

MAR 31 1997

K970377

**SAFETY AND EFFECTIVENESS SUMMARY**      K970377 p. 1/2

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 Date: December 13, 1996

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	Predicated device ① 510 K Document number K 960395	Predicated device ② 510 document number : Not known	Predicated device ③ 510 K document number : K 935342	Submitted device
Designation / Feature	PLANCON INSTRUMENTS Microlamellar Keratome	EYE TECHNOLOGY	SCMD	PLANCON INSTRUMENTS Microlamellar Keratome (single piece head)
Intended use	To perform microlamellar 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	To perform microlamellar 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 Turbine motor Fixed keratome head Keratome blade Pneumatic fixation rings Applanation lenses
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	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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	Predicated device ① 510 K Document number K 960395	Predicated device ② 510 document number : Not known	Predicated device ③ 510 K document number : K 935342	Submitted device
Designation / Feature	PLANCON INSTRUMENTS Microlamellar Keratome	EYE TECHNOLOGY	SCMD	PLANCON INSTRUMENTS Microlamellar Keratome (single piece head)
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	Gas powered Adjustable speed 0 to 20 000 RPM (recommended 14 000 RPM) Material : stainless steel, titanium and aluminium. 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	Material : stainless steel Fixed single piece head Safety : only one cut depth allowed by head principle
Pneumatic fixation rings	Material : stainless steel Double dovetails	Material : stainless steel Double devetails	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	Material : clear plastic + stainless handle Engraved inner reticle diameter