FSN Rev 1: September 2018
FSN Ref: 2935-001-005 FSCA Ref: 2935-001-005

Date: 18.11.2020

Urgent Field Safety Notice
FD-8000 Premature wear of brake-arm mechanics

For Attention of*: Finndent Dental Unit Technical Service Personnel

Contact details of local representative (name, e-mail, telephone, address etc.)*

MODIFY FOR EACH COUNTY:

	National Competent Authority	Finndent Distributor
Belgium	Federal Agency for Medicines and Health Products Eurostation building, block 2 place Victor Horta, 40/ 40 1060 Brussels Belgium Tel. +32 2 524 7111 E-mail: info.medicines@fagg-afmps.be www.fagg-afmps.be/	Medicotronix Zoning de Fleurus Avenue de l'Esperance, 44 6220 Fleurus Belgium tel. +32 (0) 71 877 873 medicotronix@skynet.be www.medicotronix.be Kerckaert Dental Equipment Wolfsakker 7 9160 Lokeren Belgium tel. +32 (0) 9 340 42 70 info@kerckaert.be www.kerckaert.be
Finland	Finnish Medicines Agency P.O. Box 55 FI-00034 FIMEA Finland Tel. +358 29 522 3341 Fax +358 9 4733 4339 www.fimea.fi	Unident Oy ja Dental Systems Oy Niittylänpolku 16 00620 Helsinki tel. +358 (0) 20 1772 372 info@dentalsystems.fi www.dentalsystems.fi
Germany	Federal Institute for Drugs and Medical Devices Kurt-Georg-Kiesinger-Allee 3 53175 Bonn Germany Tel. +49 (0)228-207-30 Fax +49 (0)228-207-5207 E-mail: poststelle@bfarm.de www.bfarm.de	FINNDENT Deutschland GmbH ..... Veilchenweg 8 34125 Kassel tel. +49 (0) 561 98836067 info@finndent.de www.finndent.de SHR Dent concept Ansprechpartner: Björn Hensen Kruppstraße 10 47475 Kamp-Lintfort tel. +49 (0) 2151 65 100 0 info@shr-dental.de www.shr-dental.de Hamburger Dentaltechnik Ansprechpartner: .... Schnackenburgallee 179 22525 Hamburg tel. +49 (0) 40 22 85 39 80 info@hhdt.de www.hhdt.de

Netherlands	Healthcare Inspectorate Stadsplateau 1 3521 AZ Utrecht The Netherlands Tel. +31 88 120 5000 Fax +31 88 120 5001 E-mail: meldpunt@igz.nl www.igz.nl	All Dent B.V. Ravelijn 15, 3905 NT, Veenendaal Netherlands Tel. +31 (0) 318 509 060 info@alldent.nl www.alldent.nl
Norway	Norwegian Medicines Agency Postboks 240 Skøyen 0213 Oslo Norway Tel. +47 22 89 77 00 E-mail:post@noma.no https://legemiddelverket.no	Alfa Dental Norge AS Hjellen 2 7224 Melhus tel. +47 (0) 913 42 750 post@alfadental.no www.alfadental.net Dental Service AS Våkleiven 43 5155 Bønes Postal address: Postal box 54, 5849 Bergen tel. +47 (0) 5522 1900 post@dentalservice.no www.dentalservice.no

Urgent Field Safety Notice (FSN)
FD-8000
Premature wear of brake-arm mechanics

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Finndent FD-8000 Dental Treatment Units
1.	2. Commercial name(s)
	FD-8000B1, FD-8000B1+, FD-8000B2, FD-8000P1, FD-8000P1+, FD-8000P2, FD-8000P2+, FD-8000KFO floor mounted KFO units
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	The intended use of the FD-8000 is to be used by dentistry professionals to give dental treatment.
1.	5. Device Model/Catalogue/part number(s)*
	FD-8000B1, FD-8000B1+, FD-8000B2, FD-8000P1, FD-8000P1+, FD-8000P2, FD-8000P2+, FD-8000KFO floor mounted KFO units
1.	6. Software version
	Only where relevant.
1.	7. Affected serial or lot number range
	Units sold between January 1, 2015 and December 31, 2017. See attached sheet of products affected.
1.	8. Associated devices
	for IVD reagents and platforms.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The brass upper lever inside the brake-arm is wearing out too quickly.
2.	2. Hazard giving rise to the FSCA*
	If the lever wears out and falls from the rotation axle, the instrument bridge can drop unexpectedly. This can result in the bridge dropping on a user or patient, or in equipment damage.
2.	3. Probability of problem arising
	This incident has occurred in one product.
2.	4. Predicted risk to patient/users
	From the output of the Health Hazard Evaluation indicate the anticipated risk (product of severity x probability) of patient/end user harm (direct or indirect).
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	Eg how the manufacturer became aware; brief details of relevant incidents; root cause if known; rationale for containment of problem to only affected devices; other risk mitigation or longer-term preventative action etc.
2.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

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

All units manufactured during the 2015-2017 period will have the brass levers replaced with steel levers.

3.	2. By when should the action be completed?	This is an immediate product service to be completed as soon as reasonably possible by the distributor.

3. 3. Particular considerations for: Choose an item.

Is follow-up of patients or review of patients' previous results recommended?
Choose an item.

Provide further details of patient-level follow-up if required or a justification why none is required

3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No

3. 5. Action Being Taken by the Manufacturer

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☒ Other ☐ None

Finndent is providing the following replacement parts to distributors during Week 50:

Part Number	**/ Name**	**/ Mandatory for Repair or As Needed**
6401005	Front lever arm, steel	Mandatory
6401000	Back lever arm, steel	Mandatory

3	6. By when should the action be completed?	Specify where critical to patient/end user safety
3.	7. Is the FSN required to be communicated to the patient /lay user?	Choose an item.

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*	New
4.	2. For updated FSN, reference number and date of previous FSN	Please reference 2935-001-005 in all communications concerning this notice.
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
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	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * See contact list in section 1 to be modified for each country.	
4.	9. List of attachments/appendices:	**Serial numbers and locations of affected units** **Instructions for replacing the lever arms**
4.	10. Name/Signature	**.....** **18.11.2020, Helsinki, FIN**

	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.