Imperative CARE

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URGENT: VOLUNTARY MEDICAL DEVICE RECALL

IMMEDIATE ACTION REQUIRED

Affected Product: Specific Lots of Zoom™ 71 Reperfusion Catheter (ICRC071137)

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Facility Name
Consignee ID
Attn Name
Street Address
City, State, Zip Code

August 18, 2021

Dear Healthcare Professionals, Risk Manager, Director of Purchasing, Recall Coordinator,

The purpose of this letter is to advise you that Imperative Care is voluntarily recalling specific lots of the Zoom™ 71 Reperfusion Catheters. Imperative Care has identified that some Zoom 71 Reperfusion Catheters can experience a distal end fracture.

Imperative Care has identified a potential risk where certain Zoom 71 Reperfusion Catheters belonging to specific lots can experience a distal end catheter fracture. To address these failures, we are voluntarily recalling these specific lot numbers of Zoom 71 Reperfusion Catheters.

Description of the problem:

The distal end of the affected Zoom 71 Reperfusion catheter can fracture and become detatched, including but not limited to, when the catheter is retracted against significant resistance or the catheter is retracted through a kinked guide catheter or other constraint.

If the distal end becomes fractured, it can remain in the patient which could lead to prolongation of the procedure, vascular injury, occlusion, stroke, or possibly death resulting from any of the prior sequelae. The device failure may also require additional interventions, including but not limited to, the retrieval of fractured pieces which in turn carries inherent risks.

Through August 17, 2021, Imperative Care is aware of eight (8) reports associated with this device failure. Eight (8) serious injuries and zero (0) deaths have been reported due to the failure mode associated with this recall. In four (4) of these incidents, the fractured distal end was removed from the patient via an additional procedure; in the other four incidents, the fractured distal end was left in place.

Actions to be taken by the user:

With this notification, Imperative Care is requesting return of affected product and in addition has taken the necessary steps to prevent further shipment of the affected product.

For affected product that has been used, no action is necessary, and patients should continue to be managed in accordance with your standard patient management protocol.

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For affected product that has not been used, Imperative Care requests that you immediately take the following actions:

1. Share this recall notification with all users of the product within your facility to ensure that they are also aware of this recall.
2. Immediately review your inventory for the specific lot numbers listed below.
3. Remove and quarantine all unused affected products in your inventory.
4. Return the potentially affected products to Imperative Care. Your local Imperative Care Sales Representative can assist in facilitating the return of product as necessary.
5. If replacement product is needed, your Imperative Care Sales Representative can assist you with identifying suitable replacement product.
6. Complete the attached Customer Confirmation Certificate and contact your local Imperative Care Sales Representative.

Affected Zoom 71 Reperfusion Catheters are identified by lot numbers listed in the Product Distribution Information Table below, should not be used, and should be immediately returned to Imperative Care.

Product and Distribution Information:

Model # ICRC071137 – UDI 00812212030194		
Lot Number		Lot Number
V2014902		F2100802
F2113004		F2035301
F2112301		F2032502
F2112001		F2031101
F2111101		F2030801
F2110601		F2029701
F2109701		F2029501
F2109601		F2028901
F2108801		F2028801
F2108101		F2026802
F2104102		F2026201
F2101301		

Please ensure that the attached Customer Acknowledgement Certificate is returned within 3 business days to acknowledge receipt within your Department/Facility. This may be a requirement within your healthcare organization.

If you have any questions regarding this voluntary recall, please contact Imperative Care Customer Service at 1-408-502-7548, your Imperative Care Sales Representative, or email us at return@imperativecare.com.

Actions taken by Imperative Care:

Imperative Care has implemented a design change which is intended to improve catheter integrity and limit future occurrences of this failure. This design change is incorporated in the product that is now included in all ongoing Zoom 71 Reperfusion Catheter shipments.

You may continue to use Zoom 71 Reperfusion Catheters that are not listed in the table above that incorporate the design change intended to improve catheter integrity.

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Contact Information:

If you have any questions or concerns, please contact Imperative Care Customer Service (return@imperativecare.com or 1-408-502-7548), available Monday - Friday 7:00 AM to 5:00 PM PST, or your Imperative Care Sales Representative.

Product quality is of utmost importance to Imperative Care, and we take this issue very seriously. We are committed to continuous product innovation with the goals of improving product performance and striving for zero product failures. We appreciate your prompt attention and cooperation in this voluntary recall.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Sincerely yours,

Donielle Baudin
Sr. Director Quality Assurance

cc:
Nora Hadding
SVP, Clinical Affairs, Regulatory Affairs, Quality Assurance