DIRECTA

Technical File TF37

Technical specification

Device group: Endodontic files

Doc-id: TF37.8_SPEC

Revision: 01 Pgs: 1 (3)

Device trade name(s)	Sendoline® K-File				
	Note: This specification applies to any brand of model K. Available variants/dimensions and packaging configuration for other brands may be less than those given for Sendoline brand in this specification.				
Device model	K				
Sample illustration					
	Note: The image is prior to mo	unting of the stopper on the file.			
File type illustration	File typ K.				
Identification symbol					
Variants/dimensions	File typ K. Sendoline K-File				
variants/uninensions	Lengths	Sizes			
	21 mm	06-140			
	25 mm	06-140			
	28 mm	06-140			
	31 mm	06-140			
	The colour of the handle is standardised as follows: 06 – pink 08 – grey				
	10 – purple 15 – white 20 – yellow				
	25 – red 30 – blue 35 – green				
	40 – black 45 – white 50 – yellow 55 – red				
	60 – blue 70 – green				

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r go. 4 (<i>o</i>)	90 black				
	80 – black				
	90 – white				
	100 – yellow				
	110 – red				
	120 – blue				
	130 – green				
	140 – black				
	140 - DidCK				
Packages	Individual sizes in blister: 6 pcs per blister of same length and size.				
	Assortments in blister: 6 pc per blister of same length and 6 different sizes:				
	<u>21 mm:</u>				
	1 x 15, 1 x 20, 1 x 25, 1 x 30, 1 x 35, 1 x 40				
	1 x 45, 1 x 50, 1 x 55, 1 x 60, 1 x 70, 1 x 80				
	1 x 90, 1 x 100, 1 x 110, 1 x 120, 1 x 130, 1 x 140				
	<u>25 mm:</u>				
	1 x 15, 1 x 20, 1 x 25, 1 x 30, 1 x 35, 1 x 40				
	1 x 45, 1 x 50, 1 x 55, 1 x 60, 1 x 70, 1 x 80				
	1 x 90, 1 x 100, 1 x 110, 1 x 120, 1 x 130, 1 x 140				
	28 mm:				
	1 x 15, 1 x 20, 1 x 25, 1 x 30, 1 x 35, 1 x 40				
	1 x 45, 1 x 50, 1 x 55, 1 x 60, 1 x 70, 1 x 80				
	1 x 90, 1 x 100, 1 x 110, 1 x 120, 1 x 130, 1 x 140				
	31 mm:				
	1 x 15, 1 x 20, 1 x 25, 1 x 30, 1 x 35, 1 x 40				
	1 x 45, 1 x 50, 1 x 55, 1 x 60, 1 x 70, 1 x 80				
	1 x 90, 1 x 100, 1 x 110, 1 x 120, 1 x 130, 1 x 140				
Package illustration					
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	李 · 中 · 中 · 中 · 中 · 中 · 中 · 中 · 中 · 中 ·				
	Note: The image is only intended to demonstrate package design. It may include files of another				
	model.				
Product description and	- Type 1: standard instrument (taper = 0.2) according to EN ISO 3630-1.				
features	- File type K: tight spiral with four cutting edges. Shaping and cleaning				
	instrument including canal localization, canal negotiation and scouting.				
	- 60° tip.				
	·				
	- Cutting ability. Debris transportation.				
	- Tight spiral.				
	- Handheld: should be used in a twisting/filing movement.				
	- ISO sizes: colour coded handle				
	- Size and type K symbol printed on handle.				
	- Handle with grooves.				
	- Silicone stopper (white) mounted on the instrument.				
	- Non-sterile package.				
	- Operative part of stainless steel.				
	- Silicone handle.				

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Revision: 01 Pgs: 3 (3)

Revision history

Revision	Date	Prepared by	Reviewed by	Approved by	Remark
01	2023-01-24	Carina Hjorth, RA	Elisabet Jakobsson,	Henric Karsk, CEO	Initial document.
			Product Manager	In KIL	
			Edal	J ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	