

## **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](http://Depuysynthesudi.com)

**Detachment Control Boxes in the Scope of the Exchange**

| DCB Codes                     | Description                                      | Images  |
|-------------------------------|--|---|
| DCB000001-20                  | DETACHMENT CONTROL BOX                           |  |
| DCB00000500 <sup>NOTE 1</sup> | ENPOWER DETACHMENT CONTROL BOX <sup>NOTE 1</sup> |  |

**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**

| <b>DPU 2-3 Codes Prefix</b> | <b>Description</b>                 |
|-----------------------------|------------------------------------|
| 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 |



**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"><b>DCB000001-20 Units to be Returned</b></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"><b>DCB00000500 (DCB05) Units to be Returned</b></p> <hr/> <p>Total Quantity of DCB00000500 boxes to be returned: _____</p> </div> <div style="border: 1px solid black; padding: 5px;"> <p align="center"><b>Codman Microcoil Delivery Systems (also known as DPU 2-3) Units to be Returned</b></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"> <li><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></li> </ul> |                                    |   |                                  |  |
| <p>Replacement Information</p>  | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;"><b>New DCB2000500 Replacements</b></td> </tr> <tr> <td>Actual Quantity of DCB2000500 placed: _____</td> </tr> <tr> <td style="text-align: center;"><b>SPECTRA Coil Replacements</b></td> </tr> <tr> <td>Actual Quantity SPECTRA Microcoils placed: _____</td> </tr> </table>  | <b>New DCB2000500 Replacements</b> | Actual Quantity of DCB2000500 placed: _____ | <b>SPECTRA Coil Replacements</b> | Actual Quantity SPECTRA Microcoils placed: _____ |
| <b>New DCB2000500 Replacements</b>  |   |                                    |   |                                  |  |
| Actual Quantity of DCB2000500 placed: _____   |   |                                    |   |                                  |  |
| <b>SPECTRA Coil Replacements</b>  |   |                                    |   |                                  |  |
| 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;"><b>Please email a copy of this completed form to the SPECTRA EMEA Distribution Mailbox</b><br/> <a href="mailto:CodmanEMEASpectra - RA-MEDGBBR CodmanEME@ITS.JNJ.com">CodmanEMEASpectra - RA-MEDGBBR CodmanEME@ITS.JNJ.com</a></p> |   |                                    |   |                                  |  |

