Report Form
Manufacturer's Field Safety Corrective Action Report

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

v.12/11

1. Administrative information	
To which NCA(s) is this report being sent? Agence nationale de sécurité du médicament et des produits de santé (ANSM) – FR Medicines and Healthcare products Regulatory Agency (MHRA) Devices – UK	
Type of report ☒ Initial report ☐ Follow up report ☐ Final report	
Date of this report August 13, 2012	
Reference number assigned by the manufacturer N-HHE-966 Mayfield Gel Pads Recall	
FSCA reference number assigned by NCA	
Incidence reference number assigned by NCA	
Name of the co-ordinating national competent authority (if applicable)	
2. Information on submitter of the report	
Status of submitter ☐ Manufacturer ☐ Authorised representative within EEA, Switzerland and Turkey ☒ Others (identify the role): EMEA Headquarters	
3 Manufacturer information	
Name INTEGRA LifeSciences Corporation	
Contact name Brian Hoy	
Address 4900 Charlemar Drive, Building A	
Postcode 45227	City Cincinnati, Ohio
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E-mail brian.hoy@integralife.com	Country USA
4 Authorised representative information	
Name Integra NeuroSciences	
Contact name Gurge Phull	

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5 National contact point information

National contact point name Integra LifeSciences Services	
Name of the contact person Jean-Charles Moncenis	
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6 Medical device information

Class

☐	AIMD Active implants	☐	IVD Annex II List A
☐	MDD Class III	☐	IVD Annex II List B
☐	MDD Class IIb	☐	IVD Devices for self-testing
☐	MDD Class IIa	☐	IVD General
☒	MDD Class I		

Nomenclature system (preferable GMDN) GMDN	Nomenclature code
Nomenclature text	
Commercial name/brand name/make Mayfield Gel Pads	
Model number	Catalogue number 440C1011 and 440C1012.
Serial number(s)	lot/batch number(s) 093990 and 093984
Device Manufacturing date	Expiry date
Software version number (if applicable)	
Accessories/associated device (if applicable) Mayfield System	
Notified body (NB) ID- number BSI	

7 Description of FSCA

Background information and reason for the FSCA

Integra LifeSciences Corporation (Integra) determined that a small number of MAYFIELD® Right Gel Pad & MAYFIELD® Left Gel Pad were packaged with the Right Gel Pad in the Left package and the Left Gel Pad in the Right package. While Integra has received customer complaints regarding this, none of the complaints reported patient injuries as a result.

Description and justification of the action (corrective/preventive)

Integra is taking a very conservative approach to resolve this inconvenience for its customers by initiating a voluntary recall to remove the remaining non-conforming products to avoid additional complaints.

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

Customers:
Integra asks to its customers to examine their inventory of MAYFIELD® Right Gel Pad (reference: 440C1012) and MAYFIELD® Left Gel Pad (reference 440C1011) to determine if they either have batch number 093990 or 093984 on the label. Then, customers have to complete the Recall Acknowledgement and Return Form provided and to return it promptly as per the instructions on the form.
If they are in possession of the products (affected reference and batch), they have to quarantine them for shipment back to Integra.
Once Recall Acknowledgement and Return Form received by Integra and if they have identified affected product(s) in their inventory, Integra will proceed to an exchange of the product and will provide them with an RMA number to ship back affected product(s) to Integra.

Distributors:
Integra asks to its distributors to examine their inventory of MAYFIELD® Right Gel Pad (reference: 440C1012) and MAYFIELD® Left Gel Pad (reference 440C1011) to determine if they either have batch number 093990 or 093984 on the label. Then, distributors have to contact the final customers who may have the affected products and to provide them with this letter. Moreover, Integra request that distributors ship the Recall letter with each new shipment of listed products (reference only). Once the audit of distributors' inventory and their final customers' inventory achieved, they have to complete the Recall Acknowledgement and Return Form provided and return it promptly as per the instructions on the form.
If distributors or their final customers are in possession of the products (affected reference and batch), they have to quarantine them for shipment back to Integra.
Once your Recall Acknowledgement and Return Form received and if they have identified affected product(s), Integra will proceed to an exchange of the product(s) and will provide them with an RMA number to ship back affected product(s) to Integra.

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

The recall will begin on Thurday 16 August 2012.

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

Time schedule for the implementation of the different actions

This time will depend of customers' and distributors' feedback.

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

Within EEA, Switzerland and Turkey:

☐ AT	☐ BE	☐ BG	☐ CH	☐ CY	☐ CZ	☐ DE	☐ DK	☐ EE	☐ ES
☐ FI	☒ FR	☒ GB	☐ GR	☐ HU	☐ IE	☐ IS	☐ IT	☐ LI	☐ LT
☐ LU	☐ LV	☐ MT	☐ NL	☐ NO	☐ PL	☐ PT	☐ RO	☐ SE	☐ SI
☐ SK	☐ TR								

Candidate Countries:

☐ HR

☐ All EEA, Candidate Countries, Switzerland and Turkey

Others:

8 Comments

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

Jean-Charles MONCENIS	Lyon, France	August 13, 2012
Name	City	Date

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.