Report Form
Manufacturer's Field Safety Corrective Action Report

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

v.01.13

1. Administrative information	
To which NCA(s) is this report being sent? Agency for Medicines and Medical Devices of Bosnia and Herzegovina	
Type of report ☒ Initial report ☐Follow up report ☐Final report	
Date of this report 8 January 2014	
Reference number assigned by the manufacturer FA599	
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): Manufacturer legal entity in Switzerland	
3 Manufacturer information	
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5 National contact point information

National contact point name	
Name of the contact person	
Address	
Postal code	City
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E-mail	Country

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 15870
Nomenclature text Prosthesis, cardiac valve, biological	
Commercial name/brand name/make Medtronic Mosaic™ Aortic Bioprosthesis	
Model number 305	Catalogue number
Serial number(s) All	lot/batch number(s)
Device Manufacturing date NA	Expiry date NA
Software version number (if applicable)	
Accessories/associated device (if applicable) n/a	
Notified body (NB) ID- number 0123	

7 Description of FSCA

Device description:

The Mosaic Aortic Bioprosthesisis indicated for the replacement of malfunctioning native or prosthetic aortic valves and is available in sizes 19mm through 29mm.

Description of Issues:

There have been a total of 679 reported events for high gradient (inclusive of reports of high gradient and stenosis) from January 2000 through October 2013. The complaint trend has been stable for the last five years, with approximately 80 reported events each year, with the exception from May 2010 to April 2011, which had 116 reported events. High gradients and stenosis are considered chronic events, and as such are not expected to occur

within short implant durations without assignable physiologic and/or anatomical cause.

There have been a total of 399 Mosaic valves explanted for high gradient and stenosis from May 2000 to October 2013 (349 Aortic/ 50 Mitral). Of the 349 Aortic valves explanted, 284 (Aortic) were returned to Medtronic for analysis. Based on total sales for Mosaic Aortic (224,427) this represents an explant rate of 0.16%. For the same period of time, for Mosaic Mitral™ (Model 310) the explant rate is 0.06% (50/83.105), which isin-line with the predicted rate.

Current root cause concludes that:

- The flexible stent of the Mosaic aortic valve may be susceptible to annulardeformation if oversized with respect to the native aortic annulus (stentdeformation).
- Deformation of the stent annulus can result in a high measured gradient. Echomeasurements tend to overstate gradients compared with pressure transducer orcatheter measurements. Overstated gradients tend to be more pronounced invalves exhibiting deformation. This phenomenon was clearly demonstrated on thebench using echo measurements (annular deformation can cause a higher gradient).
- In the absence of stent deformation, oversizing (upsizing) the valve can obstruct theflow area of the valve and/or cause altered leaflet kinematics resulting in anelevated gradient (bioprosthetic inflow obstruction).

The higher-than-expected transvalvular gradients (> 25 mmHg) of the Mosaic Aortic Bioprosthesis have occurred at a rate of 0.33% (3.3 reports per 1000 aortic implants). Asubset of these valves was explanted within five years of implantation at an overall occurrence rate of 0.1% (1 explant per 1000 aortic implants).

The complaint analysis demonstrates that the current rates, based on cumulative data, and explants returned for analysis, are within the predicted risk, with the exception of Structural Valve Dysfunction resulting in Stenosis and Tissue Overgrowth resulting in Stenosis. The predicted risk for each of the failure modes (hazards)that can lead to the patient effect (or harm) of high gradient and/or stenosisleading to explant are “Broadly Acceptable” or “As Low as Reasonable Practical” (ALARP). The clinical performance of the valve based on the most recent Clinical Evidence Report, which includes a review of current literature from the last five years (Jan. 2007 to Mar. 2012) does not indicate or suggest that the overall safety and performance of the valve has changed relative to the predicted risk.

Description and justification of the action (corrective/preventive)

1. As a safety precaution measure, Medtronic is informing the customers (Physicians, Hospital Administrators, OR Managers and Risk Managers) of these issues.
2. Medtronic has modified the iEOA Mosaic Aortic Bioprosthesis sizing chart.
3. Medtronic has modified the current Mosaic Obturators/Sizers to align with the updated sizing chart. The IFU for the modified Mosaic Obturators/Sizers has been updated to include the new sizing chart (iEOA chart).
4. Medtronic will discontinue distribution of the previous Mosaic Obturators/Sizers and iEOA sizing chart.

Advice on actions to be taken by the distributor and the user:
Customers are recommended to dispose of existing iEOA sizing charts and begin to use the new iEOA sizing chartand the Mosaic Aortic Obturator/Sizer set.

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): Customer List in your country	

Time schedule for the implementation of the different actions

This FSCA is planned to be completed by 9 April 2014

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

- within the EEA, Switzerland and Turkey:

☒ AT ☒ BE ☒ BU ☒ 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

In Bosnia and Herzegovina customers are affected by this FSCA.

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

……
Signature

Jean-Charles Moreau	Heerlen	8 January 2014
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.