



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

06 November 2025

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

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.

Please return this acknowledgement form, whether you have the affected product or not to ZENFLEX.RESPONSE@ENVISTACO.COM

Please check all that applies.

☐	*We acknowledge receipt of the ZenFlex Field Safety Notice.	
☐	I have checked my stock and quarantined inventory.	Please attach a list of affected stock so that customer care can process your return or replacement.
☐	I have identified customers that received or may have received this device.	
☐	I have informed the identified customers of this FSN.	If applies, please enter date of communication:
☐	I have received confirmation of reply from all identified customers.	
☐	I have returned affected devices - enter number of devices returned and date complete.	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.
☐	Neither I nor any of my customers has any affected devices in inventory.	
Contact Person (Print Name)*		
Signature*		
Date*		
Contact Number or E-mail*		

Mandatory fields are marked with *

Table 1: Affected ZenFlex Part Numbers and Lot Numbers

Part Number	Product Description	Lot Number	Part Number	Product Description	Lot Number
818-1206	.20/.04/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579964	818-1456	.45/.04/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579966
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579936	818-1457	.45/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579945
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579937	818-1457	.45/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579946
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579938	818-1457	.45/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042559657
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526142	818-1458	.45/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579957
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032571516	818-1556	.55/.04/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579967
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032571516	818-1557	.55/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579969
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042545592	818-1558	.55/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579970
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042545592	818-1621	ZENFLEX .06/21mm ASSORTED PACK ROW	012579958
818-1207	.20/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042545592	818-1621	ZENFLEX .06/21mm ASSORTED PACK ROW	042566049
818-1208	.20/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579947	818-1625	ZENFLEX .06/25mm ASSORTED PACK ROW	012579994
818-1256	.25/.04/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526132	818-1625	ZENFLEX .06/25mm ASSORTED PACK ROW	042526135
818-1257	.25/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579948	818-2206	.20/.06/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042513321
818-1257	.25/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526136	818-2207	.20/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579959
818-1257	.25/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526137	818-2207	.20/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042571520
818-1257	.25/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526137	818-2208	.20/.06/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579960
818-1258	.25/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579965	818-2256	.25/.06/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	022579971
818-1306	.30/.04/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579949	818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579943
818-1307	.30/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579950	818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	012579944
818-1307	.30/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	032526134	818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	022579942
818-1307	.30/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	042545590	818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042517026
818-1308	.30/.04/31mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579951	818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042517026
818-1356	.35/.04/21mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	022579952	818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042526144
818-1357	.35/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579931	818-2257	.25/.06/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW, 06 TAPER	042526144
818-1357	.35/.04/25mm ZENFLEX ROTARY NITI FILE REFILL PACK EU/ROW	012579934	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