UTEROSCOPE KIT

GYNETECH ADVANCE
Address: 12/15 Quai du Commerce,
69009 Lyon–France
Phone: +33 (0)4 28 29 69 63
Contact: info@gynetechadvance.com
Website: https://www.gynetechadvance.com

PRODUCT: UTEROSCOPE (GYNETECH ADVANCE)

1. Introduction

1.1 Intended use of product

Uteroscope is single use medical device intended to be used by gynecologists in clinics or hospitals for interventions in gynecology to dilate the vagina and cervix and expose the interior of the vagina and cervix. Uteroscope is a medical device with controlled bacteriological load.

1.2 Product description

Uteroscope is a single use medical device for gynecology dedicated to cervix dilation. It presents itself as a telescopic rod with several stages of different diameters more and more end, sliding inside protective fins which isolates it from the walls of the cervical canal, thus no friction nor injury.

The practitioner first positions the speculum into the vagina through which is introduced the dilator tube that prevents the intake of vaginal bacteria. At its end is clipped the dilator fins which have 3 mm wide and 2 mm height. Using a dilator rod carrying semi rigid fins protecting the cervical canal that slides effortlessly between the dilator fins. The dilator rod is removed and a tunnel is created which ensures perfect safety and protection of the tissues surrounding the cervical canal, thus avoiding any injuries to the cervical canal.

The opening of the protective fins offers a passage of 9 mm for most instruments which will already allow 70% of the interventions, for the remaining 30% and until 12 mm, see the detailed instructions for use below.

This cladding is then removed by a simple gesture of mini rotation once the intervention is completed.

Product is disinfected before packaging. Bioburden is $<10^1$ CFU.

1.3 Intended user

Only graduated medical staff like gynecologists.

2. Safety warnings and cautions

2.1. Warnings

WARNING: Inspect each device for shipping damage.

WARNING: Inspect each device prior use. Do not use if damaged.

WARNING: Treat used Uteroscope components as bio hazardous infectious material. Dispose of used Uteroscope in suitable disposal unit or in accordance with local regulations

WARNING: If a component is damaged, do not use any component from the same case.

WARNING: Device, when in transit or storage, may be subject to damage beyond the control of the manufacturer or supplier.

WARNING: Never use the device with laser equipment. The plastic specula may soften.

WARNING: Treat used uteroscope components as biohazardous infectious material. Dispose of used vaginal specula in suitable disposal unit or in accordance with local regulations.

WARNING: Users must adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories. If in doubt, the user of the device shall first contact the local distributor for Uteroscope to get answers.

2.2. Cautions

Used by trained personnel only.

Lifetime of the medical product Uteroscope before using is 5 years (60 Months) from the manufacturing date.

3. Regulations and standards

Medical product UTEROSCOPE is classified according to REGULATION (EU) 2017/745 as Class l by Rule 5 of Annex VIII.

The device complies with the following product standards:

- EN ISO 13485:2016/A11:2021 - Medical devices - Quality management systems - Requirements for regulatory purposes;
- EN ISO 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements;
- EN ISO 20417:2021 - Medical devices — Information to be supplied by the manufacturer;
- EN ISO 14971:2019/A11:2021 - Medical devices -- Application of risk management to medical devices;
- EN ISO 10993-1:2020 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- EN IEC 62366-1:2015 - Medical devices - Part 1: Application of usability engineering to medical Devices;
- REGULATION (EU) 2017/745;

4. Symbols

Symbol	Name/ Description
	**Name:** Catalogue number **Description:** To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.
	**Name:** Batch code **Description:** To identify the manufacturer's batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol.
	**Name:** Medical Device **Description:** Indicates the item is a medical device
	**Name:** Unique device identifier **Description:** Indicates a carrier that contains unique device identifier information
	**Name:** Country of manufacture **Description:** To identify the country of manufacture of products. The date of manufacture may be added adjacent to this symbol, when separate symbol „Date of manufacture “is precluded.
	**Name:** Date of manufacture **Description:** To indicate the date on which a product was manufactured. The symbol shall be accompanied by a date to indicate the date of manufacture.

Symbol	Name/ Description
	**Name:** Manufacturer **Description:** To identify the manufacturer of a product. Symbol is accompanied, adjacent to the symbol, by the name and, when applicable, the address of the manufacturer.
	**Name:** Do not use if package is damaged **Description:** To indicate that the device must not be used if the package holding the device is damaged, for example on packaging of medical devices.
	**Name:** Fragile; handle with care **Description:** To indicate that the contents of the transport package are fragile and the package shall be handled with care.
	**Name:** Use by date **Description**: To indicate that the device should not be used after the date accompanying the symbol, for example on a medical device or its packaging.
	**Name:** Do not re-use **Description:** To indicate that the item is for single use only and must not be used more than once, for example on packages of medical disposables.
	**Name:** Operator's manual; operating instructions **Description:** Indicates the need for the user to consult the instruction for use
	**Name:** Keep away from sunlight **Description:** To indicate that transport package shall not be exposed to sunlight
	**Name:** Keep dry **Description:** To indicate that the transport package shall be kept away from rain and in dry conditions
	**Name:** Temperature limit **Description:** To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used. The temperature values may be indicated adjacent to the symbol with the minimum temperature at the lower left and the maximum temperature at the upper right.

Dilation until 9 mm

Designed to enter into the vagina at up to 40 mm from the cervix keeping it safe from injury and easily see the entrance to the cervix.

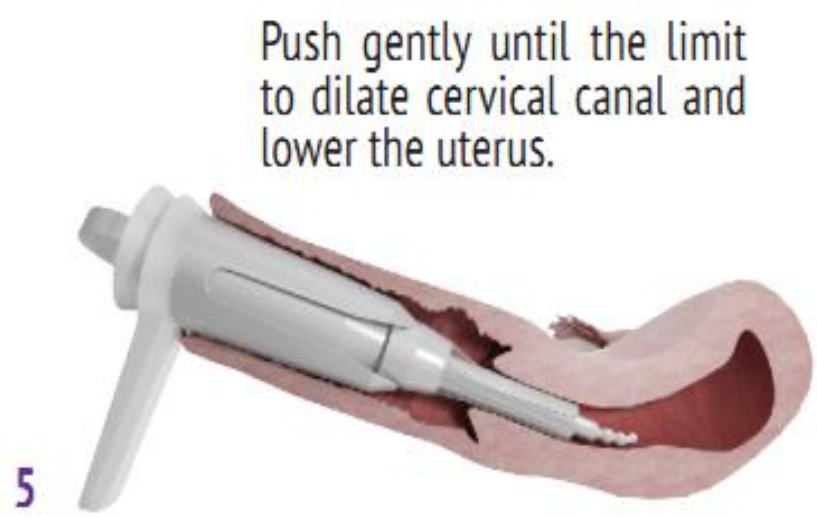
The slightly curved and wider lower part of the dilator fins, **always positioned at the bottom of the canal**, is designed for gentle penetration of the cervical canal while adapting to its natural curvature. By being introduced in an up and down movement, it also allows the dilator fins to be grouped together to eliminate any risk of injury during insertion. It is thinner than the cervical canal, so there is no pressure on the tissues or risk of injury.

3 Position gently the dilator's top in the cervical canal.

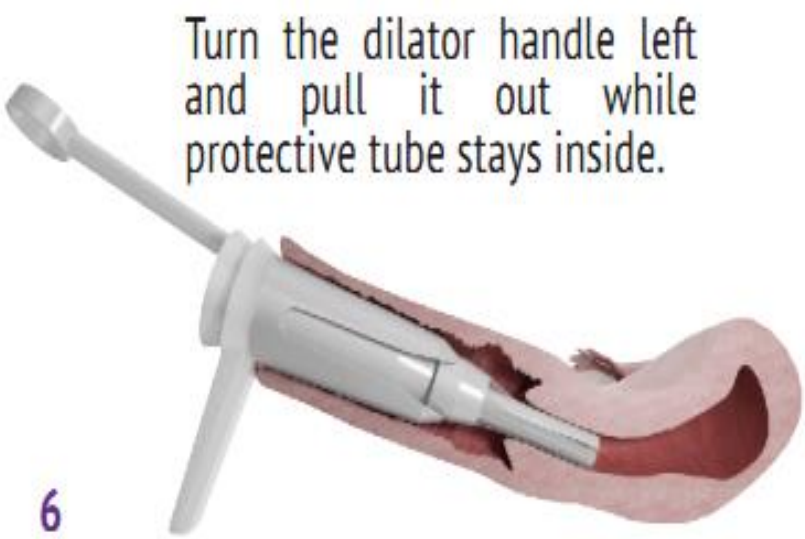
The flexible dilator part enters the cervical canal through the protective assembly made up of the SPECULUM and the DILATOR TUBE. The surrounding tissues are completely protected during dilation and the importation of vaginal bacteria is limited.

4 Enter the dilator into the holder.

Present and insert the DILATATOR ROD and PROTECTIVE FINS assembly into the DILATATOR TUBE with an up and down movement as in photo 4. The natural stop of the parts prevents any risk of perforation of the uterus



The cervical canal is dilated in just 10 seconds. The DILATOR FINS and PROTECTIVE FINS will remain in the cervical canal to protect it from the passage of instruments during the examination or surgery.



With the dilator rod removed, a protected passage of 9 mm allows the introduction of most instruments, without friction or lacerations of the canal.

Dilation from 9 mm to 12 mm

If greater dilation is required (passage of an abortion cannula for example or other) it is appropriate to proceed as follows:

• After removing the protective fins as shown in photo 8 below, leaving the speculum in place, remove the dilator tube and dilator wings assembly from the cervical canal.

• Remove the silicone ring located around the dilator fins so that it is not ejected into the uterus by the future passage of the instruments

• Do not remove the dilator fins

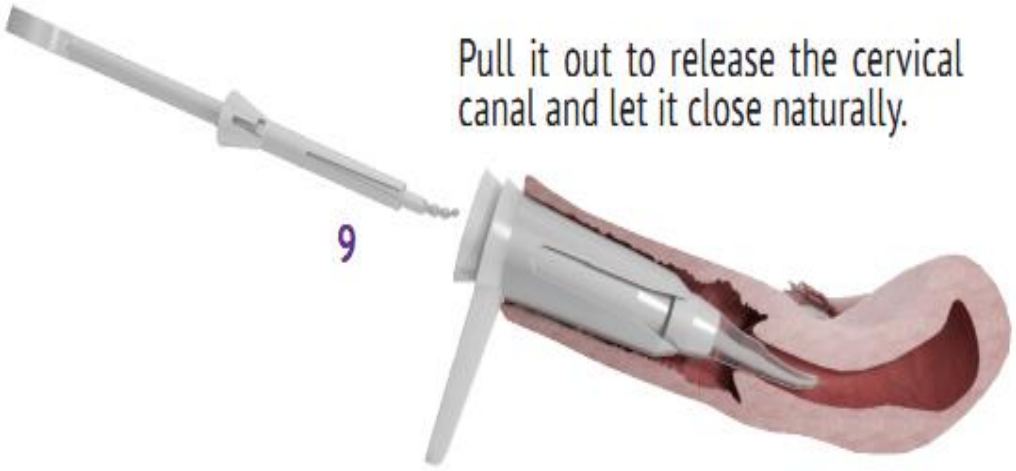
• Insert the assembly, dilator tube and dilator fins, into the cervical canal already dilated to 9 mm, grouping the ends of the wings together so as not to injure the tissues.

• It is the instrument itself (cannula or other) which completes the dilation to the necessary diameter.

• The canal tissues are protected by the dilator fins during the passage of the instruments.

• Once the intervention is completed, remove the assembly as shown in photo 9 below.

After the intervention place the dilator inside, until limit.
Rotate it right to lock the protective tube.



Pull it out to release the cervical canal and let it close naturally.

5. Legal Manufacturer information

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PRODUCT: Powder Free Sterile Nitrile Examination Gloves (Kanam Latex Industries)

Brend: nitrylex® sterile , proHAND®PF NITRILE

RANGE OF SIZES: Small, Medium, Large & X-Large

PPE REFERENCE: This disposable medical device is made up of synthetic rubber latex which is ambidextrous, intended to be used for conducting medical examination, diagnostic and therapeutic procedures, provides barrier against potentially infectious

materials and other contaminants.

REGULATORY REQUIREMENT: Regulation (EU) 2016/425

PICTOGRAMS:

<table>
<tr><th>Sl. No</th><th>Pictograms</th><th>Description of Pictograms</th></tr>
<tr><td>1.</td><td>CE 0598</td><td>CE 0598 is the identification number of SGS notified body
SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland.</td></tr>
<tr><td>2.</td><td>EN 420:2003 + A1.2009
  </td><td>It refers to the Instruction for use as per EN 420:2003 +A1.2009
<table><tr><th>Protective gloves - General Requirements</th><th>Status / Performance level</th></tr><tr><td>Sizing</td><td>Small, Medium, Large & X-Large</td></tr><tr><td>Dexterity</td><td>Performance Level</td></tr><tr><td>5pH Value</td><td>Pass</td></tr></table></td></tr>
<tr><td>3.</td><td>EN 16523-1:2015</td><td>Low chemical resistance pictogram for gloves
<table><tr><th>Resistance to Permeation by Chemical</th><th>Status / Performance level</th></tr><tr><td>n-Heptane</td><td>Class 1</td></tr><tr><td>Sodium Hydroxide 40%</td><td>Class 6</td></tr><tr><td>Hydrogen Peroxide 30%</td><td>Class 1</td></tr><tr><td>Formaldehyde 37%</td><td>Class 2</td></tr></table></td></tr>
</table>

<table>
<tr>
<td>4.</td>
<td>EN 374-1:2016 / Type C
 
JKPT</td>
<td>It refers to the Instruction for use as per EN 420 : 2003 +A1.2009

<table>
<tr><th>Protective gloves - General Requirements</th><th>Status / Performance level</th></tr>
<tr><td>Sizing</td><td>Small, Medium, Large & X-Large</td></tr>
<tr><td>Dexterity</td><td>Performance Level</td></tr>
<tr><td>5pH Value</td><td>Pass</td></tr>
</table>

Tested for protection against liquid penetration and Microorganism.
Resistance to Status / Performance

<table>
<tr><th>Resistance to Penetration</th><th>Status / Performance level</th></tr>
<tr><td>Air Leakage</td><td>Pass</td></tr>
<tr><td>Water Leakage</td><td>Pass</td></tr>
</table>
Low chemical resistance pictogram for gloves
<table>
<tr><th>Resistance to Permeation by Chemical</th><th>Status / Performance level</th></tr>
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</table>
</td>
</tr>
<tr>
<td>5.</td>
<td>EN 374-2:2014
 
LEVEL 2</td>
<td>Tested for protection against liquid penetration and Microorganism.

<table>
<tr><th>Resistance to Penetration</th><th>Status / Performance level</th></tr>
<tr><td>Air Leakage</td><td>Pass</td></tr>
<tr><td>Water Leakage</td><td>Pass</td></tr>
</table>
</td>
</tr>
<tr>
<td>6.</td>
<td>EN 374- 4 : 2013</td>
<td>Resistance to degradation by Chemicals.
<table>
<tr><th>Resistance to Permeation by Chemical</th><th>Observation</th><th>Result in %</th></tr>
<tr><td>n-Heptane</td><td>Slight swelling</td><td>45,9</td></tr>
<tr><td>Sodium Hydroxide 40%</td><td>No Change</td><td>-5,5</td></tr>
<tr><td>Hydrogen Peroxide 30%</td><td>Slight swelling</td><td>31,1</td></tr>
<tr><td>Formaldehyde 37%</td><td>Slight swelling</td><td>21,4</td></tr>
</table>
</td>
</tr>
</table>

<table>
<tr>
<td>7.</td>
<td>EN 374-5:2016
 
VIRUS</td>
<td>It refers to the Instruction for use as per EN 420 : 2003 + A1.2009

<table>
<tr><th>Protective gloves - General Requirements</th><th>Status / Performance level</th></tr>
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<tr><td>Water Leakage</td><td>Pass</td></tr>
</table>

Protection against virus:
Results:
<table>
<tr><th>Test Article Number</th><th>Pre-Challenge Concentration (PFU/mL)</th><th>Post-Challenge Concentration (PFU/mL)</th><th>Assay Titer (PFU/mL)</th><th>Visual Penetration</th><th>Test Result</th></tr>
<tr><td>1-3</td><td>1.6×10^8</td><td>1.3×10^8</td><td><1[a]</td><td>None Seen</td><td>Pass</td></tr>
<tr><td>Negative Control</td><td>1.6×10^8</td><td>1.3×10^8</td><td><1[a]</td><td>None Seen</td><td>Acceptable</td></tr>
<tr><td>Positive Control</td><td>1.6×10^8</td><td>1.3×10^8</td><td>TNTC[b]</td><td>Yes</td><td>Acceptable</td></tr>
</table>
[a] A value of <1 plaque forming unit (PFU)/mL is reported for assay plates showing no plaques.
[b] TNTC = PFUs were too numerous to count.</td>
</tr>
<tr>
<td>8.</td>
<td>EN 388
 
0000</td>
<td>
<table>
<tr><th>Sl. No.</th><th>Mechanical characteristics</th><th>Status / Performance level</th></tr>
<tr><td>a)</td><td>Abrasion Resistance</td><td>Performance Level 0</td></tr>
<tr><td>b)</td><td>Blade cut Resistance</td><td>Performance Level 0</td></tr>
<tr><td>c)</td><td>Tear Resistance</td><td>Performance Level 0</td></tr>
<tr><td>d)</td><td>Puncture Resistance</td><td>Performance Level 0</td></tr>
</table>
</td>
</tr>
<tr>
<td>9.</td>
<td colspan="2">The user information mentioned in product label.</td>
</tr>
</table>

Recommended use of the gloves:

1) Do not resterilize.
2) The product contains Synthetic Rubber Latex.
3) Dry hands thoroughly before donning.
4) Do not use package is damaged or wet.
5) Risk of reuse: Do not reuse, reuse can cause cross infection and compromise safety.

6) Storage information: Keep away from Sunlight.
7) Store in cool dry place, away from direct light & Ozone.
8) “Gloves shall not be worn where there is a risk of entanglement by moving parts of machines” is needed.
9) Dexterity performance level is 5.
10) Intended Usage: To be worn on hands usually in surgical settings\patient examinations to provide barrier against potentially infectious fluids and other contaminants.
11) Expiration Period: 3 years
12) The results do not reflect the actual duration of protection in the workplace due to other factors influencing the performance, such as temperature, abrasion, degradation etc.

Glove Opening and Donning Procedure

a) Remove the Walleted gloves (inner wrapper) from the Pouch (outer wrapper).
b) Open the Walleted glove to see “Left” and “Right” compartment.
c) Pinch back upper and lower flaps of the inner wrapper.
d) Using the middle flaps, open the wrapper touching only the 1-inch margin for safety.
e) Be sure wrapper does not close over gloves after opening to avoid contamination.
f) Using the thumb and the first two fingers of the non-dominant hand, pinch the cuff of the folded edge of the glove cuff for the dominant hand, touching only the inside surface of the glove.
g) Slide dominant hand in to the gloves keeping hand point downwards and pull up to wrist.
h) Using the glove hand insert the 4 fingers under the cuff of the other glove and pull the glove up to the arm.
i) Adjust the gloves as necessary.

Glove Removal Procedure:

a) Take hold of the first glove at the wrist.
b) Fold it over and peel it back, turning it inside out as it goes. Once the glove is off, hold it with your gloved hand.
c) To remove the other glove, place your bare fingers inside the cuff without touching the glove exterior. Peel the glove off from the inside, turning it inside out as it goes. Use it to envelope the other glove.

Warnings:

Sl. No	Pictograms	Description of Pictograms
1.	EN 374-1:2016 / Type C  JKPT	This information does not reflect the actual duration of protection in the work place and the differentiation between mixtures and pure chemicals. The Chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except incases where the glove is equal to or over 400mm – where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture' It is recommended to check that the gloves are suitable for the intended use because the conditions at the work place may differ from the type test depending on temperatures, abrasionand degradation When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc., may reduce the actual use time significantly. For corrosive chemicals, degradation can be themost important factor to consider in selection of chemical resistant gloves. Before usage, inspect the gloves for any defect or imperfections. For Single use only.
2.	EN 374-5:2016  VIRUS	The Penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.

OBM ADDRESS:

MERCATOR MEDICAL S.A UL. H.
MODRZEJEWSKIEJ 30,
31 – 327 KRAKOW, POLAND

UTEROSCOPE KIT (GYNETECH ADVANCE PROCEDURE PACK)

Intended use of procedure pack

Uteroscope Kit contains medical devices the Uteroscope and the Powder Free Sterile Nitrile Examination Gloves which are single-use medical devices intended to be used by gynecologists in clinics or hospitals for interventions in gynecology. Uteroscope Kit is a sterile procedure pack. Uteroscope and Powder Free Sterile Nitrile Examination Gloves are intended to be used together and at the same time by the user. Users use the Uteroscope for interventions in gynecology and Powder Free Sterile Nitrile Examination Gloves for the protection of patients during interventions and for protection of themselves.

Product description

Detailed description of medical devices Uteroscope and the Powder Free Sterile Nitrile Examination Gloves are given in sections above in this document.

Intended user

Only graduated medical staff like gynecologists.

Safety warnings and cautions

Warnings

WARNING: Inspect each device for shipping damage.
WARNING: Do not use if packaging is damaged.
WARNING: Treat used Uteroscope and the Powder Free Sterile Nitrile Examination Gloves as biohazardous infectious material. Dispose of used medical devices with local regulations.

Cautions

Used by trained personnel only.

Symbols

Symbol	Name/ Description	Requirement / note
	**Name:** Catalogue number **Description:** To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.	**ISO 15223-1** **ISO 7000 (Ref No:2493)**
	**Name:** Batch code **Description:** To identify the manufacturer's batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol.	**ISO 15223-1** **ISO 7000 (Ref No:2492)**
	**Name:** Medical Device **Description:** Indicates the item is a medical device	**ISO 15223-1** **MDR (EU) 2017/745**

Symbol	Name/ Description	Requirement / note
	**Name:** Unique device identifier **Description:** Indicates a carrier that contains unique device identifier information	**ISO 15223-1** **MDR (EU) 2017/745**
	**Name:** Country of manufacture **Description:** To identify the country of manufacture of products. The date of manufacture may be added adjacent to this symbol, when separate symbol „Date of manufacture“ is precluded.	**ISO 15223-1**
	**Name:** Date of manufacture **Description:** To indicate the date on which a product was manufactured. The symbol shall be accompanied by a date to indicate the date of manufacture.	**ISO 15223-1** **ISO 7000 (Ref No:2497)**
	**Name:** Manufacturer **Description:** To identify the manufacturer of a product. Symbol is accompanied, adjacent to the symbol, by the name and, when applicable, the address of the manufacturer.	**ISO 15223-1** **ISO 7000 (Ref No:3082)**
	**Name:** Fragile; handle with care **Description:** To indicate that the contents of the transport package are fragile and the package shall be handled with care.	**ISO 15223-1** **ISO 7000 (Ref No:0621)**
	**Name:** Use by date **Description**: To indicate that the device should not be used after the date accompanying the symbol, for example on a medical device or its packaging.	**ISO 15223-1** **ISO 7000 (Ref No:2607)**
	**Name:** Do not re-use **Description:** To indicate that the item is for single use only and must not be used more than once, for example on packages of medical disposables.	**ISO 15223-1** **ISO 7000 (Ref No:1051)**
 eIFU www.gynetechadvance.com	**Name:** Operator's manual; operating instructions **Description:** Indicates the need for the user to consult the instruction for use	**ISO 15223-1** **ISO 7000 (Ref No:1641)**

Symbol	Name/ Description	Requirement / note
	**Name:** Keep away from sunlight **Description:** To indicate that transport package shall not be exposed to sunlight	**ISO 15223-1** **ISO 7000 (Ref No:0624)**
	**Name:** Keep dry **Description:** To indicate that the transport package shall be kept away from rain and in dry conditions	**ISO 15223-1** **ISO 7000 (Ref No:0626)**
	**Name:** Temperature limit **Description:** To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used. The temperature values may be indicated adjacent to the symbol with the minimum temperature at the lower left and the maximum temperature at the upper right.	**ISO 15223-1** **ISO 7000 (Ref No:0632)**
	To indicate that the device is provided sterile.	**ISO 15223-1** **ISO 7000 (Ref No:2499)**

Information of Procedure Pack Manufacturer

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