Complaint Handling

Training: TRN-007 Rev B

Complaint Handling: BACKGROUND

FDA definition of a complaint:

Section 820.3(b) of the Quality Systems regulation defines a complaint as "any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution."

Complaint Handling: BACKGROUND

A complaint is any indication of the failure of a device to meet customer or user expectations for quality or to meet performance specifications.

All medical device manufacturers are subject to

- complaint requirements in 21 CFR Part 820, Quality System regulation
- reporting requirements in 21 CFR Part 803, Medical Device Reporting (MDR) regulation

Complaint Handling: BACKGROUND

Sources of oral and written complaints:

- telephone
- facsimile
- written correspondence
- sales representatives
- service representatives
- scientific articles
- FDA
- internal analyses

Information will also be submitted by health care professionals, lay users, consumers, user facilities and distributors on the MedWatch Forms.

Complaint Handling: REQUIREMENTS

- Manufacturers are required to:
  - review, evaluate, and, when appropriate, investigate complaints
  - establish and maintain written procedures describing the process used to perform these activities
  - designate a responsible individual or entity to perform these tasks.
    - **The primary contact for complaint handling at Genesys Spine:**

      Bill Sowers, VP Quality & Regulatory

      Bill.Sowers@genesysspine.com

      Phone: 512-381-7080

      Fax: 1-800-817-4938

Complaint Handling: REQUIREMENTS

- All complaints and user feedback MUST BE PROMPTLY REPORTED to Genesys Spine.
- Complaints will be reviewed by Genesys Spine to determine the seriousness of the event.
- More serious complaints have mandatory reporting requirements where Genesys Spine must submit a written (MDR) report to the FDA within 5 working days.

Complaint Handling: WHAT NEEDS TO BE REPORTED?

Report ANY INSTANCE of…

- failure, fracture, or fault of an implant either acutely or after implantation
- failure, fracture, or fault of an instrument including instances induced by wear or fatigue
- missing, incorrect, or unclear labeling – on an IFU, surgical technique, product labeling, etc.
- revision surgery - removal of Genesys Spine product(s) from a patient previously treated
- any patient issue that may be related, directly or indirectly, to a Genesys Spine product.
  - Example: when a patient suffers an infection immediately following a procedure where Genesys Spine products were used
- whenever customer expectations for Genesys Spine products were not satisfied.

Complaint Handling:
WHAT NEEDS TO BE REPORTED?

- For each complaint, the following information is to be reported to Genesys Spine:
  - Complainant Information
    - Name, Phone, Email
  - Procedure & Event Information
    - Surgeon, Representative, Distributor, Hospital
    - Date of Procedure, Date of Event
  - Product Information (for each product involved)
    - Product Description, Part #, Lot #
  - What Happened?
    - Patient Involvement, Patient Status
    - Was the device implanted?
    - Brief detailed description of event

Complaint Handling: SIGNED CONCURRENCE

I have read and understood the Genesys Spine Complaint Handling Training: TRN-007 Rev B. I will contact Bill Sowers (at 512-381-7080 or bill.sowers@genesysspine.com) at Genesys Spine if I have any questions.

_____ _____

Printed Name Name of Company / Distributorship

_____ _____

Signature Date