1. **Purpose**

This document defines the policies and procedures for documenting and addressing customer complaints in according to US FDA 21 CFR 820.198 and ISO 13485.

1. **Scope**

This procedure applies to customer complaint handling on commercially released products.

1. **General** 
   1. **Definitions** 
      1. **Adverse Event** – An event that resulted in serious injuries and/or death or a malfunction event that would likely cause or contribute to serious injury if the malfunction were to recur.
      2. **Become Aware** – When any employee has acquired information that reasonably suggests a reportable adverse event has occurred.
      3. **Complaint** – Any written, electronic, or verbal communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device following release for distribution.
      4. **Malfunction** –The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed.
      5. **Serious Injury** – An injury or illness that is life-threatening, results in permanent impairment of the body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.
   2. **Responsibilities**

**All Employees** – All employees are responsible for reporting customer complaints to the Quality Department.

**Quality Management** – Quality Management is responsible for the implementation and continued compliance with the procedures specified in this document and by the regulatory authorities.

* 1. **Training Requirement** – Quality Assurance personnel shall be trained to the procedures specified in this document. All employees shall be made aware of their responsibility to report customer complaints to the Quality Department.
  2. **Record Management** – All Customer Complaints are managed and maintained by the Quality Department.
  3. **Reference Documents and Materials**

**21 CFR 820** FDA Quality System Regulations

**21 CFR 803** FDA Medical Device Reporting

**SOR/98-282** – Canadian Medical Device Regulations

**MDR 2017/745** – EU Medical Device Regulation

**MDD 93/42/EEC** – EU Medical Device Directive

**ISO 13485** – Medical Device Quality Management Systems

**ISO 14971** – Application of Risk Management to Medical Devices

**QF-0011-1** – Customer Complaint Form

**QP-0012** –Corrective and Preventive Action (CAPA) Process

**QP-0021** – Medical Device Reporting and Recall Process

1. **Customer Complaint Handling Procedure**

This procedure guides the complaint handling process including receiving, reviewing, and evaluating customer complaints by a formally designated staff. This procedure ensures that:

1. All complaints are processed in a uniform manner and reviewed within two days after receiving them to determine reportability based upon MDR requirements;
2. Verbal complaints are documented upon receipt;
3. Complaints are evaluated to determine whether they represent reportable events as defined by MDR requirements and applicable regulations;
4. All complaint investigations are completed within 15 days unless otherwise documented with appropriate rationale.
5. Customer complaints are trended.

A customer complaint may be received by any employee and is documented on the Customer Complaint Form (QF-0011-1). Each complaint is reviewed and investigated by quality staff. Complaints involving possible failure of a device, labeling, or packaging will be reviewed and investigated, unless such investigation has already been performed for a similar complaint. Where no investigation is necessary, a rationale will be documented along with decision maker’s name.

Complaints representing events which must be reported to FDA under MDR regulation, as well as to other applicable regulatory authorities, will be promptly evaluated and investigated by designated individuals. MDRs will be processed according to QP-0021, Medical Device Reporting and Recall Procedure, and be maintained separately. Each MDR will contain the following information in addition to complaint records:

1. Patient Information
2. If the device failed to meet specifications;
3. If the device was used for treatment;
4. If the device was used in the reported incident.

The record of a complaint investigation includes:

1. The name of the device;
2. The date the complaint was received;
3. Unique device identifier (UDI) or universal product code (UPC), and any other device identification(s);
4. The name, address, and phone number of the complainant;
5. The nature and details of the complaint;
6. The dates and results of the investigation;
7. Any corrective action taken;
8. Any reply to the complainant.

Complaints can prompt initiation of CAPAs when they reveal serious or systemic issues. Complaint investigations will include a historical review and an evaluation to determine the potential impacts to other products. Additional actions may be taken as necessary dependent of the nature of the complaint. Related risk assessments (FMEAs, etc.) will be evaluated and revised as necessary following the investigation of a complaint.

* 1. **Complainant Information**

The complainant information is the identification and contact information of the party alleging the deficiency. This includes dates of the report and incident, name, address, contact information, and company affiliation.

* 1. **Product Information**

The product information includes the information necessary to identify the product associated with the complaint and includes items such as the name of the device, product model number, part number, and serial number as applicable.

* 1. **Complaint Description**

This section describes the complaint in detail and should include the following information when possible: any injuries resulting from the event, any medical interventions required, how the device was being used, environment of use, and description of users.

**Good Faith Effort**

A good faith effort shall include three documented contacts to a customer to obtain the claimed defective device involved in a complaint and additional information related to the complaint. At least one of the contacts shall be in contact with personnel at a customer site.

* 1. **Complaint Investigation**

The complaint investigation identifies the root causes of a complaint and determine if a device malfunctioned. The risk level will be assessed according to Appendix A. The level of an investigation will commensurate with the determined risk level.

Once all available information is gathered, the Quality Department will determine the appropriate actions necessary to address the complaint and reply the complainant.

If an investigation is required for a complaint, we target to finish investigation within 90 days from the complaint opening date and will document rationale if we need to extend.

**MDR Reportability Determination**

Following decision tree is used to determine MDR reportability:

1. Is there death involved? Yes ☐ No ☐
2. Is there serious injury involved? Yes ☐ No ☐
3. Is there a malfunction involved? Yes ☐ No ☐
4. If answer to 3) is Yes, will it likely cause or contribute to a death or serious injury if the malfunction were to recur? Yes ☐ No ☐

If there is a yes to any of the questions above, file an MDR according to QP-0021 MDR procedure.

* 1. **Further Actions Taken**

This section describes any corrective actions taken in response to the complaint. This may include issuing a CAPA or SCAR as applicable. Rationale shall be documented if no action is taken.

* 1. **Reply to Complainant**

Any communication replied to the complainant shall be attached to the Complaint Form.

1. **Appendix A – Risk Assessment**

The following risk assessment methodology has been developed utilizing principles from ISO 14971. Any Customer Complaint resulting in Serious or Critical Severity shall be evaluated as a Risk Category of Major

* 1. **Severity Assessment**

| **Severity**  **Index** | **Severity**  **Category** | **Description of Severity** |
| --- | --- | --- |
|
| **S1** | None | No safety concerns and minimal to no impact on quality of product or service |
| **S2** | Minor | Customer annoyed and/or insignificant injury |
| **S3** | Moderate | Loss of efficacy and/or significant injury requiring medical intervention to prevent permanent impairment |
| **S4** | Serious | Significant injury that is expected to result in permanent impairment, even with major medical intervention |
| **S5** | Critical | Severe injury where major medical intervention is required to prevent loss of life or when loss of life cannot be prevented |

* 1. **Probability of Occurrence Assessment**

| **Probability**  **Index** | **Rate of Failure** |
| --- | --- |
|
| **P1** | < 0.01 % |
| **P2** | 0.01 % - 0.10 % |
| **P3** | 0.11 % - 1.00 % |
| **P4** | 1.01 % - 10.00 % |
| **P5** | > 10.00 % |

* 1. **Risk Assessment**

| **Risk Index**  **R = S x P** | **Risk Category** |
| --- | --- |
|
| **R1 to R6** | Minor |
| **R8 to R10** | Moderate |
| **R12 to R25** | Major |

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0011 |  |  | Initial implementation of the Customer Complaints Handling Process |