Endo Tools Therapeutics S.A.
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Manufacturer FSCA reference: FSCA-2101

Gosselies, April 19, 2021

Object: Information – reinforcement of contraindication in the endomina® v2 and endomina® v2 mini IFU

Dear customer,

We are writing today to inform you about a reinforcement in the contraindication section in the endomina® IFU. The subject device are the endomina® v2 (Model IA-EM8616610505-00) and endomina® v2 mini (Model IA-EMx16x61x19x-00), all manufactured batches.

Description of the event:
An incident occurred on April 14, 2021 during a procedure with an endomina® v2 device. When removing the platform at the end of the procedure, the hypertrophic right tonsil of the patient was blocked between the shoulders, the active and passive leg of the endomina® platform at the level of the pharynx leading to the impossibility to remove the platform as usual. Healthcare professionals used endoscopic grasping forceps to push the trapped tissue out of the platform. The endomina® could then be easily removed as intended.
This incident led to the patient transfer in intensive care unit under intubation for the night as a precautionary measure due to tonsillar swelling and oedema of the epiglottis. Patient was extubated without complication the next morning.
Following our investigation, it has been showed that the platform blockage was due to the oedema probably caused during the intubation of the patient and due to the patient medical background with a known hypertrophy prior to using the device which may have been worsened by the intra-procedure movements.

Patient risk:
No patient risks associated with the use of the endomina devices are identified. The contraindication section of the IFUs is reinforced and extended as follows: “Oesophageal malformations” is replaced with “**Any malformations from mouth to oesophagus (incl. pharynx)**”.

Action to be taken by customers:

- ❑ Customers are invited to take into account this information for their future procedures.
- ❑ Please acknowledge receipt of this letter by sending us an email at regulatory@endotools.be or to your regular ETT contact.

Competent authorities in countries in which devices are distributed have been informed.

For any question or complementary information please contact: regulatory@endotools.be

Sincerely,

Karine Pruvost,
Regulatory and Quality Manager

Karine Pruvost
(Signature)
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