Thank you for purchasing the KOKEN Tracheostomy Management Simulator. Please read this instruction manual carefully to ensure correct use of the product, and store it in a safe place for easy access.

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Handling and Safety Precautions

These precautions should be strictly observed in order to ensure safe, long-term use of the product.

The following precautions should be observed particularly strictly:

1. This model is manufactured to feel to the touch like a living human body. Forceful or careless handling may damage the model.
2. Under no circumstances must the specially provided tracheal cannula be used on the living human body.
3. Do not leave the specially provided tracheal cannula attached to the trachea for a long period, as this may accelerate hardening of the cuff, making it unusable. Detach the tracheal cannula from the trachea after using the model.
4. Inspect the condition of the cuff before use, since the specially provided tracheal cannula hardens with repeated use. If hardening of the cuff makes it difficult to use, please consider obtaining a new special tracheal cannula for this model, available for separate purchase.
5. Insert the specially provided tracheal cannula using water-soluble lubricating jelly containing glycerol as the main constituent (“K-Y Lubricating Jelly” is recommended). Do not use oil lubricants (e.g., olive oil, Vaseline), alcoholic lubricants, or other lubricants containing organic solvents, as these may cause damage to the cuff.
6. Please do not use oily lubricant (baby oil, olive oil etc.), alcohol lubricant, and lubricant containing organic solvent. These may cause breakage of the model.
7. Use water to practice cleaning or disinfecting the area surrounding the tracheostomy orifice. The use of alcohol or disinfectant may cause deterioration of the neck surface skin.
8. Be careful not to lose the neck surface skin holding plate, as it is not fixed to the model.
9. Be careful to prevent the simulated sputum provided as an accessory from contacting with a living human body (e.g., eyes, mouth). (The simulated sputum is made of cosmetic materials listed in the Japanese Standards of Cosmetic Ingredients and the Japanese Cosmetic Ingredients Codex.)
10. Oily fluid may exude from the neck surface skin. Do not leave the neck surface skin attached to the main body after using the model. Wrap the neck surface skin in a paper towel or piece of gauze and store it in the specially provided plastic zipper bag.
11. Do not place any object on the main body, as doing so may change the model's shape.
12. Store the model in a place where it will not be exposed to direct sunlight or UV.
13. Tube Feeding Components (LM-097C) cannot be attached to this model.
14. This product is intended for use in standard operating environments. Do not use it in heavy industrial settings.
15. This model uses urethane foam for some of its parts, and may be susceptible to damage from pests that are attracted to urethane foam (such as insects in the ant family). When storing this model, ensure that thorough measures are taken to prevent pest damage before storing. The company will not be involved with or held liable for pest damage that occurs during storage.

1. The contents of this instruction manual are subject to change without notice.
2. This instruction manual may not be reproduced in part or in its entirety without permission.
3. Please contact the manufacturer in the event that any errors or omissions are found in the contents of this instruction manual.
4. This product should be used only as described in this instruction manual. In particular, the product should not be used in any way that contravenes the precautions noted in the instruction manual.
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1. Outline and Features

Outline
This model can be used to practice the procedures carried out for tracheostomy patients in the fields of nursing and caregiving when replacing cannulas or performing suction through a cannula. The model can be divided into two halves and the trachea component is transparent, allowing confirmation of the condition of cannula insertion status and the position of the suction catheter in the cannula during suction. In addition, with the specially provided cannula attached, a ventilator can be operated by connecting a test lung (simulated lung) to the model.

Features
・ Allows the user to practice the procedures for replacing cannulas.
・ As the trachea section is transparent, the state of inflation of the cuff can be observed, and by using the specially provided cannula, the approximate optimum pressure can be confirmed. (Because the posterior wall of the trachea is soft, the user can feel the compression of the trachea that results when the cuff is overinflated.)
・ The transparent trachea facilitates explanation of how the suction catheter should be positioned, and of how to perform suction using the upper part of the cuff. (The above mentioned practicing of suction procedures can be performed using the simulated sputum.)
・ The soft neck surface skin allows the user to feel the thyroid cartilage through the surface skin.
・ The detachable trachea section facilitates explanation of the areas where granulation tends to develop.
・ A ventilator can be operated by attaching the specially provided cannula and connecting a test lung, allowing confirmation of the alarm tone generated when air leakage occurs.
2. Components and Configuration

① Main body
② Side of face
③ Trachea
④ Neck skin surface
⑤ Specially provided tracheal cannula (The cuff is colored so that it can easily be identified when attached to the cannula.)
   *Under no circumstances must this specially provided tracheal cannula be used on the living human body.
⑥ Trachea cap
⑦ Neck surface skin holding plate
⑧ Simulated sputum (Viscosity can be adjusted by diluting with water.)
   Storage bag
   Instruction Manual (this document)
3. Handling the Model

3-1. Assembling the Model

① Take the neck surface skin out of the paper wrapping, align the hook and loop fasteners with each other, and attach the neck surface skin to the model.

② Apply water-soluble lubricating jelly (K-Y Lubricating Jelly is recommended) to the tip of the specially provided tracheal cannula, and insert the cannula into the model.

③ Operate the cuff of the specially provided tracheal cannula so as to achieve the optimum pressure [20–33 hPa (20–34 cmH₂O, 15–25 mmHg)] as indicated by the blue line located between the two red lines (“Hi” and “Lo”) on the cuff pressure indicator. In addition, the pressure in the cuff can be measured using the cuff pressure gauge while air is being injected.
3-2. Observing condition of insertion of the Tracheal Cannula and Cuff

① Hold the tag and peel open the neck surface skin.

② Detach the side of face from the main body. When doing so, pull away the side of face gradually, and do not use excessive force, as this might rip off the hook and loop fasteners.

③ Put the neck surface skin holding plate on the neck of the main body, and place the neck surface skin on the plate. Be careful not to lose the neck surface skin holding plate, as it is not fixed to the model.

*The red circle on the cross section of the main body represents the brachiocephalic artery.

*When explaining granulation, indicate the relevant area with the trachea arranged as shown. For greater clarity, indicate the areas of granulation using commercially available stickers etc.
3-3. Attaching Test Lungs

① Remove the trachea cap.

② The trachea has lines indicating the positions for attachment of the trachea cap and for attachment of test lungs designed to be connected over the trachea. Attach the test lung over the trachea by pushing on the lung up to the line indicating the relevant position. Test lungs designed for insertion inside the trachea should be pushed in deeply and firmly.
3-4. Detaching Components

① Remove the specially provided tracheal cannula.
② Detach the neck surface skin from the model in the same manner as in 3-2 ①
③ Remove the trachea.

4. Caring for the Model

1. If stained with lubricant, rinse out the neck surface skin, trachea, and specially provided tracheal cannula with water.
2. Oily fluid may exude from the neck surface skin. After using the model, do not leave the neck surface skin attached to the main body. Wrap the skin in a paper towel or piece of gauze, and store in the plastic zipper bag provided as an accessory.
3. If the neck surface skin becomes sticky, apply baby powder.
4. Stains on the model should be wiped with moist gauze or similar material using water or a neutral solvent diluted with water.
   * Do not use thinner, benzene or similar solvents.
5. After using the model, remove the specially provided tracheal cannula from the trachea, and store it separately. If it remains attached to the trachea for a long period, the cuff will harden and become unusable.
5. How to Attach the Optional Bronchus (sold separately)

The bronchus (LM-097D) and bronchus clasp (LM-097A) for Suction Training Model Type II can be attached to the KOKEN Tracheostomy Management Simulator.

① Remove the trachea cap in the same manner as in 3-3 ①.
② Attach the bronchus clasp to the bronchus for Suction Training Model Type II.

③ Next, push the bronchus onto the trachea up to the position for attachment of the trachea cap, and fasten the bronchus clasp.

④ With the bronchus attached, insert the trachea into the main body.
6. Specifications

<table>
<thead>
<tr>
<th>Product name</th>
<th>Length</th>
<th>Width</th>
<th>Height</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main body</td>
<td>Approx. 39 cm</td>
<td>Approx. 29 cm</td>
<td>Approx. 20 cm</td>
<td>Approx. 1.6 kg</td>
</tr>
<tr>
<td>Case</td>
<td>Approx. 46 cm</td>
<td>Approx. 31 cm</td>
<td>Approx. 22 cm</td>
<td>Approx. 560 g</td>
</tr>
</tbody>
</table>

Total weight: 2.4 kg (including accessories)

7. Replacement Parts (sold separately)

<table>
<thead>
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<th>Product name</th>
<th>Product No.</th>
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</thead>
<tbody>
<tr>
<td>Neck skin surface</td>
<td>LM-106A</td>
</tr>
<tr>
<td>Tracheal cannula (specially provided for KOKEN Tracheostomy Management Simulator)</td>
<td>LM-106B</td>
</tr>
<tr>
<td>Simulated sputum (100 g x 5 pcs)</td>
<td>LM-0701</td>
</tr>
</tbody>
</table>

*Must never be used on living human body.*

Optional items (sold separately)

<table>
<thead>
<tr>
<th>Product name</th>
<th>Product No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchus clasp</td>
<td>LM-097A</td>
</tr>
<tr>
<td>Bronchus</td>
<td>LM-097D</td>
</tr>
</tbody>
</table>
8. Related Products

Suction Training Model Type II (LM-097)

Outline
This model can be used to practice the insertion of suction catheters into the nasal cavity, oral cavity and tracheostomy site, as well as suction procedures, applied in the nursing and caregiving fields. Model Type II also enables the user to practice the procedure for inserting a feeding catheter into the esophagus. The facial region can be divided into two halves along the midline, allowing confirmation of the actual insertion status of a suction catheter and feeding tubes. This model is also suitable for studying the anatomical structure of the nasal cavity, oral cavity and neck.

Suction/Tube Feeding Simulator (LM-097B)

Outline
This model can be used to practice the insertion of suction catheters into the nasal cavity, oral cavity and tracheostomy site, as well as suction procedures, nasogastric tube feeding, and gastrostomy care procedures, applied in the nursing and caregiving fields. The facial region can be divided into two halves along the midline, allowing confirmation of the actual insertion status of a suction catheter and feeding tubes.