

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

INSTRUCTION FOR USE

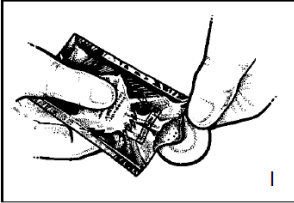
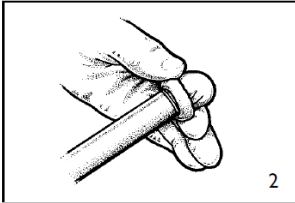
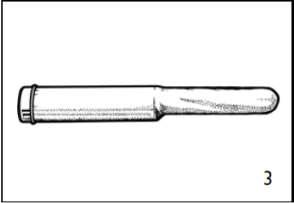


IFU LEAFLET

Remark: Equivalent statement may be used to convey the information in this IFU leaflet; however, it shall carry the same meaning



| 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 |  |  |  |
| | <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>Date of Revision: 02.04.2024 Master reference information: I-IFU-03/1 (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 | | Unique Device Identifier |
| | European authorized representative | | | | |

Remark: Add in definition of any other symbols used on the packaging

| | | |
|----------------|---|---|
| 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 |
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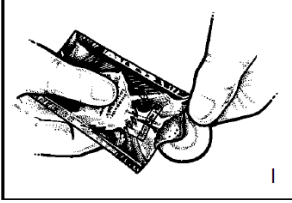
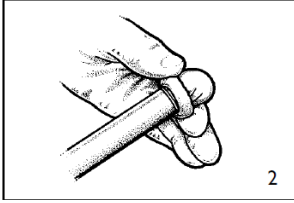
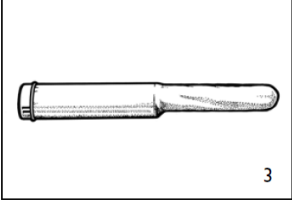


IFU LEAFLET

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| Non-sterile Natural Rubber Latex Protective Transducer Covers | |
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| 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> |
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| CONTRAINDICATION | This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions. |



| | | | |
|--|--|---|--|
| <p>INSTRUCTION FOR USE</p> |  <p>1</p> |  <p>2</p> |  <p>3</p> |
| <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>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 | | | | |

Remark: Add in definition of any other symbols used on the packaging

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

INSTRUCTION FOR USE

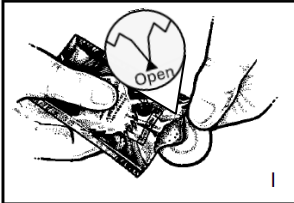
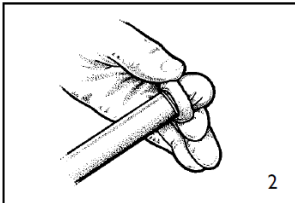
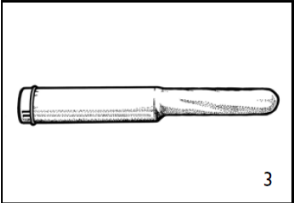


IFU LEAFLET

Remark: Equivalent statement may be used to convey the information in this IFU leaflet; however, it shall carry the same meaning

| 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> |
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| 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> | <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>1</p> </div> <div style="text-align: center;">  <p>2</p> </div> <div style="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="margin-top: 10px;">Date of Revision: 08.04.2024 Master reference information: I-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 | | |

Remark: Add in definition of any other symbols used on the packaging

| | | |
|-----------------------|---|--|
| <p>CE mark</p> | <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> |
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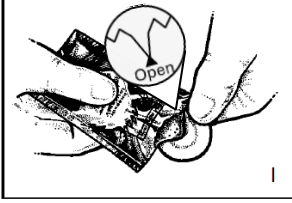
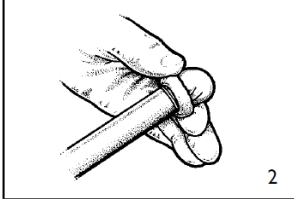
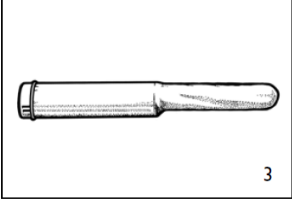


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
| Sterile Natural Rubber Latex Protective Transducer Covers | |
|--|---|
| INTENDED USE | Transducer cover is intended for barrier protection during invasive medical examination and diagnosis using transducer probe. |
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| 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; align-items: center;">    </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> |
|-----------------------------------|---|

| | | | | | |
|--|----------------------------------|--|------------------------------------|--|-------------------------------|
| | 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 | | |

Remark: Add in definition of any other symbols used on the packaging

| | | |
|-----------------------|--|---|
| <p>CE mark</p> |  <p>Karex Industries Sdn. Bhd. PTD 7906 & 7907, Taman Pontian Jaya, Batu 34 Jalan Johor, 82000 Pontian, Johor, Malaysia.</p> |  <p>Advena Limited Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta</p> |
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**NON-STERILE SYNTHETIC
POLYISOPRENE LATEX (NON-LATEX)
PROTECTIVE TRANSDUCER COVERS**

INSTRUCTION FOR USE

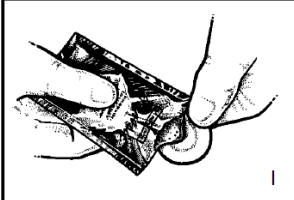
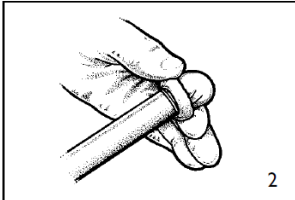
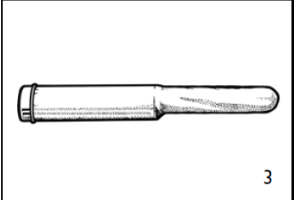


IFU LEAFLET

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| 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 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 | No known contraindication. |



| | | | |
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| <p>INSTRUCTION FOR USE</p> |  1 |  2 |  3 |
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| <p>Date of Revision: 02.04.2024 Master reference information: K-IFU-05/1 (v2)</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 | | Importer |
| EC REP | European authorized representative | MD | Medical device | UDI | Unique Device Identifier |

Remark: Add in definition of any other symbols used on the packaging

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

INSTRUCTION FOR USE

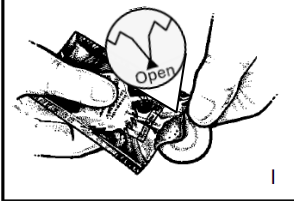
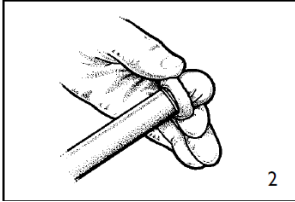
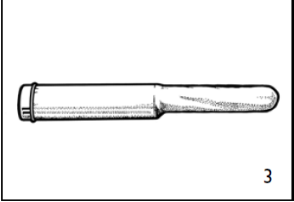


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| CONTRAINDICATION | No known contraindication. |



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| | | | | | |
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| | 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 |
| EC REP | European authorized representative | | Single sterile barrier system | STERILE R | Sterilized using irradiation |
| | Do not resterilize | | | | |

Remark: Add in definition of any other symbols used on the packaging

| | | | | |
|-----------------------|--|--|----|-----|
| <p>CE mark</p> |  <p>Karex Industries Sdn. Bhd. PTD 7906 & 7907, Taman Pontian Jaya, Batu 34 Jalan Johor, 82000 Pontian, Johor, Malaysia.</p> | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: center;">EC</td> <td style="width: 10%; text-align: center;">REP</td> </tr> </table> <p>Advena Limited Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta</p> | EC | REP |
| EC | REP | | | |