CAPINTEC, INC.

*****PRODUCT ALERT – CORRECTIVE ACTION*****

Attention: Nuclear Medicine Department Supervisor

November 1, 2018

CAPTUS 3000 SPRING ARM FAILURE

Captus 3000 and Captus 700 Thyroid Uptake Systems Shipped between August 1, 2011 and April 30, 2012

Captus 3000 Serial Numbers 901100 through 901309
models 5430-0076 and 5430-0077 only

Captus 700 Serial Numbers 700004 through 700018
models 5430-3137 and 5430-3138 only

Captus 3000 S/N 900785 and CNV 720, serviced with arm replacement

The purpose of this ALERT is to notify you of reports of spring arm failure with Captus 3000 Thyroid Uptake Systems.

The failures are the result of a broken tension rod (a component inside the arm). A break in the tension rod can cause the collimator to fall downward to its lowest point of travel, which is approximately 25 inches from the ground. The collimator and arm collectively weigh 45 pounds, and there is the potential for injury if the collimator were to come into contact with a patient or operator. In the reported cases, the failure occurred during movement of the arm.

We believe that systems and replacement spring arms which used tension rods from this same batch were shipped between August 2011 and April 2012. *[NOTE:The Captus 3000 and Captus 700 systems use the same spring arm assembly.]* Records indicate that your facility was shipped a Captus 3000 System or Captus 700 or replacement spring arm during this time period. **Capintec will send a replacement arm and installation instructions as soon as possible to your facility.** In the interim, we are providing you with information about these reports so you can take appropriate action in the interest of patient and operator safety.

7 Vreeland Road • Florham Park, NJ 07932 U.S.A. • (201) 825-9500 FAX (201) 825-1336

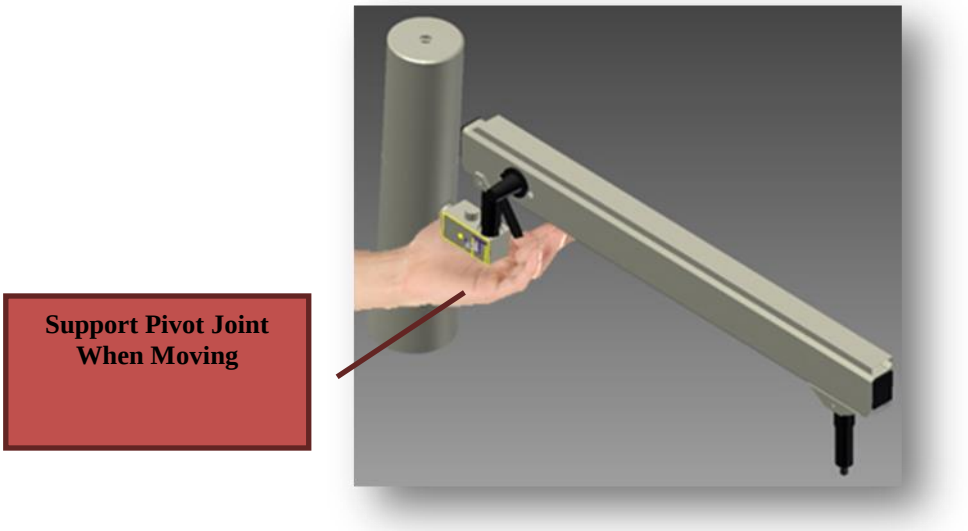
Preventative Action:

1. Review this Alert and ensure that all affected personnel, including all operators of Captus 3000 and 700 Systems, are aware of the contents.

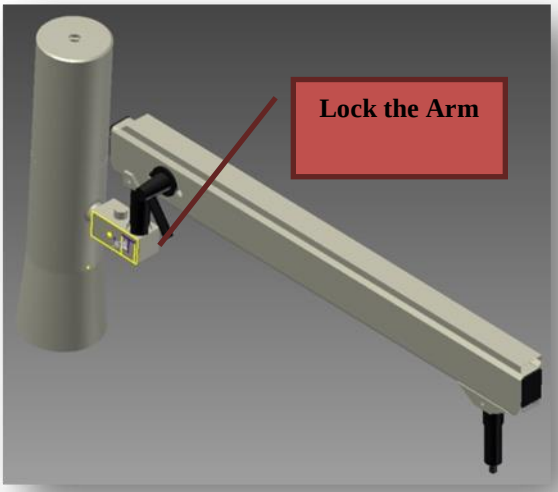
2. Instruct affected personnel and operators to comply with the following steps in the interest of patient and operator safety:

    a. Prior to moving the arm, ensure that the positioning locks are released.

    b. Use caution when moving the arm. **Support** the arm at the collimator pivot point as shown in the photograph below when moving the arm.



    c. Once in position, secure the arm by tightening the locking handle prior to performing Thyroid Uptake and Bioassay Procedures, as shown in the photograph below.



d. Perform Thyroid Uptake and Bioassay Procedures with patient (or employee, for Bioassay Procedures) in a **seated position**, rather than a supine position on a table.

e. Store the arm in an upright position. This places the least amount of stress on the internal components.

If you have any questions about this Safety Alert, the Preventive Action steps outlined above, or your Captus 3000 or 700 System, please contact Capintec Customer Support at the phone number or email listed below. If you notice any unusual change in the performance or functional response of the arm in your system (e.g. arm is making an unusual noise or arm does not move smoothly at any articulation joint), please contact Capintec Customer Support.

Capintec Customer Support:
1-800-631-3826
capintec.techsupport@capintec.com

Please confirm receipt and review of this CAPTUS 3000 and Captus 700 SAFETY ALERT by completing and signing the notification in the lines indicated below, and sending a confirmatory email to capintec.techsupport@capintec.com.

Thank you for your understanding in this matter.

**********PRODUCT ALERT**********

I acknowledge receipt and review of this CAPTUS 3000 and Captus 700 ALERT NOTICE for your Captus 3000 or Captus 700 Serial Number _____.

Ship the replacement spring arm to the contact person and address listed below:

Name/Title (please print): _____

Facility: _____

Address: _____

Phone Number: _____

Email: _____

Signature and Date: _____

Please complete and return this form by one of the following methods: ----------

FAX: 201-825-1336

Email: capintec.techsupport@capintec.com