Instructions for use and reprocessing for cryoprobes

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Precision is our passion

Symbole

Manufacturer | Item number | Serial number | Protect from sunlight | Follow the instructions | Caution | CE 0297 Notified body

This instruction applies to the following cryoprobes

REF Invasive Cryoprobes

22068	Retina probe for infants Ø 1.6 mm / 60°
22072	Retina probe ball Ø 2.5 mm / 60°
22074	Retina probe ball, bulb Ø 2.5 mm / 60°
22076	Retina probe ball, long 2.5 mm / 60°
22080	Retina probe ball Ø 3 mm / 90°
22084	Glaucoma probe Ø 3 mm / 70°
22088	Retina probe spatula bent, 4 mm / 60°
22090	Retina probe spatula straight, 4 mm
22092	Trichiasis probe, 4 mm x 10 mm

REF Surgically Invasive Cryoprobes

22060	Cataract probe straight,, Ø 2 mm
22064	Cataract probe bent, Ø 2 mm
22096	Endo Cryo probe straight, Ø 0.9 mm

Intended Use

The cryoprobes are intended for cryonecrosis, inflammatory response and for cryoadhesion purposes.

Indications

Retina ablatio / retinal fissures, glaucoma, proliferative diabetic retinopathy, lens extraction / cataract, ectopia lentis, premature retinopathy, trichiasis.

The physician is solely responsible for the appropriate cryoprobe selection to be used for patient treatment.

Contraindications

- The physician must clarify the patients suitability for a cryo-medical treatment (medical examination) prior to medical intervention.

Intended User

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

Local laws must be followed when reporting serious incidents.

Potential risks

Known risks associated with the general application of cryoprobes:

- Infection caused by insufficient cleaning or sterilization of the cryoprobe.
- Eye necrosis caused by prolonged exposure to freezing temperature.
- Injury caused by medical treatment of a wrong location.
- Injury caused by using a defective cryoprobe.

Potential side effects of ophthalmologic surgery in general

Infections, edema, increase of intra-ocular pressure.

Precautions for therapeutic use

- Ensure precise positioning of the cryoprobe to avoid injury to other structures.
- Limit time of applying freezing temperature to the minimum required for therapeutic success.
- Restrict the number of repeated freeze-thaw cycles to those therapeutically necessary.

The listed cryoprobes are compatible with the following control units

Product	Manufacturer
ERBOKRYO AE (10731)	ERBE Elektromedizin GmbH
ERBOKOMBI E (10732)	ERBE Elektromedizin GmbH
Cryo-Line (131002)	Optikon 2000 S.p.A

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.

General safety instructions

- Never unplug the device by pulling the devices cables.
- The cryoprobes must be protected from mechanical damage.
- Roll up the hoses loosely, do not kink them.
- Handle the cryoprobes with care, do not drop or throw them.
- Avoid any hard mechanical impact on cryoprobe tip.
- Clamping the probe tubing in the drawer, standing on the tubing, passing over the tubing with equipment trolleys and other similar incidents can lead to invisible defects inside the tubing.
- Upon named event the cryoprobe cannot be used any longer and shall be sent to the manufacturer for inspection purposes.
- The shipping or transport of the cryoprobe shall take place in the original packaging or in a package which offers equivalent protection.
- Do not modify the cryoprobe. Any modification will result in the exclusion of liability by H.P. BRAEM AG and the warranty will be forfeited. (Guarantee: 12 months).

1. Prior to any surgery

Cryoprobe must be reprocessed before each use (including the first).

Check the operative readiness of the cryoprobe prior to medical intervention by conducting a test run!

- Check the gas pressure on the control unit. Do not use cryoprobes when gas pressure is above 60 bar.
- Cryoprobe, connectors, hoses and O-rings must be checked for damage.
- The cryoprobe must be checked for leaks and its freezing ability. For this purpose, the cryoprobe tip is placed in sterile water.
- If the cryoprobe head is mechanically damaged (bent or twisted) or damaged on the surface, the cryoprobe cannot be used any longer.

2. During surgery

- Observe the temperature of the cryoprobe (if present) on the display of the cryogenic unit.

3. Pre-treatment immediately after each use, at the latest within 30 minutes

- Rinse the tips directly after surgery with distilled or demineralised water.
- Wipe the cryoprobe tip with a soft cleaning tissue.

4. After surgery

- Do not disconnect the cryoprobe from the control unit before its completely defrosted.
- Right after clinical use, attach the protective cap (REF22040) to the gas connector and lock the bayonet lock by turning it. During the entire preparation, the protective cap must be closed correctly.
- Moisture entering the tubing system may cause malfunctions!
- No liability will be assumed if the protective cap (REF 22040) is not fitted correctly. An incorrect fitted sealing cap (REF 22040) may result in the exclusion of liability by H.P. BRAEM AG and the warranty will be forfeited.

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 (Washer-Disinfector appliances, WD) for cleaning/disinfection. Based on obvious inferior repeatibility 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.
- The cryoprobe is not intended 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 that the cleaning program used corresponds to a validated procedure and contains sufficient rinsing processes for these products and that the validated parameters are observed for each cycle.
- Place the cryoprobe 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.
- Ensure that the air used for drying is filtered.

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

Machine cleaning / disinfection

- 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.
- Remove the cryoprobe from the washer-disinfector immediately after the programme has ended.

Validated machine cleaning and disinfection process:

Precleaning with a soft brush under cold water (=tap water <40°C with drinking water quality) to remove gross contamination. Automatic reprocessing was carried out in Miele Disinfector G7835 CD, program ´Des-Var-TD` with the Mobile Injector Unit E450/1.
Two pre-cleaning steps (à 1 min. and à 3 min.) were carried out with cold water (<40°C).
A first washing step at 45°C +1°C/-1°C for 5 min (neodisher®MediClean forte, alkaline, 0.5%) was followed by a second washing step at 55°C +1°C/-1°C for 5 min (Neodisher Mediclean forte, alkaline, 0.5%). These steps were followed by two washing steps: once for 3 min with cold water (<40°C) and then for 2 min with cold deionised water (<30°C). This was followed by 10 minutes of thermal disinfection (Ao>3000, EN ISO 15883-1:2014) with >93°C +2°C. The automatic reprocessing process was finished with a drying step (program parameter: 30 min, 90°C +/- 2°C).

6. Post control of cleaning and disinfection

- Examine the cryoprobe for visible dirt, wear and damage.
- If defective, do not use the products!
- If necessary, repeat the cycle.
- Mount the white PVDF protective sleeve to protect the cryoprobe tip (caution: do not confuse with the sealing cap REF 22040).

7. Packaging

- 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 EN 868/EN ISO 11607-1.
- Do not kink the hose of the cryoprobe, just roll it up loosely.

8. Sterilization

H.P. BRAEM AG recommends a steam steriliser according to EN 13060 or EN 285 and process validation according to EN ISO 17665-1. 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.
- 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.
- After sterilization, allow the probe to cool to room temperature.

Validated sterilization process

The packaging was done with sterilization bags KC300 Kimguard One-Step from Kimberly Clark. These were placed in an Aesculap sterile container. Sterilization parameters (moist heat, partial cycle, autoclave Tuttnauer 3870 EHS): 3 prevacuum steps, holding time 2.5 min. at 134°C, drying step for 20 min.

9. 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.

10. maintenance by the customer

If the O-rings are defective on the gas adapter, these can be replaced (qualified personnel), see the enclosed spare parts (REF60022).

Life time

The lifetime is limited to 2 years or 100 cycles: decisive is the event that arrives earlier. The probe must then be sent to the manufacturer for inspection.