Urgent Field Safety Notice, Medical Device Correction #130646

RayStation/RayPlan 8B, 9A, 9B, 10A, 10B, 11A, 11B, 12A, 12B, 2023B, 2024A including some service packs

To determine if your version is affected, see build numbers listed in PRODUCT NAME AND VERSION below

February 23, 2024
RSL-P-RS-FSN Class II 130646

Issue

This notice concerns a use error that has occurred with RayStation/RayPlan, where material override using Silicon, Si, was incorrectly selected for a silicone gel polymer implant.

Intended audience

This notice is directed to all users of RayStation/RayPlan who use patient modeling with material override.

Product Name and Version

The products affected by this notice are sold under the trade names RayStation/RayPlan 8B, 9A, 9B, 10A, 10B, 11A, 11B, 12A, 12B, 2023B, 2024A including some service packs. To determine if the version you are using is affected, open the About RayStation/RayPlan dialog in the RayStation/RayPlan application and check if the build number reported there is any of the ones listed below. If so, this notice applies to your version.

The single registration number (SRN) of the manufacturer: SE-MF-000001908

Product name (build number)		UDI-DI
RayStation/RayPlan 8B	(8.1.0.47)	07350002010129 20181209
RayStation/RayPlan 8B SP1	(8.1.1.8)	07350002010204 20190214
RayStation/RayPlan 8B SP2	(8.1.2.5)	07350002010235 20190524
RayStation/RayPlan 9A	(9.0.0.113)	07350002010174 20190612
RayStation/RayPlan 9A SP1	(9.0.1.142)	07350002010488 20220420
RayStation/RayPlan 9B	(9.1.0.933)	07350002010266 20191220
RayStation/RayPlan 9B SP1	(9.2.0.483)	07350002010297 20200310
RayStation/RayPlan 10A	(10.0.0.1154)	07350002010303 20200526
RayStation/RayPlan 10A SP1	(10.0.1.52)	07350002010365 20200526
RayStation/RayPlan 10A SP2	(10.0.2.10)	07350002010655 20220608
RayStation/RayPlan 10B	(10.1.0.613)	07350002010310 20201216

RayStation/RayPlan 10B SP1	(10.1.1.54)	0735000201047120220128
RayStation/RayPlan 11A	(11.0.0.951)	0735000201038920210518
RayStation/RayPlan 11A SP1	(11.0.1.29)	0735000201043320210610
RayStation/RayPlan 11A SP2	(11.0.3.116)	0735000201044020210916
RayStation/RayPlan 11A SP3	(11.0.4.15)	0735000201063120220616
RayStation/RayPlan 11B	(12.0.0.932)	0735000201042620211208
RayStation/RayPlan 11B SP1	(12.1.0.1221)	0735000201049520220312
RayStation/RayPlan 11B SPC1	(12.1.1.41)	0735000201058720220330
RayStation/RayPlan 11B SP2	(12.0.3.68)	0735000201050120220422
RayStation/RayPlan 11B SPC2	(12.1.2.91)	0735000201061720220517
RayStation/RayPlan 11B SP3	(12.0.4.12)	0735000201060020220620
RayStation/RayPlan 11B SPC3	(12.1.3.162)	0735000201066220221003
RayStation/RayPlan 11B SPC4	(12.1.4.113)	0735000201070920230222
RayStation/RayPlan 11B SPC5	(12.1.5.60)	0735000201074720230914
RayStation/RayPlan 11B SPT1	(12.3.0.119)	0735000201057020221222
RayStation/RayPlan 12A	(13.0.0.1547)	0735000201054920220616
RayStation/RayPlan 12A SP1	(13.1.0.144)	0735000201067920221007
RayStation/RayPlan 12A SP2	(13.1.1.89)	0735000201073020230913
RayStation/RayPlan 2023B	(14.0.0.3338)	0735000201055620230630
RayStation/RayPlan 2024A	(15.0.0.430)	0735000201072320231213

Description

RayStation/RayPlan supports material overrides to improve dose calculation accuracy when image data contains implants or artifacts. The user can select from pre-defined materials in the RayStation/RayPlan default material list and / or user-defined materials that can be added to the list. The chemical element Silicon is included in the RayStation/RayPlan default material list. In RayStation/RayPlan 2023B and higher, Silicon is displayed as "Silicon [Si]" in the default material list. In earlier versions it appears as "Silicon".

RaySearch has received two reports of patient mistreatment after users selected "Silicon" when creating a material override for a *silicone* gel polymer implant. The pure Silicon in the material list has a density of 2.33 g/cm³ while the correct density of silicone gel polymers is close to that of water. The incorrect material selected led to a radiation overdose to the patients.

There was no malfunction. Mistreatment was caused by a user mistake, confusing the chemical element Silicon, Si, with silicone gel polymer.

If this use error occurs, detectability of the mistake should be high. Although the material names may be similar, the density is displayed with the material names, so all information needed for correct identification is available in the user interface. There are several places where the material overrides that have been used are displayed, including the ROI list, the material view, and plan reports (whether sent to PDF or a paper printout).

The review and approval by a qualified user before a treatment plan is used for clinical purposes is a fundamental safety barrier, explicitly required by the radiotherapy treatment planning system safety

standard, IEC 62083. The RayStation Instructions for Use specifically requires a user review of regions of interests, input to dose calculation, and resulting treatment plans.

For RayStation versions 11B and higher, Silicon can be removed from the material list by RaySearch support personnel.

Actions to be taken by the user

- Educate planning staff and all users about the possibility of the described use error.
- If the use error is deemed likely to occur at your clinic, take actions to ensure that proper review of assigned materials is performed before a patient model is used for treatment planning.
- If you wish to have the Silicon chemical element removed from the material list, contact RaySearch support for assistance. This is especially recommended for clinics that perform ion beam treatments, where the harm caused by the use error could be significant.

- Inspect your product and identify all installed units with the above software version number(s).
- **Confirm you have read and understood this notice by replying to the notification email.**

Solution

The Silicon chemical element will not be included in the next version of RayStation/RayPlan, scheduled for market release in April 2024 (subject to market clearance in some markets). If requested by the customer, it can be removed from the material list of existing installations.

Transmission of this Notice

This notice needs to be passed on to all those who need to be aware within your organization. Maintain awareness of this notice as long as any affected version is in use.

Thank you for your cooperation, and we apologize for any inconvenience.

For regulatory information, please contact quality@raysearchlabs.com.

RaySearch will notify the appropriate regulatory agencies about this Field Safety Notice.

CONFIRMATION OF RECEIPT

Please confirm that you have received this FSN

Reply to the same email address that sent you this notice, stating you have read and understood it.

Alternatively, you can email or phone your local support to acknowledge this notice.

If you want to attach a signed reply form to the email, please fill in the below. You can also fax this form to Fax: +1-631-828-2137 (US only).

From: _____ (name of institution)

Contact person: _____ (please print)

Telephone no: _____

Email: _____

I have read and understood the notice.

Comments (optional):

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