## Class 2 Recall CooperSurgical

See Related Information[23]

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| **Date Posted** | July 17, 2015 |
| **Recall Status[1]** | Open |
| **Recall Number** | Z-2098-2015 |
| **Recall Event ID** | 71582[24] |
| **Product Classification** | Dilator, Vaginal[25] - **Product Code** HDX[26] |
| **Product** | Milex Vaginal-Hymenal Silicone Dilators Set of 4 P/N MX20 Product Usage: The CooperSurgical Milex Vaginal-Hymenal Silicone Dilators are used for progressive vaginal dilation therapy involving the treatment of vaginismus (muscular spasm of the vagina) and conditions that result in constriction of the vaginal and/or rectal orifice |
| **Code Information** | LOT 156966 |
| **Recalling Firm/ Manufacturer** | CooperSurgical, Inc.<br>75 Corporate Dr<br>Trumbull, Connecticut 06611-1350 |
| **For Additional Information Contact** | SAME<br>203-601-5200 |
| **Manufacturer Reason for Recall** | Incorrect expiration date on outer carton kit label |
| **FDA Determined Cause [2]** | EXPIRATION DATING: Incorrect or No Expiration Date |
| **Action** | CooperSurgical sent an Urgent Medicall Device Recall dated June 19, 2015 to affected customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to discontinue use of the affected products and complete the attached Acknowledgement and Receipt Form for a replacement. For questions call 203.601.5200. |
| **Quantity in Commerce** | 40 kits |
| **Distribution** | US Nationwide Distribution in the states of: CA, FL, GA, HI, IL, KY, MD, MN, NC, NY, OH, TX, VT, and W A. |
| **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.

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