stryker

Medical Device Correction

Airo TruCT system

Transport Mode Labeling Update

Attn: Risk Manager/Operating Room Director/Radiology Director
Recall number: RA2022-3159042
December XX, 2022

Catalog number	UDI-DI	Product description	Serial numbers*
MobiCT®-32	00869346000200	Airo TruCT Mobile CT Scanner	All serial numbers

Purpose of Notification

Stryker is notifying Airo TruCT customers that we will be highlighting certain information that is already in the Airo TruCT User Manual on labels affixed to the Airo TruCT unit itself. Stryker received one report of an injury to an untrained user that occurred while the untrained user was moving an Airo TruCT unit in reverse. The Airo TruCT unit at issue did not experience a malfunction.

Product description

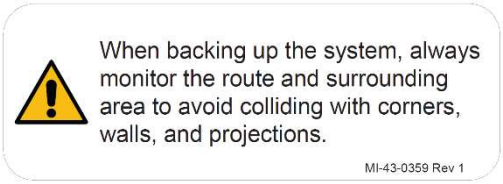
The Airo TruCT System is a mobile computed tomography (CT) system, including a mobile base that supports the Gimbal and Ring.

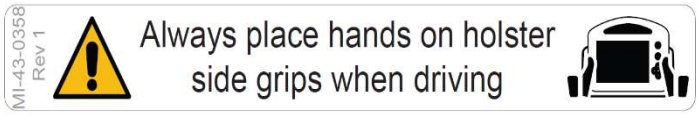
Potential risks

If a user is not trained to operate the Airo TruCT in transport mode, there is a risk of injury to the user, ranging from strain/sprain, bruising and minor lacerations to fractures and other serious injuries.

Summary of Action

To increase visibility of instructions for users to consider when transporting an Airo TruCT unit in reverse, the following labels will be affixed onto the Airo unit.





(a) **(b)**

Figure 1(a) & (b)- Image of labels

Figure 2- Image depicting location of where labels will be affixed.

Actions needed:

1. A service representative will contact your facility, when labels are available (anticipated February 2023), to schedule a time to affix the labeling to your Airo TruCT unit.
2. In the interim, please share this letter with Airo TruCT users as well as any other relevant personnel in your facilities.
3. Airo TruCT use must be limited to trained users only. As stated in Manual Sections 1.7.1 and 2.10.1:
    - "Users must receive and complete training from Mobius Imaging or its authorized agents before using AIRO. For training, contact your distributor or Mobius Imaging."
    - "Cautions and Warnings: Never allow untrained persons to move or operate Airo TruCT as this creates a hazard of collision and equipment damage."
    -
4. Inform Stryker if any of the subject devices have been distributed to other organizations.
    - Please provide contact details so that Stryker can inform the recipients appropriately.
    - If you are a Distributor, note that you are responsible for notifying your affected customers.
5. Please inform Stryker of any adverse events concerning the use of the subject devices.
    - Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
6. **Complete the attached customer response form.** It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter.
    - Therefore, **please complete even if you no longer have any of the subject devices in your physical inventory.**
7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA

We request your support in finalizing the required steps within 14 calendar days from the date of receipt.
Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: email:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused.
We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Sincerely,
XXXXXXX XXXXXXX
RAQA Specialist

Business Reply Form

RA2022-3159042 - Airo® TruCT System

December XX, 2022

Catalog number	Product	Serial number(s)	Facility name
MobiCT-32	Airo TruCT System		

☐ If you no longer have affected product on hand, please check here.

- Please state disposition of product no longer on hand: _____

Customer information

Customer name _____

Name of person completing this form_____Title_____

Direct phone #_____Email_____

Address_____City_____State____ Postal code _____

Country _____

If you have further distributed any affected product, please indicate to whom:

Product(s) distributed		**Quantity distributed**	
Facility name		**Contact person**	
Full address			

☐ ***Your signature indicates that you have read and acknowledge the purpose of this notification.***

Name (print)_____Signature_____Date

Return completed Business Reply Form to xxxxx@stryker.com.