Class 2 Device Recall QuickGraft

Class 2 Device Recall QuickGraft See Related Information [22]

Date Initiated by Firm	August 15, 2019
Create Date	September 20, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-2548-2019
Recall Event ID	83644[23]
510(K)Number	K181633[24]
Product Classification	Suture, nonabsorbable, synthetic, polyethylene[25] - **Product Code** GAT[26]
Product	QuickGraft¿ Model # 430PST
Code Information	Serial # 00319004921075 00319004921073 00319007681048 00319014411085 00618052231059 03319006511040 03319009191029 03319019231072 035190
Recalling Firm/ Manufacturer	Musculoskeletal Transplant Foundation, Inc. 125 May St Ste 300 Edison NJ 08837-3264
For Additional Information Contact	MTF Customer Service Department 800-433-6576
Manufacturer Reason for Recall	Measurement listed on the label is not taken under tension, and this would cause possible extension of surgical time needed to complete the procedure.
FDA Determined Cause [2]	Under Investigation by firm
Action	You may choose to add the additional label to the unit(s), this may be completed by an appropriate Sales Representative or hospital staff. Or, you may choose to have the unit(s) returned to MTF for the labelling correction
Quantity in Commerce	9 Qty
Distribution	NY NC LA TX MO OH
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 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 = GAT and Original Applicant = Musculoskeletal Transplant Foundation[29]

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4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
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14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
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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=83644
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K181633
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=GAT
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=GAT
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=GAT
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=GAT&knumber=&applicant=Musculoskeletal%20Transplant%20Foundation

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5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
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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=83644
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K181633
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=GAT
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=GAT
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=GAT
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=GAT&knumber=&applicant=Musculoskeletal%20Transplant%20Foundation