



Altomed Limited, Tyne and Wear.

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Instructions For Use Altomed Single Use Knives and Blades

Symbols Used to BS EN ISO 15223-1 and ASTM F 2503:



Use by

date



Keep away from direct sunlight and keep dry



Sterilized in Gamma



Do not use if pack damaged Meets EU CE mark requirements

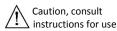


LOT



Catalogue number







Manufactured

Intended Use

REF	Description	Intended Use	
A64	Sterile, Miniature blade, round tip, sharp one side (Box of 12)	The blades are used to make incisions of varying lengths and depths in Cataract,	
A10130	Sterile, 15° 5mm blade with collet (Box of 12)	Refractive, Vitreoretinal, Corneal, Glaucoma, Oculoplastic and other Ophthalmic procedures. These are to be used with the A169 metal handles.	
A10134	Sterile, 30° 3.5mm blade with collet (Box of 12)		
A10150	Sterile, Scleral blade (Box of 6)	A blade used for making incisions in the sclera. These are to be used with the A1725 or A1725L metal handles with collet removed.	
A10154	Sterile, Lamellar blade, angled, bevel-up (Box of 6)	The blades are used to make incisions of varying lengths and depths in Cataract, Refractive, Vitreoretinal, Corneal, Glaucoma, Oculoplastic and other Ophthalmic procedures. These are to be used with the A1725 or A1725L metal handles with collet removed.	
A10080	Sterile, 20G MVR knife (Box of 6)	The knives are used primarily in Cataract and Vitreoretinal and paracentesis procedures to make 20 gauge incisions of varying depths. They are also used to create side ports to allow for the introduction of instruments. They can also be used in Refractive, Corneal, Glaucoma, Oculoplastic and other ophthalmic procedures.	
A10102	Sterile, 15° 5.0mm knife (Box of 10)	The knives are used to make incisions of varying lengths and depths in Cataract, Refractive, Vitreoretinal, Corneal, Glaucoma, Oculoplastic and other ophthalmic	
A10112	Sterile, 30° 3.5mm knife (Box of 10)		
A10157	Sterile, Scleral Knife (Box of 6)	procedures.	
A10182	Sterile, Tunnel II crescent knife, angled, bevel-up (Box of 6)	Primarily used for tunnel incisions. These knives can also be used in other	
A10184	Sterile, Tunnel II crescent knife, angled, beveldown (Box of 6)	ophthalmic surgical procedures.	

Device Description

Altomed Knives and Blades are made from surgical grade stainless steel (containing chromium and nickel) with a high strength thermoplastic resin handle or blade mount. The blades are intended to be used with the A1725 or A1725L handles.

Precautions

- Ensure the size marked on the blade or knife packaging is the one that is required.
- Use the A1725 or A1725L Handle as trained to remove the blades from the foam pack. Once the blade has been removed it should be examined to verify that it is being held securely in a handle and that is correctly positioned and aligned.
- Inspect the cutting edge under a microscope before use to ensure it has not been damaged during removal or assembly and use straight away.
- This knife has a very sharp blade. Take extreme care when handling to avoid unintentional injury to healthcare providers or patients. External injury caused by a contaminated blade can lead to pathogenic infection linked to blood disorders. If unintentional stick occurs, do not use the device.
- Do not drop or let the cutting edge contact any hard surfaces. These blades are very fine and delicate and can be blunted if forces are applied.
- Do not use excessive force or use with inappropriate equipment.
- Altomed knives and blades are sold as sterile. Sterility is guaranteed unless the packaging has been opened or damaged. If the packaging has been unintentionally opened or damaged prior to use, it is recommended to dispose of the device.
- Dispose of unwanted devices by following your facility approved procedures.
- Do not re-sterilize or reuse. Altomed assumes no liability for devices that have been altered, dismantled, reassembled, resterilized and/or reused. Reuse may cause infection risks, an inadequate cut due to physical damage of the cutting edge, corrosion, or patient injury such as chemical burns from inadequate processing.
- Please use the knives and blades responsibly.
- These devices are only to be used by qualified and trained medical professionals.

Storage

These devices should be stored in their outer cardboard packing in normal room conditions, away from direct light and away from contamination risks such as water. Do not use if the use by date, identified by the hour glass symbol, has passed.

Biocompatibility

Altomed Knives and blades are made from internationally recommended grades of surgical stainless steel, however as with many other stainless steel medical devices, there may be trace elements of nickel. Altomed knives do not contain latex or phthalates.

Full Product Range and Unique Device Identifiers (UDI) as Global Trade Identification Numbers (GTIN)

See ALT I093 in the "Current Instructions For Use" in "User Guides and Downloads" on the Altomed Web-site www.altomed.com

Full Product Range and Unique Device Identifiers (UDI) as Global Trade Identification Numbers (GTIN)

Order Code REF	Description	GTIN
A64	Sterile, Miniature blade, round tip, sharp one side (Box of 12)	05055505116683
A10130	Sterile, 15° 5mm blade with collet (Box of 12)	05055505106448
A10134	Sterile, 30° 3.5mm blade with collet (Box of 12)	05055505106455
A10150	Sterile, Scleral blade (Box of 6)	05055505106486
A10154	Sterile, Lamellar blade, angled, bevel-up (Box of 6)	05055505106493
A10080	Sterile, 20G MVR knife (Box of 6)	05055505106554
A10102	Sterile, 15° 5.0mm knife (Box of 10)	05055505106394
A10112	Sterile, 30° 3.5mm knife (Box of 10)	05055505106417
A10157	Sterile, Scleral Knife (Box of 6)	05055505106509
A10182	Sterile, Tunnel II crescent knife, angled, bevel-up (Box of 6)	05055505106561
A10184	Sterile, Tunnel II crescent knife, angled, bevel-down (Box of 6)	05055505106592
Accessories:		
A1696	Troutman razor fragment holder / blade breaker Straight 120mm	05055505108541
A1725	100mm stainless steel handle for single use blades, includes collet	05055505108671
A1725L	150mm stainless steel handle for single use blades, includes collet	05055505108688