Interventional pulmonology

ERBECRYO® 2 with flexible single-use cryoprobes
Our flexible cryosurgical technology has been adopted in medical practice for more than two decades and continues to evolve as a leading modality in therapeutic and diagnostic applications in pulmonology.¹

Routine clinical applications include cryoextraction and cryodevitalization.¹
Cryextraction enables the removal of foreign bodies, mucus plugs, blood clots, necrotic tissue, tissue tumors (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 latest requirements in pulmonology and supported by decades of our practical experience in cryosurgery and cryotherapy.

The ERBECRYO® 2 provides several new features introduced to improve clinical convenience for the user and to support state-of-the-art clinical results.¹

94 % of the users rate the overall impression and the freezing power as good to very good.¹⁴
The gas – Carbondioxide only

The ERBECRYO® 2 is designed and optimized to be used with CO₂ gas only. This configuration helps to standardize clinical results worldwide with a non-narcotic, user-friendly gas.²

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.³

Design integration – the pulmonology workstation

The ERBECRYO® 2 can be combined on one cart with our electrosurgical and APC devices. This multi-modular system supports a high level of handling convenience, is space-saving and facilitates multiple applications in interventional pulmonology.

80 % of clinicians consider, that the plug and operate interface and the error management lead to increased clinical efficiency.¹₄
The ERBECRYO® 2 is the next generation of Erbe cryo units and was designed with a focus on improved reproducibility for state-of-the-art flexible cryo applications. Several new features support ease-of-use and enhance the technical and clinical performance.

**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.1,3

**Error management – system feedback**

The plug and operate detects malfunctioning connections of all components which lowers the time of searching for errors. The flow control can detect malfunctions of the unit and the probes which helps to identify the source of failures.2

**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.1,2

**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.2

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** Effect and program settings
The flexible single-use cryoprobes are available in various sizes. They can be used for various clinical applications such as tissue devitalization and extraction of foreign bodies, mucous plugs, blood clots, necrotic tissue, tissue tumors (recanalization) and tissue biopsies.¹

ADVANTAGES OF THE ERBE SINGLE-USE CRYOPROBES:

☑ The consistent technical performance supports
  → Consistent target tissue effects
  → Superior reproducibility
  → Improved standardization²,³

☑ Expanded application possibilities and compatibilities due to miniaturization⁴

☑ Enhanced ergonomics and handling characteristics through patented elements⁵,⁶

☑ No reprocessing
  → Saves time and cost
  → Reduces risk of cross-contamination

８４％ of all users believe, that single-use cryoprobes support the standardization of flexible cryo applications.¹⁴

Handling

Single-use cryoprobes provide the following improved characteristics:⁶,⁷,¹²

→ Enhanced shape memory
→ Patent protected 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.

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.
The new portfolio includes three single-use probes with diameters of 1.1, 1.7 and 2.4 mm for expanded application possibilities. Several patented key elements enable a slim, light and ergonomic design.1,2

The miniaturized 1.1 mm and 1.7 mm probes enable enhanced clinical utility and compatibility, for example, with navigation catheters.5

The 2.4 mm probe supports applications with an optimized tip design and maximum freezing performance.3

Additionally to the single-use cryoprobes, we offer a range of different flexible reusable cryoprobes:

**Reusable cryoprobes**

- **Pneumo-Cryoprobe, flexible, OD 2.4 mm, length 900 mm**
  No. 20402-032

- **Pneumo-Cryoprobe, flexible, OD 1.9 mm, length 900 mm**
  No. 20402-037

- **Pneumo-Cryoprobe, flexible, OD 1.9 mm, length 1150 mm**
  No. 20402-040
The cryoprobe with oversheath
no removal of the bronchoscope necessary

1.1 mm – miniaturization for extended 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 a 1.2 mm working channel.5

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 of the specimen. Furthermore, it protects the bronchoscope against the thermal influence of the cryoprobes and the mechanical pressure of the frozen biopsies.4,9,10
The unique extraction method with the new probe and the oversheath provides 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)

92% of physicians confirm, that the cryoprobe with oversheath can be used as a replacement for flexible biopsy forceps.

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 1.1mm 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
Clinical applications of the ERBECRYO® 2 with flexible cryoprobes

Cryobiopsy

The target tissue freezes to the tip of the cryoprobe and can be removed from the target area by pulling. Central (endobronchial) as well as peripheral (transbronchial) cryobiopsies are possible.

Flexible cryoprobes enable biopsies with superior quality. Crush artifacts and tissue bleeding can be avoided while the morphological structure of the specimen remains intact. Furthermore, the extraction with flexible cryoprobes enables much bigger biopsies than flexible forceps.

SUPERIOR DIAGNOSTIC YIELD FOR LUNG BIOPSIES

Central biopsies:
- Diagnostic yield cryo: 95 %
- Diagnostic yield forceps: 85.1 %

Peripheral biopsies:
- Diagnostic yield cryo: 80 %
- Therefore, surgical biopsies can be avoided in 80 % of cases.

Since the target tissue can be frozen to the cryoprobe frontally and tangentially, a biopsy is also possible in hard to reach target areas.

Cryorecanalization

With cryoadhesion, exophytic stenosis in the tracheobronchial tract can be recanalized immediately. Like cryobiopsies, the tumor can be frozen to the tip of the cryoprobe and removed. An effective cryorecanalization is thus possible in up to 91 % of the cases.

In the same way, various foreign bodies can be removed. This includes foreign body materials like for example chewing gum, nuts or peas, as well as body substances like mucus plugs and blood clots.

Compared to hot techniques like electrosurgery, APC or laser, the oxygen concentration doesn't have to be reduced during cryorecanalization.
Cryodevitalization

Due to the low temperatures at the tip of the cryoprobe, tissue can be devitalized. Several freezing and defrosting cycles at the same spot increase the effectiveness. For example, this technique can be used for the treatment of exophytic tumors in early stages. Studies show effective cryodevitalization at 45 % to 89 %.1

THE CLINICAL ADVANTAGES AT A GLANCE1

☑ Probes for diagnostic and interventional procedures
☑ Superior diagnostic yield (compared to flexible forceps biopsies)
  ➔ bigger biopsies
  ➔ better biopsy quality (very few crush artifacts or sample-internal bleeding; the morphological structure remains intact)
☑ Diagnosis of ILD (Interstitial lung disease) is possible
  ➔ Surgical biopsies can be avoided
☑ Effective recanalization and foreign body removal
☑ Effective devitalization

References:
1 Clinical assessment of cryoprobes D104429
2 Instructions for use ERBECRYO® 2 80113-400
3 Internal measurements D144193
4 Internal test report D147320
5 Internal measurements D135206
6 Internal measurements D099747
7 Usability report D129848
8 Internal measurements D147473
9 Internal measurements D145597
10 Internal measurements D134929
11 Internal measurements D134927
12 Current patents: https://www.erbe-med.com/ip
13 Raghu et al. 2018: Diagnosis of idiopathic pulmonary fibrosis – An official ATS/ERS/JRS/ALAT clinical practice guideline
14 User acceptance test report D162230
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