Class 2 Device Recall DeRoyal (R) KNEE ARTHROSCOPY PACK

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Date Posted	July 29, 2014
Recall Status[1]	Open
Recall Number	Z-2124-2014
Recall Event ID	68744[22]
Product	DeRoyal (R) KNEE ARTHROSCOPY PACK, REF 89-6192.04, 1 Per Pack, Rx Only, STERILE EO, Distributed by: DeRoyal Industries, Inc. 200 DeBusk Lane, Powell, TN 37849, USA; Manufacturer: DeRoyal Industries, Inc. 200 DeBusk Lane, Powell, TN 37849, USA
Code Information	Lot Numbers: 30674381, 30721925, 30733281, 31029711, 31442590, 31649363
Recalling Firm/ Manufacturer	DeRoyal Industries Inc 200 Debusk Ln Powell, Tennessee 37849-4703
For Additional Information Contact	Tracy Edmundson 865-362-2334
Manufacturer Reason for Recall	The firm distributed surgical kits which contained Irrigation Sets which were subsequently recalled by Hospira.
Action	The recall was initiated by letter delivered via UPS on 6/4/2014. The firm requested that the consignee contact Stericycle to arrange for return and replacement of the product. A second notice was sent on 7/22/2014 to those accounts who did not respond to the initial notice. Distributors were requested to notify their end-users or provide a list of end-users to DeRoyal for direct notification. Effectiveness checks will be sent via email for those customers who have provided an email contact and via UPS for those customers who have not responded.
Quantity in Commerce	128 units
Distribution	Distributed in the states of MI, GA, OH, IL, MO, and IN.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[23]

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