

K960395

SAFETY AND EFFECTIVENESS SUMMARY

Designation / Feature	Submitted device PLANCON INSTRUMENTS	Predicated device ①	Predicated device ②
Intended use	To perform micro lamellar keratoplasty for the correction of myopia or hyperopia	To perform micro lamellar keratoplasty for the correction of myopia or hyperopia	To perform micro lamellar keratoplasty for the correction of myopia or hyperopia
System composition	Power unit Turbine motor Adjustable keratome head Keratome blade Pneumatic fixation rings Applanation lenses Plate checking gauge	Power unit Turbine motor Adjustable keratome head Keratome blade Pneumatic fixation rings Applanation lenses Plate checking gauge	Power unit Turbine motor Adjustable keratome head Keratome blade Pneumatic fixation rings Applanation lenses Plate checking gauge
Power unit	Vacuum pump Battery Vacuum release valve Knob to regulate gas pressure Gas & vacuum pressure gauges Vacuum & turbine quick connectors Battery charger unit	Vacuum pump Battery Vacuum release valve Knob to regulate gas pressure Gas & vacuum pressure gauges Vacuum & turbine quick connectors Battery charger unit	Vacuum pump Battery Vacuum release valve Knob to regulate gas pressure Gas & vacuum pressure gauges Vacuum & turbine quick connectors Battery charger unit

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	PLANCON INSTRUMENTS	PREDICATED DEVICE 1	PREDICATED DEVICE 2
Turbine motor	Gas powered Adjustable speed 0 to 20 000 RPM (recommended 14 000 RPM) Material : stainless steel, titanium, and aluminium. No gear system	Gas powered Adjustable speed Material : stainless steel No gear system	Gas powered Adjustable speed from 10 to 24 000 RPM Pre-set speed 14 000 RPM Material : stainless steel and brass No gear system
Keratome	Material : stainless steel Adjustable Safety : maximum cut depth, and checking gauge	Material : stainless steel Adjustable Permanent adjustable head with adjustment knob Safety : - maximum cut depth and checking gauge	Material : stainless steel Adjustable Safety : - maximum cut depth and checking gauge
Pneumatic fixation rings	Material : stainless steel Double dovetails	Material : stainless steel Double dovetails	Material : stainless steel Double dovetails
Applanation lenses	Material : clear plastic + stainless handle Engraved inner reticle diameter	Material : clear plastic + stainless handle Engraved inner reticle diameter	Material : clear plastic + stainless handle Engraved inner reticle diameter