

- One form per event/patient. Form to be completed by BV employee.
- A Complaint is 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.
- Complaints must be reported within **one working day of becoming aware**.
- To report a complaint, send this completed form to Customer Service:
 - USA: cssurgical@bioventusglobal.com
 - Canada: surgical.canada@bioventusglobal.com
- **All replacement, credit/reimbursement, and return requests shall be made directly to Customer Service.**
- Email complaints@bioventusglobal.com with any questions regarding complaints or the complaint handling process.

Date of Occurrence:		Bioventus Aware Date:	
BV employee completing this form:		Country:	
Who reported this complaint to you?			
Account #:			
Physician Name:		Phone:	
Physician Address:		Fax:	
Distributor:		Phone:	
Distributor Address:		Email:	
Patient Name or Initials:		Date of Birth:	Male Female
Patient Address:		Phone:	
PRODUCT INFORMATION			
Part Number:			
Product Name:			
Donor/Lot Number		Serial Number (as applicable)	
CS Action needed:	Replacement	Credit	Return NONE
Unit(s) available for return?	YES	NO	If NO, Implanted Discarded or Other _____
Pictures provided?	YES	NO	

Description of Event: Use specifics – Who, what, when, where

PRODUCT COMPLAINT

Type of Complaint: Packaging Labelling Visual Handling Hydration Other

Issue Identified: Prior to entering OR In OR during prep In OR during procedure After leaving OR

What was the intended/completed procedure?

Date of Procedure:

Was unit(s) hydrated? NO YES If YES, how long? _____ N/A

Any concomitant products:

Any impact to the patient/user? NO YES If YES, also complete Adverse Event section below

ADVERSE EVENT

Describe any medical intervention required:

The name of any suspected transmissible disease or disease agent, if known:

Event led to: Hospitalization (Dates of admission: _____) Death None

Other (Describe: _____)

Does the physician relate this event to the use of the Bioventus product? YES NO Undetermined

Current Patient Status: Recovered Ongoing Improving Unknown

Relevant concomitant medications, tests/laboratory data, imaging, and medical history: