
Urgent Medical Device Recall
Dual Path Guide

July 30, 2018

Attention: Ultrasound Department

This is to inform you of a product recall involving the products labeled as identified below:
676-144 – Needle Guide with covers for use with Siemens BP9-4 transducers
676-150 – Needle Guide for use with Siemens BP9-4 transducers

Lot numbers:

676-144

A018067	A025606	A029383	A035568	A040839
A021026	A026609	A032036	A037150	A041444
A021226	A026610	A033139	A037231	A041723
A022447	A028159	A033153	A037585	
A023876	A028645	A035009	A039417	
A025137	A029293	A035010	A040376	

676-150

A035054	A042207			

Dear Valued Customer,

CIVCO has recently discovered a quality issue with dual path needle guide for use with the Siemens BP9-4 transducer. You are being notified, as your facility has been identified as having received product from the affected manufacturing lots. .

Description of the Problem:
The assembly of the needle guides were found to be either missing adhesive or did not have adequate adhesive to hold the assembled cannula in place on the needle guide.

Needle guide assembled

Bond failure

Action to be Taken by the Customer:
CIVCO requests return of all needle guides received from the affected lots identified on the box.

To return the bracket and schedule replacement contact your Account Representative by phone at 800-445-6741 or 319-248-6757 or via email at order@civco.com.

Transmission of this Recall Notification:
This notice is being communicated to all customers who have purchased a kit in which the needle guide is contained 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.

Thank you for your cooperation and communication on this issue. Please feel free to contact me if you have any questions or concerns regarding the above information.

Sincerely,

James Leong
Regulatory Manager
CIVCO Medical Solutions

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Return By: 17 August 2018

I have been informed of the recall notice by CIVCO Medical Solutions involving the dual path needle guide.
This notice has been read and understood by the responsible party involved.

1. _____ I have reviewed my inventory for the affected products and no longer have any in stock.

2. _____ I have reviewed my inventory for the affected products and I need a Return Authorization Number to return the product.

List Lot Number	List # units	List Lot Number	List # units
_____	_____	_____	_____

3. _____ Other, please provide details.

_____
Facility Name

_____ _____ _____
Street Address City, State Phone

_____ _____ _____
Print Name / Title Signature Date

Please return this certification by FAX at 319-248-6660 or email to order@civco.com.
Attn: Infiniti Bracket at 319-248-6660.

Please contact a CIVCO Customer Service representative for additional assistance. You may reach your Customer Consultant by calling CIVCO Medical Solutions, Multi-Modality Imaging, at 800-445-6741 or 319-248-6757 between 7:00AM and 5:30PM CST. You may also contact us via email at order@civco.com.

Thank You.

Urgent Medical Device Recall (OEM / Dist Cover Letter)
Infiniti Bracket (Sold as part of CIVCO brand Biopsy Starter Kits and Biopsy Bracket)

July 30, 2018

Dear Sir or Madam,

Enclosed please find a notification letter for the dual path guide. We have identified that you have distributed kits which include the needle guide from the affected lots listed we have detailed.

This recall is being conducted to the medical facility / user level. We ask that you forward a copy of this notification letter to all customers who have received this product.

Please contact your Account Representative concerning the replacement instructions if you have any questions. You may reach your Representative by calling CIVCO Medical Solutions, Multi-Modality Imaging, at 800-445-6741 or 319-248-6757 between 7:00AM and 5:30PM CST. You may also contact us via email at order@civco.com

We appreciate your assistance with this matter.

Sincerely,

Jim Leong
Regulatory Affairs Manager
CIVCO Medical Solutions