Date Initiated by Firm | August 15, 2019  
Create Date | September 20, 2019  
Recall Status | Open, Classified  
Recall Number | Z-2546-2019  
Recall Event ID | 83644  
510(K) Number | K181633  
Product Classification | Suture, nonabsorbable, synthetic, polyethylene - Product Code GAT  
Product | QuickGraft®  
Model # | 430PST  
Code Information |  
Recalling Firm/Manufacturer | Musculoskeletal Transplant Foundation, Inc.  
125 May St Ste 300  
Edison NJ 08837-3264  
For Additional Information Contact | MTF Customer Service Department  
800-433-8576  
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 | 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  

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.
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

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4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
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
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29. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm

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9/24/2019 Class 2 Device Recall QuickGraft
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Class 2 Device Recall QuickGraft

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
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
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?
   start_search=1&productcode=GAT&knumber=&applicant=Musculoskeletal%20Transplant%20Foundation