URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject: **Incorrect source step size may occur in Oncentra Brachy plans for Ring or Venezia applicator models with microSelectron.**

Product: **Oncentra® Brachy.**

Scope: **Oncentra Brachy versions 4.5, 4.5.1, 4.5.2.**

Notification Released: August 2017

Description of Problem:

The default step size set in RDStore is typically used during the planning process. The measured source paths for a ring-type applicator always have a source step size of 2.5 mm for the microSelectron afterloader. When creating an Oncentra Brachy plan for a Ring applicator with a measured source path, the step size of the measured source path will be used for the entire plan.

The issue is caused by the measured source paths for the applicators listed below, which have a source step size of 2.5 mm for the microSelectron afterloader. If you use such an applicator model to create a plan, while the default step size of the afterloader is 5.0, the step size in the ring or lunar-shaped ovoids will be incorrect. They will be shown as 2.5 mm, while the afterloader will deliver at 5.0 mm if the error is not detected during plan approval.

Details:

This issue occurs when using Applicator Models with a measured source path in combination with a specific afterloader configuration. Table 1 shows for which configurations the issue occurs.

Table 1. Combinations that cause the issue

Oncentra Brachy	Version 4.5, 4.5.1, 4.5.2
	Applicator Modeling with a measured source path
	RDStore default step size 5.0 mm, 10.0 mm
Afterloader	microSelectron HDR/PDR V2, V3/Digital
Applicators	Ring Applicator Sets
	Ring CT/MR Applicator sets
	Interstitial CT/MR Rings
	Vienna CT/MR Rings
	Advanced Gynecological Applicator - Venezia™ with Lunar-shaped ovoids

In this bulletin the Ring applicator will be used to represent all applicable applicators. Where ring is mentioned also lunar-shaped ovoids apply (Advanced Gynecological Applicator). Where 5.0 mm is used as a default step size this could also be 10.0 mm.

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

When using an applicator model, the default step size set in RDStore is always used during the planning process. When an applicator with a measured source path is used, the step size of the measured source path will be used for the entire plan instead. For a microSelectron afterloader the step size of a measured source path is always 2.5 mm.

However, that doesn't happen if the user selects a microSelectron afterloader during planning which is setup in RDStore with a default step size of 5.0 mm.

In such a case the override of the default step size by the step size of the measured source path is incorrectly performed. The Case Explorer shows a step size of 5.0 mm, while this should be 2.5 mm, see Figure 1.

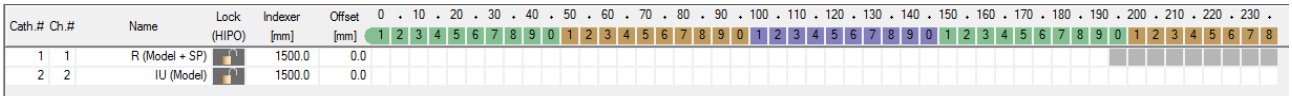

Figure 1. Example of the Case Explorer with the incorrect step size

The 3D view of the applicator will show a step size of 2.5 mm for the ring and 5.0 mm for the tandem, see Figure 2. When activating dwell positions in the Case Explorer, it seems a 5.0 mm step size is used, while the 3D view shows a 2.5 mm step size for the ring.

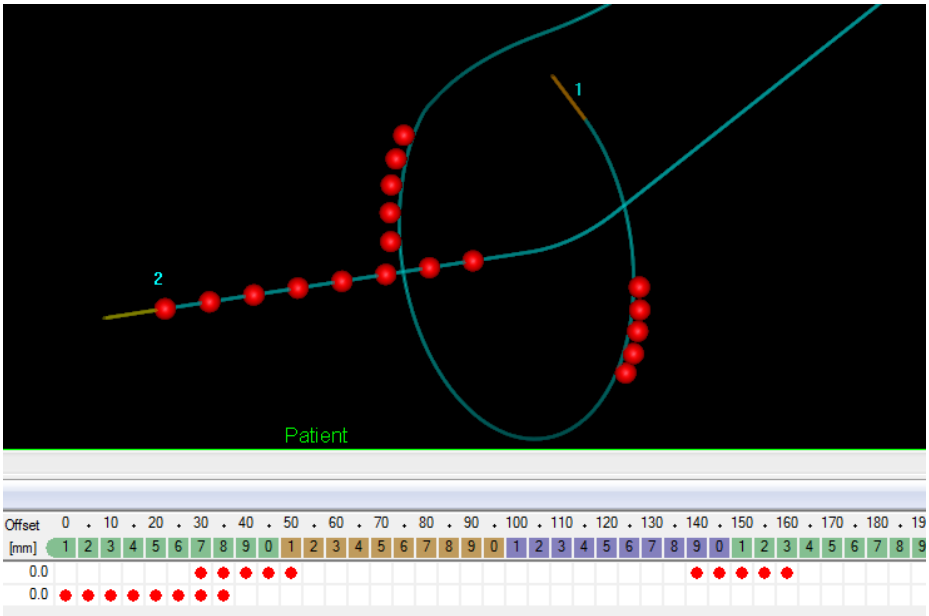

Figure 2. Example of the 3D reconstruction area with the differences in the step size.

The dose calculated for the plan will correspond to a 2.5 mm step size for the ring and a 5.0 mm step size for the tandem. The Oncentra Brachy Treatment Printout will show a 5.0 mm step size for both ring and tandem.

When this plan is exported, a step size of 5.0 mm will be sent to the microSelectron afterloader. The afterloader Pre Treatment Report will show a 5.0 mm step size as will be delivered by the afterloader.

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Clinical Impact:
If such a plan is exported to the microSelectron Treatment Control System (TCS) and delivered, the treated dwell positions in the ring will be incorrect. When loading the plan in TCS only the dwell position numbers and the source step size are taken over from the Oncentra Brachy plan. This leads to a shift of the treated dwell positions in the ring due to the incorrect step size.

Recommended User Action:
Until an upgraded version of Oncentra Brachy is available, it is strongly recommended to only use a default source step size of 2.5 mm for microSelectron afterloaders in RDStore.

If a larger default source step size is required in RDStore, a workaround is to reselect the same afterloader in the Prescription dialog in the Oncentra Brachy planning module. The source step size is then forced to the correct value of 2.5 mm.

It is strongly advised to perform proper Quality Assurance for all treatment plans before delivery of the first fraction to the patient.

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 the content of this letter

Elekta Corrective Actions:
The issue will be solved in the next version of Oncentra Brachy.

This notice has been provided to the appropriate Regulatory Authorities.

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

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Acknowledgement Form

In order to meet regulatory requirements, you are required to complete this form and return it to Elekta immediately upon receipt but no later than 30 days.

Classification:	Important Field Safety Notification	FCO Reference Number:	806-01-BTP-001
Description	Incorrect source step size may occur in Oncentra Brachy plans for Ring or Venezia applicator models with microSelectron.		

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

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

Name: Title:

Customer Signature: Date:

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

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

Name: Title:

Signature: Date: