



# #65119

EN

## Instructions for use of the One® Single-Use XL Guarded Punch #17208Dxxx

### Indication for use

The Moria ONE® Single-Use XL Guarded Punch is designed for performing lamellar keratoplasty, in which one corneal incision is made at a depth of over 200 µm.

### Device components

- Cutting block base (A) (see Fig. 1)
- Trephine blade housing (B) (see Fig. 1)
- Syringe (C) (see Fig. 1)
- Clamp (D) (see Fig. 1)

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 responsibility 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 punch 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 cutting block base, trephine blade housing and the syringe from the blister.
- 4 / Connect the tubing to the syringe with the Luer™ lock connection (Fig. 2).
- 5 / Check the integrity of the trephine blade under the microscope.
- 6 / Press the piston of the syringe half way and hold.
- 7 / Place the graft on the cutting block base, endothelial side up.
- 8 / Center the graft using the 4 cardinal holes diametrically opposite of 9.5 mm.
- 9 / Release the piston of the syringe to create the vacuum that will hold the graft in position on the cutting block base. Check that the graft is still well centered.  
If the graft is not well centered at the end of this preparation, repeat the steps 6, 7, 8 and 9 to obtain a perfect centering.
- 10 / 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. 3) then press down gently to cut the graft (Fig. 4) **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. 5).
- 11 / 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.
- 12 / Disassemble the syringe from the tubing to release the vacuum. The donor button is now ready to be used on the patient.
- 13 / 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).

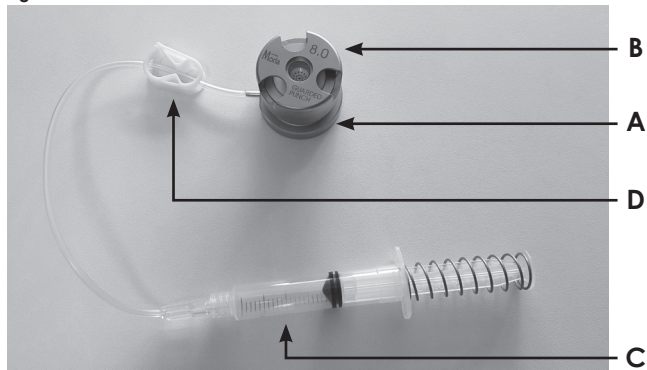
**CAUTION for USA only: US federal laws restrict this device to sale by, or on the order of, a physician.**

Explanation of symbols

 xxxxxx	CATALOGUE REFERENCE
	QUANTITY
 YYYY/MM	USE BY
 xxxxxx	BATCH CODE
	STERILIZED USING ETHYLENE OXIDE
	DO NOT REUSE
 xxxxxxx	MANUFACTURER
 xxxxxx	CAUTION: CONSULT ACCOMPANYING DOCUMENT(S)
 xxxxxx	CONSULT OPERATING INSTRUCTIONS
	DO NOT USE IF PACKAGE IS DAMAGED
	DISCARD IN A SEPARATE COLLECTION BIN

Reference	#17208Dxxx
Designation	Single-Use XL Guarded Punch Dxxx
Packaging	1 per box, sterile, single-use

Fig.1



<b>A</b>	Cutting block base
<b>B</b>	Trephine blade housing
<b>C</b>	Syringe
<b>D</b>	Clamp

Fig.2



Fig.3

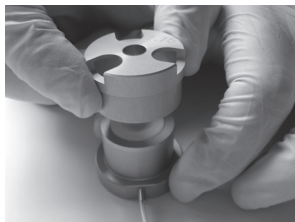


Fig.4

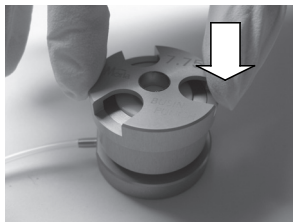
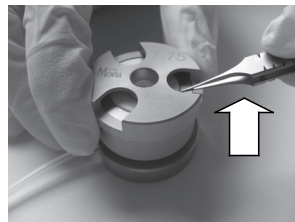


Fig.5



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