

Urgent Field Safety Notice

Fannin *Integral* Silicone Laryngeal Mask - standard size 2 (single use)

Date: 18th July 2015

Attention: Healthcare Professionals

INCORRECT WEIGHT INFORMATION PRINTED ON TUBE

Details on affected devices:

Product code **LM2010S2**

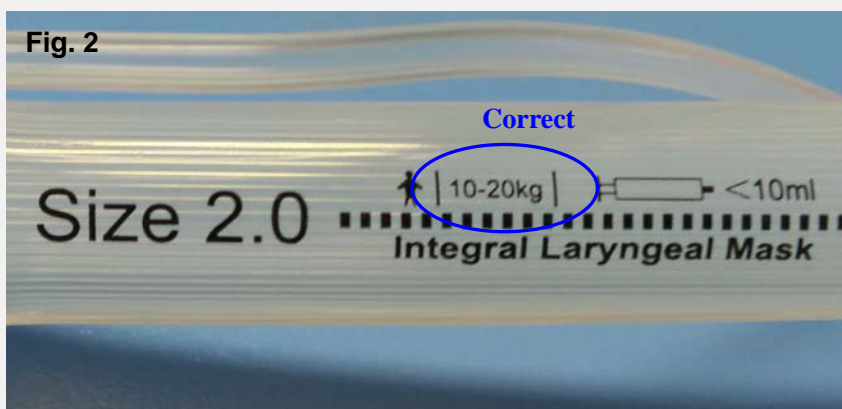
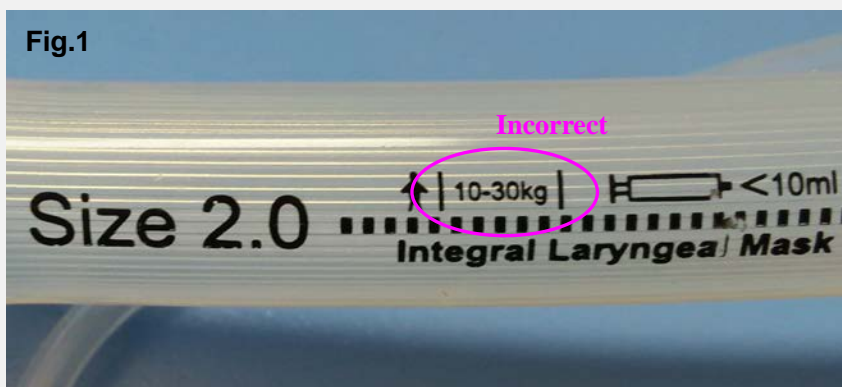
Product description **Fannin *Integral* Silicone Laryngeal Mask - standard size 2 (single use)**

Lot numbers 141006, 141020, 141115, 141204, 150107 and 150112

Description of the problem

There is a printing error on the tube of the Fannin *Integral* Silicone Laryngeal Mask - standard size 2 (single use).

A size 2 is recommended for the patient weight of 10-20Kg but has been printed on the tube as 10-30Kg. The printing error is shown in Fig. 1; the correct print is shown in Fig. 2.



Health Hazard Assessment

1. Normal use of the product

Intended Use:

A Fannin *Integral* Silicone Laryngeal Mask is applied to assist patient breathing during anaesthesia and artificial ventilation. After Fannin *Integral* Silicone Laryngeal Mask insertion into the laryngopharynx and subsequent cuff inflation, the laryngopharynx will be sealed which assists with patient breathing and may be also used under positive pressure ventilation.

Product sizes and recommended patient weight ranges --Table 1

Size	Patient weight
1	< 5 Kg
1.5	5-10 Kg
2	10-20 Kg
2.5	20-30 Kg
3	30-50 Kg
4	50-70 Kg
5	70-100 Kg

2. Description of potential risk

Due to incorrect weight range printing, it may lead to incorrect size choice. For example, a size 2 may be chosen for a 25 Kg patient rather than the recommended size 2.5 (see Table 1).

3. Assessment of risk occurrence

3.1 All Fannin *Integral* Silicone Laryngeal Masks - standard size 2 (single use) are correctly marked on the manufacturing internal lot number documents and all corresponding patient weight information on individual pouches are correct (see Fig. 3). Also, the weight information on box, carton and IFU are all correct. If a Fannin *Integral* Silicone Laryngeal Mask is required, clinicians will choose the size according to a patient's weight. Before use, clinicians check the size on unit label as preparation so the possibility of using an incorrect Fannin *Integral* Silicone Laryngeal Mask size is extremely low.

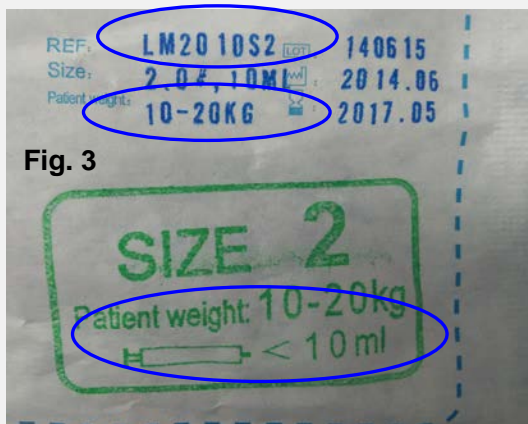
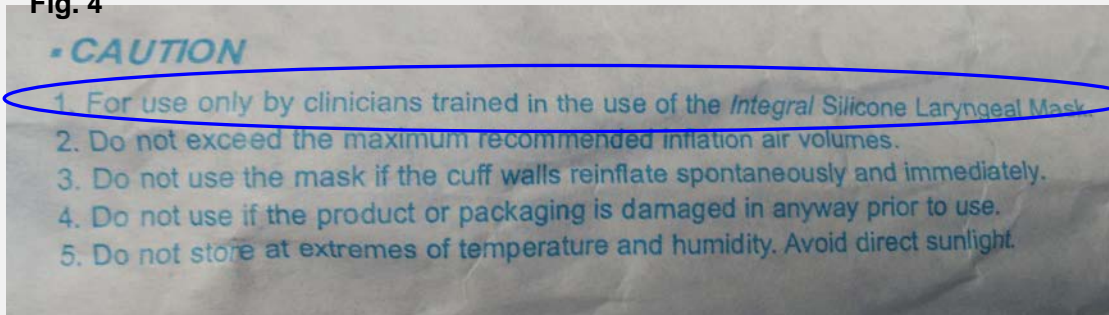


Fig. 3

3.2 On each pouch, under Caution, it states, “For use only by clinicians trained in the use of the Fannin Integral Silicone Laryngeal Mask”, (Fig. 4). The possibility of choosing the wrong Fannin Integral Silicone Laryngeal Mask size is very low.

Fig. 4



4. Corrective Action

Although the possibility of using the incorrect Fannin *Integral Silicone Laryngeal Mask* size is very low, this Field Safety Notice (FSN) has been issued to inform all our customers.

Please refer to the correct weight information on the individual pouch, box/carton labels and IFU but not the printing on the tube of the highlighted Fannin *Integral Silicone Laryngeal Mask* - standard size 2 (single use) lot numbers.

If you have any questions or concerns, please contact Fannin Ltd., our exclusive UK and Ireland distributor.

QA Manager *Phyllis Liang*

Signature : *2015.07.24*

Integral Medical Products Co. Ltd