

URGENT - FIELD SAFETY NOTICE

Field Safety Notice #: 1226348-1/28/15-001R

February 23, 2015

Voluntary Removal and Replacement of CODMAN® CERTAS™ Therapy Management System (TMS)

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

Dear Codman CERTAS Therapy Management System Users:

Please be aware that *Codman Neuro* is initiating a voluntary removal and replacement of the CODMAN® CERTAS™ Therapy Management System (TMS) 1st generation (product codes 82-8850 & 82-8850D).

Reasons for this Action:

Codman Neuro has re-designed the CERTAS Therapy Management System (1st generation) and developed a new CODMAN CERTAS® Tool Kit (2nd generation). This new CERTAS Tool Kit (2nd generation) contains improvements for the indication and adjustment of the valve setting.

In addition, some components of the new CERTAS Tool Kit (2nd generation) are not compatible with the components of the CERTAS Therapy Management System (1st generation). Specifically, the 1st generation Indicator is not compatible with the 2nd generation Locator tool. If the parts are interchanged, this incompatibility could result in reduced indicating / adjusting performance and lead to symptoms associated with over / under drainage of Cerebrospinal Fluid (CSF).

Based on this tool kit incompatibility it is very important that you gather all of the CERTAS Therapy Management System devices (1st generation) and work with your *Codman Neuro* Sales Representative to complete the removal and replacement process as identified in this notification.

This incompatibility is between Tool Kit components only. The new CERTAS Tool Kit (2nd generation) is fully compatible with implanted CODMAN® CERTAS™ Programmable Valves and can be used to treat patients upon removal of the 1st generation CERTAS Therapy Management System from your facility.

Affected Product (all lots): 1st generation TMS units were provided as separate product codes as noted below:

Code	GTIN	Description
82-8850	10886704071402	CERTAS Therapy Management System (TMS) 1 st generation
82-8850D	10886704071419	CERTAS Therapy Management System (TMS) 1 st generation DEMO Sample

Removal and Replacement Process:

Your *Codman Neuro* Sales Representative will schedule time to work with you to remove and replace the TMS devices (1st generation). They will also be providing you with training on the use of the new CERTAS Tool Kit (2nd generation). The removal and replacement process will need to be documented on the attached business reply form.

1. Upon receipt of this notification, please complete and sign PART 1 of the attached Business Reply Form to acknowledge that you have received this notification.
2. Please confirm location and number of TMS devices in your hospital for replacement. Your Sales Representative will schedule a time to collect all CERTAS Therapy Management Systems (1st generation) and complete an in-service to provide you with replacement CERTAS Tool Kits (2nd generation). Prior to providing the returned TMS devices, please plan to ensure the devices are cleaned / decontaminated in accordance with hospital policy.
3. Once the removal, replacement and training has been completed during the follow-up visit, please confirm the information for the returned devices and training by signing the Hospital Training & Replacement Acknowledgement section in PART 2 of the attached Business Reply Form.

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,



J. Thomas Megerian MD, PhD
Vice President - Strategic Medical Affairs and Medical Sciences

PART 1

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OUS Business Reply Form
Codman CERTAS Therapy Management System (TMS)
(82-8850 & 82-8850D) Removal and Replacement Action

PART 2

Sales Representative	Name: Address: Contact Tel.: Email:																	
Hospital Account Information	Account Number: Hospital Name: Address:																	
Hospital Acknowledgement	<p>The table below indicates the number of devices the hospital intends to return.</p> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <tr> <th colspan="3" style="text-align: center;">CERTAS Therapy Management System (TMS) (1st generation) Catalog Numbers 82-8850 & 82-8850D to be Returned</th> </tr> <tr> <th style="width: 33%;">Product Code</th><th style="width: 33%;">Lot Number</th><th style="width: 33%;">Quantity to be Returned</th> </tr> <tr> <td>82-8850</td><td></td><td></td> </tr> <tr> <td>82-8850</td><td></td><td></td> </tr> <tr> <td>82-8850D</td><td></td><td></td> </tr> </table>	CERTAS Therapy Management System (TMS) (1 st generation) Catalog Numbers 82-8850 & 82-8850D to be Returned			Product Code	Lot Number	Quantity to be Returned	82-8850			82-8850			82-8850D				
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82-8850D																		
Actual Product Removal and Replacement Confirmation	<p>This information must be completed and the form returned to receive new Tool Kits. Please ensure the devices are cleaned / decontaminated in accordance with hospital policy.</p> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <tr> <th colspan="3" style="text-align: center;">CERTAS Therapy Management System (TMS) (1st generation) Catalog Numbers 82-8850 & 82-8850D Returned</th> </tr> <tr> <th style="width: 33%;">Product Code</th><th style="width: 33%;">Lot Number</th><th style="width: 33%;">Quantity Returned</th> </tr> <tr> <td>82-8850</td><td></td><td></td> </tr> <tr> <td>82-8850</td><td></td><td></td> </tr> <tr> <td>82-8850D</td><td></td><td></td> </tr> </table> <p style="text-align: center; margin: 10px 0;">Replacement Information</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; padding: 5px;"> CERTAS Tool Kit 2nd Generation Replacements Catalog Number 82-8851 </td> </tr> <tr> <td style="padding: 5px;"> Quantity replaced: _____ </td> </tr> </table>	CERTAS Therapy Management System (TMS) (1 st generation) Catalog Numbers 82-8850 & 82-8850D Returned			Product Code	Lot Number	Quantity Returned	82-8850			82-8850			82-8850D			CERTAS Tool Kit 2nd Generation Replacements Catalog Number 82-8851	Quantity replaced: _____
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CERTAS Tool Kit 2nd Generation Replacements Catalog Number 82-8851																		
Quantity replaced: _____																		

Hospital Training & Replacement Acknowledgement	<p>I acknowledge the receipt of the new CERTAS Tool Kit (2nd Generation) Catalog Number: 82-8851 devices and the receipt of training on the use of these new devices.</p> <p>Hospital Representative (Name) _____</p> <p>Signature_____Date_____</p>
Codman Sales Representative Confirmation	<p>I confirm I have collected and replaced the above indicated devices and provided the required Training.</p> <p>Name: _____ Date _____</p> <p>Signed _____</p>
<p align="center">Please email a copy of this completed form to: tmsreplacement@its.jnj.com</p>	