Brignais, the 10/02/2023

Object :

Field Safety Notice

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

Type of action :

Field safety notice for distributors and end-users

1- Affected device

Batches 21-0014, 22-0015 and 22-0016 of end-ball® intra-gastric balloon, ENDT110.

2- Description of the problem

1) The ENDALIS company initiates a field safety to notify the use of an alligator clamp in case of a needle locked in the balloon during release.

The potential hazards identified associated with removal of the balloon with the needle locked without the alligator clip: increased procedure time, pharyngoesophageal, duodenal and/or gastric wall injuries/perforations, need for an additional medical procedure.

The device IFU (Instructions For Use) and the user manual have been updated at June 2022 with these instructions.

3- Actions undertake by the manufacturer

Changes to the notice at June 2022:

The major changes made are:

1) Addition of the need to **have an Alligator clamp available in case of complications during procedure**, section 8.1.b of the instructions for use: "The practitioner must ensure they have the appropriate equipment available for removing the balloon in case of complication during insertion (needle locked in the balloon during release, balloon leakage, for example):

- Alligator clamp
- ENDAC03 extraction kit".

2) Addition of a point to check when performing the procedure, section 8.1.b of the instructions for use: "**The correct placement of the balloon in the stomach before inflation and release**".

3) Addition of recommendations on **what to do in case of a needle stuck in the balloon during release**, section 8.1.c of the instructions for use: "After releasing the balloon, under endoscopic control, check that the balloon is properly inflated (tight bag, smooth appearance, etc.), the correct positioning and freedom of movement of the balloon in the stomach and the integrity of the balloon. This ensures that the introducer needle is disconnected from the balloon and there is no leakage. If the introducer needle remains locked in the balloon after delivery or if a leak in the balloon is detected, the balloon should be removed immediately using suitable equipment (e.g. Alligator clamp for removing the locked needle, ENDAC03 extraction kit in the event of a leak)".

4) Addition of recommendations on **visual inspection** of the device, section 8.1.c of the instructions for use: "A visual inspection of the introduction system must be carried out after its removal (in particular, the presence of the inflation needle)".

These measures impact newly marketed devices and those already on the market, and have no influence on the devices already implanted in patients.

Changes to the user manual at June 2022:

The major changes made are:

1) Addition into the procedure, section 1 of the user manual: “Have the appropriate equipment available for removing the balloon in case of complication during installation (ENDAC03 extractor kit, Alligator clamp)”.

2) Modifications of the titles of sections 2, 3 and 4:

- 2. Insertion **under endoscopic control**
- 3. Filling **under endoscopic control**
- 4. Releasing **under endoscopic control**

3) Addition in the list of elements to check after releasing of the balloon, section 4 of the user manual: “Under endoscopic control, check the position, **integrity** and mobility of the balloon in the stomach.”. As well as the paragraph “After releasing the balloon, under endoscopic control, check that the balloon is properly inflated (tight bag, smooth appearance, etc.), the correct positioning and freedom of movement of the balloon in the stomach and the **integrity of the balloon**. **This ensures that the introducer needle has not remained in the balloon valve and there is no leakage from the balloon**.”.

4) In the list of actions to be taken after the balloon is released, section 4 of the user manual: “Second, remove the catheter: **check its integrity (in particular, the presence of the inflation needle)**.”

Please note that the instructions for use and the user manual are going to be updated again soon by ENDALIS to provide more details on what to do in case of a blocked needle in the balloon valve. The following elements will be added:

"In case of complications during delivery related to the needle stuck in the balloon valve after its release, the following steps should be performed in order:

1. Drill the balloon in several places with the ENDAC03 Extraction Kit draining needle to allow for gradual deflation
2. Once the balloon is sufficiently deflated, if possible, make a cut in the balloon with endoscopic scissors
3. Grasp the needle stuck in the balloon with the Alligator clamp
4. Gently remove the balloon.

These items will be added to the instructions for use and user manual, which will then be included in future marketed devices.

4- Actions to be taken by the user

- The update of the notice and the user manual (June 2022) must be taken into account by the user each time the end-ball® intra-gastric system balloon ENDT110 is used.
- Sending of the attached acknowledgement of receipt by e-mail (padenis@endalis.com, qualite@endalis.com) within 5 working days.

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

Signature :

Pierre-André DENIS

Acknowledgment of receipt

The undersigned confirms that he/she has received the FSN of 10 February 2023 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 :