YASUI

koplight

koplight™ Cordless Lighted Retractor

Instructions for Use

Contents

⚠ *Read these instructions carefully before use.*

Intended use

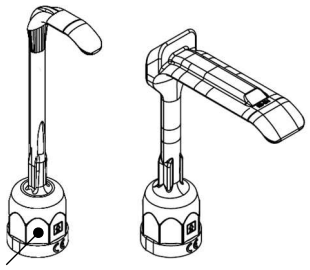
Intended uses of this product are to provide 1) access to the operative field by retracting the incisions and/or wounds with the blade, and 2) auxiliary illumination to the operative field with LED lighting. This product is a combination of two medical devices for convenience in clinical use.

Contraindications

There are no known contraindications.

Name of parts

"Blade"



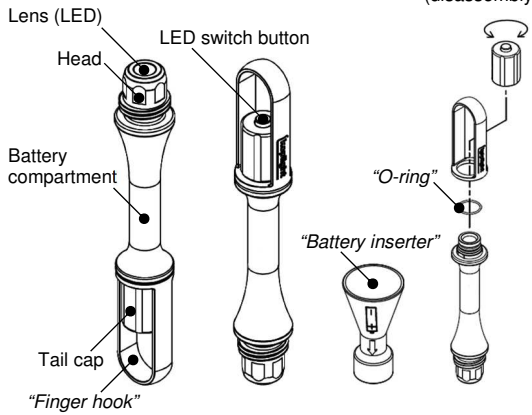
(fig.1)

• Product name: koplight blade

(fig. 2)

• Product name: koplight HT blade

"Light handle" and accessories



(fig. 3) (fig. 4) (fig. 5) (fig. 6)

Note:
- O-ring does not have to be removed from the light handle unless damaged.
- Light handle's head should not be disassembled.

• Product name: koplight light handle
• Accessories:
koplight light handle finger hook – *"Finger hook"*
koplight light handle O-ring – *"O-ring"*
koplight battery inserter – *"Battery inserter"*

Warnings and precautions

⚠ Warnings

- This product is not sterile. Cleaning and sterilization must be performed before each use.
- Do not use the device more than the maximum number of uses. Doing so can cause injuries:

Product	Maximum number of uses	Details
Blade	Two (2) times	Material degrades after the third time. Maintain a usage record.
Light handle and accessories	Not defined	Stop use when there is a malfunction and/or damage. Refer to "Inspection and maintenance."

- Do not reuse the device if it is used in a patient with Creutzfeldt-Jakob disease or related diseases.
- Remove the batteries before sterilization to avoid battery explosion.
- Do not point the LED light directly at eyes.
- Do not use the device in combination with blades, light handles, or accessories from other manufacturers.
- Do not modify or disassemble the device, unless specified in these Instructions for Use.

⚠ Precautions

- Handle the device with care to avoid malfunction of the light handle and injuries during use:
  - Do not throw, bend, or place heavy items on the device.
  - Reprocess the device if it has been dropped on the floor.
  - Do not use the blade if there is any deformation, cracks, or major scratches.
- The blade is made of durable material and unlikely to break under normal circumstances. However, in the rare event of blade breakage, carefully collect the pieces fallen into the patient's body.
- Do not use the light handle in an oxygen rich environment. Doing so can cause fire.
- Avoid direct contact of the light handle with the patient because there is risk of electric shock. It is recommended that you spread an insulation sheet over the patient's body.
- Device temperature may reach 55 °C when the LED light is continuously used. It is recommended that you turn the

LED off when the device is not used.

- LED switch button becomes hard when the temperature is between 0 °C to 15 °C. It is recommended that you use the product in between 15 °C to 40 °C.

⚠ Precautions for batteries

- Two (2) × AAA batteries are required to make a light handle work. Provide the batteries separately because they are not included in the retail packaging:

Battery type	Precautions
Nickel-metal hydride (NiMH) rechargeable	Recommended. Fully charge before each use.
Alkaline/manganese dry cell	Battery run time will be shorter. Also, product life may be shortened.
Lithium dry cell Lithium-ion rechargeable	*Do not use* to avoid battery leakage and/or overheating.

Note: Battery run time depends on the battery type, capacity, and environment of use.

- In order to avoid battery leakage, corrosion, and/or overheating:
  - Do not mix old and new dry cell batteries, rechargeable batteries with different charge levels, batteries of different capacities, types, and brands.
  - Observe correct polarity. Insert the batteries positive terminal first.
  - Remove batteries after use.

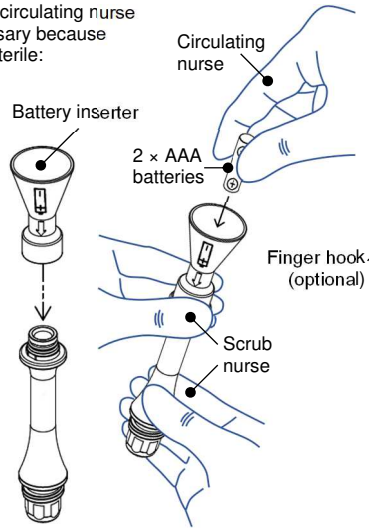
Assembling and how to use

Assembling

Use the battery inserter and ask for help from a circulating nurse to assemble a sterile light handle. This is necessary because the batteries and battery compartment are not sterile:

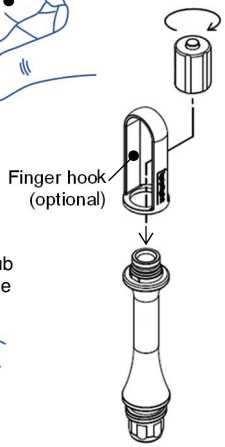
1. Unfasten tail cap.
2. Attach battery inserter to light handle (figure 7).
3. Hold light handle and battery inserter, and ask circulating nurse to insert two (2) × AAA batteries, positive terminal first (figure 8).
4. Remove battery inserter.
5. Attach finger hook (optional) to light handle, and firmly tighten tail cap (figure 9).
6. Insert the light handle's head into the blade handle, and fix by firmly tightening the screw (figure 10).

Note: Check that the device is correctly and firmly assembled before each use. Make sure that the unsterile batteries will not compromise the sterile field.

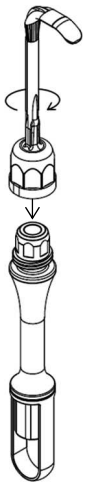


(fig. 7)

(fig. 8)



(fig. 9)

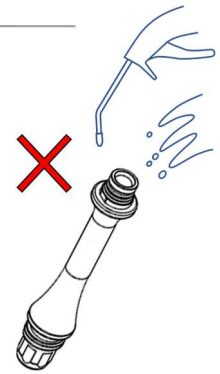

(fig. 10)

How to use

Press the LED switch button to turn on the LED light and use the blade to retract the tissues. The LED light transmits through the blade and illuminates the operative field.

Cleaning and disinfection

⚠ Precautions for cleaning and disinfection


(fig. 11)

- Wear personal protective equipment (PPE) during the procedure.
- *Keep the battery compartment dry* to prevent malfunction of the light handle (figure 11):
  - Keep tail cap firmly tightened during the procedure.
  - Keep tail cap firmly tightened when an air blower is used.
  - Keep tail cap's interior side dry also.
  - The tail cap can be removed to clean the interior side of the tail cap and battery compartment hole. Use a slightly wet cloth to wipe the part. Keep battery compartment dry after wiping.
- Handle the blade in the following ways to avoid material degradation and injuries during use:
  - Do not apply agents unapproved by the manufacturer, including alkaline or acidic agents.
  - Do not soak in alcoholic disinfectants.
  - Do not use ultrasonic cleaning.
- Handle the light handle and accessories in the following ways to avoid damage to the surface and/or malfunction:
  - Use purified water for rinsing and thermal disinfection during the machine (automated) process.
  - Alkaline and/or acidic agents may damage the surface. Choose appropriate detergent and/or disinfectant by referring to detergent and/or disinfectant's instructions for use. Refer to "Specifications" for material information of koplight.
  - Do not use polishing powder and/or metallic scrubbing brushes.
  - Do not soak in alcoholic disinfectants and/or saline solution.
  - Do not use ultrasonic cleaning.

Initial treatment at point of use

- Press LED switch button to turn off LED light after use.
- Remove excess soil with a disposable wipe immediately after use.
- It is recommended that you perform the rest cleaning procedure immediately after use. If immediate cleaning is not feasible, take measures to prevent the soil from being dried according to the institute procedures.
- Use suitable closed or covered containers to transport the device to the decontamination area.

Preparation before cleaning

Prepare device as follows before the main cleaning procedure:

1. Disassemble blade from light handle.
2. Unfasten tail cap.
3. Remove finger hook and batteries.
4. Tighten tail cap.

Recommended procedure for cleaning and disinfection

	Step	Time	Water type	Temperature	Detergent
Manual pre-cleaning	1. Soaking	5 minutes	Utility water	Cold	N/A
	2. Brush with soft brush under running water	Until visibly clean	Utility water	Cold	N/A
	3. Rinse with running water	Until visibly clean	Utility water	Cold	N/A
	Continue to machine (automated) cleaning				
Machine (automated) cleaning [a)]	4. Pre-wash	1 minute	Utility water	Cold	N/A
	5. Wash	5 minutes	Utility water	45 °C	Enzymatic neutral detergent
	6. Rinse	1 minute	Purified water	Cold	N/A

	7. Rinse	3 minutes	Purified water	Cold	N/A
	8. Thermal disinfection [b)]	2.5 minutes	Purified water	93 °C	N/A
	9. Dry	Until thoroughly dry	N/A	Minimum 100 °C	N/A

a) Washer-disinfector should be compliant with EN ISO 15883 series.
b) Disinfection process may be required depending on the guidelines of your country. This product is compatible with thermal disinfection at temperatures between 80 °C to 93 °C.

Inspection and maintenance

Inspection

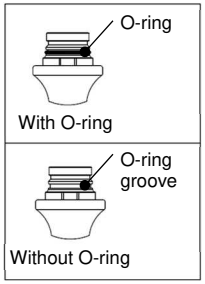
Inspect the items below before each use. Do not use the device if any problems are found.

- No damage or deformation
- No dirt, foreign object, and/or peel-offs on surface
- No cracks or major scratches on blade
- No cracks on lens
- Light handle's head (LED side) does not rotate
- Tail cap can be firmly tightened
- LED switch button is not broken and LED works

Maintenance

- Wipe the metal wear debris off when it is found around the tail cap's screw thread. It is recommended that you apply lubricant:
  1. Remove tail cap.
  2. Apply suitable amount of medical lubricant to a cloth.
  3. Hold light handle and point the battery compartment hole downward.
  4. Wipe screw thread with the cloth, paying attention that the lubricant does not enter the battery compartment.

  Note: Do not directly apply lubricant to the light handle.
- Damaged O-ring should be replaced to keep the light handle waterproof:
  1. Unfasten tail cap.
  2. Remove damaged O-ring.
  3. Set new O-ring in the right position (figure 12), paying attention not to scratch it.
  4. Check that new O-ring is not distorted.
  5. Attach finger hook (optional), and firmly tighten the tail cap.

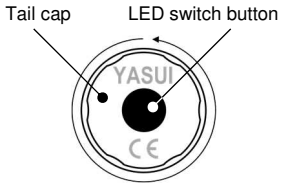


(fig. 12)

Packaging

- The device should be packaged in sterile packaging before sterilization. The packaging material and procedure should be in accordance with EN ISO 11607-1 and EN ISO 11607-2.
- Prepare light handle as follows before packaging. Noncompliance can lead to battery explosion during sterilization and/or incomplete sterilization:
  1. Check that there are no batteries in the battery compartment.
  2. Firmly tighten the tail cap.
  3. Loosen the tail cap by one (1) rotation (about 360°, figure 13).

  Note: Do not completely separate the tail cap during sterilization unless you use ethylene oxide gas sterilization. Doing so can cause malfunction.



(fig. 13 – loosen 360°)

Sterilization

⚠ Precautions for sterilization

- There will be malfunctions and/or material degradation when the device is sterilized by any methods other than the recommended methods.

- Do not change the sterilization method during the product lifetime.

Recommended sterilization

- Applicable sterilization methods

Product	Steam	Hydrogen peroxide	Ethylene oxide gas
Light handle	*Not applicable*	Applicable	Applicable
Blade, finger hook, and battery inserter	Applicable	Applicable	Applicable

- Steam sterilization parameters

Item	Recommended condition	Precautions
Cycle type	Pre-vacuum	• Steam sterilization must not be applied to the light handle. • Temperature must not exceed 121 °C.
Temperature	121 °C	
Exposure time	30 minutes	

- Hydrogen peroxide sterilization parameters

Item	Recommended condition	Precautions
Temperature	47 °C to 55 °C	• Repeated hydrogen peroxide sterilization may cause early material degradation.
Exposure time	47 minutes	

Note: The manufacturer used a sterilizer equivalent to STERRAD®100NX® in the validation.

- Ethylene oxide gas sterilization parameters

Item	Recommended condition	Precautions
Temperature	50 °C to 60 °C	
Relative humidity	≥40%	
Gas concentration	300 to 1100 mg/L	
Exposure time	≥4 hours	
Aeration time	≥8 hours	

Storage

- Check for the points below before storage:
  - Batteries are removed
  - Device is cleaned
  - Device is thoroughly dried, including battery compartment
  - Tail cap is firmly tightened
- Store the product under the conditions below:
  - Clean place at room temperature
  - No direct sunlight
  - Avoid ultraviolet light
  - Avoid high humidity

Disposal

Dispose of the product according to the institute procedures and any applicable laws, regulations, and rules of your country.

Limitation of liability/Incident reporting

Yasui Co., Ltd. does not assume any liability when the product is misused and/or mishandled. Read these Instructions for Use carefully before use and keep in an easily accessible place for later reference. Only professionally trained healthcare personnel are allowed to use this product.

If a serious incident occurs in relation to this product, it should be reported to the manufacturer and/or distributor. In the European Union, it should also be reported to the competent authority of the member state in which the user and/or patient is located.

Troubleshooting

Problem	Possible cause	Solution
LED does not illuminate	LED switch button not pressed.	Press LED switch button.
	Wrong battery polarity.	Check battery polarity and set correctly (refer to “Assembly”).
	Batteries have run out.	Replace with charged or new batteries.
	Tail cap not firmly tightened.	Firmly tighten tail cap.
	Serial number label in battery compartment has peeled off and is blocking the battery terminals.	Remove serial number label.
	Water has entered the battery compartment and caused a circuit malfunction.	Contact the distributor.
Cannot press the LED switch button	Temperature too low.	Warm the tail cap.
Flickering/weak light	Tail cap not firmly tightened.	Firmly tighten tail cap.
	Batteries have run down.	Replace with charged or new batteries.
Short battery run time	Electrical contact failures.	Clean electrical contacts of the light handle, tail cap, and batteries using a dry cloth or cotton swab.
	Small battery capacity.	Replace with larger-capacity batteries (NiMH rechargeable batteries of ≥900 mAh capacity are recommended).
Product too hot	Light handle may be damaged.	Stop using the device immediately and contact the distributor.

Contact your local distributor if the problem still exists after applying the solutions above. Repairs must be conducted by the authorized persons of the manufacturer.

Appendices

Specifications

- Product name: koplight blade

Model code	Tip width (mm)	Blade length (mm)	Total length (mm)
KS-1	10	30	139
KS-2	13	45	139
KS-3	18	45	139
KS-4	18	59	113
KS-5	25	84	113
Material: Polycarbonate			

- Product name: koplight HT blade

Model code	Tip width (mm)	Blade length (mm)	Total length (mm)
KS-4H	18	61	122
KS-5H	25	86	122
KS-6H	25	111	122
Material: Polycarbonate			

- Product name: koplight light handle

Model code	KG-1	
Material	Body:	Anodized aluminum
	Lens:	Polycarbonate
	LED switch button:	Fluorine resin
Battery	2 × AAA nickel-metal hydride (NiMH) rechargeable battery	
Recommended battery	Manufacturer:	FDK CORPORATION
	Model code:	HR-4UTHC
	Nominal voltage:	1.2 V
	Battery capacity:	900 mAh

Rated input	2.4 V DC
LED	Color temperature: 5,000 K Note: There are slight variances in the color temperature and brightness of the LED.
Dimension	Diameter: 15 mm (narrowest point) × Total length: 155 mm
Operating/storage temperature	0 °C to 40 °C Note: Recommended operating temperature range is 15 °C to 40 °C. Waterproof performance degrades in between 0 °C to 15 °C due to hardened O-ring. Recommended to store at room temperature.
Relative humidity	30% to 90%, non-condensing
Atmospheric pressure	70 kPa to 106 kPa
Storage/Transfer condition	Remove batteries

- Accessories

Product name	Model code	Material
koplight light handle finger hook	KY-1	Polycarbonate
koplight light handle O-ring	KP-1	Fluorine resin
koplight battery inserter	KD-1	Polycarbonate

Retail packaging

Product name	Content
koplight blade/koplight HT blade	12 × blades per package.
koplight light handle	1 × light handle, 1 × finger hook, 1 × O-ring, 1 × battery inserter per package. Note: Batteries are not included.

Safety classifications

Protection against electrical shock	Internally powered ME equipment
Degree of protection against electric shock	Blade is type BF applied part
Method of sterilization or disinfection	Refer to "Cleaning and disinfection" and "Sterilization"
Degree of protection against ingress of water (IEC 60529)	IPX7
This product is not for use in an oxygen rich environment.	

Precautions for interference with other equipment

In order to avoid LED lighting malfunction caused by interference with other equipment:

- Keep away from portable wireless communication devices such as cellular phones by more than 30 cm.
- Do not use close to or stacked on other equipment.
- If electrosurgical instruments can cause malfunctions, try not to use them at the same time.
  Note: No malfunction will occur when the device comes into contact with an electric scalpel. Electrosurgical instruments are generally compatible with the device, but some may cause malfunctions. For further information, refer to “Electromagnetic Compatibility (EMC).”

Electromagnetic Compatibility (EMC)

This product complies with EMC Standard EN60601-1-2: 2015. This product is intended for use in the electromagnetic environment specified in the following tables. The following problems may be encountered if the product is used in an unintended environment:

- LED light does not turn on.
- LED light turns on, but flickering occurs.
- LED light turns on, but there is a significant increase or decrease in illumination that can be visually confirmed.
- LED switch button does not work.

1) Electromagnetic emissions (for all equipment and systems)

Guidance and manufacturer's declaration – electromagnetic emissions		
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	This product uses only RF energy for internal functions. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	CLASS B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Not applicable	

2) Electromagnetic immunity (for all equipment and systems)

Guidance and manufacturer's declaration – electromagnetic immunity			
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test level	Compliance	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV in air	±8 kV contact ±15 kV in air	Floors should be wood, concrete, or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be greater than 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	The power frequency magnetic field should be the same level on a typical location in a standard commercial or hospital environment.

3) Electromagnetic immunity (for non-life support equipment and systems)

Guidance and manufacturer's declaration – electromagnetic immunity			
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test level	Compliance	Electromagnetic environment – guidance
Conducted disturbances, induced by radio-frequency fields IEC 61000-4-6	3 Vrms 150 kHz–80 MHz 6 Vrms 150 kHz–80 MHz ISM and amateur radio bands in between 80% amplitude-modulation (1 kHz)	3 Vrms 150 kHz–80 MHz 6 Vrms 150 kHz–80 MHz ISM and amateur radio bands in between 80% amplitude-modulation (1 kHz)	Portable and mobile RF communications equipment should be used no closer to any part of this product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ (ISM, out of amateur radio band) $d = 2.0 \sqrt{P}$ (ISM, amateur radio band) Recommended separation distance $d = 1.2 \sqrt{P}$ 80 MHz–800 MHz $d = 2.3 \sqrt{P}$ 800 MHz–2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF electromagnetic fields IEC 61000-4-3	10 V/m 80 MHz–2.7 GHz	10 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1. At 80 MHz and 800 MHz, the higher frequency range applies. Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
Note a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this product. Note b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

4) Recommended separation distances between portable and mobile RF communication devices and this product

This product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this product can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this product as recommended below, according to the maximum output power of the communications equipment.						
Test frequency (MHz)	Bandwidth [a] (MHz)	Services [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380–390	TETRA400	Pulse-modulation [b] 18 Hz	1.8	0.3	27
450	430–470	GMRS460 FRS460	FM ±5 kHz Deviation 1 kHz sine	2	0.3	28
710 745 780	704–787	LTE Band 13,17	Pulse-modulation [b] 217 Hz	0.2	0.3	9
810 870 930	800–960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse-modulation [b] 18 Hz	2	0.3	28
1720 1845 1970	1700–1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	Pulse-modulation [b] 217 Hz	2	0.3	28
2450	2400–2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse-modulation [b] 217 Hz	2	0.3	28
5240 5500 5785	5100–5800	WLAN 802.11 a/n	Pulse-modulation [b] 217 Hz	0.2	0.3	9
Note a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50% duty cycle square wave signal.						

References

- EN 60601-1:2006+A12:2014: Medical electrical equipment – General requirements for basic safety and essential performance
- EN 60601-1-2:2015: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- EN ISO 17664:2017: Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
- EN ISO 15883-1:2009+A1:2014: Washer-disinfectors – General requirements, terms and definitions and tests
- EN ISO 17665-1:2006: Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- EN ISO 11135:2014+A1:2019: Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
- EN ISO 11607-1:2017: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN ISO 11607-2:2017: Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
- EN 1041:2008+A1:2013: Information supplied by the manufacturer of medical devices

- EN ISO 15223-1:2016: Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

Symbols used

MD — Indicates the item is a medical device	LOT — Lot number	0 °C / 40 °C — Temperature limitation: 0–40 °C
Manufacturer	REF — Catalog number	30% / 90% — Humidity limitation: 30%–90%
EC REP — European Authorized Representative	NON STERILE — Non-sterile	70 kPa / 106 kPa — Atmospheric pressure limitation: 70 kPa–106 kPa
Date of manufacture	STERILE EO — Sterilized using ethylene oxide	Type BF applied part
Use by date	Do not reuse	RoHS — RoHS Directive 2011/65/EU 2015/863/EU
Consult instructions for use	Do not use if package is damaged or opened	
Warnings and precautions	Sterile barrier system	

Note: Not every symbol appears on the product.

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EC REP MT Promedt Consulting GmbH
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Germany
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CE