

Tierrett Animal Endotracheal Tube

Instructions for use

Contraindicated to re-use

[WARNINGS]

<Combined medical device>

[1] Make sure to check the connection when connecting this product to a breathing circuit, etc. (No problems such as leaks, blockages, loose connections, etc.)

[If the connection is insufficient, it may cause ventilation problems.]

For details, refer to [Precautions], <Important basic caution> [8].

[2] If high-concentration oxygen is administered through this product, do not use a laser scalpel or electric scalpel near the site where this product is used in principle.

[There is a risk of sudden ignition in oxygen, airway burns due to ignition, and the generation of toxic gas.]

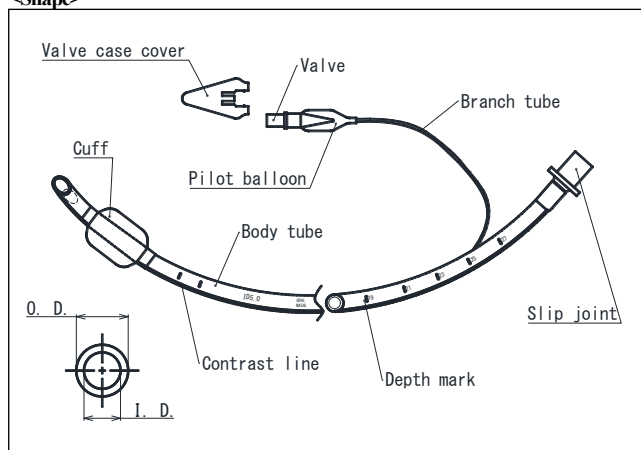
[CONTRAINDICATIONS • PROHIBITION]

Do not reuse the product (single use only).

[Shape, structure, principle]

- This product is sterilized with ethylene oxide gas.
- This product uses polyvinyl chloride (plasticizer: di (2-ethylhexyl) phthalate).

<Shape>



• No cuff

Size	I. D.	O. D.
ID2.0	2.0mm	2.9mm

• With cuff

Size	I. D.	O. D.	Size	I. D.	O. D.
ID2.5	2.5mm	3.5mm	ID6.5	6.5mm	8.7mm
ID3.0	3.0mm	4.2mm	ID7.0	7.0mm	9.3mm
ID3.5	3.5mm	4.9mm	ID7.5	7.5mm	10.0mm
ID4.0	4.0mm	5.5mm	ID8.0	8.0mm	10.7mm
ID4.5	4.5mm	6.2mm	ID8.5	8.5mm	11.3mm
ID5.0	5.0mm	6.8mm	ID9.0	9.0mm	12.0mm
ID5.5	5.5mm	7.5mm	ID9.5	9.5mm	12.7mm
ID6.0	6.0mm	8.0mm	ID10.0	10.0mm	13.3mm

<Raw Materials>

PVC

<Principles>

This product is intubate orally or nasally. With a cuff, air is injected into the cuff to fix and indwell to secure the airway. Connect an appropriate ventilation system to the slip joint.

[Intended purpose, efficacy or effect]

It is inserted into the trachea via the nasal cavity or oral cavity and used to secure the airway.

[Operating or using method]

The below is a general procedure.

<No cuff>

- [1] Remove the product from the packaging material hygienically and carefully, check no abnormalities.
- [2] Make sure that the connection between the tube body and the slip joint is secure and does not come off during use.
- [3] Have the patient take the proper position for intubation.
- [4] Apply an anesthetic near the intubation.
- [5] Guide the tip of this product to an appropriate intubation position using the equipment required for intubation of this product. At this time, in the case of oral intubation, the patient's mouth is opened with one hand, the tongue is excluded by tongue depressor and intubated.
- [6] After intubation, monitor breath sounds and if breath sounds are diminished or absent on one or both sides, adjust the tube position as needed.
- [7] The position of the tracheal tube is confirmed by observing the position of the tube tip on a chest X-ray image.
- [8] Make sure to fix this product with a fixing tool (bandage, etc.). Fix with a bite block if necessary.
[To prevent misalignment after intubation, make sure to fix the tube to the patient in an appropriate way.]
- [9] Connect an appropriate ventilation system to the slip joint.

<With cuff>

- [1] Remove the product from the packaging material hygienically and carefully, check no abnormalities.
- [2] Remove the valve case cover before use.

Fig. 1

Fig. 2

Hold tight the valve case cover and valve as shown in Fig. 1. Keep the valve case cover horizontal and bend the valve down until it comes off the valve case cover as shown in Fig. 2. Discard the valve case cover after removing.



- [3] Make sure that the connection between the tube body and the slip joint is secure and does not come off during use.
- [4] Connect a syringe to the valve of this product, inject air, and make sure that the cuff expands normally.
- [5] After checking the inflated state of the cuff, remove completely the air from the cuff. At this time, the wrinkles of the cuff can be reduced by removing the air while grasping the cuff.
- [6] Have the patient take the proper position for intubation.
- [7] Apply an anesthetic near the intubation.
- [8] Guide the tip of this product to an appropriate intubation position using the equipment required for intubation of this product. At this time, in the case of oral intubation, the patient's mouth is opened with one hand, the tongue is excluded by tongue depressor and intubated.

- [9] When the product reaches the intubation position, hold tight not to move, and gradually inflate the cuff with air using a syringe until the pressure becomes appropriate.
- [10] Make sure that the product is placed in the trachea by performing positive pressure ventilation and examining the patient's chest swelling and auscultation or chest X-ray image.
- [11] Make sure to fix this product with a fixing tool (bandage, etc.). Fix with a bite block if necessary.
[To prevent misalignment after intubation, make sure to fix the tube to the patient in an appropriate way.]
- [12] Connect an appropriate ventilation system to the slip joint.

<Extubation method>

- [1] Disconnect the slip joint and the ventilation system.
- [2] Aspirate the secretions from the top of the cuff and remove the air from the cuff.
- [3] Extubate slowly.

<Precautions for the using method>

- [1] Make sure not to damage the cuff during open and take out the product.
- [2] Test the cuff, branch tube, pilot balloon, and valve for malfunction (leakage / blockage) before use. After checking, remove the air inside the cuff completely.
- [3] Do not block the tube lumen with lubricant.
[The airway may not be open.]
- [4] Make sure not to damage the pilot balloon or cuff with the equipment (forceps, etc.) or internal protrusions (cartilage, etc.) used during insertion.
- [5] Pay attention to the following when inflating or deflating the cuff.
- 1) Use air to inflate the cuff, inject slowly and carefully.
[May damage the tracheal wall.]
 - 2) Use a general slip-type disposable syringe for cuff inflating.
[With a lock type syringe, it is impossible to insert very inside of the valve. If the taper does not match, the valve will be damaged.]
 - 3) Use a clean syringe to keep foreign matter out of the valve.
[Foreign matter (dry body fluid, lint, etc.) may get caught in the valve and the cuff may not inflate.]
 - 4) Make sure to push the tip of the syringe into the valve.
[If the insertion is shallow, it may not be possible to inject or remove air.]
 - 5) When removing the syringe, make sure to hold the valve and rotate the syringe to remove.
[The valve may shift rarely, sometimes come off.]
 - 6) Operate the syringe slowly when shrinking the cuff.
[If the syringe is operated rapidly, the cuff may stick to the cuff hole and the air remaining in the cuff may not be released.]
- [6] Check the cuff pressure during use regularly and manage appropriately.
- [7] Since the cuff pressure gauge cannot be used with this product, the amount of air injected during use should be the amount when the cuff is gradually inflated and the noise due to air leakage disappears by auscultation of the neck.
[May damage the airway wall.]
- [8] Always use a bite block for oral intubation.
[There is a risk of tube blockage and cutting by biting the tube.]
[Ventilation may be impossible by biting the tube.]
- [9] When removing, pull out slowly and carefully because granulation may get caught and this product may not come off easily or bleeding may occur.
- [10] After removal, observe that no symptoms of ventilatory insufficiency such as dyspnea.
- [11] Prepare for tracheal intubation, etc. so that the airway can be secured promptly in case of ventilation failure after removal.

[Precautions]

<Important basic caution>

- [1] Note that di (2-ethylhexyl) phthalate, which is a plasticizer for polyvinyl chloride, may elute from fat-soluble pharmaceuticals or chemicals.
[This product uses polyvinyl chloride.]
- [2] Pay attention to anatomical individual differences such as airway length. Based on sufficient clinical judgment without relying on depth marks. Select a size suitable for each patient based on sufficient clinical judgment.
- [3] Fix it properly with a fixing tool (bandage, etc.) so that the product will not come off.
[The tube may deviate from the trachea due to loose fixing.]
- [4] Properly humidify the patient's airways to minimize coagulation of secretions inside the tube and prevent damage to the tracheal mucosa.
- [5] Make sure to check that the tube does not bend and obstruct the lumen when changing positions or performing surgery in a special position, and the insertion position does not shift when changing the position of the patient.
[Can cause dyspnea and damage to the airway mucosa.]
- [6] Suction is performed as appropriate to prevent obstruction by secretions adhering to the inside of the tube.
- [7] Confirm that the cuff internal pressure and respiratory control status are appropriate after the suction operation.
- [8] When connecting a respiratory circuit, etc. to this product, pay attention not to apply excessive force to this product.
[This may cause deviation from the trachea of this product, disconnection from the respiratory circuit, blockage of this product or the respiratory circuit, etc.]
- [9] Do not pull on the branch tube and pilot balloon.
[May cause a malfunction or leak.]
- [10] Do not connect a 3-way stopcock or an infusion extension tube to the valve of the pilot balloon.
[The valve was damaged when removing the 3-way stopcock, etc., It may not be injected air into the cuff or released.]
- [11] Before measuring the internal pressure of the cuff, make sure that no liquid has accumulated in the branch tube, pilot balloon, etc.
[Condensation events have been reported inside the cuff as water vapor permeates the cuff membrane. May not be possible to accurately measure the internal pressure of the cuff because it is sealed with water due to condensation on the branch tube.]
- [12] Completely remove air from the cuff before inserting or removing the product and fixing its position.
[May damage the trachea.]
- [13] Aspirate the secretions that have accumulated in the oral cavity before remove the air from the cuff.
[When the air is removed from the cuff, secretions may flow into the lungs.]
- [14] If the air cannot be removed from the cuff, cut the branch tube and remove the air.
- [15] Replace with a new one according to the condition of the patient, changes in the affected area, and the condition of the product.
- [16] If you find that the endotracheal tube is about coming off, do not rush and contact your veterinarian immediately. After re-intubation, confirm that the intubation was performed properly by listening to breath sounds.
[If the endotracheal tube is about coming off, the tip of the tube may have already deviated from the trachea. In this case, if the tracheal tube is pushed in as it is, there is a risk of being erroneously inserted into the esophagus.]

<Failures • Adverse events>

Failures

- [1] Burst of cuff
[Burst due to the following causes.]
- Contact with the patient's teeth.
 - Damage due to improper handling when inserting the product (damage by tweezers, forceps, scissors, knives, or other devices)

- Excessive infusion volume (overexpansion)
- Infusion of gas other than air for cuff inflation
- Abrupt load due to self-extubation, etc.
- Other multiple causes due to the above-mentioned events

[2] Disconnection of tube

[Disconnection due to the following causes]

- Damage by tweezers, forceps, scissors, knives, or other devices
- Abrupt load on the product due to self (accidental) extubation
- Excessive load on the product placed when peeling the bandage off abruptly.
- Other multiple causes due to the above-mentioned events

[3] If bite block is not used for oral intubation, it may cause obstruction and disconnection of the tube due to biting of the tube.

[4] Inability of extubation

In the event that the cuff doesn't deflate, deflate the cuff by disconnecting the branch tube under the guidance of a doctor.

[5] Lumen obstruction and damage of the tube

Excessive application of lubricant on the tube may cause lumen obstruction resulting in partial or complete inhibition of ventilation.

[6] Air leakage

Use of the product with attachments insecurely connected to the joint may cause inhibition of ventilation.

Adverse events

When performing endotracheal intubation, the following adverse events are expected:

[1] Adverse events during intubation

Lip injury, tooth injury, pharyngeal mucosa injury, vocal cord injury, bleeding, nasal mucosa injury, inadvertent esophageal intubation, and tracheal injury.

[2] Adverse events during the tube placement

Lumen obstruction in endotracheal tube, movement of endotracheal tube, tracheal injury, pneumothorax, tongue edema, injury/necrosis of the palatine uvula, intranasal injury/necrosis, hypoglossal nerve paralysis, otitis media, and inability of ventilation due to insecure connection with ventilation unit.

[3] Adverse events during extubation

Laryngeal (glottic) spasm, aspiration, pharyngeal pain, pharyngeal edema, recurrent nerve paralysis, pulmonary edema, tracheal injury, pneumothorax, arytenoid cartilage subluxation, laryngeal granuloma, airway narrowing, paradoxical movement of the vocal cord, and cricoid cartilage necrosis.

[4] If bite block is not used for oral intubation, it may cause inability of ventilation due to biting of the tube.

[5] Inappropriate air volume

If air infusion volume in the cuff is inappropriate, it may cause troubles such as injury of the trachea wall and influx of secretion such as saliva to the trachea.

[6] If laser surgical units or electric surgical instruments are used in the vicinity of the product, contact with laser beam or electrode may cause sudden inflammation.

[7] Remains in the body due to the cutting of the tube.

<Other notes>

[1] When performing anesthesia using a gas mixed with nitrous oxide, pay attention to the shrinking and expanding of the cuff.

[It has been reported that nitrous oxide permeates the cuff, increasing the internal pressure of the cuff and damaging the trachea.]

[2] When using this product outside the hospital, healthcare professionals must explain to the handler of this product how to use and operate safely.

[Storage conditions and duration of use]

<Storage conditions>

Store the product hygienically, avoiding the direct sun light, high humidity and ultraviolet rays such as a sterilizing lamp and taking care of wetting.

<Expiration date >

If proper storage is maintained, refer to the expiration date on the individual packaging.

[By self-authentication (our data).]

<Expiration date >

This product has developed as "use within 30 days".

[By self-authentication (our data).]

Manufacturer

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