Field Corrective Action Reference: FCA-NU-0008

This notice reference: 806-01-BTP-003

URGENT
IMPORTANT FIELD SAFETY NOTIFICATION

Subject:	A reconstruction error may occur when using the Catheter Bending functionality in Applicator Modeling or Implant Modeling
Product:	Oncentra® Brachy
Scope:	Oncentra® Brachy version 4.0 and higher In combination with: Applicator Modeling or Implant Modeling
Notification Released:	November 2022
UDI Reference:	08717213052758, 08717213038660, 08717213020610, 08717213052321, 08717213052314, 08717213052307, 08717213052291, 08717213052246, 08717213052239, 08717213051881, 08717213051843, 08717213051782, 08717213051775, 08717213051294, 08717213020610, 08717213053717, 08717213053700

Description of Problem:

Oncentra® Brachy offers Applicator Modeling and Implant Modeling functionality, which aids the end-user in the reconstruction of an entire applicator geometry. It includes a catheter bending functionality, that allows users to bend the geometry of the model's catheters to the actual shape of the inserted applicator.

In a rare situation, a reconstruction error may be introduced by Oncentra® Brachy to an existing catheter reconstruction, when using the catheter bending functionality. Erroneously placed reconstruction points may be added that create a double kink in the reconstruction (see Figure 1). If unnoticed, this reconstruction error can result in a difference between the dose distribution in the treatment plan and the delivered dose distribution.

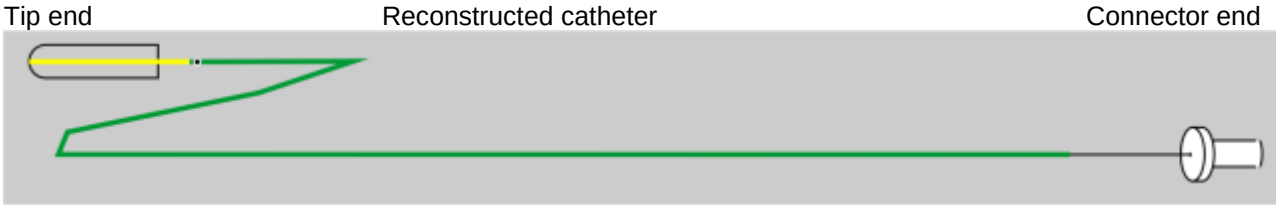

Figure 1. Illustration (not to scale) of the double kink reconstruction error that may be introduced in a rare situation

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Details:
To bend a reconstructed catheter, the user must select two manipulation points: the Bending Indicator and the Bending Point. To ease the selection of those manipulation points, a 2 mm margin around the catheter center line is defined where the user can click to select the manipulation points. This margin is erroneously also applied at the tip end and at the connector end of the catheter.

Figure 2 shows the erroneous margin around the last catheter reconstruction points at the tip end (1) and connector end (2).

Figure 2. Margins around the reconstructed catheter. Green dashed line indicates the 2 mm margin around the catheter. The erroneous margins are shown as red dashed lines, at the tip end (1) and connector end (2).

A reconstruction error may occur in the following rare scenarios:

A. At the tip end: when you position the Bending Indicator beyond the most distal reconstruction point. The Bending Indicator (semi-circle with arrowheads) should not be positioned in the 2 mm area beyond the last catheter point or in the tip end (yellow line in Figure 3). Instead, it should be positioned within the green area as indicated in Figure 4.

B. At the connector end: when you position a Bending Point beyond the most proximal reconstruction point. The Bending Point (circle with arrowheads) should not be selected in the 2 mm area beyond the first catheter point at the connector end (black line in Figure 3). Instead, it should be positioned within the green area as indicated in Figure 4.

Figure 3 shows an illustration of scenario A and B as described above.

Figure 3. Scenarios A & B in which the use of the Catheter Bending functionality can lead to the introduction of a reconstruction error.

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Figure 4 shows how the catheter bending functionality can be used safely .

Figure 4. Scenario in which the use of the Catheter Bending functionality can be safely used.

The Bending Indicator and Bending Point can be safely positioned along the green part of the reconstructed catheter. Keep a distance from the last and first catheter reconstruction points, to ensure that the error does not occur. To increase visibility of the green part of the catheter, adjust the line thickness in the Applicator Visualization setting in the Case Explorer.

Figure 5 shows how a kink in a reconstructed catheter results in a shift in dwell positions during treatment delivery. The extent of this reconstruction error will depend on where the bending was applied. The added reconstruction length can be up to 8 mm.

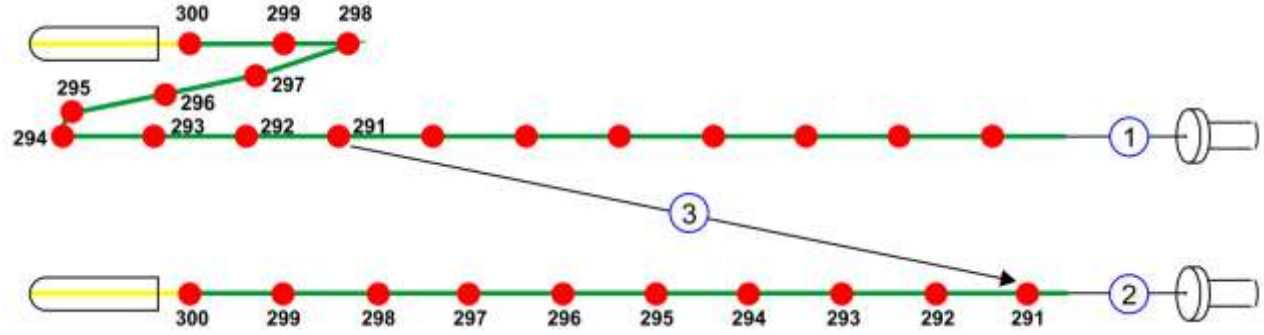

Figure 5. Illustration to explain the shift in planned dwell positions.

(1) Dwell positions in a reconstructed catheter in treatment planning, when bending results in a reconstruction error.

(2) Dwell positions in the catheter during treatment delivery.

(3) Shift in dwell positions.

How to recognize the issue in Oncentra® Brachy

Since the double kink folds almost exactly over the catheter center line itself, it is barely visible in the 2D and 3D views and therefore difficult to identify visually. The incorrect reconstruction points can be observed in the Case Explorer when inspecting the coordinates of the possible dwell positions or the catheter reconstruction points. In case a double kink is present, the sequence of coordinates in X, Y and/or Z direction will show a sudden increase and decrease in value. Figure 6 shows an example of a correct reconstruction. Figure 7 shows an example containing a reconstruction error. The reconstruction error can be present in either X, Y and/or Z axis, depending on the reconstruction direction of the catheter.

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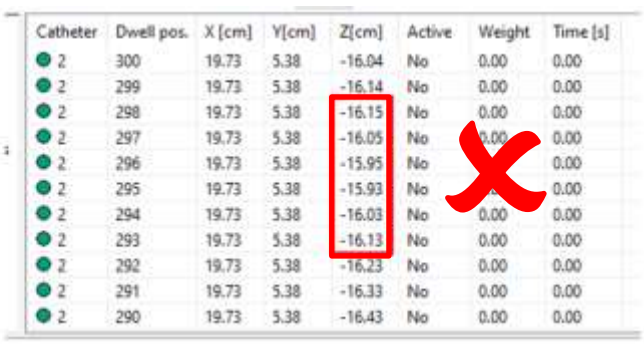
Catheter	Dwell pos.	X [cm]	Y[cm]	Z[cm]	Active	Weight	Time [s]
2	300	19.73	5.38	-16.04	No	0.00	0.00
2	299	19.73	5.38	-16.14	No	0.00	0.00
2	298	19.73	5.38	-16.24	No	0.00	0.00
2	297	19.73	5.38	-16.34	No	0.00	0.00
2	296	19.73	5.38	-16.44	No	0.00	0.00
2	295	19.73	5.38	-16.54	No	0.00	0.00
2	294	19.73	5.38	-16.64	No	0.00	0.00
2	293	19.73	5.38	-16.74	No	0.00	0.00
2	292	19.73	5.38	-16.84	No	0.00	0.00
2	291	19.73	5.38	-16.94	No	0.00	0.00
2	290	19.73	5.38	-17.04	No	0.00	0.00

Figure 6. Dwell position coordinates for a correct reconstruction.



Catheter	Dwell pos.	X [cm]	Y[cm]	Z[cm]	Active	Weight	Time [s]
2	300	19.73	5.38	-16.04	No	0.00	0.00
2	299	19.73	5.38	-16.14	No	0.00	0.00
2	298	19.73	5.38	-16.15	No	0.00	0.00
2	297	19.73	5.38	-16.05	No	0.00	0.00
2	296	19.73	5.38	-15.95	No	0.00	0.00
2	295	19.73	5.38	-15.93	No	0.00	0.00
2	294	19.73	5.38	-16.03	No	0.00	0.00
2	293	19.73	5.38	-16.13	No	0.00	0.00
2	292	19.73	5.38	-16.23	No	0.00	0.00
2	291	19.73	5.38	-16.33	No	0.00	0.00
2	290	19.73	5.38	-16.43	No	0.00	0.00

Figure 7. Dwell position coordinates for an incorrect reconstruction.

Clinical Impact

When a reconstruction error is introduced, the treatment plan shown in Oncentra® Brachy can have multiple active dwell positions at (almost) the same location in the affected catheter reconstruction. This can have an effect on plan optimization, but also on plan normalization if the dwell positions are close to normalization points. When the treatment plan with the reconstruction error is used for treatment, there will be a difference between the dose distribution in the treatment plan and the delivered dose distribution.

Recommended User Action:

- When using the catheter bending functionality, always position the manipulation points in the middle of the reconstructed catheter and keep a distance from the last and first catheter reconstruction points (see Figure 4).

- Always inspect the coordinates of the reconstructed catheter points in the Case Explorer for the presence of any kinks.

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:

The issue will be solved in an update 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-003
Description	A reconstruction error may occur when using the Catheter Bending functionality in Applicator Modeling or Implant Modeling		

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: