Product Description

General

The Day Cassette System is an accessory to the ophthalmic surgery system Qube pro. It is connected to the surgery system in order to enable irrigation and aspiration during ophthalmic intervention. To gain economic benefits without neglecting hygiene standards, the Day Cassette System is based on subassemblies. These combine the safety of disposables with cost reducing effects of reusables. As none of the subassemblies can be used separately, their instructions for use are summarized within this document.

Included Products

The following products are necessary to assemble the Day Cassette System:

REF	Description
03LU67	IOP-Set
03QA17	Cassette Body
03QA18	Collection Bag
03QA19	I/A tube
03QA20	Side element for cassette body

Delivery Condition / Pretreatment

The system combines disposables, reusables suitable for reprocessing and reusables without the need of reprocessing.

REF	Zustand	Vorbehandlung
03LU67	sterile	None, dispose after use.
03QA17	non-sterile	None, dispose after 1 day of use.
03QA18	non-sterile	None, dispose after 1 day of use.
03QA19	sterile	None, dispose after use.
03QA20	non-sterile	Reprocessing according to reprocessing instructions[1] before use.

Intended Purpose

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The Cassette System is intended for ophthalmic anterior and posterior segment surgery. Balanced salt solution is supplied via the irrigation line. Tissue, balanced salt solution, and chamber water are aspirated and stored in the Cassette System.

Intended Users

Intended users (ophthalmic surgeons, surgical personnel, medical technicians) are trained, knowledgeable, and qualified to install, use, and maintain the ophthalmic surgical system and the accessories.

Intended Patient Population

The device is intended for use in patients requiring ophthalmic intervention as indicated by an ophthalmologist.

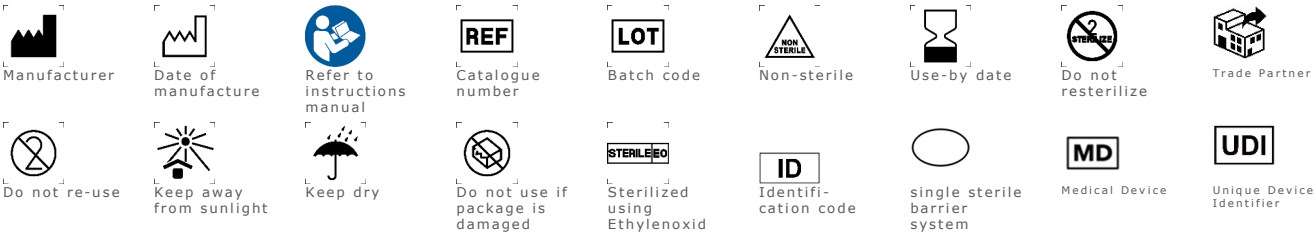
Indications

The Cassette System as independent medical device is necessary to enable the functionality of the Qube pro surgical system. Thus there is no standalone medical indication.

Contraindications

There are currently no contraindications related to the use of the accessories.
Note: the contraindication of the Qube pro surgical system applies (Prudence is required for patients with implanted cardiac pacemaker or pacemaker electrodes. The application of diathermy may interfere with, or damage the pacemaker, which may lead to ventricular fluttering.
The surgeon should carefully evaluate the pre-operative situation and make sound clinical judgment on the risk/benefit of the treatment.).

Explanation of symbols



Safety Instructions

Warnings

Warnings contain information about possible injuries. Observe without exception.

⚠ WARNING
Strictly follow the order of the application steps. Otherwise, the sterile fluid pathways could get contaminated during application.
DK1

⚠ WARNING
Observe the warnings and cautions in IFU for Qube pro and Accessories Manual additionally.
DK2

[1] 01RI21GB - IFU Reprocessing

Application

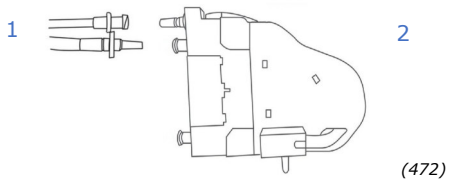
The assembly and application to the surgery system has to be performed by two persons. Person A executes the aseptic assembly steps, Person B is responsible for application to the device.

Note: Some figures might not show all details. This is intended and serves for better visualization.

(1) Person A connects the I/A tube (1) to Side Element for Cassette Body (2) in sterile environment as shown in fig. 472.

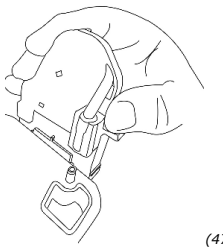
(2) Person B prepares the cassette part by connecting the collection bag to the cassette body.

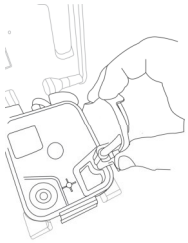
(3) Person B inserts the cassette into the cassette holder.



(472)

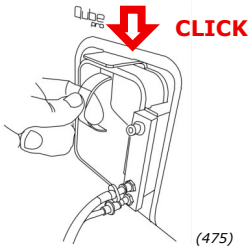
(4) Person A mounts the side element on the cassette part.
See Figs. 473 and 474.


(473)


(474)

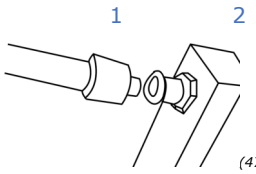
(5) Person A grasps the handle of the cassette system and locks the cassette body into the Qube pro.

(6) A clear clicking sound should be audible. See Fig. 475.



(475)

(7) Person A connects the IOP-Set (1) to the side element (2)
See Figs. 476 and 477.



(476)


(477)

(8) Person B connects the filter of the IOP-Set to the rear of the system as described in the accessories manual.

(9) Person B opens the IOP-Set. The system is now ready for priming.

Disassembly and Follow-Up-Intervention

After an intervention, follow the instructions given in the accessories manual for Qube pro to unmount the Day Cassette System from the surgery system (Ch. 3.11 Removal of the Qube Cassette). Follow the steps of application vice versa to disassemble the system to its single components. Dispose products intended for single use. Reuse Cassette Body and Collection bag without reprocessing, if intended use-by-time has not expired. Carry out validated reprocessing procedure on Side Element for cassette body.

Storage and disposal

Always store products dry, away from sunlight, dust-protected, clean and free of pests. For disposal, please follow the hygiene regulations of your medical practice/hospital and national regulations for contaminated medical devices.

Additional information

If accessories designed for sterile application are delivered in a non-sterile condition, a corresponding warning sign will indicate that sterilization is required ("Non-sterile – Sterilize prior to use!"). If Ruck accessories are delivered in a sterile condition, the user must ensure that the sterile packaging is undamaged, the indicated use-by-date is not expired, and the sterilization has been conducted properly (indicator check). The use of products after their use-by date is not approved.

Distributed by

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