May 1, 2025

URGENT: MEDICAL DEVICE RECALL
BX2 Needle Guide

(1) Attention to Customer:

Attention: Ultrasound Department or Recall Coordinator

(2) Purpose of this letter

This is CIVCO's final notification to advise you that CIVCO Medical Instruments Co., Inc. initiated a voluntarily recall of the BX2 Needle Guide sold within the product reference number and lot numbers below.

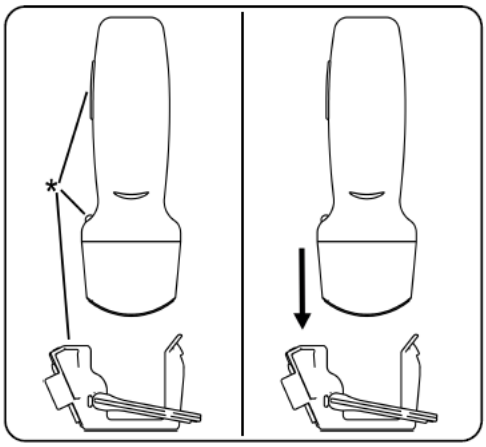
Part #	Description	Lot Number Range
644-094	BX2 Needle Guide	A174424 – A260607

(3) Reason for the Voluntary Recall:

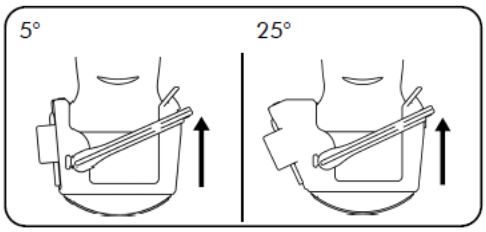
CIVCO has discovered an interaction issue with the BX2 Needle Guide. You are being notified, as your facility has been identified as having received BX2 Needle Guides manufactured by CIVCO.

During the attachment of the needle guide to the covered probe, the tight tolerance and fit of the needle guide can cause a pinhole breach in the transducer cover when latching the guide in place.

Using proper sterile technique, attach unlocked needle guide onto transducer by aligning needle guide attachment with transducer locating feature.



Rotate locking latch into locked position. Ensure needle guide is securely attached.



(4) Risk to Health:

The presence of pinhole in the cover can lead to cross contamination of the probe and the patient during a procedure.

(5) Actions to be taken by the Customer/User:

CIVCO requests that you check your inventory for any BX2 Needle Guides and complete the supplied response letter for the appropriate action.

Please contact your distribution partner to return any existing inventory, or report its destruction by completing the attached response form.

Please complete the enclosed response form even if you do not have any BX2 Needle Guides remaining in your inventory to assist in our reconciliation process. Response forms can also be sent via email to distorder@civco.com.

(6) Product and Distribution Information:

Product Names, Unique Device Identifier	Product Number/Catalog Number	Lot Number Range
00841436120050	644-094	A174424 – A260607

(7) Type of Action by the Company:

This notice is being communicated to all customers who have purchased a BX2 Needle Guide from affected lots. CIVCO requests you provide this notification to the appropriate personnel within your facility. If the affected product was distributed outside of your organization, please notify those locations down to the medical facility level.

(8) OTHER INFORMATION:

- Attachments of Acknowledgement and Product Reconciliation Forms (separate sheets)

Sincerely,

James Leong
Regulatory Affairs Manager
CIVCO Medical Instruments Co., Inc.

.

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

Customer Information:

Facility _____
Customer Name _____
Street Address _____
Town, State, Zip Code _____
Signature _____

BX2 Needle Guide

Lot/Serial numbers:

I have read and understand the recall instructions provided in the May 1 letter. Yes _ No_

Have there been any adverse events associated with recalled product? Yes _ No _

If yes, please explain:

_____
_____
_____
_____

Affected Product Information:

Affected Product Information Table				
Product/Brand Names, UDI (if applicable)	Manufacturer's Product Number/Catalog Number	Lot Number shipped to Customer	Quantity in inventory	Quantity destroyed/ returned

Return Response Box:

Please provide any additional information, if applicable.

Distributor Actions:

I have checked my stock and have quarantined inventory consisting of _____ boxes.

I have identified and notified my customers that were shipped this product. Yes _ No _

I have reconciled the inventory of product shipped to customers of the affected products and provided the information to back to CIVCO.

Comments:

_____
_____
_____
_____

Signature of Receipt _____

Name/Title	
Telephone	
Email address	

PLEASE SEND COMPLETED RESPONSE FORM to email to distorder@civco.com.