CRYOSURGERY

ERBECRYO® 2

an evolutionary step in Bronchoscopy & Interventional Pulmonology

Our flexible cryosurgical technology has been adopted in medical practice for more than two decades and continues to evolve in therapeutic and diagnostic applications in pulmonology.

Routine clinical applications include cryoextraction and cryodevitalization.

Cryoextraction
enables the removal of foreign bodies, mucus plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization) and tissue biopsies.

Cryodevitalization
enables destruction of tissue by the application of extreme cold.

The new ERBECRYO® 2 and accessories were developed based on our latest expertise in flexible cryo technology and supported by decades of our practical experience in cryosurgery and cryotherapy.

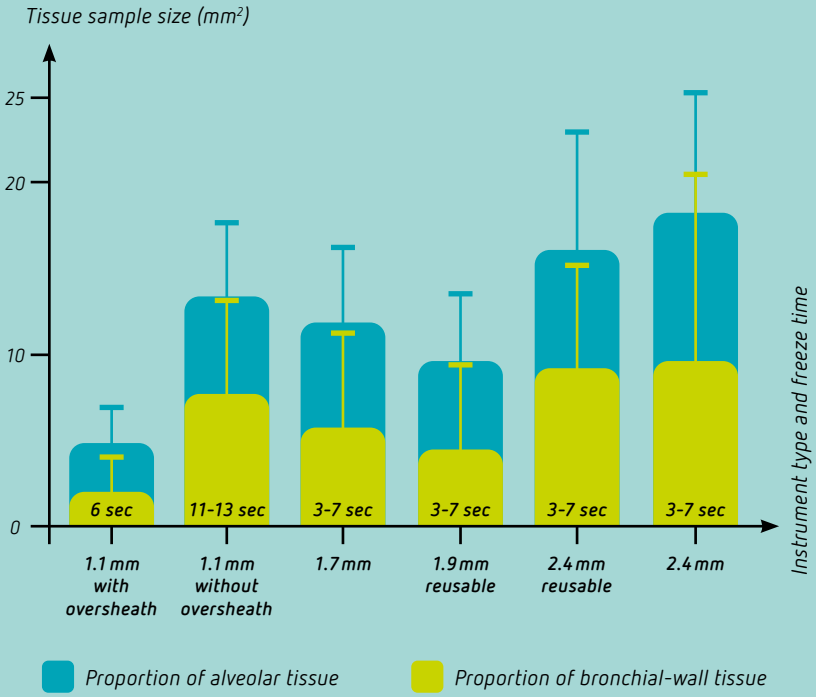
The ERBECRYO® 2 provides several new features intended to improve clinical convenience for the user and to support state-of-the-art clinical results.

Multi-modal workstation:
VIO® 3 – Electrosurgery
APC® 3 – Plasmasurgery
ERBECRYO® 2 – Cryosurgery

Design integration – the pulmonology workstation

The ERBECRYO® 2 can be combined on one cart with our VIO® and APC® devices. This multi-modal system facilitates multiple applications in Bronchoscopy & Interventional Pulmonology, supports handling convenience and saves space.

Improved freezing performance



Hetzel et al.; Evaluation of Efficacy of a New Cryoprobe for Transbronchial Cryobiopsy: A Randomized, Controlled in vivo Animal Study; Respiration 2020

Additional data on file

The gas – carbon dioxide only

The ERBECRYO® 2 is designed and optimized to be used with CO_2 gas only. This configuration helps to standardize clinical results worldwide with a non-narcotic, user-friendly gas.

Flow control – improved reproducibility with every probe

The optimal amount of gas which runs through a probe is important for the system's performance. The flow control of the ERBECRYO® 2 provides just as much gas as the probe needs to reach it's maximum freezing power – for every probe size. Furthermore, it saves gas and provides reproducible freezing results which supports standardization.

Technology – focus on reproducibility

The ERBECRYO® 2 unit together with flexible single-use probes is the next generation of Erbe cryo technology that is designed with a focus on improved reproducibility.

Plug and operate – system communication

Once connected, the system automatically detects the size of the cryoprobe. The flow control then sets the right parameters for an optimal freezing result based on probe size. Additionally, the gas bottle and footswitch connections are actively monitored.

Error management – system feedback

The plug and operate design enables real–time troubleshooting, which resolves connection malfunctions, errors in gas flow and other possible unit errors. The flow control can detect malfunctions of the unit and the probes which helps to identify the source of failures.

Timer – clinical standardization

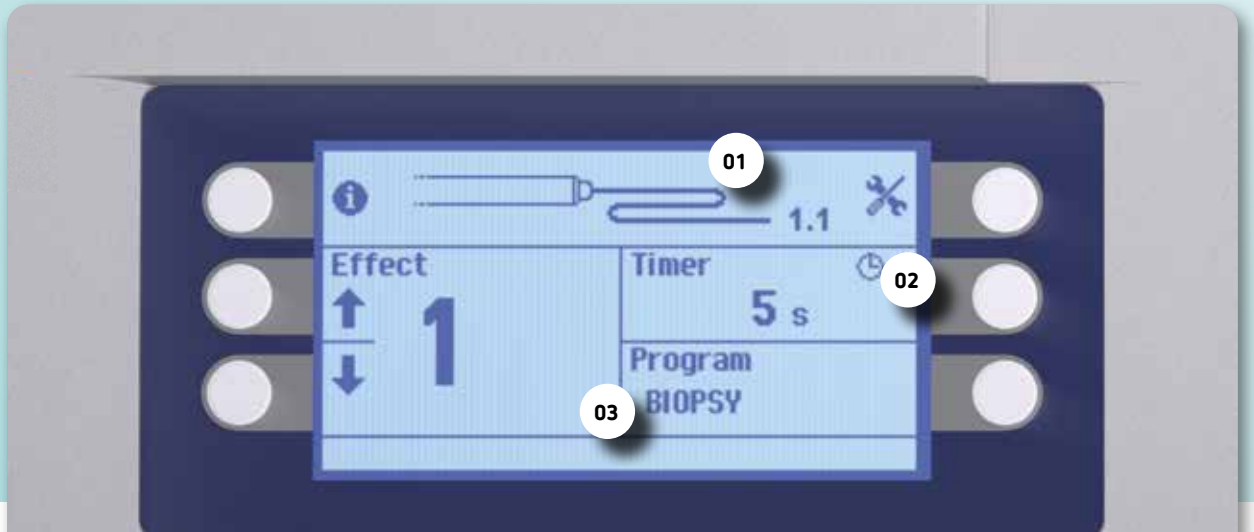
The timer provides visual and acoustic feedback of the freezing time. This supports standardization and reproducibility as the freezing time is a highly relevant factor of cryo target tissue effect.

Design – improved convenience

The new socket design allows the connection of the cryoprobes with just one push. The digital display gives the user an overview of all important working parameters.

All important information and setting options are shown on the new digital display:

01 Probe information, e.g. size **02** Visual and acoustic timer **03** Program settings



Standardization – single-use cryoprobes

The flexible single-use cryoprobes are available in various sizes. They can be used for various clinical applications such as palliative tissue devitalization and extraction of foreign bodies, mucous plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization) and tissue biopsies.

ENHANCED CLINICAL UTILITY

- ☑ The consistent technical performance supports
  → Consistent target tissue effects
  → Improved reproducibility
  → Improved standardization
- ☑ Expanded compatibilities (e.g. mini bronchoscopes and navigation catheters) and enhanced clinical utility due to miniaturization
- ☑ Enhanced ergonomics and handling characteristics
- ☑ No reprocessing
  → Saves time and cost
  → Reduces risk of cross-contamination

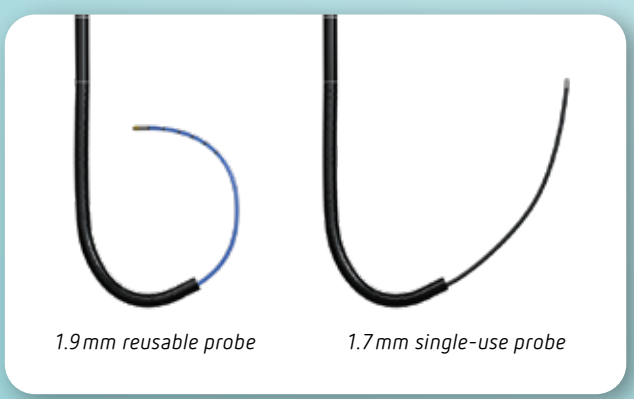
Removal tool – support of procedural convenience

The removal tool can be used to release a biopsy from the cryoprobe. This helps to standardize and expedite the biopsy process.

Handling

Single-use cryoprobes provide the following improved characteristics:

- → Enhanced shape memory
- → Slim, light and ergonomic design
- → Atraumatic tip design for smooth positioning and maximum freezing performance
- → Redesigned plug for ease of connection and disconnection
- → Architecture which supports positioning by easy identification under fluoroscopic guidance

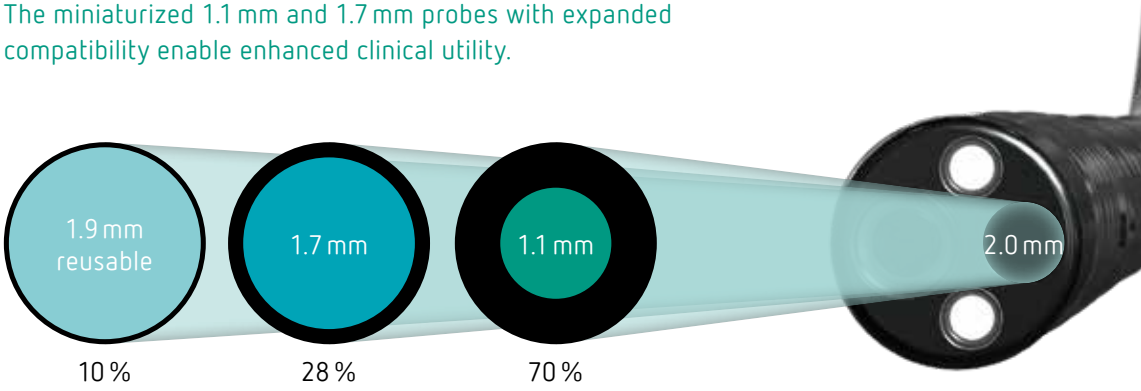


1.9 mm reusable probe *1.7 mm single-use probe*

The new portfolio includes three single-use probes with diameters of 1.1, 1.7 and 2.4 mm for expanded application possibilities. Several key elements enable a slim, light and ergonomic design.

Miniaturization

The miniaturized 1.1 mm and 1.7 mm probes with expanded compatibility enable enhanced clinical utility.



Free working channel area with inserted probe in %.

2.0 mm channel

Flexible cryoprobe, OD 1.1 mm, L 1.15 m
with oversheath, OD 2.6 mm, L 817 mm

Flexible cryoprobe, OD 1.7 mm, L 1.15 m

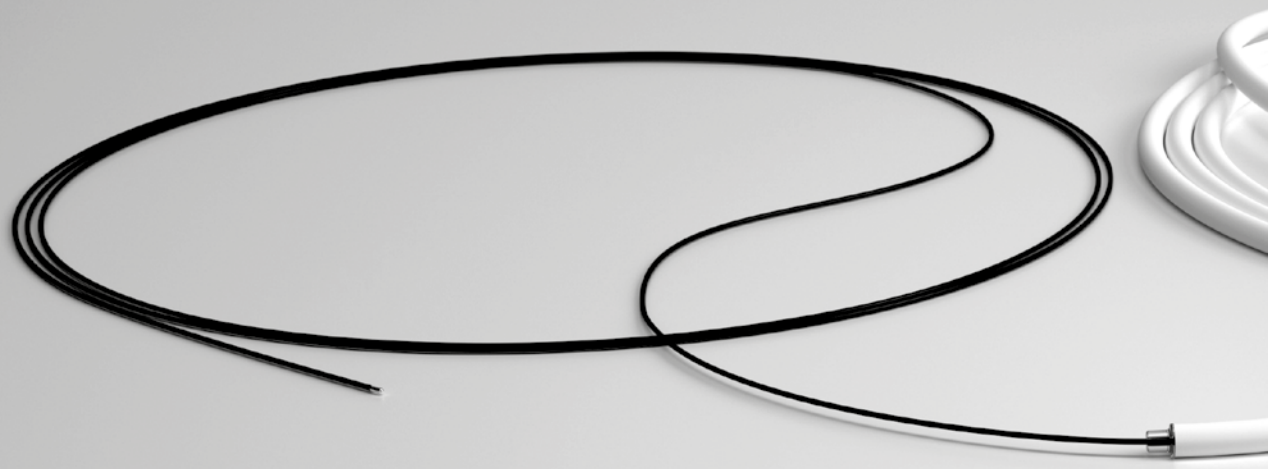
Improved tip architecture

The 2.4 mm probe has an optimized tip design and the highest freezing performance due to the largest contact surface of the probe tips available.

Flexible cryoprobe, OD 2.4 mm, L 1.15 m

The cryoprobe with oversheath

no removal of the bronchoscope necessary



1.1 mm – miniaturization for enhanced clinical utility

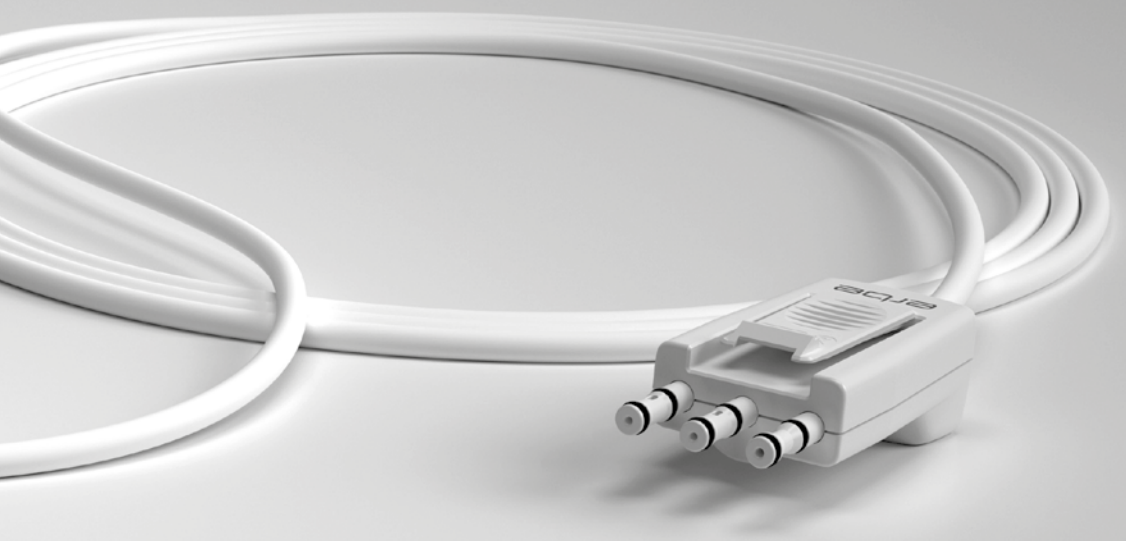
The cryoprobe with oversheath is our latest technology extension – measuring 1.1 mm, the thinnest cryoprobe in our portfolio. This extends compatibility and clinical utility, for example, with navigation catheters and bronchoscopes with smaller working channels.

Oversheath – protection

The atraumatic oversheath supports a quick and easy retrieval of the biopsy through the bronchoscope. It protects the biopsy and supports a high quality specimen. Furthermore, it protects the bronchoscope against the thermal influence of the cryoprobes and the mechanical pressure of the frozen biopsies.

The extraction method with the 1.1 mm probe and the oversheath is intended to provide several advantages for the user:

- Extraction of the biopsy through the oversheath in the working channel of the bronchoscope
- Permanent visual control of the target area
- Shorter reaction times in complication management (e.g. bleeding)



Multiadapter – easy application

The multiadapter is used to secure the oversheath and enables easy connection to standard bronchoscopes. It can be connected easily with the bronchoscope's working channel and holds a seal throughout the procedure. With the oversheath extracted, suction and the insertion of flexible instruments is always enabled by an integrated seal. Furthermore, the multiadapter allows the connection and use of conventional and luer syringes.

Improved application convenience

In combination with the oversheath, biopsies can be removed through the working channel of a therapeutic bronchoscope* with the 1.1 mm cryoprobe. The bronchoscope doesn't have to be removed in toto from the target area during cryoextraction anymore. This saves procedure time and improves convenience. With the bronchoscope left in place, the physician can maintain visual control throughout the entire procedure.

* Working channel ≥ 2,8 mm

Product data

Products	
ERBECRYO® 2 Cryosurgical unit	10402-000
ERBECRYO® 2 1-pedal footswitch AP & IP X8 Equipment US	20402-201
Flexible gas hose; L 1m for Erbokryo CA/AE/ERBECRYO® 2	20410-004
Gas bottle adapter H; CO_2; Pin index	20410-011
ERBECRYO® 2 Cart	20402-300
Wire basket; 339x205x155 / 100 mm	20180-010

Single-use cryoprobes	
Flexible Cryoprobe, OD 1.1 mm, L1.15 m with oversheath, OD 2.6 mm, L817 mm	20402-401
Flexible Cryoprobe, OD 1.7 mm, L1.15 m	20402-410
Flexible Cryoprobe, OD 2.4 mm, L1.15 m	20402-411

Optional	
Switching valve w/ 2 Adapt. H; for ERBECRYO® 2; CO_2; Pin Index	20402-051
Extension cable for ERBECRYO® 2 footswitch; L 0.4 m	20402-202
Exhaust gas hose; L 10 m open end for ERBECRYO® 2; ID=13; OD=18	20402-008
VIO® Cart System carrier	20180-000
Fastening strap for gas cylinder	20180-120
Cylinder pad for gas cylinder	20180-080
Fastening set for ERBECRYO® 2 to VIO®/APC® 2	20180-144

tissue acquisition

Cryorecanalization

CLINICAL VALUE AT A GLANCE

- ☑ Target tissue can be frozen to the cryoprobe en face, tangentially and circumferentially (360°), enabling clinical applications in challenging anatomy and hard to reach target areas
- ☑ Higher diagnostic yield compared to flexible forceps biopsies
  → bigger specimen size
  → better specimen quality (minimized crush artifacts and blood artifacts within the specimen; the morphological structure remains intact)
- ☑ Compared to hot techniques like electrosurgery, APC® or laser, the oxygen concentration doesn't have to be reduced during cryorecanalization

Technical data

Device-specific data	
Number of program memory locations	10
Activation	Footswitch
Cooling gas	CO_2
Input pressure	45–65 bar, (653–943 psi)
Power connection	
Rated supply voltage	100 V to 240 V (± 10 %)
Rated supply frequency	50/60 Hz
Line current	0.4–0.8 A
Grounding terminal	Yes
Power fuse	2 x T 1.0A H 250 V
Dimensions and weight of the unit	
Width x height x depth	410 x 130 x 370 mm
Weight	6.7 kg
Ambient conditions for transport and storage of the unit	
Temperature	-20 °C to +55 °C, (-4 °F to +131 °F)
Relative humidity	15 % to 80 %
Ambient conditions for operating the unit	
Temperature	+15 °C to +40 °C, (+59 °F to +104 °F)
Relative humidity	30 % to 75 %, non-condensing
Standards	
Classification in accordance with EU directive 93/42/EEC	II b
Protection class in accordance with EN 60601-1	I
Type in accordance with EN 60601-1	CF

Cryobiopsy

Cryodevitalization

Erbe USA Incorporated
2225 Northwest Parkway
Marietta, GA 30067
USA

Phone 800 778 3723
Fax 770 955 2577
sales@erbe-usa.com
erbe-usa.com

 2023-06 MKT/5074/01