PLASMATICA®

PLASMAShield®

User Manual and Instructions for Use

PLASMATICA®

PLASMAShield® User Manual

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1 Before You Start

Before using PLASMAShield® for the first time, read this User Manual in its entirety.
Pay particular attention to Section 6: *Using PLASMAShield®* on page 10.
Important: Keep this User Manual for future reference.

1.1 Base Package Contents

- PLASMAShield® Base (A)
  - Charger Input Port (1)
  - Display Screen (2) – see Fig. 2 for details
  - Disposable Inlet (3)
- Charger (B)
  - AC Plug (4)
  - Charger (5)

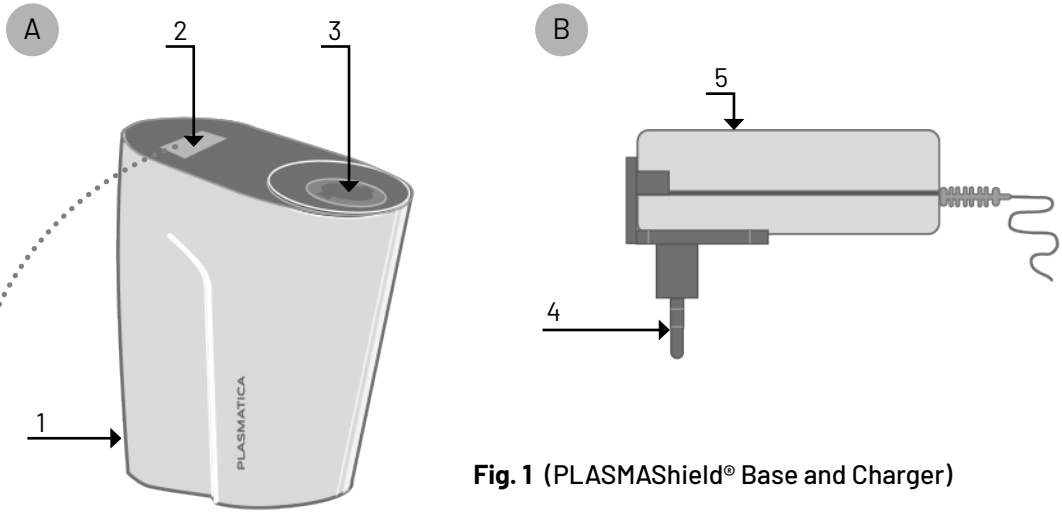


Fig. 1 (PLASMAShield® Base and Charger)

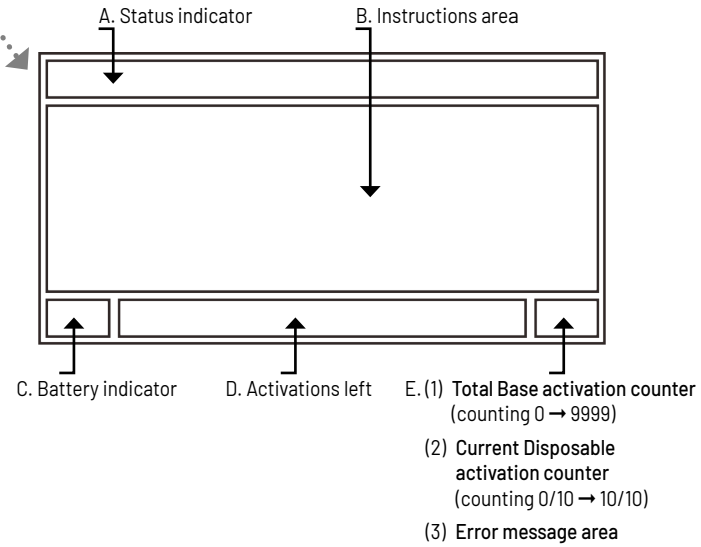


Fig. 2 (Base Display Screen)

1.2 Disposable Package Contents

- PLASMAShield® Disposable (C)
  - The Disposable (6)
  - Drape Adhesive Tape (7)
  - Disposable Drape (8)
  - 5 mm Scope Adapter (9)
- Anti-Fog Solution (D) (see page 17)
  - Anti-Fog Sponge (shape may vary) (10)
  - Anti-Fog Solution Bottle (11)
- Trocar and Scope Cleaning Set (E) (see page 18)
  - Trocar and Scope Cleaning Cloth (12)
  - Trocar and Scope Cleaning Swabs (13)

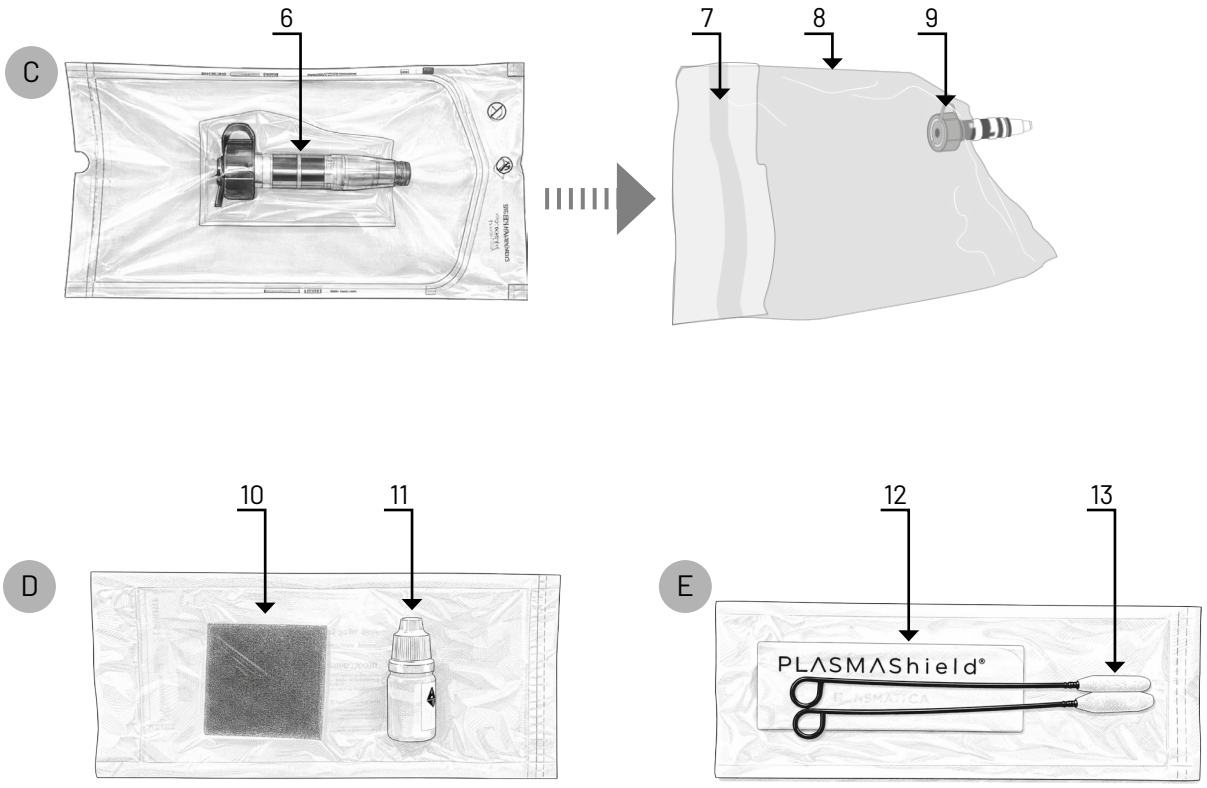


Fig. 3 (PLASMAShield® Disposable, Anti-Fog Solution, and Trocar and Scope Cleaning Set)

Note: The Base Package and the Disposable Package are provided separately.

1.3 PLASMAShield® Description

PLASMAShield® is for use in an operating room, and is intended for use prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens. PLASMAShield® reduces laparoscopic and endoscopic lens fogging by performing cold plasma treatment of the scope lens. Cold plasma is generated using high-voltage Radio Frequency (RF) and creates a superhydrophilic surface on the scope lens after treatment (activation). PLASMAShield® does not interact directly with the patient's body.

PLASMAShield® consists of the following components and accessories:

- The **Base** – a reusable part that generates the cold plasma required to treat the scope to prevent fogging.
- The **Disposable** – a disposable, single-patient, sterile component that interfaces with the scope itself and is used per procedure (can be used multiple times within the same procedure for the same patient). The Disposable is designed to be used for a single procedure and must be disposed of afterwards. The Disposable component includes a folded surgical Drape and is packaged in a pouch.
- The **Anti-Fog Solution** - a single-use, sterile **Anti-Fog Solution Bottle and Sponge** packaged in a pouch and supplied together with the Disposable.
- A **Trocar and Scope Cleaning Set** - a single-use, sterile cleaning set packaged in a pouch and supplied together with the Disposable.

2 PLASMAShield® Indications of Use Statement

PLASMAShield® is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.

3 Warnings and Contraindications

Warnings

To avoid potential serious injury to the user and patient and/or damage to PLASMAShield®, the user must follow the warnings below:

- The Disposable, Anti-Fog Solution, and Trocar and Scope Cleaning Set are designed for single-patient use only. Reuse or reprocessing may lead to failure and subsequent patient injury. Do not reuse, reprocess or re-sterilize the Disposable, Anti-Fog Solution, or Trocar and Scope Cleaning Set.
- Do not use PLASMAShield® if the Drape is damaged.
- Do not use the Disposable, Anti-Fog Solution, or Trocar and Scope Cleaning Set if they have expired.
- Sterility of contents is guaranteed unless the package has been opened or damaged.
- Do not use PLASMAShield® with attachments or accessories not recommended by Plasmatica Ltd.
- Only use the Charger supplied.
- Do not use the Base or the Charger if they are damaged (see Section 10 for more information).
- Do not attempt to open or repair the Base. Only authorized Plasmatica Ltd. personnel are permitted to perform repairs.
- The Base should only be cleaned according to the cleaning instructions in this manual.
- Procedures in the Operating Room should only be performed with sterile gloves.
- Follow the hospital's instructions regarding sterile environments.

Contraindications

There are no contraindications.

4 Signs & Symbols

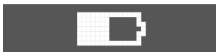
Symbol	Description
	Indicates a medical device that is intended for single use only.
	Indicates the need for the user to consult the Instructions for Use or User Manual for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Indicates the need for the user to consult the Instructions for Use or the User Manual, or consult the electronic Instructions for Use or User Manual.
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates a medical device that must not be re-sterilized once it has been sterilized.
	Indicates a medical device that should not be used if the package has been damaged or opened.
	Indicates the medical device manufacturer.
	Indicates the date of manufacture.
	Indicates a medical device that has been sterilized using ethylene oxide.
	Indicates the date after which the medical device is not to be used.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.

Symbol	Description
℞ ONLY	Federal law restricts this device to sale only by, or on the order of, a licensed healthcare practitioner, per 21 CFR § 801.109(b)(1).
IPX1	Indicates the device is drip-proof and is protected against vertically falling water drops.
	Indicates Lithium-ion battery inside.
	The Waste Electrical and Electronic Equipment (WEEE) symbol indicates the device must be disposed of separately and responsibly, in an environmentally friendly way.
SN	Indicates the device Serial Number.
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Indicates the temperature limits to which the medical device can be safely exposed.
UDI	Indicates a medical device that contains unique device identification. This symbol may be used when multiple data carriers are present on the label.
	Indicates the absence of natural latex as a material of construction within the medical device or the packaging of the medical device.
	Indicates a medical device that needs to be protected from moisture.
	Indicates a medical device that needs protection from light sources.
	Indicates a single sterile barrier system with protective packaging outside.

5 Base Charging

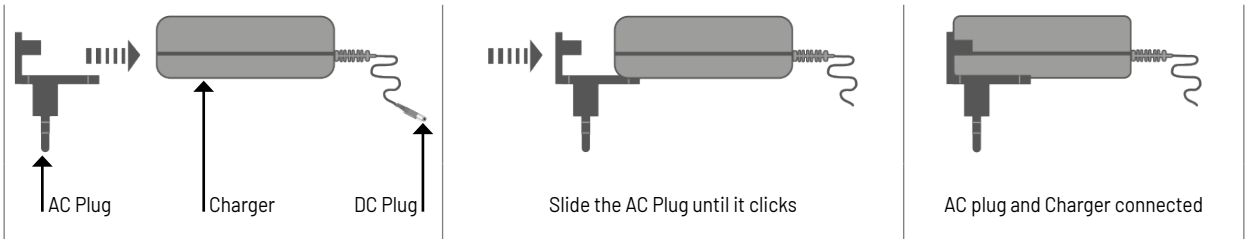
Always check the Base battery level before use. This appears on the Base Display Screen (see Fig. 2, C).

Battery Indications:

	Fully charged battery
	75% charged battery
	Half-full battery
	Low battery
	Critically low battery

Charging the Base:

1. Connect the AC Plug to the Charger:
   Slide the AC Plug into position, until you hear a click.



2. Connect the Charger to the electricity supply and connect the DC plug to the Base.

Charger Status Indicators:

Charger LED Indicator	Charging Status
Constant Orange	Charging
Flashing Orange	Charge is over 80%
Constant Green	Charge completed
Flashing Green	Charger is plugged in but the Base is not connected
Flashing Red	Charging error

Note: It is recommended to charge the Base before the first use and between uses.
The Base does not operate during charging.

6 Using PLASMAShield®

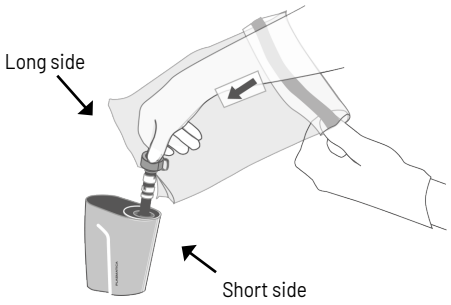
6.1 Setting Up PLASMAShield®

PLASMAShield® is compatible with laparoscopes of 5 mm to 10 mm in diameter.
For 10 mm scopes, remove the 5 mm Scope Adapter from the Disposable. For 5 mm scopes, use the Scope Adapter (see Fig. 3, C-9).

Note: If the Disposable or the accompanying Disposable Drape seem damaged in any way, do not use them. The Base itself is not sterile. Make sure it is correctly wrapped with the Drape before placing it in the sterile zone.

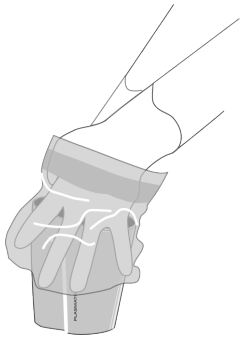
1. Open the Disposable sterile pouch in the sterile field. Insert the Disposable fully into the Disposable Inlet (see Fig. 1, A-3) in the Base until it clicks into position, and the Display Screen shows "READY".

   Note: The long side of the Drape should be near the Display Screen.

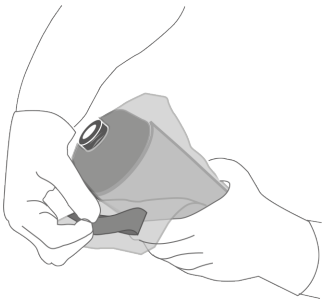


2. With both hands inside the Drape, roll the Drape down so it covers the Base.

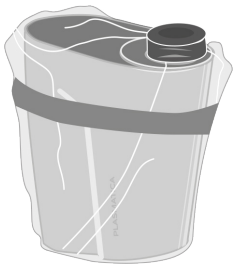
   Note: Maintain sterility by making sure that the internal side of the Drape (the inside where your hands are) does not contact the Base.



3. Cover the Base completely by removing the Drape adhesive tape liner (see Fig. 3, C-7) and taping the Drape closed.

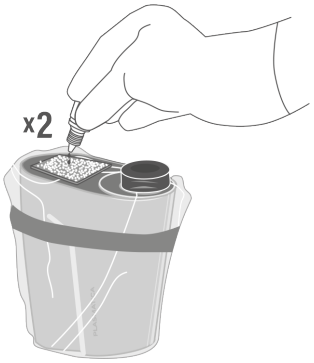


4. Make sure the Base is completely covered and that the adhesive tape closes the Drape.



5. Open the Anti-Fog Solution and Sponge pouch (see Fig. 3, D) in the sterile zone. Remove the adhesive tape liner and stick the Sponge onto the Base Drape above the Disposable, making sure not to cover the Display Screen with the Sponge.

6. Apply 2 drops of the Anti-Fog Solution onto one side of the Sponge. Leave the other side dry.



6.2 Activating the Scope Lens

1. Verify that the scope is clean and sterile before using it with PLASMAShield®.
2. Insert the scope into the Disposable. Keep the scope perpendicular to the top of the Base and maintain this angle throughout the entire insertion process.
3. Push the scope down firmly until it is fully inserted. PLASMAShield® will automatically initiate the scope lens activation process by applying cold plasma for 10 seconds.
4. Once the scope lens activation is finalized, "SCOPE ACTIVE" will appear on the Base Display Screen. Remove the scope.
5. Gently tap the scope onto the Sponge to apply the Anti-Fog Solution droplets, then gently tap the dry side of the Sponge to remove excess Anti-Fog Solution.
6. In case there is a need for reactivation during surgery, first wipe the scope with the cleaning cloth and/or swabs (see Fig. 3, E-12 / 13) and then perform the lens activation.

PLASMAShield® Use Indications:
The Disposable is intended for single-patient use and cannot be used for more than 10 activations. After 10 activations with the same Disposable, PLASMAShield® will issue an alert and will cease to operate.

The PLASMAShield® Base is limited to 10,000 activations.
It will display an alert when 99% of maximum usage is reached – "BASE NEAR END OF LIFE".
Once maximum usage is reached, it will display an alert – "END OF LIFE, RETURN BASE" - and will cease to operate.

PLASMAShield® Use Indication Display Messages:
This appears on the Base Display Screen (see Fig. 2, B).

Display Indication	Sound Indication	Status
	N/A	Startup (displayed briefly upon insertion of the Disposable). The version number is displayed on the screen and the total number of activations for this Base are displayed on the bottom right corner.
	N/A	PLASMAShield® is ready for scope insertion. The total number of activations performed on the current Disposable in use is displayed on the bottom right corner starting at 0/10 and ending at 10/10.
	N/A	After the scope is inserted, the pump starts operating. A progress bar will start moving, indicating progress.
	2 beeps at the start	PLASMAShield® performs the lens activation (Plasma Generation). Countdown from 10 to 1 is displayed on the screen.
	'Success' chime	Lens activation was performed successfully; the scope can be removed.

6.3 After Use

After the use of PLASMAShield®, the Disposable, the Anti-Fog Solution, and the Trocar and Scope Cleaning Set should be disposed of in accordance with local guidelines for medical waste (see Section 11).
The Base should be cleaned according to the instructions in Section 7.

7 Care and Maintenance

Cleaning the PLASMAShield® Base

1. Make sure the Base is not connected to the Charger.
2. Completely immerse a clean wipe/cloth (for the outer surface) and swab (for the Disposable Inlet surface) in a disinfectant solution such as IPA 70%.
3. Thoroughly clean the outer surface using the immersed wipe/cloth for at least 30 seconds and repeat as necessary.
4. Thoroughly clean the Disposable Inlet surface using the immersed swab for at least 30 seconds and repeat as necessary.
5. Wipe the Base with a single-use dry and clean wipe.
6. Leave the Base to air dry at room temperature for at least 10 minutes.

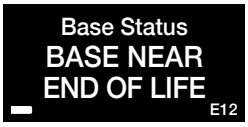
Storage
The PLASMAShield® Base should be stored in a clean, dry location at room temperature. Avoid prolonged exposure to elevated temperatures.
For long-term storage, fully charge the Base battery at least once every 3 months.
The PLASMAShield® Disposable package with the AMD Anti-Fog Solution and Trocar and Scope Cleaning Set should be stored at 15°C- 25°C.

8 Troubleshooting

Each of the following troubleshooting stages is accompanied by a fail sound.
Follow the instructions on the Base Display Screen (see Fig. 2, B).
Note the Error code in the bottom right corner (E##).

Error code	Display	Problem and Solution
E00		The scope was removed before activation began. Remove the scope from the Base, wait for the READY message to appear on the Display Screen, then reinsert the scope fully into the Disposable and wait for activation to begin.
E01		The scope was not fully inserted into the Disposable, and activation did not begin. Remove the scope from the Base, wait for the READY message to appear on the Display Screen, then insert the scope all the way into the Disposable until it is fully inserted, and wait for activation to begin.
E01		The scope is still not fully inserted into the Disposable, and activation did not begin. Remove the scope from the Base, wait for the READY message to appear on the Display Screen, then insert the scope all the way into the Disposable until it is fully inserted, and wait for activation to begin.
E01		This is the third activation fail occurrence, indicating an issue with the Disposable. Replace the Disposable, then insert the scope all the way into the Disposable until it is fully inserted, and wait for activation to begin.

Error code	Display	Problem and Solution
E02		A loss of vacuum error occurred during the activation cycle and activation was not successfully completed. Remove the scope from the Base, wait for the READY message to appear on the Display Screen, then insert the scope all the way into the Disposable until it is fully inserted, and wait for activation to begin.
E02		A loss of vacuum error has occurred for the second time, during the activation cycle and activation was not successfully completed. Remove the scope from the Base, wait for the READY message to appear on the Display Screen, then insert the scope all the way into the Disposable until it is fully inserted, and wait for activation to begin.
E02		A loss of vacuum error has occurred for the third time, indicating an issue with the Disposable. Replace the Disposable and start the activation process again.
E03 E04		An internal system error has occurred. Remove the scope from the Base, wait for the READY message to appear on the Display Screen, then reinsert the scope and start the activation process again.
E03 E04		An internal system error has occurred for the second time, indicating an issue with the Disposable. Replace the Disposable, then reinsert the scope and start the activation process again.
E05 E06 E07		An internal system error has occurred. Remove the scope from the Base, wait for the READY message to appear on the Display Screen, then reinsert the scope and start the activation process again.
E05 E06 E07		An internal system error occurred for the second time, indicating an issue with the Base. Replace the Base, use a new sterile Disposable, and start the activation again. If this issue persists, contact Customer Service to arrange for Base replacement. Do not discard the Base.
E08		The Disposable has reached its maximum number of uses (10). Replace the Disposable and start the activation process again.

Error code	Display	Problem and Solution
E09		The system did not initialize properly. Remove the scope from the Base, wait for the READY message to appear on the Display Screen, then reinsert the scope to start the activation process again.
E10		The Base battery level is low (below 35%). The Base can be used for the current procedure, but it must be recharged afterward.
		Indicates the Base is ready to be used for the current procedure, but it must be recharged afterward.
E11		Battery charge is insufficient for device operation. The Base needs to be recharged before using.
E12		The Base is near the end of its service life (99% of 10,000 activations). Contact Customer Service to arrange for Base replacement. Do not discard the Base.
		Indicates the Base is ready for use, but only has 99 activations left. Please note the number of remaining activations displayed at the bottom of the screen. The Base will need to be replaced soon.
E13		The Base has reached the end of service life (10,000 activations). Contact Customer Service to arrange for Base replacement. Do not discard the Base.

9 Consumables

You can purchase more PLASMAShield® Disposables on our website: **www.plasmatica.com**.

10 Contact Information

Please report any faults with PLASMAShield® that prevent operation or require replacement, and any cases where the Base has reached the end of its service life, or for ordering a paper copy of the User Manual, to: **Plasmatica Customer Service** at

Tel: **1-800-280-2183 (USA)**
Email: **info@plasmatica.com**

Please include in the report the error message number that appears in the bottom right-hand corner of the Base Display Screen (see Fig. 2, E-3).

Plasmatica Ltd.
25 HaTa'asiya Street
Ra'anana, Israel 4365413

11 Disposal

The PLASMAShield® Base reaches the end of its service life either when it reaches its maximum usage and the display shows "END OF LIFE, RETURN BASE", or if it stops working for any other reason. When this happens, the Base must be returned to Plasmatica. Please contact Plasmatica for return instructions.

The Disposable, Anti-Fog Solution, and Trocar and Scope Cleaning Set should be disposed of after use.

- Separate the packaging by material type before disposal. Dispose of cardboard and cartons as paper waste, and dispose of plastic film through your local recyclable materials collection service.
- In accordance with Directive 2012/19/EU on waste electrical and electronic equipment (WEEE), all waste electrical and electronic equipment (WEEE) should be collected separately and not disposed of with regular household waste. Please dispose of this product and all its parts in a responsible and environmentally friendly way.

12 Anti-Fog Solution Instructions for Use

Advanced Medical Design CO., LTD.
4F~5F, No29, Wuquan 5th Rd., Wugu Dist ., New Taipei city, 248 Taiwan
TEL: 886-2-22902627 FAX: 886-2-22988501

Instruction for Use

Product: Anti-Fog Solution

The Following information should be read before using this device.

Description:

The Anti-Fog Solution is a sterile, single use, disposable medical device intended to prevent condensation on the distal lens of endoscope and laparoscopes. The Anti-Fog consists of a 6ml vial of solution and a sponge applicator with adhesive backing.

Instructions for Use:

Step 1. Examine sterile pouch, have a new pack if the package is damaged.
Step 2. Place the Anti-Fog bottle on the sterile field.
Step 3. Drop few into the sponge till the foam is moist.
Step 4. Apply distal tip of rigid telescope to sponge till some bubbles on the foam surface.
Step 5. Upon completion of the endoscopic procedure, dispose of this device in accordance with local regulation.

Cautions/Warnings:

- This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or re-sterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or re-sterilize this device.
- Contents sterile unless enclosed package has been opened or damaged. Store at 15°C~25°C.
- Dispose used product following local state or federal guidelines.
- Federal (U.S.A) law restricts this device to sale, distribution, and use by, or on the order of a physician.

Caution	Sterilized using irradiation	Consult instructions for use
Do not use if package is damaged	Batch code	Do not reuse
Keep away from sunlight	Date of manufacture	Keep dry
Do not re-sterilize	Use by	Authorised representative in the European community
Catalogue number	Manufacturer	Temperature limitation: 15°C~25°C
Notified body: DNV Product Assurance AS, with CE2460	Not made with natural rubber latex	Federal law restricts this device to sale by or on the order of a physician
Medical device	Single sterile barrier system	Single sterile barrier system with protective packaging outside

Swiss Authorised Representative

If further information is required, please contact:

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Bruderholzallee 53, 4059 Basel, Schweiz
swiss.ar@arazygroup.com

CE 2460

13 Trocar and Scope Cleaning Set Instructions for Use REF PLA-TC10

Indications for Use / Clinical Benefits

The Trocar and Scope Cleaning Set is designed for use during endoscopic and laparoscopic procedures to maintain a clean and debris-free scope lens and trocar valves.

Contraindications
This device should only be used as indicated.

Cautions
- Ensure compatibility. Examine the endoscope/laparoscope and trocar for any sharp edges that could affect the components of the Trocar and Scope Cleaning Set (microfiber cloth and trocar swabs).
- Incorrect use of the Trocar and Scope Cleaning Set may result in patient injury and/or damage to the endoscope/laparoscope and trocar.
- Avoid inserting trocar swabs at an angle or extending them past the distal end of the trocar.

Warnings
- The Trocar and Scope Cleaning Set is intended, tested, and manufactured for single-patient use only. Dispose of the Trocar and Scope Cleaning Set after use in accordance with local medical waste disposal guidelines.
- The device remains sterile as long as the packaging is dry, intact, and unopened. Do not use if the pouch is damaged or if the seal is broken.
- Do not attempt to re-sterilize the device. Re-sterilization may compromise device integrity and pose a risk of contamination or unintended patient infection.
- Discard the Trocar and Scope Cleaning Set if mishandling has led to potential damage or contamination, or if it is past its expiration date.

Instructions for Use
Using sterile technique, remove the Trocar and Scope Cleaning Set microfiber cloth and two trocar swabs from the packaging. Inspect the device and packaging for any signs of damage or contamination; discard if any issues are noted. If undamaged, place it on the sterile field.

During the procedure, each time the scope is removed from the body:

1. Use the microfiber cloth to clean the scope lens.
2. To clear debris from the trocar valves, use the small trocar swab for 5-8mm trocars and the larger trocar swab for 10-12mm trocars.

   Note: The trocar should be fully inserted into the abdominal cavity before using the trocar swabs in the Trocar and Scope Cleaning Set.
3. Select the appropriate trocar swab and insert the foam end into the trocar valve. Advance the swab into the valve without extending the foam beyond the distal end of the trocar. Move the swab back and forth to absorb any fluid and clear debris from the cannula. Do not release the trocar swab.

   Note: The shafts of the trocar swabs are radiopaque. The Trocar and Scope Cleaning Set should be used under direct visualization.
4. Check for clear passage through the cannula. If obstructed, repeat the cleaning process.
5. Before discarding the trocar swabs and microfiber cloth, visually inspect each item to ensure they are intact and that all components have been retrieved.
6. At the end of the procedure, dispose of the Trocar and Scope Cleaning Set in biohazard waste as per standard protocol.

Any serious incident involving this device should be reported to both the manufacturer, the U.S. FDA, and the relevant authority in the user's or patient's Member State.

14 Base Specifications

Technology	PLASMAShield® Base
Operation & Safety	Battery BMS for protection The Disposable opening is smaller than standard finger
Size	15*10*7cm
Power	11.1V Rechargeable batteries 1150MAh Lithium Ion
Charger	Type 3743 100-240V; 50-60Hz; 0.5A
Device was tested and complies with:	IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-2-2 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories. IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
Weight	1kg max
Operating Environmental Conditions	
Temperature	10 to 40°C (50 to 104°F)
Relative humidity	20 to 80%
Atmospheric pressure	66 to 106 kPa (9.57 to 15.37 psi)
Storage Environmental Conditions	
Temperature	5 to 60°C (41 to 140°F)
Relative humidity	20 to 90%
Atmospheric pressure	90 to 106 kPa (13.05 to 15.37 psi)

15 Electro-Magnetic Compatibility (EMC)

EMC environment of intended uses: the professional healthcare facility environment

Warning: Changes or modifications to this equipment not expressly approved by the manufacturer could cause EMC issues with this or other equipment. Contact the manufacturer for assistance. This device is designed and tested to comply with applicable regulations regarding EMC as follows.

Warning: Use of other electrical equipment on or near the Base may cause interference. Verify normal operation of equipment before use on patients.

Warning: PLASMAShield® is not Magnetic Resonance Imaging (MRI) compatible.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The compliance for EMISSIONS and IMMUNITY standards:

Test	Standard	Class/ Severity Level	Test Result
Emission (IEC 60601-1-2 section 7 & IEC 60601-2-2 sec. 202.7)			
Conducted Emission Freq. range: 150 kHz- 30 MHz	CISPR 11	Group 1 Class A on 230 & 120 VAC mains	Complies
Radiated Emission Freq. range: 30 - 1000 MHz	CISPR 11	Group 1 Class A	Complies
Harmonic Current Emission Test	IEC 61000-3-2	AC mains	Complies
Voltage Changes, Voltage Fluctuations and Flicker Test	IEC 61000-3-3	AC mains	Complies
Immunity (IEC 60601-1-2 section 8 & IEC 60601-2-2 sec. 202.8)			
Immunity from Electrostatic Discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from Radiated Electromagnetic Fields	IEC 61000-4-3	3.0 V/m 80 MHz ÷ 2.7 GHz, 80% AM, 1kHz	Complies
Immunity from Proximity Field from Wireless Communications Equipment	IEC 61000-4-3	List of frequencies (Table 9), from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies

Test	Standard	Class/ Severity Level	Test Result
Immunity from Electrical Fast Transient (EFT)	IEC 61000-4-4	± 2.0 kV on AC mains Tr/Th - 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	± 1.0 kV DM on AC mains; Tr/Th – 1.2/50 (8/20) µs	Complies
Immunity from Conducted Disturbances Induced by Radio-Frequency Fields	IEC 61000-4-6	3.0, 6.0 VRMS on AC mains 0.15 + 80 MHz, 80% AM, 1 kHz	Complies
Immunity from Power Frequency Magnetic Field	IEC 61000-4-8	30 A/m, 50/60 Hz	Complies
Immunity from Voltage Interruptions	IEC 61000-4-11	230 VAC / 120 VAC mains: 0% - 10 ms; 0% - 20 ms; 70% - 500 ms; 0% - 5sec	Complies