

PRODUCT COMPLAINT FORM

Instructions:

A Complaint is any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, safety, reliability, effectiveness, or performance of a device after it is released for distribution.

To report a complaint, send this completed form to complaints@bioventus.com.

- Complaints must be reported within **one working day of becoming aware**.
- One form per event/ patient.
- Email: complaints@bioventus.com with any questions regarding complaints or the complaint handling process.

All replacement, reimbursement, and return requests shall be made to the following:

Product Line	Contact	Product Line	Contact
Hyaluronic Acid Products: DUROLANE, SUPARTZ FX, GELSYN-3	USA: 1-800-836-4080, CustomerServiceUSA@bioventus.com International: +31 (0)23-554-88888, customercare-international@bioventus.com Durolane: Canada.Durolane@bioventus.com	XCELL PRP	USA: 1-800-836-4080 CustomerServiceUSA@bioventus.com
Bone Graft: Osteoamp, Signafuse, Interface, Osteomatrix Plus	Surgical Customer Service: cssurgical@bioventus.com Canada Surgical Customer Service: surgical.canada@bioventus.com	Peripheral Nerve Stimulation Products: StimRouter Plus, TalisMann, StimPod, and StimTrial	USA: 1-800-836-4080 CustomerServiceUSA@bioventus.com International: +31 (0)23-554-88888 customercare-international@bioventus.com
EXOGEN	USA: 1-800-836-4080, CustomerServiceUSA@bioventus.com Canada: 1-855-771-0606 Exogen: ctca.dexogen@bioventus.com International: +31 (0)23-554-88888, customercare-international@bioventus.com		

PART A- EMPLOYEE REPORTER INFORMATION:

1. Reported by: <input type="checkbox"/> Customer <input type="checkbox"/> Distributor <input type="checkbox"/> Sales Rep <input type="checkbox"/> Other		2. Reporters Country:
3. Reporter Name (<i>Name of person completing this form</i>) and Reporter Title (if known):		
4. Date a Bioventus representative was made aware of the report:		
5. Date Form Completed		
6. Reporter's Address:		
7. Reporter Phone Number:		
8. Reporter Email Address:		

PART B- CUSTOMER/ PHYSICIAN INFORMATION:

9. Account # :	
10. Account Name:	11. Phone:
12. Account Address:	13. Fax:
14. Physician's Name, email and contact information (if known):	

PART C- PATIENT INFORMATION (IF KNOWN)

15. Patient Name or Initials:		16. Phone:
17. Patient Address:	18. Date of Birth:	19. <input type="checkbox"/> Male <input type="checkbox"/> Female
20. Other Contact:		

PART D- DESCRIPTION OF THE EVENT


21. Date of the event:	
22. When did the event first occur? <input type="checkbox"/> Before Procedure <input type="checkbox"/> During Procedure <input type="checkbox"/> After Procedure	

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23. Was troubleshooting performed? Yes No (If yes, please explain below):

24. Detailed description of the event (*Use specifics – Who, What, When Where*):

PART E – PRODUCT IMPLICATED IN THE EVENT

Bone Stimulator	Hyaluronic Acid (HA)	Surgical	Stimulation/ Rehab Devices (PNS)	XCELL PRP
<input type="checkbox"/> EXOGEN <input type="checkbox"/> STRAP <input type="checkbox"/> GEL BOTTLE <input type="checkbox"/> EXOGEN TOTE <input type="checkbox"/> Other	<input type="checkbox"/> DUROLANE <input type="checkbox"/> GELSYN-3 <input type="checkbox"/> SUPARTZ-FX <input type="checkbox"/> CURAVISC <input type="checkbox"/> Other 	<input type="checkbox"/> SIGNAFUSE Putty <input type="checkbox"/> SIGNAFUSE Strip <input type="checkbox"/> INTERFACE <input type="checkbox"/> OSTEOMATRIX+ <input type="checkbox"/> OSTEOAMP SELECT <input type="checkbox"/> OSTEOAMP <input type="checkbox"/> EXTRACTOR <input type="checkbox"/> OSTEOPRESCISION <input type="checkbox"/> OAF-C <input type="checkbox"/> Other	<input type="checkbox"/> StimRouter <input type="checkbox"/> StimRouter Plus <input type="checkbox"/> StimTrial <input type="checkbox"/> StimPod <input type="checkbox"/> TalisMann <input type="checkbox"/> Other	<input type="checkbox"/> Centrifuge <input type="checkbox"/> Convenience Kit <input type="checkbox"/> BVS Equipment Pack <input type="checkbox"/> Evaluation Kit <input type="checkbox"/> Other
EXOGEN message shown if error displayed:	HA Part:	Surgical:	PNS Device Error:	XCELL:
<input type="checkbox"/> Contact Customer Service (!) <input type="checkbox"/> Add Gel (+) <input type="checkbox"/> Low Battery <input type="checkbox"/> Other	<input type="checkbox"/> Luer Lock <input type="checkbox"/> Glass syringe at the flange <input type="checkbox"/> Glass syringe at the tip <input type="checkbox"/> Plunger <input type="checkbox"/> Other	<input type="checkbox"/> Hydration- Material too thick or too thin <input type="checkbox"/> Visual Issues- Color <input type="checkbox"/> Contamination- Particulates <input type="checkbox"/> Labeling <input type="checkbox"/> Other	<input type="checkbox"/> Will not turn on <input type="checkbox"/> Will not charge <input type="checkbox"/> Will not connect to app <input type="checkbox"/> Problems with surgical kit <input type="checkbox"/> Electrode patches <input type="checkbox"/> Other	<input type="checkbox"/> Out of Box Failure <input type="checkbox"/> Missing Components <input type="checkbox"/> Will not turn on <input type="checkbox"/> Counterbalance Leaking <input type="checkbox"/> Other
Action Needed: <input type="checkbox"/> Replacement Credit <input type="checkbox"/> Other	Unit available for return? <input type="checkbox"/> Yes <input type="checkbox"/> No RMA:	Pictures Provided? <input type="checkbox"/> Yes <input type="checkbox"/> No	Any impact to the patient/ user? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Part Number (list of all part numbers impacted including accessories)	Lot Number/ Donor Number:	Serial Number:	Quantity	

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PART F - CLINICAL INFORMATION (THIS SECTION MUST BE COMPLETED)

25. Was there a patient/ user injury or death reported? Yes No (If yes, please describe below)

26. Was there a delay in treatment of the patient? Yes No (If yes, how long was the delay)

27. Was medical intervention needed? Yes No (If yes, please describe below)

28. If applicable, what medical procedure was being performed on the patient at the time of the event? (Please describe below)

29. Please provide any relevant concomitant medications, tests/laboratory data, and/ or medical history below.

PART G- ISSUE SPECIFIC QUESTIONS

30. Exogen: Number of Treatments:

31. Application Site:

32. Surgical Product: Was the unit (s) hydrated?

Yes No

(If yes, how long?)

33. HA/PRP Product: Ultrasound guidance used?

Yes No

34. Injection Site:

35. Date of HA/PRP Injection:

Gauge of Needle Used:

36. Does the physician relate this issue to the use of the Bioventus product?

Yes No Undetermined

37. Current Patient Status:

Recovered Ongoing Improving Unknown