

**NON-STERILE NATURAL RUBBER
LATEX PROTECTIVE TRANSDUCER
COVERS**

INSTRUCTION FOR USE



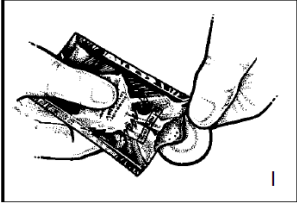
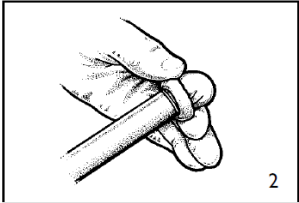
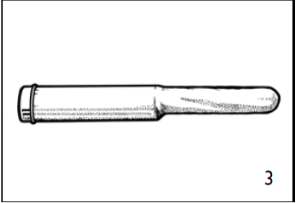
Non-sterile Natural Rubber Latex Protective Transducer Covers

IFU LEAFLET

Non-sterile Natural Rubber Latex Protective Transducer Covers	
INTENDED USE	Transducer cover is intended for barrier protection during invasive medical examination and diagnosis using transducer probe.
INTENDED USER	<p>It is intended to be used by healthcare provider trained in the use of ultrasound. There are no unique skills or user abilities required for protective transducer cover use.</p> <p>User groups may include, but not limited to: Anesthesiologists, Department Nursing staff, Emergency Medicine physicians, Endocrinologists, Interventional Radiologists & Interventional Radiology Technologists, Radiologists, Sonographers, Surgeons, Surgical Technicians, and other clinicians.</p>
INDICATION	Transducer cover is a medical device used to prevent cross-contamination of transducer probe during endocavity (i.e. transvaginal or transrectal) ultrasound procedure.
CLINICAL BENEFITS	Prevent cross-contamination of probes and consequently reduce the risk of cross infection in patients undergo invasive ultrasound examinations and diagnoses (i.e transvaginal and transrectal scan).
WARNINGS/ PRECAUTIONS	<p>Before use, you should be trained in ultrasonography.</p> <p>DISPOSE of single use components as infectious waste.</p> <p>Transducer cover are for single use only, DO NOT REUSE transducer covers. Reuse or reprocessing may create a risk of contamination of the device and cause patient infection or cross-infection.</p> <p>USE ONLY WATER BASED LUBRICANT, avoid the use of oil-based lubricants, such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine, etc., as these are deleterious to the integrity of the condom.</p> <p>Disinfection of the transducer probe after each examination could reduce the probability of cross-contamination.</p> <p>Report any serious incident occurred from using the device to the manufacturer and the relevant national competent authority.</p>
CONTRAINDICATION	This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.



INSTRUCTION FOR USE

- Carefully tear off the foil pack. Make sure not to damage the cover.
- During removal from foil, avoid damage to the cover by sharp edges, fingernails and etc.
- Place the cover over the transducer. Pull cover tightly over the transducer to remove wrinkles and air bubbles, taking care to avoid puncturing the cover.
- Inspect the cover to ensure no holes or tears.

Date of Revision: 02.04.2024
Master reference information: I-IFU-03/1 (v2)

	Store in a cool, dry place		Keep away from sunlight		Use by date
	Contains natural rubber latex		Manufacturer		Consult instruction for use
	Do not use if package is damaged		Do not reuse		Batch code
	Importer		Medical device		Unique Device Identifier
	European authorized representative				
CE mark	 Innolates Sdn. Bhd. Lot 591 & 594, Persiaran Raja Lumu, Pandamaran Industrial Estate, 42000 Port Klang, Selangor, Malaysia.		Advena Limited Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta		

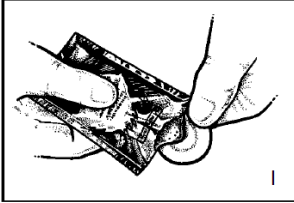
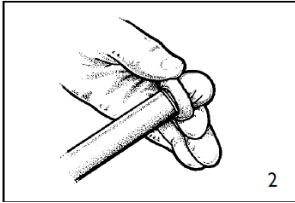
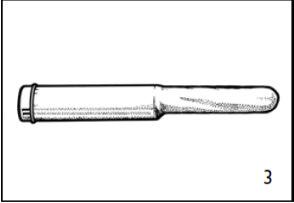

















Non-sterile Natural Rubber Latex Protective Transducer Covers

IFU LEAFLET

Non-sterile Natural Rubber Latex Protective Transducer Covers	
INTENDED USE	Transducer cover is intended for barrier protection during invasive medical examination and diagnosis using transducer probe.
INTENDED USER	<p>It is intended to be used by healthcare provider trained in the use of ultrasound. There are no unique skills or user abilities required for protective transducer cover use.</p> <p>User groups may include, but not limited to: Anesthesiologists, Department Nursing staff, Emergency Medicine physicians, Endocrinologists, Interventional Radiologists & Interventional Radiology Technologists, Radiologists, Sonographers, Surgeons, Surgical Technicians, and other clinicians.</p>
INDICATION	Transducer cover is a medical device used to prevent cross-contamination of transducer probe during endocavity (i.e. transvaginal or transrectal) ultrasound procedure.
CLINICAL BENEFITS	Prevent cross-contamination of probes and consequently reduce the risk of cross infection in patients undergo invasive ultrasound examinations and diagnoses (i.e transvaginal and transrectal scan).
WARNINGS/ PRECAUTIONS	<p>Before use, you should be trained in ultrasonography.</p> <p>DISPOSE of single use components as infectious waste.</p> <p>Transducer cover are for single use only, DO NOT REUSE transducer covers. Reuse or reprocessing may create a risk of contamination of the device and cause patient infection or cross-infection.</p> <p>USE ONLY WATER BASED LUBRICANT, avoid the use of oil-based lubricants, such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine, etc., as these are deleterious to the integrity of the transducer probe.</p> <p>Disinfection of the transducer probe after each examination could reduce the probability of cross-contamination.</p> <p>Report any serious incident occurred from using the device to the manufacturer and the relevant national competent authority.</p>
CONTRAINDICATION	This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.



INSTRUCTION FOR USE			
	<ol style="list-style-type: none"> 1. Carefully tear off the foil pack. Make sure not to damage the cover. 2. During removal from foil, avoid damage to the cover by sharp edges, fingernails and etc. 3. Place the cover over the transducer. Pull cover tightly over the transducer to remove wrinkles and air bubbles, taking care to avoid puncturing the cover. 4. Inspect the cover to ensure no holes or tears. <p style="margin-top: 10px;">Date of Revision: 28.03.2024 Master reference information: K-IFU-03/1 (v2)</p>		

	Store in a cool, dry place		Keep away from sunlight		Use by date
	Contains natural rubber latex		Manufacturer		Consult instruction for use
	Do not use if package is damaged		Do not reuse		Batch code
	Importer		Medical device		Unique Device Identifier
	European authorized representative				
CE mark	 Karex Industries Sdn. Bhd. PTD 7906 & 7907, Taman Pontian Jaya, Batu 34 Jalan Johor, 82000 Pontian, Johor, Malaysia.	 Advena Limited Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta			

**STERILE NATURAL RUBBER LATEX
PROTECTIVE TRANSDUCER COVERS**

INSTRUCTION FOR USE

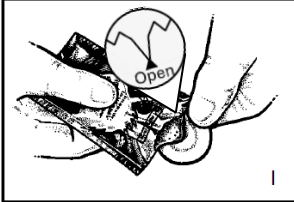
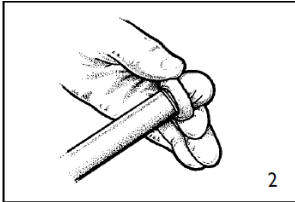
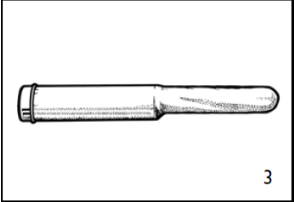


Sterile Natural Rubber Latex Protective Transducer Covers

IFU LEAFLET

Sterile Natural Rubber Latex Protective Transducer Covers	
INTENDED USE	Transducer cover is intended for barrier protection during invasive medical examination and diagnosis using transducer probe.
INTENDED USER	<p>It is intended to be used by healthcare provider trained in the use of ultrasound. There are no unique skills or user abilities required for protective transducer cover use.</p> <p>User groups may include, but not limited to: Anesthesiologists, Department Nursing staff, Emergency Medicine physicians, Endocrinologists, Interventional Radiologists & Interventional Radiology Technologists, Radiologists, Sonographers, Surgeons, Surgical Technicians, and other clinicians.</p>
INDICATION	Transducer cover is a medical device used to prevent cross-contamination of transducer probe during endocavity (i.e. transvaginal or transrectal) ultrasound procedure.
CLINICAL BENEFITS	Prevent cross-contamination of probes and consequently reduce the risk of cross infection in patients undergo invasive ultrasound examinations and diagnoses (i.e transvaginal and transrectal scan).
WARNINGS/ PRECAUTIONS	<p>Before use, you should be trained in ultrasonography.</p> <p>DISPOSE of single use components as infectious waste.</p> <p>Transducer cover are for single use only, DO NOT REUSE transducer covers. Reuse or reprocessing may create a risk of contamination of the device and cause patient infection or cross-infection.</p> <p>USE ONLY WATER BASED LUBRICANT, avoid the use of oil-based lubricants, such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine, etc., as these are deleterious to the integrity of the condom.</p> <p>Disinfection of the transducer probe after each examination could reduce the probability of cross-contamination.</p> <p>Report any serious incident occurred from using the device to the manufacturer and the relevant national competent authority.</p> <p>DO NOT USE the transducer covers if the individual package is obviously damaged or unintentionally open before use. Discard that covers and use a new one from an undamaged package.</p>
CONTRAINDICATION	This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.



<p>INSTRUCTION FOR USE</p>			
<ol style="list-style-type: none"> 1. Carefully tear off the foil pack at the location where the package can be opened (Example: ▲ and/or Open here). Make sure not to damage the cover. 2. Remove the cover using proper sterile technique. During removal from foil, avoid damage to the cover by sharp edges, fingernails and etc. 3. Place the cover over the transducer. Pull cover tightly over the transducer to remove wrinkles and air bubbles, taking care to avoid puncturing the cover. 4. Inspect the cover to ensure no holes or tears. 			
<p>Date of Revision: 08.04.2024 Master reference information: I-IFU-03/2 (v2)</p>			

	Store in a cool, dry place		Keep away from sunlight		Use by date
	Contains natural rubber latex		Manufacturer		Consult instruction for use
	Do not use if package is damaged		Do not reuse		Batch code
	Importer		Medical device		Date of Manufacture
	Unique Device Identifier		European authorized representative		Single sterile barrier system
	Sterilized using irradiation		Do not resterilize		
CE mark	<p>Innolates Sdn. Bhd. Lot 591 & 594, Persiaran Raja Lumu, Pandamaran Industrial Estate, 42000 Port Klang, Selangor, Malaysia.</p>		<p>Advena Limited Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta</p>		

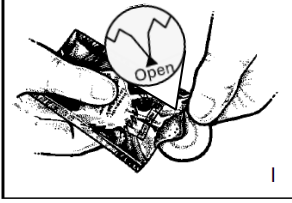
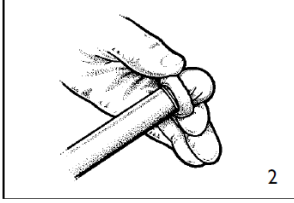
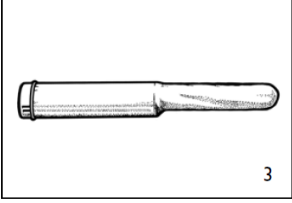


Sterile Natural Rubber Latex Protective Transducer Covers

IFU LEAFLET

Sterile Natural Rubber Latex Protective Transducer Covers	
INTENDED USE	Transducer cover is intended for barrier protection during invasive medical examination and diagnosis using transducer probe.
INTENDED USER	<p>It is intended to be used by healthcare provider trained in the use of ultrasound. There are no unique skills or user abilities required for protective transducer cover use.</p> <p>User groups may include, but not limited to: Anesthesiologists, Department Nursing staff, Emergency Medicine physicians, Endocrinologists, Interventional Radiologists & Interventional Radiology Technologists, Radiologists, Sonographers, Surgeons, Surgical Technicians, and other clinicians.</p>
INDICATION	Transducer cover is a medical device used to prevent cross-contamination of transducer probe during endocavity (i.e. transvaginal or transrectal) ultrasound procedure.
CLINICAL BENEFITS	Prevent cross-contamination of probes and consequently reduce the risk of cross infection in patients undergo invasive ultrasound examinations and diagnoses (i.e transvaginal and transrectal scan).
WARNINGS/ PRECAUTIONS	<p>Before use, you should be trained in ultrasonography.</p> <p>DISPOSE of single use components as infectious waste.</p> <p>Transducer cover are for single use only, DO NOT REUSE transducer covers. Reuse or reprocessing may create a risk of contamination of the device and cause patient infection or cross-infection.</p> <p>USE ONLY WATER BASED LUBRICANT, avoid the use of oil-based lubricants, such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine, etc., as these are deleterious to the integrity of the transducer cover.</p> <p>Disinfection of the transducer probe after each examination could reduce the probability of cross-contamination.</p> <p>Report any serious incident occurred from using the device to the manufacturer and the relevant national competent authority.</p> <p>DO NOT USE the transducer covers if the individual package is obviously damaged or unintentionally open before use. Discard that covers and use a new one from an undamaged package.</p>
CONTRAINDICATION	This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.



<p>INSTRUCTION FOR USE</p>	<div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 5px; text-align: center;">  <p>1</p> </div> <div style="border: 1px solid black; padding: 5px; text-align: center;">  <p>2</p> </div> <div style="border: 1px solid black; padding: 5px; text-align: center;">  <p>3</p> </div> </div> <ol style="list-style-type: none"> 1. Carefully tear off the foil pack at the location where the package can be opened (Example: ▲ and/or Open here). Make sure not to damage the cover. 2. Remove the cover using proper sterile technique. During removal from foil, avoid damage to the cover by sharp edges, fingernails and etc. 3. Place the cover over the transducer. Pull cover tightly over the transducer to remove wrinkles and air bubbles, taking care to avoid puncturing the cover. 4. Inspect the cover to ensure no holes or tears. <p style="text-align: right; margin-top: 20px;">Date of Revision: 08.04.2024 Master reference information: K-IFU-03/2 (v2)</p>
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	Store in a cool, dry place		Keep away from sunlight		Use by date
	Contains natural rubber latex		Manufacturer		Consult instruction for use
	Do not use if package is damaged		Do not reuse		Batch code
	Importer		Medical device		Date of Manufacture
	Unique Device Identifier		European authorized representative		Single sterile barrier system
	Sterilized using irradiation		Do not resterilize		
CE mark	 Karex Industries Sdn. Bhd. PTD 7906 & 7907, Taman Pontian Jaya, Batu 34 Jalan Johor, 82000 Pontian, Johor, Malaysia.	 Advena Limited Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta			

**NON-STERILE SYNTHETIC
POLYISOPRENE LATEX (NON-LATEX)
PROTECTIVE TRANSDUCER COVERS**

INSTRUCTION FOR USE

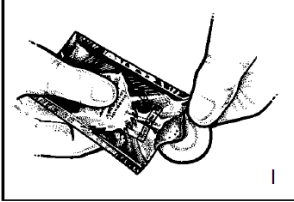
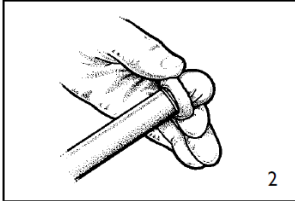
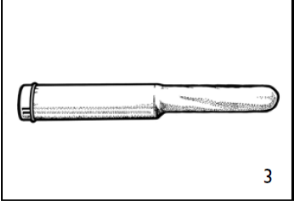


Non-sterile Synthetic Polyisoprene Latex (Non-Latex) Protective Transducer Covers

IFU LEAFLET

Non-sterile Synthetic Polyisoprene Latex (Non-Latex) Protective Transducer Covers	
INTENDED USE	Transducer cover is intended for barrier protection during invasive medical examination and diagnosis using transducer probe.
INTENDED USER	<p>It is intended to be used by healthcare provider trained in the use of ultrasound. There are no unique skills or user abilities required for protective transducer cover use.</p> <p>User groups may include, but not limited to: Anesthesiologists, Department Nursing staff, Emergency Medicine physicians, Endocrinologists, Interventional Radiologists & Interventional Radiology Technologists, Radiologists, Sonographers, Surgeons, Surgical Technicians, and other clinicians.</p>
INDICATION	Transducer probe cover is indicated to prevent cross-contamination of transducer probe and reduce the risk of cross-infection in patients during endocavity (i.e. transvaginal or transrectal) ultrasound procedure.
CLINICAL BENEFITS	Reduce the risk of cross-infection in patients undergo invasive ultrasound examinations and diagnoses (i.e transvaginal and transrectal scan).
WARNINGS/ PRECAUTIONS	<p>Before use, you should be trained in ultrasonography.</p> <p>DISPOSE of single use components as infectious waste.</p> <p>Transducer cover are for single use only, DO NOT REUSE transducer covers. Reuse or reprocessing may create a risk of contamination of the device and cause patient infection or cross-infection.</p> <p>USE ONLY WATER BASED LUBRICANT, avoid the use of oil-based lubricants, such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine, etc., as these are deleterious to the integrity of the transducer cover.</p> <p>Disinfection of the transducer probe after each examination could reduce the probability of cross-contamination.</p> <p>Report any serious incident occurred from using the device to the manufacturer and the relevant national competent authority.</p>
CONTRAINDICATION	No known contraindication.



<p>INSTRUCTION FOR USE</p>	 1	 2	 3
<ol style="list-style-type: none"> 1. Carefully tear off the foil pack. Make sure not to damage the cover. 2. During removal from foil, avoid damage to the cover by sharp edges, fingernails and etc. 3. Place the cover over the transducer. Pull cover tightly over the transducer to remove wrinkles and air bubbles, taking care to avoid puncturing the cover. 4. Inspect the cover to ensure no holes or tears. 			

	Store in a cool, dry place		Keep away from sunlight		Use by date
	Manufacturer		Consult instruction for use	LOT	Batch code
	Do not use if package is damaged		Do not reuse		Importer
EU REP	European authorized representative	MD	Medical device	UDI	Unique Device Identifier
CE mark	<p>Karex Industries Sdn. Bhd. PTD 7906 & 7907, Taman Pontian Jaya, Batu 34 Jalan Johor, 82000 Pontian, Johor, Malaysia.</p>				

**STERILE SYNTHETIC POLYISOPRENE
LATEX (NON-LATEX) PROTECTIVE
TRANSDUCER COVERS**

INSTRUCTION FOR USE

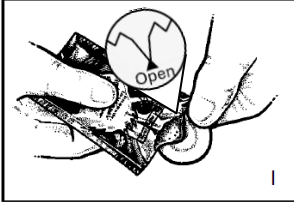
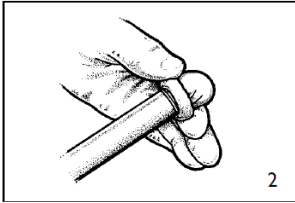
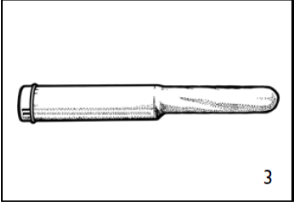


Sterile Synthetic Polyisoprene Latex (Non-Latex) Protective Transducer Covers

IFU LEAFLET

Sterile Synthetic Polyisoprene Latex (Non-Latex) Protective Transducer Covers	
INTENDED USE	Transducer cover is intended for barrier protection during invasive medical examination and diagnosis using transducer probe.
INTENDED USER	<p>It is intended to be used by healthcare provider trained in the use of ultrasound. There are no unique skills or user abilities required for protective transducer cover use.</p> <p>User groups may include, but not limited to: Anesthesiologists, Department Nursing staff, Emergency Medicine physicians, Endocrinologists, Interventional Radiologists & Interventional Radiology Technologists, Radiologists, Sonographers, Surgeons, Surgical Technicians, and other clinicians.</p>
INDICATION	Transducer probe cover is indicated to prevent cross-contamination of transducer probe and reduce the risk of cross-infection in patients during endocavity (i.e. transvaginal or transrectal) ultrasound procedure.
CLINICAL BENEFITS	Reduce the risk of cross-infection in patients undergo invasive ultrasound examinations and diagnoses (i.e transvaginal and transrectal scan).
WARNINGS/ PRECAUTIONS	<p>Before use, you should be trained in ultrasonography.</p> <p>DISPOSE of single use components as infectious waste.</p> <p>Transducer cover are for single use only, DO NOT REUSE transducer covers. Reuse or reprocessing may create a risk of contamination of the device and cause patient infection or cross-infection.</p> <p>USE ONLY WATER BASED LUBRICANT, avoid the use of oil-based lubricants, such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine, etc., as these are deleterious to the integrity of the transducer cover.</p> <p>Disinfection of the transducer probe after each examination could reduce the probability of cross-contamination.</p> <p>Report any serious incident occurred from using the device to the manufacturer and the relevant national competent authority.</p> <p>DO NOT USE the transducer covers if the individual package is obviously damaged or unintentionally open before use. Discard that covers and use a new one from an undamaged package.</p>
CONTRAINDICATION	No known contraindication.



<p>INSTRUCTION FOR USE</p>			
<ol style="list-style-type: none"> 1. Carefully tear off the foil pack at the location where the package can be opened (Example: ▲ and/or Open here). Make sure not to damage the cover. 2. Remove the cover using proper sterile technique. During removal from foil, avoid damage to the cover by sharp edges, fingernails and etc. 3. Place the cover over the transducer. Pull cover tightly over the transducer to remove wrinkles and air bubbles, taking care to avoid puncturing the cover. 4. Inspect the cover to ensure no holes or tears. <p style="margin-top: 10px;">Date of issue: <i>(The date of issue may align with the issuance date of the actual IFU in any acceptable format (i.e May 2025). If the actual IFU has been revised, revision identifier may be added next to the new issuance date (i.e May 2025 (v2))</i> Master reference information: K-IFU-05/2 <i>(Optional)</i></p>			

	Store in a cool, dry place		Keep away from sunlight		Use by date
	Manufacturer		Consult instruction for use	LOT	Batch code
	Do not use if package is damaged		Do not reuse		Date of Manufacture
	Importer	MD	Medical device	UDI	Unique Device Identifier
EU REP	European authorized representative		Single sterile barrier system	STERILE R	Sterilized using irradiation
	Do not resterilize				
<p>CE mark <i>(minimum height of 5mm with notified body's number)</i></p>	<p>Karex Industries Sdn. Bhd. PTD 7906 & 7907, Taman Pontian Jaya, Batu 34 Jalan Johor, 82000 Pontian, Johor, Malaysia.</p>				