
Manufacturer's Information

No. MI_CP01-16

Mainparkstrasse 6-10 D-63801 Kleinostheim fon: +49(0)6027-508-350 · fax: +49(0)6027- 508-208 · email: apm@eye-tech.net

Product: **CARRIAZO-PENDULAR**

Subject: **Disposable Blade, Technical Data Sheet**



Convex-shaped blade

Article no.: 11977

Intended use: For use with medical device Carriazo-Pendular only.

The **blade**, when installed in the Carriazo-Pendular cutting head and coupled with the motor handpiece and operating console, is used for cutting corneal flaps.

Variant: There is only one variant of the blades;
The thickness of the corneal flap depends on which Pendular cutting head is used.

Material

Blade: Stainless steel 1.4037, biocompatible

Blade holder: Plastic: CX 2402 MT Natural FS, Manufacturer: Ticona,
low-shrinking; biocompatible

Blade case: Plastic: PP-RG835MO (turquoise and blue), Manufacturer: Borealis

The case accommodates the blade and protects it from mechanical damage. The blade case consists of two pieces:

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Material: Blade case housing 1294700:

Borealis PP-RG835MO color phantone 282 (similar RAL 5003)

Material: Blade case slider 1294800:

Borealis PP-RG835MO color phantone 320c (similar RAL 5018)

Packaging



Every blade is individually packed and has an expiration date printed on the labelled packing.

The disposable blades are delivered in a sterile packaging with blade case to protect them from damage.

Primary Packaging with attachment of the primary packaging label	Soft blister	Wipak Fitform130 PA/PE
	Lid	Medical grade paper MM60-4
	Dimensions:	Approx. 60 x 100 mm
	includes a quantity of one sterile disposable blade	Gamma sterilization
Secondary Packaging with attachment of the secondary packaging label	Pouch	ALU/PE peel
	Dimensions:	Approx. 180 x 380 mm
	Desiccant bag	Silica gel (30 g)
	includes a quantity of ten sterile disposable blades and one desiccant bag	
Tertiary Packaging with attachment of the tertiary (= secondary) packaging label as well as safety notice and sealing labels	Folding box	GC1 300g/qm
	Dimensions:	Approx. 180 x 40 x 360 mm
	includes a quantity of one pouch; serves as mechanical protection during storage	
Quarternary Packaging with attachment of the quarternary (=secondary) packaging label	One-Piece-Folder (box)	Corrugated cardboard
	Dimensions:	Approx. 181 x 41 x 362 mm
	includes a quantity of one folding box; serves as mechanical protection during delivery/transport	

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Storage

Time: Max. 4 years Date printed on each individual packaging
Condition: 15 - 25°C; up to 60% rel. humidity



WARNING!

Do not use the disposable blade more than once!

Do not use blades when the sterile (primary) packaging is damaged or already open.

The sterile (primary) packaging may be opened prior to treatment only.

For further details refer to current release version of the Carriazo-Pendular User Manual (IfU).