



Communication Plan

FIELD SAFETY NOTIFICATION FOR:

Solstice™ Tilting Head Fixation System

PN: CHS03, CHS04, CHS03K, CHS04K, CHS03SGK, CHS04SGK

Letter to Customers
Product Reconciliation Form
Cover Letter to Distributors
Internal Phone Script

www.civcort.com

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Global Sales Office | 1401 8th Street SE | Orange City, IA 51041 | USA | **office** +1 (712) 737.8688 | **fax** +1 (877) 613.6300

Urgent: Field Action Notice – Customer Communication

Solstice™ Tilting Head Fixation System

Part Numbers: CHS03, CHS04, CHS03K, CHS04K, CHS03SGK, CHS04SGK

April 16, 2019

Attention: Chief Radiation Therapist, Chief Physicist and Administrative Director

Dear Customer,

CIVCO Radiotherapy has initiated a field action due to potential for movement of the Solstice™ Tilting Head Fixation System during patient setup and/or treatment. Patient motion, if not detected could lead to mistreatment.



The movement can occur during initial patient setup when the patient moves from an inferior to superior position while placing their head into the bowl. The patient's motion and force against the bowl may also cause pitch even when the device is locked.

It was also observed through internal testing, that movement is possible when patients with a certain body habitus are set up in a hyperextended neck position. The body habitus most likely to cause this movement has a very short neck, high shoulders, and carries weight across their upper back, likely resulting in their upper back being positioned near or on the inferior flange of the Solstice device. With this type of body habitus there may be increased force applied to the inferior flange of the bowl, therefore causing pitch movement (chin down) after setup, and possibly during treatment. We are currently evaluating options to address the possibility of movement, in the meantime, if you choose to continue using the device, please take the action steps detailed below to mitigate the risk of unintentional patient movement.

The risk of movement during setup can be mitigated by taking the following actions:

1. Ensure bowl is in the unlocked position during patient setup.
2. Lock bowl into desired indexing location once patient is set up appropriately for treatment.
3. Visually confirm bowl indexing location with reference to patient setup sheet.
4. Perform a setup confirmation image prior to treatment and/or utilize Surface Guided Radiation Therapy (SGRT) if available during treatment to monitor patient position.
5. Recheck the tilt indexing location after treatment to confirm desired setup was maintained.

The risk of movement during treatment can be mitigated by:

1. Ensuring patients with a shorter neck or high shoulders are positioned such that pressure is not being exerted on the inferior flange of the bowl.
2. Not setting up the patient into a hyperextended position if patient anatomy makes achieving this position difficult. Forced hyperextension of the patients' neck may increase the likelihood of movement from setup position.
3. Utilizing Surface Guided Radiation Therapy (SGRT) if available during treatment to monitor patient position.

Please utilize the attached form to identify your course of action within 2 weeks of receiving this notification. If you have any questions, please contact CIVCO Product Manager Heather Wilkerson. Heather can be reached at Heather.Wilkerson@civcort.com or 319-248-6657.

Sincerely,

Jennifer Blauvelt

Sr. Director of Quality, Regulatory Affairs and Special Projects

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Urgent: Field Action Notice – Product Reconciliation Form

Solstice™ Tilting Head Fixation System

Part Numbers: CHS03, CHS04, CHS03K, CHS04K, CHS03SGK, CHS04SGK

Return By: 29 April 2019

I have been informed of the field safety notice by CIVCO Radiotherapy involving the Solstice™ Tilting Head Fixation System. This notice has been read and understood by all operators of the device:

I have reviewed my inventory for the affected products.

1. _____ I no longer have the Solstice™ Tilting Head Fixation System
2. _____ I currently have the Solstice™ Tilting Head Fixation System. I do not wish to take any action, I assume responsibility for this action.
3. _____ I currently have the Solstice™ Tilting Head Fixation System. I request a Return Authorization Number to return the unit to CIVCO Radiotherapy for replacement.

Quantity to be returned : _____

Facility Name

Street Address

City, State

Phone

Print Name / Title

Signature

Date

Please return this certification by FAX or email to the appropriate contact below.

Attention: CIVCO Radiotherapy Solstice™ Tilting Head Fixation System
North American Customer use: Order@CivcoRT.com or 1-800-842-8688

International Customers use: DistorderCivcoRT.com or 1-712-737-8688

Please contact a CIVCO insides sales representative for additional assistance. You may reach your representative by calling CIVCO Radiotherapy, at the numbers above between 8:00AM and 5:00PM CST.

Thank You.

www.civcort.com



Urgent: Field Action Notice – Distributor Communication

Solstice™ Tilting Head Fixation System

Part Numbers: CHS03, CHS04, CHS03K, CHS04K, CHS03SGK, CHS04SGK

April 16, 2019

Dear Sir or Madam,

CIVCO Radiotherapy has initiated a field action due potential for movement of the Solstice™ Tilting Head Fixation System during patient setup and/or treatment.

We have identified that you have distributed the Solstice™ Tilting Head Fixation System under the following part numbers: CHS03, CHS04, CHS03K, CHS04K, CHS03SGK or CHS04SGK.

Enclosed please find a notification letter which is required to be sent to all customers who received this product. We require that the enclosed product reconciliation form be completed by each customer and returned to CIVCO as soon as possible, no later than 26 April 2019.

Please contact your CIVCO Representative if you have any questions.

We appreciate your assistance with this matter.

Sincerely,

Jennifer Blauvelt
Sr. Director of Quality, Regulatory Affairs and Special Projects

www.civcort.com



Urgent: Field Action Notice – Internal Telephone Script

Solstice™ Tilting Head Fixation System

Part Numbers: CHS03, CHS04, CHS03K, CHS04K, CHS03SGK, CHS04SGK

We are asking sales territory managers to contact each of the customer or distributor who have received the Solstice™ Tilting Head Fixation System to ensure the risk of use is communicated as we value the safety of their patients. Sales territory manager will inform the user of the issue and determine each site's course of action for the device.

Each customer contacted will need to respond to the field action through completion and return of a product reconciliation form. Contact with the customer will be initially via email, with the request for read receipt. Follow up contact may be through email or phone. Email communication attempts will be documented through retention of email communication as well as read receipts if they are provided by the customer. For phone contact attempts, document the date and time the call was placed and to whom the call was received by, if applicable.

Contact: Chief Radiation Therapist, Chief Physicist, Administrative Director or most responsible person on-site

Part Numbers Affected

Solstice™ Tilting Head Fixation System

Part Numbers: CHS03, CHS04, CHS03K, CHS04K, CHS03SGK, CHS04SGK

Telephone Script:

We are informing our customers of a safety notification associated with the Solstice™ Tilting Head Fixation System.

Movement of the device can occur during initial patient setup when the patient moves from an inferior to superior position while placing their head into the bowl. The patient's motion and force against the bowl may also cause pitch even when the device is locked.

It was also observed through internal testing, that movement is possible when patients with a certain body habitus are set up in a hyperextended neck position. The body habitus most likely to cause this movement has a very short neck, high shoulders, and carries weight across their upper back, likely resulting in their upper back being positioned near or on the inferior flange of the Solstice device. With this type of body habitus there may be increased force applied to the inferior flange of the bowl, therefore causing pitch movement (chin down) after setup, and possibly during treatment.

Due to the potential for unintentional patient motion, which could lead to patient mistreatment if motion is not detected, we are requesting that the devices be returned for replacement.

Please utilize the supplied product reconciliation form to identify your course of action within 14 days of receiving this notification.

Advise on the action to be taken by the user and their determination must be documented and returned on the response sheet:

- 1. If the user no longer has the Solstice™ Tilting Head Fixation System.**
- 2. If the user currently has the Solstice™ Tilting Head Fixation System and does not wish to take any action. If this option is chosen, site assumes responsibility for safe use of the device.**
- 3. If the user has the Solstice™ Tilting Head Fixation System and is requesting return authorization number to return device to CIVCO Radiotherapy for replacement.**

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