Class 2 Device Recall Teleflex(R) Percuvance(TM) Percutaneous Surgical System, Gripper Grasper

See Related Information[22]

Class 2 Device Recall Teleflex(R) Percuvance(TM) Percutaneous Surgical System, Gripper Grasper

Date Initiated by Firm	October 18, 2017
Create Date	October 31, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-0059-2018
Recall Event ID	78340[23]
510(K)Number	K153063[24]
Product Classification	Electrosurgical, cutting & coagulation & accessories[25] - **Product Code** GEI[26]
Product	Teleflex(R) Percuvance(TM) Percutaneous Surgical System, Components: (a) 5 mm Atraumatic Johans Grasper, Catalog Number PCVJG5 (b) 5 mm Maryland Dissector, Catalog Number PCVMD5 (c) 5 mm Hem-o-lok Clip Applier, Catalog Number PCVHCA5 (d) 5 mm Traumatic Gripper Grasper, Catalog Number PCVGG5 (e) 5 mm Scissors, Catalog Number PCVSC5 The Percuvance Percutaneous Surgical System is a family of instruments used to perform laparoscopic procedures. Without the need for additional insertion conduits (trocars), the 2.9mm insulated Shafts are inserted percutaneously with the assistance of an Introducer needle tool tip. The Shaft is then advanced retrograde through a 5mm, or larger, port to facilitate the extracorporeal attachment of interchangeable Tool Tips. These interchangeable tools can be used to grasp, retract, manipulate, cut, coagulate and deliver Hem-o-lok¿ ligating clips to soft tissue. Each Percuvance System Handle includes an integrated male cautery adapter that can be connected to most monopolar electrosurgical units (ESU) via a standard 4mm monopolar cable.
Code Information	(a) Catalog Number PCVJG5, Lot Numbers: 73E1700794, 73G1700271, 73G1700515, 73H1700081, 73H1700367 (b) Catalog Number PCVMD5, Lot Numbers: 73E1700796, 73G1700273 73H1700083 (c) Catalog Number PCVHCA5, Lot Numbers: 73E1700798, 73H1700084 (d) Catalog Number PCVGG5, Lot Numbers: 73E1700793, 73G1700272, 73H1700082, 73H1700247 (e) Catalog Number PCVSC5, Lot Number: 73H1700569
Recalling Firm/ Manufacturer	Teleflex Medical 2917 Weck Dr Research Triangle Park NC 27709-0186
For Additional	

Information Contact	847-572-8014
Manufacturer Reason for Recall	Teleflex is recalling these products because the jaws of the tool tip may break, causing a fragment of the tool tip to fall off during use.
FDA Determined Cause [2]	Under Investigation by firm
Action	Teleflex sent an Urgent Medical Device Recall 1st Notification letter dated October 18, 2017, via FedEx. The customers were instructed to take the following actions : 1. If you have affected stock, immediately discontinue use and quarantine any products with the product codes and lot numbers listed above. 2. To return product, complete the enclosed Recall Acknowledgement Form and fax it to 1-855-419-8507, Attn: Customer Service or email to recalls@teleflex.com. This will allow us to document the amount of product you have on hand for return. A customer service representative will contact you with a Return Goods Authorization (RGA) Number and will provide instructions for the return of products to Teleflex Medical. 3. If you have no affected stock, please complete the enclosed Recall Acknowledgment Form and fax it to 1-855-419-8507, Attn: Customer Service or email to recalls@teleflex.com. This will allow us to document your receipt of this letter." For further questions please call (847) 572- 8014.
Quantity in Commerce	3904 units
Distribution	Worldwide Distribution - USA (nationwide) Distribution and to the countries of : Australia, Belgium, Hong Kong, Japan, S. Korea and Singapore.
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 = GEI and Original Applicant = Teleflex Medical, Inc.[29]

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