Instructions for use and reprocessing Ultrasonic (U/S) handle 28kHz and accessories Phaco

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Precision is our passion

Symbols

Manufacturer	Item number	Lot number	Serial number	Manufacturing date	Non-sterile	Protect from sunligh	Keep dry	Caution	Observe Instructions	CE-Mark Notified Body
	REF	LOT	SN		NON STERILE					CE 0297

Handpiece, accessories and serial number (REF)

Handpiece
12300
12350 (G & B type)

Set

12406	12407	12408
12409	12411	12412

Tips

12318	12319	12320
12321	12322	12323
12324	12333	10302

Sleeves

10215	10216	10217
10255	10256	10257

Key
10115 10116

Test chamber
10102

Technical data

The 28kHz handpiece can be operated with Phaco-devices with the following technical specs:

Operating voltage:	max. 250 V (RMS)
Operating frequency:	27.0 to 30.0 kHz
Power input:	max. 54 W

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 supplier for further information.

Intended Use

Phacoemulsification (phaco) Handpieces and their accessories are intended for phacoemulsification in cataract surgery.

Intended User

Phaco handpieces and accessories may only be used by medical professionals with appropriate education and experience in ophthalmic procedures.

The medical specialist decides on effective application. The doctor must clarify the suitability of the patient for the use of a phacoemulsification before the procedure. Local laws must be followed when reporting serious incidents.

Potential risks

- Potential risks of ophthalmic surgery: capsular tear, infection, edema, increased intraocular pressure.
- Infection due to insufficient cleaning or sterilization of handpiece and accessories.
- Extended surgery time due to reduced performance of a damaged handpiece.
- Extended surgery time due to non-sharp ultrasound tip caused by incorrect application or reprocessing
- The doctor is responsible for the correct selection of the appropriate instruments for each patient.

General Safety Instructions

- Examine products for damage before every use.
- Never activate the handle when dry or without an ultrasonic tip (danger of overheating/damages!).
- Protect instruments from mechanical damage. In particular do not bump attachments (points, cutting tips, ...). Put instruments down with care, do not drop or even throw them.
- After sterilization, use the ultrasonic handpiece only after it has cooled down to room temperature. Cooling should not be accelerated by rinsing with cold water.
- During activation, never touch the ultrasonic tip or touch any other instrument with it.
- Do not aspirate or irrigate silicone oil.
- Damaged instruments must not be used (such as bent or defective tips).
- Do not modify the product, e.g. to bend or bend back an ultrasonic tip.
- Any modification will result in the exclusion of liability by H.P. BRAEM AG and the warranty will be forfeited. (Guarantee: 12 months).
  - Do not kink or wrap the cable tightly e.g. around the handpiece.
  - Never pull on the cable (e.g. when preparing for cleaning).
  - Never remove the plug from the socket by pulling on the cable.
- The shipping or transport should only take place in the original packaging or in a package which offers equivalent protection.

Compatibility

Tips, sleeves, and sets from H.P. BRAEM AG are tested and approved for use on handles from H.P. BRAEM AG, Oertli®, Geuder®, D.O.R.C.®, Bausch+Lomb® and Hoya-Ruck®.

Life-time

A handpiece may be reprocessed a maximum of 200 times, tip, and metal key a maximum of 100 times, sleeves, and test chamber a maximum of 10 times.
The lifetime of the instruments is limited to a maximum of 9 years.

1. Prior to any surgery

1. Handpiece and accessories must be reprocessed before each use (including the first).
2. Tighten the REF10116. The aspiration tube is attached to the central luer of the handpiece. The irrigation tube is connected to the lateral luer. ultrasonic tip firmly with the key: For bent tips only use the key.

The luer connections may only be connected to a fluid exchange system for ophthalmic use.

3. Place the sleeve over the tip.
4. Position the sleeve level with the tip.
5. Attach test chamber for primers/test run.
6. Before each use, completely fill the tubing system, handpiece with ultrasound tip and sleeve with sterile solution.
7. Check the operative readiness of the instruments prior to medical intervention by conducting a test run! There-fore, use the test chamber. 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).

- Immediately after use, put the protective cap on the handpiece to protect the ultrasound tip and silicone sleeve from damage.

Reprocessing: cleaning, disinfection, and sterilization (EN ISO 17664)

Reprocessing may only be carried out by qualified personnel

General information on cleaning

H.P. BRAEM AG recommends a machine procedure (Was-her-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!
- For operation, please refer to the respective operating instructions for the devices (disinfectors/autoclaves/sterilizers) 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.
- 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.
- Remove the ultrasonic tip and sleeve from the handpiece 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.
- Make sure that the air used for drying is filtered.

- The instruments are not intended for cleaning in an ultrasonic bath!
- Do not dry with compressed air.

3. Maschinell: Reinigung und Desinfektion – innerhalb von höchstens zwei Stunden nach Vorbehandlung

- 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 handpiece, tip, and sleeve to the rinsing connection of the disinfector using suitable connecting hoses.

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° - Increase temperature to 60°	600
	60		
Neutralize tap water	<30	Neodisher N 0.15%	60
Rinse tap water	40		60
Desinfection Disinfectant	95		600
Dry	90		600

Disinfection device, Miele Cie. GmbH & Co.

- Remove the instruments from the disinfector immediately after the programme has ended.
- Examine the products for visible dirt, wear, and damage.
- If defective, do not use the products!
- If necessary, repeat the cycle.
- Do not dry with compressed air.

4. Packaging

- After cleaning and disinfection, directly pack the products.
- Protect products from damage when sterilising!
- We recommend the use of a sterilisaton 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.

- 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.