CODMAN NEURO

DePuy Synthes
COMPANIES OF Johnson & Johnson

URGENT FIELD SAFETY NOTICE

No. 1226348-9/10/14-001R

September 12, 2014

Voluntary Recall Notification:
EDS 3™ CSF External Drainage System

PLEASE DISTRIBUTE THIS INFORMATION TO CLINICIANS WHO USE THIS DEVICE

Dear OR Manager, Materials Manager, ICU/Neuro ICU Manager:

Please be aware that Codman Neuro is initiating a voluntary recall of all lots of EDS 3 CSF External Drainage Systems, with expiration on or before August 2017 (2017-08, please see attachment). The system is indicated for draining cerebrospinal fluid (CSF) and other fluids of similar characteristics as a means of reducing intracranial pressure and CSF volume when the insertion of a permanent, internal shunt is not indicated. Please be aware that products in your possession may be affected.

Affected Product (all lots)

Code	Description
82-1730	EDS 3CSF External Drainage System with Ventricular Catheter
82-1731	EDS 3CSF External Drainage System (no Ventricular Catheter)
82-1738	Lumbar Drainage Catheter Kit II with EDS 3System

This recall is being initiated because the tubing within the system that drains CSF may leak or disconnect from the joints. Leakage and tube separations may result in over- or under-drainage of CSF from the ventricular system or introduction of air into the ventricular system (pneumocephalus). This may result in collapsed ventricles, subdural bleeding, or an inability to properly control elevated intracranial pressure. The tubing disconnection or leakage may also increase the risk of ventriculitis. If undetected or untreated each of these events may cause severe brain injury, which may lead to coma, stroke or death.

Actions for Clinicians Treating Patients with the EDS 3 System

These systems are most often used on neurocritical care floors and these issues are likely to be detected immediately. For patients currently being managed with the EDS 3 System, the system

should be replaced immediately. In the case where no substitute drainage system is immediately available, the EDS 3 System may continue to be used until an alternative product can be obtained. Manipulation of tubing should be minimized and extra vigilance is required for early detection of leakage and/or disconnection.

As of September 9, 2014, approximately 0.051 percent of complaints reported a failed connection from the joint and 0.030 percent reported leakage according to the most recent complaint data, but some customers' complaint rates have been as high as 2.6 percent.

The relevant National Competent Authorities are informed of this action. Please provide this notice to any neurosurgeons or other clinicians at your facility who are managing patients with the EDS 3 System, and to other organizations to which products may have been transferred.

We request that you immediately check all inventory to determine if you have affected product. Please use the included instructions to report your inventory status and return affected product.

We apologize for the inconvenience this recall may cause. At Codman Neuro, we are dedicated to delivering products that meet the highest quality standards. We regret the need to undertake this voluntary recall and we are committed to resolving this issue.

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 +1 (866) 685-7325. Thank you for your cooperation.

Sincerely,

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

FIELD SAFETY NOICE No. 1226348-9/10/14-001R
INSTRUCTIONS FOR REPORTING INVENTORY STATUS, RETURNING PRODUCT, AND OBTAINING CREDIT

You are receiving this voluntary recall notification because our records indicate that you are the recipient of one or more EDS 3 systems affected by this recall. Please follow the instructions in this field safety notice for the products identified in this recall. Please complete the enclosed Acknowledgement Form and fax the completed form to: **001-508-977-6665**. **It is important that we receive this acknowledgement form, even if you have no affected product in your inventory.**
You may also e-mail the form to us at Codmanproductcomplaints@dpyus.jnj.com

PRODUCT RETURNS:

All affected products are to be returned to the address below for credit.

GMED Healthcare
EDC Quality Dept
Rue de Luxembourg 5
ZI Trazegnies
BE - 6180 Courcelles
Belgium

TEL: 32-7-146-9404

Once again, it is very important that you complete the acknowledgement form, as soon as possible, even if you do not have any affected product inventory in your possession. You may fax the completed acknowledgement form to the U.S. at **001-508-977-6665**. You may also e-mail the form to us at Codmanproductcomplaints@dpyus.jnj.com . If you have any questions on concerns in regards to this recall, please contact your Codman Neuro consultant.

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Field Safety Notice Acknowledgement Form
FSN: 1226348-9/10/14-001R

This signed form acknowledges receipt of the recall letter issued by Codman Neuro regarding the EDS 3™ CSF External Drainage System. Not completing this form is in its entirety can cause a delay in processing your credit. Please return this completed form to your local Codman Neuro Consultant or fax to: < NOTE: Add Local Fax Number Here>

We have checked our current inventory for affected products listed in the recall announcement and indicated our inventory levels below:

☐ We acknowledge the receipt of this information but **do not have** the affected EDS 3 CSF External Drainage System products in stock.

☐ We acknowledge the receipt of this information and the products listed below **are in stock** and will be returned to Codman Neuro for dollar credit.

☐ We have affected product, but it is currently in use with no available alternative, so we are retaining product to address emergent patient need. We will return affected product once an alternative product is available.

Product Code	***Lot Number***	***Quantity***

Hospital Name/Location:_____

Print Name:_____

Phone Number: _____

Authorized Signature/Date

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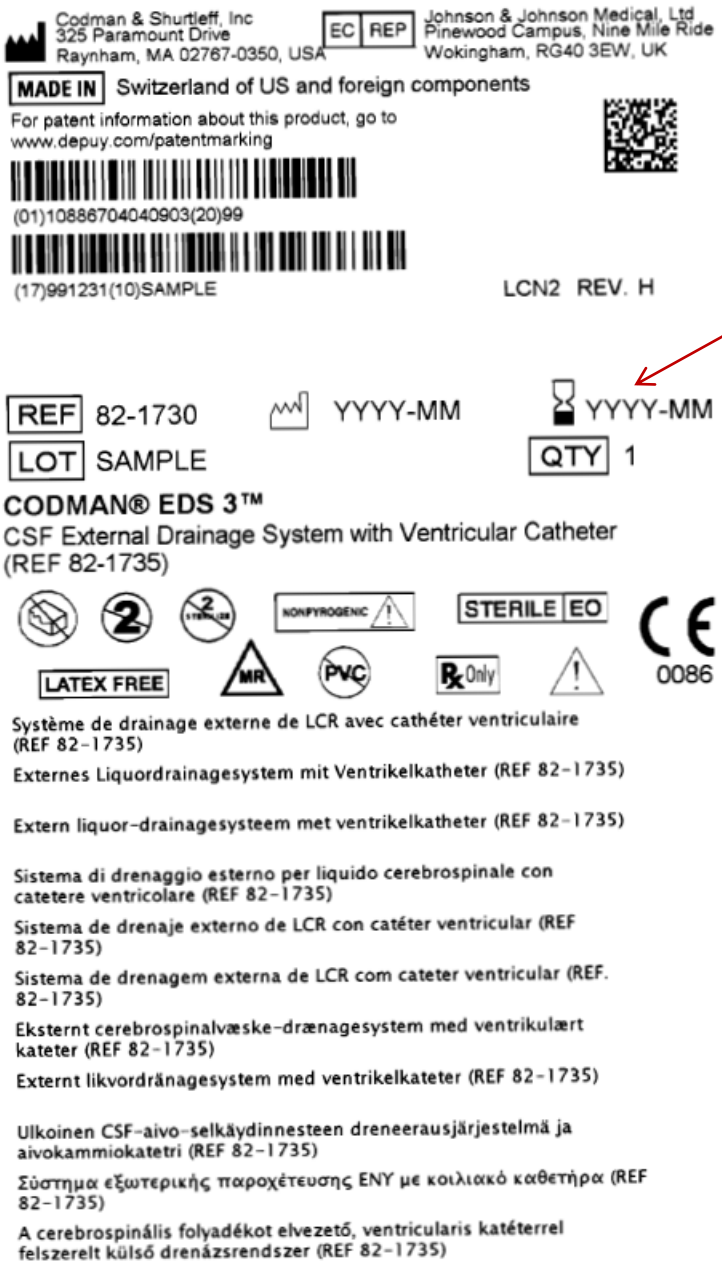
ATTACHMENT 1

EDS 3™ CSF External Drainage System (Sample) Product Label



Expiration date information located here. All product affected expires on or before 2017-08.