Altomed Omnifit Punch System* and the Sterile PTFE (Polytetrafluorethylene) Cutting Blocks

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

Single use Device	Keep away from direct sunlight and keep dry	STERILE EO — Sterilized in Ethylene Oxide
Instructions for use	Do not use if pack damaged	Meets EU CE mark requirements
Use by date	LOT — Lot number	REF — Catalogue number
Fragile handle with care	Caution, consult instructions for use	Manufactured by

CE 1639
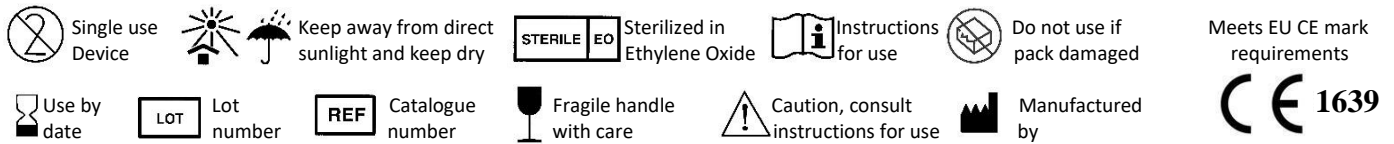
Intended Use:

Intended to be used with the Altomed Omnifit Trephination System* or by hand to act as a base to cut donor corneal tissue. These devices are designed to be single use and should be disposed of after use.

Device Description:

Altomed corneal punch blocks are made from PTFE and have been designed to provide a bowl shaped cutting block for cutting donor corneal tissue. These can be used with the Altomed range of trephines.

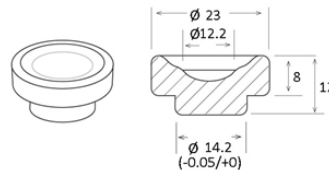*The Omnifit Trephination System has now been discontinued.*

A7010   A7010A   A7011
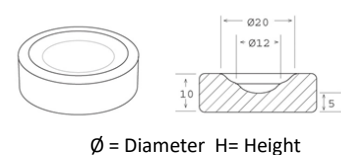
A7012S PTFE Corneal Cutting Block 9mm High

Dimensions in mm

Ø 15, 9, 4, Ø 14.2 (-0.05/+0)
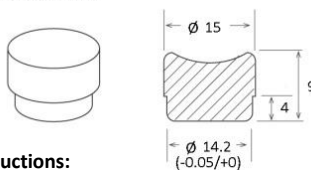
A7022S McRae PTFE Corneal Cutting Block

Dimensions in mm

Ø 23, Ø12.2, 8, 12, Ø 14.2 (-0.05/+0)

A7023S PTFE Corneal Punch Cutting Block Large Hand Held

Dimensions in mm

Ø20, Ø12, 10, 5

Ø = Diameter H= Height

Instructions:

Only to be used by suitably trained healthcare professionals. The PTFE Blocks act as a cutting base for the donor cornea. The **A7012S** and **A7022S** Corneal Cutting Blocks are designed to be used in the Omnifit Punch System **A7010** or **A7011** or **Similar System** which holds and guides the trephine in a vertical trajectory.

- Ensure Omnifit Punch System is on a flat secure surface, place sterilized PTFE Cutting Block in base hole, ensure fit is correct, i.e. Block lip is fully flush against base and there is no lateral movement. If the block does not fit then it cannot be used on the Punch System in question. Contact Altomed for alternative blocks.
- Remove the Piston from the base and place Altomed Trephine Blade over its three arms so the non-cutting edge is snug against the ridges. Rotate the silver barrel clockwise to open the arms, ensure the trephine is secure and positioned correctly. Release and reseat the trephine if the blade is at an angle. Do not over tighten the piston arms.
- Place the Donor Tissue with the endothelial surface upwards on the PTFE Cutting Block. Ensure the donor tissue is lined up as required to obtain the correct incision site.
- Carefully insert the piston into the base, ensure the tissue is still in the correct position, then press down firmly on the piston to cut the corneal button. DO NOT PULL THE DONOR TISSUE DURING THE CUT AS IT MAY MISHAPE IT. Ensure the cut is complete.
- Retract the piston and obtain the corneal button from the block. If the tissue remains inside the trephine blade, carefully drip a balanced salt solution onto the endothelium to dislodge it.
- Dispose of the trephine and cutting block by following hospital procedures for contaminated devices. Reuse of the cutting blocks may result in harm such as corneal abrasion, a malformed tissue shape or incorrect or incomplete tissue cut, and increased risk of cross infection.
- The **A7023** are designed to be held by hand. Place the donor cornea into the cutting block with the endothelial side up and use a hand held trephine blade to cut the donor button to size. Ensure cut is made vertically.

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.

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

Order Code REF	Description	GTIN
A7012S	PTFE Corneal Punch Block	05055505141968
A7022S	McRae PTFE Corneal Cutting Block	05055505142040
A7023S	PTFE Corneal Cutting Block Large Hand Held	05055505142064