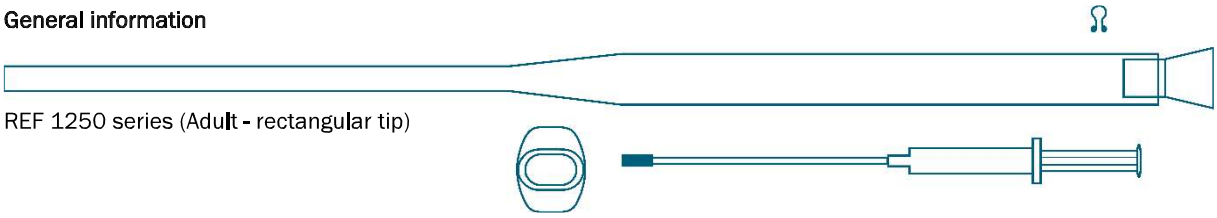
Ultrasound Transducer Cover

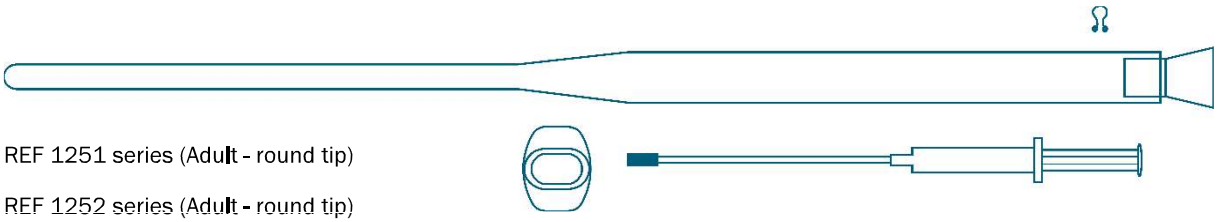
For use with

Transesophageal Echocardiography (TEE/TOE) Transducers

General information



REF 1250 series (Adult - rectangular tip)



REF 1251 series (Adult - round tip)

REF 1252 series (Adult - round tip)

REF 1260 series (Paediatric - round tip)

REF 1280 series (Micro - round tip)

Material: Polyurethane
Available both sterile and non-sterile

Size: REF 1250 & 1251 series
Tip diameter: 15 mm over 500 mm in length / Diameter end of the cover: 31 mm
Total length cover: 1100 mm

Size: REF 1252 series

Tip diameter: 19,4 mm over 500 mm in length / Diameter end of the cover: 31 mm
Total length cover: 1100 mm

Size: REF 1260 series

Tip diameter: 11 mm over 500 mm in length / Diameter end of the cover: 31 mm
Total length cover: 1000 mm

Size: REF 1280 series

Tip diameter: 9 mm over 500 mm in length / Diameter end of the cover: 31 mm
Total length cover: 980 mm

Depending on the reference number a cover (kit) ***could*** include the following accessories:

- an applicator,
- an extended 10 ml syringe filled with ultrasound transmission gel
- a twist-lock
- an adult or paediatric bite guard.

Technical data PU Material

Properties	Test Method	Values
Durometer	ASTM D2240	84 Shore A
Specific Gravity	ASTM D792	1.1
Elongation at Break Elast	ASTM D412	660%
Tensile Strength at Break Elast	ASTM D412	3,800 psi
100% Modulus	ASTM D412	750 psi
300% Modulus	ASTM D412	1,150 psi
Tear Strength	ASTM D624 Die C	435 pli

Superior resilience, excellent hydrolytic stability and resistance to attack by microorganisms.

Tests Applied:

In Vitro Cytotoxicity ISO 10993-5:2009, Biological Evaluation of Medical Devices - Part 5.

Primary Skin irritation Test -ISO Method ISO 10993-10

Technical data Ultrasound transmission gel

Description:	Viscous, clear, colorless to pale yellow, aqueous gel
Composition (INCI)	Reverse osmosis (RO) water, humectant, polymer, and preservatives
Preservatives	Propyl paraben and methyl paraben
pH Range	6.5-7,0
Density	1.03 (gm/cm^3)
Viscosity	150,000 - 210,000 cps (Brookfield Viscometer, Model RVT, Spindle T-C, 2.5 RPM)

Tests Applied:

Cytotoxicity - Minimal Essential Media (MEM) Elution - Per ISO 10993-5 Reactivity grade is not greater than grade

2 or a mild reactivity at 1:4 dilution

Irritation - ISO/USP intracutaneous Reactivity irritation Test ISO 10993-10
Sensitization - ISO 10993-10
In Vitro Skin irritation - EpiDerm™ Reconstructed Human Epidermis

Symbol	Title of the Symbol	Description of the Symbol
	Manufacturer (ISO 15223-1, 5.1.1)	Indicates the medical device manufacturer.
	Date of manufacture (ISO 15223-1, 5.1.3)	Indicates the date when the medical device was manufactured.
	Use-by date (ISO 15223-1, 5.1.4)	Indicates the date after which the medical device is not to be used.
	Batch code (ISO 15223-1, 5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalog number (ISO 15223-1, 5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Sterilized using irradiation (ISO 15223-1, 5.2.3)	Indicates a medical device that has been sterilized using irradiation.
	Do not use if package is damaged (ISO 15223-1, 5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.
	Keep away from direct sunlight (ISO 15223-1, 5.3.2)	Indicates a medical device that needs protection from light sources.
	Keep dry (ISO 15223-1, 5.3.4)	Indicates a medical device that needs to be protected from moisture.
	Do not re-use (ISO 15223-1, 5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Consult instructions for use (ISO 15223-1, 5.4.3)	Indicates the need for the user to consult the instructions for use.
	Not made with natural rubber latex (ISO 15223-1, 5.4.5 and Annex B)	Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging.
	European Conformity (EU MDR 2017/745, Article 20)	Indicates manufacturer declaration that the product complies with the essential requirements of the relevant European health, safety and environment protection legislation.
	Medical Device (MedTech Europe Guidance: Use of Symbols to Indicate Compliance with the MDR)	Indicates the product is a medical device.
	Quantity (IEC 60878, 2794)	To indicate the number of pieces in the package.
	Single sterile barrier system (ISO 15223-1, 5.4.3)	Single sterile barrier

Intended use

Probetection™ transducer covers are to be placed over diagnostic ultrasound transducers. The cover allows use of the transducer in scanning procedures for body surface and endocavity diagnostic ultrasound, while helping to prevent the transfer of micro-organisms, body fluids etc. The cover also provides a sterile field (sterile covers only). Probetection™ Ultrasound Transducer Covers are available sterile & non-sterile and are for single use only.

Indications for use

Transesophageal echocardiology (TEE/TOE) - Diagnostic imaging and monitoring of heart chambers, valves and vessels.

Patient population

Intracavity transducer covers are intended for use with adults, paediatrics and neonates of all body builds.

Intended users

Probetection™ Ultrasound Transducer covers are to be used by medical trained professionals in the use of Trans Oesophageal or Trans Esophageal Echocardiography (TOE / TEE) for adults, paediatrics and neonatal patients.

Performance characteristics

Probetection™ Ultrasound Transducer Cover serves as a bacterial and viral barrier to protect patients and equipment from cross-contamination.

Contraindication and Warning

- Before use, you should be trained in medical ultrasonography. For instructions for use of your transducer, please see your system's manual.
- Users of this product have an obligation and responsibility to provide the highest degree of infection control to patients, co-workers and themselves. To avoid cross-contamination, follow infection control policies established by your facility.
- See your system's user guide for the reprocessing of the transducer between use.
- Product is for single use only.
- Check the packaging integrity before use, if damaged do not use.
- Do not use if the expiration date has passed.
- If serious incidents related to the product occur, a notification must be sent to Palmedic and/or the competent authority in your country.
- Review product labeling for the sterile symbol. If the sterile symbol appears on the label, the cover is sterilized using gamma irradiation.
- Do not re-use, reprocess or re-sterilize single-use devices before written approval by Palmedic. Re-use, reprocessing or re-sterilization may create a risk of cross contamination.
- Always place a cover over the transducer to protect patients and user from cross-contamination.
- Use only water-soluble agents or gels. Petroleum or mineral oil-based materials may harm the Ultrasound cover.
- Make sure there are no air bubbles present prior to use. Air left between cover and transducer face may result in poor image quality.

There are no potential contraindications known that we are aware of.

NOTE: Product is latex free

To apply the cover to the transducer

1. Inspect if the packaging has any damage (If the case does not use the cover)
2. Remove the cap from the tip of the syringe.
3. Insert the extended syringe filled with ultrasonic transmission gel into the cover and fill the tip of the cover with an appropriate amount of gel.
4. Place the transducer through the applicator into the transducer cover.
5. Tighten the applicator to the control unit and install the twist lock.
6. Place the Bite guard between the patients' teeth.
7. Apply the transducer through the Bite guard.
8. After use Remove the transducer from the patient
9. Remove the twist lock and remove the applicator from the control unit.
10. Pull down the first approximately 30cm (12") of the cover from the transducer tip
11. Slide the applicator slowly down. The cover will turn inside out to slide the cover inside out of the transducer.

Storage Conditions

- Store our products under normal storage conditions (dry, clean, well-ventilated area)
- Do not store the products in direct sunlight.

Disposal

Caution

Dispose of single use components as infectious waste