Class 2 Recall Green Mamba Suture Passer

See Related Information[22]

Date Posted	October 09, 2014
Recall Status[1]	Open
Recall Number	Z-0057-2015
Recall Event ID	69360[23]
Product Classification	Passer[24] - **Product Code** HWQ[25]
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 Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]

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6. /scripts/cdrh/devicesatfda/index.cfm

Class 2 Recall Black Mamba Suture Passer

See Related Information[22]

Date Posted	October 09, 2014
Recall Status[1]	Open
Recall Number	Z-0056-2015
Recall Event ID	69360[23]
Product Classification	Passer[24] - **Product Code** HWQ[25]
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 Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]

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6. /scripts/cdrh/devicesatfda/index.cfm

Class 2 Recall
Mamba Disposable Nitinol Needle

See Related Information[22]

Date Posted	October 09, 2014
Recall Status[1]	Open
Recall Number	Z-0058-2015
Recall Event ID	69360[23]
Product Classification	Crimper, Pin[24] - **Product Code** HXQ[25]
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 Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]

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