REVISION HISTORY

Rev	DCN	Change Description	Release Date
A	073	Initial release.	1/27/2014
B	121	Updates company name and logo	7/3/2014
C	154	Add requirement to collect patient weight per FDA inspection recommendation	2/11/2015

1.0 PURPOSE

The primary purpose of this document is to facilitate the acquisition of a set of data/documents necessary to reconstruct events leading to a complaint involving a used CCS product in a timely and effective manner. The document provides a road map for data collection.

2.0 SCOPE

ClearFlow Inc. Quality Affairs is the initiator of this document. It will serve ClearFlow Inc to fulfill the reporting requirements in accordance with internal operating procedures and in compliance with directives and guidance documents issued by, and not limited to, the following regulatory bodies--The European Community, Health Canada and the US Food and Drug Administration.

3.0 REFERENCE DOCUMENTS

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2D/Step4/E2D_Guideline.pdf
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126834.pdf
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=803.52

4.0 DATA AND DOCUMENTS FROM REPORTING ENTITY[1]

Patient details:

- Initials
- Other relevant identifier (i.e., patient number)
- Gender
- Age, age category (i.e., if applicable--infant, adolescent, elderly), or date of birth
- Weight
- Hospital discharge letter, or, if not available-
  - Concomitant conditions
  - Medical history

[1] Disclaimer: to comply with patient privacy laws in any country where a product complaint has been reported, DO NOT ACCEPT ANY DOCUMENT WITH ANY INFORMATION THAT CAN REVEAL THE PATIENT IDENTITY. PERSONAL PATIENT NAME, OR ANY OTHER IDENTIFYING INFORMATION MUST BE WHITED OUT BEFORE ACCEPTING THE DOCUMENT (I.e., age and gender can be revealed since these do not breach on patient privacy and this information is required as part of reporting the complaint).

- Relevant family history
- Physician notes about the surgery (I.e., CABG, valve repair/ replacement, re-operation)

Product details:

- Catalogue/Model number
- Lot number
- Expiration date (Obtain the package label if possible)

Details of the incidence: (Provide as complete as possible)

- Setting (I.e., hospital OR, hospital ICU, Hospital step down unit)
- Occurrence date and time
- Resolution date and time
- Where was the system inserted (I.e., By surgeon in the OR, by surgeon in the ICU, by another healthcare provider in the ICU)
- Was the operator trained on the use of the product?
- Chest tube placement (I.e., mediastinum, front, back, pleural space, other)?
- Was the clearance wire actuated before the incidence (Number and frequency of actuations)?
- Clearance wire loop position when incident occurred (I.e., distal in chest tube, parked proximally, other)
- Was the wire in the chest tube when it was pulled out of the chest?
- Was there resistance in pulling the wire from distal to proximal position that caused decoupling?
- Was there resistance in pushing the wire from a proximal position distally that caused decoupling?
- Were fluids draining out through the PleuraFlow chest tube when the incident occurred?
- Was there any damage to the wire (describe)?
- If the incident resulted in an injury-
  - Details of the injury, severity, treatment, resolution
  - Impact on ICU stay, hospital discharge, readmission, etc.)
- Relatedness of product to event (I.e., device-related, procedure-related, combination)
- Patient outcome (Recovery and any sequelae)
- For fatal outcome state the cause of death
- Relevant autopsy and post-mortem findings

Details of the reporter:

- Name
- Mailing address
- Email address
- Telephone and/or fax number
- Reporter type (I.e., healthcare professional, consumer, distributor, etc.)
- Profession (Specialty, i.e., physician, nurse, etc.)

Administrative:

- Date event reported was first received by manufacturer/company
- Country in which the event occurred

Other administrative:

- Obtain the product and ship to CCS or delegate in accordance with management of biohazard materials (Contact CCS QA with any questions regarding shipment of the product).
- Summary of note from interviewing the healthcare provider who reports the complaint; healthcare providers who used the product before during and after the event triggering the complaint, and cardiac surgeons who placed the chest tube or the system. Ask questions that cover the when, who, what, how, and the outcome. A good way to assess the quality and breadth of the data obtained is asking oneself whether the story is complete and whether it makes sense.