

Instructions for use and reprocessing I/A Bimanual and I/A Monomanual

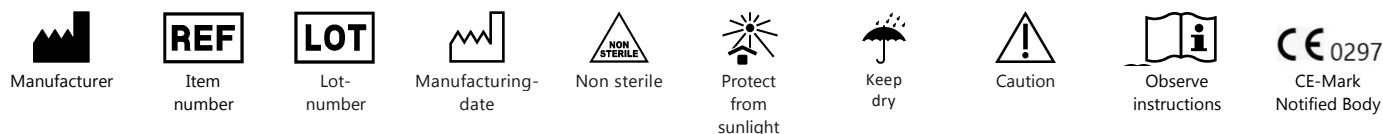


H.P. Braem AG
Industriestrasse 4
9552 Bronschhofen
Schweiz

T: +41 (0)71 866 19 33
F: +41 (0)71 866 19 80
E: info@hpbraem.ch
W: www.hpbraem.ch

Precision is our passion

Symbols



I/A Bimanual and I/A Monomanual (REF)

Bimanual	Monomanual					
40300	Monomanual Handpiece		Monomanual Tips		Monomanual Sleeves	
40301			40401 40402 40403		10215 10255	
40302	40400		40404 40405 40411		10216 10256	
			40412 40416 40417		10217 10257	

This Instruction For Use does not replace the instruction manual of the control unit in use. Read this Instruction For Use or contact H.P. BRAEM AG or your distribution partner for further information.

Intended Use

Bimanual / Monomanual are used for anterior chamber surgery. To do this, they are connected to an aspiration/irrigation unit via a tubing set.

Potential risks

Infectious endophthalmitis, TASS, intraoperative suprachoroidal haemorrhage, cystoid macular oedema (CME), retinal detachment, leaking wound, persistent corneal oedema, IOL dislocation, ptosis, corneal decompensation, diplopia, and blindness.

Intended User



Bimanual / Monomanual may only be used by medical professionals with appropriate training and experience.

It is explicitly pointed out that the use or application of Bimanual / Monomanual is at the discretion of a specialist or the doctor. The specialist must decide when the effectiveness of the intended use is given.

Local laws must be followed when reporting serious incidents

General safety instructions

- Before every use, verify if the products are damaged.
- Protect instruments from mechanical damage. In particular, do not bump tips. Handle instruments with care, do not drop or even throw them.
- Do not aspirate or add silicone oil.
- Damaged instruments must not be used.
- Do not modify the product.
- Any modification will result in the exclusion of liability by H.P. BRAEM AG and the warranty will be forfeited. (Guarantee: 12 months).
- The shipping or transport should only take place in the original packaging or in a package which offers equivalent protection.

1. Prior to any surgery

1. Bimanual / Monomanual must be reprocessed before each use (including the first).
2. Connect the tips firmly to the handpiece with the bayonet lock.
3. Connection: the aspiration tube is connected to the male luer, the irrigation tube to the female luer.
4. Prior to any surgery, fill the Bimanual / Monomanual completely with sterile solution.
5. Check the operative readiness of the Bimanual / Monomanual prior to medical intervention by conducting a test run!
6. Never perform a test in the patient's eye.

2. Immediately after each use, at the latest within 30 minutes

Instruments with lumens: Immerse the point of the equipment still installed in the surgical unit immediately after use into a bowl with demineralised solution. Activate the instrument

for approx. 10s in order to vacuum off tissue remnants.
or:
Flush the instrument with the point installed from the

connections with distilled or demineralised water by means of a single use syringe (at least 50ml volume) and blow dry with compressed air afterwards.

Reprocessing may only be carried out by qualified personnel.

General information on cleaning

- H.P. BRAEM AG recommends a machine procedure (Washer-Disinfector appliances, WD) for cleaning/disinfection. Based on obvious inferior repeatability of a manual procedure, it should be applied only upon unavailability of a machine procedure. Subsequent a manual cleaning will lead to a shorter life time.
- Do not use sharp or abrasive material for cleaning!
 - Ensure that distilled or demineralised water with sufficiently low endotoxin and particle burden is used for the final rinsing only.
 - Cleaning and sterilization shall be carried out according to a validated procedure.
 - After use, detergents and disinfectants shall be washed away by following the instructions exactly!
 - Please consider the instructions for use of the disinfectors/autoclaves/sterilizers to be used.

- Please pay attention to the relevant regulations valid in your country, as well as the to the hygiene requirements of the doctor's office or hospital. In particular to the various requirements regarding effective prion inactivation.
- Suitable for cleaning in an ultrasonic bath.
- To avoid adherence of blood or – proteins, cleaning with a soft tissue or a soft synthetic brush under running water shall take place in a first step. Aldehyde free disinfectants can be used for this purpose.
- Possible cleaning solution: neodisher®MediClean forte (DR. WEIGERT).
- Ensure the cleaning program applied has been validated. It shall include sufficient rinsing process cycles for the products to be cleaned. The validated parameters shall be monitored while processing.

- When cleaning and disinfecting, make sure that all lumens are well flushed.
- Disassemble the Monomanual before cleaning / disinfection and clean / disinfect separately.
- Place the handpiece and accessories in a suitable disinfector basket.
- Avoid overfilling instrument trays and wash trays.
- Ensure that no parts, especially the tip, protrude from the basket to avoid damage from the WD.
- Caution: The instrument should be placed on a nonslip surface. Contact of instruments with one another or with the container must be avoided.
- Ensure that the air used for drying is filtered.



3. Cleaning and disinfection – within a maximum 2 hours after pretreatment

- Start a verified programme suitable for the instruments with preferably thermal disinfection (at least 10min at 93°C) that performs a final rinse with distilled or fully demineralised water and provides for sufficient product drying with filtered drying air.
- Connect the Bimanual / Monomanual to the rinse connection of the disinfector by means of Luer with suitable connecting hoses.
- Remove the instruments from the disinfector immediately after the programme has ended.
- Examine the products for visible dirt, wear, and damage.

Validated machine cleaning and disinfection process:

Steps	°C	Chemistry	Sec
Pre-rinse tap water	<30		60
Cleaning tap water	40	Mediclean Forte 1.0% Dosing temperature 40° -	600
	60	Increase temperature to 60°	
Neutralize tap water	<30	Neodisher N 0.15%	60
Rinse tap water	40		60
Disinfection Disinfectant	95		600
Dry	90		600

Disinfection device, Miele Cie. GmbH & Co.

- If defective, do not use the products!
- If necessary, repeat the cycle.

4. Packaging

- After cleaning and disinfection, directly pack the products.
- Protect products from damage when sterilising!
- We recommend the use of a sterilisation tray with suitable positioning aids.
- Pack the products thus prepared into a sterilisation container

and/or single use sterilisation packaging (single or double packaging) made of paper / plastic according to DIN EN 868/ANSI AAMI ISO 11607.

5. Sterilization

- H.P. BRAEM AG recommends steam sterilization according to DIN EN 13060 / DIN EN 285, validated according to DIN EN 554/ANSI ISO 11134. Steam sterilisation: fractionated vacuum method, holding time 5-20 min at 134°C.
- The use of other sterilization methods is beyond the responsibility of H.P. BRAEM AG.
- Sterilise only cleaned and disinfected products.
 - Sterilization should be carried out in a sterilization cassette.

Validated sterilization process

Steps	°C	Cycle type / Method	Min
Sterilisation	134	full cycle	5-20
		fractionated vacuum 1	



- Do not sterilize in hot air.
- Do not perform plasma, EtO, or formaldehyde sterilization.
- Sterilisation in the original packaging is not permissible.
- Do not expose products to temperatures above 138°C.


6. Storage

Instruments should be stored in a clean, dry environment. They should be stored individually in their packaging or in a protective container with compartments for individual storage.

7. Maintenance by the customer

If the O-rings on the monomanual tips are defective, they can be replaced (by qualified personnel) (REF40490).

8. Life time

-  Bimanuals, / Monomanual handpieces and Monomanual tips may be reprocessed max. 100 times, Monomanual sleeves max. 10 times. The lifetime of the instruments is limited to a maximum of 9 years.