Symbols

↓ Consult Instructions For Use	⇆ Use By
↑ Catalog Number	→ Batch code
⇆ Single Use	↶ Do not use if package is damaged
↺ Manufacturer	↙ Temperature Limit in ˚C
 1.5 T MR Conditional: to be used only in 1.5T MRI environment	◢ EU Authorized Representative
 Only for use on patients who weigh >15kg	Contact Quality & Non-Contact Quality Monitor Dispersive Electrode compatible with Contact Quality and Non-Contact Quality Monitor Generators
Advantage-MR Use dispersive electrode with Advantage-MR EP Recording/Stimulator System	CE 0123 Notified body CE Mark

imricor

Vision-MR™ Dispersive Electrode

INSTRUCTIONS FOR USE

VMR300

60133, Rev B

Single Use Only.

The Vision-MR Dispersive Electrode bears the CE Marking according to directive 93/42/ECC and conforms to IEC 60601-2-2 and ISO 10933-1.

DEVICE DESCRIPTION

The Vision-MR Dispersive Electrode is a single-use, non-sterile, dual-lobe dispersive electrode used with a detached cable. The purpose of the dispersive electrode is to complete the electrical circuit between the patient and the radiofrequency (RF) generator. The Vision-MR Dispersive Electrode is designed for use with the Advantage-MR EP Recorder/Stimulator system.

The Vision-MR Dispersive Electrode includes adhesive conductive gel (hydrogel) to ensure full contact with the patient's skin.

INTENDED USE

The Vision-MR Dispersive Electrode is a self-adhesive, ready-to-use product and is an accessory for RF surgery in monopolar applications. The electrode completes the electrical circuit between the patient and RF generator. The Vision-MR Dispersive Electrode is intended for use with patients > 15kg.

WARNINGS

- Only trained medical personnel with experience in electrosurgical procedures may use the dispersive electrode.
- No modification of the dispersive electrode is allowed. The Dispersive Electrode cannot be cleaned and/or sterilized. Modification may result in patient or operator harm.
- The Vision-MR Dispersive Electrode is for use on patients weighing more than 15 kg provided there is sufficient surface area to ensure full contact of the pad and the patient's skin. Failure to achieve good skin contact with the hydrogel surface of the dispersive electrode may result in electrosurgical burns or poor electrosurgical performance.
- The Advantage-MR system does not have an alarm to communicate faulty connections with the dispersive electrode.
- Conductive parts of the dispersive electrode and associated connectors should not be in contact with any other conductive parts including earth. This contact may increase risk of harm to patient or operator.
- Contact your Biomedical Engineering department and/or the electrosurgical generator manufacturer directly for questions pertaining to any technical specifications or requirement listed here.
- Follow the operating Instructions for the RF generator being used.
- Always use the lowest power settings to achieve the desired surgical effect. Do not exceed 65W.
- Do not coil dispersive electrode cable or allow the cable to overlie other electrosurgical monitoring cables or equipment, as the unintended transfer of potentially harmful RF energy may result.
- Difficulty in achieving cutting, coagulating or ablating energies require evaluation. Stop. Do not proceed or increase power settings until you have checked all components of the electrosurgical circuit including the active electrode and its cable, the patient pad adherence and integrity, and the electrical generator and its connectors. Indiscriminate power increase may result in patient burns.
- Separation of the dispersive electrode from the patient may cause injury if not monitored. Check dispersive electrode adhesion if the patient shifts or has been moved. If at any point the dispersive electrode is not fully adhered, replace it with a new dispersive electrode.
- Remove the dispersive electrode slowly to avoid skin irritation. Applying pressure to nearby skin during removal may reduce skin irritation.
- Heat applied by thermal blankets or other sources are cumulative with heat produced at the pad. Choice of an application site removed from other heat sources reduces the risk of patient injury.
- Do not apply to the patient's back or outer thigh.

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- Use only with compatible devices. Use with non-compatible RF generators with CQM may not trigger an alarm before excessive heating occurs.
- Avoid skin to skin contact using dry gauze when necessary.

PRECAUTIONS

- Do not use the product if the pad is discolored or expired.
- Inspect all components before use. Do not use if the package or items in the package appear damaged or defective. Contact Imricor Medical Systems, Inc. with the part number and lot number from the package if the seal or package is damaged or if there are any concerns regarding product integrity.
- When removing liner do not pull on the tab of the dispersive electrode. Doing so may result in a compromise of the integrity of the pad and increased risk of harm to the patient.
- Prior to applying to patient, ensure the hydrogel is moist.
- Ensure there are no folds in the dispersive electrode.
- Additional electrode gel is not required and should not be used.
- Do not re-use or re-locate the dispersive electrode after initial application. If re-used, the dispersive electrode could cause thermal injury.
- Keep application site free of topically applied products such as oils and lotions. If necessary, clean and disinfect area in accordance with facility protocol and allow to dry before application.
- Do not apply where the circumference of the leg is less then 25cm.
- To minimize the potential for electrosurgical burns, remove hair before placement of the pad.
- Ensure the longer edge of the pad is nearest to the RF application site and makes full contact with the skin. See Figure 2.
- No alarm will sound if connections or placement of the dispersive electrode aren't secure.
- If patient is repositioned, re-inspect dispersive electrode and all connections.
- Keep the dispersive electrode and cabling away from patient monitoring electrodes
- Do not use a needle monitoring ECG electrode with dispersive electrode.
- When applying the pad, the pad must not touch or overlap itself.
- Avoid applying pressure to the pad through use of straps, tie downs, tape, etc.

COMPATIBLE EXTERNAL DEVICES & ACCESSORIES

The dispersive electrode must only be used with the following devices:

- Advantage-MR EP Recorder/Stimulator System (AD-001). Supplied separately.

CONTRAINDICATIONS

The dispersive electrode must not be applied to damaged or injured skin.

DIRECTIONS FOR USE

Refer to the Advantage-MR EP Recorder/Stimulator System and compatible RF generator instructions for use for directions on proper connection and operation of these devices when used with the Vision-MR Dispersive Electrode.

1. Remove the dispersive electrode from the pouch by carefully ripping the edge at the perforated notch of the pouch without harming the dispersive electrode.
2. Slowly remove the liner from the dispersive electrode diagonally as shown in Figure 1. Do not damage hydrogel layer. After liner removal, carefully inspect the pad to ensure that no hydrogel has separated from the underlying layers. If hydrogel separation is present, discard the pad.
3. Lightly touch the surface of the hydrogel to ensure that it is moist. Do not use a dry dispersive electrode.
4. Prepare application site. Remove hair, ensure free of topically applied products.
5. Apply the dispersive electrode to the inner thigh of either leg with the tab facing toward the feet of the patient. Avoid scar tissue, bony areas, excessive fatty tissue, and areas where fluid may pool. Do not apply where the circumference of the leg is less than 25cm. Ensure there are no metal implants e.g. endoprosthetics or bone plates in the path of the current.

60133, Rev B

6. Do not apply to the patient's back.
7. During the electrode application, massage the entire surface of the dispersive electrode to ensure secure contact with the patient skin (Figure 2). After application, carefully inspect the electrode to ensure that it is fully adhered.
8. Inspect the dispersive electrode cable for damage. If damaged, replace cable.
9. Connect the dispersive electrode to the dispersive electrode cable ensuring that the dispersive electrode remains fully adhered and the conductive foil on the tab is not exposed.
10. Connect the other end of the dispersive electrode cable to the PDI of the Advantage-MR system. Do not wind or wrap the cable around or under the leg. Avoid routing the cable near other cabling. Ensure that all connections are secure.
11. Follow the operating instructions for the RF generator being used.
    - An RF generator with compatible Contact Quality Monitoring (CQM) will monitor the dispersive electrode contact with the patient automatically.
    - An RF generator without CQM does not monitor the dispersive electrode contact with the patient. Check dispersive electrode adhesion if the patient shifts or has been moved.
12. Ensure that the dispersive electrode remains fully adhered if the patient shifts or has been moved. If at any point the dispersive electrode is not fully adhered, replace it with a new dispersive electrode.
13. After procedure, disconnect the dispersive electrode cable and remove the dispersive electrode with care. Dispose in accordance with hospital or facility protocol.

Figure 1: Liner Removal

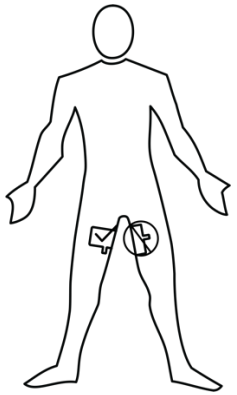

Figure 2: Application Orientation

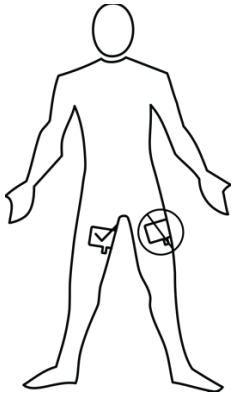

Figure 3: Application Location

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MR CONDITIONS FOR USE

The Vision-MR Dispersive Electrode is MR Conditional. It is safe for use in the MR environment under the following conditions:

- Must be placed on inner thigh
- Must be used with the Advantage-MR EP Recorder/Stimulator system
- Must only be used in a 1.5T MRI Scanner

STORAGE CONDITIONS

Store in a dry environment protected from heat and radiation at room temperature.

60133, Rev B

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60133, Rev B