Report Form
Field Safety Corrective Action

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 8)

1. Administrative information
Destination

To which NCA(s) is this report being sent?
Agency for Medicinal Products and Medical Devices of the Republic of Slovenia
Ptujskaulica 21, SI-1000 Ljublijana. Slovenia

Type of report

■ Initial report

☐ Follow up report

☐ Final report

Date of this report
12 September 2014

Reference number assigned by the manufacturer
1226348-9/10/14-001R

FSCA reference number assigned by NCA

Name of co-coordinating national competent authority (if applicable)

2 Information on submitter of the report

Status of submitter

■ Manufacturer

■ Authorized representative within EEA

☐ Others (identify the role):

3 Manufacturer information

Name Codman Neurosciences, SARL	
Contact name James Kenney	
Address Rue Girardet 29	
Postal code 2400	City LeLocle
Phone 001-508-828-2726	Fax 001-508-977-6403
E-mail Jkenney1@its.jnj.com	Country U.S.A.

4 Authorized representative information

Name Codman, a Division of Johnson and Johnson Medical Ltd
Contact name Mr. Donal Hempenstall
Address Johnson & Johnson Medical Ltd

Pinewood Campus Nine Mile Ride	
Postal code RG40 3EW	City Wokingham, Berkshire
Phone 44.1344.871186	Fax 44.1344.324687
E-mail dhempen@its.jnj.com	Country United Kingdom
5 National contact point information	
National contact point name Same as above	
Name of the contact person Same as above	
Address Same as above	
Postal code Same as above	City Same as above
Phone Same as above	Fax Same as above
E-mail Same as above	Country Same as above
6 Medical device information	
Class ☐ AIMD Active implants ■ MDD Class III (821738 & 821730) ☐ IVD Annex II List A ☐ MDD Class IIb ☐ IVD Annex II List B ☐ MDD Class IIa ☐ IVD Devices for self-testing ■ MDD Class I Sterile (821731) ☐ IVD General	
Nomenclature system (preferable GMDN) GMDN	Nomenclature Code 36151
Nomenclature text Ventricular cerebrospinal fluid drainage kit	
Commercial name/brand name/make EDS III	
Model number	Catalog numbers: 821730, 821731, 821738
Serial number(s) and/or lot/batch number(s)	Lot/batch number(s) All lots of EDS 3 CSF External Drainage Systems, with expiration on or before August 2017 (2017-08, please see FSN).
Device manufacturing date See the attached: Affected Product list	Expiry date See the attached: Affected Product list
Software version number (if applicable) Not applicable	
Accessories/associated device (if applicable)	

Not applicable

Notified body (NB) ID- number
BSI – 0086

7 Description of FSCA

Background information and reason for the FSCA

Codman has identified an increased product complaint rate for leaking tubing and or tubing disconnections. During the review and investigation, it was identified that there has been a decrease in the average bond strength from historical production levels.

Description and justification of the action (corrective/preventive)

A voluntarily product recall is being initiated as an immediate step. During the review and investigation into the decrease in the average bond strength from historical production levels, actions have been identified to improve the T=0 bond strength – such as improved visual standards and cleaning of the tubing prior to applying the adhesive.

Advice on actions to be taken by the distributor and the user

Local Codman affiliates will contact users regarding the FSCA and to assure they receive a Field Safety Notice (FSN) to be distributed to all affected customers.

Progress of FSCA, together with reconciliation data (mandatory for a Final FSCA

Attached please find	FSN Status
■ Field Safety Notice (FSN) in English	☐ Draft
☐ FSN in national language	■ Final
☐ Others (please specify):	

Time schedule for the implementation of the different actions:
Field Safety Notices will commence in the week of 15 September 2014 or shortly thereafter.

These countries within the EEA and Switzerland are affected by this FSCA

Country Name	Country Name	Country Name	Country Name
United Arab Emirates	Estonia	Kuwait	Portugal
Argentina	Egypt	Kazakhstan	Reunion
Austria	Spain	Lebanon	Romania
Australia	Finland	Lithuania	Serbia
Aruba	France	Luxembourg	Russian Federation
Belgium	Gabon	Latvia	Rwanda
Bahrain	Great Britain	Mauritius	Saudi Arabia
Bolivia	French Guiana	Mexico	Sweden
Brazil	Greece	Malaysia	Singapore
Bahamas	Guatemala	Mozambique	Slovenia

Canada	Hong Kong	New Caledonia	Slovakia
Switzerland	Croatia	Nigeria	Tunisia
Chile	Hungary	Netherlands	Turkey
People's Republic of China	Ireland	Norway	Trinadad And Tobago
Columbia	Israel	New Zealand	Taiwan
Costa Rica	India	Oman	Ukraine
Cyprus	Iran	Panama	Uruguay
Czech Republic	Italy	Peru	Venezuela
Germany	Jordan	Poland	Mayotte
Algeria	Kenya	Palestine	South Africa

8 Comments

I affirm that the information given above is correct to the best of my knowledge.

……
Signature

Name	City	Date
James Kenney	Raynham, MA. USA	12 September 2014

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorized representative or the national competent authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.