URGENT: Medical Device Field Safety Notice

IMPORTANT INFORMATION

UPDATE

To: Distributors / Resellers / Hospital Professionals
Date: December 17th, 2020
REF: CAPA-2020003

Dear Customer,

The purpose of this updated letter is to inform you about the final corrective action to be undertaken regarding the initiation of the Field Safety Corrective Action from September 2020. 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 Bien-Air Surgery, the 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 the National Authority on your territory 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

	Product Serial Number: See below table for the impacted SN

16YZZZZ		17YZZZZ		18YZZZZ		19YZZZZ	
16A		17A		18A		19A	
16B		17B		18B		19B	
16C		17C		18C		19C	
16D		17D		18D		19D	
16E		17E		18E		19E	
16F	0001 up to	17F	0001 up to	18F	0001 up to		0001 up to
16G	9999	17G	9999	18G	9999		9999
16H		17H		18H			
16I		17I		18I			
16J		17J		18J			
16K		17K		18K			
16L		17L		18L			

Where to find the foot pedal's reference and serial numbers:	
On the bottom	Zoom on the label
	

REASON	This field safety corrective action has been initiated because there is a 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 unexpected 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.
HEALTH HAZARD ANALYSIS	Before implementing and releasing this Field Safety Corrective Action, Bien-Air Surgery SA performed a detailed Health Hazard Analysis (HHA) following its internal procedure. There is a possibility if the failure occurs that the motor does not stop running or start untimely which may cause patient injury. To date, no patient injury has been reported.
IMPORTANT INFORMATION	Bien-Air Surgery SA was able to show that this hazardous situation is mainly linked to high mechanical shocks during handling of the foot pedal. **We therefore ask the users to treat this device with great caution and to avoid shocks.** Bien-Air Surgery SA already requested to implement in September a curative action (immediate and temporary), by applying an adhesive tape on the magnet of the pedal and by inspecting the foot pedal before each use. This updated document concerns the solution to prevent the magnet coming off, by applying a dedicated magnet protection which provides a safe and effective solution and organizing a replacement.

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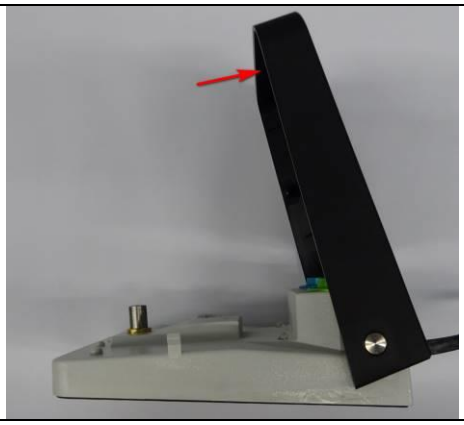
PROCEDURE

Please find below the procedure to follow:
Detailed video of the entire procedure is available **HERE**.

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) Completely remove the adhesive tape applied for the curative action.
5) Carefully inspect the position of the magnet using the below illustration. When slightly pressing on the magnet, it should not move.

The magnet is well positioned	The magnet is partially off or moves when pressing	The magnet is fully off
		
Continue with step N°6	**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	

6) Carefully clean the magnet and the plastic area around the magnet with a disinfectant wipe (alcoholic or ammonia solution only) and a cotton swab to correctly clean the corners.

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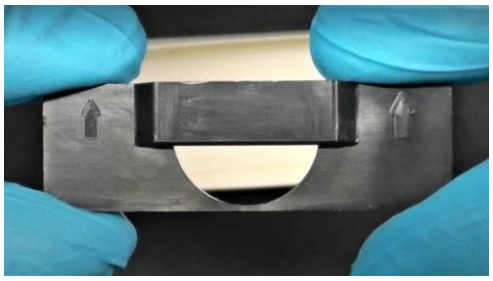
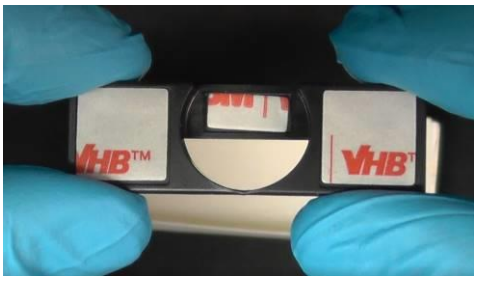
7) Make sure the surface is clean and dry. Then, apply the magnet protection provided by Bien-Air Surgery by following steps below:

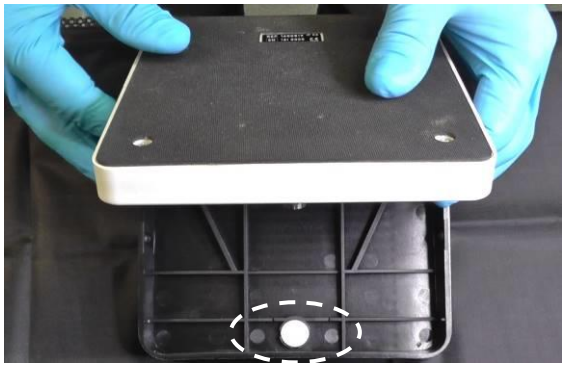
a. Take the magnet protection out of its package and check that it has three adhesives on the bottom, and it is not broken.

	
Magnet protection, top view. Note the two arrows for a next step	Magnet protection, bottom view. There must be three adhesives

b. Peel the backing from the adhesive magnet protection, using a scalpel or a cutter.

	
Peel the backing from the adhesive magnet protection	Manipulate the magnet protection without touching adhesive areas

c. Position the magnet protection with arrows oriented inward

	
Position the magnet protection over the magnet	Make sure that arrows of the magnet protection are oriented inward

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<table>
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d. Press firmly 30 seconds on both sides of the magnet protection, and then 5 seconds on the middle, using your fingers as shown below.
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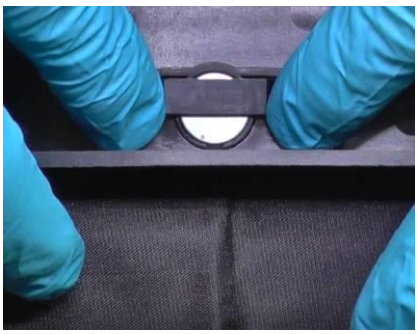
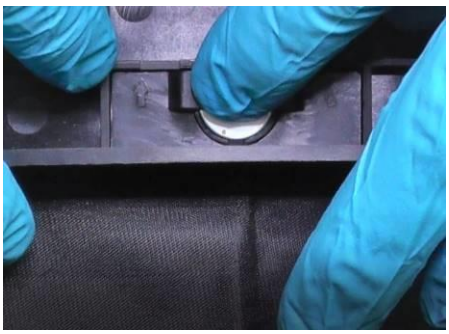
<td>  </td>
<td>  </td>
</tr>
<tr>
<td>Press 30 seconds on both sides of the magnet protection</td>
<td>Press 5 seconds on the middle of the magnet protection</td>
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8) Let the adhesive magnet protection set for 12 hours before using the foot pedal
9) Connect the foot pedal to the control unit and switch it ON
10) Proceed with the following tests before performing the first surgery
a. Select one motor (BASCH, 80K, NANO, RAPIDO) or one handpiece (S120, 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.
11) You will be contacted soon by your Bien-Air Surgery local representative for a replacement of your foot pedal
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<td>ADDITIONAL INFORMATION</td>
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Bien-Air Surgery SA regrets the inconvenience caused to you by this action and would like to thank you for your cooperation 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.
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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 & COUNTRY:			
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 requested actions have been undertaken.

Product Name	**Reference number**	**Serial number**	**Location** (own stock or customer name & address)	**Magnet Protection Applied?** (YES/NO)	**If no, provide rationale**

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Please complete and return this form as soon as possible to:

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