Health Canada Santé Canada

Health Products and Food Branch Inspectorate
Medical Devices Problem Report Form

Reporter File Number:
This area for HPFBI office use only - Incident ID #:

General Information

1. Preliminary Mandatory Report 10-Day __ 30-Day __
   Update to Mandatory Report __
   Final Mandatory Report __
   Voluntary Report __
2. Name of Reporter:
3. Manufacturer __ Importer __ Distributor __ User __
4. Institution/Company:
5. Address:
6. Postal Code/Zip Code:
7. Telephone:
8. Fax:
9. Contact Person (if different from reporter):
10. Problem Reported to: Manufacturer __ Importer __ Distributor __
11. Who was the device purchased from?
12. Address:
13. Is the device available for evaluation? Yes __ No __
14. Date of Problem Occurence (Y/M/D):
15. Manufacturer/Importer Awareness Date (Y/M/D):

Medical Device Information

16. Trade Name:
17. Manufacturer Medical Device Identifier (catalogue/model #):
18. Control/Lot/Serial #:
19. Device Licence Number:
20. Age of Device:
21. Software Version:
22. Was the device labeled as sterile? Yes __ No __

23. **Manufacturer:**
24. Address:
25. Postal Code/Zip Code:
26. Telephone:
27. Fax:
28. Establishment Licence Number (if applicable):

29. **Importer:**
30. Address:
31. Postal Code/Zip Code:
32. Telephone:
33. Fax:
34. Establishment Licence Number (if applicable):

35. **Name of Reporter to Manufacturer/Importer:**
36. Address:
37. Postal Code/Zip Code:
38. Telephone:
39. Fax:

Signature
40. This problem report has been submitted by: Date (Y/M/D):

Problem Description
41. Details of incident including consequences to patient, user or other person, and description of other devices or accessories involved in the incident:

42. Manufacturer's preliminary comments:

43. Course of action proposed including timetable for investigation and submission of final report: