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

New Search

Date Initiated by Firm: October 18, 2017
Create Date: October 31, 2017
Recall Status: Open, Classified
Recall Number: Z-0059-2018
Recall Event ID: 7834023

510(K)Number: K15306324

Product Classification: Electrosurgical, cutting & coagulation & accessories - Product Code GE

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 PCVMDS5
(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 clips, 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: PCVMDS5, 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:
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. 4. 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 Report²⁷

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. 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

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
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16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
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18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=159243

11/7/2017