MDA/GD/0015
June 2020
First Edition

MEDICAL DEVICE GUIDANCE DOCUMENT

MEDICAL DEVICE RECALL

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

Contents Page

Preface iii
0 Introduction 1
1 Scope and application 1
2 Terms and definitions 1
3 Requirements for voluntary recall 2
4 Requirements for mandatory recall 3
5 Recall Process 3
5.1 Initiation of recall 4
5.2 Implementation of recall 6
6 Record of recall 7
6.1 Initiation of recall 7
6.2 Retention of recall records 7
Annex A Process flow for medical device recall 8
Annex B Medical device recall report form 9
Annex C Template for recall notification to the user 13
Annex D Reason of recall termonology 17

Preface

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737);

b) Medical Device Regulations 2012; and

c) Medical Device (Duties and Obligation of Establishments) Regulations 2019.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

When a requirement is required to be “documented”, it is also required to be established, implemented and maintained.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the incident of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

CONTACT INFORMATION

For further information, please contact:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website:mda.gov.my

MEDICAL DEVICE RECALL

0 Introduction

It is necessary to protect public health and patient safety by ensuring that all medical devices in the Malaysian market meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely.

The Medical Devices (Duties and obligations of establishment) Regulations 2019 detailed out requirements for post-market surveillance and vigilance as provided in Chapter 3 of the Medical Devices Act 2012 (Act 737). These regulations are imposed to ensure licensees carry out their responsibilities to monitor and continuously ensure the safety and performance of their medical devices in the market.

Recall is part of a post-marketing risk assessment measure to ensure the continued safe use of medical devices and is an important part of the post-market surveillance system.

1 Scope and application

This guidance document elaborates requirements pertaining to recall of a medical device that has issues of safety and performance as stipulated in Section 42 of Act 737 and Regulation 7 and 8 of Medical Device (Duties and Obligations of Establishments) Regulations 2019. This guidance document applies to:

a) medical device as defined in Section 2 of Act 737; and

b) establishments.

2 Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

2.1 affected person

All recipients of medical device affected by the recall according to distribution record.

2.2 corrective action

Action to eliminate the cause of nonconformities to prevent a recurrence.

2.3 incident

An event that causes, or has a potential to cause, unexpected or unwanted effects involving the safety of any person who use a medical device or any person associated with the use of a medical device.

Note. Incident is referred as adverse event in ASEAN Medical Device Directive.

2.4 intended purpose

The objective intent of the manufacturer regarding the use of product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

2.5 recall strategy

A planned specific course of action to be taken in conducting a specific recall, which include but not limited to depth and scope of recall, the need for public warnings, and extent of effectiveness checks for the recall.

2.6 serious public health threat

Any incident which results in imminent risk of death, serious deterioration in state of health, or serious illness that requires prompt remedial action. This would include:

a) incidents that are of significant and unexpected nature such that they become alarming as a potential public health hazard, e.g. human immunodeficiency virus (HIV) or Creutzfeldt-Jacob Disease (CJD). These concerns may be identified by either the Authority or the manufacturer; or

b) the possibility of multiple deaths occurring at short intervals.

2.7 use error

Act or omission of an act, that has a different result to that intended by the manufacturer or expected by the user of the medical device.

2.8 user

person using or operating a medical device on any person acquiring services in a healthcare facilities and related facilities.

3 Requirements for voluntary recall

Recall is any action taken by the establishment of the medical device to remove the medical device from the market or to retrieve the medical device from any person to whom it has been supplied and to notify its affected person of its defectiveness or potential defectiveness, after becoming aware that the device:

a) may be hazardous to health;

b) may fail to conform to any claim made by the manufacturer/ Authorised Representative relating to its effectiveness, benefits, performance characteristics or safety; or

c) may not meet the requirements of the law.

4 Requirements for Mandatory Recall

The Authority has the right to order for a medical device recall if a medical device possesses a high public health risk from the market as described in section 42 (4) of Medical Device Act 2012 (Act 737). Establishment is responsible for all recall procedure as per Clause 3. The Authority will monitor the whole recall process. The Authority may also take role in communicating with stakeholders involved as necessary.

4.1 The Authority will assess the health hazard presented by a medical device that is being considered for a mandatory recall action. As examples, the following factors may be taken into account:

a) whether any serious illness or injury has already occurred from use of the device, and the likelihood of occurrence of the incident when the device is continued to be used;

b) whether any existing conditions could contribute to a clinical situation that could expose the public to a health hazard;

c) whether it gives potential hazard to individual groups within the exposed population (such as children, the elderly, patients having surgery or to those who are with special conditions, as an example: immune compromised individual), and the degree of seriousness of the health hazard to which the population will be exposed;

d) whether there are serious illnesses and injuries reported that have already occurred from the use of the device, and the establishment is aware about the risk but not acting on its own initiative;

e) whether alternative treatment options are available, including the risk associated with providing no treatment if an alternative is not available.

4.2 The recall risk classification and level of recall will be agreed upon by the Authority and the establishment on the basis of the information available as stated in 3.1.2.

4.3 The Authority will instruct the establishment in writing, stating its decision to recall a medical device.

4.4 The Authority will decide the timeline given to the establishment to initiate, to provide a follow up information and finally to complete the mandatory recall implementation.

4.5 The establishment shall provide all the information required by the Authority as in Annex B and Annex C of this Guidance Document.

5 Recall Process

An establishment shall put in place a documented procedure on recall to describe actions to be taken in initiating and carrying out the recall process timely and effectively to meet the requirements imposed in Section 42 of Act 737 and Regulations

7 and 8 of Medical Device (Duties and obligation of establishments) Regulations 2019. Recall process is carried out in two phases;

i) Phase 1: Preparation; and

ii) Phase 2: Implementation.

5.1 Initiation of recall

5.1.1 Problem identification

Recall may be initiated when there is problem associated with medical device that may pose hazard or potential risk to the users or public, identified through post market information (incident or problem) received from customers. The problem may also be identified from trends analysis of complaints and incidents.

5.1.2 Risk assessment & decision to recall

The establishment shall assess the hazard or potential risk presented by the problem associated with the medical device, and classifies the recall in accordance with Regulation 7 of Medical Device (Duties and obligation of establishments) Regulations 2019. The establishment shall determine the class of recall according to the potential risk to public health to determine the level of priority and assign a time frame for notification to the Authority, communication to the person affected by the recall and completion of the recall. The class of recall is as follows;

Class of recall	Description	Timeframe*
Class I - High risk	Represents the most serious type of recall. In a Class I recall, there is a reasonable probability that the product will cause serious health consequences or even death. Example: a) Wrong products (label and contents are different products); b) Microbial contamination of sterile injectable or ophthalmic product; c) Chemical contamination with serious medical consequences; d) Mix up of some products with other products; and e) Wrong active ingredient in a combination product with serious medical consequences.	within 48 hours
Class II - Medium risk	Represents a medium risk, which is less risk than the Class I recall. In a Class II recall, there is either a probability that the device will cause temporary or reversible health consequences, or there is remote probability that the device will cause serious consequences. Example:	within 3 working days

	a) Mislabelling (e.g. wrong or missing text or figures); b) Missing or incorrect information – from product's leaflets or inserts; c) Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences; d) Chemical / physical contamination (significant impurities, cross contamination, particulates); e) Detectable mix up of products in containers; f) Non-compliance with specification; and g) Insecure closure with serious medical consequences.	
Class III - Low risk	Represents the lowest risk. In a Class III recall, there is low probability that using or being exposed to a device will cause health consequences. By considering that the product is having problem, there is still a need to take an action to address the problem. Example: a) Faulty packaging e.g. wrong or missing batch number or expiry date; b) Faulty closure; or c) Contamination - microbial spoilage, dirt or detritus, particulate matter.	within 5 working days
***time frame to notify the Authority and the person affected by the recall. If additional timeline is required to notify all affected person, the establishment shall notify the Authority in preliminary report.*		

5.1.3 Preparation of recall strategy

The establishment shall prepare and document a recall strategy to;

a) plan the execution of recall including specifying the level in the distribution chain to extend the recall as follows;

   i- consumer or user level;
   ii- retail level; and
   iii- distributor level.

b) identify all personnel involved, along with their functions and responsibilities,

c) identify the stock of the defective medical devices as per distribution record,

d) set out the channels and means of communications for executing the recall,

e) arrange quarantine facilities to quarantine recalled medical device,

f) determine and arrange further action to ensure all defective medical devices are no longer available in the market.

5.1.4 Notification to the Authority and the affected person

Establishment shall, on or before initiating a recall of a medical device, notify the Authority (using the form in Annex B) and all affected person (using form in Annex C) within the timeframe as shown in the above table. The establishment shall inform the affected person to identify and isolate the defect medical devices, cease the use of the defect medical devices immediately, cease the sale or distribution of the defect medical devices.

5.1.4.1 In the notification to the Authority, the establishment shall provide the anticipated closure date of the recall. A rationale shall also be provided if the completion is expected to take longer than the anticipated closure date.

5.1.4.2 If the medical device is exported to other countries, the establishment should follow requirements imposed in the importing country.

3.1.4.3 If additional timeline is required to notify all affected person, the establishment shall notify the Authority in preliminary report.

5.2 Implementation of recall

5.2.1 Recall execution

The establishment shall verify that all affected person have received the recall notification and have taken appropriate action to recall the medical device. All recalled medical device shall be identified and isolated accordingly so that it will not be put back in the market unless rectification has been completed on the said device. The establishment shall perform effective check on recall execution through site visits, phone calls, fax, emails letters or a combination of those means.

5.2.2 Collection of affected medical device in stocks

The establishment shall arrange for collection of recalled medical device from the affected person. The establishment shall ensure all recalled medical devices collected are as per identified (in the distribution record) in the recall strategy.

5.2.3 Quarantine of recalled medical device

The establishment shall arrange transportation and storage facilities to quarantine recalled medical devices. The establishment shall take control measures to ensure recalled medical devices will not be placed back in the market.

5.2.4 Further action to eliminate recalled medical device from the market

Depending on the type of recall, the establishment shall carry out the appropriate actions after initiation of the recall such as, but not limited to:

a) removal of the medical device from its current location;

b) quarantine of the affected medical devices;

c) return of the medical device to the establishment;

d) disposal of the medical device; and/or

e) issuance of public warnings. Public warnings are for urgent situations and are issued to alert the public that a product being recalled presents a serious hazard to health, and where other means for preventing the use of a recalled product appear inadequate.

5.2.5 Submission of recall final report to the Authority

The establishment shall submit a report of recall within 30 days after the completion of a recall. The report to the Authority shall contain the following:

a) the circumstances leading to the recall;

b) the consequent action taken by the establishment/manufacturer;

c) the extent of distribution of the relevant batch in the country and oversea (if applicable);

d) the result of the recall - quantity of stock returned or corrected;

e) confirmation, that all affected person have received the recall notice;

f) the method of disposal of the recalled products (if applicable); and

g) proposed to be implemented in future to prevent a recurrence of the problem.

Establishment may use the report template in Annex B. The recall report shall be submitted to the Authority via e-mail at recall_enquiry@mda.gov.my. The Authority may notify the closure of the recall to the establishment in writing if the Authority is satisfied with the recall report submitted by the establishment.

6 Record of recall

6.1 Maintenance of recall record

All records pertaining to initiation and implementation of recall including instruction of mandatory recall issued by the Authority shall be kept accordingly. The records shall include;

a) recall plan and strategy;

b) notification to the Authority and the persons affected by the recall; and

c) information on recalled medical device, location of recalled medical device being quarantined and action taken after recall is completed.

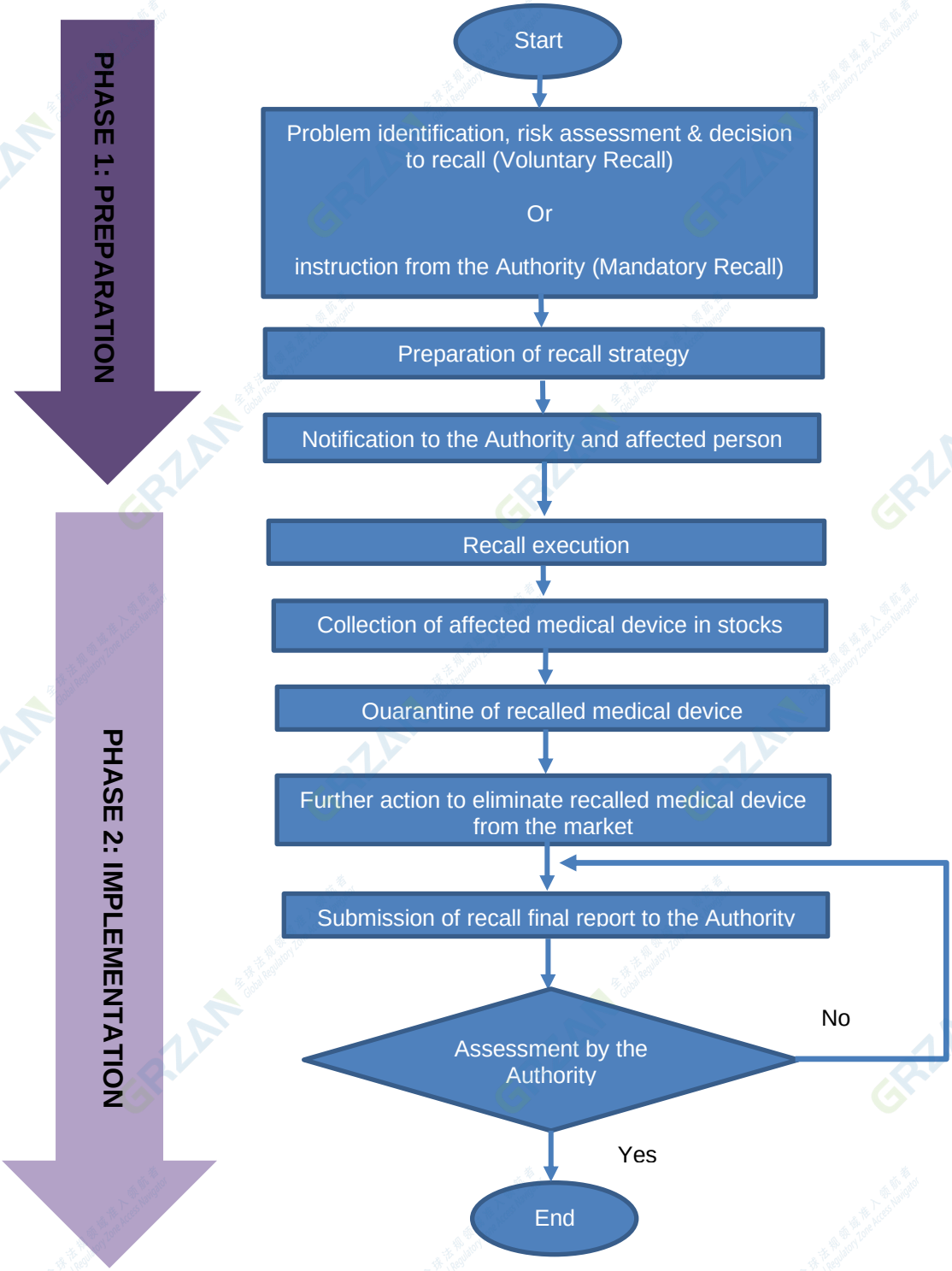
6.2 Retention of recall records

Recall records maintained with respect to a medical device shall be retained for a period of 5 years on top of the projected useful life of the medical device as

determined by the manufacturer (for example, if the projected useful life of the medical device is one year, the recall records should be kept for six years).

Annex A
(informative)

Process flow for medical device recall



Annex B
(informative)

Medical Device Recall Report Form

Notes:
1. This reporting form may be used by establishment as a template (for medical device manufacturer (local)/ authorised representative/ distributor) to submit a report on medical device recall for medical device registered in Malaysia.
2. Although the format of the form might differ from one establishment to another, the contents of this form are mandatory. It is mandatory to complete all the information.
3. Recall report is to be submitted to recall_enquiry@mda.gov.my

Medical Device Recall Report Form			
Recall Initiated by	☐ Establishment ☐ Authority (Recall Ref no. : _____)		
Type of Report	☐ Notification/ Preliminary Report ☐ Follow Up Report (Report no. :_____) ☐ Final Report		
Establishment Details			
Name of establishment			
Establishment address			
MDA Establishment License No.			
Contact person name			
Job title			
Tel No.		Fax No.	
Email Address			
Device Details			
Affected Device Name			
Device intended use			
Device category	☐ Non-invasive device ☐ Invasive device ☐ Active device	☐ Implantable device ☐ IVD device ☐ Other (specify):	
MDA Device Registration No.			
Table of Device Details			
Product Number/ Catalogue Number	Lot/Serial Number	UDI Code *(if applicable)*	Quantity
(If the list is more, please provide an attachment)			
Manufacturer Name			
Manufacturer Address			
Notification Report Section: Recall Information			
Date of report	(Date: _____(dd/mm/yyyy))		
Did the recall arise due to an adverse incident? *(Please select only one)*	☐ Yes ☐ No		
If yes, what is the category of adverse incident? *(Please select all applicable)*	☐ Serious Public Health Threat ☐ Death ☐ Serious Injury ☐ Non-serious Injury		

Did this adverse incident occur in Malaysia?	☐ Yes ☐ No
Has the adverse incident been reported to the Authority? (Please select only one)	☐ Yes (Adverse incident ref. no.: _____) ☐ No

Reason for recall (Refer to Annex D)	☐ A01: Patient Device Interaction Problem ☐ A02: Manufacturing, Packaging or Shipping Problem ☐ A03: Chemical Problem ☐ A04: Material Integrity Problem ☐ A05: Mechanical Problem ☐ A06: Optical Problem ☐ A07: Electrical /Electronic Property Problem ☐ A08: Calibration Problem ☐ A09: Output Problem ☐ A10: Temperature Problem ☐ A11: Computer Software Problem ☐ A12: Connection Problem ☐ A13: Communication or Transmission Problem ☐ A14: Infusion or Flow Problem ☐ A15: Activation, Positioning or Separation Problem ☐ A16: Protective Measures Problem ☐ A17: Compatibility Problem ☐ A18: Contamination / decontamination Problem ☐ A19: Environmental Compatibility Problem ☐ A20: Installation-Related Problem ☐ A21: Labelling, Instructions for Use or Training Problem ☐ A22: Human-Device Interface Problem ☐ A23: Use of Device Problem ☐ A24: Adverse Event Without Identified Device or Use Problem ☐ A25: No Apparent Adverse Event ☐ A26: Insufficient Information ☐ A27: Appropriate Term/Code Not Available
Recall class	☐ Class I : High Risk ☐ Class II : Moderate Risk ☐ Class III : Low Risk
Recall strategy and action to be taken	
Extension timeline for notification affected customers if required, justification	
Action to be taken by the customer/user	
Date of recall initiation *(Expected date of first notification to affected customer)*	
Estimated Date to complete recall	
Expected date to submit recall report to the Authority	
Attachments	☐ A copy of the Recall communication to affected person ☐ Table of affected device details

Recall Report Section:	
Has recall communication been sent to all affected person?	☐ Yes (Date sent: _____(dd/mm/yyyy)) ☐No (Expected date to be sent: _____(dd/mm/yyyy)) If the above do not meet the time line given by the Authority according to the recall class, please state the reason why: _____
Total number of affected units supplied to each affected person	
List of impacted countries *(if any)*	
Date of commencement of recall by manufacturer (dd/mm/yyyy)	
Date of commencement of recall **in Malaysia** (dd/mm/yyyy)	
Proposed date of completion of recall in Malaysia Note: complete retrieval product from the market. (dd/mm/yyyy)	
Expected date to submit final report to the Authority	
The method of quarantine and segregation for the recalled products	
Attachments	☐ List of hospital/customer/user with number of affected device in their storage ☐ Copy of acknowledgment receipt on the product recall by the affected customers
Final Report Section:	
Has the recall exercise been completed?	☐ Yes (Date : _____(dd/mm/yyyy)) ☐ No, *(justification)*: _____ _____ _____
The method of disposal for the recalled products	Specify method: _____ If other: Date of completion: (Date : _____(dd/mm/yyyy))
Final risk evaluation (if different from the initial risk evaluation)	
Proposed action(s) to prevent recurrence of the problem	

Table of Final Device Status

Product/ Catalogue Number	Lot/ Serial No.	Total affected unit **(z=x+y)**	Quantity remaining in warehouse **(x)**	Quantity sold **(y=a+b+c)**	Quantity Recalled **(a)**	Quantity consumed by customer **(b)**	Quantity un-identified **(c)**	Quantity corrected **(p)**	Quantity disposed **(q)**	Others **(r)**

(If the list is more, please provide an attachment) (x+a)=(p+q+r)

Justification on total quantity of unidentified device (if applicable)	
Attachments	☐ Table of final device status ☐ Health risk assessment report ☐ Report on action(s) to prevent recurrence of the problem (if applicable) ☐ Evidence of returning affected device to the manufacturer (if applicable) ☐ Evidence of disposal process (if applicable)

Other information

Attestation

I attest that the information submitted is true and correct.

Signature : _____
Name of Reporting Person : _____
Position : _____
Date of this report : _____ (dd/mm/yyyy)
Company stamp : _____

Annex C
(informative)

Template for recall notification to the user

Company Name & Letterhead
Date (Month, Day, Year)

URGENT: MEDICAL DEVICE RECALL <PRODUCT NAME>

(1) Attention to customer:

Customer Name

Address

City, State, Postcode

Dear Device Customer/Distributor,

(2) Purpose of this letter

The purpose of this letter is to advise you that Company Name is voluntarily recalling Product X (include the name, intended use statement, and any additional identification detail not covered in the Product and Distribution Information section).

Note: If any serious injuries and/or deaths have occurred or could occur as a result of the failure of the device, add this sentence in bold font: **"Serious injuries and/or deaths have occurred or could occur due to the failure mode associated with this recall."**

(3) Reason for the voluntary recall:

Identify the product concerns/problems, whether actual or potential, in detail (For example, what happens when the device fails). Include the following information, if available:

- **Frequency of failures and complaints (**for example, "We are aware of [number of] product failures and [number of] complaints associated with the problem.")
- **Magnitude of the error, if applicable** (for example, the failure results in values 15% lower than true values)
- **Adverse incidents** (e.g. injuries, deaths)

(4) Risk to health:

a) Explain how the device failure or problem will affect patients, health care providers, or other persons who are exposed to the device. If the device failure can cause injuries, delays in surgical procedures, or other delays in treatment or therapy, provide an explanation of why that is so.

b) Add the statement "How to recognize that the device may fail." Describe the methods of recognition of the device failure by the customer/user. Give an explanation (in lay terms) of how the failure occurs and how to detect/recognize the issue.

(5) Actions to be taken by the customer/user:

Describe actions for safe handling of the recalled product (for example: discontinue use, discard or correct the product, return the product, etc.) State whether these actions are temporary or long-term and, if applicable, when a long-term solution will be implemented. At a minimum, ensure that the following elements are included:

- recommended treatment or actions for users to minimize risks of illness or injury;
- actions to be taken pending corrective or removal action;
- alternative products that can be used, if applicable, and/or whether removal of the product will cause a shortage;
- specific instructions for recall (for example, private labelling or associated kits, if applicable); and
- Instructions for acknowledgement (reply by fax, email, telephone, etc.).

(6) Product and distribution information:

Describe product information in the sufficient level for user to enable clear identification of devices subject to recall. This information can be given as a text or in tabular format. The information should contain relevant details in order to ensure sufficient understanding by the user, such as information in the table below. Photographs of the product are optional.

Product and Distribution Information Table					
Product name, Unique device identifier (if applicable)	Manufacturer's Product number/ Catalog number	Lot/ Serial number	Manufacturing/ Distribution dates	Expiry date (MM/DD/YYYY)	Quantity

(7) Type of action by the company (if applicable):

What is the firm doing to correct this issue? – (for example, system updates, removal, and change in labelling). When will these corrective actions be taken by the company (short and long-term)?

- Investigation findings:

(8) Other information:

a) Contact information for questions.

b) Attachments of Acknowledgement and Receipt Form (separate sheets).

Authorised by:

Name: (Print)

Signature:

Title:

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form
Response is required

Customer Information:
Customer Name:
Address:

PRODUCT NAME

Please distribute this information to the appropriate personnel at your facility including surgeons who may have received the product which is the subject of this recall notice.

Lot/Serial numbers:

I have read and understand the recall instructions provided in the <date of> letter.
Yes _ No _

Any adverse incidents associated with recalled product? Yes _ No _
If yes, please explain:

Was this device implanted? (If yes, please specify the implant dates, the quantities implanted, and provide available tracking information).

Affected product information: Include information that is applicable for affected product.

Affected Product Information Table			
Product/ Brand names, UDI (if applicable)	Manufacturer's Product number/ Catalogue number	Lot/ Serial number shipped to customer	Quantity in inventory/ returned

Return Response Box:

Please provide any additional information, if applicable.

PLEASE RETURN COMPLETED RESPONSE FORM TO:

Fax. # < >, ATTN: < >
OR MAIL TO: FIRM NAME AND ADDRESS

Annex D
(informative)

Reason of recall terminology

Term	Definition	Code
Patient Device Interaction Problem	Problem related to the interaction between the patient and the **device**.	A01
Manufacturing, Packaging or Shipping Problem	Problem associated with any deviations from the documented specifications of the **device** that relate to nonconformity during manufacture to the design of an item or to specified manufacturing, packaging or shipping processes (out of box problem).	A02
Chemical Problem	Problem associated with any from the documented specifications of the **device** that relate to any chemical characterization, i.e., element, compound, or mixture.	A03
Material Integrity Problem	Problem associated with any deviations from the documented specifications of the **device** that relate to the limited durability of all material used to construct device.	A04
Mechanical Problem	Problems associated with mechanical actions or defects, including moving parts or subassemblies, etc.	A05
Optical Problem	Problem associated with transmission of visible light affecting the quality of the image transmitted or otherwise affecting the intended application of the visible light path.	A06
Electrical /Electronic Property Problem	Problem associated with a failure of the electrical circuitry of the **device**.	A07
Calibration Problem	Problem associated with the operation of the **device**, related to its accuracy, and associated with the calibration of the **device**.	A08
Output Problem	Problem associated with any deviation from the documented specifications of the **device** that relate to the end result, data, or test results provided by the **device**.	A09
Temperature Problem	Problem associated with the **device** producing unintended temperatures.	A10

Computer Software Problem	Problem associated with written programs, codes, and/or software system that affects device performance or communication with another device.	A11
Connection Problem	Problem associated with linking of the **device** and/or the functional units set up to provide means for a transfer of liquid, gas, electricity or data.	A12
Communication or Transmission Problem	Problem associated with the **device** sending or receiving signals or data. This includes transmission among internal components of the **device** to which the **device** is intended to communicate.	A13
Infusion or Flow Problem	Problem associated with the **device** failing to deliver liquids or gases as intended (e.g. delivering drugs at incorrect rate, Problems with drawing fluid from a system.)	A14
Activation, Positioning or Separation Problem	Problem associated with any deviations from the documented specifications of the **device** that relate to the sequence of events for activation, positioning or separation of device. NOTE 1 “Deployment” is synonymous with “activation”.	A15
Protective Measures Problem	Problem associated with any deviations from the documented specifications of the **device** that relate to the implemented and inherited design features specific to devices used for reducing risks to patient or caregiver or maintaining risks within specified levels.	A16
Compatibility Problem	Problem associated with compatibility between device, patients or substances (medication, body fluid, etc.)	A17
Contamination / decontamination Problem	Problem associated with the presence of any unexpected foreign substance found in the **device**, on its surface or in the package materials, which may affect performance or intended use of the **device**, or problem that compromise effective decontamination of the **device**.	A18
Environmental Compatibility Problem	Problem associated with the surrounding conditions in which the **device** is being used such as temperature, noise, lighting, ventilation, or other external factors such as power supply.	A19
Installation-Related Problem	Problem associated with unsatisfactory installation, configuration, and/or setup of a specific **device**.	A20

Labelling, Instructions for Use or Training Problem	Problem associated with **device** markings / labelling, instructions for use, training and maintenance documentation or guidelines.	A21
Human-Device Interface Problem	Problem associated with an act or omission of an act that has a different result than that intended by the manufacturer or expected by the operator.	A22
Use of Device Problem	Problem associated with failure to process, service, or operate the **device** according to the manufacturer's recommendations or recognized best practices.	A23
Adverse Event Without Identified Device or Use Problem	An adverse event (e.g. patient harm) appears to have occurred, but there does not appear to have been a problem with the **device** or the way it was used.	A24
No Apparent Adverse Event	A report has been received but the description provided does not appear to relate to an adverse event. This code allows a report to be recorded for administration purposes, even if it doesn't meet the requirements for adverse event reporting.	A25
Insufficient Information	An adverse event appears to have occurred but there is not yet enough information available to classify the **device** problem.	A26
Appropriate Term/Code Not Available	The **device** problem is not adequately described by any other term. Note: this code must not be used unless there is no other feasible code. The preferred term should be documented when submitting an adverse event report. This information will be used to determine if a new term should be added to the code table.	A27

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

Contact Information:

MEDICAL DEVICE AUTHORITY
Ministry of Health Malaysia
Level 6, Prima 9, Prima Avenue II
Block 3547, Persiaran APEC
63000 Cyberjaya, Selangor
MALAYSIA
T: (03) 8230 0300
F: (03) 8230 0200
Website:mda.gov.my

GRZAN 全球法规领航者 Global Regulatory Zone Access Navigator