Class 2 Device Recall COSEAL Surgical Sealant

See Related Information[22]

Recall Date	May 31, 2016
Recall Status[1]	Open
Recall Number	Z-1839-2016
Recall Event ID	74139[23]
Product Classification	Sealant,polymerizing[24] - **Product Code** NBE[25]
Product	COSEAL Surgical Sealant Kit, 4 mL, Product Code: 934071; For use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.
Code Information	HA160151, HA151205, HA151036, HA151035, HA160229
Recalling Firm/ Manufacturer	Baxter Healthcare Corp 21026 Alexander Ct Hayward CA 94545-1234
For Additional Information Contact	800-422-9837
Manufacturer Reason for Recall	Potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	An Urgent Product Recall letter dated 5/13/16 was sent to customers to inform them that Baxter Healthcare Corporation is issuing a voluntary product recall for the product codes and lots listed below due to the potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use. The letter provides the customers with the list of affected products, hazards involved, and actions to be taken. Customers with questions regarding the recall communication, are instructed to contact Baxter Product Surveillance at (800) 437-5176, 8-5pm, Monday-Friday.
Quantity in Commerce	6,804 units
Distribution	Distributed US (nationwide) including Puerto Rico and in the Bahamas, Canada, and Singapore.
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]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php

Class 2 Device Recall COSEAL Surgical Sealant

See Related Information[22]

Recall Date	May 31, 2016
Recall Status[1]	Open
Recall Number	Z-1838-2016
Recall Event ID	74139[23]
PMA Number	P030039[24]
Product Classification	Sealant,polymerizing[25] - **Product Code** NBE[26]
Product	COSEAL Surgical Sealant Kit, 2 mL, Product Code: 934070; For use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.
Code Information	HA160136
Recalling Firm/ Manufacturer	Baxter Healthcare Corp 21026 Alexander Ct Hayward CA 94545-1234
For Additional Information Contact	800-422-9837
Manufacturer Reason for Recall	Potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	An Urgent Product Recall letter dated 5/13/16 was sent to customers to inform them that Baxter Healthcare Corporation is issuing a voluntary product recall for the product codes and lots listed below due to the potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use. The letter provides the customers with the list of affected products, hazards involved, and actions to be taken. Customers with questions regarding the recall communication, are instructed to contact Baxter Product Surveillance at (800) 437-5176, 8-5pm, Monday-Friday.
Quantity in Commerce	274 units
Distribution	Distributed US (nationwide) including Puerto Rico and in the Bahamas, Canada, and Singapore.
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.

PMA Database	PMAs with Product Code = NBE and Original Applicant = BAXTER BIO SCIENCE[29]

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Class 2 Device Recall COSEAL Surgical Sealant

See Related Information [22]

Recall Date	May 31, 2016
Recall Status[1]	Open
Recall Number	Z-1839-2016
Recall Event ID	74139[23]
Product Classification	Sealant,polymerizing[24] - **Product Code** NBE[25]
Product	COSEAL Surgical Sealant Kit, 4 mL, Product Code: 934071; For use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.
Code Information	HA160151, HA151205, HA151036, HA151035, HA160229
Recalling Firm/ Manufacturer	Baxter Healthcare Corp 21026 Alexander Ct Hayward CA 94545-1234
For Additional Information Contact	800-422-9837
Manufacturer Reason for Recall	Potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	An Urgent Product Recall letter dated 5/13/16 was sent to customers to inform them that Baxter Healthcare Corporation is issuing a voluntary product recall for the product codes and lots listed below due to the potential for incomplete dissolution of the polyethylene glycol (PEG) component during the reconstitution of the product, which may affect the consistency of the hydrogel formation during use. The letter provides the customers with the list of affected products, hazards involved, and actions to be taken. Customers with questions regarding the recall communication, are instructed to contact Baxter Product Surveillance at (800) 437-5176, 8-5pm, Monday-Friday.
Quantity in Commerce	6,804 units
Distribution	Distributed US (nationwide) including Puerto Rico and in the Bahamas, Canada, and Singapore.
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]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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