Class 2 Device Recall OmniWire Pressure guide wire

Date Initiated by Firm	May 16, 2022
Create Date	June 16, 2022
Recall Status[1]	Open[3], Classified
Recall Number	Z-1270-2022
Recall Event ID	90292[23]
510(K)Number	K202543[24]
Product Classification	blood pressure cuff[25] - **Product Code** DXQ[26]
Product	Philips OmniWire Pressure guide wire REF 89185J PN 300000252891
Code Information	Model Number: 89185J Part Number: 300000252891 UDI Code: (01)00845225003050(11)220309(17)250309(10)0302535768 Serial Numbers: 37583 37586 37590 37598 37612 37648 37655 37692 37694 37709 37719
Recalling Firm/ Manufacturer	Volcano Corp 3721 Valley Centre Dr Ste 500 San Diego CA 92130-3328
For Additional Information Contact	Emily Dentler 619-380-1318
Manufacturer Reason for Recall	Due to a potential failed sterilization process.
FDA Determined Cause [2]	Under Investigation by firm

Action	On May 16, 2022, Philips sent an "URGENT Medical Device Recall" Letter via email to Philips Sales Representatives who then delivered directly to the affected customer. The Letter informed customers that between 05/04-12/2022, potentially non-sterile products were shipped to customers. Customer are asked to immediately check their product inventory and quarantine any affected products to prevent use. Affected product is requested to be returned to Philips IGTD for replacement products. To acknowledge receipt of this notification, please complete, sign, and return the Customer Reply Form within 30 days upon receipt of this notice to Email: igtdc.r@philips.com For further information or support concerning this issue, contact the local Philips representative: Philips IGTD Customer Service: Phone: 1-800-722-9377, Option 1 Email: IGTD.CustomerInquiry@philips.com Hours of Operation: Monday - Friday 8:00AM 5:00PM PST
Quantity in Commerce	11 devices
Distribution	U.S.: WA and WI O.U.S.: Canada
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database	510(K)s with Product Code = DXQ and Original Applicant = Volcano Corporation[29]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm

8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=90292
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K202543
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DXQ
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DXQ
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=DXQ
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=DXQ&knumber=&applicant=Volcano%20Corporation

Page Last Updated: 07/01/2022

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of Health & Human Services

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php

3. https://www.fda.gov/
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=90292
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K202543
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DXQ
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DXQ
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=DXQ
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=DXQ&knumber=&applicant=Volcano%20Corporation