

Reprocessed by



Sustainability Solutions

Instructions for Use Reprocessed Arthroscopic Wands and Electrodes


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 Icons


 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

 Product Code

 Do Not Reuse

 See Instructions For Use

Reprocessed Arthroscopic Wands and Electrodes

Description

Arthroscopic wands and electrodes are radiofrequency (RF) surgical tools designed for removal and dissection of tissue in arthroscopic surgeries. A generator or controller serves as the power unit. Arthroscopic wands and electrodes are available in a wide range of sizes and angles; some models include thermal or suction functions.

Indications for Use

When coupled with a compatible electrosurgical unit, a reprocessed arthroscopic wands and electrodes is intended for resection, ablation, and coagulation of soft tissues, and for hemostasis of blood vessels during arthroscopic procedures of the knee, shoulder, ankle, elbow and wrist that utilize a conductive irrigant.

Contraindications for Use

Reprocessed arthroscopic wands and electrodes are contraindicated for:

- Surgical or arthroscopic procedures where a conductive solution (e.g. saline, Ringer's lactate) is not used as an irrigant.
- Non-arthroscopic procedures.
- Individuals with electronic device implants such as heart pacemakers.
- Any other condition where an arthroscopic procedure is contraindicated for any reason. Please refer to the medical literature for arthroscopic procedures.

Warnings

- These instruments are only intended for use by individuals with adequate training and familiarity with arthroscopic surgical procedures. For further information about techniques, complications and hazards, consult the medical literature.
- The use of these instruments requires a thorough understanding of the techniques and principles of electrosurgical procedures. Inappropriate use may result in shock and burn hazards to both patient and physician, or damage to medical equipment.
- Follow all safety instructions provided by the electrosurgical generator's manufacturer.
- Never touch the electrode tip while power is being supplied to the arthroscopic wand or electrode.
- Always inspect instrument carefully for overall integrity before use.
- Never insert or withdraw the arthroscopic wand or electrode when it is activated.
- Do not use the arthroscopic wand or electrode without the tip being completely surrounded by conductive irrigant solution.
- Avoid allowing cables running to surgical electrodes to come in contact with patient or with other leads.
- Avoid allowing the patient to come in contact with grounded metal parts.
- Do not allow the arthroscopic wand or electrode to come into contact with staples, clips or any metal object while it is energized.
- Set the voltage/power at the lowest possible setting that provides the desired surgical effect. Activating an electrosurgical device when it is not in contact with target tissue may cause capacitive coupling and inadvertent burning.
- While it is normal to observe bubbling during activation of the electrodes, avoid accumulation of bubbles in the joint area, as this could diminish device performance or result in overheating and possible injury to surrounding tissue.
- Using instruments when the working end is not fully visible can result in unintended tissue damage.
- Continuous activation of the electrodes for more than 30 seconds can result in excessive thermal spread and unintended injury to surrounding tissues.
- Electrosurgery should not be employed in high-oxygen concentration environments or in the presence of flammable solutions or gases.
- Verify hemostasis after withdrawing instrument. If bleeding is still observed, employ appropriate techniques to achieve hemostasis.

Precautions

- Become familiar with specific arthroscopic wand or electrode model prior to employing it in a surgical procedure to avoid damage to patient, operator or instrument.
- Careful handling of instruments is necessary to avoid damage or breakage as a result of excessive force.
- Do not allow the end of the arthroscopic wand or electrode handle with the cable to come into contact with any fluid.
- High frequency electrosurgical equipment may interfere with the operation of other equipment. Keep monitoring electrodes as far as possible from the surgical electrodes.
- Do not use these or any electrosurgical instruments with a cable that does not make good, secure contact with the instruments' electrosurgical adapter as well as the electrosurgical generator.

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- Do not coil or loop electro-surgical cables or hang a looped cable on a metal object such as the operating room table or an IV pole.
- Vigorous use against bony surfaces may result in excessive wear of the electrodes.
- The ArthroCare Saber™ Wand is not recommended for use with a cannula.
- ArthroCare® devices with a black connector are compatible ONLY with the ArthroCare Atlas® controller. ArthroCare® devices with a gray connector are compatible with the Atlas® controller and earlier versions of ArthroCare® controllers.
- Mitek VAPR Suction Sheath Accessories (Part Numbers: 225401 and 225402) are not compatible with reprocessed Mitek VAPR Arthroscopic Wands and Electrodes.

Adverse Reactions

Electrosurgical damage to surrounding tissue.

Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised. Do not use the instrument if the sterility has been compromised. If the package is damaged or if it was opened and the instrument was not used, return the instrument and package to Stryker Sustainability Solutions.
3. Do not attempt to re-sterilize.
4. Inspect the instrument for overall condition and physical integrity. Do not use the instrument if any damage is noted. Return the instrument and packaging to Stryker Sustainability Solutions if it is not in acceptable condition for surgery.
5. Before beginning the procedure, verify overall compatibility of all instruments and accessories.
6. Refer to the Operator's Manual of the compatible electro-surgical unit (ESU) for directions on electrical connections, power settings, operation/alarm modes of the system, and sterilization of the handpiece and cable (if required).
7. Select a arthroscopic wand or electrode with the size, tip angle and function most appropriate to the procedure.
8. Remove the instrument from the package and place it in a sterile work area using aseptic technique.
9. Prepare the patient pre-operatively according to standard procedures.
10. It is important to use only conductive irrigant solution and to ensure proper irrigation of the arthroscopic wand or electrode tip during activation.
11. Verify that the generator is switched OFF or is in standby mode.
12. Connect the appropriate sterile cable to the generator (refer to manufacturer's operator manual), then connect the arthroscopic wand or electrode to the distal end of the cable.
13. Multiple equipment cables should not be placed in parallel with each other.
14. For wands without integrated cables, connect a sterile handpiece to the ESU, and then connect the wand electrode to the handpiece. For wands with integrated cables, connect the cable to the ESU.
15. Switch on the ESU power. Proper connection of Arthroscopic Wand electrodes is verified by illumination of a green light on the controller panel. The VAPR® system displays the symbol "INSERT ELECTRODE" until proper connection of the electrode is detected.
16. For ArthroCare® Atlas® and Mitek VAPR® controllers, the controller will automatically set to default output settings. The maximum set point for each wand is limited. If a set point is chosen outside the default setting, confirm proper activation of the device.
17. If a suction wand is being used, attach the suction tubing adapter to standard hospital suction equipment.
18. Carefully insert the non-active electrode under arthroscopic guidance into the joint cavity and position the electrodes at the target site.
19. Turn the generator ON and set the power output according to the ablator model and procedure. Always use the lowest possible power setting needed to achieve the desired effect. While activated, the electrodes should remain in contact with tissue and be kept in continuous motion. Always ensure adequate flow and circulation of conductive solution to prevent overheating of solution that could result in tissue damage.
20. For suction wands, adjust the roller clamp for optimum suction (200 mmHg to 400 mmHg for ArthroCare® devices). The suction wands may not activate properly if the suction is too strong. The suction function is designed to remove bubbles and/or small pieces of tissue and not for large-volume suction.
21. Other electrical equipment such as video recording equipment may experience interference when positioned near the system.
22. Follow a suitable surgery protocol.
23. If an alarm can be heard when the arthroscopic wand or electrode is activated, deactivate immediately.
24. Do not withdraw the arthroscopic wand or electrode from the surgical site while the instrument is activated.
25. At the end of the procedure, disconnect the wand electrode from the handpiece or ESU and the suction pump (if required).

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Compatibility

Mitek VAPR® Generator	ArthroCare Corporation Atlas® Controller	ArthroCare Corporation System 2000 Controller	ArthroCare Corporation Model 970 Controller
VAPR® electrode VAPR® FLEX electrode VAPR® T thermal	All ArthroWand® electrode models	Some ArthroWand® electrode models	Some ArthroWand® electrode models are not compatible with the controller electrode model 970

Storage and Handling

Store in a dry environment at controlled room temperature (max. 77° F / 25° C), away from direct heat.

Reprocessed Arthroscopic Wands and Electrodes

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.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE 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.

Reprocessed Arthroscopic Wands and Electrodes

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 gas (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.

Atlas[®], ArthroCare[®] and ArthroWand[®] are registered trademarks of AthroCare Corporation.
ArthroCare Saber[™] is a trademark of ArthroCare Corporation.
Mitek VAPR[®] is a registered trademark of DePuy Mitek, Inc.

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