

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.

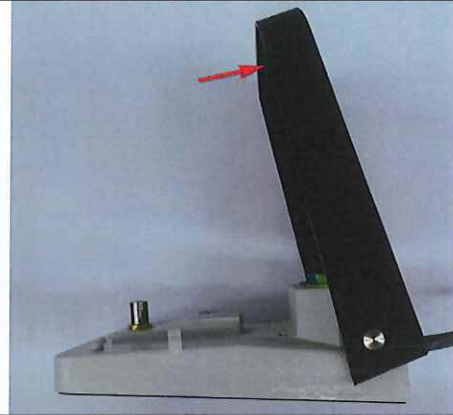
We request that you **read this notice carefully and follow the instructions** given.

PRODUCT	<p>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:</p> <ul style="list-style-type: none"> - OSSEODUO - OSSEOUNO - OSSEODOC - OSSEOSTAP <p>Bien-Air Surgery SA's foot pedals impacted by this Field Safety Corrective action are identifiable as follows:</p> <p>Product Name: OSSEODUO foot pedal Product Reference Number (Bien-Air Surgery's catalogue): Ref. 1600517</p> <p>&</p> <p>Product Name: OSSEODOC foot pedal (used with OSSEOUNO&OSSEODOC) Product Reference Number (Bien-Air Surgery's catalogue): Ref. 1600407</p> <p>&</p> <p>Product Name: OSSEOSTAP control unit Product Reference Number (Bien-Air Surgery's catalogue): Ref. 1600686</p>
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	<p>Product Serial Number: See below table for the impacted SN</p> <table border="1"> <thead> <tr> <th colspan="2">16YZZZZ</th> <th colspan="2">17YZZZZ</th> <th colspan="2">18YZZZZ</th> <th colspan="2">19YZZZZ</th> </tr> </thead> <tbody> <tr><td>16A</td><td></td><td>17A</td><td></td><td>18A</td><td></td><td>19A</td><td></td></tr> <tr><td>16B</td><td></td><td>17B</td><td></td><td>18B</td><td></td><td>19B</td><td></td></tr> <tr><td>16C</td><td></td><td>17C</td><td></td><td>18C</td><td></td><td>19C</td><td></td></tr> <tr><td>16D</td><td></td><td>17D</td><td></td><td>18D</td><td></td><td>19D</td><td></td></tr> <tr><td>16E</td><td></td><td>17E</td><td></td><td>18E</td><td></td><td>19E</td><td></td></tr> <tr><td>16F</td><td>0001 up to</td><td>17F</td><td>0001 up to</td><td>18F</td><td>0001 up to</td><td></td><td>0001 up to</td></tr> <tr><td>16G</td><td>9999</td><td>17G</td><td>9999</td><td>18G</td><td>9999</td><td></td><td>9999</td></tr> <tr><td>16H</td><td></td><td>17H</td><td></td><td>18H</td><td></td><td></td><td></td></tr> <tr><td>16I</td><td></td><td>17I</td><td></td><td>18I</td><td></td><td></td><td></td></tr> <tr><td>16J</td><td></td><td>17J</td><td></td><td>18J</td><td></td><td></td><td></td></tr> <tr><td>16K</td><td></td><td>17K</td><td></td><td>18K</td><td></td><td></td><td></td></tr> <tr><td>16L</td><td></td><td>17L</td><td></td><td>18L</td><td></td><td></td><td></td></tr> </tbody> </table>				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			
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	<p>Where to find the foot pedal's reference and serial numbers:</p> <table border="1"> <thead> <tr> <th colspan="2">On the bottom</th> <th colspan="2">Zoom on the label</th> </tr> </thead> <tbody> <tr> <td colspan="2"></td> <td colspan="2"></td> </tr> </tbody> </table>				On the bottom		Zoom on the label																																																																																																					
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REASON	<p>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.</p> <p>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.</p>																																																																																																											
HEALTH HAZARD ANALYSIS	<p>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.</p>																																																																																																											
IMPORTANT INFORMATION	<p>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.</p> <p>Bien-Air Surgery SA will implement curative (immediate and temporary) and corrective (long term) actions to prevent the magnet coming off:</p> <ul style="list-style-type: none"> - 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. 																																																																																																											

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	

CURATIVE ACTIONS

- 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



Adhesive tape correctly applied



Too short

Too width, not correctly applied

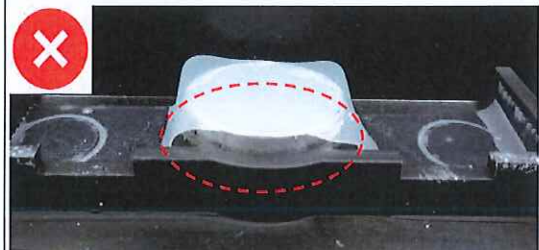


THE FOLLOWING ACTIONS MUST BE PERFORMED BEFORE EACH SURGERY

- 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,

	<p>OSSEOSTAP, PERFO) depending on your needs</p> <ol style="list-style-type: none"> 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
<p>OTHER INFORMATION</p>	<p>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.</p> <p>We are kindly requesting you to acknowledge this notification by sending us back the below reply form as soon as possible.</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> - qa.bienair.surgery@bienair.com - +41 32 953 35 35.

On and for the behalf of Bien-Air Surgery:



Arnaud Billot
Regulatory Affairs Manager



Jonas Guerdat
CTO



Juan Elices
CEO

Please complete and return this form to:

Bien-Air Surgery SA
Regulatory Affairs Department
Rue de l'Ouest 2b
CH-2340 Le Noirmont
Switzerland
Fax: +41 32 953 35 37
e-mail: qa.bienair.surgery@bienair.com