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? NL: NETHERLANDS, Healthcare Inspectorate Postal Address: P.O. Box 2680, NL - 3500BS Utrecht, The Netherlands meldpunt@igz.nl
Type of report ☒ Initial report ☐ Follow up report ☐ Final report
Date of this report November 3, 2016
Reference number assigned by the manufacturer 2955842-07/14/16-010-R
FSCA reference number assigned by NCA
Incidence reference number assigned by NCA
Name of the co-ordinating national competent authority (if applicable) Swiss Agency for Therapeutic Products (Swissmedic)
2. Information on submitter of the report
Status of submitter ☐ Manufacturer ☒ Authorised representative within EEA, Switzerland and Turkey ☐ Others (identify the role):
3 Manufacturer information
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4 Authorised representative information	
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6 Medical device information	
Class ☐ AIMD Active implants MDD Class III MDD Class IIb ☒ MDD Class IIa ☐ MDD Class I	IVD Annex II List A IVD Annex II List B IVD Devices for self-testing IVD General
Nomenclature system (preferable GMDN) GMDN	Nomenclature code 58483

Nomenclature text Endoscopic motorized cutting stapler	
Commercial name/brand name/make • IS4000 EndoWrist® Stapler 45 • IS4000 EndoWrist® Stapler 30 • IS4000 EndoWrist® Stapler 30 Curved-Tip	
Model number • 470298 • 470430 • 470530	Catalogue number N/A
Serial number(s) N/A	lot/batch number(s) Refer to the attachment A in the FSN and to the Table 1 in the Product Notice Extension
Device Manufacturing date From 09/06/2015 to 17/06/2016	Expiry date N/A
Software version number (if applicable) N/A	
Accessories/associated device (if applicable) N/A	
Notified body (NB) ID- number 0543	
7 Description of FSCA	
Background information and reason for the FSCA: Intuitive Surgical is voluntarily initiating a Medical Device Recall related to specific *EndoWrist*® Stapler 45 and 30 instruments for the *da Vinci*® *Xi*™ Surgical System. This recall follows from a field failure where the stapler remained clamped on tissue, even when the Stapler Release Kit was used. Intuitive Surgical has determined that this issue is the result of a bearing failure within the housing of the instrument. The bearing failure is associated with components from a specific bearing supplier and, as such, is found only in certain manufacturing lots of instruments as identified in Attachment A of the FSN and attached stop-use notification. The purpose of this Medical Device Recall notification is to advise customers of the return and replacement process for specific Xi Stapler 45 and 30 instruments with the identified bearing issue. Only the EndoWrist Xi Stapler 45 and 30 instrument lot numbers listed in Attachment A of the FSN and of the stop-use notice are affected by this Medical Device Recall. There were two clinical cases where this failure resulted in the instrument being clamped on tissue and could not be opened using the Stapler Release Kit.	

Description and justification of the action (corrective/preventive)

Intuitive Surgical will take the following actions:

- Intuitive Surgical will notify affected customers and distributors via a Field Safety Notice.
- Intuitive Surgical will ship replacement instruments at no charge once recalled EndoWrist Xi Stapler instruments are received from the customer.

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

- Customers and distributors will be required to provide Intuitive Surgical with an acknowledgement of FSN receipt and implementation of required actions.
- In addition, they are requested to return affected devices listed in the attachment A of the FSN

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

Progress will be reported with reconciliation data, once the final FSCA has been completed.

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

- The Field Safety Notice will be sent to affected customers immediately
- This FSCA is expected to be completed once the replacement Staplers are distributed and not later than 30th December 2016

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: Australia, Japan, South Korea, Taiwan, United States.

8 Comments

Difference between this Medical Device Recall (ref. **2955842-07/14/16-010-R**) and the Xi Stapler Partial Fires FSCA (ref. **2955842-07/08/16-009-R**, dated 22/07/2016):

- The two actions are separate based on the possible failure mode.
- This recall is regarding an inability to remove the stapler once clamped on tissue even when the

Stapler Release Kit is used.

- The action regarding partial fires is when the stapler firing sequence is interrupted prior to completion of the full staple line.
- All Xi System users have been notified for the partial fire FSN. Only users with specific lot numbers of Xi Stapler instruments will receive the recall communication.

Please be informed that this action was initiated in Europe in July 2016 but additional product LOTs were then identified as being affected by this Field Safety Corrective Action, with one single affected product remaining in use in Europe (in the Netherlands);
These additional product LOTs were identified as also affected as the sub-component causing the device failure was also used in their manufacturing.

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

……
Signature

…	Aubonne	November 3, 2016
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.