PROPOSED DOCUMENT

Title: Field Safety Corrective Action (FSCA) Report Form

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Date: 18 November 2010

FIELD SAFETY CORRECTIVE ACTION (FSCA)
REPORT FORM

FSCA Ref	
Report No. (Official Use Only)	

Reporting FSCA to _____

FSCA Type	☐ Device Removal ☐ Device Modification ☐ Implant Alert ☐ Device Precaution ☐ User Warning ☐ Other - please specify: _____		
FSCA classification (If known)	☐ Class I (Can lead to death or serious injury) ☐ Class II (Can lead to temporary injury) ☐ Class III (Will not cause any injury)		
Authorized Representative Particulars			
Name of company			
Company address			
Contact person name			
Job title			
Mobile Phone No.		Fax No.	
Email Address			
Device Information			
Device Name			
Device intended use			
Product License No.			

Product Registration No.	
Nomenclature System	AMDNS/UMDNS Code :
	GMDN Code :
Catalogue No.	
Serial No.	
Lot / Batch No.	
Accessories/Associated Devices affected *(if any)*	
Legal Manufacturer and contact details	
Wholesaler(s) and contact details (If known)	
FSCA Information	
Did the FSCA arise due to an adverse event?	☐ Yes ☐ No
Reason for the FSCA	
Did this adverse event occur locally?	☐ Yes ☐ No
Has the adverse event been reported to the local Regulatory Authority before?	☐ Yes (Adverse event ref. no.: _____) ☐ No
Evaluation of the risk associated with affected device **(Please provide Health Hazard Evaluation Report)**	☐ Serious public health concern ☐ Possible deaths ☐ Possible serious injury ☐ Possible minor injury ☐ Other - please specify: _____

Please provide a copy of the FSCA communication materials	☐ Dear doctor letter ☐ Dear customer letter ☐ Dear distributor letter ☐ Other - please specify: _____
Has the FSCA communication been sent to stakeholders? (If applicable)	☐ Yes (Date sent: _____ (dd/mm/yyyy)) ☐ No (Expected date to be sent: _____ (dd/mm/yyyy))
Number of affected units supplied **(Please enclose distribution list)**	- Total numbers of units imported _____ (A) - Total numbers of units supplied to the distributors _____ (B) - Total numbers of units consumed _____ (C) - Total numbers of units implanted _____ (D) - Total numbers of units in the warehouse _____ (E) - Total numbers of units returned _____ (F) - Total numbers of units could not be located _____ (G) - Total numbers of units in transit _____ (H) A = B+C+D+E+F+G
Regulatory Authorities to which this FSCA has been reported *(if any)*	

Date of commencement of FSCA by legal Manufacturer (dd/mm/yyyy)	
Date of commencement of FSCA by Authorized Representative (dd/mm/yyyy)	
Proposed date of completion of FSCA by Authorized Representative (dd/mm/yyyy)	
Other Information	

I attest that the above information submitted is to the best of my knowledge. I understand that the above information may be communicated to other parties or disseminated to the public for protecting the public health.

Signature : _____

Name of Reporting Person : _____

Date of this Notification : _____ (dd/mm/yyyy)

Company/Organization : _____

Mobile Phone No. : _____

Remarks (for official use only)

This page should not be included in the submission

Guidance on how to fill this form

Please answer every question with an appropriate answer, N/A (not applicable) or N/K (not known at this time). If some of the applicable information required in this form is not available by the time the deadline for the particular category of report has expired, a report should be submitted containing all the available information.

A statement as to why any required information is not available and a date when it will be submitted must be included.

The form may be filled longhand or electronically using Word® - simply <tab> to the appropriate field and type the required information.

The following provides some guidance on what information is required in some parts of the form. It is envisaged that the fields not mentioned in this explanatory note are self-explanatory.

Definition of Field Safety Corrective Action:
A field safety corrective action (FSCA) is an action taken by a product owner to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device.

This may include:
- Device removal;
- device modification;
- implant alert;
- device precaution
- user warning;

Device modifications may include (non-exhaustive):
- retrofit in accordance with the product owner's modification or design change;
- permanent or temporary changes to the labelling or instructions for use;
- software upgrades including those carried out by remote access;
- modification to the clinical management of patients to address a risk of serious injury or death related specifically to the characteristics of the device.

Device Details

Market authorization no.: The number assigned to the device in by the agency that approved it for the use in the market.

Legal Manufacturer: means any natural or legal person2 with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s). Refer to the GHTF document, GHTF/SG1/N055: 2009 for the full definition of the term.

Authorized Representative: means any natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation.

Wholesaler(s) and contact details: A wholesaler is a person who supplies the medical device by wholesale in their respective market.

FSCA Information

If yes, has the adverse event been reported to local regulatory authority?: Adverse event ref no refers to the reference number assigned to the adverse event report submitted by the company to the local authority.

Evaluation of the risk associated with affected device (Health hazard evaluation report): This refers to a report containing an assessment of the hazard posed by the affected medical device and an estimation of the probability of the defect or malfunction occurring, the severity of injury to individuals exposed to the product and the probability of the injury occurring during exposure to the medical device.

Reason for the FSCA: Please include in this section a description of device defect or possible defect, consequences of using the affected device, date on and circumstances under which the defect or possible defect was discovered.

A copy of the FSCA communication: This refers to any communication issued by the company to notify its consignees about the FSCA. Consignee means anyone who has received, purchased or used the product being recalled or corrected.

FSCA strategy: Please include in this section information on depth of FSCA, FSCA communications, effectiveness checks and stock control.