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? **State Institute for Drug Control** Šrobárova 48, 100 41 Prague 10, Czech Republic	
Type of report ☒ Initial report ☐ Follow up report ☐ Final report	
Date of this report 03/30/2015	
Reference number assigned by the manufacturer **FCA-57**	
FSCA reference number assigned by NCA N/A	
Incidence reference number assigned by NCA N/A	
Name of the co-ordinating national competent authority (if applicable) **Bundesinstitut für Arzneimittel und Medizinprodukte - BfArM**	
2. Information on submitter of the report	
Status of submitter ☐ Manufacturer ☒ Authorised representative within EEA, Switzerland and Turkey ☐ Others (identify the role): National Contact for Authorised representative	
3 Manufacturer information	
Name Edwards Lifesciences LLC	
Contact name Walter Wiegand	
Address One Edwards Way	
Postcode 92614	City Irvine
Phone +1.949.250.2443	Fax
E-mail EC_REP@edwards.com	Country USA
4 Authorised representative information	
Name Edwards Lifesciences Services GmbH	
Contact name Dr. Robert Madjno	
Address Edisonstr. 6	

Postcode 85716	City Unterschleißheim
Phone +49 89 95475 203	Fax +49 89 95475 305
E-mail Robert_madjno@edwards.com	Country Germany

5 National contact point information

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

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 **37695**

Nomenclature text
Catheter, perfusion

Commercial name/brand name/make
Peripheral Access Cannulas

Model number / Lot number / Expiration date

Product Code	Lot Number	Expiration Date
FEMII008A	59751073	5/1/2017
FEMII008A	59775775	5/1/2017
FEMII008A	59775776	5/1/2017
FEMII008A	59775777	5/1/2017
FEMII008A	59852930	8/1/2017
FEMII008AT	59807985	7/1/2017
FEMII008AT	59867050	9/1/2017
FEMII008AT	59873263	11/1/2017
FEMII008V	59873250	9/1/2017
FEMII008V	59873251	10/1/2017
FEMII010A	59740468	5/1/2017
FEMII010A	59773806	5/1/2017
FEMII010A	59792415	5/1/2017
FEMII010A	59792416	5/1/2017
FEMII010A	59852934	8/1/2017

Product Code	Lot Number	Expiration Date
FEMII010V	59751074	5/1/2017
FEMII010V	59849119	8/1/2017
FEMII010V	59890924	11/1/2017
FEMII012A	59801792	8/1/2017
FEMII012A	59867064	9/1/2017
FEMII012A	59884766	11/1/2017
FEMII012A	59884778	11/1/2017
FEMII012AT	59852940	8/1/2017
FEMII012AT	59867051	9/1/2017
FEMII012V	59723307	5/1/2017
FEMII012V	59796683	6/1/2017
FEMII012V	59849124	8/1/2017
FEMII012V	59873252	11/1/2017

Catalogue number
N/A

FEMII010AT	59747819	5/1/2017
FEMII010AT	59807986	6/1/2017
FEMII010AT	59852935	8/1/2017
FEMII010AT	59890916	11/1/2017
FEMII010AT	59896910	11/1/2017

Serial number(s) N/A	Lot/batch number(s) **See table**
Device Manufacturing date N/A	Expiry date **See table**
Software version number (if applicable) N/A	
Accessories/associated device (if applicable) N/A	
Notified body (NB) ID- number **DEKRA, 0344**	

7 Description of FSCA

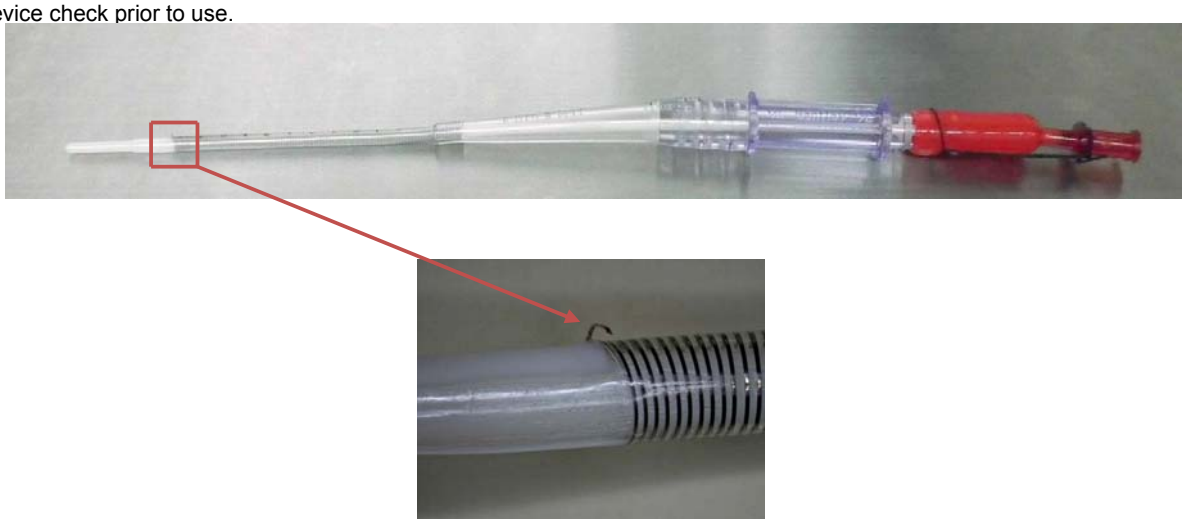
Background information and reason for the FSCA

Product Description:

The Edwards Femoral Access Venous and Arterial cannulae without Duraflo coating are wire-reinforced, thin-wall polyurethane or PVC cannulae. The wire reinforcement is intended to prevent kinking during use. The clear proximal section of the cannula is unreinforced for clamping and terminates in either a barbed connector for 1/4' or 3/8" tubing connection.
The cannulae are available on various sizes and lengths. Each cannula is supplied with a dilator and/or introducer that will pass over a .038" (0.96 mm) guidewire. Barium stripes on the tubing aid in cannula placement. Some codes include an additional non-lumen dilator. Some product codes may also include a suture ring. Some cannulae models include two barium stripes on the tubing and an additional non-lumen dilator to aid in placement.
Edwards Lifesciences femoral access cannulae are intended for use in situations which require rapid femoral venous and arterial access for short-term (≤ 6 hours) cardiopulmonary bypass.
The product has three year shelf life.

Issue Description and Reason for the FSCA

Through post market surveillance, Edwards Lifesciences has identified a potential health risk to patients regarding the use of Fem-Flex II Femoral Access Cannula, sizes 8, 10, and 12 French only. Edwards has received one customer complaint regarding a released wire, located at the tip area of the cannula (see Figure 1 and 2), which was identified during the device check prior to use.



Although the condition does not affect the functionality of the cannula, there is potential patient safety risk if a protruding wire is not detected prior to use as it could cause a vascular injury that could require surgical or interventional repair.

These devices are used by highly trained clinicians, experienced in identifying and mitigating any hazards that arise during their use. In addition, these devices are typically used in Operating Rooms, where the patients are closely monitored.

While there have been no reports of injury associated with this, Edwards is taking this action to eliminate the chance of tissue damage caused by a protruding wire.

Description and justification of the action (corrective/preventive)
All customers will be notified via FSN. Product is to be returned as part of this FSCA. Product can either be re-worked at the manufacturing facility and properly re-distributed with a new assigned lot number, or can be destroyed via certified burial.
CAPA has been initiated to document investigation and corrective actions.

Advice on actions to be taken by the distributor and the user
Distributor / user is notified via FSN requiring to review inventory for the listed lots listed in the recall letter. Once the inventory is verified customer is advised to complete and return back the acknowledgment form that is part of the FSN. Affected products will be returned to Edwards and replacement product will be obtained after contacting Edwards's representatives.

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

N/A

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

Time schedule for the implementation of the different actions

3 months from initiation

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								

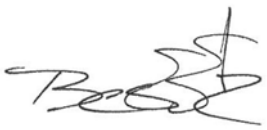
Candidate Countries:
☐ HR

☐ All EEA, Candidate Countries, Switzerland and Turkey

Others:
USA, Israel, UAE, South Africa, Egypt

8 Comments

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



Petr Bestak
Sr. Officer, Regulatory Affairs EMEA
Edwards Lifesciences

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.