varian

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URGENT MEDICAL DEVICE REMOVAL
FIELD SAFETY NOTIFICATION

Subject:	***Detachment of Trocar Tip Reported***
Commercial Name:	***Stainless Steel Interstitial Needles, 17 Gauge***
Affected Part Number(s):	***GM11009500, GM11009510, GM11009520 and GM11009530***
Affected Version(s) / Lot(s):	***Lot T48 and U13***
Reference / FSCA Identifier:	***CP-2019-01813***
Date of Notification:	***25 JUNE 2019***
Type of Action:	***Notification and Removal***

DESCRIPTION OF ISSUE:

Varian has received several reports that the trocar tip detached from a 17-gauge stainless steel interstitial needle. In one case, four (4) needles were identified with detached tips. Two (2) of the trocar tips were confirmed lodged in the patient's prostate. The other two (2) tips were confirmed in the instrument tray post treatment. There were no adverse health consequences reported due to this incident.

The trocar tip breakage was discovered either during commissioning [1 tip GM11009250 and 1 tip GM11009530], or after it was removed from the patient [1 tip GM11009520] per the other reports. In total, Varian has been notified of seven (7) trocar tips breaking off from a 17-gauge stainless steel interstitial needle. The affected needles were from lots T48 and U13.

There have been no reports of adverse health consequences due to this issue. There also have been no reports of trocar tip failures in any other manufacturing lots.

DETAILS:

The investigation is on-going. Root cause of the trocar tip detachment has not been established.

RECOMMENDED USER ACTION:

Varian recommends that Users **CEASE USE** of **17 Gauge Stainless Steel Interstitial Needles, Lot T48 or U13, part numbers: GM11009500, GM11009510, GM11009520 and GM11009530.** The photos depict the location of the lot information via yellow circle on the packaging and the product for user reference. The lot reference is on the *connector end of the needle*.

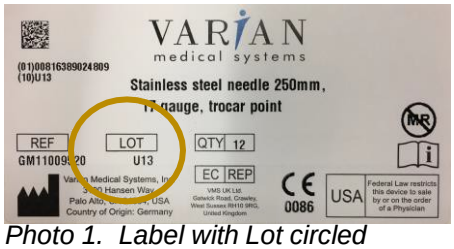

Photo 1. Label with Lot circled

Photo 2. Sample needle with Lot circled

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Users may contact Varian Support (contact information below) to return the affected products for credit or refund. Returns will require a Return Material Authorization (RMA) number. All affected Interstitial Needles should be returned in accordance with instructions.

VARIAN MEDICAL SYSTEMS ACTION:

Varian Medical Systems will issue a credit or refund for returned **17 Gauge Stainless Steel Interstitial Needles; Lot T48 or U13, part numbers: GM11009500, GM11009510, GM11009520 and GM11009530**

Varian Medical Systems is investigating this issue. The timeline of a technical solution is currently unknown.

This document contains important information for the continued safe and proper use of your equipment.

- Please retain a copy of this document along with your most current product labeling.
- Advise the appropriate personnel working in your radiotherapy department of the content of this letter.

In compliance with regulatory requirements, we request that you complete the Return Response form provided with this notification. Kindly return the completed form to returnresponse@varian.com.

We sincerely apologize for any inconvenience and thank you in advance for your cooperation. If you require further clarification, please feel free to contact your local Varian Medical Systems service manager. This notice will be provided to the appropriate Regulatory Authorities as required.

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Varian Medical Systems

Varian Support Information:

Phone North America: +1.888.827.4265
Phone Outside of North America: https://www.myvarian.com/s/contactus?lang=en
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