Technical File TF12

Product Specification
Device group: Manual tooth extraction
Doc-id: TF12.1_SPEC
Revision: 01
Pgs: 1 (2)

DIRECTA

Product Specification

Trade name(s)	• **Luxator® Periotome** • **Luxator® Periotome Titanium** • **Luxator® Dual Edge Periotome** • **Luxator® Dual Edge Periotome Titanium** • **Luxator® Short Periotome** • **Luxator® P-series**
Sample illustration	
Intended use	Instrument are used to luxate the tooth before final extraction. Intended users are dentists and dental surgeons. To be processed by dental personnel.
Features	• Specially designed periodontal ligament knives • Easy and controlled insertion into the periodontal space • Ergonomic design • Atraumatic extraction • Unique Dual Edge tip for removal of roots • Minimize the force • Durable
Models	TF12_List of item numbers.
Dimensions	Shapes and sizes as per drawings.
Packages	506355 Luxator L1S, 1mm, straight blade, green, 1 pc 506352 Luxator L2S, 2mm, straight blade, dark green, 1 pc 506341 Luxator L3C, 3mm, curved blade, black, 1 pc 506340 Luxator L3S, 3mm, straight blade, grey, 1 pc 506353 Luxator L3CA, 3mm, contra angle, dark blue, 1 pc 506354 Luxator L3IC, 3mm, inverted curved, light blue, 1 pc 506343 Luxator L5C, 5mm, curved blade, brown, 1 pc 506342 Luxator L5S, 5mm, straight blade, tan, 1 pc 506399 Luxator Sharpening Tool L10, 1 pc 506330 Luxator Kit L-K4 including: Luxator L3C, L3S, L5C, L5S and Luxator sharpening tool L10. 506331 Luxator Kit L-K7 including: Luxator L2S, L3C, L3S, L3CA, L3IC, L5C, L5S and Luxator sharpening tool L10.

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	506332 Luxator L-K VET including: Luxator L1S, L2S, L3C, L3S, L3CA and Luxator sharpening tool L10. 506358 Luxator S2S, 2mm, straight blade, dark green, 1 pc 506359 Luxator S3C, 3mm, curved blade, black, 1 pc 506360 Luxator S3S, 3mm, straight blade, grey, 1 pc 506361 Luxator S3CA, 3mm, contra angle, dark blue, 1 pc 506362 Luxator S5S, 5mm, straight blade, tan, 1 pc 506399 Luxator Sharpening Tool L10, 1 pc 506333 Luxator SK4 Kit including: Luxator S3C, S2S, S3S, S3CA and Luxator sharpening tool L10 506433 Luxator L3S TiN 3mm, titanium straight blade, grey, 1 pc 506434 Luxator L2S TiN 2mm, titanium straight blade, green, 1 pc 506435 Luxator DE3 TiN 3mm/1,5mm, titanium dual edge, grey, 1 pc 506436 Luxator L3A TiN 3mm, titanium angled blade, lilac, 1 pc
Single use/re-usable	Re-usable.
Material	Stainless steel working part: 1.4197 YU Plastic handle: Polyamide PA6.6, 30% glass fibre reinforced Titanium coating (only valid for relevant types): Balinit A - Titanium nitride (TiN)
Shelf-life	The devices have no shelf-life restrictions. No unusual requirements for storage and handling conditions other than those that would normally be expected by the intended user.
Storing and transport conditions	None.
Supply	Supplied non-sterile.
Hazards likely with re-use of single use medical devices	N/a, devices are re-usable.

Revision history

Revision	Date	Completed by	Approved by	Remark
01	2022-10-06	Mark Nordin	Tomas Skeppmark, QA/RA Manager	Initial document.