IMPORTANT FIELD SAFETY NOTIFICATION
URGENT: MEDICAL DEVICE CORRECTION

Subject: Intrauterine tubes tip inspection.

Product: Intrauterine tubes (IU tubes) with a 4 mm diameter used in the following applicators:

- CT/MR Applicators (Standard, Ring, Fletcher, Utrecht Interstitial).
- Advanced Gynecological Applicator - Venezia.
- Geneva.

Scope: Intrauterine tubes (IU tubes) with a 4 mm diameter. A detailed list of the affected products can be found in **Annex 1.**

Notification Released: March 2026.

UDI References:

08717213034679	08717213055001	08717213056039
08717213034693	08717213055018	08717213056053
08717213035171	08717213055025	08717213056077
08717213034273	08717213055049	08717213056091
08717213035744	08717213055056	08717213056398
08717213035768	08717213055063	08717213056411
08717213035782	08717213055087	08717213056435
08717213035805	08717213055094	08717213056459
08717213035829	08717213055100	08717213056473
08717213038622	08717213055117	08717213056497
08717213038639	08717213055131	08717213056510
08717213038646		08717213056534
08717213038653		08717213056558
08717213030763		08717213056572
08717213024236		08717213056596
08717213024502		08717213056619
		08717213056633
		08717213056657

Contact Information at:

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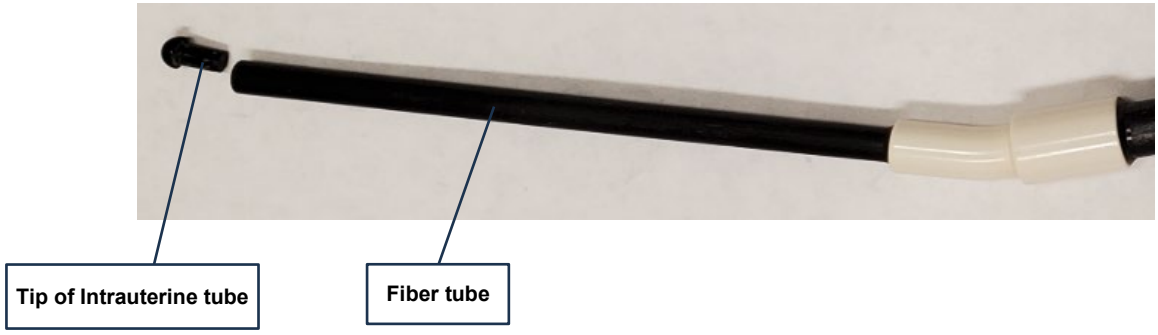
Description of Problem:
We are issuing this Safety Notification to inform you of a user safety concern regarding the detachment of the tip of an Intrauterine tube (IU tube) with a 4 mm diameter that remained in the patient.
Example of a 4 mm IU tube with the tip detached:



An extensive root cause analysis identified the primary contributing factor of the tip detachment as an inadequate application of the epoxy adhesive between the tip and the inner and end surfaces of the fiber tube.

Clinical impact:
If the IU tube tip remains in the uterus and is not expelled naturally, encapsulation of the tip may carry a risk of reduced fertility and a potential risk of inflammation and pain associated with the retained tip.

Recommended User Action:
To prevent any potential health risks related to a detached tip, we emphasize the importance of adhering to the Instructions for Use:

- Do not use an IU tube beyond its 3-year life expectancy or 300 reprocessing cycles, whichever comes first.
- During the treatment preparation phase, before insertion of the applicator: Visually inspect parts for indication of damage, weakening, bending, cracks, corrosion, or general deterioration.
- Inspect joints and connections on play, strength or other forms of degradation.

In addition, we recommend the following:

- Inspect the end of the IU tube to ensure that there is no gap between the tip and the fiber tube and that the tip is not detached.
- During inspection, insertion and removal: avoid the use of excessive force that could damage the IU tube.
- After removal: Ensure that all applicator parts have been removed from the patient and that the tip is not detached.

In case you find a damaged or detached IU tube tip, remove it from clinical use and contact Elekta for a replacement.

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

- Please post this notice in a place accessible to all users, e.g. Instructions for Use, until this action is closed.
- Advise the appropriate personnel working with this product on the content of this letter.

Elekta Corrective Actions:
As part of our commitment to quality and continuous improvement, Elekta has optimized the manufacturing process to prevent detachment of the tip.

This notice has been submitted to the appropriate Regulatory Authorities.

We sincerely apologize for any inconvenience this action may cause and thank you in advance for your cooperation.

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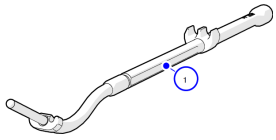
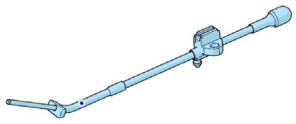
Annex 1. Intrauterine tubes (IU tubes) with a 4 mm diameter.

CT/MR Applicators: Standard, Ring, Fletcher, Utrecht Interstitial	Part numbers [1]	Description
	110296 110298 110300 110302 110303 110304 110305 110306 110307 110665 110666 110667 110668 110970 110971 110972	THIN IU TUBE 4MM 15 DEGREES THIN IU TUBE 4MM 30 DEGREES THIN IU TUBE (4MM) 45 DEGREES IU TUBE (4MM) 40 DEGREES - 50 IU TUBE (4MM) 30 DEGREES - 40 IU TUBE (4MM) 45 DEGREES - 40 IU TUBE (4MM) 60 DEGREES - 20 IU TUBE (4MM) 60 DEGREES - 40 IU TUBE (4MM) 60 DEGREES - 60 IU TUBE, 4MM, L=20MM, FOR 45° IU TUBE, 4MM, L=60MM, FOR 45° IU TUBE, 4MM, L=20MM, FOR 30° IU TUBE, 4MM, L=60MM, FOR 30° IU-TUBE (4MM), 15 DEGREES IU-TUBE (4MM), 30 DEGREES IU-TUBE (4MM), 45 DEGREES
Advanced Gynecological Applicator - Venezia	**Part numbers [1]**	**Description**
	126013 to 126023	INTRAUTERINE TUBE – All dimensions.
Geneva	**Part numbers [1]**	**Description**
	152007 to 152024	INTRAUTERINE TUBE – All dimensions.

[1] ALL versions.

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Acknowledgement Form

In order to meet regulatory requirements, you are required to either acknowledge receipt of this notification via the Elekta Care™ Community or complete this form and return it to Elekta immediately upon receipt, but no later than within 30 days.

Classification:	Important Field Safety Notification	FCO Reference Number:	806-01-APL-002
Description	Intrauterine tubes tip inspection.		

Hospital:	
Device Serial No(s): (if applicable)	Location or Site:

I acknowledge that I have read and understood this Notice and accept the implementation of any given recommendation.

Name: Title:

Customer Signature: Date:

New installation confirmation to be signed by the installing Elekta engineer or a Representative employee, when the installed product has a physical IFU/manual:

I acknowledge that the customer has been informed of the content of this notice and that it has been inserted into the applicable copy of the User Manual, or added on record with the applicable User Manual:

Name: Title:

Signature: Date:

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