

URGENT IMPORTANT FIELD SAFETY NOTIFICATION

Subject: Mirroring of Applicator Model may occur in Oncentra® Brachy

Product: Oncentra® Brachy

Scope: Oncentra Brachy version 4.0 and higher

In combination with:

Applicator Library version 1.0.0 and higher

Notification Released: October 2021

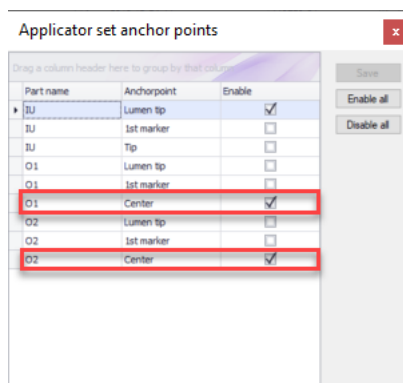
UDI References: 08717213052758, 08717213038660, 08717213020610, 08717213052321, 08717213052314, 08717213052307, 08717213052291, 08717213052246, 08717213052239, 08717213051881, 08717213051843, 08717213051782, 08717213051775, 08717213051294, 08717213020610, 08717213053717, 08717213053700

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Description of Problem:

Oncentra® Brachy offers Applicator Modelling functionality, which aids the end-user in the reconstruction of an entire applicator geometry by using Anchor Points. In two rare scenarios, the applicator model may get mirrored. This is caused by a design fault in the mapping of the applicator model to the user provided anchor points. If unnoticed, this could result in a difference between the planned and delivered dose. The applicable scenarios are as follows:

1. In the unique scenario, where applicator modelling is used for the Venezia™ applicator (called Advanced Gynecological Applicator in the Applicator Library Manager) in combination with using both the O1 center and O2 center Anchor points as part of the used set of anchor points.



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2. In the exceptional scenario, where during placement of the applicator anchor points the user accidentally swaps two symmetrically located anchor points of the model, the applicator could get placed with the left and right channels mirrored. This situation could apply to all Applicator Models that are symmetrical in the left-right direction.

Details:

In the following section the differences will be shown between a normal treatment plan and one in which the applicator model has been mirrored. This will be illustrated using the Venezia™ applicator, but for scenario 2 this can also be applicable to other applicator models.

When the applicator insertion procedure for the Venezia™ applicator is finalized, catheter 1 (lunar-shaped ovoid right) is positioned against the right side of the patient cervix and catheter 2 (lunar-shaped ovoid left) is positioned against the left side of the patient cervix.

After the imaging procedure and usage of the Applicator Modelling functionality to reconstruct the entire applicator geometry, Figures 1 and 2 show an example of the isodose distribution when source dwell positions have been activated.

Note that the activated source dwell positions composition in this example is not placed in a clinically relevant pattern but are placed such to make the comparison clearly visible with the mirrored situation.

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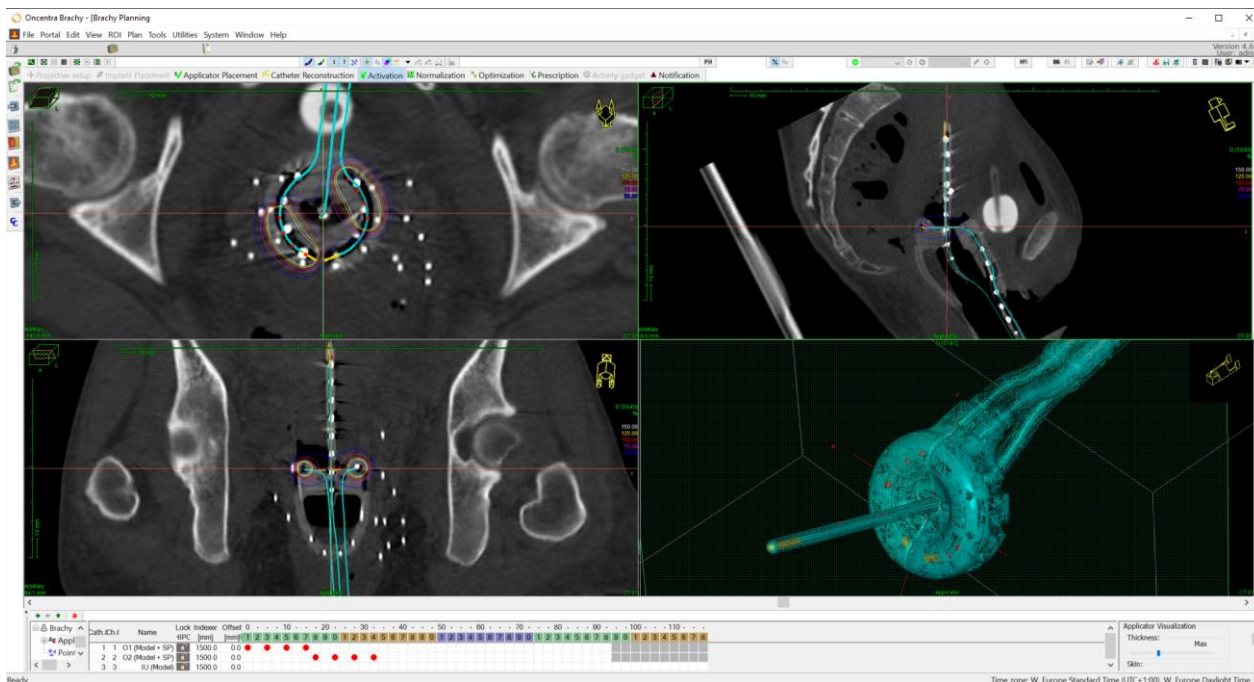


Figure 1: Display of Applicator Model in normal situation

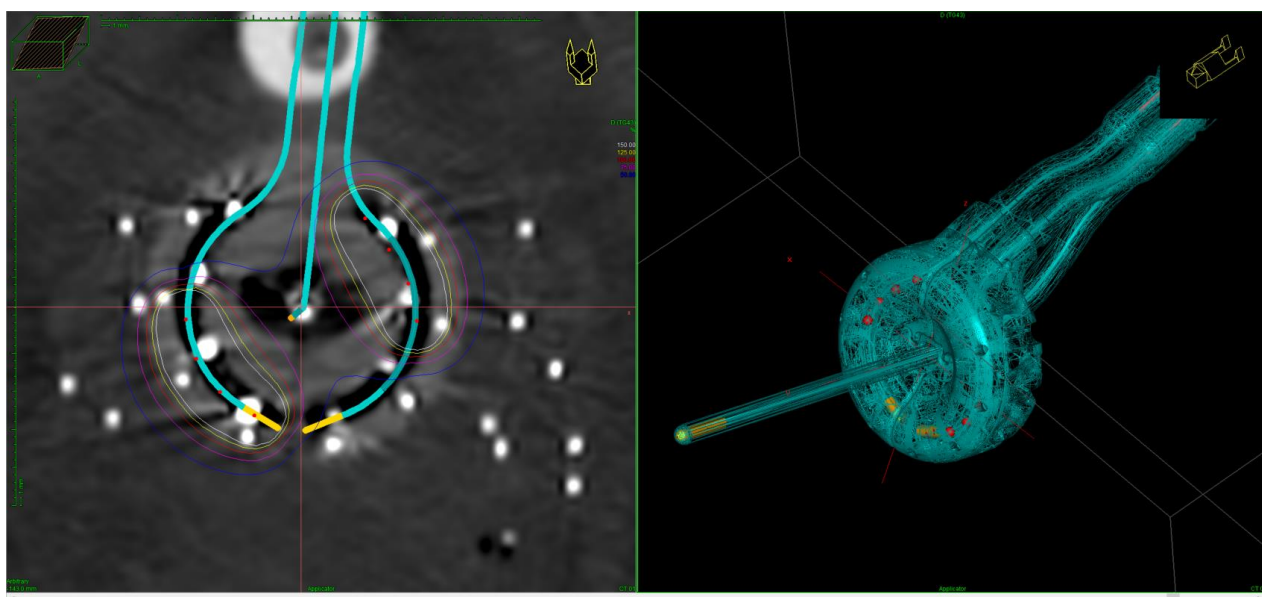


Figure 2: Display of Applicator Model in normal situation

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In the following example (Figure 3 and Figure 4) a mirroring of the Applicator Model has occurred with the Venezia™ applicator.

The mirroring of the Applicator Model can be observed by the fact that the activated source positions at the tip of catheter #1 (named 'O1 model + SP' in the case explorer) show up in the Axial image on the patient left side, while they should relate to the applicator channel on the patient right side. The activated source positions in catheter #2 (named 'O2 model + SP' in the case explorer) that are more distal from the tip of the applicator show up in the Axial image on the patient right side, while they should relate to the applicator channel on the patient left side.

Additionally in the 3D view display, you can observe that the Applicator Model is visualized with incorrect shading (too dark) when using the Triangles option for visualization of the applicator skin.

Note that the activated source dwell position composition in this example is not placed in a clinically relevant pattern but is placed such that the incorrect behavior is better visible.

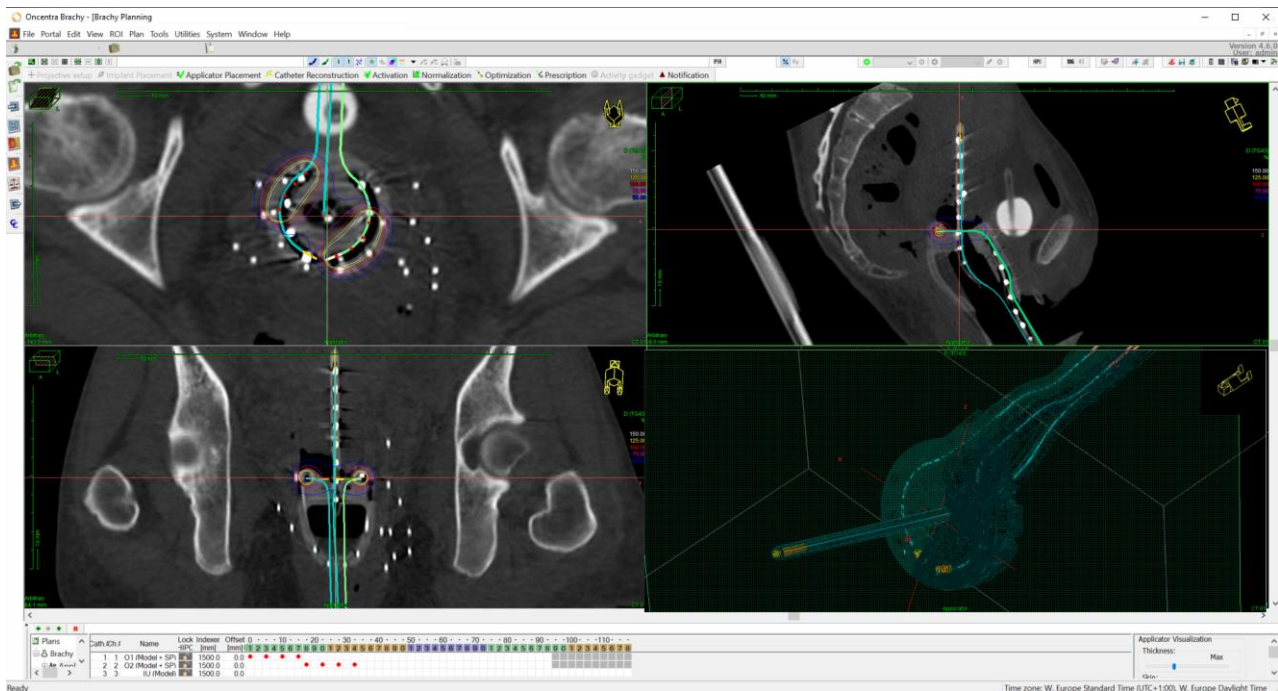


Figure 3: Display of Applicator Model in mirrored (incorrect) situation

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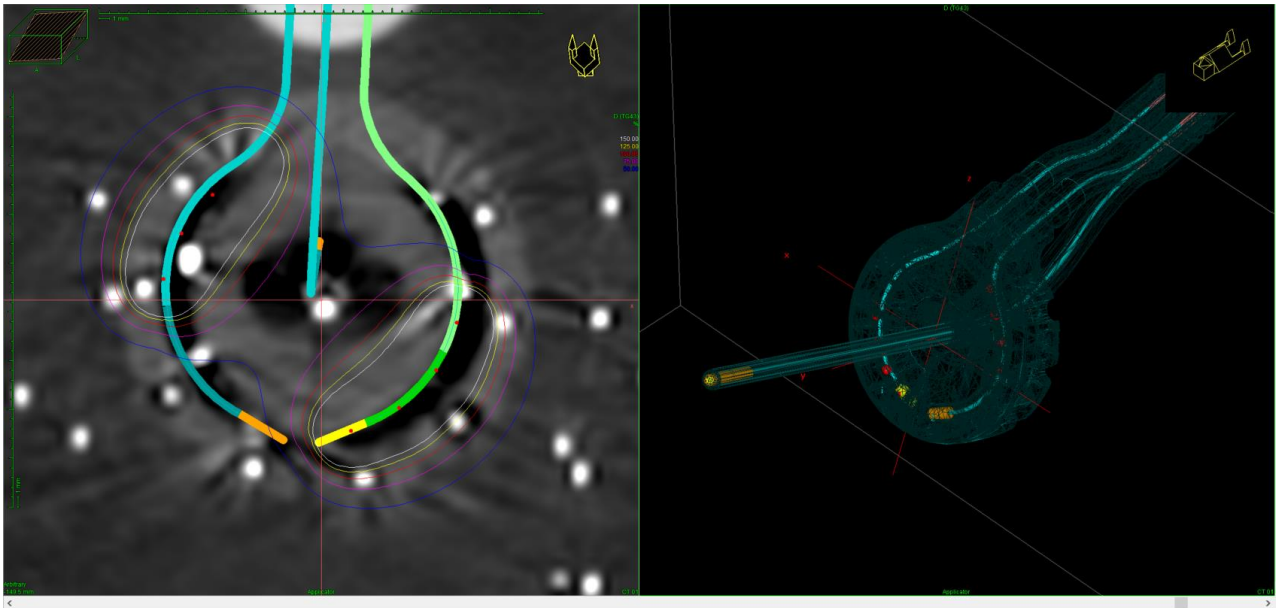
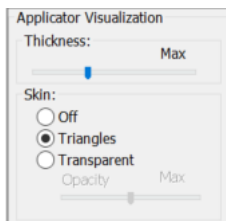


Figure 4: Display of Applicator Model in mirrored (incorrect) situation

Also note the incorrect Applicator Model shading (too dark) in the 3D view when using the option Triangles for visualization of the applicator skin.



The following figures give a side-by-side comparison of the non-mirrored (figure 5 and 7) and mirrored situation (figure 6 and 8) when using a dwell position composition as shown in figure 9.

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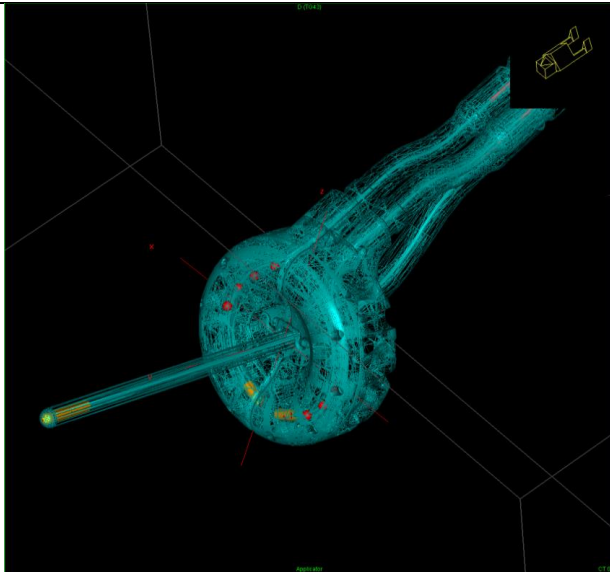


Figure 5: Correct (non-mirrored) 3D view when using the Triangles option for Applicator skin visualization.



Figure 6: Incorrect (mirrored) 3D view when using the Triangles option for Applicator skin visualization.

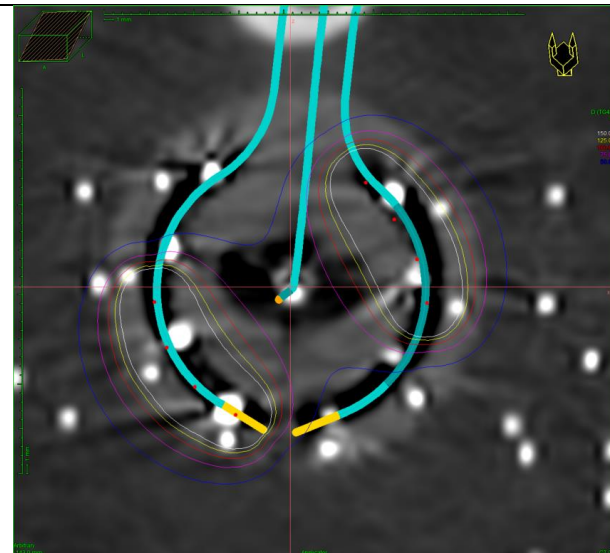


Figure 7: Correct (non-mirrored) transverse view.

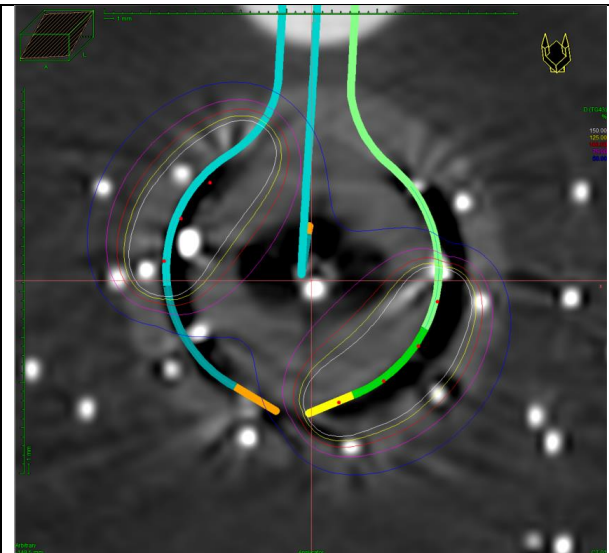


Figure 8: Incorrect (mirrored) transverse view.

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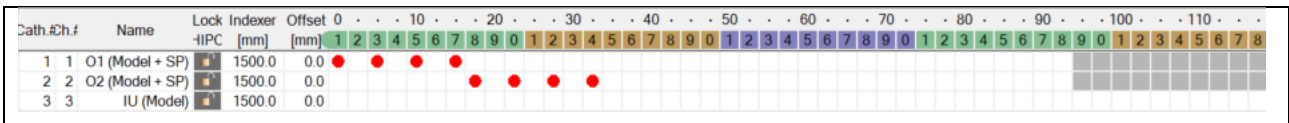


Figure 9: Dwell position composition for Catheter #1 and Catheter #2.

Clinical Impact:

When a Treatment Plan contains a mirrored Applicator Model and is exported to the Treatment Delivery System, there can be a difference between the planned and delivered dose of the two ovoid channels. Only when a non-interstitial treatment procedure with identical source loading patterns and dwell times are used for catheter #1 and catheter #2, treatment delivery is still correct when the applicator model was mirrored.

Recommended User Action:

Recommended User Action in the unique scenario, which is only applicable for the Venezia™ applicator:

- Avoid use of the combination of the two Venezia™ applicator Anchor Points O1-Center and O2-Center by disabling one of them in the Applicator Library Manager.

Recommended User Action in the exceptional situation that may also occur for other Applicator Models:

- Avoid incorrect placement of the Anchor Points, especially exchanging left / right anchor point positions.

Recommended User Actions for both scenario's:

Until an updated version of Oncentra® Brachy is available, it is strongly advised:

- To use additional Anchor Points during applicator modelling. This will further reduce the chance of mirroring the Applicator Model.
- To cross-check the source dwell position information from the Case Explorer to be in accordance with the source dwell positions in the image views.
- Use the Triangles option for the applicator skin visualization in the 3D view, and review whether the Applicator Model has a correct shading display.
- Perform proper Quality Assurance for all treatment plans before treatment delivery.

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

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- 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:

The issue will be solved in the next version of Oncentra® Brachy.

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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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-BTP-002
Description: Mirroring of Applicator Model may occur in Oncentra® Brachy	

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 on 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: