

Reprocessed by



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

REF Ascent Product Code

 Do Not Reuse

 See Instructions For Use

Reprocessed Soft Tissue Ablators

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

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instruments' electrosurgical adapter as well as the electrosurgical generator.

- Do not coil or loop electrosurgical 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.

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 Ascent Healthcare Solutions.
3. Do not attempt to resterilize.
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 Ascent Healthcare 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 electrosurgical 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.

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Warranty

Ascent Healthcare Solutions (**ASCENT**) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. ASCENT warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent does not warrant reprocessed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.

This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

Only Ascent Healthcare Solutions bears the responsibility for this device. 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.