RUCK

Qube & QUBE pro

ACCESSORIES MANUAL

CE 0123

Accessories Manual – for the Qube & Qube pro eye surgery system.

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Content

1 Preliminary remarks 6

2 Important notes and general remarks 7

2.1 General information 7
2.2 The eye surgery systems and their accessories 7
2.3 Intended Purpose 8
2.4 Safety instructions 9
2.5 Labelling of accessories 10
2.6 Materials used 11
2.7 Disposal of medical devices 11
2.8 Accompanying documents 12
2.9 Contact to legal manufacturers 12

3 The cassette system 13

3.1 Intended purpose 13
3.2 Product description 13
3.3 Combination of products 13
3.4 Qube Cassette System Standard 14
3.5 Qube Cassette System, IPC 14
3.6 Cassette System without infusion line (currently inactive) 15
3.7 Infusion System FPA (currently inactive) 15
3.8 Application guidelines for Standard- and IPC-Operating Mode 15
3.9 Application guidelines for FPA-Operating Mode (currently inactive) 16
3.10 Guidelines for bottle change in FPA-Operating Mode (currently inactive) 17
3.11 Removal 17

4 The Phaco handle REF 02PH42 18

4.1 Intended purpose 18
4.2 Product– and functional description 18
4.3 Preparation and reuse of the phaco handle 19
4.4 Design and performance data 19
4.5 Implementing electrical and functional safety measures 19

5 Accessories for phacoemulsification 20

5.1 Intended purpose 20
5.2 Product description 21
5.3 Assembly of Phaco needles, Sleeve and Test chamber 22
5.4 Functional test of the assembled system 24
5.5 Reprocessing of phaco needles, sleeves and test chamber 25
5.6 Instructions for the surgeon 25

6 I/A–Handpieces and accessories 26

6.1 Intended purpose 26
6.2 Product description 26
6.3 Installation and testing the I/A–Handpieces 27
6.4 Application procedure 28
6.5 Reprocessing of reusable I/A–Handpieces 28

7 Bipolar Diathermy 29

7.1 Intended purpose 29
7.2 Product description 29
7.3 Operation of the Diathermy function 29
7.4 Disconnection 31
7.5 Reprocessing of bipolar diathermy accessories 31

8 Vitrectomy accessories 32

8.1 Product description 32
8.2 Connecting and applying pneumatic vitrectomes 33
8.3 Operation of the vitrectome 34
8.4 Using an infusion sleeve 35

9 Irrigation and aspiration of silicone oil 36

9.1 Intended purpose 36
9.2 Product description 36
9.3 Oil infusion using the oil infusion unit 37
9.4 Operating the oil infusion unit 37
9.5 Reprocessing of VFI accessories 38

10 Air Fluid Exchange 39

10.1 Intended purpose 39
10.2 Product description 39

1 Preliminary remarks

This accessories manual provides an overview of all medical devices and consumables which are used as accessories in conjunction with the Qube family consisting of Qube, Qube pro and Qube pro – powered by eyeflexa surgical systems. It explains the application and use of the accessories and serves as a supplement to the instructions for use for the respective devices.
All accessories for the Qube family shall only be used for their intended purposes. Please skip explanations about accessories which are not included in your equipment. Each chapter contains a list of accessories currently offered by Ruck for the respective device function (including the REF). You will also be informed about the delivery condition of the products, their assembly and disassembly and the connection to the device
The reprocessing of all reusable medical devices and accessories for sterile application offered by Ruck is described within the separated general instructions for reprocessing.

2 Important notes and general remarks

2.1 General information

To draw your attention to important passages in this Accessories Manual, special instructions are illustrated with the symbols below:

> ⚠ **WARNING**
> Warnings have highest importance. They contain warnings about possible injuries. Observe without exception.
> 2

> ⚠ **CAUTION**
> Cautions require special attention and serve to prevent damage to the device. Non-compliance with this warning can lead to damage to property or the environment.
> 1

In case of any serious incident related to one of the mentioned products occurred, please immediately report to the legal manufacturer and the competent authority of your member state.
Please contact your sales representative, if you have any further questions or would like any additional information.

2.2 The eye surgery systems and their accessories

The Qube family offers the possibility of cataract and vitrectomy function depending on customers order and configuration of powered by eyeflexa systems. To gain facilitated reading flow, the following text will not differ between devices or configurations, where possible, and use Qube family emblematically of all surgery systems.
Qube family is designed for a reliable, safe and simple application. The devices are equipped with a venturi pump, for which they require a suitable compressed air supply.
There is a wired or wireless, multifunctional footswitch, an equipment trolley, an electronically height-adjustable infusion pole as well as numerous other accessories (such as handles) and consumables (such as the cassette/tubing system for single use) corresponding to the appropriate device type to fully equip the surgery system. These items are referred to as "accessories" throughout this manual.
Bytec LM are responsible for the manufacture of many of the articles in the range of accessories for the Qube family and places these on the market. For other accessories this is not the case and other companies are the responsible manufacturers. However, all items described in the accessories manual have been tested by Bytec LM.

Ruck has expressly declared the combination of all accessories with the Qube family as approved.

2.3 Intended Purpose

This chapter describes the intended purpose in general for all accessories, which are covered by the legal manufacturer's responsibility of Bytec LM. If there are product related particularities, they will be explained in detail within their respective chapter.

Intended purpose

The intended purpose is described separately within the respective chapter.

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 accessories as independent medical devices are 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.).

2.4 Safety instructions

⚠WARNING

The use of accessories other than those described in this handbook can negatively impact the safe usage of the system. Bytec LM and Ruck therefore assume no responsibility for malfunctions or incidents resulting from the use of parts that are not permissible for use.

A01

⚠WARNING

The products described in the accessories manual may only be used by persons who have the knowledge necessary for eye surgery, such as eye surgeons.

A02

⚠WARNING

Single-use medical devices shall not be reused! The reuse of products intended for single use involves the risk of cross-contamination for patients and users!

A03

⚠WARNING

All accessories that are described in the following sections are only to be used in conjunction with the Qube family!

A27

⚠WARNING

Sterile single-use product must not be re-sterilized if sterile packaging is damaged or has been opened.

A28

⚠ CAUTION

Please first refer to this manual before using any accessories. Please observe in particular the information on cleaning, disinfection and sterilization from the general instructions for reprocessing.

Check the re-usable accessory parts before use using a microscope in order to ensure that there are no abnormalities, that could lead to malfunctions. If these instructions are not fulfilled, Bytec LM and Ruck shall assume no responsibility.

A04

PRODUCTS FOR SINGLE USE OR REUSE:

Accessories are divided into two different product groups, depending on the frequency of their approved reuse:

- Products for single use (e.g. cassette/tubing systems for single use)
- Products for limited reuse (e.g. sleeve for max. 25 applications)

⚠ CAUTION

With deliveries of Ruck surgical system accessories, please always pay attention to the product labelling and enclosed product information!

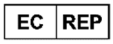
A05

Single-use products are clearly marked with the corresponding EN ISO 15223-1 symbol. 'Single use' of a medical device is defined as 'single use on a single patient'.
Reusable medical devices designed for sterile application must be processed prior to their application (i.e. cleaned, disinfected and sterilized) and packaged in a sterile condition. For further information on reprocessing, please refer to the general instructions for reprocessing.

2.5 Labelling of accessories

Ruck supply accessories for the Qube family in sterile and non-sterile conditions. 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 accessories from Bytec LM are delivered in a sterile condition, the user must ensure that the sterile packaging is undamaged, the indicated usage period is not expired, and the sterilization has been conducted properly (indicator check). The use of products after their use-by date is not approved.

EXPLANATION OF SYMBOLS:

	Do not re-use		Date of manufacture		Non-sterile
	Consult instructions for use		Sterilized using ethylene oxide		Do not use if package is damaged
	Caution		Catalogue number		Keep dry
	Use-by date		Manufacturer		Refer to instructions manual
	Batch code		CE-mark with ID of the notified body		Do not resterilize
	Serial number		Keep away from sunlight		Rotate wing bolt for **one** click before moving the FPA-Needle
	Contains DEHP		Medical device		Authorized representative in the European Community
	Unique Device Identification		Trade partner		Sterilized using ethylene oxide + sterile barrier

2.6 Materials used

Only materials which do not pose a risk to the patient, the user or the environment are used in our accessories. Medical devices made from PVC are generally phthalate-free. In exceptional cases where one of these plasticizers is nonetheless used, this is indicated with the corresponding symbol on the label of the outer packaging.
We also do not use products or components made from latex.

2.7 Disposal of medical devices

Please follow the hygiene regulations of your facility and national regulations for the disposal of contaminated medical devices.

2.8 Accompanying documents

The accessories manual will on the one hand refer to reprocessing instructions for reusable devices several times. These instructions released by Ruck are available to you as *General Instructions for Reprocessing (REF 01RI21)*. On the other hand, it refers to Qube family instructions for use. These instructions are available to you as *Qube pro – Instructions for use (01QL10)* or *Qube pro – powered by eyeflexa Instructions for use (01EF20).*

2.9 Contact to legal manufacturers

Sales and Technical Service

Ruck Ophthalmologische Systeme GmbH
Ernst-Abbe-Str. 30b
52249 Eschweiler, Germany

Tel: +49 (0) 02403 9455 0
Fax: +49 (0) 02403 9455 50
E-Mail: info@ruck-gmbh.de
Internet: www.ruck-gmbh.de

Legal Manufacturer

Bytec Legal Manufacturer GmbH
Ernst-Abbe-Str. 30b
52249 Eschweiler, Germany

Tel: +49 (0) 02403 92095 0
E-Mail: info@bytec-lm.com
Internet: www.bytec-lm.com

3 The cassette system

3.1 Intended purpose

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.

3.2 Product description

Besides the medical application, the cassettes facilitate the measurement of the vacuum in the aspiration line and provide full protection against contamination of the patient. The system forms a closed circuit and ensures that there is no contact between the circulating fluids and the Qube family. The following products are available for order:

STERILE ACCESSORIES FOR SINGLE USE:

REF	Description	Qube	Qube pro	eyeflexa		CE
03QA10 / 03QA10-2	Qube Cassette System, Standard	•	•	•	Bytec LM	0123
03QA11 / 03QA11-2	Qube Cassette System, IPC	•	•	•	Bytec LM	0123
03QA15	Cassette System without infusion line	•	•	•	Bytec LM	0123

3.3 Combination of products

Depending on the desired operating mode, there are various products to be combined in order to use the functionalities of Qube family. Following the necessary product combinations as well as the software settings are described for the operating modes *Standard* and *IPC*.

Operating mode	Necessary products	Software settings
Standard	03QA10 **or** 03QA10–2	IPC–Function inactive. FPA– Function inactive.
IPC	03QA11 **or** 03QA11–2	IPC– Function active. FPA– Function inactive.

The explanation of operation modes configuration of the user profiles can be found in the respective chapter of Qube family instructions for use.

3.4 Qube Cassette System Standard

The Qube Cassette System, Standard consists of the following components:

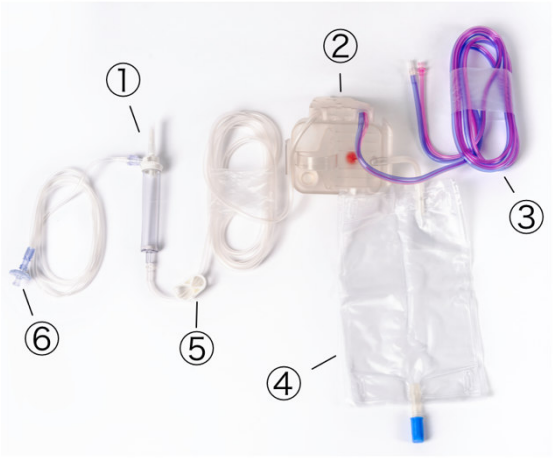
033

REF 03QA10 / 03QA10–2

1. Drip chamber with spike
2. Vacuum cassette
3. I/A–tube
4. Collection bag with drain valve
5. Clamp

3.5 Qube Cassette System, IPC

The Qube Cassette System, IPC consists of the following components:



034

REF 03QA11 / 03QA11–2

1. Drip chamber with spike
2. Vacuum cassette
3. I/A–tube
4. Collection bag with drain valve
5. Clamp
6. IPC–Connection line

3.6 Cassette System without infusion line (currently inactive)

In order to use the Infusion System FPA, it is mandatory to combine it with the Cassette System without infusion line (*REF 03QA15*). It consists of the following components:

1. Luer–Connector for infusion line
2. Vacuum cassette
3. I/A–tube
4. Collection bag with drain valve

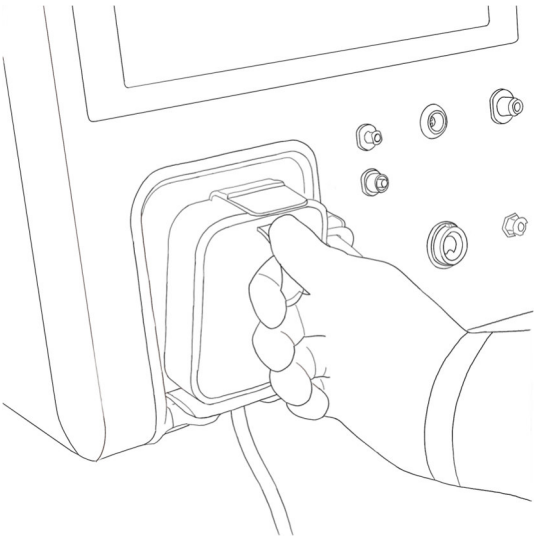
286

3.7 Infusion System FPA (currently inactive)

3.8 Application guidelines for Standard- and IPC-Operating Mode

Step 1:

Insert the lower part of the cassette into the guides of the cassette holder.



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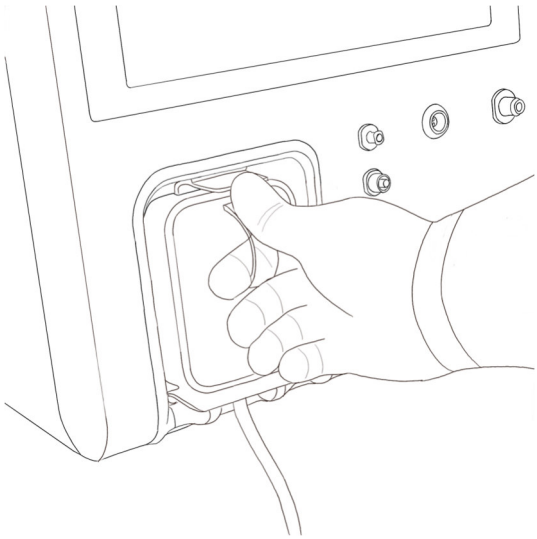
Step 2:

Swing in the cassette into the cassette holder until the lock mechanism clicks into place and the cassette is fixed within the holder.



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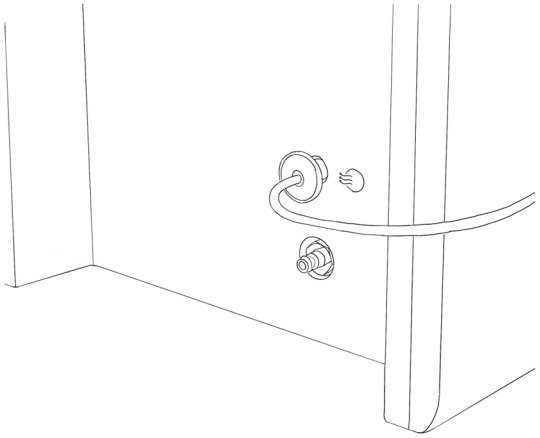
Step 3:

Connect the IPC–Connection line to the devices backside (only Qube Cassette System, IPC).



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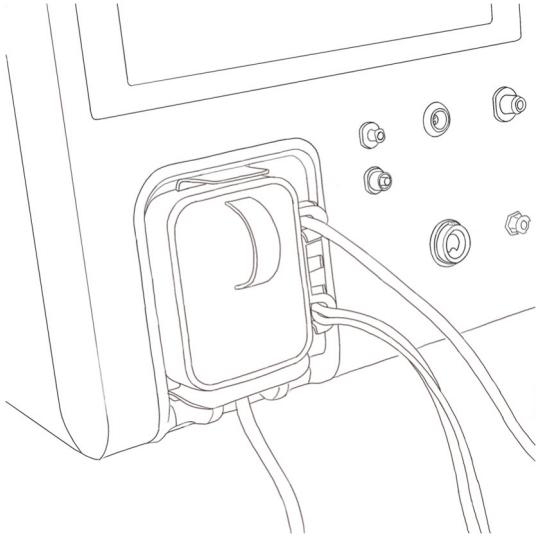
Step 4:

The inserted cassette will be recognized automatically by the switched-on system.



032

3.9 Application guidelines for FPA-Operating Mode (currently inactive)

3.10 Guidelines for bottle change in FPA-Operating Mode (currently inactive)

3.11 Removal

REMOVAL OF THE QUBE CASSETTE

Release the cassette, tip the *Unlock* button on the screen.

177

Confirm the unlocking of the cassette. Afterwards push down the cassettes lip and remove the cassette out of the cassette holder.

> ⚠ **CAUTION**
>
> The Qube family single-use cassette/tubing system as well as any disposable items must be exchanged for every new patient to eliminate the risk of infection.
>
> A31

> ⚠ **WARNING**
>
> The Qube family is equipped with a level sensor to detect if the cassette is full.
>
> Follow the instruction on the screen.
>
> A32

REMOVAL OF THE INFUSION SYSTEM FPA

Follow the instructions given in *3.10 Guidelines for bottle change in FPA-Operating Mode* and dispose used products.

4 The Phaco handle REF 02PH42

4.1 Intended purpose

The phaco handles are intended as accessories of eye surgery systems and in combination with other accessories to fragment and remove the natural crystalline lens during cataract surgery. They are not intended for bone segmentation or dental applications.

4.2 Product– and functional description

Phaco board and phaco handles for the Qube family are tailored to one another. For this reason, only the above mentioned phaco handle REF 02PH42 may be connected to the Qube family in combination with the accessories described. Please contact your sales representative if you have any further questions**.**
The following illustration shows the phaco handle with the phaco needle and sleeve ①, the handle ② and the connections for irrigation ③, aspiration ④ and power supply cable ⑤ for the ultrasound probe.

298

The service life of a phaco handle is not inherently limited by its construction but can be shortened considerably by external influences such as temperature fluctuations. The phaco handle must therefore cool down sufficiently after steam sterilization.

> **⚠WARNUNG**
> Modifications or incorrect handling of the phaco handle or the phaco needle (such as bending or engraving) can lead to malfunctions or even breakage of the phaco needle. Never touch the phaco needle while the phaco handle is activated as this can result in injury.
>
> A34

FUNCTIONAL DESCRIPTION

The surgery system generates an alternating voltage which causes the piezo crystal inside the handle to vibrate. These vibrations are transferred to the phaco needle

which can thus mechanically destroy the crystalline lens. A physiological saline solution runs through the handle and then is channeled along the needle aided by a sleeve. The removed lens particles are aspirated by the phaco needle and the phaco handle.

4.3 Preparation and reuse of the phaco handle

The phaco handle is delivered in unsterile condition and has to prepared accordingly to the instructions out of the general instructions for reprocessing before the first, and every following application.

> ⚠ **WARNING**
> It must be ensured that no cleaning agents or disinfectants are used that cannot be removed from the instrument cavities without leaving residues as this can lead to severe damage or hazing of the cornea.
>
> A13

4.4 Design and performance data

The phaco handle is designed for power electronics in the range of 40 kHz +/- 2000 Hz. The maximum alternating voltage is 300 V at a maximum amperage of 2 A.

4.5 Implementing electrical and functional safety measures

The implementation of electrical and functional safety measures can only be described in full in combination with the protective mechanisms of the relevant surgical system. Further information on surgical systems other than those of Ruck can be provided upon request. The phaco handles are equipped with a double earthing protection whose connection is monitored by the abovementioned surgical system. The use of plastic plugs additionally completely protects the system against short circuits. Connections for irrigation and aspiration lines cannot be mixed up due to the use male/female Luer connections in accordance with EN ISO 80369-7. The correct tubing systems are specified or described in the instructions for use by the respective surgical system manufacturers.

5 Accessories for phacoemulsification

5.1 Intended purpose

PHACO NEEDLES:

The needles are intended to fragment and remove the natural crystalline lens during cataract surgery.

PHACO WRENCH:

The wrenches are used to mount and unmount phaco needles on the tip of the ultrasonic phaco handles.

SLEEVES:

The sleeves are intended to perform irrigation in phaco procedure during cataract surgery (anterior eye segment).

TEST CHAMBER:

The test chamber is intended for functional checking of irrigation/aspiration flow for commencing before the intervention.

PHACO NEEDLE SETS:

- The needles are intended to fragment and remove the natural crystalline lens during cataract surgery.
- The sleeves are intended to perform irrigation in phaco procedure during cataract surgery (anterior eye segment).
- The test chamber is intended for functional checking of irrigation/aspiration flow for commencing before the intervention

SLEEVE SETS:

- The sleeves are intended to perform irrigation in phaco procedure during cataract surgery (anterior eye segment).
- The test chamber is intended for functional checking of irrigation/aspiration flow for commencing before the intervention

5.2 Product description

The accessories for the Qube family "phaco" operating mode are delivered in a sterile condition and are for single use. Alternatively, non-sterile and reusable accessories are available which must be processed and sterilized **before** use. The following products are available for order

STERILE ACCESSORIES FOR SINGLE USE:

REF	Description	Qube	Qube pro	eyeflexa		CE
03QP19-1	Phaco needle set 19G	•	•	•	Bytec LM	0123
03QP20-1	Phaco needle set 20G	•	•	•	Bytec LM	0123
03QP21-1	Phaco needle set 21G	•	•	•	Bytec LM	0123
03QP23-1	Phaco needle set 23G	•	•	•	Bytec LM	0123

Reusable non-sterile accessories:

REF	Description	Qube	Qube pro	eyeflexa		CE
02PH42	Phaco handle 'Titan', non-sterile	•	•	•	Lumed	0123
02PH58	Phaco wrench '5R', stainless steel, non-sterile	•	•	•	Bytec LM	•
03PH55	Phaco Tip `Turbo`, 30°, Ø 1,2 mm / Ø 0,7 mm (low bubble)	•	•	•	Bytec LM	0123
03PH60	Phaco Tip Fragmentation, 30°, 20G, Ø 0,85 mm / Ø 0,65 mm	•	•	•	Bytec LM	0123
03PH62	Phaco Tip `Turbo`, 30°, Ø 0,89 mm (low bubble)	•	•	•	RU Bytec LM	0123
03PH63	Phaco Tip `Mini Turbo`, 30°, (for incision size 1,8 mm)	•	•	•	Bytec LM	0123
03PH66	Phaco Tip Fragmentation 30°, 23G, Ø 0,60 mm / Ø 0,50 mm	•	•	•	Bytec LM	0123
03PH90	Test chamber	•	•	•	Bytec LM	•
03PH95	Silicone sleeve light blue, 19 G	•	•	•	Bytec LM	0123
03PH96	Silicone sleeve white, 20G	•	•	•	Bytec LM	0123
03PH97	Silicone sleeve transparent, 21 G	•	•	•	Bytec LM	0123
03PH98	Silicone sleeve orange, 23 G	•	•	•	Bytec LM	0123

COMPATIBILITY OF PHACO NEEDLES TO SLEEVE–SETS

Phaco needles		combinable Sleeve–Sets	
REF	**Description**	**REF**	**Description**
03PH55	Phaco Tip `Turbo`, 30°, Ø 1,2 mm / Ø 0,7 mm (low bubble)	03QP29-1 03QP31-1	Sleeve-Set 19G Sleeve-Set 19G CoolFlow
03PH62	Phaco Tip `Turbo`, 30°, Ø 0,89 mm (low bubble)	03QP30-1 03QP31-1	Sleeve-Set 20G Sleeve Set 21G
03PH62B	Phaco Tip bent 'Turbo', 30°, Ø 0,89 mm / Ø 0,5 mm	03QP31-1	Sleeve Set 21G
03PH63	Phaco Tip `Mini Turbo`, 30°, (for incision size 1,8 mm)	03QP33-1	Sleeve-Set 23G

5.3 Assembly of Phaco needles, Sleeve and Test chamber

All phaco needles supplied by Ruck are to be used in a sterile condition. Needles and accessories that are delivered in non-sterile condition must be treated accordingly to the instructions out of the general instructions for reprocessing. Use only phaco needles with the following technical data:

- Material: Titan
- Connection thread: 4/40 UNC
- Weight: 0.150 g +/- 0.030 g

Use a suitable wrench to screw the phaco needle onto the phaco handle REF 02PH42. Phaco needles supplied by Ruck are preassembled in the corresponding phaco wrench.

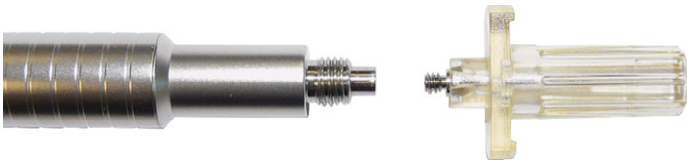
METHOD FOR ASSEMBLING THE PHACO NEEDLE, SLEEVE AND TEST CHAMBER

Step 1: Before assembling the phaco needle ensure that the needle is fully intact.

> ⚠ **WARNING**
> Check phaco needles for damage before mounting on the phaco handle. Phaco needles whose surface shows visible abnormalities or bending should never be used. In particular, the sonotrode contact surfaces and the threads of phaco needle and phaco handle must be clean and undamaged.
>
> A07

Step 2: Only use phaco wrenches recommended by Ruck to mount needles onto the handles.

Step 3: Screw the phaco needle tight to the phaco handle REF 02PH42 with an appropriate wrench.



Apply the wrench with the needle.

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Rotate clockwise until the needle is fully screwed onto the phaco handle.

300

Pull the phaco wrench off.

301

⚠ CAUTION

Please only use phaco wrenches approved by manufacturer Pay careful attention to the correct phaco wrench position and the necessary "frictional locking", otherwise there is a risk that the inner corners of the phaco wrench will be sheared off rendering the phaco wrench unusable.

A08

⚠ WARNING

Make sure that the phaco needle is screwed on tightly. If the phaco needle is not fully screwed tight, the phaco handle will pulse with low power even when pulsation is not activated!

A09

Phaco needles and their recommended sleeves are tailored to each other. For information on possible combinations, please refer to our current product portfolio, alternatively your sales representative will be happy to assist you.

Step 4: Now screw the sleeve onto the phaco needle.

Step 5: Please ensure the correct position of the sleeve as shown in the following illustration. The tip of the phaco needle should only emerge very slightly from the end of the sleeve.

302

Step 6: Put a test chamber on the sleeve.

303

5.4 Functional test of the assembled system

Step 1: Plug in the phaco handles connection line to the surgical system.

Step 2: Connect irrigation- and aspiration lines to the phaco handle.

Step 3: Check the system consisting of phaco handle, phaco needle, sleeve and test chamber thoroughly for external damage. Give special attention to possible damages to the cable insulation.

> ⚠ **WARNING**
>
> Phaco handles that do not pass the visual inspection must be discarded immediately! Please return these phaco handles to the manufacturer for inspection.
>
> A06

Step 4: Open the infusion line's tube clamp on the infusion set before starting the filling program.

Step 5: Start the surgical system's filling program. Check for sufficient flow of infusion fluid during the filling program. The flow is sufficient when the test chamber is filled and is not collapsed at the end of the filling process.

> ⚠ **WARNING**
>
> An insufficient flow of infusion liquid impedes essential cooling and leads to overheating of the phaco needle (also during the test program). The phaco needle can be damaged to the point of breakage.
>
> A10

Step 6: During the filling program, the handle's phaco function is also activated in the "phaco operating modes". Please check whether the noise occurring deviates from the usual level (volume, intensity, pitch)

Step 7: The phaco needle is subject to natural wear through usage. Therefore, please check if the tip is rounded, cracked or bent using a surgical microscope.

⚠WARNING

Bent or worn phaco needles must be replaced. The use of worn phaco needles will increase the duration of phaco surgery and cause the patient unnecessary stress.

A11

Step 8: After the functional inspection, the phaco handle is ready for use.

⚠WARNING

Phaco handles that do not pass the functional test must be discarded immediately. Please inform your sales representative or directly return the defective phaco handle for inspection to Ruck.

A12

5.5 Reprocessing of phaco needles, sleeves and test chamber

Phaco needles, sleeves and test chamber designed for single use must be disposed of after use.
Phaco needles, sleeves and test chamber that are suitable for reuse and supplied in a non-sterile condition must be treated accordingly to the general instructions for reprocessing before use.

5.6 Instructions for the surgeon

In order to avoid burning of the cornea during surgery, only phaco needles and silicone sleeves approved by Manufactuer should be used with our phaco handles.
Depending on the sleeve chosen, a cutting width of 1.8 mm to 3.2 mm is recommended for the surgical opening.
The residual risk of corneal burning is further reduced using 'turbo' type phaco needles, as their outer diameter is smaller than that of "standard" phaco needles and this enhances the infusion liquid flow through the silicone sleeve. Moreover, when using the turbo needle, the surgery can be performed with lower phaco power.
The use of inappropriate sleeves can lead to insufficient infusion fluid flow or no flow at all and/or to insufficient space between the phaco needle and silicone sleeve. Both of these can also lead to corneal burnings.

6 I/A–Handpieces and accessories

6.1 Intended purpose

I/A–Handpieces

The I/A-Handpieces are intended for ophthalmic anterior segment surgery for irrigation and/or aspiration during cataract surgery (anterior eye segment). They are used to remove pathological tissues or viscoelastic fluids while stabilizing the eye. Irrigation fluid can be irrigated if desired.

Sleeves

Please refer to the intended use given in the chapter *5. Accessories for phacoemulsification*.

Test chamber

Please refer to the intended use given in the chapter *5. Accessories for phacoemulsification*.

6.2 Product description

We offer mono-manual and bimanual handles for the irrigation and aspiration of liquids to and from the eye. Reusable I/A–Handpieces, sleeves and test chambers are supplied in a non-sterile condition and must be treated according to the general instructions for reprocessing before use! The following illustration shows a mono manual I/A–Handpiece:

1. Irrigation line
2. Irrigation connector
3. Sleeve
4. Angled tip
5. Aspiration connector
6. Aspiration line

304

Mono manual I/A–Handpieces are offered either with a fixed metallic sleeve or with a screw-on silicone sleeve

> ⚠ **WARNING**
> Never bend, cut or engrave the handpieces or their tips, as they could malfunction or break!
>
> A16

Only the I/A handles listed below with their accessories should be connected to the Qube family.

STERILE ACCESSORIES FOR SINGLE USE:

REF	Description	Qube	Qube pro	eyeflexa		CE
03IA53	Bimanual I/A set 21 G, aspiration opening Ø 0.35 mm	•	•	•	Bytec LM	0123

REUSABLE NON-STERILE ACCESSORIES:

REF	Description	Qube	Qube pro	eyeflexa		CE
02IA21-1	I/A Handle 21G, 45° angled tip (with sleeve)	•	•	•	Bytec LM	0123
02IA33-1	I/A Handle 19 G, Tip 45° Curved (with Sleeve)	•	•	•	Bytec LM	0123
02IA34-1	I/A handle 19 G; pointed 30° curved (with sleeve)	•	•	•	Bytec LM	0123
02IA36	Bimanual handle for aspiration 21 G (with roughened tip, aspiration opening Ø 0.25 mm)	•	•	•	Bytec LM	0123
02IA37	Bimanual handle for irrigation 21 G (with roughened tip, two irrigation openers Ø 0.5 mm)	•	•	•	Bytec LM	0123
03PH90	Test chamber	•	•	•	Bytec LM	•
03PH95	Silicone sleeve light blue, 19 G	•	•	•	Bytec LM	0123
03PH96	Silicone sleeve white, 20G	•	•	•	Bytec LM	0123
03PH97	Silicone sleeve transparent, 21 G	•	•	•	Bytec LM	0123
03PH98	Silicone sleeve orange, 23 G	•	•	•	Bytec LM	0123

6.3 Installation and testing the I/A–Handpieces

Step 1: Inspect the handle for external damage (e.g. tip bent differently, corroded metal).

Step 2: The tip is subject to natural wear through usage. For this reason, please check if the tip is rounded, cracked or bent using a surgical microscope.

Step 3:

- (only for handle REF 02IA34-1): Screw the silicone sleeve onto the tip and check the correct position under the microscope.
- (only for handle REF 02IA21-1): Align the irrigation openings of the sleeve with a 90° angle to the angled tip and slide the sleeve over the thread. This prevents the tip of the I/A handle from entering the irrigation port of the sleeve. Check the correct position of the sleeve under the microscope.
- (only for handles REF 02IA34-1 and REF 02IA21-1): Finally put the test chamber onto the sleeve.

Step 4: Please check for sufficient flow of infusion liquid during the surgical system's filling program.

After the functional inspection the I/A handle is ready for use.
I/A handles that do not pass the functional test must be discarded immediately. Please inform your Ruck sales representative or return the defective handle directly to Ruck for inspection.

6.4 Application procedure

A typical application procedure would be:

Step 1: After phacoemulsification, insert the handpieces (bimanual) or the handpiece (mono-manual) into the anterior chamber of the eye via the corresponding accesses. Now it is possible to remove cortex or other tissue from the eye.

Step 2: After implanting the intraocular lens, reinsert the handpiece(s) to remove the viscoelastic fluid from the anterior chamber.

6.5 Reprocessing of reusable I/A–Handpieces

I/A handles delivered in unsterile condition, suitable for reuse must be treated according to the general instructions for reprocessing before reuse.

7 Bipolar Diathermy

7.1 Intended purpose

Diathermy cables enable the function of selected diathermy instruments with the diathermy modules of Ruck surgery system.

7.2 Product description

This chapter describes the required accessories for the diathermy module of the Qube family. Diathermy pens and forceps are electrosurgical instruments which are used in surgery in or on the eye. The accessories that can currently be combined with the Qube family are supplied in a non-sterile condition and must be treated according to the general instructions for reprocessing before use. For Accessories which are not covered by legal manufacturer responsibility of Bytec LM, instructions for reprocessing are provided by the respective legal manufacturer.

> ⚠ **CAUTION**
> Please read the attached product information for all diathermy forceps and pens!
> A17

The following products are available for order:

STERILE ACCESSORIES FOR SINGLE USE: NA

REUSABLE NON-STERILE ACCESSORIES:

REF	Description	Qube	Qube pro	eyeflexa		CE
02BI46	Cable for bipolar diathermy, for plastic forceps and endothermic pencils	•	•	•	Med Contact	•

Pursuant to the MDD 93/42/EEC respectively MDR (EU) 2017/745, Bytec LM does not assume producer responsibility for the diathermy forceps and pens mentioned here. All accessory components have however been tested in combination with the Qube family for their safety and usability. The use of these products in combination with the Qube family has been expressly declared to be permissible.

7.3 Operation of the Diathermy function

Please connect the desired diathermy handpiece with the cable for bipolar diathermy REF 02BI46.

307

1. Plug diathermy handpiece
2. Plug device side

⚠WARNING

The performance of the diathermy device is largely dependent on the diathermy cable. Please only use the connection cable approved by Bytec LM!

A18

CONNECTING THE HANDPIECE ①:

Please ensure that the cable and the diathermy device are properly connected. The illustration shows the exemplary connection of diathermy cable REF 02BI46 with diathermy forceps REF 02BI61.

308

CONNECTING TO THE DEVICE ②:

Please now connect the device side connector of the diathermy cable with the socket of the surgical system. The socket is marked with the symbol on the left hand. While observing the locking groove the connector must be inserted until the clicking sound of the locking mechanism can be heard. The diathermy function is now ready for use.

168

⚠WARNING

The improper connection of electrosurgical components can be hazardous for the patient and the user!

A29

⚠ WARNING

Independent repairs or modifications can be hazardous for the patient and the user and are therefore not permitted.

A30

⚠ CAUTION

Recurring safety inspections (STK):
Alongside the device's diathermy module, a safety inspection of the diathermy accessories must also be performed every 12 months!

A20

7.4 Disconnection

Please disconnect the diathermy cable from the diathermy forceps or the diathermy pen. In the next step please disconnect the diathermy cable from the surgical system. To unlock the cable, it must be pulled directly on the device side plug itself, otherwise the cable, the plug or the socket might be damaged.

7.5 Reprocessing of bipolar diathermy accessories

For instructions on cleaning, disinfecting and sterilizing diathermy forceps and pens please refer to the accompanying product information.
The diathermy cable delivered in unsterile condition, suitable for reuse must be treated according to the general instructions for reprocessing before reuse.

8 Vitrectomy accessories

8.1 Product description

This chapter describes the required accessories for the vitrectomy module of the Qube family. The vitrectomy accessories that can currently be combined are supplied in a sterile condition and are intended for single use. The following products are available for order:

STERILE ACCESSORIES FOR SINGLE USE:

REF	Description	Qube	Qube pro	eyeflexa*		CE
03VI34	Infusion sleeve for pneumatic cutter	•	•	•	Peregrine	0344
AK-0208_AA	Cutter 20 G, Connector A-A	•	•	•	Aktive SRL	0477
AK-0208_AA2	Cutter Dual 20 G, Connector A-A	•	•	•	Aktive SRL	0477
AK-0238_AA	Cutter 23 G, Connector A-A	•	•	•	Aktive SRL	0477
AK-0238_AA2	Cutter Dual 23 G, Connector A-A	•	•	•	Aktive SRL	0477
AK-0268_AA	Cutter 25 G, Connector A-A	•	•	•	Aktive SRL	0477
AK-0268_AA2	Cutter Dual 25 G, Connector A-A	•	•	•	Aktive SRL	0477

*Vitrectomy functions are only available at combined surgical system.

⚠ CAUTION

Please read the attached product information for these products!

A21

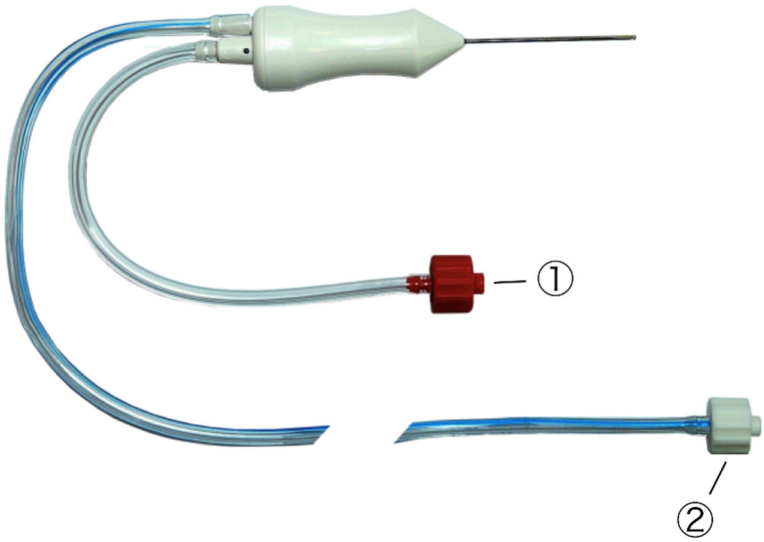
Pursuant to the MDD 93/42/EEC respectively MDR (EU) 2017/745, Bytec LM does not assume producer responsibility for the products mentioned in this section. All accessory components have however been tested in combination with the Qube family for their safety and usability. The use of these products in combination with the Qube family has been expressly declared to be permissible.

8.2 Connecting and applying pneumatic vitrectomes

Before unpacking and using the vitrectomes, please always check that the packaging is undamaged and use-by date has not expired.

> **⚠ CAUTION**
> When removing the vitrectome from its packaging, please make sure to take hold of it at the handle and not at the needle as the needle might bend.
>
> A22

The following describes the procedure for connecting the vitrectomes, which are supplied in a sterile condition with the appropriate connection tubes.



309

ASPIRATION CONNECTION ①:

Aspiration is performed via the short tube with the red Luer adapter ①. Please ensure that the short tube is connected to the central connection of the vitrectome housing. Now connect the Luer adapter of the short tube ① to the aspiration line of your I/A tube system.

COMPRESSED AIR CONNECTION ②:

154

Please connect the white Luer adapter ② of the long, compressed air supplying hose line with the Qube family pneumatic connection. The connection on the front side of the device is marked with the corresponding symbol.

⚠WARNING

Please make absolutely sure that the tube connections of the vitrectome are not mixed-up!

A23

⚠WARNING

Make sure you perform the tests described here before using the vitrectome!

A24

8.3 Operation of the vitrectome

Step 1: Check needle and cutting opening under a surgical microscope for external damage.

Step 2: Activate the vitrectome and check whether the cutting opening closes and reopens completely under the microscope at a low cutting rate.

Step 3: Fill the aspiration tube by placing the cutting opening into a bowl with a sterile infusion solution and activating the surgical systems aspiration function. If you notice any air bubbles coming from the cutting opening during this process, do not use the vitrectome under any circumstances!

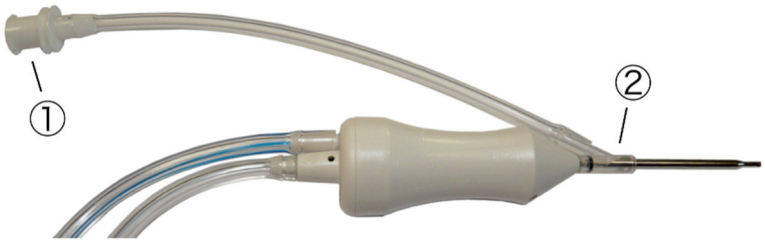
⚠WARNING

If any air bubbles emerge from the cutting opening, do not use the vitrectome under any circumstances!

A25

8.4 Using an infusion sleeve

INFUSION SLEEVE FOR 20 G VITRECTOMES:



310

With the pneumatic vitrectomes you can channel fluid directly into the eye with the aid of an infusion sleeve for pneumatic cutter ② (REF 03VI34). Put the infusion sleeve over the cutting tube of the vitrectome and connect the infusion tube of the I/A tubing system of the surgical system with the sleeves Luer adapter ①.

9 Irrigation and aspiration of silicone oil

9.1 Intended purpose

OIL INFUSION

The oil infusion unit REF 02OEL10 or 03QO10 are intended for use with a 10 ml silicone oil syringe to infuse viscous fluid into the eye (silicone oil tamponade). The connection between oil infusion unit 02OEL10 / 03QO10 and the eye surgery system is established via the connecting tube REF 02OEL32 / 03QO32.

OIL ASPIRATION

The Oil Aspirator (REF 03QO45) is designed for aspirate viscous fluid (silicone oil tamponade) out of the posterior eye segment in combination with a 20ml syringe and the aspiration line from the eye surgery device.

9.2 Product description

This chapter describes the required accessories for the Qube family "Viscous Fluid Injection and Removal (VFI)" module. This chapter does explicitly not apply for Qube as it is not equipped with the VFI–functionality. The VFI is for the exchange (irrigation and/or aspiration) of silicone oil. Sterile products for single use and alternatively products that can be reprocessed are compatible with the Qube family. The following products are available for order:

STERILE ACCESSORIES FOR SINGLE USE:

REF	Description	Qube	Qube pro	eyeflexa*		CE
03QO10	Oil injection unit single use	-	•	•	Bytec LM	0123
03QO32	Connection Tube Oil Injection, single use	-	•	•	Bytec LM	0123

Detailed instructions on single use products are included in a booklet which is part of your delivery on order.

REUSABLE NON-STERILE ACCESSORIES:

REF	Description	Qube	Qube pro	eyeflexa*		CE
02OEL10	Oil Injection Unit	-	•	•	Bytec LM	0123
02OEL32	Oil Injection Unit	-	•	•	Bytec LM	•

*VFI functions are only available at combined surgical system.

9.3 Oil infusion using the oil infusion unit

The oil infusion unit consists of a syringe holder with screw connection and Luer-lock-connection. The plastic syringe is sealed by one O-ring and one flat gasket. The unit is delivered in non-sterile condition.
Before use, the Oil Infusion Unit and corresponding accessories are to be treated according to the general instructions for reprocessing.

Screw connection 311

Flat gasket 312

O-Ring 313

Syringe holder 314

9.4 Operating the oil infusion unit

The oil infusion unit is for use with a 10 ml plastic syringe filled with silicone oil in combination with the Qube family. When using an injection system, make sure that the supply connection, syringe and infusion cannula are properly connected.

Step 1: Without exception use only reprocessed products. Make sure that all components are present and that the gaskets are undamaged.
Step 2: Ensure that the oil infusion function (VFI) is activated.
Step 3: Put the syringe filled with silicone oil on the syringe holder (fig. 315).
Step 4: Position the flat gasket in the screw connection.
Step 5: Place the screw connection above the syringe and screw it down tightly (fig. 316).
Step 6: Connect the pneumatic supply 02OEL32 to the pneumatic connector of Qube family and the luer-lock-connector the oil infusion unit.
Step 7: Remove the front syringe cap and connect an injection system.
Step 8: Rotate the assembly slowly until the syringe faces upwards. Remove any air bubble from the syringe and injection system by lightly depressing the foot pedal. Absorb discharged silicone oil with a sterile swab.
Step 9: Start the infusion with low pressure initially.

315

316

9.5 Reprocessing of VFI accessories

The articles oil infusion unit and connection tube delivered in unsterile condition, suitable for reuse must be treated according to the general instructions for reprocessing before reuse

Step 1: Slacken the connection between screw connection and syringe holder.
Step 2: Discard single use products
Step 3: Remove the flat gasket.
Step 4: Proceed according to reprocessing instructions.
Important: Do not reassemble before reprocessing! Make sure not to lose separated components.

It is not permissible to clean tube systems and syringes that have been in contact with silicone oil. Ruck therefore recommend that infusion cannulas and syringes be used as single-use articles.

10 Air Fluid Exchange

10.1 Intended purpose

The AFX set is intended for introducing air or infusion-solution into the eye (during a vitrectomy). It is attached to the air outlet of the ophthalmic surgery system Qube pro as well as to the irrigation line of the cassette system (infusion fluid supply)

10.2 Product description

Air-Fluid-Exchange controls the transition between an air (gas) filled eye to a water (fluid) filled eye and vice versa. The following products are available for order:

STERILE ACCESSORIES FOR SINGLE USE:

REF	Description	Qube	Qube pro	eyeflexa*		CE
03QF10	AFX Set, single use	-	●	●	Bytec LM	0123

*AFX functions are only available at combined surgical system.

Detailed instructions are included in a booklet which is part of your delivery on order.