

Complaint Form

Complaint Number	
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Section I Customer Information

Date of Complaint	Customer Name
Person Completing Form	Customer Number
Complainant	Customer Address
Title	Contact Name
Phone	Contact Phone

Section I Product Information

Product Name	Filling Location
Lot/Batch Number	Distribution Location
Cylinder Serial Number	Investigating Location

Did this event cause any adverse reaction to a person or animal (i.e., loss of consciousness, injury, hospitalization)?
 _____ Yes _____ No If Yes, Explain:

Which Adverse Event Reporting (FAERS) or Medical Device Reporting (MDR) requirements apply?

Check if FDA MedWatch Form FDA 3500A was submitted. Date of submittal: _____
 [Attach copy]

Alleged Complaint:

[Attach additional Information/Comments]

Section II Investigation Information	
Person Responsible for Investigation:	Date investigation/evaluation started:
Initial Evaluation:	
Investigation Results:	

Section II Testing	
Name of person (s) performing test(s):	Date:
Test Results: If investigation or testing is not required, indicate why:	
Summary Conclusion:	
Review Signature:	Date:

Section III Corrective/Preventative Action	
Action(s) Taken:	
Responsible Person:	Date:
Follow-up Responsible Person:	Date:

Section IV Reply to Customer	
Date of Reply to Customer:	Contact:
Person Replying:	
Reply: (attach additional pages if needed)	

Section V Complaint Closure	
Complaint Closed By:	
Title:	
Date Complaint Reviewed, Closed and Filed:	