#65120

EN **Instructions for use of the One® Single-Use XL Guarded cover #17206DXXX**

Indication for use

The Moria ONE® Single-Use XL Guarded cover is designed for performing lamellar keratoplasty.
The One® Single-Use XL Guarded cover #17206DXXX is used after using the One® Single-Use Guarded Punch #17207DXXX.

Device components

• Trephine blade housing (see Fig. 1)
To be used with a cutting block base (A) (see Fig. 2), a syringe (C) (see Fig. 2) and a clamp (D) (see Fig. 2), provided separately with the One® Single-Use Guarded Punch #17207DXXX.

The most recent version of this document is available on Moria website (http://www.moria-surgical.com) via the restricted access heading «Documentation/Library». Translations are also available in other languages under that same heading. Registration required.

Warning

• These instructions explain only how to use this medical device and do not describe the steps necessary to perform a corneal graft. The surgical procedure remains the responsability of the surgeon experienced in performing corneal grafts.
• Check the integrity of the pouch.
• Check also the expiration date on the packaging.
• The ONE® Single-Use XL guarded cover is sterile and ready for use. Do not use it if the pouch in which it is packaged is damaged.
• Design of this medical device does not allow its reuse. Reusing this medical device affects its clinical performances and exposes the patient to adverse events.
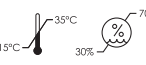
Directions

1 / Check the blade diameter which is stamped on top of the trephine blade housing.

2 / Remove the sterile blister from the pouch.

3 / Remove the trephine blade housing from the blister.

4 / Take the cutting block base and the syringe previously connected with the Luer™ lock (components provided separately with the One® Single-Use Guarded Punch #17207DXXX) with the graft on it and already trephined.

5 / Check the integrity of the trephine blade under the microscope.

6 / Place the trephine blade housing on the cutting block base, let it lower down by gravity to avoid setting it with a wrong angle (risk of blockage) (Fig. 4) then press down gently to cut the graft (Fig. 5) **Warning : Do not turn the punch during or after trephination.** While holding the assembled punch, grasp the sclera, through the "top lateral" window, with a tooth forceps then gently lift the trephine blade housing up (Fig. 6).

7 / Pull gently upward the trephine housing blade from the cutting block base. The donor button should be kept in place on the cutting block base thanks to the aspiration. Then remove completely the trephine housing blade.

8 / Disassemble the syringe from the tubing to release the vacuum. The donor button is now ready to be used on the patient.

9 / At the end of the surgical procedure, discard the ONE® Single-Use XL Guarded Punch into an appropriate container for destruction (according to the regulations in force).

CAUTION for USA only: US federal laws restrict this device to sale by, or on the order of, a physician.

Explanation of symbols

Symbol	Meaning
REF XXXXXX	CATALOGUE REFERENCE
XX	QUANTITY
YYYY/MM/DD	USE BY
LOT XXXXXX	BATCH CODE
STERILE EO	STERILIZED USING ETHYLENE OXIDE
(do not reuse symbol)	DO NOT REUSE
XXXXXXX	MANUFACTURER
YYYY/MM/DD	DATE OF MANUFACTURE
XXXXXX	CAUTION: CONSULT ACCOMPANYING DOCUMENT(S)
XXXXXX	CONSULT OPERATING INSTRUCTIONS
(damaged package symbol)	DO NOT USE IF PACKAGE IS DAMAGED
15°C–35°C, 30%–70%	STORAGE CONDITIONS: • TEMPERATURE: 15°C – 35°C / 59°F – 95°F • HUMIDITY RATE: 30% – 70%
(umbrella symbol)	KEEP DRY
(bin symbol)	DISCARD IN A SEPARATE COLLECTION BIN
Rx only	CAUTION FOR USA ONLY: US FEDERAL LAWS RESTRICT THIS DEVICE TO SALE BY, OR ON THE ORDER OF, A PHYSICIAN.

Reference

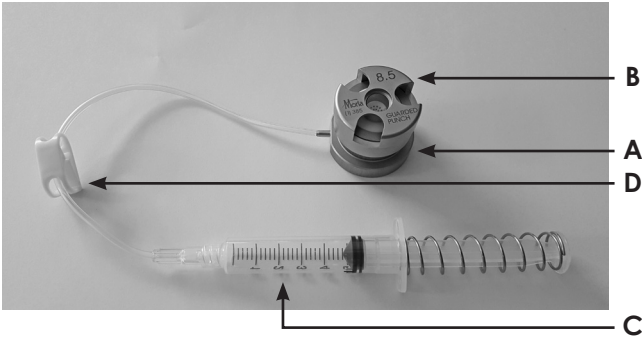|	
Reference	#17206DXXX
Designation	Single-Use XL Guarded cover DXXX
Packaging	1 per box, sterile, single-use

Fig.1

#17206DXXX contains the following element

 ←——————— Trephine blade housing

Fig.2

To be used with #17207DXXX, which contains the following elements:

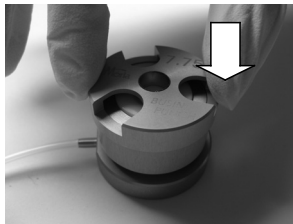| A	Cutting block base
B	Trephine blade housing
C	Syringe
D	Clamp

Fig.3

Fig.4

Fig.5

Fig.6

Moria
Ophthalmic Instruments
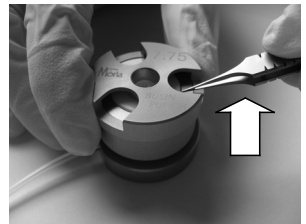
To obtain more information

Moria
Ophthalmic Instruments