

06 novembris 2025

STEIDZAMI: OPERATĪVS DROŠUMA PAZIŅOJUMS PAR MEDICĪNAS IERĪCĒM

Cienījamais klient!

Uzņēmums Kerr brīvprātīgi sniedz operatīvo paziņojumu par ZenFlex rotējošās failes lietošanas instrukcijās konstatētu neatbilstību attiecībā uz tīrīšanas laiku. Ietekmēto ZenFlex daļu numuri un partiju kodi ir norādīti **1. tabulā**.

Ietekmētais produkts var būt nosūtīts jūsu iestādei laikā no 2025. gada 28. februāra līdz 2025. gada 19. jūnijam.

Nesen mums kļuva zināms, ka lietošanas instrukcijā ir radusies kļūda tīrīšanas sadaļas 1. solī, kas attiecas uz ultraskaņas cikla laiku. Lietošanas instrukcijā ir nepareizi norādīts:

“Ieteicams izmantot piecu (5) minūšu ultraskaņas ciklu un pH neitrālu enzimatisku ultraskaņas tīrīšanas šķīdumu.”

Lietošanas instrukcijā pareizi jābūt norādītam:

“Ieteicams izmantot desmit (10) minūšu ultraskaņas ciklu un pH neitrālu enzimatisku ultraskaņas tīrīšanas šķīdumu (Enzol® Enzymatic Detergent vai līdzīgu).”

Netiek prognozētas tūlītējas vai ilgtermiņa sekas veselībai, jo šīs failes pirms lietošanas nepieciešams sterilizēt.

Uzņēmums Kerr lūdz Jūs sadarboties, aizpildot un pa e-pastu nosūtot atpakaļ pievienoto apstiprinājuma veidlapu, lai neatkarīgi no tā, vai jūsu inventāra sarakstā ir šāds izstrādājums, apliecinātu, ka saņēmāt šo vēstuli ar operatīvo drošuma ziņojumu.

Ja esat pilnvarots uzņēmuma Kerr izplatītājs, mēs aicinām Jūs identificēt klientus, kuriem, iespējams, ir piegādāts ietekmētais izstrādājums, un sazināties ar šiem klientiem, lai informētu viņus par šo problēmu.

Mēs atvairinājamies par neērtībām, ko šī situācija radījusi Jums un Jūsu klientiem!

Ja jums ir jautājumi, sazinieties ar Kerr klientu apkalpošanas dienestu pa e-pastu **CustomerService-EMEA@kerrdental.com**.

Pateicamies par Jūsu pacietību un atbalstu.

Ar cieņu

Kerr komanda



Via Passanti
174 84018 Scafati (SA) Italy
Tälrunis: 00800 30 32 30 32
KerrDental.com

[English Version]

URGENT: MEDICAL DEVICE FIELD SAFETY NOTICE

Dear Valued Customer:

Kerr is initiating a voluntary field notice due to identifying a discrepancy on the Instructions for Use (IFU) for ZenFlex Rotary File regarding cleaning time. See **Table 1** for affected ZenFlex part number and lot numbers.

The affected product may have been shipped to your facility from 28 February 2025 to 19 June 2025.

It has recently come to our attention that the IFU has an error in the cleaning section step #1 for the ultrasonic cycle time. The IFU incorrectly stated:

“An ultrasonic cycle of five (5) minutes using a neutral-pH enzymatic ultrasonic solution is recommended.”

The IFU should state:

“An ultrasonic cycle of ten (10) minutes using a neutral-pH enzymatic ultrasonic solution (Enzol® Enzymatic Detergent, or equivalent) is recommended.”

There are no immediate or long-range health consequences expected as these files must be sterilized prior to use.

Kerr kindly requests your cooperation in completing and emailing back this enclosed acknowledgement form in order to confirm your receipt of this field safety notice letter, regardless of whether you have any product in your inventory.

If you are an authorized Kerr distributor, we request that you identify those customers that may have been shipped the affected product and contact these customers to inform them of the issue.

We sincerely apologize for the inconvenience this situation causes you and your customers.

If you have any questions, contact Kerr Customer Care at **CustomerService-EMEA@kerrdental.com**.

Thank you for your patience and support.

Sincerely Yours,

The Team at Kerr

Acknowledgement Form for ZenFlex Rotary File

Apstiprinājuma veidlapa par ZenFlex rotējošo faili

Please refer to the enclosed Part Number & Lot Number Table, **Table 1**, to determine if you have any of the affected product in your inventory.

Lūdzu, skatiet pievienoto daļu numuru un partiju kodu tabulu (**1. tabula**), lai noteiktu, vai Jūsu inventāra sarakstā ir kāds no ietekmētajiem izstrādājumiem.

Please return this acknowledgement form, whether you have the affected product or not to

Neatkarīgi no tā, vai Jums ir ietekmētais izstrādājums, lūdzu, nosūtiet šo apstiprinājuma veidlapu atpakaļ uz e-pasta adresi

ZENFLEX.RESPONSE@ENVISTACO.COM

Please check **all** that applies.

Lūdzu, atzīmējiet **visas** atbilstošās atbildes.

☐	*We acknowledge receipt of the ZenFlex Field Safety Notice. * Mēs apstiprinām ZenFlex operatīvā drošuma ziņojuma saņemšanu.	
☐	I have checked my stock and quarantined inventory. Es pārbaudīju savas iestādes krājumus un karantīnā ievietoto inventāru.	Please attach a list of affected stock so that customer care can process your return or replacement. Lūdzu, pievienojiet ietekmēto krājumu sarakstu, lai klientu apkalpošanas dienests varētu apstrādāt izstrādājumu atgriešanu vai nomaiņu.
☐	I have identified customers that received or may have received this device. Es identificēju klientus, kuri ir saņēmuši vai var būt saņēmuši šo ierīci.	
☐	I have informed the identified customers of this FSN. Es informēju identificētos klientus par šo operatīvo drošuma paziņojumu.	If applies, please enter date of communication: Ja attiecināms, norādiet saziņas datumu:
☐	I have received confirmation of reply from all identified customers. Es saņēmu apstiprinājumu vai atbildi no visiem identificētajiem klientiem.	
☐	I have returned affected devices - enter number of devices returned and date complete. Es atgriezu atpakaļ visas ietekmētās ierīces; norādiet atgriezto ierīču skaitu un datumu.	Please attach a list that states the quantity, Part Number, Lot/Serial Number, and Date Returned so that customer care can process your return or replacement. Lūdzu, pievienojiet sarakstu, kurā norādīts daudzums, daļas numurs, partijas/sērijas kods un atgriešanas datums, lai klientu apkalpošanas dienests varētu apstrādāt izstrādājumu atgriešanu vai nomaiņu.
☐	Neither I nor any of my customers has any affected devices in inventory. Ne man, ne maniem klientiem krājumā nav nevienas ietekmētās ierīces.	
Contact Person (Print Name)* Kontaktpersona (vārds un uzvārds)*		



Via Passanti
174 84018 Scafati (SA) Italy
Tālrunis: 00800 30 32 30 32
KerrDental.com

Signature* Paraksts*	
Date* Datums*	
Contact Number or E-mail* Tālruņa numurs vai e-pasta adrese saziņai*	

Mandatory fields are marked with *
Obligāti aizpildāmie lauki ir atzīmēti ar *

Table 1: Affected ZenFlex Part Numbers and Lot Numbers

1. tabula. Ietekmēto ZenFlex daļu numuri un partiju kodi

Part Number	Product Description	Lot Number
818-1206	.20/.04/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579964
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579936
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579937
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579938
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526142
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032571516
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032571516
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042545592
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042545592
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042545592
818-1208	.20/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579947
818-1256	.25/.04/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526132
818-1257	.25/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579948
818-1257	.25/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526136
818-1257	.25/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526137
818-1257	.25/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526137
818-1258	.25/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579965
818-1306	.30/.04/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579949
818-1307	.30/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579950
818-1307	.30/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526134
818-1307	.30/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042545590
818-1308	.30/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579951
818-1356	.35/.04/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579952
818-1357	.35/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579931
818-1357	.35/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579934

Part Number	Product Description	Lot Number
818-1456	.45/.04/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579966
818-1457	.45/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579945
818-1457	.45/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579946
818-1457	.45/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042559657
818-1458	.45/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579957
818-1556	.55/.04/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579967
818-1557	.55/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579969
818-1558	.55/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579970
818-1621	ZENFLEX .06/21mm ASSORTED PACK ROW	012579958
818-1621	ZENFLEX .06/21mm ASSORTED PACK ROW	042566049
818-1625	ZENFLEX .06/25mm ASSORTED PACK ROW	012579994
818-1625	ZENFLEX .06/25mm ASSORTED PACK ROW	042526135
818-2206	.20/.06/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042513321
818-2207	.20/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579959
818-2207	.20/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042571520
818-2208	.20/.06/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579960
818-2256	.25/.06/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	022579971
818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579943
818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579944
818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	022579942
818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042517026
818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042517026
818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042526144
818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042526144
818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042559656

Part Number	Product Description	Lot Number
818-1357	.35/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579935
818-1357	.35/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579935
818-1357	.35/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526138
818-1357	.35/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526139
818-1357	.35/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042529161
818-1357	.35/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042529161
818-1358	.35/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579953
818-1358	.35/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042559658
818-1406	.40/.04/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579954
818-1407	.40/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579939
818-1407	.40/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579939
818-1407	.40/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579940
818-1407	.40/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042539908
818-1408	.40/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579955
818-1408	.40/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042598741
818-1421	ZENFLEX ROTARY NITI FILE ASSORTED PACK 04 Taper EU/ROW	012579956
818-1425	ZENFLEX .04/5mm ASSORTED PACK ROW	022579990
818-1425	ZENFLEX .04/5mm ASSORTED PACK ROW	022579991
818-1425	ZENFLEX .04/5mm ASSORTED PACK ROW	032526140
818-1425	ZENFLEX .04/5mm ASSORTED PACK ROW	042517027
818-1425	ZENFLEX .04/5mm ASSORTED PACK ROW	042517027
818-1425	ZENFLEX .04/5mm ASSORTED PACK ROW	042517027

Part Number	Product Description	Lot Number
818-2258	.25/.06/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	022579973
818-2306	.30/.06/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	032513317
818-2307	.30/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579961
818-2307	.30/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042526133
818-2308	.30/.06/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579975
818-2356	.35/.06/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579976
818-2357	.35/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579962
818-2358	.35/.06/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579977
818-2406	.40/.06/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579963
818-2407	.40/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579978
818-2408	.40/.06/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579980
818-2456	.45/.06/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579981
818-2457	.45/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579982
818-2458	.45/.06/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579983
818-2506	.50/.06/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579984
818-2507	.50/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579985
818-2508	.50/.06/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579986
818-2556	.55/.06/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	022579987
818-2557	.55/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	022579988
818-2558	.55/.06/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	022579989
818-2558	.55/.06/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	022579989