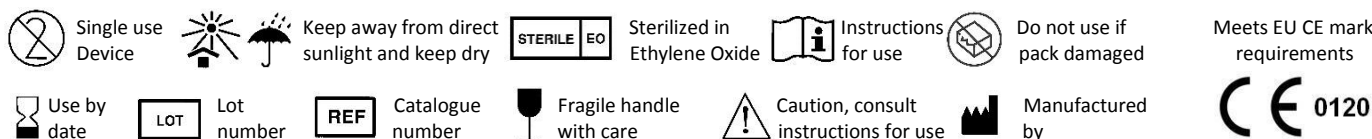


Instructions For Use The Use Of Short And Long Corneal Trephine Blades A6816L to A6884L

<http://www.altomed.com>
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Symbols Used to BS EN ISO 15223-1 and ASTM F 2503:



Intended Use

Altomed Trephines are intended to be used for trephination of the donor or recipient cornea in ophthalmic procedures such as keratoplasty. It is recommended to use the Jedmed Hessburg-Barron Vacuum Trephine on the recipient cornea due to the extra security and accuracy these devices offer (available from Altomed REF A7028 to A7040).

The Altomed Trephines are not intended to be reused and should not be used if passed their Use By Date denoted by the hourglass symbol. Short trephine blades are intended to be used with the Altomed Handle A6830 or the Omnifit Punch System A7010 or A7011. The long trephine blades can be held directly between the fingers. When cutting donor tissue, it is recommended to use an Altomed Cutting Block such as A7012S, A7022S on the Omnifit System or A7023S as a freestanding block.



A6830 Handle For
Short Trephines

Device Description

The corneal trephines are made from surgical grade stainless steel consisting of a cylinder with a cutting blade at one end. They are supplied sterile, single use and can be held by hand if a long blade, or with an A6830 Handle if using a short blade.



Short

Long

Precautions

- Ensure the size marked on the blade itself is the one that is required and matches the carton and pouch labelling.
- Use the A6830 Handle as trained to remove the small trephine blade. If necessary, a pair of general purpose forceps can be used to remove the blade from the mount.
- 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.
- Care should be taken at all times to avoid unintentional injury to healthcare providers or patient. If unintentional contact is made resulting in an injury, 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. Short handled trephines are to be used See Altomed products REF: A6830, A7010 and A7011.
- Altomed Trephines are sold 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, re-sterilized 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 trephines responsibly.
- After use, the blade should be returned to the protective ring and disposed of by following hospital approved procedures for disposal of contaminated sharps
- 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.

Biocompatibility

Altomed Trephines 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 Trephines do not contain latex or phthalates.

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

See ALT I005 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
A6816L	Trephine Blade Long 2.5mm	05055505117086
A6818L	Trephine Blade Long 3.0mm	05055505117093
A6820L	Trephine Blade Long 3.5mm	05055505117109
A6822L	Trephine Blade Long 4.0mm	05055505117116
A6824L	Trephine Blade Long 4.5mm	05055505117123
A6826L	Trephine Blade Long 5.0mm	05055505117130
A6828L	Trephine Blade Long 5.5mm	05055505117147
A6832	Trephine Blade 6.0mm	05055505117161
A6832L	Trephine Blade Long 6.0mm	05055505117178
A6834	Trephine Blade 6.25mm	05055505117185
A6834L	Trephine Blade Long 6.25mm	05055505117192
A6836	Trephine Blade 6.5mm	05055505117208
A6836L	Trephine Blade Long 6.5mm	05055505117215
A6838	Trephine Blade 6.75mm	05055505117222
A6838L	Trephine Blade Long 6.75mm	05055505117239
A6840	Trephine Blade 7.0mm	05055505117246
A6840L	Trephine Blade Long 7.0mm	05055505117253
A6842	Trephine Blade 7.25mm	05055505117260
A6842L	Trephine Blade Long 7.25mm	05055505117277
A6844	Trephine Blade 7.5mm	05055505117284
A6844L	Trephine Blade Long 7.5mm	05055505117291
A6846	Trephine Blade 7.75mm	05055505117307
A6846L	Trephine Blade Long 7.75mm	05055505117314
A6848	Trephine Blade 8.0mm	05055505117321
A6848L	Trephine Blade Long 8.0mm	05055505117338
A6850	Trephine Blade 8.25mm	05055505117345
A6850L	Trephine Blade Long 8.25mm	05055505117352
A6852	Trephine Blade 8.5mm	05055505117369
A6852L	Trephine Blade Long 8.5mm	05055505117376
A6854	Trephine Blade 8.75mm	05055505117383
A6854L	Trephine Blade Long 8.75mm	05055505117390
A6856	Trephine Blade 9.0mm	05055505117406
A6856L	Trephine Blade Long 9.0mm	05055505117413
A6858	Trephine Blade 9.25mm	05055505117420
A6858L	Trephine Blade Long 9.25mm	05055505117437
A6860	Trephine Blade 9.5mm	05055505117444
A6860L	Trephine Blade Long 9.5mm	05055505117451
A6862	Trephine Blade 9.75mm	05055505117468
A6862L	Trephine Blade Long 9.75mm	05055505117475
A6868	Trephine Blade 10.0mm	05055505117529
A6868L	Trephine Blade Long 10.0mm	05055505117536
A6870	Trephine Blade 10.5mm	05055505117543
A6870L	Trephine Blade Long 10.5mm	05055505117550
A6872	Trephine Blade 11.0mm	05055505117567
A6872L	Trephine Blade Long 11.0mm	05055505117574
A6874	Trephine Blade 11.5mm	05055505117581
A6874L	Trephine Blade Long 11.5mm	05055505117598
A6876	Trephine Blade 12.0mm	05055505117604
A6876L	Trephine Blade Long 12.0mm	05055505117611
A6878	Trephine Blade 12.5mm	05055505117628
A6878L	Trephine Blade Long 12.5mm	05055505117635
A6880	Trephine Blade 13.0mm	05055505117642
A6880L	Trephine Blade Long 13.0 mm	05055505117659
A6882	Trephine Blade 13.5mm	05055505117666
A6882L	Trephine Blade Long 13.5mm	05055505117673
A6884	Trephine Blade 14.0mm	05055505117680
A6884L	Trephine Blade Long 14.0mm	05055505117697
Accessories:		
A6830	Trephine Handle Universal	05055505117154