URGENT FIELD SAFETY NOTIFICATION

Device	Catalog Numbers	Lot Number
Disposable Bipolar Ablator	C3390A, C3390NA, C3350A, C3350NA, C2455NA, C1860NA	All lots within expiration date

Dear Valued Distributor,

This letter is to inform you of an Urgent Field Safety Notification related to the products listed above. This letter contains important information that needs your immediate attention. There can be a **potential breach of the sterile packaging barrier** due to the development of pinholes at the crease of the double-folded edge of the current package configuration. If pinholes develop, there can be potential loss of primary package integrity resulting in **contamination of the device and patient infection** when used during surgery. To date, there have been no reports of contamination or infection. See the attached customer notification for additional information.

Actions Required by You:

1) Inform your customers about the notification:
    a. Distributors will need to contact every one of their customers (consignees) that have received the products listed on the Urgent Field Safety Notification (FSN).
    b. Provide them with a copy of the FSN letter and acknowledgement form attached to this notice.
2) Track customer (consignee) responses to determine the response rate (effectiveness of FSN) as required by Regulatory Agencies worldwide.
3) Support the Regulatory Agency inquiries in their region regarding consignee lists and which consignees have responded.

Please complete and return the enclosed Distributor Acknowledgement and Receipt Form as soon as possible and no later than by February 6, 2021 so we are assured you have received this important communication and implemented the required actions.

If you have any questions regarding this notice, please contact Distributor / Dealer.

Thank you in advance for your cooperation.

Sincerely,

Dr. Topaz Kirlew, MBA, MT(ASCP)
Vice President, Regulatory Affairs & Quality Assurance

Enclosure: Response Form

5115 Ulmerton Road ▪ Clearwater, FL 33760-4004

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Device	Catalog Numbers	Lot Number
Disposable Bipolar Ablator	C3390A, C3390NA, C3350A, C3350NA, C2455NA, C1860NA	All lots within expiration date

Dear Valued Customer,

This letter is to inform you of an Urgent Field Safety Notification related to the products listed above. This letter contains important information that needs your immediate attention.

ISSUE:	There can be a **potential breach of the sterile packaging barrier** due to the development of pinholes at the crease of the double-folded edge of the current package configuration. Issue was discovered after worst case transportation/handling/shipping/extreme temperature conditions showed package integrity failure in 10.5% of samples tested.
IMPACT:	If pinholes develop, there can be potential loss of primary package integrity resulting in **contamination of the device and patient infection** when used during surgery. To date, there have been no reports of contamination or infection.
ACTION REQUIRED:	Immediately check your inventory, do not use any of the devices with the above catalog numbers even if you do not observe pinholes, complete the enclosed response form and **immediately return all devices in your inventory to your Distributor**.
RESOLUTION:	Package configuration design will be changed to a configuration that eliminates double folding.

Please share this information with your Operating Room staff and retain this notification as part of your Device Quality documentation. If you have forwarded any of the affected product(s) listed above to another facility, please provide them a copy of this letter. We have notified the appropriate regulatory agencies and competent authorities of this issue.

Please complete and return the enclosed Response Form as soon as possible but no later than February 6th, 2021 so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact your local Distributor or Representative. We consider patient safety and customer satisfaction our primary priority. We appreciate your time and attention in reading and acting upon this important notification.

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Sincerely,

Dr. Topaz Kirlew, MBA, MT(ASCP)
Vice President, Regulatory Affairs & Quality Assurance

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