Case no. (To be completed by the reporting center): Report received date (To be completed by the reporting center): (MM/DD/YYYY)

Food and Drug Administration, Ministry of Health and Welfare
Medical Device Serious Adverse Event Report Form

Website: http://qms.fda.gov.tw
Email: mdsafety@fda.gov.tw

I. Basic Information

*1. Type of report: □ Initial report □ Follow-up, report number ____, initial report case no. ____

*2. Date of occurrence: _____ (MM/DD/YYYY)

*3.Date the reporter was notified: _____ (MM/DD/YYYY)

*4. Source of case: □ Domestic, or □ Overseas, (Country name)

*5. Source of the original medical device adverse event notification:
□ Notified by healthcare professional (□ Physician □ Pharmacist □ Nurse □ Medical Engineer □ Other __)
□ Notified by health authority (□ Department of Health (Health Center) □ Other _____)
□ Manufacturer
□ Voluntarily informed by the public
□ Literature
□ Other

6. Initiate event investigation and follow-up reports (To be completed by the medical device firm)
□ Yes, estimated reporting date: _____ (MM/DD/YYYY) □ No, reason(s):

*7. Attachment: □ No □ Yes, a total of ____ event(s)

8. Product designated under medical product safety monitoring by announcement: □ Yes □ No □ Unknown

*9. Reporter information:
Name: Email address:
Phone number: Address:
Employing Organization: _____
Type: □ Medical personnel (Title: □ Physician □ Pharmacist □ Nurse □ Medical Engineer □ Other ____)
□ Manufacturer
□ General public
□ Health authority

*10. Are you willing to provide the manufacturer with the name of your employing organization to help with the analysis of the adverse event: □ Yes □ No

11. Internal case number of the reporting unit: _____

II. Patient Information

12a. Patient ID No.: _____ (To be encoded by the reporter)

12b. Gender: □ Male □ Female

12c. Date of birth: _____ (MM/DD/YYYY) (Or approximate age _____)

12d. Weight: _____ kg

12e. Height: _____ cm

III. Medical Device Information

*13a. License number / Listing number:

*13b. Product name in Chinese:

13c. License holder or firm that has completed the listing:

13d. Main/Subcategory of medical device:

13e. Name of manufacturer:

13f. Country of manufacturer:

13g. Medical device class:

*14a. Model number:

*14b. Batch number:

Note: 1. Please note that fields marked with * are required to be filled in for ensuring the completeness of reporting information. 2. Please fill in optional items as necessary; leave items blank if information is not available.

14c. Serial no.:
14d. Software version:
14e. Date of manufacture:
14f. Expiration date:
15. UDI number:
16. GMDN code:
17a. Use of medical device: □ First time use □ Reuse □ Repaired/Refurbished □ Other ___
17b. This product is a single-use medical device that has been reprocessed and used repeatedly □ No □ Yes, the unit of reprocessing: _____, re-disinfection _____ times
17c. Continuing from the above, if the single-use medical device is reprocessed, it was □ reviewed and approved by the Ministry of Health and Welfare □ approved by the Food and Drug Administration □ other ___
*18. Source of medical device (name of the vendor/distributor/pharmacy): _____
*19. Current status of medical device: □ Destroyed □ Still under investigation □ Still in use or still implanted inside the patient's body □ Returned to the manufacturer (original manufacturer) on _____ (MM/DD/YYYY)
*20. Has the dealer/manufacturer been contacted: □ No □ Yes, name of the contact _____
IV. Adverse Event Information
*21. Adverse event type (Select all that apply) □ Adverse reaction (has caused substantial injury) □ Product problem (found product defect or function failure, etc.)
*22. Adverse event outcome (Select one) □ A. Death, date:_____ Cause of death: _____ □ B. Life-threatening condition □ C. Permanent disability □ D. Congenital anomaly of fetus or infant □ E. Requiring hospitalization or prolonged hospitalization □ F. Other complications that may result in permanent injuries □ G. Other serious adverse event that is still under evaluation (Please describe) _____
23. Classification of product problem (Check all that apply) □ Device operation (nonconformance issue with specifications during device operation, e.g., software or compatibility issues) □ Environment/facility (environmental issues related to device delivery, storage, maintenance, or operation) □ Human factor (problem between product and user, e.g., misinterpretation of user manual or misuse of device, etc.) □ Physical characteristics (material integrity or problem related to manufacturing process, e.g., leak, missing part, etc.) □ Other (Please describe) _____
*24. Organization that handled the serious adverse event: _____ □ Same as the reporting organization □ Unknown
25. Medical device operator: □ Medical personnel □ Patient or his/her family □ Other
26. Was the adverse event mitigated after discontinued use? □ Yes □ No □ Unknown
27. Did the same reaction reoccur following reuse? □ Yes □ No □ Unknown
28. Adverse event related codes (Please refer to the Terminologies for Categorized Adverse Event Reporting compiled by the IMDRF [International Medical Device Regulators Forum] for coding. If the space provided is not enough, please add fields as necessary.)

Code Item	No.	Code
Health Effect -Clinical Code	#1	
Health Effect -Impact Code	#1	
Medical device problem codes	#1	
Component codes	#1	

Note: 1. Please note that fields marked with * are required to be filled in for ensuring the completeness of reporting information. 2. Please fill in optional items as necessary; leave items blank if information is not available.

*29. Description of the adverse event (Please describe the event in sequential order, which shall include: (1) region where the adverse reaction occurred, symptom, and severity level; (2) description of product problem; (3) factors and processes that may result in serious injury; (4) patient's follow-up treatment, etc.)							
30. Related examination and test data	No.	Test date	Test item		Test data		
	#1						
31. Medical device used in combination	No.	License number / Listing number	Chinese name of the product	License holder or firm that has completed the listing	Model no.	Main category of medical device	Date of use/purpose
	#1						
32. Concomitant drugs	No.	Generic name / product name	Content / dosage form	Administration method	Dosing frequency	Period/purpose of use	
	#1						
33. Other related information	Other information related to risk factors that may contribute to the assessment of adverse events, including: underlying conditions, history of allergies, pregnancy status, smoking, alcohol use, drug abuse, life habits, environment, etc.						

If the medical device firm has finished investigation of the event, please continue on to Items 34-39.

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V. Information Regarding the Event Investigation (To be completed by the medical device firm)

*34. Medical device evaluation results

Has the medical device been returned to the manufacturer for testing? □ Yes □ No, reason(s) _____

Summary of the medical device evaluation results (Please provide the complete test report as an attachment. It should include the reason/purpose for testing, testing authority / responsible person, testing items, testing methods, acceptance criteria, test results, and the report with reviewer signatures.):

*35. Investigation results (Please provide the complete investigation report as an appendix. It should clarify the timing and sequence of events, confirm the relevance of the contributing factors and the outcome, as well as analyze the root cause or possible causes of the adverse event.)

Investigation summary:

If no investigation was initiated, please provide an explanation:

36. Adverse event codes (Please refer to the Terminologies for Categorized Adverse Event Reporting compiled by the IMDRF [International Medical Device Regulators Forum] for coding. If the space provided is not enough, please add fields as necessary.)

Code Item	No.	Code
Health Effect -Clinical Code	#1	
Health Effect -Impact Code	#1	
Medical device problem codes	#1	
Component codes	#1	
Cause investigation: Type of investigation	#1	
Cause investigation: Investigation findings	#1	
Cause investigation: Investigation conclusion	#1	

37. Incidence rate of similar events (It is recommended to use the IMDRF coding procedures to identify similar events and to explain the incidence rate or trend changes in a specific period.)

*38. Are there corrective and preventive measures in place?

(According to the investigation results and the incidence rate of similar events, evaluate the odds of recurrence, and whether corrective and preventive measures are required.)

□ Yes □ No

Description:

*39. Conclusion (Based on the results above, evaluate whether there are new risks and whether these are controllable within an acceptable range, or provide suggestions related to medical device safety.)

Note: 1. Please note that fields marked with * are required to be filled in for ensuring the completeness of reporting information. 2. Please fill in optional items as necessary; leave items blank if information is not available.