

Urgent – Field Safety Notice

Field Safety Notice # - 1226348-10-25-16-001R

January 31, 2017

Device Exchange for Codman Microcoil Delivery Systems and Detachment Control Boxes (DCB000001-20 & DCB00000500)

**PLEASE DISTRIBUTE THIS INFORMATION TO
CLINICIANS WHO USE THIS DEVICE**

Codman Neuro will be launching a new line of SPECTRA Embolic Microcoils with a new Detachment Control Box (DCB2000500).

This Field Safety Notice is being issued as once the new products are launched there are risks to using the current and new generation products together. Therefore, Codman Neuro, on behalf of Medos International SARL, will be removing the current generation of products (Attachment 1) from the market and replacing with the SPECTRA Embolic Microcoils and a new Detachment Control Box (DCB2000500).

Reasons for this Action:

As part of the SPECTRA design process, a reduced detachment cycle time was established for the new Detachment Control Box (DCB2000500) versus the detachment cycle time for the previous generations DCB00000500 and DCB000001-20.

While the current Codman Microcoil Delivery Systems (also known as DPU 2-3) can work with new and current generation Detachment Control Box (DCB), there is reduced performance in detachment when the new DCB2000500 is used with the current generation of Codman Microcoil Delivery Systems (Attachment 1). In addition, if the DCB00000500 or DCB000001-20 are used to detach the new SPECTRA microcoils, there is a potential increase in friction in the microcatheter caused by deformation of the distal outer sheath, which is used to provide insulation to the Resistive Heater (RH) of the Device Positioning Unit (DPU) assembly.

All lots of previous generation DCB Codman Microcoil Delivery Systems product codes will be affected (Attachment 1).

Action Required of the Customer:

1. Upon receipt of the Field Safety Notification - Complete Part 1 of the Reply Form (Attachment 2) to acknowledge receipt of this Field Safety Notice.
2. When your market is scheduled for the Spectra Launch - Your Codman Neuro Sales Representative will contact you directly to complete the removal and replacement process via Attachment 3. Until such time, you can continue to use and replenish the current generation of products (Attachment 1).

We apologize for the inconvenience this removal and replacement may cause. Thank you for your support in completing this removal and replacement action.

In addition, the relevant national competent authorities have been informed.

If you have any questions regarding this action please contact your *Codman Neuro* Sales Representative or contact me directly.

Sincerely,

Kimberly Soter



Codman Neuro – Director of Quality and Regulatory Compliance

Attachment 1

Product Code List for Affected Previous Generation Codman Microcoil Delivery Systems and Detachment Control Boxes (DCB000001-20 & DCB00000500)

Note: GTIN Codes are available via the following website: Depuysynthesudi.com

Detachment Control Boxes in the Scope of the Exchange

DCB Codes	Description	Images
DCB000001-20	DETACHMENT CONTROL BOX	
DCB00000500 ^{NOTE 1}	ENPOWER DETACHMENT CONTROL BOX ^{NOTE 1}	

Note 1 – The replacement DCB2000500 has a similar appearance from the front but the rear label is Orange (Not Blue).

Codman Microcoil Delivery Systems (DPU 2-3) Catalog PREFIXES in the scope of the Exchange

DPU 2-3 Codes Prefix	Description
641	ORBIT GALAXY® G2 Detachable Coils
CDF	DELTAPAQ CERECYTE MICROCOILS
CDX	DELTAMAXX CERECYTE MICROCOILS
CFS	ULTIPAQ CERECYTE MICROCOILS
CHE	HELIPAQ CERECYTE MICROCOILS
CPL	DELTAPLUSH CERECYTE MICROCOILS
CRC	CASHMERE CERECYTE MICROCOILS
CSP	MICRUSPHERE CERECYTE MICROCOILS
DFS	DELTAPAQ PLATINUM MICROCOILS
DMX	DELTAMAXX PLATINUM MICROCOILS
DPL	DELTAPLUSH PLATINUM MICROCOILS
FSR	ULTIPAQ PLATINUM MICROCOILS
HEL	HELIPAQ 18 PLATINUM MICROCOILS
HSR	HELIPAQ 10 PLATINUM MICROCOILS
PC4	PRESIDIO MICROCOILS
SPH	MICRUSPHERE PLATINUM MICROCOILS
SRC	CASHMERE PLATINUM MICROCOILS
SSR	MICRUSPHERE XL PLATINUM MICROCOILS

<u>Attachment 2 - Reply Form Part 1</u>	
Device Exchange for Codman Microcoil Delivery Systems and Detachment Control Boxes (DCB000001-20 & DCB00000500)	
<i>To be complete upon receipt of the Field Safety Notice</i>	
PART 1	
Sales Representative	Name: UCN: Contact Tel.: Email:
Hospital Account Information	Account Number: Hospital Name : Address Line 1: City Name: State: Postal Code:
Hospital Acknowledgment of Withdrawal	Hospital Representative Name: _____ Hospital Representative Signature: _____ Date: _____ <i>By signing the acknowledgement section of this form, the hospital acknowledges understanding of the following:</i> <ul style="list-style-type: none"><i>• If the new DCB2000500 is used with the current generation of Codman Microcoil Delivery Systems (Attachment 1) there is reduced performance in detachment.</i><i>• If the previous generation DCBs (DCB00000500 or DCB000001-20) are used with SPECTRA Microcoils there is a potential increase in friction in the microcatheter caused by deformation of the distal outer sheath</i><i>• Codman Neuro will be removing all previous generation Detachment Control Boxes (DCB000001-20 and DCB00000500) and Codman Microcoil Delivery Systems (Attachment 1) and will be replacing them with the new DCB2000500 and SPECTRA Coils.</i> <p style="text-align: center;">Please email a copy of this completed form to your local SPECTRA Distribution Mailbox</p> <p style="text-align: center;"><i><u>Local Affiliates to add email / mailbox address here to receive back Part 1</u></i></p>

Attachment 3 - Reply Form Part 2

Device Exchange for Codman Microcoil Delivery Systems and Detachment Control Boxes (DCB000001-20 & DCB00000500)

To be completed with your Codman Neuro Sales Representative, only when your market is scheduled for the Spectra Launch

PART 2

<p>Sales Representative</p>	<p>Name:</p> <p>Address:</p> <p>Contact Tel.:</p> <p>Email:</p>
<p>Hospital Account Information</p>	<p>Account Number:</p> <p>Hospital Name:</p> <p>Address:</p>
<p>Hospital Acknowledgement</p>	<p>The table below indicates the number of devices the hospital intends to return.</p> <p>Please ensure previous generation DCB's are cleaned / decontaminated in accordance with hospital policy prior to returning.</p> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p align="center">DCB000001-20 Units to be Returned</p> <hr/> <p>Total Quantity of DCB000001-20 boxes to be returned: _____</p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p align="center">DCB00000500 (DCB05) Units to be Returned</p> <hr/> <p>Total Quantity of DCB00000500 boxes to be returned: _____</p> </div> <div style="border: 1px solid black; padding: 5px;"> <p align="center">Codman Microcoil Delivery Systems (also known as DPU 2-3) Units to be Returned</p> <p align="center">Reference Attachment 1 - List of Affected Catalog Numbers</p> <hr/> <p>Total Quantity of DPU 2-3 coils be returned: _____</p> </div>

<p>Actual Product Removal and Replacement Confirmation</p>	<p>This information must be completed and the form returned to receive the new DCB2000500 and SPECTRA Microcoils. Please work directly with your Codman Neuro Sales Representative on the best option for you to receive new replacement product.</p> <p>Replacement Options - Please choose 1 of the following options to receive placement product:</p> <p><input type="checkbox"/> <u>Option 1:</u> The Codman Neuro Sales Rep will remove previous generation DCBs and Embolic Microcoils (DPU2-3) inventory and replace it with the new DCB2000500 and SPECTRA Microcoils in one visit</p> <p><input type="checkbox"/> <u>Option 2:</u> The Codman Neuro Sales Representative will remove previous generation DCBs and Embolic Microcoils (DPU2-3) inventory from your account and new DCB2000500 and SPECTRA Microcoils will be shipped directly to you.</p> <ul style="list-style-type: none"> <i>Note: As there is an expected delay in receiving new SPECTRA product with Option 2 – please work directly with your sales representative to proactively manage cases during this time</i> 				
<p>Replacement Information</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">New DCB2000500 Replacements</td> </tr> <tr> <td>Actual Quantity of DCB2000500 placed: _____</td> </tr> <tr> <td style="text-align: center;">SPECTRA Coil Replacements</td> </tr> <tr> <td>Actual Quantity SPECTRA Microcoils placed: _____</td> </tr> </table>	New DCB2000500 Replacements	Actual Quantity of DCB2000500 placed: _____	SPECTRA Coil Replacements	Actual Quantity SPECTRA Microcoils placed: _____
New DCB2000500 Replacements					
Actual Quantity of DCB2000500 placed: _____					
SPECTRA Coil Replacements					
Actual Quantity SPECTRA Microcoils placed: _____					
<p>Hospital Replacement Acknowledgement</p>	<p>I acknowledge the receipt of the new DCB2000500 and SPECTRA Microcoils.</p> <p>Hospital Representative (Name) _____</p> <p>Signature _____ Date _____</p>				
<p>Codman Sales Representative Confirmation</p>	<p>I confirm I have collected and replaced the above indicated devices. In addition, I have provided documentation for all previous generation DCBs and Embolic Microcoils (DPU 2-3) units being removed and replaced – including Catalog #'s, Lot 's and Quantity per the attached form.</p> <p>Name: _____ Date _____</p> <p>Signature _____</p>				
<p style="text-align: center;">Please email a copy of this completed form to the SPECTRA EMEA Distribution Mailbox CodmanEMEASpectra - RA-MEDGBBR CodmanEME@ITS.JNJ.com</p>					

