Class 2 Recall StarMedTec LightTrail Reusable Fibers

See Related Information[22]

Date Posted	October 08, 2014
Recall Status[1]	Open
Recall Number	Z-0049-2015
Recall Event ID	69404[23]
Premarket Notification 510(K) Number	K111475[24]
Product Classification	Powered Laser Surgical Instrument[25] - **Product Code** GEX[26]
Product	StarMedTec LightTrail® Reusable Fibers, 365 um; Material/Part Number: 6453
Code Information	Material/Part Number: 6453 Batch Code: 2011-00238
Recalling Firm/ Manufacturer	Boston Scientific Corporation 100 Boston Scientific Way Marlborough, Massachusetts 01752-1234
Manufacturer Reason for Recall	Product is not cleared for use with lasers other than the Auriga XL system
FDA Determined Cause [2]	PREMARKET APPROVAL: No Marketing Application
Action	Boston Scientific sent an " Urgent Medical Device Recall Removal Immediate Action Required" letter dated September 30, 2014, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. The notification instructs the account to check their inventory, remove any affected product from their inventory, and contact Boston Scientific for further instructions on returns. The notification also requests the completion of a Reply Verification Tracking Form as a method of documenting the presence or absence of affected product in their inventory. We ask that you complete and return the Reply Verification Tracking form, included with this letter, according to the instructions on page 3, even if you no longer have inventory of the recalled lots. If you identify any of the affected lots within your inventory, please segregate it immediately and you will be contacted by Boston Scientific with additional instructions after you return your form. You will receive credit, as appropriate, for any affected product in your inventory. Fax to : Field Action Center at 1-866-213-1806. For further questions call (508) 382-9555.
Quantity in Commerce	5 units
Distribution	US Distribution including the states of NY and TX.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = GEX and Original Applicant = STARMEDTEC GMBH[29]

Links on this page:

Class 2 Recall StarMedTec LightTrail Reusable Fibers

See Related Information[22]

Date Posted	October 08, 2014
Recall Status[1]	Open
Recall Number	Z-0051-2015
Recall Event ID	69404[23]
Premarket Notification 510(K) Number	K111475[24]
Product Classification	Powered Laser Surgical Instrument[25] - **Product Code** GEX[26]
Product	StarMedTec LightTrail® Reusable Fibers, 800 um; Material/Part Number: 6457
Code Information	Material/Part Number: 6457 Batch Code: 2011-00217, 2012-00239, 2012-00249, 2012-00258
Recalling Firm/ Manufacturer	Boston Scientific Corporation 100 Boston Scientific Way Marlborough, Massachusetts 01752-1234
Manufacturer Reason for Recall	Product is not cleared for use with lasers other than the Auriga XL system
FDA Determined Cause [2]	PREMARKET APPROVAL: No Marketing Application
Action	Boston Scientific sent an " Urgent Medical Device Recall Removal Immediate Action Required" letter dated September 30, 2014, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. The notification instructs the account to check their inventory, remove any affected product from their inventory, and contact Boston Scientific for further instructions on returns. The notification also requests the completion of a Reply Verification Tracking Form as a method of documenting the presence or absence of affected product in their inventory. We ask that you complete and return the Reply Verification Tracking form, included with this letter, according to the instructions on page 3, even if you no longer have inventory of the recalled lots. If you identify any of the affected lots within your inventory, please segregate it immediately and you will be contacted by Boston Scientific with additional instructions after you return your form. You will receive credit, as appropriate, for any affected product in your inventory. Fax to : Field Action Center at 1-866-213-1806. For further questions call (508) 382-9555.
Quantity in Commerce	33 units
Distribution	US Distribution including the states of NY and TX.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = GEX and Original Applicant = STARMEDTEC GMBH[29]

Links on this page:

Class 2 Recall StarMedTec LightTrail Reusable Fibers

See Related Information[22]

Date Posted	October 08, 2014
Recall Status[1]	Open
Recall Number	Z-0050-2015
Recall Event ID	69404[23]
Premarket Notification 510(K) Number	K111475[24]
Product Classification	Powered Laser Surgical Instrument[25] - **Product Code** GEX[26]
Product	StarMedTec LightTrail® Reusable Fibers, 600 um; Material/Part Number: 6455
Code Information	Material/Part Number: 6455 Batch Code: 2012-00268, 2013-00443
Recalling Firm/ Manufacturer	Boston Scientific Corporation 100 Boston Scientific Way Marlborough, Massachusetts 01752-1234
Manufacturer Reason for Recall	Product is not cleared for use with lasers other than the Auriga XL system
FDA Determined Cause [2]	PREMARKET APPROVAL: No Marketing Application
Action	Boston Scientific sent an " Urgent Medical Device Recall Removal Immediate Action Required" letter dated September 30, 2014, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. The notification instructs the account to check their inventory, remove any affected product from their inventory, and contact Boston Scientific for further instructions on returns. The notification also requests the completion of a Reply Verification Tracking Form as a method of documenting the presence or absence of affected product in their inventory. We ask that you complete and return the Reply Verification Tracking form, included with this letter, according to the instructions on page 3, even if you no longer have inventory of the recalled lots. If you identify any of the affected lots within your inventory, please segregate it immediately and you will be contacted by Boston Scientific with additional instructions after you return your form. You will receive credit, as appropriate, for any affected product in your inventory. Fax to : Field Action Center at 1-866-213-1806. For further questions call (508) 382-9555.
Quantity in Commerce	7 units
Distribution	US Distribution including the states of NY and TX.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = GEX and Original Applicant = STARMEDTEC GMBH[29]

Links on this page: