

STANDARD OPERATING PROCEDURE

Title: Medical Device Reporting Europe

Effective Date: _____

Approvals (Signature and Date):

Responsible Department Head

Technical Authority

QA/QC

1. PURPOSE

- 1.1 This SOP describes the procedure to be followed in case a complaint may be a reportable event according to Customer complaint procedure.
- 1.2 The procedure describes how to make the decision on whether to report the event and to which Competent Authority.
- 1.3 If the event is reportable, this procedure identifies the time limits involved and the actions to be taken.

2. SCOPE

- 2.1 This procedure applies to all CE marked medical devices that are placed on the market or put into service in Europe under the provisions described in the Medical Device directive (93/42/EEC).
- 2.2 It covers any complaint, worldwide, that may be reportable.

3. RESPONSIBILITY

- 3.1 All employees are responsible for initiating the manufacturer's Customer Complaint procedure.
- 3.2 European Regulatory Affairs Department will make, in consultation with the manufacturer, the decision on whether to report in Europe and is responsible for the reporting to the appropriate Competent Authorities.
- 3.3 QA Europe is responsible for maintaining the Medical Device Reporting (MDR) files, and for forwarding a copy of the report to the manufacturer and the Notified Body.

4. REFERENCES AND APPLICABLE DOCUMENTS

- 4.1 Customer Complaint Procedure of the Manufacturer
- 4.2 MEDDEV 2.12/1: Guidelines on a Medical Device vigilance system
- 4.3 Medical Device directive (93/42/EEC)

5. MATERIALS AND EQUIPMENT

- 5.1 None

6. HEALTH AND SAFETY CONSIDERATIONS

- 6.1 None

7. DOCUMENTATION REQUIREMENTS

- 7.1 MDR file
- 7.2 Initial Reporting Form
- 7.3 Final Reporting Form

8. DECISION PROCEDURE

- 8.1 Whenever, per Customer Complaint Procedure, an event is quoted as possibly reportable, this procedure applies.
- 8.2 Manufacturer forwards all available information within 3 days to European Regulatory Affairs Department.
- 8.3 Based on that information, European Regulatory Affairs department decides, after consulting with the manufacturer, whether the event is reportable to the European Competent Authorities. During the decision/consulting process, the manufacturer and European Reg Affairs Dept should assess the following points when deciding whether an event should be reported:
 - 8.3.1 Type of incident (or potential incident)
 - 8.3.2 Whether any medical device may have been involved which was made by the manufacturer or under its authority
 - 8.3.3 Whether the incident was caused (wholly or partially), or could have been caused by the device or by shortcomings in the information supplied with the device
- 8.4 Following events are reported:
 - 8.4.1 Incidents that were caused (wholly or partially) or could have been caused, by the device or by shortcomings in the information supplied with the device and:
 - 8.4.1.1 That led to death or to a serious deterioration in the state of health of a patient, user, or other person (INCIDENT).
 - 8.4.1.2 That might lead to death or a serious deterioration in health if it reoccurs (NEAR INCIDENT).
 - 8.4.2 If an examination of the device or information supplied with the device indicates some factor which could lead to an incident involving a death or a serious deterioration in health.
 - 8.4.3 Incidents caused by misuse of a device do not have to be reported if there are no shortcomings in the information supplied with the device.
 - 8.4.4 In case of doubt, the incident is reported to the Competent Authority.
- 8.5 The decision is documented and attached to the Customer complaint form. The manufacturer is immediately informed of the decision taken.
 - 8.5.1 If the event is not reportable, continue with customer complaint procedure only.
 - 8.5.2 If the event is reportable, continue this procedure.

9. INITIAL REPORTING

9.1 Regulatory Affairs Europe prepares and submits an Initial Report to the Competent Authorities within 10 days for incidents and 30 days for near incidents.

9.1.1 The Competent Authority to report to is:

- the Competent Authority in the country of occurrence of the incident
- reports on incidents concerning medical devices in class II or III occurring in countries outside the EEA (European Economic Area), should be made to the Competent Authority in the state where the Notified Body is situated and which made the attestation which led to the CE marking being attached to the device.
- Reports on incidents concerning medical devices in class I occurring in countries outside the EEA, should be made to the Competent Authority of the state in which the manufacturer or the person responsible for placing on the market or putting into service, has made his notification within article 14 of the Medical Device directive.

9.2 A copy of the initial incident report is filed in the MDR file, and a copy is forwarded to the manufacturer and the Notified Body.

10. INVESTIGATION

10.1 A full investigation is performed by the manufacturer and done as described in his customer complaint procedure.

10.2 Whenever new information or interim reports of the investigation become available, they are immediately sent to European Regulatory Affairs Dept, who keeps the Competent Authority informed of the progress.

10.3 The manufacturer may wish to have access to the device said to be involved in the incident for the purpose of deciding whether the incident should be reported to the Competent Authority. Nevertheless in case of alteration of the device, the manufacturer should consider to inform the Competent Authority in advance.

11. FINAL REPORTING

11.1 After completion of the investigation, European Regulatory Affairs Dept writes the final report based on all available information and submits it to the Competent Authority.

11.2 A copy of the Final Incident Report is filed in the MDR file, and a copy is forwarded to the manufacturer and to the Notified Body.

12. DECISION CRITERIA TO BE USED

12.1 A link is available if the incident was caused (wholly or partially) or could have been caused by the device or by shortcomings in the information supplied with the device.

12.1.1 In evaluating the link between the (near) incident and the device and/or information supplied with the device, the manufacturer should take account of:

- the opinion, based on available evidence, of the health care professional
- the results of the manufacturers own preliminary assessment
- the evidence of previously similar incidents
- other evidence

12.1.2 In the following circumstances a link is demonstrated:

- if a device shows a malfunction = the failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions (including single fault conditions)
- if a device shows a deterioration in the characteristics and/or performance
- if a device shows no malfunction or deterioration, but nevertheless has a characteristics that could lead to an incident (near incident)
- if the instructions supplied on or with the device include inaccuracies. This does not include absence of information that should generally be known by the intended user

12.2 A serious deterioration includes:

- permanent impairment of a body function
- permanent damage to a body structure