Brignais, the 20/05/2022

Object :

Field Safety Notice – Recall

end-ball® intra-gastric system balloon, reference ENDT110

Type of action :

Field safety notice for distributors and end-users

1- Affected device

Batches 22-0001, 22-0002 and 22-0003 of end-ball® intra-gastric balloon, ENDT110.

2- Description of the problem

The ENDALIS company initiates a field safety notice following several customer complaints related to needles of the introduction system remaining stuck in the valve of the balloon at the time of its release in the patient's stomach (material vigilance issued by ENDALIS to the competent authorities).

To date, at least 6 devices have been concerned by this default.

The potential hazards identified associated with continued use of these devices are: increased procedure time, pharyngoesophageal, duodenal and/or gastric wall injuries/perforations, need for an additional medical procedure.

3- Actions undertake by the manufacturer

Considering the nature of the potential hazards identified, ENDALIS has decided to take the following measures:

- Recall of the devices of the concerned lots.
- Isolation of the stock of devices from the affected batches.
- Investigation of the origin of the problem and implementation of appropriate modifications.

4- Actions to be taken by the user

- Identification of devices from the lots affected by the recall.
- Quarantine the devices.
- Return, without delay, the affected devices to the following address:

ENDALIS
1 Allée des Tilleuls
69530 Brignais
FRANCE

- Sending of the attached acknowledgement of receipt by e-mail (padenis@endalis.com, qualite@endalis.com) within 5 working days, even if you do not have any devices concerned by the batch recall.

5- Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

6- Contact reference person

If you have any questions, please contact us:

Country	Address	Contact	Phone	E-mail
France	ENDALIS 1 Allée des Tilleuls 69530 Brignais	Pierre-André DENIS Marie-Ange BOILLETOT	(33)435575700	padenis@endalis.com qualite@endalis.com

The ENDALIS company confirms that the French heath Competent Autorithy (ANSM) was informed of the FSN.

Signature :

Pierre-André DENIS

Acknowledgment of receipt

The undersigned confirms that he/she has received the FSN of 20 May 2022 and he/she will act accordingly.

Country:

Name:

Name of the notified body:

Do you have any affected devices to return :

☐ Yes : Batch number …… Quantity: ……
Batch number …… Quantity: ……
Batch number …… Quantity: ……

☐ No

Date and signature :