

EN

ONE - DEEP WELL TRI-FOLD COVER

#17215RXXX (XXX=750,775,800)

The most recent version of the instruction for use is available on MORIA website:
<http://www.moria-surgical.com>

1-INTENDED AND INDICATION FOR USE

The ONE - Deep Well Tri-Fold Cover (#17215RXXX) is specific to partially cut donor corneal tissue and is not intended for patient use. It is to be used on donor tissue only.
This system is indicated for use without restriction to the target population (age, sex and health status). There are no contra-indication.

2-DESCRIPTION / FEATURES

The device is EO (Ethylene Oxide) sterilized and ready for use.
The device is available in different sizes based on radial blade diameter.
The device consists of one support with two radial blades in different diameters, to be used in combination with the receptacle of the ONE-Deep Well Guarded Punch (#17212Dxxx) (see Fig. 1).
See details of references in part "7. List of references".

3-INTENDED PERFORMANCE AND CLAIMS

More specifically, the ONE - Deep Well Tri-Fold Cover is designed to create two radial incisions on the endothelial side at different diameters.

4-PRE-REQUISITES BEFORE USE AND DIRECTIONS FOR USE

To prepare device: follow step 1 to 4.
To check the integrity of the radial blades: follow step 5.
To maintain donor corneal tissue with the punch: follow step 6 to 7.
To proceed to trephination : follow step 8 to 9.
To finish the procedure: follow step 10.

Preparing the device :

- 1- Select the proper diameter of the ONE - Deep Well Tri-Fold Cover : it has to be identical to the diameter of the ONE-Deep Well Guarded Punch with which donor tissue has previously been trephined.
- 2- Check the diameter of the ONE - Deep Well Tri-Fold Cover which is marked on top of the radial blades support.
- 3- Remove the sterile blister from the pouch.
- 4- Remove the radial blades support from the blister.

Checking the integrity of the blade under a microscope :

- 5- Check under the microscope (minimum 20x) that the cutting edge of the two radial blades has no visible defect. Defects can compromise the performance of the cut.

Maintaining the donor corneal tissue :

- 6- Refer to instruction for use (#65121) coming with the ONE-Deep Well Guarded Punch (#17212Dxxx).

Trephining the donor corneal tissue :

- 7- Place the radial blades support on the base to ensure the two hinges are at the bottom of the graft, where the donor tissue is left attached. This will help prevent the tissue from further tearing at the laceration points.
- 8- Let the radial blades support lower down by gravity to avoid setting it with a wrong angle (risk of blockage) (see Fig. 2 and Fig. 3), then press down gently.

Warning: Do not turn the radial blades support during or after trephination.

- 9- Gently pull the radial blades support upward from the base. The graft should stay in place on the base as a result of the vacuum. Then completely remove the blade support (see Fig. 4).

End of procedure :

- 10- At the end of the surgical procedure, discard the ONE - Deep Well Tri-Fold Cover into an appropriate container for destruction (according to appropriate regulations).

5-WARNING / CAUTION / PRECAUTION / ADVERSE EVENTS

- This device must be used only by experienced ophthalmic surgeons or eye banks technicians.
- These instructions explain only how to use this medical device and do not describe the steps necessary to perform a corneal graft. Manual manipulation of the donor cornea with hand held instruments, and the surgical procedure, remain the responsibility of the eye banks technicians and/or the surgeon experienced in performing keratoplasty.
- Do not use if expiration date has passed.
- Do not use if storage conditions have failed (humidity traces). This device should be stored in a clean, dry location at room temperature and away from direct sunlight.
- Do not use if the packaging or device is damaged (check the integrity of pouch and inspect the radial blades under a microscope before use).
- Do not have any physical contact with the cutting edge of the radial blades to avoid injuries.
- Do not use in combination with other version of guarded and classic punch (series 17200Dyyy, 17206Dyyy, 17207Dyyy, 17208Dyyy).
- Stop the use of the device in case of any malfunction during the procedure, including potential complication described in part 6.
- The design of this medical device is « single use only ». Reuse of this device may affect its mechanical and biological features, and its clinical performances; and may cause device failures or may expose the patient to adverse events such as contamination, bacterial infections or allergic reactions.

6-POSSIBLE SIDE EFFECTS AND INFORMATION TO RELAY

To date, the risks identified by the manufacturer associated to donor punches are:

- loss of suction
- graft attachment on the blade
- incomplete cut.

Any serious incident occurring in conjunction with this device must be reported to the manufacturer and the competent authority of the user's and/or patient's Member State.

7-LIST OF REFERENCES

REFERENCE	DESIGNATION	CE MARKING
17215R750	ONE - Deep Well Tri-Fold Cover R7.50 mm X1	-
17215R775	ONE - Deep Well Tri-Fold Cover R7.75 mm X1	-
17215R800	ONE - Deep Well Tri-Fold Cover R8.00 mm X1	-

8- LABELING INFORMATION

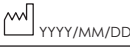
SYMBOL	MEANING
	CATALOGUE REFERENCE
	QUANTITY
	USE BY DATE
	BATCH CODE
	STERILIZED USING ETHYLENE OXIDE
	DO NOT REUSE
	MANUFACTURER
	DATE OF MANUFACTURE
	CAUTION : CONSULT ACCOMPANYING DOCUMENT(S)
	CONSULT OPERATING INSTRUCTIONS
	DO NOT USE IF PACKAGE IS DAMAGED AND CONSULT INSTRUCTION FOR USE
	KEEP DRY
	KEEP AWAY FROM SUNLIGHT
	CAUTION for USA only: US federal laws restrict this device to sale by, or on the order of, a physician.
	MEDICAL DEVICE
	UNIQUE STERILE BARRIER SYSTEM WITH INNER PROTECTIVE PACKAGING

Fig.1



Fig.2



Fig.3

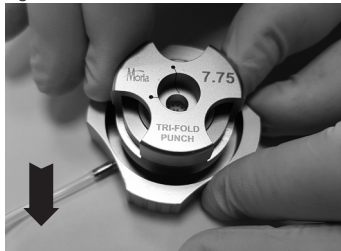
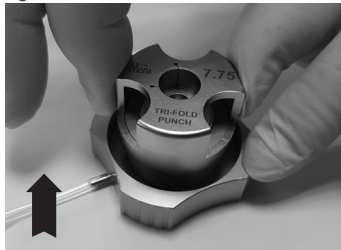


Fig.4



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