

AQ Solutions GmbH • An der Hasenkaule 10 • 50354 Hürth, Germany

AQ Solutions GmbH
An der Hasenkaule 10
50354 Hürth
Germany
T +49 2233 460 96 60
F +49 2233 460 96 99
info@aq-solutions.de

Hürth, 22.04.2021

Urgent Field Safety Notice

Recall of

REVISIO® RTM Femoral tibial stems

Sender:

AQ Solutions GmbH
An der Hasenkaule 10
50354 Hürth
Germany

Addressee:

User

Dear customer,

We would like to inform you that several batches of REVISIO® RTM Femoral tibial stems were manufactured with wrong dimensions and partly delivered to you. When implanting these REVISIO® RTM Femoral tibial stems, the implant cannot be inserted flush into the prepared bone, proximally at the tibia or distally at the femur, and there is a risk of fracturing the bone.

Quality and safety are our top priorities. Therefore, we would like to act consistently and transparently as usual and request you within the scope of your duty to cooperate according to medical device legislation and to implement this recall to ensure that no user can use the affected products. Please return the affected REVISIO® RTM Femoral tibial stems in your company to AQ Solutions GmbH immediately.

The following products with the listed lot numbers must be returned to AQ Solutions GmbH:

REF	Product name	Size	LOT	Expiry date
60062202	REVISIO® RTM Femoral tibial stem C, long straight	4/LG=200MM (uncoated)	1192203	11.09.2025
60062205	REVISIO® RTM Femoral tibial stem C, long straight	4/LG=200MM (coated)	1192204	11.09.2025
			1194944	29.09.2025
			1195045	16.11.2025
60062206	REVISIO® RTM Femoral tibial stem C, long straight	5/LG=200MM (coated)	1192207	11.09.2025
			1194955	29.09.2025
60062302	REVISIO® RTM Femoral tibial stem C, long curved	4/LG=200MM (coated)	1192838	11.09.2025
			1195864	16.11.2025
60062303	REVISIO® RTM Femoral tibial stem C, long curved	5/LG=200MM (coated)	1192835	11.09.2025
			1195682	27.11.2025
60067009	REVISIO® RTM Femoral tibial stem C, short	4/LG=135MM (coated)	1191955	11.09.2025
			1192820	11.09.2025
			1195068	16.11.2025
60067010	REVISIO® RTM Femoral tibial stem C, short	5/LG=150MM (coated)	1192836	11.09.2025
			1195602	16.11.2025

Passing through of the information described herein:

Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Field Safety Notice. If you have handed over the products to third parties, please forward a copy of this information or inform the contact person indicated below.

Please keep this information at least until the measure has been completed.

AQ Solutions GmbH has reacted immediately to the product defect and initiated measures to ensure that this defect will not be repeated.

The German Federal Institute for Drugs and Medical Devices and the Agencia Española de Medicamentos y Productos Sanitarios has received a copy of this Urgent Field Safety Notice.

We thank you for your cooperation in handling this Urgent Field Safety Notice and ask you to pass this information on to your staff without delay. Please ensure that the products are returned to AQ Solutions GmbH.

We would like to sincerely apologize for the occurrence of this error and at the same time thank you for your understanding in connection with the measure and the associated inconvenience.

Contact:

Safety Officer
vigilance@aq-solutions.de
T +49 02233 4609 671
M +49 162 2024604

Signature