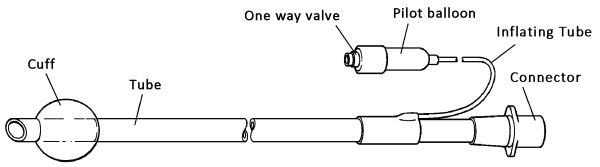
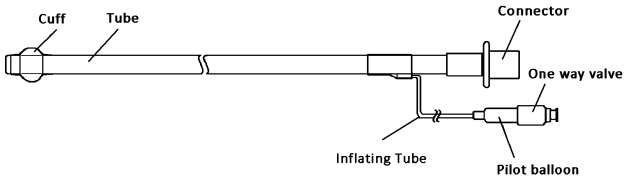
Endotracheal Tube, Wire Reinforced, With Cuff
Endotracheal Tube, Wire Reinforced, With Cuff Long Type

Fuji Systems

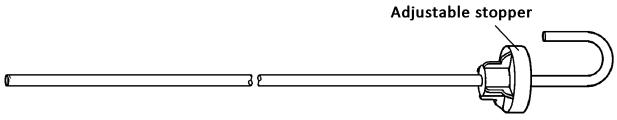
Device Description :
- The products are made of medical-grade silicone, has two types "With Cuff" and "With Cuff Long Type".
- A stylet is provided to facilitate oral intubation.



With Cuff Type



With Cuff Long Type



Stylet

Indications for Use :
Endotracheal Tubes are intended for oral / nasal intubation and are indicated for use in airway management and other suitable medical application.

Warnings :
[General]
- Do not use if the sterile package is open, wet or damaged.
- Avoid contact of laser beam or an electrosurgical knife in the immediate area. Such contact can result in a sudden ignition of Endotracheal Tube in the presence of mixtures of nitrous oxide and oxygen or pure oxygen.
- Do not use the stylet in nasal intubation.
- Do not undergo MRI scans while the product is intubated. Metal parts are used in this product.

[Cuff Related]
- Do not over-inflate the max cuff volume.
- Do not use the product if air leakage and / or odd expansion is observed on the cuff during the inflation test.
- The cuff should not be treated with forceps or the like. This may damage the cuff.
- Use only air to inflate the cuff.

Precautions :
[General]
- Single use only (If the product is to be re-used, it may cause infection to patients or damage to the product).
- It should not be replaced with a new piece of the same type after 30 days of use.
- Use by "Use-by" date.
- Care must be taken to avoid occlusion at the tip part of Endotracheal Tube when applying lubricant.
- Tube depth mark is only an indication to judge setting the cuff. Expert clinical judgment should be exercised in positioning the tip and the cuff in patient's trachea.
- Additional process including pulling with excessive force, adjusting the length and making holes should not be done.
- Do not pull the inflating tube with a tension more than 9.8 N (1.0 kgf).
- Respiratory circuits of the respirator must be fit with standard 15mm connector. The 15mm connector of this product must be fit firmly with the respiratory circuits.
- Do not use a device that has been damaged. Use of damaged devices may result in complications.

[Cuff Related]
- Conduct inflation test for the cuff prior to use.
  The suggested maximum cuff volume for inflation test is refer to the following tables.

Table 1. Cuff inflation volume for "With Cuff"

Size (Fr)	16	18,20	22,24,26	28,30	31,33,35,37,40
Max Cuff Volume (mL)	10	15	30	40	50

Table 2. Cuff inflation volume for "With Cuff Long Type"

Size (Fr)	24,26,28,30	31	33,35	37,40
Max Cuff Volume (mL)	7	8	10	12

- After cuff inflation test, remove air completely (until the pilot balloon is completely deflated) from the cuff.
- When inflating the cuff, make sure that fibers and other objects do not enter from the valve.
- When inflating the cuff, use a clean syringe.
- Thoroughly lubricate the entire cuff including the tip at the tube before intubation. Not applying lubricant may result in damage to the cuff, or may be traumatic to the patient's trachea.
- The internal pressure (or inflation volume) of the cuff should be determined by expert clinical judgement. Excessive inflation may damage the cuff or may be traumatic to the patient's trachea.
- After inflation of the cuff, disconnect the syringe from each valve. Leaving the syringe attached will keep the valve open, permitting air to come out.
- The inflation condition of the cuff should be monitored at all times. Due to gas diffusion through the cuff, the internal cuff pressure (or inflation volume) changes over time. If inflation or deflation of the cuff is required, be sure to remove air completely from the cuff (until pilot balloon is also collapsed) first and then inflate the cuff again to the appropriate volume.
- Before intubation, extubation, and adjustment of the cuff position, be sure to remove air completely from the cuff (until pilot balloon is also collapsed). Otherwise, it may damage the cuff or may be traumatic to the patient's trachea.

Recommended Procedure :
The followings are general directions for use.
Expert clinical judgement should be exercised for each individual patient.
1. Remove the product from the sterilized package carefully and check to see that it is not damaged.
2. Check for defects such as air leakage or odd inflation by injecting air into the cuff using a syringe.
3. After checking the cuff, completely remove all air from the cuff and disconnect the syringe from the valve.
4. Intubate the product orally into the trachea.
5. Connect syringe to one way valve and inflate the cuff until suitable seal can be reached.
6. When connecting to respirator, make sure the 15mm connector is firmly attached to the respiratory circuit.
7. Cuff pressure should be monitored after intubation.
8. Extubation should be performed currently accepted medical techniques.
9. Discard the Endotracheal Tube.

Adverse Reactions :
The following adverse reactions have been reported to be associated with the use of Endotracheal Tube during the intubation procedure, the intubation period, or in extubation procedure. The order of listing is alphabetical and does not indicate frequency or severity: cartilage necrosis; consequences of failure to ventilate including death; damage to the perichondrium; emphysema; rhinorrhagia; excoriated membranes of pharynx; glottic edema; pharyngitis; sinusitis; laryngeal obstruction; laryngeal stenosis; bronchitis; submucosal hemorrhage; tracheorrhagia; tracheal stenosis; traumas (lips, pharynx, trachea, glottis, and etc.).

Storage Conditions :
Keep the product dry and store in clean conditions, avoiding high temperature, humidity and direct sunlight.

Symbols Used on Product Labels :

	Caution
	Do not re-use
	Contains or presence of phthalate
LOT	Lot number
REF	Catalogue number
STERILE EO	Sterilized using Ethylene Oxide
	Use-by date
CE 2797	CE Marking
EC REP	Authorized Representative in European Community
	Manufacturer

Authorized Representative in European Community :

EC REP **Dr. Hans-Joachim Lau**

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