Breathbag & Mouthpiece
Instructions For Use

Product names

Breathbag

References: 8004 (Single Breathbag) / 8005 (Double Breathbag)

Mouthpiece

Reference: 8007

Classification

The Breathbag is a Class A in vitro diagnostic medical device according to Regulation (EU) 2017/746.

The Mouthpiece is a Class I medical device according to Regulation (EU) 2017/745.

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CE IVD

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1. Product overview

1.1. General description

Breathbag is a device for the breath collection, intended for single use only and should always be used together with the appropriate Mouthpiece. Breathbag can then be tested with the Kibion® Dynamic System (Kibion® Dynamic base and Kibion® Dynamic pro).

Breathbag consists of a plastic envelope with a collection channel and is available in 2 formats. Single Breathbag is available in pack of 50, mostly used for the Kibion® Dynamic System monthly and daily auto-adjustments. Double Breathbag is available in pack of 50, used for patient samples. Their identification can be done directly onto the Breathbag with a non-erasable pen.

1.2. Intended purpose

1.2.1. Breathbag

The Breathbag is a non-automated device intended for the manual collection of breath specimen from lay persons under the supervision of healthcare professionals in a clinical or laboratory environments, in order to contain ^{13}C and ^{12}C- labelled CO_2. The Breathbag is a device of the Kibion® Dynamic System that is intended, with a non-invasive ^{13}C Urea Breath Test (^{13}C UBT), for the qualitative detection of *Helicobacter pylori* causing infections in the gastrointestinal tract (stomach and duodenum).

The Breathbag is a single use consumable intended to be used with the Mouthpiece [Kibion GmbH - REF: 8007 / Catalogue n°: 0K50503].

1.2.2. Mouthpiece

The Mouthpiece is to be used with Breathbag for sampling of breath test samples for analysis by Kibion Dynamic and IRIS analyzers and under the supervision of trained medical staff.

1.3. Intended users and operating environment

- For sample collection, the Breathbag & the Mouthpiece are intended to be used by lay persons from the general adult population, under the supervision of healthcare professionals.
- After sample collection, the devices are intended to be used by healthcare professionals.

The Breathbag and the Mouthpiece are not intended for self-testing and/or near-patient testing.

The devices are intended to be used in clinical and/or laboratory environments.

1.4. Contraindications

There is no specific contraindication for the use of the devices.

1.5. Adverse effects

There are no adverse effects associated with the normal use of the devices.

2. Overview of the medical condition

2.1. Indication

The Breathbag & the Mouthpiece are indicated for the qualitative detection of *Helicobacter pylori* infection in the gastrointestinal tract (stomach and duodenum).

2.2. Target patient population

Lay persons with a suspected or diagnosed *Helicobacter pylori* infection from the general adult population.

2.3. Principle of the procedure

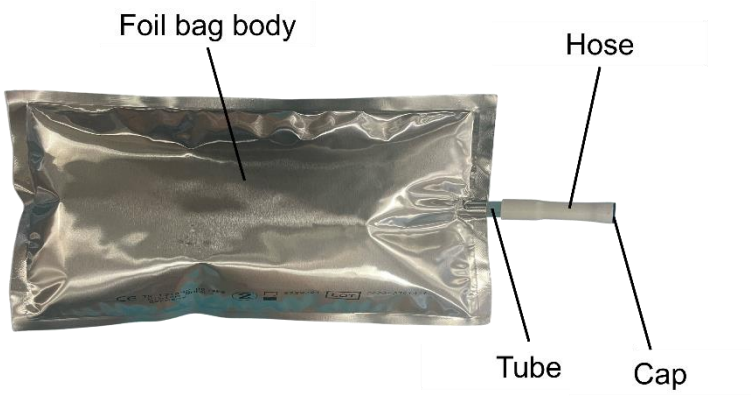
Helicobacter pylori produces urease, an enzyme that catalyzes the hydrolysis of ^{13}C-urea to $^{13}CO_2$ and NH_3. $^{13}CO_2$ is excreted in exhaled air while NH_3 and excess ^{13}C-urea are excreted in urine. Under healthy conditions (absence of *Helicobacter pylori*), ^{13}C-urea is not hydrolyzed and a basal amount of $^{13}CO_2$ will be present in exhaled air. Hence, $^{13}CO_2$ is more present in exhaled air during *Helicobacter pylori* infection.

For Urea Breath Test (UBT) sampling, the patient first exhales into an Breathbag through the Mouthpiece to provide a basal sample. The patient then swallows a substrate containing ^{13}C-urea and waits the required amount of time before exhaling a second time through the Mouthpiece into a separate Breathbag (alternatively, the unused bag body of a double Breathbag), providing a test sample. The diaphragm contained within the Mouthpiece prevents inhalation of the sample once it has been expressed into the Breathbag.

The sample analysis is the performed using the Kibion® Dynamic base, with or without its extension the Kibion® Dynamic pro.

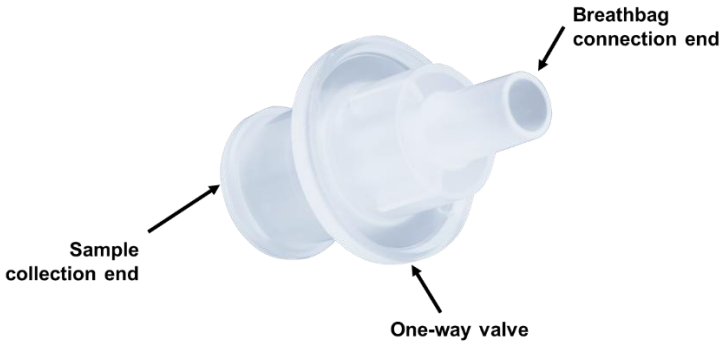
3. Materials

3.1.Breathbag



Component	Function
Foil bag body	Core part of the Breathbag designed to retain the breath samples without leakage.
Tube	Transparent plastic tube of the Breathbag designed to connect the “Foil bag body” to the “Hose”.
Hose	Flexible tube designed to simplify sample collection and sample analysis through the connection to the appropriate equipment.
Cap	Cap designed to seal the specimen receptacle so that the breath sample may not leak from the Breathbag.

3.2.Mouthpiece



Component	Function
Sample collection end	End section designed to facilitate the breath sample collection.
One-way valve	Section designed to ensure a smooth collection of the breath sample without leakage.
Breathbag connection end	End specifically designed to connect to the hose of the Breathbag.

3.3.Materials required but not provided

The following medical device considered as an accessory during the protocol is required for use but not provided with the Breathbag:

Manufacturer	Product name	Reference number(s)
Kibion GmbH	Mouthpiece	8007

The following equipment is required for use but not provided with the Breathbag:

Manufacturer	Product name	Reference number(s)
Kibion GmbH	Kibion® Dynamic base	8031-B 8031-N

The following equipment extension has been validated for use but is not provided with the Breathbag:

Manufacturer	Product name	Reference number(s)
Kibion GmbH	Kibion® Dynamic pro	8032-B

A ^{13}C substrate is required for use but not provided with the Breathbag. The following substrates have been validated with the Breathbag:

Market Authorisation Holder(1)	Product name
Mayoly Spindler Laboratories	HELIKIT 75mg
Mayoly Spindler Laboratories	Diabact UBT 50 mg tablets 13C-urea
Mayoly Spindler Laboratories	Espikur 50 mg tablets 13C-urea
Mayoly Spindler Laboratories	Helidiag 50 mg tablets 13C-urea

(1) Note: The Market Authorisation Holder may vary depending on your country. Please contact your local distributor for further information.

4. Storage and transport

4.1. Before sample collection

4.1.1. Breathbag

- The Breathbag should be transported and stored at 15-25°C in its primary packaging (sealed bag of 50 units)
- The Breathbag should not be exposed to direct sunlight.

4.1.2. Mouthpiece

- The Mouthpiece should not be exposed direct sunlight during transport and storage.

4.2. After sample collection

4.2.1. Breathbag

- The Breathbag should be processed within 7 days after sample collection.
- If not processed immediately, the Breathbag should be sealed with its cap(s), transported and stored at 15 - 25°C and should not be exposed to direct sunlight.

5. Instruction for use

In the following instructions :

- Indicates when the step is to be performed directly by the patient under the supervision of a healthcare professional.
- Indicates when the step is to be performed exclusively by the healthcare professional.

IDENTIFY

Identify the patient and bag body content (baseline or sample) non-erasable marker with a smooth tip.

PREPARE

Take a Mouthpiece and remove the cap of the Breathbag.

CONNECT

Place the Mouthpiece in the white hose of the Breathbag.

COLLECT BASELINE

Exhale into the baseline bag body of the Breathbag. The Breathbag must be fully inflated.

CLOSE BASELINE

Pinch the white hose after exhaling to ensure that the baseline does not leak when removing the Mouthpiece.
Close the hose of the Breathbag with the cap.

SWALLOW

Take a substrate and wait the amount of time specific to the substrate.

COLLECT SAMPLE

Exhale into the sample bag body of the Breathbag. The Breathbag must be fully inflated.

CLOSE SAMPLE

Pinch the white hose after exhaling to ensure that the sample does not leak when removing the Mouthpiece.
Close the hose of the Breathbag with the cap.

CONNECT

While pinching the white hose, remove the cap from the hose and connect the latter to the Breathbag to the Kibion® Dynamic base or its extension, the Kibion® Dynamic pro.

The final analysis steps are further detailed in the User Manual of the Kibion® Dynamic base.

6. Warnings and precautions for use

Preparation of the Breathbag
Do not disassemble the Mouthpiece nor the Breathbag.
Ensure accurate patient / sample identification. Make sure to identify the baseline and sample bag bodies. Do not forget the patient identification.
Do not use a sharp pen for the identification of the patient / sample. Where the foil bag body of the Breathbag shows signs of alteration (*e.g.* punctures) after the identification, do not use the Breathbag.
Sample collection with the Breathbag
Use only with breath sample. The devices are not adapted for liquids.
Breathbag must be fully inflated by the breath sample of the patient.
Avoid saliva in the Breathbag during the sampling step. Humidity in the sample could damage the Analyzer.
Follow the instructions of the substrate. If the instructions of the substrate are not followed (*e.g.* waiting time not respected), there is a risk of incorrect diagnosis.
Analysis of the Breathbag
Analyse with an appropriate device. The sample must be analysed using a compatible and validated device.
Disposal
Dispose according to local rules or guidelines.
After use, potential presence of pathogenic germs. Handle and dispose of the Breathbag and Mouthpiece with care.
Miscellaneous
Do not reuse. The devices are single use only. A single use for the Mouthpiece considers the filling of the 2 bag bodies (baseline and sample).
Do not use after the expiry date. For the Breathbag, the expiry date is printed directly on it and on the packaging labels. For the Mouthpiece, the expiry date is printed on the packaging labels.

7. Additional information

7.1. Key features

The Breathbag can store a respiratory sample containing CO_2 until it is analyzed.

7.2. Device disposal

After use, the device shall be destroyed in accordance with local laboratory and healthcare facility procedures and in accordance with local regulations for the disposal of clinical waste.

7.3. Symbols

	Manufacturer
	In vitro diagnostic medical device
	Catalogue number
	Batch code
	Caution
	Do not use if package is damaged and consult *instructions for use*
	Do not re-use
	Use-by date
	Temperature limit
	Keep away from sunlight

Keep dry

Consult *instructions for use* or consult electronic *instructions for use*

7.4. Customer support and contact information

Please contact your local distributor or Kibion GmbH for support.

- ⇨ info-bremen.kibion@mayoly.com
- ⇨ +49 421 278650

7.5. Serious incidents

Any serious incident that as occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

The manufacturer must be contacted at the following email address:

- ⇨ quality.kibion@mayoly.com

For Europe, the contact points of the competent authorities are available on the website of the European Commission:

- ⇨ https://ec.europa.eu/tools/eudamed

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