

BlueLavage®

BlueLavage® Suction and Irrigation System for Use in Endoprosthetics

Instructions for Use

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1. INSTRUCTIONS FOR USE

SAFETY INSTRUCTIONS

Please read the information in this manual carefully. Improper handling and misuse can lead to premature wear and tear or create risks for patients and users.

To ensure safe use, the *BlueLavage*® Suction and Irrigation System must always be used with original UTK Solution accessories.

- The *BlueLavage*® Suction and Irrigation System is intended for use by trained and qualified medical staff only.
- Since technical problems can never be ruled out completely, make sure to keep a fully operational backup system on hand during clinical procedures.
- The *BlueLavage*® Suction and Irrigation System is intended for use on humans.
- The *BlueLavage*® Suction and Irrigation System must not be used on the central nervous system.
- When using electrosurgical devices, inadvertent moisture in the operating area may produce a short circuit through the negative electrode and cause burns to the patient. It is always important to ensure that the negative electrode is correctly positioned and affixed and that the surgical site is not excessively moist.
- The *BlueLavage*® Suction and Irrigation System must never be held under running water nor immersed in liquids!

UTK SOLUTION GMBH ASSUMES NO LIABILITY IN THE EVENT THAT THE PRODUCT IS NOT USED IN FULL COMPLIANCE WITH THESE INSTRUCTIONS FOR USE. THE RESPONSIBILITY FOR CORRECT STORAGE, SETUP, USE AND DISPOSAL OF THE PRODUCT LIES WITH THE USER.

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CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician.

1.1 INTENDED USE

The *BlueLavage*® suction and rinsing system is a surgical instrument system, which can be used for rinsing and suction of a surgical site in the field of arthroplasty. It is designed to remove loose tissue parts, bone meal and bone cement residues from the surgical site, particularly during revision procedures in arthroplasty. The attachments can be used to treat cavities of different depths.

1.2 INTENDED PATIENT POPULATION

The suction and irrigation system is intended for use on the following patient groups:

- Adults
- Elderly patients
- Physically or mentally handicapped persons

1.3 INDICATIONS

The *BlueLavage*® Suction and Irrigation System is used in arthroplasty.

1.4 CONTRAINDICATIONS

The contraindications for the use of the *BlueLavage*® Suction and Irrigation System depend on the individual patient's clinical condition and the intended surgical procedure.

General contraindications are:

- Presence as well as risk of infection
- Local inflammation
- Fever or leucocytosis
- Allergy to component materials
- Haemophilia
- Any use involving the central nervous system



1.5 PRODUCT-RELATED RISKS

The *BlueLavage*® Suction and Irrigation System does not cause any known side effects. However, the following risks may be associated with the use of a pulse lavage system:

1. Local infections and delayed wound healing.
2. Cementation impairment due to an inadequate volume of irrigation.
3. Insufficient cementation caused by device failure.

1. Infections or delayed wound healing may occur if the device is not handled correctly. The following directions must always be strictly observed:

- Do not reuse components that are explicitly intended for single use only.
- Do not reprocess nor resterilize components that are explicitly intended for single use.
- Do not use the product if the package is damaged.
- The device must be operated in accordance with these instructions for use.

2. An inadequate volume of irrigation may affect cementation results.

- If the volume of irrigation is too low, the cementation result may be unsatisfactory due to bone dust, tissue or residual bone cement remaining in the surgical site.
- If the volume of irrigation is too high, bone tissue damage may occur in patients with osteoporotic bone.

In order to enable safe cementation and prevent injuries, the following actions must always be taken:

- Start irrigation at the low flow rate (trigger down, low speed flow rate 600ml / minute).
- Adjust the flow rate in accordance with the clinical situation, the patient's overall condition and the desired result. When cleaning near soft tissues, set the flow rate to the low level!
- Always take care to completely remove debris (bone dust, tissue or residual bone cement) from the surgical site without damaging the surrounding tissue or bone structure.

3. Failure of the *BlueLavage*® Suction and Irrigation System may affect the cementation result.

A failure will only occur if the device is not handled correctly, including the following issues:

- Failure to lock the lid after inserting the *BlueLavage*® DriveUnit.
- Inserting an uncharged DriveUnit.
- Failure to open the tubing clamps as indicated.

In order to avoid device failure during operation, these instructions for use must always be followed carefully.

THE UTK SOLUTION GMBH DISCLAIMS ANY AND ALL LIABILITY FOR DAMAGES DUE TO THE FAILURE TO FOLLOW THESE INSTRUCTIONS FOR USE EITHER WHOLLY OR IN PART.

1.6 PRODUCT SPECIFICATIONS

The *BlueLavage*® Suction and Irrigation System consists of the following items:

1.6.1 BL2000.1 *BlueLavage*® 2.0 Disposable system with FunnelTip

The set includes: • *BlueLavage*® handpiece with insertion funnel • Suction and irrigation tubing • Connections to vacuum • Reducing clamps • Spike with protective cap • FunnelTip for knee endoprosthesis	
Performance characteristics	• High speed flow rate in excess of 1200ml/minute • Low speed flow rate: 600ml/minute • Irrigation pressure: 15 PSI
Service life	The *BlueLavage*® Disposable System with rinsing attachment is provided sterile for single use only. Product lifetime is determined by the designated expiration date. The expiration date is specified on the label and the product packaging. The device must not be used after the expiration date or if the integrity of the packaging has been compromised.
Disposal	The *BlueLavage*® Disposable System with FunnelTip must be disposed of properly in accordance with hospital protocol for disposal of single use products. Reuse of the device is prohibited!

1.6.2 BL2000.2 *BlueLavage*® 2.0 Disposable system with LongBoneTip

The set includes: • *BlueLavage*® handpiece with insertion funnel • Suction and irrigation tubing • Connections to vacuum • Reducing clamps • Spike with protective cap • LongBoneTip for hip endoprosthesis	
Performance characteristics	• High speed flow rate in excess of 1200ml/minute • Low speed flow rate: 600ml/minute • Irrigation pressure: 15 PSI
Service life	The *BlueLavage*® Disposable System with rinsing attachment is provided sterile for single use only. Product lifetime is determined by the designated expiration date. The expiration date is specified on the label and the product packaging. The device must not be used after the expiration date or if the integrity of the packaging has been compromised.
Disposal	The *BlueLavage*® Disposable System with LongBoneTip must be disposed of properly in accordance with hospital protocol for disposal of single use products. Reuse of the device is prohibited!

1.6.3 BL2000.3 *BlueLavage*® 2.0 Disposable system with LongBone- and FunnelTip

The set includes: • *BlueLavage*® handpiece with insertion funnel • Suction and irrigation tubing • Connections to vacuum • Reducing clamps • Spike with protective cap • FunnelTip for knee endoprosthetics • LongBoneTip for hip endoprosthesis	
Performance characteristics	• High speed flow rate in excess of 1200ml/minute • Low speed flow rate: 600ml/minute • Irrigation pressure: 15 PSI
Service life	The *BlueLavage*® Disposable System with rinsing attachment and LongBoneTip is provided for single sterile use only. Product lifetime is determined by the designated expiration date. The expiration date is specified on the label and product packaging. The device must not be used after the expiration date or if the integrity of the packaging has been compromised.
Disposal	The *BlueLavage*® Disposable System with LongBone- and FunnelTip must be disposed of properly in accordance with hospital protocol for disposal of single use products. Reuse of the device is prohibited!

1.6.4 BL2000.4 *BlueLavage*® 2.0 Disposable system with Brush- and FunnelTip

The set includes: • *BlueLavage*® handpiece with insertion funnel • Suction and irrigation tubing • Connections to vacuum • Reducing clamps • Spike with protective cap • BrushTip for hip endoprosthesis • FunnelTip for knee endoprosthesis	
Performance characteristics	• High speed flow rate in excess of 1200ml/minute • Low speed flow rate: 600ml/minute • Irrigation pressure: 15 PSI
Service life	The *BlueLavage*® Disposable System with rinsing attachment is provided for single sterile use only. Product lifetime is determined by the designated expiration date. The expiration date is specified on the label and product packaging. The device must not be used after the expiration date or if the integrity of the packaging has been compromised.
Disposal	The *BlueLavage*® Disposable System with Brush- and FunnelTip must be disposed of properly in accordance with hospital protocol for disposal of single use products. Reuse of the device is prohibited!

1.6.5 BL2000.5 *BlueLavage*® 2.0 Disposable system with LargeTip	
The set includes: • *BlueLavage*® handpiece with LargeTip • Suction and irrigation tubing • Connections to vacuum • Reducing clamps • Spike with protective cap • LargeTip for hip endoprosthesis	
Performance characteristics	• High speed flow rate in excess of 1200ml/minute • Low speed flow rate: 600ml/minute • Irrigation pressure: 15 PSI
Service life	The *BlueLavage*® Disposable System with rinsing attachment is provided sterile for single use only. Product lifetime is determined by the designated expiration date. The expiration date is specified on the label and product packaging. The device must not be used after the expiration date or if the integrity of the packaging has been compromised.
Disposal	The *BlueLavage*® Disposable System with LargeTip must be disposed of properly in accordance with hospital protocol for disposal of single use products. Reuse of the device is prohibited!

1.6.6 BL2003.1 *BlueLavage*® BrushTip	
BL2003.1 *BlueLavage*® BrushTip for hip endoprosthesis	
Service life	The *BlueLavage*® attachment is provided for single, sterile use only. Product lifetime is determined by the designated expiration date. The expiration date is specified on the label and product packaging. The device must not be used after the expiration date or if the integrity of the packaging has been compromised.
Disposal	The *BlueLavage*® attachment must be disposed of properly in accordance with hospital protocol for disposal of single use products. Reuse of the device is prohibited!

1.6.7 BL2004.1 *BlueLavage*® LongBoneTip	
BL2004.1 *BlueLavage*® LongBoneTip for hip endoprosthesis	
Service life	The *BlueLavage*® attachment is provided for single, sterile use only. Product lifetime is determined by the designated expiration date. The expiration date is specified on the label and product packaging. The device must not be used after the expiration date or if the integrity of the packaging has been compromised.
Disposal	The *BlueLavage*® attachment must be disposed of properly in accordance with hospital protocol for disposal of single use products. Reuse of the device is prohibited!

1.6.8 BL2005.1 *BlueLavage*® Funnel 2.0	
BL2005.1 *BlueLavage*® Funnel 2.0	
Service life	The *BlueLavage*® Funnel is provided for single, sterile use only. Product lifetime is determined by the designated expiration date. The expiration date is specified on the label and product packaging. The device must not be used after the expiration date or if the integrity of the packaging has been compromised.
Disposal	The *BlueLavage*® Funnel must be disposed of properly in accordance with hospital protocol for disposal of single use products. Reuse of the device is prohibited!

1.6.9 BL2006.1 *BlueLavage*® FunnelTip	
BL2006.1 *BlueLavage*® FunnelTip for knee endoprosthesis	
Service life	The *BlueLavage*® attachment is provided for single, sterile use only. Product lifetime is determined by the designated expiration date. The expiration date is specified on the label and product packaging. The device must not be used after the expiration date or if the integrity of the packaging has been compromised.
Disposal	The *BlueLavage*® attachment must be disposed of properly in accordance with hospital protocol for disposal of single use products. Reuse of the device is prohibited!

1.6.10 BL2007.1 *BlueLavage*® LargeTip	
BL2007.1 *BlueLavage*® LargeTip for hip endoprosthesis	
Service life	The *BlueLavage*® attachment is provided for single, sterile use only. Product lifetime is determined by the designated expiration date. The expiration date is specified on the label and product packaging. The device must not be used after the expiration date or if the integrity of the packaging has been compromised.
Disposal	The *BlueLavage*® attachment must be disposed of properly in accordance with hospital protocol for disposal of single use products. Reuse of the device is prohibited!

Product Safety Information *BlueLavage*® Disposable System and Irrigation Tips

- The *BlueLavage*® Disposable System and irrigation tips are intended for single use only.
- The *BlueLavage*® Disposable System and irrigation tips must not be reused. If reused, functioning may be limited, or the devices may not function at all.
- Reprocessing the *BlueLavage*® Disposable System and/or irrigation tips will irreversibly modify the components' material microstructure and macrostructure and impair device performance if reused.
- Reuse of the *BlueLavage*® Disposable System and/or irrigation tips causes
  - Increased infection risk
  - Material degradation
  - Malfunction
  - Endotoxic reactions

NEVER RESTERILIZE STERILE DEVICES.

- Examine the sterile packaging carefully before use.
- Do not use the product if
  - The package or seals are damaged.
  - The content is damaged.
  - The expiration date has been exceeded.
- It is important to ensure aseptic removal of the products from the package!
- WHEN UNPACKING THE *BlueLavage*® DISPOSABLE SYSTEM AND IRRIGATION TIPS, IT IS IMPORTANT TO VERIFY THAT THE PRODUCT MATCHES THE DESCRIPTION ON THE PACKAGE (ART.-NR./LOT-NUMBERS). IN ADDITION, YOUR COUNTRY'S ASEPTICAL REGULATIONS AND GUIDELINES MUST BE OBSERVED.

1.6.11 BL2001.2 *Blue*Lavage® DriveUnit 2.0	
BL2001.2 *BlueLavage*® DriveUnit 2.0	
Performance characteristics	• Maximum cell voltage: 7.4V DC • Capacity: 350mAh to 450mAh • Maximum continuous discharge current: 10C=4.5A • Nominal voltage: 7.4V DC • Current consumption: 2.5A to 3.5A • Speed: 6,000 rpm to 11,000 rpm
Mode of operation	The *BlueLavage*® DriveUnit is designed for non-continuous operation. After start-up, operating time is 1 minute, after which the unit must be restarted for another minute of operating time. Maximum total operating time is 8 minutes, although this may vary depending upon usage. Subsequently, the *BlueLavage*® DriveUnit must be recharged for at least 2 hours to full charge. ON Successive one-minute duty cycles OFF Rest period / charging time minimum 2h
Service life	Maintenance-free. Replace after a maximum of 3 years or 200 uses.
Storage conditions	After each use, the *BlueLavage*® DriveUnit must be returned to the *BlueLavage*® DockingStation to be recharged. Always hold the *BlueLavage*® DriveUnit by the blue lever to insert and remove it from the *BlueLavage*® DockingStation.
Disposal	Do not dispose of the product as unsorted municipal waste, but rather return it to the manufacturer. The manufacturer will ensure that the electronic parts are disposed of properly. If returning the product is not possible, please observe your country's laws regarding disposal of electronic parts and send the manufacturer a certificate of disposal.
Reprocessing	The *BlueLavage*® DriveUnit must be wipe disinfected before and after each use in accordance with the reprocessing instructions provided in these instructions for use. Non-acidic, alkaline cleaning and disinfection agents are used to reduce the surface bacteriological count by a microbial reduction factor of 10^{-5}. The *BlueLavage*® DriveUnit must never be partially or completely immersed in liquids nor held under water, as penetrating liquids can destroy the device.

Product Safety Information *BlueLavage*® DriveUnit 2.0 BL2001.2

- The *BlueLavage*® DriveUnit is provided non-sterile and must not be sterilized.
- The *BlueLavage*® DriveUnit must be wipe disinfected before and after each use.
- The product operator and user are responsible for proper disinfection of the *BlueLavage*® DriveUnit. National regulations, including any restrictions, must be observed.
- Do not use automated reprocessing methods to clean and disinfect the *BlueLavage*® DriveUnit.
- When unpacking the *BlueLavage*® DriveUnit, it is important to verify that the product matches the description on the packaging (article and serial numbers). In addition, your country's aseptic regulations and guidelines must be observed.
- The *BlueLavage*® DriveUnit must be handled and used in accordance with these instructions for use.
- When inserting the *BlueLavage*® DriveUnit into the *BlueLavage*® handpiece, sterile funnel BL2005.1 must always be in place on the handpiece.
- Never hold the drive unit under flowing liquid nor immerse it in liquid!

Power and status light indicators

Light Indicator	Meaning
Steady green light	Ready for use
Steady yellow light	Charge after use
Fast blinking yellow light	Needs charging! All functions disabled
Slow blinking yellow light	Charging in progress
Slow blinking blue light	Charging in progress, replace soon
Steady red light	Replace DriveUnit

When the *BlueLavage*® DriveUnit has reached its maximum operating time, the light signal shows a continuous red light. The *BlueLavage*® DriveUnit switches off automatically. Please return the *BlueLavage*® DriveUnit to the manufacturer. The fact that the maximum service life will soon be reached is indicated during the charging process. Instead of the usual yellow light, it then shows a blue flashing light.

PRECAUTION:

The power status indicator of the *BlueLavage*® DriveUnit must display the steady green light prior to use. If the *BlueLavage*® DriveUnit is removed from the *BlueLavage*® DockingStation without having been fully charged, as indicated by any of the yellow status indicators, it will not function when inserted into the *BlueLavage*® handpiece!

1. CHARGING PROCESS

- **Steady green light**: The battery is fully charged. The *BlueLavage*® DriveUnit is ready for use.
- **Slow blinking yellow light:** Battery charging in progress, not yet 100%. The device is not ready for use.
- **Steady red light:** The *BlueLavage*® DriveUnit has reached the end of its service life or is defective. Replacement required. All functions disabled.
- **No light signal:** The *BlueLavage*® DockingStation is not plugged in or defective or the *BlueLavage*® DriveUnit is defective.

2. BEFORE AND DURING OPERATION

- **Steady green light:** The battery is fully charged. The *BlueLavage*® DriveUnit is ready for use.
- **Steady yellow light:** Battery charge no longer 100%. When the *BlueLavage*® Suction and Irrigation System is in use, the LED indicator switches from steady green to steady yellow. The irrigation process can be completed as planned. Subsequently, the *BlueLavage*® DriveUnit must be returned to the DockingStation to be recharged.
- **Fast blinking yellow light:** The battery is empty. The *BlueLavage*® DriveUnit cannot be used and must be recharged. All functions disabled.
- **Steady red light:** The *BlueLavage*® DriveUnit has reached the end of its service life or is defective. Replacement required. All functions disabled.
- **No light signal:** The *BlueLavage*® DriveUnit is in sleep mode or defective.
  If the irrigation process is not initiated within 10 minutes after start-up, the *BlueLavage*® DriveUnit will switch to sleep mode. After a duty cycle, the *BlueLavage*® DriveUnit will remain activated for approximately 200 minutes before switching to sleep mode.



Troubleshooting the *BlueLavage*® DriveUnit 2.0 BL2001.2

If you are unable to correct a problem using the information in the table below, contact the manufacturer or your distributor to have the *BlueLavage*® DriveUnit serviced. To avoid further damage, do not continue to use the *BlueLavage*® DriveUnit.

Symptom	Cause	Solution
The LED light does not light up when the *BlueLavage*® DriveUnit is placed in the DockingStation.	The *BlueLavage*® DockingStation is disconnected from the power supply or the mains socket.	Make sure the *BlueLavage*® DockingStation is correctly connected to the power supply and the mains socket.
	The *BlueLavage*® DockingStation is defective.	Use another *BlueLavage*® DockingStation. Return the defective *BlueLavage*® Docking-Station to the manufacturer.
	The *BlueLavage*® DriveUnit is not inserted correctly into the *BlueLavage*® DockingStation.	Check and reposition the *BlueLavage*® DriveUnit.
	The *BlueLavage*® DriveUnit is defective.	Use another *BlueLavage*® DriveUnit. Return the defective *BlueLavage*® DriveUnit to the manufacturer.
The green LED light does not light up when attempting to deactivate the sleep mode during function check of the device prior to use.	The *BlueLavage*® DriveUnit is not fully charged.	Return the *BlueLavage*® DriveUnit to the docking station for recharging. Use another *BlueLavage*® DriveUnit, making sure its power status indicator displays a steady green light before removing it from the *BlueLavage*® DockingStation.
	BlueLavage® DriveUnit is defective.	Use another *BlueLavage*® DriveUnit. Return the defective *BlueLavage*® DriveUnit to the manufacturer.
The green LED light lights up during function check, but the *BlueLavage*® device does not start.	*BlueLavage*® DriveUnit is defective.	Use another *BlueLavage*® DriveUnit. Return the defective *BlueLavage*® DriveUnit to the manufacturer.
The LED light does not light up during operation of the *BlueLavage*® DriveUnit .	The *BlueLavage*® DriveUnit is defective.	Use another *BlueLavage*® DriveUnit. Return the defective *BlueLavage*® DriveUnit to the manufacturer.

IEC 60601-1 Medical Electrical Equipment Classification

Protection against electric shock	Protection Class II
Degree of protection against electric shock	Type B applied part
Applied parts	Irrigation attachments
Environmental conditions during operation	Ambient temperature: 15-25°C / 60-75°F Relative humidity: 10-90 % Atmospheric pressure: 700-1060 hPa
Typical mode of operation	Duration of use: 10 minutes maximum under testing conditions

Electromagnetic Interference (EMI)

WARNING:

Use of the *BlueLavage*® System near other electrical or electronic devices or simultaneously with other electrical or electronic devices should be avoided, as device operation may be adversely affected. If such use is unavoidable, both the *BlueLavage*® System and the other devices must be monitored closely during use to make sure that they are functioning properly.

WARNING:

Sources of radio waves may affect the device.

Walkie-talkies, commercial and amateur radio stations, television transmitters and cell phones are examples of sources of radio waves that may adversely affect the operation of electrical or electronic medical devices.

Since an incident could result in serious injuries, please observe the following instructions to minimize the likelihood of occurrence:

1. Portable and mobile RF communications equipment and its accessories, such as antenna cables, external antennas and the cable specified by the manufacturer of the communications equipment, should be used no closer than 30 cm (12 inches) to any part of the *BlueLavage*® Suction and Irrigation System (BL2000.1, BL2000.2 and BL2000.3). Otherwise, degradation of product performance may result.
2. Be aware of nearby transmitters located outside the operating room or the healthcare facility, such as radio and television stations, and keep as far away from them as possible.
3. In the event that the device reacts differently than expected during use, suspend use immediately and turn it off.
4. Adding accessories or other components or modifying the device can greatly reduce its immunity to interference. Only use original accessories!
   (Note: **There is no simple method to check electromagnetic compatibility and safety of the device yourself.)**
5. Report all incidents to the manufacturer of the device, making sure to indicate whether there was a nearby source of radio waves.
6. Portable and mobile high frequency communications equipment, such as mobile phones and pagers, may affect electromedical devices.

WARNING:

The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this device may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and adversely affect its operation.

IMPORTANT INFORMATION

10 volts per meter (V/m) typically constitute a realistic and adequate degree of immunity against interference from sources of radio waves (as of May 1994) (the higher the degree, the greater the protection).
Without attached accessories, the device offers an immunity level of 10 V/m.

1.6.12 BL2002.02, BL2002.04, BL2002.06, BL2002.08, BL2002.10 *BlueLavage*® DockingStation with Power Supply and Adapter

BL2002.02 *BlueLavage*® DockingStation with power supply (Type FRIWO FW8001M/12) and adapter	 Figure 1. DockingStation  Figure 2. Power Supply  Figure 3. Adapter
Power supply performance characteristics/specifications (Type FRIWO FW8001M/12)	• Power supply dimensions 50 mm (1.97 inches) width, 34 mm (1.34 inches) height, 80 mm (3.15 inches) depth • Universal AC input voltage 100-240 V AC ±10% • Input frequency 50-60 Hz • Input current 400-200 mA • DC output voltage 12 V DC ±5% • Output current 1500 mA
BlueLavage® DockingStation performance characteristics/specifications	• *BlueLavage*® DockingStation dimensions 165mm (6.5 inches) width, 55mm (2.2 inches) height, 146mm (5.75 inches) depth • *BlueLavage*® Docking station input voltage 12V DC • *BlueLavage*® Docking station output voltage 10V DC
Service Life	Maintenance-free. Replace after a maximum of 3 years.
Storage Conditions	To prevent deep discharge and potentially irreversible damage to the drive unit batteries, the *BlueLavage*® DockingStation must remain connected to the power supply and the mains socket at all times. Keep the *BlueLavage*® DockingStation in a clean, dry area of the operating room or operating room storage space.
Disposal	Do not dispose of the *BlueLavage*® DockingStation as unsorted municipal waste, but rather return it to the manufacturer. The manufacturer will ensure that the electronic parts are disposed of properly. If returning the product is not possible, please observe your country's laws regarding disposal of electronic parts and send the manufacturer a certificate of disposal.
Reprocessing	Disinfect the *BlueLavage*® DockingStation using a non-acidic, alkaline cleaning agent in accordance with the reprocessing instructions provided in these instructions for use. Wipe disinfection is required to reduce the surface bacteriological count by a reduction factor of 10^{-5}. The *BlueLavage*® DockingStation must never be partially or completely immersed in liquids, as penetrating liquids may damage the device irreparably. Disconnect the *BlueLavage*® DockingStation from the power supply for cleaning.
Power supply	The FRIWO power supply unit functions as mains isolator. Make sure that the SMPSU (Switch Mode Power Supply Unit) is easily accessible at all times.

Product Safety Information *BlueLavage*® DockingStation with power supply (Type FRIWO FW8001M/12) and adapter

- The *BlueLavage*® DockingStation must always be used with the power supply provided (Type FRIWO FW8001M /12).
- The *BlueLavage*® DockingStation is provided non-sterile and must not be sterilized.
- The product operator and user is responsible for proper cleaning and disinfection of the *BlueLavage*® DockingStation
- National regulations, including any restrictions, must be observed.
- Do not use automated reprocessing methods to clean and disinfect the *BlueLavage*® DockingStation. It is intended to be wipe disinfected only.
- When unpacking the *BlueLavage*® DockingStation, it is important to verify that the product matches the description on the packaging (article and serial numbers). In addition, your country's aseptic regulations and guidelines must be observed.

Troubleshooting the *BlueLavage*® DockingStation with power supply and adapter

If you are unable to correct a problem using the information in the table below, the *BlueLavage*® DockingStation must be sent back to the manufacturer for replacement. To avoid further damage, do not continue to use the *BlueLavage*® DockingStation.

Symptom	Cause	Solution
The LED light of the *BlueLavage*® DriveUnit does not light up when the unit is placed in the *BlueLavage*® DockingStation.	The *BlueLavage*® DockingStation is disconnected from the power supply.	Make sure the *BlueLavage*® DockingStation is correctly connected to the power supply and the mains socket.
	The *BlueLavage*® DockingStation is defective.	Use another *BlueLavage*® DockingStation. Return the defective *BlueLavage*® DockingStation to the manufacturer.
	The *BlueLavage*® DriveUnit is not inserted correctly into the DockingStation.	Check and reposition the *BlueLavage*® DriveUnit.
	The *BlueLavage*® DriveUnit is defective.	Use another *BlueLavage*® DriveUnit. Return the defective *BlueLavage*® DriveUnit to the manufacturer.

BlueLavage® DockingStation and *BlueLavage*® DriveUnit – before first use

The *BlueLavage*® DriveUnit must be fully charged prior to use.

1. Remove the *BlueLavage*® DockingStation from its packaging.
2. Connect the plug of the power supply unit to the socket provided for this purpose on the bottom of the *BlueLavage*® DockingStation.
3. Insert the cable of the power supply unit into the cable spacers located underneath the *BlueLavage*® DockingStation.
4. Connect the the power supply unit to the mains socket using the adapter plug appropriate to your country's socket type.
5. The *BlueLavage*® DockingStation must be positioned on a stable surface.
6. Remove *BlueLavage*® DriveUnit from its packaging.
7. While holding the *BlueLavage*® DriveUnit by the blue lever, place it into the docking station for charging.
8. Repeat with the other *BlueLavage*® DriveUnit.
9. The yellow status light should start blinking slowly, indicating unit is charging.
10. Leave the *BlueLavage*® DriveUnit to charge fully. This will take about two hours.

1.7 REPROCESSING INSTRUCTIONS

1.7.1 Scope:

This section provides instructions for cleaning and disinfecting the UTK Solution GmbH *BlueLavage*® DriveUnit and *BlueLavage*® DockingStation. Implementation of proper cleaning and disinfection procedures prevents disease transmission and device performance issues due to physical contaminants. The procedure has been validated by an accredited testing lab.

1.7.2 Safety Considerations

1.7.2.1 Environmental Conditions

The device is intended to be cleaned and disinfected under the environmental conditions specified by the manufacturers of the cleaning and disinfecting products.

1.7.2.2 General Information

WARNING:

The BlueLavage® DriveUnit and *BlueLavage*® DockingStation are provided non-sterile by the manufacturer and must be reprocessed prior to first use.

NOTE:

- The reprocessing instructions must be followed without exceptions.
- Surgeries may only be performed with an undamaged, clean and disinfected *BlueLavage*® DriveUnit.
- Noncompliance with these reprocessing instructions may cause pathogens to be transmitted to patients and/or users or cause damage to the devices.
- The devices must be reprocessed in accordance with these instructions for use before and after each use.
- Reprocessing of the *BlueLavage*® Suction and Irrigation System may only be performed by qualified and appropriately trained staff.

PRECAUTIONS:

- The *BlueLavage*® DriveUnit is provided non-sterile and must not be sterilized.
- The *BlueLavage*® DriveUnit must be wipe disinfected before and after each use.
- The product operator and user is responsible for proper disinfection of the *BlueLavage*® DriveUnit. National regulations, including any restrictions, must be observed.
- Do not use automated reprocessing methods to clean and disinfect the *BlueLavage*® DriveUnit.
- Never hold the DriveUnit under flowing liquid nor immerse it in liquid!

1.7.2.3 Warranty and Product Liability

The product must be reprocessed and handled in accordance with the instructions provided in this section, including the precautions and safety considerations. Improper handling may result in damage to the product. In such cases, all warranty claims are waived. The manufacturer assumes no liability for the harm that may be caused to the user and/or the patient due to continued use of a damaged product.

1.7.2.4 Validated Cleaning Agents and Disinfactants

- CaviCide cleaning and disinfecting agent, manufactured by METREX RESEARCH, EPA Reg No. 46781-6 (USA), Article No. 13-1000.
- RobbyRob cleaning and disinfecting agent, manufactured by Walter Schmidt Chemie GmbH, Biocide Registration Number N-86853 (Germany).

NOTE: In the event that the above-mentioned cleaning and disinfecting agents are not available, make sure that any alternative product that you use complies with the following specifications:

- pH level 7 to 9.
- Strictly avoid strong alkaline detergents and disinfectants with a pH level greater than 11, since they may damage the product.
- Make sure that the cleaning and disinfecting agent does not contain the following substances:
  - Hypochlorite solution
  - High chlorine content
  - Iodine

1.7.3 Reprocessing the *BlueLavage*® DriveUnit

CAUTION: The following steps should be performed immediately before and immediately after surgery to minimize the risk of contamination.

The *BlueLavage*® DriveUnit must never be partially or completely immersed in liquids nor held under running water, as penetrating liquids can irreparably damage the device.

1. Put on new, clean gloves before performing the following steps.
2. Clean the *BlueLavage*® DriveUnit with ready-to-use, lint-free disinfectant and cleaning wipes, making sure to remove all visible soil in accordance with the product manufacturer's instructions. All accessible surfaces must be carefully and thoroughly wiped. An additional non-acidic, alkaline cleaning product can be used, if necessary, to remove stubborn contamination. Make sure that no residues of the additional cleaning product remain on the device.

- Remove the lever of the *BlueLavage*® DriveUnit by pulling it out of its fixing point.
- Hold the *BlueLavage*® DriveUnit in one hand and the disinfectant and cleaning wipe in the other hand.
- Apply some force as you wipe the device thoroughly until the entire surface is wet, switching the wipe and the *BlueLavage*® DriveUnit from hand to hand as necessary.
- Place the *BlueLavage*® DriveUnit on a clean, disinfected surface and discard the wipe.
- Clean the lever of the *BlueLavage*® DriveUnit in the same fashion using a new disinfectant and cleaning wipe.
- Discard the wipe.
- Reinsert the lever into the *BlueLavage*® DriveUnit by pressing it into its fixing point.

3. For disinfection, it is not necessary to remove the lever from the *BlueLavage*® DriveUnit. Spray all accessible surfaces of the device with the undiluted disinfectant. To ensure effective disinfection, it is important for the surface of the device to remain visibly wet during the entire dwell time specified in the manufacturer's instructions for use (for CaviCide, 180 ±15 seconds; for RobbyRob, 60 ±5 seconds).
4. After the dwell time, use a clean and dry lint-free tissue to wipe the disinfectant residue off the device.

- Hold the *BlueLavage*® DriveUnit in one hand and the clean tissue in the other hand.
- Apply some force as you wipe the device thoroughly until the entire surface is dry, switching the tissue and the drive unit from hand to hand as necessary.

5. If you are performing the reprocessing procedure prior to surgery, hold the clean and disinfected *BlueLavage*® DriveUnit by the blue lever. Immediately place it into the *BlueLavage*® handpiece in accordance with the instructions provided in Section 2.2 Start-up before Use. Do not set the *BlueLavage*® DriveUnit aside for later.
6. If the reprocessing procedure was performed after surgery, immediately insert the clean and disinfected *BlueLavage*® DriveUnit into the *BlueLavage*® DockingStation.

1.7.4 Reprocessing the *BlueLavage*® DockingStation

NOTE: The procedure for reprocessing the *BlueLavage*® DockingStation must be incorporated into your hospital's routine general cleaning and disinfection protocol. Weekly reprocessing is recommended.

1. Put on new, clean gloves.
2. Disconnect the *BlueLavage*® DockingStation from the power supply.
3. Remove any *BlueLavage*® DriveUnits from the DockingStation.
4. For cleaning use ready-to-use, lint-free disinfectant and cleaning wipes, making sure to remove any visible soil from the *BlueLavage*® DockingStation. All accessible surfaces must be carefully and thoroughly cleaned in accordance with the instructions for use provided by the manufacturer of the cleaning and disinfectant agent.
5. For disinfection, spray all accessible surfaces of the device with the undiluted disinfectant. To ensure effective disinfection, it is important for the surface of the device to remain visibly wet during the entire dwell time specified in the manufacturer's instructions for use (for CaviCide, 180 ±15 seconds; for RobbyRob, 60 ±5 seconds).
6. After the dwell time, use a clean and dry lint-free tissue to wipe the disinfectant residue off the device and to dry it. **IMPORTANT! It is very important in particular for electrical contacts to be completely dry.**
7. Reinsert any previously removed *BlueLavage*® DriveUnits.

2. DEVICE OPERATION

Since technical problems can never be ruled out completely, make sure to keep a fully operational backup system on hand during clinical procedures.

The *BlueLavage*® Suction and Irrigation System must not be used on the central nervous system.

When using electrosurgical devices, inadvertent moisture in the operating area may produce a short circuit through the negative electrode and cause burns to the patient. It is always important to ensure that the negative electrode is correctly positioned and affixed and that the surgical site is not excessively moist.

2.1 DEVICE SETUP

PRECAUTIONS

- Perform a visual inspection to ensure that all components and the sterile packaging are in faultless condition.
  - If any components are damaged or defective, do not use the system.
  - Do not use a sterile, single-use product after the expiration date indicated on the label or if the package is damaged or contaminated.
- The function check described in Section 2.2 START-UP BEFORE USE must always be performed prior to using the *BlueLavage*® Suction and Irrigation System!
- Suction and irrigation process
  - Before using the device, make sure that the tubing clamps are open.
  - The suction and irrigation speed must be adapted to the clinical needs of the patient.
  - Avoid obstruction and/or kinks of the suction and irrigation tubing.

ATTENTION: When the device is no longer needed during surgery, place it in a designated dry area of the operating room until the end of the procedure. Do not put it in a collection bag, a kidney dish (emesis basin) or a container with saline.

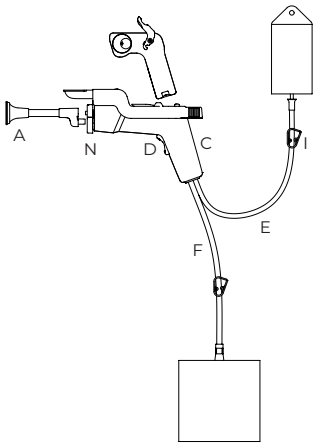
The *BlueLavage*® Suction and Irrigation System must never be held under running water nor immersed!

A failure will only occur if the device is not handled correctly, including the following issues:

- Failure to lock the lid after inserting the *BlueLavage*® DriveUnit.
- Inserting an uncharged *BlueLavage*® DriveUnit.
- Failure to open the tubing clamps as indicated.

2.2 START-UP BEFORE USE

The circulating nurse and the scrub nurse need to work together to start up the *BlueLavage*® Suction and Irrigation System.



Position	Component
A	Irrigation attachment
B	*BlueLavage*® DriveUnit
C	*BlueLavage*® handpiece
D	Trigger
E	Irrigation tubing
F	Suction tubing
G	Suction pump
H	NaCl solution bag
I	Tube clamp
J	Spike
K	Suction connection
L	Insertion funnel
M	Lid
N	Lock

1. The circulating nurse opens the white carton and removes the instructions for use and the *BlueLavage*® Suction and Irrigation System.

ATTENTION: This is where the non-sterile process ends.

2. The circulating nurse opens the non-sterile outer poly bag (secondary packaging), taking care not to touch its contents.
3. The scrub nurse removes the sterile header bag (primary packaging) containing the *BlueLavage*® Suction and Irrigation System. Care must be taken to ensure that the sterile header bag is not touched by the circulating nurse nor comes into contact with the outside of the non-sterile poly bag.
4. The scrub nurse opens the sterile header bag (primary packaging) and aseptically removes its contents.
5. The scrub nurse checks to ensure that sterile insertion funnel (L) is in place on handpiece (C). If the funnel has slipped out of the handpiece during transport, put it back into the correct position.
6. The circulating nurse grasps the blue lever of the *BlueLavage*® DriveUnit (B) to remove it from the *BlueLavage*® DockingStation, making sure to select a DriveUnit whose power status indicator displays a steady green light. A *BlueLavage*® DriveUnit displaying any other charging status will not function!
7. The circulating nurse proceeds to clean and disinfect the *BlueLavage*® DriveUnit in accordance with the instructions provided in Section 1.6.3 Reprocessing the *BlueLavage*® DriveUnit. The *BlueLavage*® DriveUnit (B) is non-sterile and may only be prepared for use and touched by the circulating nurse!

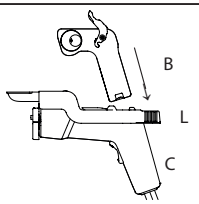
NOTE:

The power status indicator of the *BlueLavage*® DriveUnit must display the steady green light prior to use.

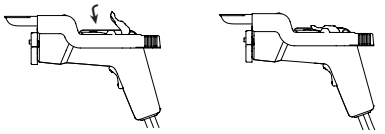
If the *BlueLavage*® DriveUnit is removed from the *BlueLavage*® DockingStation without having been fully charged, as indicated by any of the yellow status indicators, it will not function when inserted into the *BlueLavage*® handpiece!

Warning-contamination risk! The sterile insertion funnel (L) prevents the sterile *BlueLavage*® handpiece from being contaminated by the non-sterile DriveUnit.

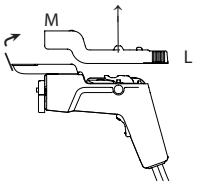
8. The circulating nurse holds the disinfected DriveUnit (B) by the lever ONLY and inserts it through the sterile insertion funnel (L) into the *BlueLavage*® handpiece (C).



a. The circulating nurse locks the DriveUnit into place inside the *BlueLavage*® handpiece by flipping the lever forward, as illustrated.



9. The circulating nurse removes the contaminated funnel (L) WITHOUT TOUCHING the *BlueLavage*® handpiece.
   WARNING contamination risk! The circulating nurse must not touch the BlueLavage® handpiece (C)!
10. The scrub nurse closes the sterile lid (M) of the *BlueLavage*® handpiece, snapping it into place to lock it.



Function Check

11. The scrub nurse performs a two-step function check of the *BlueLavage*® Suction and Irrigation System (dry run without saline solution) immediately after completing the above steps.

    a. Press the trigger once to deactivate the sleep mode. A green LED light will light up, indicating that the device is ready for use.
    b. Press the trigger again to check whether the *BlueLavage*® DriveUnit starts up correctly. The *BlueLavage*® handpiece will produce an audible sound and vibrate slightly.

If (a) the green LED light does not light up or (b) the DriveUnit does not kick in, the *BlueLavage*® DriveUnit or the *BlueLavage*® handpiece is not functioning correctly. Set the nonfunctioning *BlueLavage*® Suction and Irrigation System aside and reinitiate the startup procedure from the beginning using a new, sterile *BlueLavage*® Suction and Irrigation System and a fully charged backup *BlueLavage*® DriveUnit.

Alternately, if the green LED light does not light up a new sterile funnel may be used to insert a backup *BlueLavage*® DriveUnit into the sterile handpiece. The scrub nurse holds the *BlueLavage*® handpiece from below with their left hand and simultaneously depresses the round marks located on either side of the *BlueLavage*® handpiece with their left thumb and index finger to unlock the lid, pushing the lid it up with the thumb of their right hand to open it.

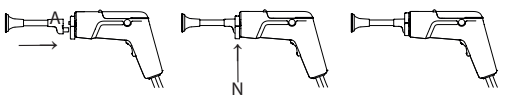
Unpack a new sterile funnel aseptically and place it onto the *BlueLavage*® handpiece.

The circulating nurse flips up the blue lever on the DriveUnit and lifts the *BlueLavage*® DriveUnit out of the handpiece by the lever, taking care not to touch the *BlueLavage*® handpiece.

Repeat steps 6 to 11 above using a backup *BlueLavage*® DriveUnit.

Return the nonfunctioning DriveUnit to the *BlueLavage*® DockingStation for recharging or to your distributor for inspection. A nonfunctioning *BlueLavage*® handpiece must be returned to the distributor for inspection.

12. The scrub nurse connects the appropriate irrigation attachment (A) to the *BlueLavage*® handpiece by sliding the blue lock (N) down, inserting the irrigation attachment and sliding the blue lock (N) back up again to fasten the irrigation attachment securely in place, as illustrated.



13. The circulating nurse removes the spike cap from the spike and inserts spike (J) into the port of the NaCl solution bag (H) to connect irrigation tube (E) to the bag.
14. The circulating nurse connects suction tube (F) to suction pump (G) with suction connector (K).
15. Before use, the surgeon checks whether both tubing clamps (I) are open and adjusts them as necessary.

2.3 CLINICAL USE

CAUTION:

The speed level of the *BlueLavage*® system must be adapted to the clinical picture, the overall condition of the patient and the desired result for each application. Never use the pulsating waterjet at the highest speed level in the immediate vicinity of sensitive tissue.

Speed Levels:

The *BlueLavage*® Suction and Irrigation System is operated by depressing trigger (D). The raised lines on the upper and lower portion of the trigger serve to identify the two available speed levels.



High Speed (1200ml / minute) – two raised lines

Low Speed (600ml / minute) – one raised line

1. **Sleep Mode Deactivation**
   To deactivate the sleep mode and wake up the *BlueLavage*® Suction and Irrigation System, briefly depress the trigger once. The LED light of the *BlueLavage*® DriveUnit will light up, indicating whether the system is ready for operation or not. (See the power and status indicators and their meanings in Section 1.6.11)

2. **Irrigation Function**
   Precaution: To begin with, always select the low speed.

- During the first minute or two of operation, the LED light will be green. Subsequently, it will switch to a steady yellow. The irrigation process can be completed as planned.
- Maximum device operating time is 8 minutes.

Irrigation

- Start irrigation by briefly depressing the lower part of the trigger once to turn on the low flow rate of 600ml/ minute.
- To switch to the high flow rate of 1200ml/minute, briefly depress the upper part of the *BlueLavage*® trigger.

Continuous operating mode

- Squeeze and briefly hold the *BlueLavage*® trigger to activate the **continuous operating mode**. The LED light will blink off and on again, signaling that continuous irrigation has been activated. Release the *BlueLavage*® trigger.
- After 1 minute of continuous operating time, the unit switches off automatically.
- To stop irrigation after less than 1 minute, simply depress the *BlueLavage*® trigger briefly.
- To reactivate the continuous operating mode, squeeze and briefly hold the BlueLavage® trigger. The LED light will blink off and on again, signaling that continuous irrigation has been activated. Release the trigger.
- To stop irrigation after less than 1 minute, simply depress the trigger briefly.

When the device is no longer needed during surgery, place it in a designated dry area of the operating room until the end of the procedure. Do not put it in a collection bag, a kidney dish (emesis basin) or a container with saline.

The *BlueLavage*® Suction and Irrigation System must never be held under running water nor immersed!

In order to enable safe cementation and prevent injuries, the following actions must always be taken:

- Start irrigation at the low flow rate (trigger down, low speed flow rate 600ml / minute).
- Adjust the flow rate in accordance with the clinical situation, the patient's overall condition and the desired result. When cleaning near soft tissues, set the flow rate to the low level!
- Always take care to completely remove debris (bone dust, tissue or residual bone cement) from the surgical site without damaging the surrounding tissue or bone structure.

An inadequate volume of irrigation may affect cementation results.

- If the volume of irrigation is too low, the cementation result may be unsatisfactory due to bone dust, tissue or residual bone cement remaining in the surgical site.
- If the volume of irrigation is too high, bone tissue damage may occur in patients with osteoporotic bone.

2.4 DISASSEMBLY AFTER USE

ATTENTION: **Steps 1-5 must be performed at point of use in the operating room!**

After completing the surgical procedure, the *BlueLavage*® DriveUnit must be removed from the *BlueLavage*® handpiece. The disassembly procedure must be performed by two persons.

Person 1:

1. Put on clean gloves.

Person 2:

2. Hold the *BlueLavage*® handpiece from below with your first hand, placing your ~~left~~ thumb and index finger on the round marks located on either side of the *BlueLavage*® handpiece.
3. Simultaneously depress the round marks to unlock the lid.
4. With the thumb of your second hand, push the lid up as indicated.



Person 1:

5. Flip up the blue lever on the *BlueLavage*® DriveUnit. Hold the lever to lift the drive unit out of the handpiece.

ATTENTION: STEP 6 MUST BE PERFORMED OUTSIDE THE OPERATING ROOM!

6. Reprocess the *BlueLavage*® DriveUnit as described in **Section 1.6 Reprocessing Instructions.**
7. Dispose of the *BlueLavage*® handpiece as contaminated waste.

3. SYSTEM SPECIFICATIONS

Environmental conditions during operation, storage and transport

	Operation	Storage	Transport
Temperature	+15 °C ..+25°C	-10 °C ..+40°C	-10 °C..+40°C
Relative humidity	10..90 %	10..90 %	10..90 %
Air pressure	70..106 kPa	70..106 kPa	70..106 kPa

During storage and transport, make sure that the device is kept dry and protected from dust, shocks and jarring. Do not place anything heavy on the device nor subject it to significant temperature fluctuations. Do not store it in the immediate vicinity of aggressive media.

Guidelines and Manufacturer's Declaration – Electromagnetic Emissions
The *BlueLavage*® Suction and Irrigation System is intended for use in the electromagnetic environments specified below. The user of the *BlueLavage*® System must ensure that it is used in such environments.

Emission Test	**Elektromagnetic Environment – Guidelines**
Emissions of high frequencies (HF) according to CISPR 11	CISPR 11, Group 1, Class B
Mains harmonics according to IEC61000-3-2	IEC 61000-3-2, Class A
Emissions from voltage dips/fluctuations	IEC 61000-3-3

Guidlines and Manufacturer's Declaration – Immunity
The *BlueLavage*® Suction and Irrigation System is intended for use in the electromagnetic environments specified below. The user of the *BlueLavage*® System must ensure that it is used in such environments.

Interference Immunity Tests - Test Level According to IEC 60601-1	**Interference Immunity Tests - Test Level According to IEC 60601-1**
Electrostatic Discharge (IEC 61000-4-2)	Contact Discharge: ±8 kV Air Discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV
Radiated RF EM field (IEC 61000-4-3)	80-2700 MHz; 1kHz AM 80 %; 3 V/m
Proximity fields from RF wireless communications equipment (IEC 61000-4-3)	385 MHz; Pulse Modulation: 18 Hz; 27 V/m 450 MHz, FM ± 5 Hz deviation: 1 kHz sine; 28 V/m 710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse Modulation: 217 Hz; 28 V/m 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m; 5240, 5500, 5785 MHz; Pulse Modulation: 217 Hz; 9 V/m
Electrical fast transients / bursts (IEC 61000-4-4)	Power lines: 2 kV; 100 kHz repetition frequency Signal lines: 1 kV; 100 kHz repetition frequency
Surges (IEC 61000-4-5)	L-N: 1kV
Conducted disturbances induced by RF fields (IEC 61000-4-6)	0.15-80 MHz; 1kHz AM 80 %; 3 Vrms, 6 Vrms in ISM radio band
Rated power frequency magnetic fields (IEC 61000-4-8)	30 A/m, 50 Hz
Voltage dips/Voltage interruptions (IEC 61000-4-11)	0 % U_T for 0.5 cycle at 0°,45°,90°,135°,180°,225°,270°,315° 0 % U_T for 1 cycle at 0° 70 % U_T for 25/30 cycles at 0° 0 % U_T for 250/300 cycles 0°

4. SYMBOLS

	Manufacturer		Not to be disposed of as unsorted municipal waste!
	Date of manufacture		Do not re-use
	Use-by date		Do not immerse in any liquid!
	Batch code		
	Catalog number		
	Sterilized using ethylene oxide		
	Do not resterilize		
	Non-sterile		
	Do not use if package is damaged		
	Keep away from sunlight		
	Type B Applied Part		
	Keep dry		
	Caution		
	Consult instructions for use		



BlueLavage®

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