Reprocessed for

stryker

Instructions for use

Reprocessed Aquamantys 6.0 Bipolar Sealer
REF: 23-112-1

Aquamantys bipolar sealer description:

The Reprocessed Aquamantys Bipolar Sealer is a sterile, single-use device. The device employs radiofrequency (RF) energy and saline irrigation for hemostatic sealing and coagulation. The device is equipped with a dual-electrode tip with saline apertures at its distal end. Saline and electrical lines exit the opposite end of the handpiece from the electrodes. The handpiece is equipped with an on-off button that simultaneously activates both RF and saline flow. A saline fluid delivery line is provided with the device and includes a section of pump tubing and a drip chamber or spike. The three-pin electrical connector is designed to be plugged into a qualified pump generator.

Indications for use:

The Reprocessed Aquamantys Bipolar Sealer is a sterile, single-use bipolar electrosurgical device intended to be used in conjunction with a qualified pump generator for delivery of radio-frequency (RF) energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site.

The Reprocessed Aquamantys 6.0 Bipolar Sealer is intended for, but not limited to orthopedic, spine, thoracic and open abdominal surgery.

This device has been reprocessed for Stryker:

- This device is a reprocessed device designed for an additional single use.
- This device has been sterilized using ethylene oxide gas. Do not use this device if the packaging has been prematurely opened or damaged.
- Federal law restricts this device to sale by or on the order of a licensed physician.
- In order to ensure the safe and effective use of this device, read the Instructions for Use in its entirety prior to using this device.
- For further information regarding this device, contact Stryker at +1 888 888 3433

Reprocessed device for single use

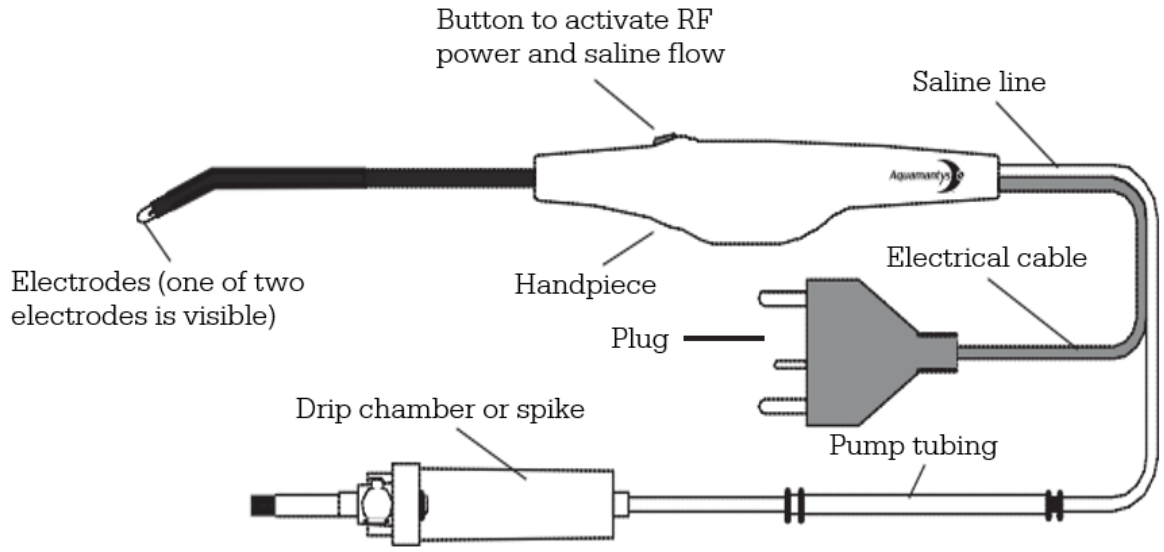
Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- STERILE

Explanation of symbols

Symbol	Rules/ Standard Reference	ISO 7000 Registration Number	Symbol Title	Description
	21CFR801	N/A	Prescription only	Indicates Federal (USA) law restricting device to sale by or on order of a physician.
	ISO 15223-1 Clause 5.1.1	3082	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Clause 5.2.3	2501	Sterile using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1 Clause 5.1.4	2607	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 Clause 5.1.6	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Clause 5.1.5	2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	N/A; Stryker Symbol	N/A	Quantity	Quantity
	ISO 15223-1 Clause 5.4.3	1641	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 Clause 5.4.2	1051	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1 Clause 5,2,6	2608	Do not resterilize	Indicates a medical device that is not to be resterilized.
	ISO 15223-1 Clause 5.2.8	2606	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1 Clause 5.4.4	0434	Caution	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.
	ISO 15223-1 Clause 5.3.7	0632	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1 Clause 5.3.4	0626	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1 Clause 5.6.3	2724	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.

Figure one: Side view of the Aquamantys bipolar sealer (length of cable and saline lines not to scale)



Contraindications for use:

- The device is not intended for contraceptive tubal coagulation (permanent female sterilization).
- Reprocessed Aquamantys Bipolar Sealers are contraindicated for the following:
  - Dura with critical underlying structures
  - Nerve roots
  - Skin and skin edges
  - Intact nerves
  - Intact tendons and ligaments
  - Areas near eloquent cortex
  - Areas near brainstem and cranial nerve
  - Epidural veins
  - Bone surfaces that are intended to be fused
  - Vertebral end plates after discectomy
  - Subcutaneous tissue
  - Bone to be covered by implant
  - Main arteries or named arteries off of the Circle of Willis

Warnings:

- Special care should be taken when using the device in the proximity of neural tissue to avoid damage to nerves and similar sensitive structures.
- **Ensure that both electrodes are in contact with the tissue to be treated. Activation and saline flow occur simultaneously. Ensure that saline is flowing at the time of activation.** Activating device with tips pointing straight upward may result in inadequate saline flow to the surface intended for treatment.
- **If saline flow stops during the electrosurgical procedure, stop using the device and attempt to resume saline flow. Ensure that the pump tubing segment has been loaded**

properly into the pump head located on the generator and that the saline bag is not empty. If unable to resume saline flow, discontinue use and obtain a new device and return the used device to Stryker for evaluation.

- This device is not intended to be bent, or used as a pry, or any other use not cleared by the FDA. Bending or using the device as a pry could cause part breakage.
- The device is provided as a sterile, non-pyrogenic, single-use device. **Do not resterilize or reuse this device.** Reprocessing (resterilizing or reusing) this device can result in occluded saline apertures, reducing or preventing the flow of saline.
- Be aware that all exposed metal on the electrodes is capable of treating tissue. Use caution to avoid inadvertent treatment of tissue and adjacent structures.
- Be aware that the device employs RF coupled with saline. This coupling effect may result in a deeper tissue effect than conventional RF and has the potential for hot saline run-off onto delicate structures.
- Protect delicate structures from hot saline run-off by utilization of suction or other protective measures.
- Use suction to avoid activating the device in a pool of saline. Activating in pooled saline may reduce the hemostatic effectiveness of the device.
- Use suction to minimize the potential for activation of the device in a pool of blood. Activating in a pool of blood may limit the hemostatic effectiveness of the device or increase the risk of an electrode becoming clogged by coagulated blood.
- The tip of the suction wand should not touch the electrodes since this might interfere with the proper function of the device. However, the tip of the suction wand can be as close as 1 – 2 mm from the electrodes when the device is activated.
- Overuse or excessive application of this device may result in contraction, inflammation or necrosis of tissue.
- Use of this device on the skin may result in incisional complications such as necrosis or desiccation of the skin.
- Inspect the device and cord for breaks, cracks, nicks or other damage before use. Failure to observe this caution may result in injury or electrical shock to the patient or surgical team.
- Interference produced by the operation of the RF surgical equipment may adversely influence the operation of other electronic equipment.
- Failure of the RF surgical equipment could result in an unintended increase of output power.
- Use the lowest setting possible to achieve the desired tissue effect to avoid overtreatment which could result in swelling, fluid, seroma or unintended tissue necrosis.
- Adequate ventilation to reduce electrosurgical smoke by use of a smoke-plume evacuator or other means is recommended.

Precautions:

- Surgery should be performed by persons with adequate training and preparation. Personnel should fully understand the nature and use of RF before performing electrosurgical procedures to avoid the risks of shock and burn hazards to both the patient and the operator and damage to the instrumentation.
- The cable on the device should be positioned in a way to avoid contact with the patient or other cables.
- Consult the operating and user manuals for light sources, other electrosurgical units, and other ancillary devices for operating instructions, warnings and cautions prior to their use in the same surgical field as the reprocessed device.
- It is recommended that physicians utilize pre-clinical training, review of pertinent literature and other appropriate educational tools before attempting newer surgical procedures, such as endoscopic, laparoscopic or thoracoscopic procedures.
- Examine the shipping carton, packaging, sterile barrier and device for any signs of transit damage. If there are any shortages, breakage or apparent damage, do not use the device. Return the device to Stryker and use a new device.
- This device does contain phthalates.

- **Use this device only with a qualified pump generator.** Read the warnings, precautions and instructions provided with the selected, qualified pump generator before using. Specific instructions are not included in this manual.
- Use the device with caution in the presence of pacemakers, as electrosurgical devices may cause interference with pacemakers or other active implants.
- Place any monitoring electrodes being used as far away as possible from the device to avoid electrical interference with monitoring equipment.
    - Avoid needle-monitoring electrodes.
    - Use monitoring systems incorporating high-frequency current limiting devices.
- High power settings may result in a deeper tissue effect than lower power settings.
- The depth of effect is deeper and increases with time if the electrodes are held stationary with less depth of effect if the electrodes are moved over tissue.
- The zone (depth and width) of thermal damage may increase with repeated activation at the same site.
- DO NOT use electrosurgery in the presence of flammable anesthetics or other flammable gases, near flammable fluids or objects, or in the presence of oxidizing agents, as fire could result.
- The patient should not come into contact with metal parts that are earthed or have an appreciable capacitance to Earth (e.g. operating table supports, etc.)
- Skin to skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.
- For surgical procedures where the RF current could flow through parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable in order to avoid unwanted tissue damage.
- Before using the device, confirm the following:
    - The cable from the device is connected to the selected pump generator.
    - All electrical connections are tight, clean and dry.
    - All fluid connections are secure.
    - The generator is set at the desired power level.
    - The saline delivery tubing and device have been fully primed with sterile saline (0.9% NaCl) solution.

Setting up Reprocessed Aquamantys Bipolar Sealers

Warning:

- **Electric shock hazard.** Ensure that the device plug is correctly connected and that no metal pins are exposed.

Precaution:

- Read the instructions, warnings and precautions provided with the electrosurgical device and the selected pump generator before using.

Step one: Connect the Aquamantys bipolar sealer to the qualified pump generator

1. Using the aseptic technique, open the device package and deliver the contents to the sterile field.
2. Using the aseptic technique, pass the capped drip chamber or spike of the saline line off the sterile field, making sure to maintain an adequate length of the saline line and electrical cable on the sterile field.

3. Connect the Aquamantys bipolar device to the pump generator by inserting the plug of the device into the plug receptacle on the front panel of the pump generator.

Step two: Load the pump segment portion of the Aquamantys bipolar sealer into the pump head of the pump generator

1. Open the saline pump.
2. Place the saline tube in the center of the guide slots in the pump segment, to avoid pinching the tubing. The black tubing connector must be positioned toward the front panel of the generator, with the white tubing connector positioned closest to the back of the generator.
3. Close the saline pump.

The saline delivery tubing of the Aquamantys bipolar sealer includes a special pump segment portion designed to operate with the pump head of the qualified pump generator. The pump segment portion of the saline delivery tubing is located between a black tubing connector and a white tubing connector.

The pump head is located on the right side of the generator when looking at the unit from the front. It is best to position yourself facing the right side of the unit to load the pump segment portion of the Aquamantys bipolar sealer into the pump head.

Warnings:

- Always close the pump head prior to priming or device activation. Always allow the pump head rotor to come to a complete stop prior to opening the pump head. Do not attempt to load or adjust the positioning of the pump segment of the Aquamantys bipolar sealer in the pump head while the pump head rotor is turning. Fingers or loose clothing could be caught in the pump rollers.
- Do not peel saline delivery segment apart from the electrical cable before placing the pump segment in the pump head.
- Peeling the tubing first increases the potential for loading the pump segment in the reversed position.
- Keep fingers clear when lowering the pump head to avoid pinching fingers along with the pump segment.

Step three: Spike the saline bag

1. Hang a 500 ml or larger bag of sterile saline (0.9% NaCl) solution on an I.V. support, which is in close proximity to the pump generator.
2. Remove the protective cover over the spike at the end of the Aquamantys bipolar sealer saline delivery tubing.
3. Using aseptic technique, spike the bag of sterile saline (0.9% NaCl) solution.
4. If a drip chamber is present, squeeze the drip chamber once or twice to fill the drip chamber to a level of at least one-third full.
5. Open the vent cap if the source of sterile saline (0.9% NaCl) solution is a non-vented glass bottle.

Step four: Prime the Aquamantys bipolar sealer

1. Press the START PRIME button on the front panel of the pump generator. This action must be taken after saline has been properly hooked up and the saline bag has been spiked, but before activating the device on tissue.
2. This button initiates priming of the Aquamantys bipolar sealer with saline. Allow for the priming cycle to complete prior to activating the device or pressing the START PRIME button again. Refer to the selected pump generator User Guide.

Warnings:

- Temporarily unused active electrodes should be stored in a location that is isolated from the patient. Always place the device into a holster when not in use to avoid unintended activation that can cause injury to the patient or surgical team.
- Always place the device into a holster or over a container to collect the saline that exits the electrodes as a result of the priming process. If excess saline is not collected, saline could drip on the patient, patient drapes, surgical instruments or operating room surfaces.
- Lack of saline flow from both of the electrodes can result in a lack of tissue effect and may damage the electrodes during device activation. Use caution to avoid the following conditions that can result in a lack of adequate saline flow from the device.
    - Pump segment portion of the saline delivery tubing loaded improperly into the pump head or saline pump not securely closed. See Step two: Load the pump segment for assistance.
    - Priming not complete.

Step five: Set RF power

- Set the RF power using the POWER SETTING buttons located on the front panel of the selected pump generator.
    - Press the ▲ button to increase the RF power.
    - Press the ▼ button to decrease the RF power.

Warning:

- Use the lowest setting possible to achieve the desired tissue effect to avoid overtreatment, which could result in swelling, fluid, seroma or unintended tissue necrosis.

Step six: Set saline flow rate

- Select the desired saline flow rate setting by pressing the appropriate “Saline Flow Rate” button located on the front panel of the selected pump generator.

Activating the Aquamantys bipolar sealer

1. Place the electrodes of the device on the tissue to be treated.
2. Press the activation button on the handpiece of the device to simultaneously activate RF power and saline flow from the device.
3. Release the activation button on the handpiece of the device to shut off both RF power and saline flow from the device.
4. Repeat as necessary by positioning the device over the next area to be treated.
5. Ensure that the electrodes are only in contact with tissue to be coagulated.
6. For optimum performance, the electrodes must be kept free of debris. The electrodes can be cleaned using a sterile moist or dry sponge or sterile brush.
7. If the source of saline needs replenishing, stop using the device and re-prime the saline delivery system and the device using the prime button on the front panel of the generator.
8. If saline flow stops during the electrosurgical procedure, stop using the device and attempt to resume saline flow. Ensure that the pump tubing has been loaded properly into the pump head located on the generator and that the saline bag is not empty. **If unable to resume saline flow, discontinue use and obtain a new device and return the used device to Stryker.**
9. Pressing the activation button on the Aquamantys bipolar sealer will activate the pump generator. The RF Power Activation Indicator will illuminate blue and a continuous RF activation tone will sound to indicate the presence of RF power output. **If the device does**

not activate when the activation button is depressed, discontinue use, and obtain a new device and return the used device to Stryker.

Warnings:

- Do not activate the Aquamantys bipolar sealer when the electrodes are not in contact with the tissue to be treated. Activating the device when not in contact with tissue may result in inadvertent tissue damage or user injury due to contact with hot saline.
- Do not wrap the electrical cable of the device around metal objects. This may induce currents that could lead to shocks, fires or injuries to the patient or surgical team.
- Do not continuously activate the device for extended periods of time. Extended activation could potentially overheat the pump generator and increase the risk of device malfunction or fire hazard.
- Do not use the Aquamantys bipolar sealer in an immersed setting (e.g. arthroscopic surgery). Use in an immersed setting could potentially overheat the pump generator and increase the risk of device malfunction or fire hazard.
- Only activate the Aquamantys bipolar sealer on tissue intended to be treated. Activation over another location may result in hot saline run-off onto unintended tissue, patient, patient drapes, hospital staff and OR surfaces.
- Use caution to prevent inadvertent activation of the Aquamantys bipolar sealer during the procedure. Inadvertent activation may result in injury to the patient or surgical team.
- **If the device remains activated when the activation button is released, discontinue use and obtain a new device and return the used device to Stryker.**

Precaution:

- Confirm that the Aquamantys bipolar sealer is properly connected to the qualified pump generator.

Changing the RF power setting

- Change the RF power setting by using the POWER SETTING buttons located on the front panel of the pump generator.

Changing the saline flow rate setting

1. The saline flow rate can be adjusted by pressing the appropriate “Saline Flow Rate” button located on the front panel of the pump generator.
2. The Flow Rate Setting Indicator next to the selected flow rate will be illuminated to indicate the current flow rate setting.

Precautions:

- Using the low flow rate setting at the high-power setting may result in more steam production at the electrodes than with the medium or high flow rate settings, and may result in electrode charring or damage, with reduced hemostatic effectiveness.
- Reduced saline flow can result if one or more of the saline slots or holes in either of the electrodes on the Aquamantys bipolar sealer is clogged by tissue or coagulated blood. If this occurs, clean electrodes with gauze ensuring precautions are taken to avoid inadvertent device activation when cleaning electrodes. Do not attempt to clean electrodes with a scalpel or other surgical instruments. If the above does not correct the problem, discontinue use and obtain a new device and return the used device to Stryker.

Disposing of the Aquamantys bipolar sealer

Dispose of the Aquamantys bipolar sealer and the used saline bag according to the procedures for your institution.

Precautions:

- The Aquamantys bipolar sealer and the saline bag will contain unused saline following use of the device.
- Take precautions to prevent the unused saline from flowing onto OR surfaces by placing the handpiece into waste receptacle prior to opening pump head and removing the pump segment portion of device.

Technical specifications

General information:

- Sterile, EO
- Single-use, do not reuse
- Non-pyrogenic
- **Caution:** read Instructions for Use (IFU) before using this device

Physical description:

- **Height:** 1.15 in (2.92 cm)
- **Length (without cables):** 11 in (27.9 cm)
- **Length of electrical cable:** approximately 10 feet (3 meter)
- **Length of saline cable:** approximately 16 feet (5 meters)
- **Weight (with cables):** 5.0 oz (143 grams)

Operating conditions:

- **Temperature:** 50 ˚F to 86 ˚F (10 ˚C to 30 ˚C)
- **Humidity:** 15% - 85%, non-condensing

Storage conditions:

- **Temperature:** 50 ˚F to 104 ˚F (10 ˚C to 40 ˚C)
- **Humidity:** 0% - 85%, non-condensing

Handling conditions:

- **Temperature:** -20 ˚F to 122 ˚F (-29 ˚C to 50 ˚C)
- **Humidity:** 15% - 85%, non-condensing

Disposal

- Dispose of used devices as a biohazard

Customer service

Any complaints should be reported immediately to Stryker's Sustainability Solutions. To report a complaint in the US, call 888 888 3433.

Warranty

Reprocessed products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

Products for which Stryker is the original manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General warranty terms applicable to all products

To the fullest extent permitted by law, the express warranty set forth herein is the only warranty applicable to the products and is expressly in lieu of any other warranty by Stryker, expressed or implied, including, but not limited to, any implied warranty or merchantability or fitness for a particular purpose. In no event will Stryker's liability arising in connection with the sale of the product (whether under the theories of breach of contract, tort, misrepresentation, fraud, warranty, negligence, strict liability or any other theory of law) exceed the purchase price, current market value or residual value of the products, whichever is less. Stryker shall not be liable for indirect, special, incidental, punitive, or consequential damages resulting from any breach of warranty or under any other legal theory.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

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