Company Name/LogoDenTi System Kft.

Rev 1: September 2018

FSN Ref: FSN-2025-003 en FSCA Ref: FSCA-2025-002 en

Date: 2025.08.15.

Urgent Field Safety Notice
Denti Dental Implant System

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Vajdovich Nóra E-mail: vajdovichn@dentisystem.hu Telephone: +36309028449 Cím: 6600 Szentes, Bese László utca 8.

Company Name/Logo

Rev 1: September 2018

FSN Ref: FSN-2025-003 en FSCA Ref: FSCA-2025-002 en

Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The devices are dental implants, medical devices for human medical use. Implants which are non-active surgical dental imlants designed for tooth replacement, can be used in case of single missing tooth or even to treat partial or even complete edentulous status. Implants can be implanted during surgical exploration intraosseally, under the gum or trans gingivally. Implants can be used sterilely, these are marketed sterilely.
1.	2. Commercial name(s)
	Denti Dental Implant System
1.	3. Unique Device Identifier(s) (UDI-DI)
	5999575432505 5999575432512 5999575430044 5999575430068 5999575430105 5999575430112 5999575430037 5999575430013 5999575430006 5999575430204 5999575430211 5999575430297 5999575430198 5999575430228 5999575430303 5999575430051 5999575430099 5999575430143 5999575430150 5999575430310 5999575430327 5999575430334
1.	4. Primary clinical purpose of device(s)*
	Implants can be used in case of single missing tooth or even to treat partial or even complete edentulous status. Implants can be implanted during surgical exploration intraosseally under the gum or trans gingivally.
1.	5. Device Model/Catalogue/part number(s)*
	R 1033-115, R 1033-135, R 1543-095, R 1538-115, R 1538-115, DF 12410, DF 12412, CP 1038-100, CP 1038-130, CP 1042-100, CP 1042-100, CP 1042-115, CP 1038-085, R 1033-115, R 1543-115, CP 1033-115, CP 1038-100, CP 1033-100, CP 1042-115, N 12313, N 12315, NB 12813, BL 1038-115, BL 1038-115, BL 1038-135, BL 1043-115, R 1543-135, R 1548-135, BL 1043-095, BL 1043-115, BL 1038-115, K 1043-065, K 1048-065, K 1048-080, BL 1038-115, BL 1038-115, BL1048-095, BL 1038-135, BL 1043-135, BL 1048-115, NB 12311, NB 12811, NB 12813, NB 12815, CP 1038-100, CP 1038-100,

	CP 1038-115, CP 1033-100, CP 1038-085, CP 1042-085, CP 1042-085, CP 1048-070, CP 1038-130, CP 1048-085, CP 1038-100, CP 1038-115, CP 1038-085, CP 1042-100, CP 1038-085, CP 1033-100, R 1538-115, DF 12110, DF 12114, DF 12112, DF 12114, DF 12114, DF 12410
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	see Appendix 1.
1.	8. Associated devices
	Within context of the FSCA eg for IVD reagents and platforms.

2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	The devices in the attachment were packaged in expired Tyvek packaging. This is the product's sterile barrier system. The expire date of the Tyvek was 03.02.2025., and the packaging were happened until 15.05.2025.
2.	2. Hazard giving rise to the FSCA*
	Ensure sterility to avoid infection. Risk mitigation elements that keep the risk sufficiently low to protect users should be prioritised:- ensuring continued sterility of the product, sterility testing and weld seal testing- ensuring appropriate storage conditions- microbial barrier, packaging and simulation testing to demonstrate compliance.
2.	3. Probability of problem arising
	See Appendix 2.
2.	4. Predicted risk to patient/users
	See Appendix 2.
2.	5. Further information to help characterise the problem
	See Appendix 3.
2.	6. Background on Issue
	It was recorded as a Major CAR in the MDR Stage 2 audit. Root cause of problem: The usability of the packaging materials used was not checked. There are no documented criteria or instructions in the EU 8261 v01 procedure to check or verify the expiry date of packaging materials. There is no systemic warning or validation control to prevent the use of expired packaging. Personnel are not trained or instructed to check the expiry date of packaging materials before use.
2.	7. Other information relevant to FSCA
	-See Appendix 4.

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***
	☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device
	☐ On-site device modification/inspection
	☐ Follow patient management recommendations
	☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

	☐ Other ☐ None 1/ Quarantine of affected products 2/ Start of investigation, FSN / FSCA written to analyse the problem, assess the risks. Based on preliminary investigation, the case is not considered a public health risk. 3/ Contact with TYVEK supplier to assess risks, write risk assessment and confirm possible impact on sterile integrity post expiry. Based on the results, the products concerned will be released with the original expiry date or repackaged. 4/ Random sampling of affected LOTs, Visual dye penetration test according to ISO 11607 Accelerated ageing simulation	
3.	2. By when should the action be completed? 2026. April 1. 3.	If expired packaging material is used, there is no evidence that the product is sterile. Based on the adequacy of the sterility test results performed, the sterility of the products that have already been implanted is confirmed.For the products that have been quarantined, further tests are ongoing to ensure long-term compliance.
3.	4. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? Yes 1. notification of the treating doctor 2. patient identification 3. request information on the results of follow-up tests	
3.	5. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes 2025. August 31.
3.	**6. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified. 1/ We are amending the rules on the documentation of the packaging process. EU 8261 v01 Inspection and testing will be updated to include mandatory inspection and documentation of the expiry date of packaging materials before use. 2/ Tightening the rules for inspection and approval. We will introduce a controlled packaging record listing lot numbers, receipt dates, expiry dates and current status (valid/expired). A responsible person will be appointed. Update instruction VU 7401 v02 for checking and logging expiry dates of packaging materials in preparation for production. 3/ Provide training on: - New procedures - The importance of sterile barrier system compliance - How to read, check and record expiry dates Training should be documented and effectiveness should be demonstrated by tests and on-the-job observation. 4/- Basic contamination test: tested for product, both primary packaging (capsules and caps) and secondary packaging (tyvek and wipak multipacks) -weld-seal test, -sterility tests -microbial barrier test, -visual and physical testing of expired Tyvek compared to newly purchased Tyvek packaging	

	material, verification of appropriate storage conditions based on the storage conditions specified by the packaging material manufacturer, 5/Accelerated ageing test to verify long-term compliance, 6/A depending on the test results, action to lift quarantine (with original expiry date) or repackaging option.	
3	By when should the action be completed? 2026.April 01.	If expired packaging material is used, there is no evidence that the product is sterile. Based on the adequacy of the sterility test results performed, the sterility of the products that have already been implanted is confirmed. For the products that have been quarantined, further tests are ongoing to ensure long-term compliance.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	FSN 2025-002 date: 2025.August.04.
4.	**3.** For Updated FSN, key new information as follows:	
	All distributors and direct HCPs have been notified of the affected products, and any products still in stock have been recalled and quarantined in our own warehouse pending the results of the ongoing investigations.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**DenTi System Kft.**
	b. Address	**Hungary, 6600 Szentes, Bese László u. 8.**
	c. Website address	**www.dentisystem.hu**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**Appendix 1. List of the product, Appendix 2. Risk assessment Appendix 3. Risk assessment total Appendix 4. CAPA Appendix 5. Customer reply form**
4.	10. Name/Signature	**Vajdovich Nóra Executive director 2025.08.01.**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.