Class 1 Device Recall MoniTorr

Class 1 Device Recall MoniTorr See Related Information 22

Date Initiated by Firm	April 08, 2019
Create Date	May 20, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-1310-2019
Recall Event ID	82659[23]
510(K)Number	K022554[24] K062599[25] K920156[26]
Product Classification	Shunt, central nervous system and components[27] - **Product Code** JXG[28]
Product	MoniTorr 10100 10-100 CSF Drainage System w/Patient Line One Way Valve MoniTorr 10102 10-102 CSF Drainage System w/Patient Line One Way Valve w MoniTorr 10110 10-110 CSF Drainage System used with Pole Mount System MoniTorr 10140 10-140 CSF Drainage System w/Vinyl Measuring Strip MoniTorr 10150 10-150 CSF Drainage System Simple Bag and Line MoniTorr 10110A 10-110A CSF Drainage System w/o Manifold Stopcock MoniTorr SP0017 SP0017 Special EVD 10-110 w/o Y Site Latex Free Sites MoniTorr SP0042 SP0042 Special EVD 10-100 w/o Y Site MoniTorr SP0090 SP0090 Special EVD 10-110 w/o Y Site MoniTorr SP0164 SP0164 Special EVD 10-140 w/Y Site & Stopcock Reverse MoniTorr SP0236 SP0236 INS 1100 WITH NEEDLE AT Y-ACCESS AND NEEDLELESS SI Product Usage: The MoniTorr ICP External CSF Drainage and Monitoring Systems provide a simple to use, closed system for the drainage of cerebrospinal fluid (CSF) from ventricles of the brain or the lumbar subarachnoid space to a drainage bag. The system may be used with a pole mounted assembly that allows for simple, quick and accurate alignment with the patient and secure positive or negative pressure level setting. The system also has been designed to provide for ease of patient transport through a compact design and antimicrobial hydrophobic vent feature that resists occlusion. Indications: The MoniTorr ICP system allows for drainage and monitoring of CSF from the lateral

	ventricles of the brain and the lumbar subarachnoid space in selected patients to reduce intracranial pressure (ICP), to monitor CSF, to provide temporary drainage of CSF inpatients with infected CSF shunts, and to monitor ICP.
Code Information	All lots
Recalling Firm/ Manufacturer	Integra LifeSciences Corp. 311 Enterprise Dr Plainsboro NJ 08536-3344
For Additional Information Contact	Dr. Patricia Kihn 609-275-0500
Manufacturer Reason for Recall	The firm has identified a complaint trend regarding breakage of the LimiTorr Transducer Mount stopcock and MoniTorr Panel Mount stopcock.
FDA Determined Cause [2]	Device Design
Action	On April 8, 2019, the firm distributed Urgent Medical Device Correction letters to its affected customers. The communication advised customers of the possible breakage of the stopcock. Customers were advised to take the following precautions: When connecting a fluid-filled transducer (FFT) to the Panel Mount/Transducer Mount stopcocks: " Do not apply excessive force while attaching the FFT to the stopcock. " Take care during the priming process to not torque or bend the syringe and FFT. " Ensure luer lock is "finger tight;" do not over-tighten connection at the stopcock junction. When managing an external ventricular or lumbar drain (EVD) with a FFT attached: " Take care when manipulating the stopcock to zero the FFT and to obtain pressure readings, do not apply excessive force to the stopcock junction. " Use caution during patient transportation and during routine ICU care, to avoid direct contact of the FFT with other devices or equipment. " If the FFT must be flushed or replaced, do not apply excessive torque or force to the FFT/ stopcock junction. " If the FFT is connected to the ICU bedside monitor, ensure the interface cable is positioned so that it does not place excess force on the FFT (e.Q. do not allow cable to touch the floor. Customers were asked to determine if they had any affected product on hand, review and understand the precautions, and complete and return a completed acknowledgement form to the firm. Distributors were asked to forward the customer letter to any customers who received the affected product. Should you have any questions regarding these instructions, please contact Customer Service Monday to Friday 8:00 AM - 8:00 PM EST USA: 1-800-654-2873: email: custsvcnj@integralife.com Outside USA: 781-565-1401
Quantity in Commerce	42102 units
Distribution	Worldwide Distribution - US Nationwide International distribution to Argentina, American Samoa, Australia, Canada, and Guam.
Total Product Life Cycle	TPLC Device Report[29]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[30].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database

510(K)s with Product Code = JXG and Original Applicant = CLINICAL NEURO SYSTEMS LLC.[31]
510(K)s with Product Code = JXG and Original Applicant = INTEGRA LIFESCIENCES CORPORATION[32]
510(K)s with Product Code = JXG and Original Applicant = INTEGRA NEUROSCIENCES[33]

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30. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
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