Complaint Reporting Training

For MAP and Sub-Grantees 2019

Purpose

- To provide MAP and Sub-Grantees personnel with a basic understanding of the Edwards complaint handling/reporting process and requirements

Agenda

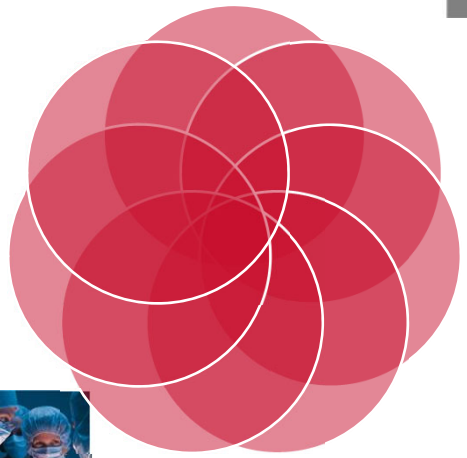
- What is a Complaint
- Examples of Surgical Structural Heart (Edwards) Complaints
- How to Report Complaints
- Required Timelines
- Complaint Investigation
- Impact of Complaint Investigation

Where Do Complaints Come From?

Verbal reports received from hospital staff/physicians

Written reports sent by regulatory agencies

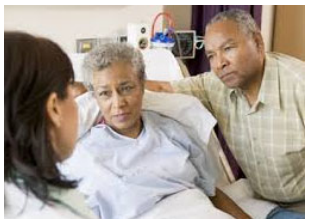
Marketing initiatives, studies, or post market surveillance



Advisory boards, focus groups, or product evaluations

Field visits or informal conversations with doctors

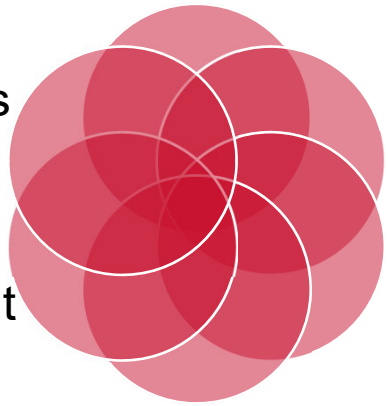
Where Do Complaints Come From?



Patients and their family/friends

Personal acquaintances

Pre/post market studies and registries



Implant Patient Registry

Company websites

Attorneys

What is a Complaint?

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.

What is a Complaint?

Edwards DOC-0084997 further defines a complaint as:

- Devices received by the customer damaged or otherwise unusable, even if the condition occurred during transportation.
- Nonconformances, excluding cosmetic defects identified at an Edwards facility, after the manufacturing site has released the product. This includes non-conformances identified at a receiving warehouse.
- Awareness of a device malfunction or other failure of an Edwards product to meet its product specifications (including labeling or packaging) or otherwise perform as intended.
  - Intended performance refers to intended use for which the device is labeled or marketed
- Use errors related to “usability” (a user action/lack of user action while using the device that leads to a different result than that intended by the manufacturer or expected user).
- A report that reasonably suggests that the use. Misuse, or malfunction of an Edwards device may have caused or contributed to a patient or user injury, deterioration in the state of health, or death.

"Cause or Contribute"

- If a medical device was or may have been a factor in a death, a serious injury, or an adverse event, it is a complaint!

- This may include events resulting from:
  - Device failure
  - Malfunction
  - Improper / Inadequate design
  - Manufacturing-related issues
  - Labeling (including IFU)
  - Training (inadequacies) or
  - Use error

Malfunctions

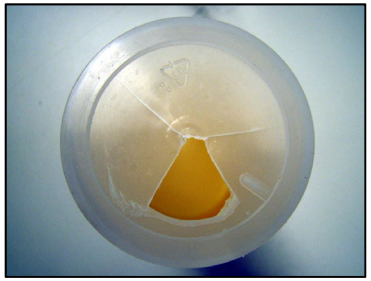
- The failure of a device to meet its performance specifications or otherwise perform as intended
  - Performance specifications include all claims made in the labeling for the device
  - Intended performance refers to intended use for which the device is labeled or marketed

Examples of Surgical Complaints

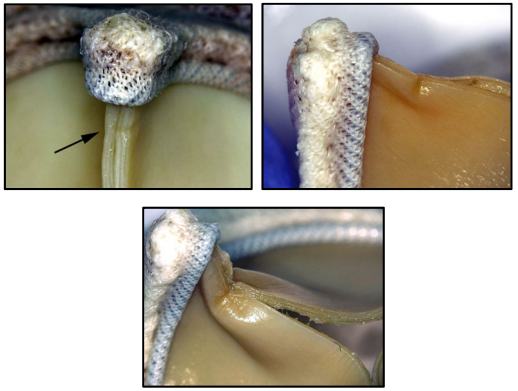
- "Out of the box" issues:
  - Leaflets not coapting (*out of the box*)
  - Discoloration of leaflet
  - Particulate or foreign material on product
  - Damaged or cracked container or package
- Sizer did not match actual size of valve or ring
- Cracked handle or sizer

- Any explant (including at time of implant/intra-operative)
- Regurgitation
- Peri-valvular leak
- Calcification or host tissue overgrowth
- Leaflet tear
- Elevated gradients, stenosis or regurgitation on echo
- "Failing" valves being evaluated for valve-in-valve or other intervention

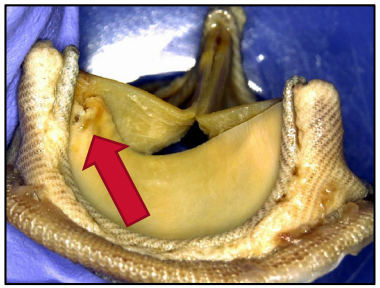
Examples of Surgical Complaints



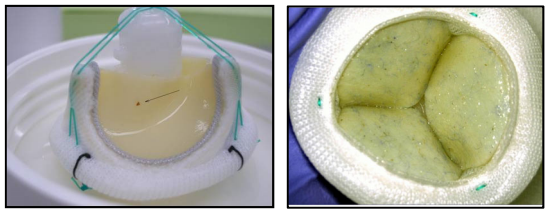
Cracked container



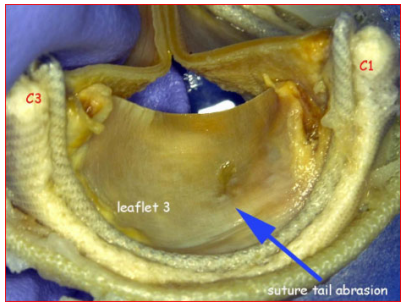
Suture loop, leaflet immobility, regurgitation



Leaflet tear, regurgitation

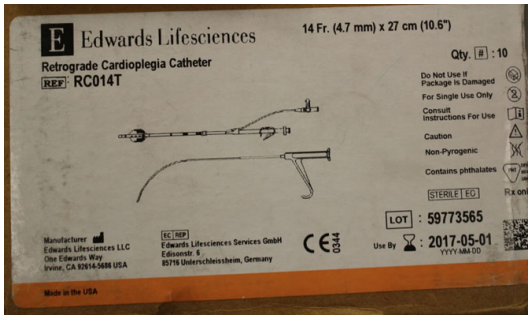


Particulates

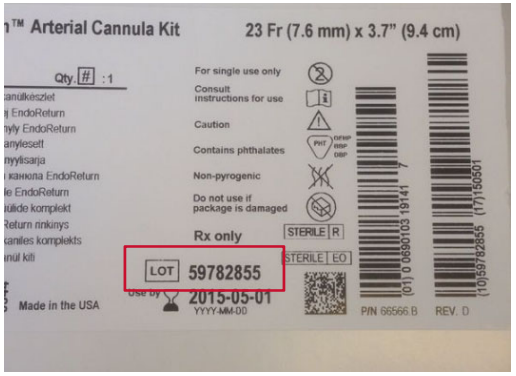


Suture Tail Abrasion

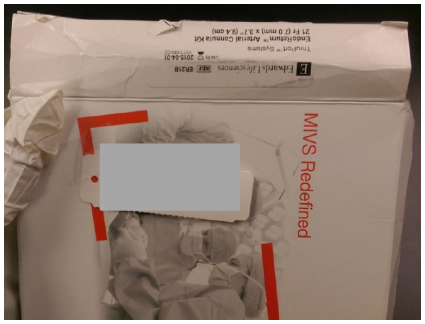
Examples of Packaging/Labeling Complaints

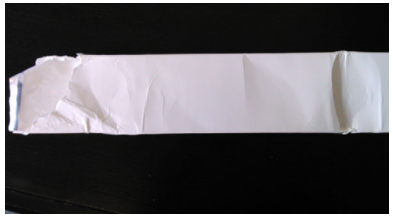


Wrong product in box compared to device label
(EO60s were in box)



Lot number discrepancy





Packaging damage

What and When to Report

- At a minimum the following information is needed:
  - Description of complaint ("*What*" and "*How*" it happened)
  - Type of Edwards product with lot number/serial number if you have it
  - Contact/hospital information
  - Aware Date (the date the reporter is aware of the event)

- Per Edwards procedure:
  - Submit within 2 working days from awareness of a death of a person or serious public health threat.
  - Submit within 4 working days from awareness for all other events.

A complaint should be reported immediately even if minimal information is known and/or the device is not available to be returned to Edwards.
Don't wait! Submit what you know!

How & Where to Report in the US

- Report *directly* to the Complaints Department
  - Forms: *12116 (implantables), 16762 (accessories), 20027 (EPC-MIS)*
- E-mail event report and complaint form to:
  HVT_Complaints@edwards.com
- Call Complaints Hotline (949) 250-3612
  - Option 2: All SSH products
- Or fax complaint forms to (949) 250-3579

Do not report complaints to employees in the Complaints Department – use the channels listed above

Where to Report Outside the US

- **Brazil/ Latin America**, contact your Quality/Regulatory Affairs Manager
  Fax (11) 5567-5233 or phone (11) 5567-5200
- **Europe,** dial extension 4455 (External +41 22 787 44 55)
  Five languages available (English, German, French, Spanish, Italian)
  Or send an e-mail to: complaints_eu@edwards.com
- **Australia**, contact your Business Manager and Quality Assurance Administrator.
  Fax forms to 1800 222 602
- **New Zealand**, fax forms to +61 2 8811 2696
- **Canada**, contact Anthony Hung at Anthony_Hung@edwards.com , or
  Fax 1-800-993-4284 or phone 1-800-268-3993
- **Japan**, contact your Market Surveillance personnel via e-mail at
  Keiji_Ota@edwards.com

Critical Timelines for Reporting

- Clock for Reporting

  The clock starts the day any Edwards employee becomes "reasonably aware" of an incident or event. So, for reporting surgeons and associates it's important to report as soon as possible in order for Edwards to get information quickly and accurately.

- Why is this important?
  - As a device manufacturer, Edwards is required to report certain types of events to the FDA, Competent Authorities, and other regulatory bodies.
  - We have strict time frames within which we must report; some events must be reported within 10 calendar days or less.

- What does this mean for you?
  - When you become aware of a complaint, report it immediately!

Remember… The clock is ticking!!!

Who is Responsible for Reporting Complaints?

We ALL are!

- If you are on the front line, selling or marketing products, supporting cases and/or training customers, you *WILL* receive complaints and be made aware of negative “customer experiences”.
- Reporting and investigating these events is part of your responsibilities and vital to our business.

What is Your Role?

- Report all complaints as soon as possible.

  If you are unsure whether or not to report an event or "customer experience," report it. The Complaints Department will follow up and determine if further investigation is required.

- Help collect information to investigate the complaint, as needed.
- Help facilitate return of the complaint device.
- Communicate results of the investigation to the customer.
  - This is our chance to ensure that the customer is satisfied with Edwards' response to their experience!

Why Must You Report a Complaint?

It is the LAW (for Edwards employees)!

- Failure to report complaints may result in warning letters, civil money penalties, citations, injunctions or prosecution, depending on the severity of the issue.
- There can be a “hold” on processing approvals for new product release if the company is not in good standing with the FDA or other Regulatory Agencies.
- The company’s doors can be shut!

Why are Complaints Good?

- They are essential for obtaining feedback from the field – complaints data is trended monthly and reviewed by R&D/Quality/Mfg and others to see if improvements need to be made
- Bi-weekly meetings are also held to review complaints as they occur so R&D/Quality can ensure any additional information needed for assessment is obtained
- They form the basis of product improvement
- They are part of the service provided to customers
- Through product analysis, we have better understanding of customer's issues and problems with our products
- Quick escalation of product issues is essential to limiting patient exposure in the event of product recalls – urgent high risk complaints may be escalated the same day we receive them

Complaint Investigations

To properly investigate, some complaints may also require the following:

- Calls to physician's office
- Operative Report, Discharge Summary, Death Summary, Pathology Report, Progress Report
- Fluoroscopic and/or Echo Images with Imaging Review
- Physician to physician discussion
- Site visits
- Follow up by Product Safety or Product Quality Clinicians

Complaint Product Return

- If a product that is associated with a complaint is being returned for investigation, please do not manipulate it, and/or try to determine what is wrong with it; please send it back as-is.
- Once you report a complaint, a product return kit (Biokit) will be sent as requested directly to the customer or Edwards personnel.
  - 3-4 days
  - Please ensure you write the complaint (CER) number on the package when the device is returned.
- *Edwards will make every attempt to obtain the reported device or component in question so we can analyze it.*

Edwards' Product Analysis

- Product Evaluation
  - Visual analysis (including x-ray of device if appropriate)
  - Dimensional analysis
- R&D Evaluation
  - Functional analysis (e.g. for reports of early explant/regurgitation, or report of incomplete coaptation "out of the box")
  - Histology (e.g. for early explant not related to regurgitation, thrombosis)
- Manufacturing Records Review
  - Device History Record Review
  - Lot History Review

Outcomes of Complaint Investigation

- Regulatory Compliance
- Identification of actual or potential product safety issues
- Early escalation of significant or serious events
- Identification of design or manufacturing issues
- Inputs to Corrective Action
  - Design Changes
  - Manufacturing Changes
  - Labeling or IFU Changes
  - Additional Customer Education
- Field Action
  - Advisory Letter or Product Recall
- Improved technology for your customers / improved design of next generation products!

In Summary, you should…

- Recognize a complaint
- Understand why a complaint must be reported in a timely manner
- Appreciate that complaint reporting is the responsibility of everyone in Edwards
- Know that complaints can come from a variety of sources
- Provide complete and accurate information as soon as possible
- Promptly return the affected device and all associated products or components
- Recognize the impact of complaint reporting on the patient, the customer, the company, and YOU!

Do's and Don'ts

- Do accurately describe the events that lead to the complaint
- Do not send documents inside the Biokit
- Do not include commentary that you would not want to go in the complaint file - it will be read by others (i.e. auditors, EW staff, legal)
- Do not include "teaching points", briefs to the Edwards Surgical Team, or personal commentary in the complaint form or emails
- Do include all relevant information to the product and how it failed or what the identified issue is so Edwards can appropriately analyze it.

What You May Not Know About Complaints

- Everything you write goes into the complaint file.
- If the event is reportable to FDA, a summary of the event will be on the FDA website for the public to read (MAUDE database)
- Edwards gets audited by multiple external agencies on a yearly basis; they always look at complaints and in particular the reporting timelines of aware dates.

Questions

- Should you wait to report an event if you do not have all of the information?

  No, report what you have as additional information can be gathered later.

- The physician used the product off label and it malfunctioned. Should this be reported as a complaint?

  Yes

- The customer reported that the product “jumped out of the package” when opened and fell on the floor. Is this a complaint?

  Yes

Questions or Comments?

Edwards

Helping Patients is Our Life's Work, and *life is now*