

# Tierrett Endotracheal Tube for Large Animals

## Instructions for use

### [WARNINGS]

#### <Combined medical device>

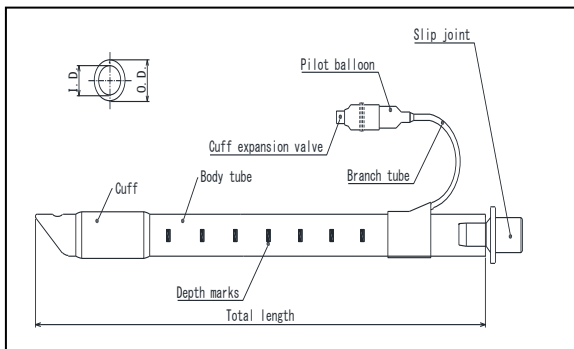
- [1] Make sure to check a connection when connecting this product to a breathing circuit or other equipment. (No problems such as leaks, blockages, loose connections, etc.)  
[An insufficient connection may cause ventilation problems.]  
For details, refer to [Precautions], <Important basic caution> [7].
- [2] When high-concentration oxygen is administered through this product, never use a laser scalpel or an 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]

Never connect this product to a Norman Elbow type connector (the shape of a gas supply inner cylinder inside a connector is protruding in the direction of a patient). For details, refer to the section <Interaction (related to combined use with other medicines, medical devices, etc.)> in [Precautions].

### [Shape, structure, principle]

#### <Shape>



Size	I. D.	O. D.	Total length
ID 7.0	7.0 mm	10.0 mm	600 mm
ID 9.0	9.0 mm	12.0 mm	
ID 11.0	11.0 mm	15.0 mm	
ID 13.0	13.0 mm	18.0 mm	650 mm
ID 15.0	15.0 mm	20.0 mm	750 mm

#### <Raw Materials>

Silicone rubber

#### <Principles>

This product is intubated into the trachea to secure the airway during upper airway obstruction, impaired consciousness, administration of anesthetics, etc. Air is injected into a cuff to fix and indwell to secure the airway. Connect an appropriate ventilation system to a slip joint.

#### [Intended purpose, efficacy or effect]

This product is intubated into the trachea to secure the airway during upper airway obstruction, impaired consciousness, administration of anesthetics, etc. Inject air

into a cuff and fix a catheter tube securely not to move after intubation of the catheter tube.

#### [Operating or using method]

The below is a general procedure.

- [1] Prepare what is necessary for endotracheal intubation according to a case.  
In addition to the size of this product that is assumed to be appropriate, prepare bigger and smaller sizes.
- [2] Remove the product from the packaging material hygienically and carefully, check no abnormalities.
- [3] Inject air into the pilot balloon of this product and check that the cuff expands normally.
- [4] After checking an inflated state of the cuff, remove completely the air from the cuff.
- [5] Have a patient take a proper position for intubation.
- [6] Apply an anesthetic near the intubation.
- [7] 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.
- [8] 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.
- [9] Make sure that the product is placed in the trachea by performing positive pressure ventilation and examining the patient's chest swelling and auscultation.
- [10] Make sure to fix this product with a fixing tool (bandage, etc.). Fix with a bite block if necessary.
- [11] 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] In sterilizing this product, never perform autoclave sterilization.  
[The slip joint and the expansion valve may be damaged.]
- [2] Make sure not to damage the cuff during opening and taking out the product.
- [3] Test the cuff, branch tube, pilot balloon, and valve for malfunction (leakage / blockage) before use. After checking, remove the air inside the cuff completely.
- [4] Never block the tube lumen with lubricant.  
[The airway may not be open.]
- [5] Make sure not to damage the pilot balloon or cuff with the equipment (forceps, etc.) or internal protrusions (cartilage, etc.) used during insertion.
- [6] 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.  
[Inserting very inside of the valve is impossible with a lock type syringe.  
Mismatching taper leads to a damaged valve.]
  - 3) Use a clean syringe to keep foreign matter out of the valve.  
[Foreign matter (dry body fluid, lint, etc.) may be clogged in the valve and the cuff may not be inflated.]
  - 4) Make sure to push the tip of the syringe into the valve.  
[If an insertion is shallow, injecting or removing air may be impossible.]
  - 5) In removing a syringe, make sure to hold the valve and rotate the syringe to remove.

[The valve may shift rarely, sometimes come off.]

6) Operate a syringe slowly when shrinking the cuff.

[If the syringe is operated rapidly, the cuff may stick to the cuff hole and the remaining air in the cuff may not be released.]

[7] Check and manage the cuff appropriately by injecting air or using a cuff pressure gauge, etc.

[8] The pressure inside the cuff should be controlled by the minimum amount of air that can seal the trachea.

[Excessive air injection into the cuff may cause damage of the cuff tracheal and necrosis.]

[9] Always use a bite block for oral intubation.

[Blockage and cutting of the tube may cause by biting a tube.]

[Ventilation may be impossible by biting a tube.]

[10] In removing the cuff, pull out slowly and carefully as granulomas may get caught and this product may not come off easily or cause bleeding.

[11] After removal, observe no symptoms of ventilatory insufficiency such as dyspnea.

[12] Prepare for tracheal intubation, etc. to quickly secure the airway in case of ventilation failure after removal.

### [Precautions]

#### <Important basic caution>

[1] Pay attention to anatomical individual differences such as airway length. Make decisions based on sufficient clinical judgment without relying on depth marks. Select a size suitable for each patient based on sufficient clinical judgment.

[2] Fix this product properly with a fixing tool (bandage, etc.) not to come off. [The tube may deviate from the trachea due to loosen fixing.]

[3] Properly humidify the patient's airways to minimize coagulation of secretions inside the tube and prevent damage to the tracheal mucosa.

[4] Make sure to check that the tube does not bend to obstruct the lumen during repositioning or surgery in a special position. Also, make sure to check the insertion position does not shift when changing the position of a patient. [Can cause dyspnea and damage to the airway mucosa.]

[5] Perform suction as appropriate to prevent obstruction by secretions adhering to the inside of the tube.

[6] Check that the cuff internal pressure and respiratory control status are appropriate after the suction.

[7] In 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.]

[8] Never pull on the branch tube and the pilot balloon. [May cause a malfunction or leak.]

[9] Never connect a 3-way stopcock or an infusion extension tube to the valve of the pilot balloon. [The valve was damaged when removing a 3-way stopcock, etc., it may not be injected air into the cuff or released.]

[10] Before measuring the internal pressure of the cuff, make sure that no liquid is 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.]

[11] Completely remove the air from the cuff before inserting or removing the product and fixing its position. [May damage the trachea.]

[12] 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.]

[13] If the air cannot be removed from the cuff, cut the branch tube and remove the air.

[14] Replace with a new one according to the condition of the patient, changes in the affected area, and the condition of the product.

[15] If you find that the endotracheal tube is about coming off, do not rush and contact your veterinarian immediately. After re-intubation, check 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.]

#### <Interaction (related to combined use with other medicines, medical devices, etc.)>

##### 1. Contraindications for combined use

Names of medical devices, etc.	Clinical symptoms / measures	Mechanism / risk factors
A medical device with a Norman Elbow type connector (the shape of a gas supply inner cylinder inside a connector is protruding in the direction of a patient)	Do not connect to this product.	This product may be occluded, causing hyperinflation of the lungs and inability to ventilate.

##### 2. Precautions for combined use

Names of medical devices, etc.	Clinical symptoms / measures	Mechanism / risk factors
A laser treatment device An electrosurgical device	When high-concentration oxygen is administered through this product, in principle, do not use a laser treatment device (a laser scalpel) or electrosurgical device (an electric scalpel) near the site where this product is used.	Using a laser treatment device (laser scalpel) or electrosurgical device (electric scalpel) in oxygen leads to suddenly igniting and a burned airway due to the ignition or a toxic gas outbreak.
A hyperbaric oxygen therapy device	Pay attention to inflate and deflate of the cuff.	Inspiratory leakage and tracheal damage may occur.

#### <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] Disusing a bite block for oral intubation may cause obstruction and disconnection of the tube due to biting of the tube.
- [4] Inability of extubation  
If 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**

In 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] Disusing a bit block for oral intubation 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] In 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] In 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).]

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