FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall Green Mamba Suture Passer

6 510(k)⁷|DeNovo⁸|Registration & Listing⁹|Adverse Events¹⁰|Recalls¹¹|PMA¹²|Classification¹³|Standards¹⁴

SuperSearch

CFR Title | Radiation-Emitting 2115

X-Ray Assembler¹⁷

Medsun Reports¹⁸

|CLIA¹⁹|TPLC²⁰|Inspections²¹

New Search

Back to Search Results

Class 2 Recall Green Mamba Suture Passer Information

Date Posted

October 09, 2014

Recall Status¹

Open

Recall Number

Z-0057-2015

Recall Event ID

69360²³

Product Classification

Passer²⁴ - Product Code HWQ²⁵

Product

Green Mamba Suture Passer. The Biomet Sports Medicine Mamba instruments are utilized to aid in passing suture through soft tissue. The Mamba Needle is designed for use with the Mamba Suture Passer. The needles are sterile, disposable, and for

single-patient use only.

Code Information

Catalog Number: 110010850 Lot Number: 231120, 253210

Recalling Firm/ Manufacturer

Biomet Inc. 56 E Bell Dr

Warsaw, Indiana 46581

For Additional Information Contact

Audrey Daenzer 574-372-1570

Manufacturer Reason

for Recall

An investigation identified that high level friction may exist between the needle and Mamba

suture passer instrument, causing the needle to break during use.

Action

On 9/26/2014, "URGENT MEDICAL DEVICE RECALL NOTICE" notifications were sent via courier to the affected distributors with instructions for returning the affected product. The recall notification included a description of the reason for the recall, affected product, consignee responsibilities, contact information, and instructions for responding to the formal

recall notification

Quantity in Commerce

12 units

Distribution

Nationwide Distribution-including the states of FL, NY, TX, VA, NV, MI, CA, IN, SD, GA,

KY, NC, and AR

Total Product Life Cycle

TPLC Device Report²⁶

Links on this page:

- 1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- 2. http://www.addthis.com/bookmark.php
- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. /scripts/cdrh/devicesatfda/index.cfm

For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55²⁷

FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall Black Mamba Suture Passer

510(k)⁷|DeNovo⁸|Registration & Listing⁹|Adverse Events¹⁰|Recalls¹¹|PMA¹²|Classification¹³|Standards¹⁴

CDRH CFR Titl
SuperSearch 2115

CFR Title | Radiation-Emitting 21¹⁵ Products¹⁶

X-Ray Assembler¹⁷ Medsun Reports¹⁸ |CLIA¹⁹|TPLC²⁰|Inspections²¹

New Search

Back to Search Results

Class 2 Recall Black Mamba Suture Passer See Related Information

Date Posted

October 09, 2014

Recall Status¹

Open

Recall Number

Z-0056-2015

Recall Event ID

69360²³

Product Classification

Passer²⁴ - Product Code HWQ²⁵

Product

Black Mamba Suture Passer. The Biomet Sports Medicine Mamba instruments are utilized to aid in passing suture through soft tissue. The Mamba Needle is designed for use with the Mamba Suture Passer. The needles are sterile, disposable, and for

single-patient use only

Code Information

Catalog Number: 110010849 Lot Number: 169620, 253190

Recalling Firm/ Manufacturer Biomet, Inc. 56 E Bell Dr

Warsaw, Indiana 46581

For Additional Information Contact

Audrey Daenzer 574-372-1570

Manufacturer Reason

for Recall

An investigation identified that high level friction may exist between the needle and Mamba

suture passer instrument, causing the needle to break during use.

Action

On 9/26/2014, "URGENT MEDICAL DEVICE RECALL NOTICE" notifications were sent via courier to the affected distributors with instructions for returning the affected product. The recall notification included a description of the reason for the recall, affected product, consignee responsibilities, contact information, and instructions for responding to the formal

recall notification.

Quantity in Commerce

15 units

Distribution

Nationwide Distribution-including the states of FL, NY, TX, VA, NV, MI, CA, IN, SD, GA,

KY, NC, and AR

Total Product Life Cycle

TPLC Device Report²⁶

Links on this page:

- 1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- 2. http://www.addthis.com/bookmark.php
- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. /scripts/cdrh/devicesatfda/index.cfm

¹ For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55²⁷

FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall Mamba Disposable Nitinol Needle 510(k) DeNovo® Registration & Listing Adverse Events Recall ⁰|Recalls¹¹|PMA¹²|Classification¹³|Standards¹⁴

CFR Title | 2115 SuperSearch

Radiation-Emitting X-Ray Assembler¹⁷ Products¹⁶

Medsun Reports¹⁸ |CLIA¹⁹|TPLC²⁰|Inspections²¹

New Search

Back to Search Results

Class 2 Recall Mamba Disposable Nitinol Needle

See Related Information

Date Posted

October 09, 2014

Recall Status¹

Open

Recall Number

Z-0058-2015

Recall Event ID

69360²³

Product Classification

Crimper, Pin²⁴ - Product Code HXQ²⁵

Product

Mamba Disposable Nitinol Needle. The Biomet Sports Medicine Mamba instruments are utilized to aid in passing suture through soft tissue. The Mamba Needle is designed for use with the Mamba Suture Passer. The needles are sterile,

disposable, and for single-patient use only

Code Information

Catalog Number: 110010851 Lot Number: 139800, 139810, 139820

Recalling Firm/ Manufacturer

Biomet Inc. 56 E Bell Dr

Warsaw, Indiana 46581

For Additional Information Contact

Audrey Daenzer 574-372-1570

Manufacturer Reason

for Recall

An investigation identified that high level friction may exist between the needle and Mamba

suture passer instrument, causing the needle to break during use.

Action

On 9/26/2014, "URGENT MEDICAL DEVICE RECALL NOTICE" notifications were sent via courier to the affected distributors with instructions for returning the affected product. The recall notification included a description of the reason for the recall, affected product consignee responsibilities, contact information, and instructions for responding to the formal

recall notification

Quantity in Commerce

164 units

Distribution

Nationwide Distribution-including the states of FL, NY, TX, VA, NV, MI, CA, IN, SD, GA,

KY, NC, and AR

Total Product Life Cycle

TPLC Device Report²⁶

Links on this page:

- 1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- 2. http://www.addthis.com/bookmark.php
- 3. http://www.fda.gov/default.htm
- 4. http://www.fda.gov/MedicalDevices/default.htm
- 5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
- 6. /scripts/cdrh/devicesatfda/index.cfm

For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55²⁷