



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Cook Recalls Flexor Check-Flo Introducer for Mislabeling Error

Recall Date	Product Description	Recalling Firm	Recall Reason
11/12/2021	Flexor Check-Flo Introducer Ansel Modification Model Number: KCFW-6.0-18/38-45-RB-ANL0-HC Order Number/GPN: G44154 Test kit SMN # 11207861	Cook Inc. Bloomington, Indiana	Products packaged with a label stating 6FR may contain a 7FR device and vice versa
11/12/2021	Flexor Check-Flo Introducer Ansel Modification Model Number: KCFW-7.0-18/38-45-RB-ANL0-HC Order Number/GPN: G44155	Cook Inc. Bloomington, Indiana	Products packaged with a label stating 6FR may contain a 7FR device and vice versa

Recall Class	Product Identification	Distribution	Affected Dates
II	Flexor Check-Flo Introducer Lot # 13895370 UDI: (01)0082700 2441545(17)240415(10)13895370	4 kits in California	November 2021 and prior
II	Flexor Check-Flo Introducer Lot # 13911710 UDI: (01)00827 002441552(17)240422(10)1391 1710	4 kits in California	November 2021 and prior

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