

Urgent Field Safety Notice (FSN)

Product Name: CODMAN® CERTAS™ Programmable Valves

FSCA-identifier: Our ref: COM-009386

Type of Action: Field Safety Notice and Field Safety Corrective Action

Date: May 15, 2013

Attention: Trust Chief Executives, Surgery,
 Theatre and Neurosurgical General Managers – Private Sector Hospitals

Affected devices: *Codman Certas Programmable Valves*

Part numbers:

| Code | Description |
|---------|--------------------------------------------------------------------------------------|
| 82-8800 | In Line Valve Only |
| 82-8801 | In Line Valve with Catheter and Accessories |
| 82-8802 | In Line Valve with Unitized Catheter and Accessories |
| 82-8803 | In line Valve with Unitized BACTISEAL® Catheter and Accessories |
| 82-8804 | In Line Valve only with SIPHONGUARD® Device |
| 82-8805 | In Line Valve with SIPHONGUARD® Device, Catheter and Accessories |
| 82-8806 | In Line Valve with SIPHONGUARD®, Unitized Catheter and Accessories |
| 82-8807 | In Line Valve with SIPHONGUARD® Device, Unitized BACTISEAL® Catheter and Accessories |

Lot No/Serial No: See attached List

Reason for this Recall:

This recall is being initiated because our testing has shown that, in a small percentage of valves, the following conditions may exist:

- The MRI resistance feature may not always operate properly.** If this occurs, it could potentially result in an unintended change in the valve setting due to exposure to an MRI procedure or other magnetic field. Based on reported complaints, this issue may have been a factor in up to 0.06% of units sold.
- The programming mechanism may not always operate properly.** If this occurs, it could potentially lead to an inability to modify the operating pressure of the valve with the hand-held programming tools, also referred to as the CODMAN® CERTAS™ Therapy Management System (TMS). Based on our reported complaints, this issue may have been a factor in up to 0.4% of units sold.

Root Cause:

This recall is being initiated because our testing has shown that, in a small percentage of valves, the conditions noted above may exist for products released. In-depth root cause analysis is not completed at the present time.

Action Required:

- Acknowledge receipt of this Field Safety Notice to verify that you have been made aware of this possible issue and report unused items to be returned.
- Return any unused items to your local Codman offices as requested by this notice.
- Return the acknowledgement form to your Codman sales representative or local Codman office.

Advice for Physicians Treating Patients with Implanted CODMAN® CERTAS™ Programmable Valves:

1. **Mitigation Steps Regarding the MRI resistance feature:** Please follow the Instructions For Use (IFU) which recommend that the settings of implanted valves are verified following exposure to an MRI. We urge you to complete this step after every MRI.
2. **Mitigation Steps Regarding the programming mechanism difficulty:** In most cases, programming could be completed with additional attempts to re-program using the Therapy Management System(TMS) device and verification of setting, as described in the IFU. If additional attempts are unsuccessful, please contact your Codman Neuro representative who can provide further support.

Corrective Action

We are in the process of taking corrective actions to prevent re-occurrence. We regret the need to undertake this action and we thank you for your cooperation.

Distribution of this Field Safety Notice:

Please share this information with any staff that may use these products, especially those following patients who have been treated with the CODMAN® CERTAS™ Programmable Valves. .

Contact Information:

Consult with your local sales representative if you have questions concerning this notice.

Authorized European Representative Contact Reference Person:

Donal Hemenstall

tel: 44.1344.871186

fax: 44.1344.324687

This FSCA has/will be sent to the appropriate Regulatory Agency.

Please provide this notice to any Neurosurgeons or other clinicians at your facility who are treating patients with an implanted CODMAN® CERTAS™ Programmable Valve.

Field Safety Notice Acknowledgement Form

Ref: FSN: COM-009386

The undersigned acknowledges receipt of the subject Field Safety Notice in reference to the CODMAN[®] CERTAS[™] Programmable Valves

Date: _____

Name (please print): _____

Signature: _____

Hospital Name: _____

City and Country: _____

Please Complete:

Please check YES or No and if YES, please identify Lot and Quantity to return:

_____ YES, I do have one or more CODMAN[®] CERTAS[™] Programmable Valves affected by this recall

Lot/Quantity: _____ / _____ (add additional page, if needed)

_____ NO, I do not have any CODMAN[®] CERTAS[™] Programmable Valves affected by this recall.

Please return this completed form to your local Codman Neuro Representative or fax to: [NOTE: Add Local Fax Number Here]