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Class 2 Device Recall QuickGraft



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Class 2 Device Recall QuickGraft



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Date Initiated by Firm	August 15, 2019
Create Date	September 20, 2019
Recall Status¹	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 _z 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 Cause²	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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