URGENT: Medical Device Field Safety Notice

IMPORTANT INFORMATION

To: Distributors / Resellers / Hospital Professionals
Date: 14th of September 2020
REF: CAPA-2020003

Dear Customer,

Bien-Air Surgery SA, manufacturer of OSSEODUO/OSSEOUNO/OSSEODOC/OSSEOSTAP control units, has initiated a **Field Safety Corrective Action** affecting devices that you may have in stock or may have further distributed in your territory. The details of this action are specified below.

This notice needs to be passed onto all those who need to be aware within your organization or any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations 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.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

This field safety corrective action is conducted with the full knowledge of Swissmedic and subject to their supervision.

We request that you **read this notice carefully and follow the instructions** given.

PRODUCT	The Field Safety Corrective Action is **only applicable to the foot pedals** that are used to drive micromotor in conjunction with the following control units: - OSSEODUO - OSSEOUNO - OSSEODOC - OSSEOSTAP Bien-Air Surgery SA's foot pedals impacted by this Field Safety Corrective action are identifiable as follows: **Product Name**: OSSEODUO foot pedal **Product Reference Number** (Bien-Air Surgery's catalogue): **Ref. 1600517** **&** **Product Name**: OSSEODOC foot pedal (used with OSSEOUNO&OSSEODOC) **Product Reference Number** (Bien-Air Surgery's catalogue): **Ref. 1600407** **&** **Product Name**: OSSEOSTAP control unit **Product Reference Number** (Bien-Air Surgery's catalogue): **Ref. 1600686**

Bien-Air Surgery SA
Offices Route de Soleure 1 CH-2504 Bienne Phone +41 (0)32 344 64 40 surgery@bienair.com
Registered office & Production Rue de l'Ouest 2b CH-2340 Le Noirmont Phone +41 (0)32 953 35 35 www.bienair.com

<table>
<tr><td></td><td>
Product Serial Number: See below table for the impacted SN
<table>
<tr><th colspan="2">16YZZZZ</th><th colspan="2">17YZZZZ</th><th colspan="2">18YZZZZ</th><th colspan="2">19YZZZZ</th></tr>
<tr><td>16A
16B
16C
16D
16E
16F
16G
16H
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16J
16K
16L</td><td>0001 up to 9999</td><td>17A
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18L</td><td>0001 up to 9999</td><td>19A
19B
19C
19D
19E</td><td>0001 up to 9999</td></tr>
</table>
<table>
<tr><td colspan="2">Where to find the foot pedal’s reference and serial numbers:</td></tr>
<tr><td>On the bottom</td><td>Zoom on the label</td></tr>
<tr><td>  </td><td> 
</td></tr>
</table>
</td></tr>
<tr><td>REASON</td><td>This field safety corrective action has been initiated because there is a low possibility that the magnet located inside the foot pedal displaces or comes off during a surgery and therefore may compromise the device’s safety.
The use of the incriminated devices may entail a risk of unattended start or unstoppable motor when acting on the foot pedal and Bien-Air Surgery SA intends to undertake the below actions to mitigate the risk.</td></tr>
<tr><td>HEALTH HAZARD ANALYSIS</td><td>Before implementing and releasing this Field Safety Corrective Action, Bien-Air Surgery SA performed a detailed Health Hazard Analysis (HHA) following its internal procedure. The Health Risk Index was defined as LOW due to a very low occurrence probability. By implementing this Field Safety Corrective Action, the occurrence probability becomes negligible to assure full safety use of the device. To date, no patient injury has been reported.</td></tr>
<tr><td>IMPORTANT INFORMATION</td><td>Bien-Air Surgery SA was able to show that this hazardous situation is mainly linked to high shocks during installation or use of the foot pedal. We therefore ask the users to treat this device with great caution and to avoid shocks.

Bien-Air Surgery SA will implement curative (immediate and temporary) and corrective (long term) actions to prevent the magnet coming off:
- Curative actions, as described below, must be implemented by a healthcare professional in order to ensure device safety until the corrective actions are implemented.
- Corrective actions will follow shortly after the release of this Field Safety Notice. Bien-Air Surgery SA will provide detailed information in a separate document. The expected corrective actions availability is December 2020, at the latest.</td></tr>
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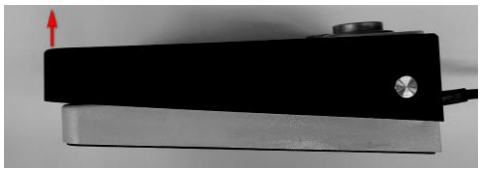
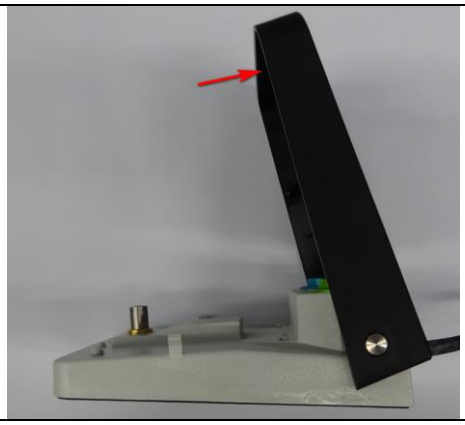
CURATIVE ACTIONS

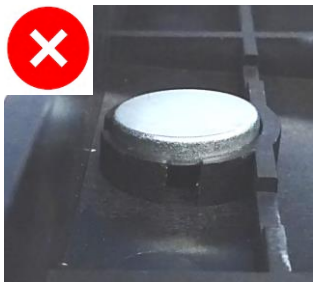
Please find below the procedure to follow for the curative actions:

1) Inspect your inventory for the product numbers/serial numbers above.
2) Quarantine any of the affected products until performing the following actions
3) Open the foot pedal rocker to have access to the incriminated magnet by pulling the black part





4) Carefully inspect the position of the magnet using the below illustration. When slightly pressing on the magnet, it shouldn't move.

The magnet is well positioned	The magnet is partially off or moves when pressing	The magnet is fully off
		
Continue with action N°5	KEEP THE FOOT PEDAL IN QUARANTINE (DO NOT USE IT ANYMORE), contact your local representative for Bien-Air Surgery products who will organize the repair	

5) Carefully clean the plastic area around the magnet with a disinfectant wipe (e.g. alcoholic solution) and a swab to correctly clean the corners

6) Make sure the surface is clean and dry before applying an adhesive tape (e.g. Scotch®, width between 10-15mm, length between 55-60mm) as described below

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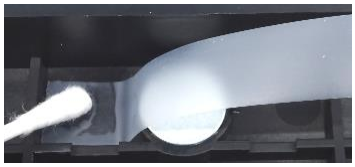
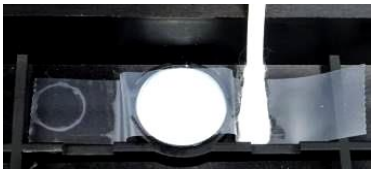
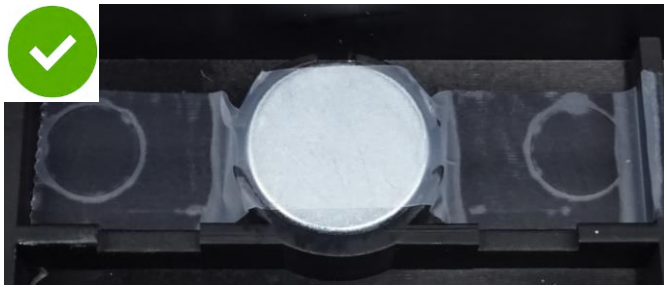




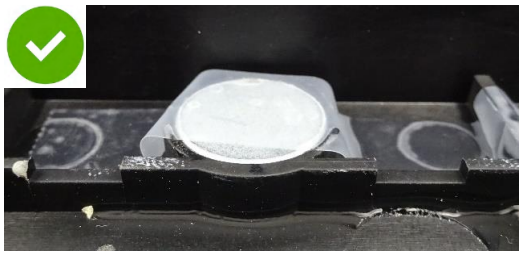
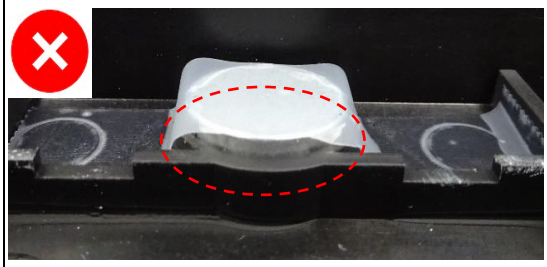
Adhesive tape correctly applied



Too short	Too width, not correctly applied
	

THE FOLLOWING ACTIONS MUST BE PERFORMED BEFORE EACH SURGERY

7) Carefully inspect that the adhesive tape is correctly holding the magnet and that the magnet is still correctly positioned. If needed, remove the tape and restart the process from step 4.

The adhesive tape is correctly applied and the magnet correctly positioned	The adhesive tape is correctly applied but the magnet NOT correctly positioned
	
Continue with action N°8	KEEP THE FOOT PEDAL IN QUARANTINE (DO NOT USE IT ANYMORE), contact your local representative for Bien-Air Surgery products who will organize the repair

8) Close the foot pedal rocker, connect the foot pedal cable to the control unit and switch it ON
9) Proceed with the following tests before performing the surgery
    a. Select one motor (BASCH, 80K, NANO, RAPIDO) or one handpiece (S120,

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	OSSEOSTAP, PERFO) depending on your needs b. Hold the motor or handpiece carefully in your hand c. Press the foot pedal until its maximal position and release it d. The motor or handpiece should run and then stop immediately. If it is not the case, you must **KEEP THE FOOT PEDAL IN QUARANTINE (DO NOT USE IT ANYMORE)**, contact your local representative for Bien-Air Surgery products who will organize the repair. If the motor or handpiece is **stopped immediately**, the system is ready for the surgery
OTHER INFORMATION	Bien-Air Surgery SA regrets the inconvenience caused to you by this action and would like to thank you for your co-operation in this matter. We are kindly requesting you to acknowledge this notification by sending us back the below reply form as soon as possible. It is important that your organisation takes the actions detailed in the Field Safety Notice and confirms that you have received the Field Safety Notice. Your organisation's reply is the evidence Bien-Air Surgery SA needs to monitor the progress of the corrective actions. Should you require any further information or have any queries on the matter please do not hesitate to contact Bien-Air Surgery SA's at: - qa.bienair.surgery@bienair.com - **+41 32 953 35 35**.

On and for the behalf of Bien-Air Surgery:

Arnaud Billot	Jonas Guerdat	Juan Elices
Regulatory Affairs Manager	CTO	CEO

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FIELD SAFETY CORRECTIVE ACTION
REPLY FORM

REF: CAPA-2020003

I hereby certify that I have received, read and understood the Field Safety Notice.
The information and required actions requested by the Field Safety Notice have been brought to the attention of all relevant users and the actions have been **executed in accordance with Bien-Air Surgery SA's instructions** provided in it.

COMPANY NAME & ADDRESS:	
CONTACT NAME:	
CONTACT POSITION:	
CONTACT PHONE NUMBER:	
CONTACT E-MAIL:	
SIGNATURE:	
DATE:	

The devices in the table below have been identified in our premises and the following actions have been undertaken.

Product Name	**Reference number**	**Serial number**	**LOCATION** (own stock or customer name & address)	**UNDERTAKEN ACTIONS**

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Please complete and return this form to:

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