


- ▶ Move the spring balanced arm to the highest possible position.
- ▶ Insert a 6 mm Allen wrench through the opening on the middle joint and adjust the spring force by turning the spring.
- ▶ Turn the screw clockwise (+) to increase the spring force (if the spring balanced arm lowers).
- ▶ Turn the screws counterclockwise (-) to reduce the spring force (if the spring balanced arm rises).

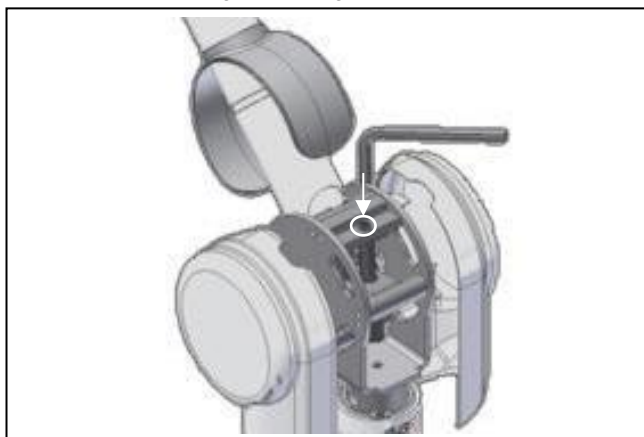
Triango 80 F

CAREFUL

- ▶ The luminaire head **must** be installed before the spring force is adjusted.



- ▶ Move the spring balanced arm to the highest position.
- ▶ Remove the lateral plastic covers and press the round plastic flap along the spring balanced arm upward.



- ▶ Adjust the screw with a 4 mm Allen wrench.
- ▶ Turn the screw clockwise (+) to increase the spring force (if the spring balanced arm lowers).
- ▶ Turn the screws counterclockwise (-) to reduce the spring force (if the spring balanced arm rises).

10 DISMANTLING

DANGER

Death hazard from electric shock.

Before dismantling the luminaire, disconnect all pins from the power supply.

WARNING

Injury hazard

The spring balanced arm is under a high spring force. If the terminal device is not in the uppermost spring balanced arm position, the spring balanced arm will move rapidly upward and cause severe injury. Only dismantle the terminal device when the spring balanced arm is in the uppermost position

10.1 Disposal

Do not discard the luminaire with household waste. Follow local regulations and bring the luminaire to a disposal site or give it to a dealer with appropriate service.
Cut the cable directly at the casing.



The products listed above are over 95% recyclable. For a high percentage of the used materials to be either physically reused or used for energy after the end of this product's life cycle, the luminaires have been designed with recycling in mind. They do not contain materials that are hazardous or require monitoring.

11. ACCESSORIES



Hand grip (order No. D10.295.000)

12 ADDITIONAL INFORMATION

The luminaire itself is maintenance free.

Additional documents may be requested from the manufacturer for this product.

Using this luminaire does not pose a risk to other equipment.

To save energy, the luminaire should be switched on only when it is actually needed.

Any serious incident that has occurred with the product **must be reported** to the manufacturer or their representative and the responsible authorities of the country in which the user is located.

13. TROUBLESHOOTING

Fault	Possible cause	Correction	User profile
The luminaire doesn't go on	Contact fault	Switch on again	All
The luminaire doesn't go on	Lamp defective	Contact manufacturer's service department	Only by manufacturer's service department
The luminaire doesn't go on	No power supply	Check voltage, check all connections	Qualified electrician

14. TECHNICAL DATA

Electrical data:	
Rated connection voltage	100-240 V
Frequency range	50-60 Hz
Power consumption	32 W (max.80 VA)
Integral electronic transformer	24VDC output
Photometric values*:	
Central illuminance E_c at 1.0m distance	80,000 lx
Light field diameter d_{10} at 1.0m distance	$\varnothing = 18$ cm
Light field diameter d_{50} at 1.0m distance	$\varnothing = 10$ cm
Color temperature	4500K
Color rendering index R_a	95
Color rendering index R_9	90
Total irradiance E_e at max. intensity	320 W/m ²
Ratio of irradiance E_e to illuminance E_c :	3.6 mW/m ² /lx
Remaining illuminance when dimmed by a shade	< 1%
Remaining illuminance when dimmed by two shades	50%
Remaining illuminance in tube	100%
Remaining illuminance in tube with one shade	< 1%
Remaining illuminance in tube with two shades	50%
Depth of illumination $L_1 + L_2$	240 cm
	* -10% / +20% tolerance
Ambient conditions for transport, storage and operation:	
Ambient temperature (storage and transport)	-20°C to +70°C
Ambient temperature (operation)	+10°C to +35°C
Rel. humidity (non-condensing) (operation)	max. 75%
Maximum height of use (operation)	3000m (above sea level)
Maximum height (storage and transport)	Unlimited
Weight:	
Luminaire head	3 kg
triango 80 C	14 kg
triango 80 W	13.5 kg
triango 80 F	20 kg

Operating mode	
Operating mode	Continuous operation
Classification	
triango 80 C / W / F	Protection class I
Protection class	IP 20
Luminaire head	IP 43 (horizontal position)
Classification according to EU REGULATION 2017/745 (MDR), article 51	Class I
U.S. FDA Device Class	Class I
Electrical safety testing and EMC according to:	AAMI ES60601-1 : 2005/A2 :2010/(R)2012 CAN/CSA-C22.2 No 60601-1:14 IEC 60601-1:2005 + A1 :2012 IEC 60601-1-2:2014 IEC 60601-2-41:200- + A1 :2013
Blue light danger according to IEC 62471:2006,modified	RG 2 (average risk)
Life cycle of the light source:	
Life cycle	50,000 h (L70/B50)

15. ELECTROMAGNETIC COMPATIBILITY (EMC)

Electrical medical devices are subject to special precautionary measures regarding electromagnetic compatibility. This device can be affected by other electrical devices.

This device was tested with accessories from the accessory list for electromagnetic compatibility. Other accessories can be used only if the electromagnetic compatibility is not interfered with. Use of noncompliant accessories can cause amplified electromagnetic emissions or decreased electromagnetic interference resistance in the device.

 **WARNING**

Hazard due to inadequate safety distance


If high-frequency mobile communication devices are used too close to this device, malfunctions can occur that may endanger the patient. A safety distance of at least 0.3 m (1 foot) must be maintained.

Electromagnetic environment

The device is only to be used in environments indicated in the "Intended use" section of the operating manual.

The medical device is intended only for operation in the electromagnetic environment indicated below.

Emissions	Correspond to	Electromagnetic environment
HF emissions EN 55011 (CISPR 11) Radiated: 30 MHz to 1 GHz Conducted: 150 kHz to 30 MHz	Class A, Group 1	CAUTION 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 reorienting the equipment.
Harmonic emissions (IEC 61000-3-2)	n/a	
Emissions from Voltage fluctuations/flickering (IEC 61000-3-3)	Requirement is met.	

Immunity against	Test level and electromagnetic environment to be maintained	Electromagnetic environment
Electrostatic discharge (IEC 61000-4-2)	Contact discharge: ± 8 kV Air discharge: ± 15 kV	Floors made of wood, concrete or ceramic tile. For a synthetic floor covering, the relative humidity should be at least 30%. The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Fast transient electrical disturbances/bursts (IEC 61000-4-4)	Power cable: ± 2 kV Longer signal input lines/signal output lines: ± 1 kV	
Impulse voltage/surges (IEC 61000-4-5)	Voltage: External conductor against external conductor: ± 1 kV External conductor against ground cable: ± 2 kV	
Voltage dips and short interruptions of the supply voltage (IEC 61000-4-11)	30% to 100%, 10 ms to 5 s, various phase angles	
Magnetic field at the supply frequency (IEC 61000-4-8)	50 Hz and 60 Hz: 30 A/m	Devices with unusually strong line-frequency magnetic fields (transformer stations, etc.) should not be operated near the medical device.
Emitted HF disturbance (IEC 61000-4-3)	80 MHz to 2.7 GHz: 10 V/m	Near equipment marked with the following symbol, disturbances are possible: 
Conducted HF interference (IEC 61000-4-6)	150 kHz to 80 MHz: $3 V_{rms}$ ISM and amateur radio bands: $6 V_{rms}$	

Recommended safety distances from portable and mobile HF communications equipment

Rated power of transmitter [W]	150 kHz – 800 MHz d = 1.2√p	800 MHz – 2.5 GHz d = 2.3√p
0.01	0.12 m (0.39 ft)	0.23 m (0.76 ft)
0.1	0.38 m (1.25 ft)	0.73 m (2.4 ft)
1	1.2 m (3.9 ft)	2.3 m (7.6 ft)
10	3.8 m (12.5 ft)	7.3 m (23.9 ft)
100	12m (39 ft)	23 m (76 ft)