EcoVue®

Sterile Ultrasound Gel
HV Sterile Ultrasound Gel

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Instructions for Use

REF	
280	20 g Packet with SafeWrap® Package
280NW	20 g Packet
380	20 g Packet with SafeWrap® Package
380NW	20 g Packet

DESCRIPTION
EcoVue® Sterile Ultrasound Gels are sterile, non-irritating, non-sensitizing, non-staining, and water-soluble scanning gels intended for use during sterile ultrasound procedures. The gels are an accessory used to couple sound waves between a patient and medical imaging equipment during ultrasound procedures in a healthcare setting. EcoVue Sterile Ultrasound Gels may be used with all commercially available ultrasound devices.

INDICATIONS FOR USE
EcoVue Sterile Ultrasound Gels may be used during ultrasound procedures on all patient populations where sterility is indicated or otherwise desired, or during procedures where cross-contamination is of concern.

CONTRAINDICATIONS
None.

WARNINGS
- If irritation occurs, discontinue use and consult a physician. NOTICE: Any serious incident that has occurred in relation to this device should be reported to HR HealthCare and the competent authority in Member State where user is established.
- EcoVue Sterile Ultrasound Gels are intended for single use only. Re-use could result in cross-contamination, risk of infection, or adverse reaction for the patient.
- CAUTION: Federal law restricts this device to sale by or on the order of a physician or medical practitioner.

PRECAUTIONS
- Discard and do not use EcoVue Sterile Ultrasound Gel if package is damaged or opened.
- To reduce the risk of cross-contamination, standard practices for sterile procedures should be used.

PRE-USE, HANDLING & INSPECTION
- EcoVue Sterile Ultrasound Gels should be thoroughly inspected prior to use to ensure packaging is not damaged or defective.
- To reduce the risk of cross-contamination, standard practices for sterile procedures should be used.

GEL WARMING
EcoVue Sterile Ultrasound Gels, in any packaging format, may be used at room temperature or warmed in an ultrasound gel warmer, such as the Acclimate® Gel Warmer. Refer to the gel warmer manufacturer's operating manual/user manual for warming instructions.

STEP-BY-STEP INSTRUCTIONS
1. Remove SafeWrap outer pouch (if applicable).
2. Manually open the packet by tearing along the perforations where indicated.
3. Apply the desired amount of EcoVue directly to the patient or probe as needed.
4. Discard packet after use.

RECOMMENDED STORAGE CONDITIONS
Store in a clean, dry place at room temperature and away from direct sunlight.

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STERILE R CE 2862 MD

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EcoVue®

Non-Sterile Ultrasound Gel
HV Non-Sterile Ultrasound Gel

Instructions for Use

REF	
281	20 g Packet
283	32 g FlexPac® Pouch
284	60 g Flip-Top Tube
286	250 ml (8.5 oz.) Bottle
381	20 g Packet
383	32 g FlexPac® Pouch
386	250 ml (8.5 oz.) Bottle

DESCRIPTION

EcoVue® Non-Sterile Ultrasound Gels are non-sterile, non-irritating, non-sensitizing, non-staining and water-soluble gels intended for use as a scanning gel in diagnostic and therapeutic ultrasound gel procedures. The gels are an accessory used to couple sound waves between the patient and medical imaging equipment during ultrasound procedures in a healthcare setting. EcoVue Non-Sterile Ultrasound Gels may be used with all commercially available ultrasound devices.

INDICATIONS FOR USE

EcoVue Non-Sterile Ultrasound Gel Single-Use Packets (REF # 281, 283, 381, and 383) are intended for use in facilities where cross-contamination is of concern on all patient populations during non-invasive ultrasound procedures on intact, unbroken skin.
EcoVue Non-Sterile Ultrasound Gel Multi-Use Products (REF # 284, 286, and 386) are intended for use in facilities where cross-contamination is of minimal concern on all patient populations during non-invasive ultrasound procedures on intact, unbroken skin.

CONTRAINDICATIONS

None.

WARNINGS

- If irritation occurs, discontinue use and consult a physician. NOTICE: Any serious incident that has occurred in relation to this device should be reported toHR HealthCare and the competent authority in Member State where user is established.
- EcoVue Non-Sterile Ultrasound Gel Single-Use Packets are intended for single-use only. Re-use could result in cross-contamination, risk of infection, or adverse reaction for the patient.
- CAUTION: Federal law restricts this device to sale by or on the order of a physician or medical practitioner.

PRECAUTIONS

- Discard and do not use EcoVue Non-Sterile Ultrasound Gel if package is damaged or opened.
- Discard and do not use EcoVue Non-Sterile Ultrasound Gel if tamper-evident seal is damaged or missing (REF # 284 only).
- Do not refill EcoVue Non-Sterile Ultrasound Gel Multi-Use Products (REF # 284, 286, and 386).

PRE-USE, HANDLING & INSPECTION

- EcoVue Non-Sterile Ultrasound Gel should be thoroughly inspected prior to use to ensure packaging is not damaged or defective.

GEL WARMING

EcoVue Sterile Ultrasound Gels, in any packaging format, may be used at room temperature or warmed in an ultrasound gel warmer, such as the Acclimate® Gel Warmer. Refer to the gel warmer manufacturer's operating manual/user manual for warming instructions.

STEP-BY-STEP INSTRUCTIONS

Single-Use Packets (REF # 281, 283, 381, and 383)

1. Manually open the EcoVue Non-Sterile Ultrasound Gel Single-Use Packet by tearing along the perforations where indicated.
2. Apply the desired amount of EcoVue directly to the patient or probe as needed.
3. Discard packet after use.

Multi-Use Products (REF # 284, 286, and 386)

1. Remove tamper-evident seal and replace cap (REF # 284 only).
2. Apply the desired amount of EcoVue directly to the patient or probe as needed. To avoid contamination, tips of containers should not come in contact with patient, staff or instruments.
3. Close cap and store in a suitable place. Discard container when empty (or sooner, if required by facility internal procedures).

RECOMMENDED STORAGE CONDITIONS

Store in a clean, dry place at room temperature and away from direct sunlight.

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SINGLE-USE PACKETS

MULTI-USE PRODUCTS

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