CODMAN NEURO

DePuy Synthes

COMPANIES OF Johnson & Johnson

Urgent Medical Device Field Safety Notification

July 18, 2014

CODMAN® CERTAS™ Programmable Valves

PLEASE DISTRIBUTE THIS INFORMATION TO CLINICIANS WHO USE THIS DEVICE

Dear Neurology/Neurosurgery Clinician:

This safety notification is being sent to clarify the CODMAN CERTAS Valve virtual off (setting 8) pressure specification outlined in the product's Instructions for Use (IFU).

No action is required for patients experiencing good outcomes with an implanted CODMAN CERTAS Valve.

This notification applies to all valve codes (shown below).

Affected Product (all lots)

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

Summary of Issue

As stated in the CODMAN CERTAS Valve IFU, the virtual off setting (setting 8) is intended to limit flow through the valve and has an **average** pressure greater than 400mm H_2O. Recent in-vitro testing of the virtual off setting showed that the operating pressure for an individual valve may fall below 400mm H_2O. This testing found only one occurrence out of 72 test instances that was significantly below 400mm H_2O (observed at 275mm H_20), although when retested, this valve performed above 400mm H_2O.

*Medos International SARL is the legal manufacturer issuing this notice.

Impact and Potential Harms Associated with the Virtual Off Setting

If a valve is considered to be virtually off, but is still operating at a physiologically relevant pressure, a clinician may inaccurately consider the patient to be shunt independent. This may result in a delay in treatment for shunt-related complications.

If the virtual off setting is being used to restore ventricular volume for patients with Slit Ventricle Syndrome or subdural hemorrhage formation resulting from overdrainage, treatment response may be delayed for valves operating significantly below 400mm H_2O. This risk of harm is mitigated by the fact that the valves recently tested in-vitro did not consistently operate below 400mm H_2O.

Actions to be Taken by Clinicians Treating Patients with CODMAN CERTAS Valves

If the Virtual Off setting is being used to address an acute overdrainage situation that has resulted in subdural hemorrhage or slit ventricle formation, close observation is advised to make sure that the patient is responding as expected (operating pressure >400mm H_2O).

This notification is based upon internal in-vitro testing. Codman Neuro is not aware of any adverse events associated with this issue. Patient symptoms resulting from this issue are similar to those seen in the standard course of treatment, so it is difficult to directly correlate complaints with the issue discussed in this Notification.

Please note, Codman Neuro is not recommending explantation of CODMAN CERTAS Valves.

Please provide this notice to any neurosurgeons or other clinicians at your facility who are managing patients with an implanted CODMAN CERTAS Valve.

Please complete the enclosed Acknowledgement Form and fax the completed form to 1-888-239-1305

It is important that we receive this acknowledgement form. You may also e-mail the form to us at codman6304@stericycle.com

If you have any questions or concerns regarding this notification, please contact your local Codman Neuro Representative or Scientific and Medical Affairs at SciMedAffairs@its.jnj.com or (866) 685-7325. Thank you for your cooperation.

Sincerely,

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

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ACKNOWLEDGEMENT FORM

This signed form acknowledges receipt of the Medical Device Safety Notification issued by Codman Neuro on July 17, 2014 regarding the CODMAN® CERTAS™ Programmable Valve.

We have received the Medical Device Safety Notification associated with the virtual off setting issue described and can attest that this Notification was provided to the appropriate clinicians in our institution.

Print Name:_____

Institution Name: _____

_____

Authorized Signature/Date

_____

Telephone Number

Please fax this completed form to XXXXXX at XXXXXXX, email XXXXX or return it to your Codman Neuro sales representative.

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