



Instructions for use

1. Intended Use

This biopsy forceps is used for taking tissue samples of the mucous membrane of the gastrointestinal tract to provide the basis for pathological assessment

- **Biopsy forceps must only be used with an endoscope!**
- **These instruments are not designed for other applications!**
- **Damaged instruments must not be used!**
- **Biopsy forceps with needle: the needle must be straight**

These instructions are intended to assist the user in using the biopsy forceps as intended, to describe their use and thus provide a higher degree of safety for the patient.

2. Design

Endoaccess GmbH offers single-use biopsy forceps in different designs for various applications. For information regarding range and sizes please contact Endoaccess GmbH directly.

3. Before use

Please study these instructions carefully before using the biopsy forceps. The functional principles and handling must be completely understood. Please inspect the instrument for defects and damages after removing it from the package. If damages or defects are detected in this inspection, the instrument must not be used on the patient and must immediately be returned to Endoaccess GmbH for inspection by an expert.

Please note that you do not need to exert much force on the handle, to carry out the biopsy. The amount of strength to be used is the equivalent of a gentle handshake.

Disposable biopsy forceps are supplied sterile. The biopsy forceps must be inspected for damage before use. Only undamaged biopsy forceps must be used! For single use only.

Disposable biopsy forceps are supplied sterile. The biopsy forceps must be inspected for damages before use. Only undamaged biopsy forceps must be used! The instrument must only be used once.

4. Cautions

- To be used by trained and/or experienced personnel only
- The product is delivered sterilized on delivery and can be used immediately
- Only to be used with an endoscope. It must not be altered, repaired, or used for other purposes as this may endanger the patient's health and may result in damage to the associated equipment

5. Contraindication

Do not use biopsy forceps on patients who suffer from:

- Severe disfunction of crur
- Systematic hemorrhage disease
- Severe hypertension and diabetes
- Serious heart and lung disease(s) that do not permit endoscopic medical examination
- Neurological diseases
- Patients who refuse this treatment
- Acute inflammation in upper digestive tract and/or ulcer
- Narrowness in the upper digestive tract that does not allow endoscopic examination
- Patients with allergies to components of the product or contrast agent
- Patients who are not suitable for the procedure due to their diagnosis.

6. Handling

6.1 Introducing the biopsy forceps into the endoscope:

The biopsy forceps must only be introduced into the operating channel of the endoscope with forceps jaws closed. For this, appropriate diameters of biopsy forceps and operating channels must be considered (see Product Catalogue).

6.2 Patient population: adults only

Models:

Product Name	Product code	Working Length	Instrument Diameter in mm
Disposable oval cups Biopsy Forceps	EA-S18C10	1000 mm	Ø 1.8
	EA-S18C12	1200 mm	Ø 1.8
	EA-S18C15	1500 mm	Ø 1.8
	EA-S18C16	1600 mm	Ø 1.8

	EA-S24C16	1600 mm	Ø 2.4
	EA-S24C18	1800 mm	Ø 2.4
	EA-S24C21	2100 mm	Ø 2.4
	EA-S24C23	2300 mm	Ø 2.4
	EA-S30C23	2300mm	Ø 3.0
Disposable oval cups Biopsy Forceps (coated)	EA-S18OC10	1000 mm	Ø 1.8
	EA-S18OC12	1200 mm	Ø 1.8
	EA-S18OC15	1500 mm	Ø 1.8
	EA-S18OC16	1600 mm	Ø 1.8
	EA-S24OC16	1600 mm	Ø 2.4
	EA-S24OC18	1800 mm	Ø 2.4
	EA-S24OC21	2100 mm	Ø 2.4
	EA-S24OC23	2300 mm	Ø 2.4
	EA-S30OC23	2300mm	Ø 3.0
Disposable oval cups with spike Biopsy Forceps	EA-S18OW10	1000 mm	Ø 1.8
	EA-S18OW12	1200 mm	Ø 1.8
	EA-S18OW15	1500 mm	Ø 1.8
	EA-S24OW16	1600 mm	Ø 2.4
	EA-S24OW18	1800 mm	Ø 2.4
	EA-S24OW21	2100 mm	Ø 2.4
	EA-S24OW23	2300 mm	Ø 2.4
Disposable oval cups with spike Biopsy Forceps (coated)	EA-S18CW10	1000 mm	Ø 1.8
	EA-S18CW12	1200 mm	Ø 1.8
	EA-S18CW15	1500 mm	Ø 1.8
	EA-S24CW16	1600 mm	Ø 2.4
	EA-S24CW18	1800 mm	Ø 2.4
	EA-S24CW21	2100 mm	Ø 2.4
	EA-S24CW23	2300 mm	Ø 2.4
Disposable alligator cups Biopsy Forceps	EA-S18A10	1000 mm	Ø 1.8
	EA-S18A12	1200 mm	Ø 1.8
	EA-S18A15	1500 mm	Ø 1.8
	EA-S24A16	1600 mm	Ø 2.4
	EA-S24A18	1800 mm	Ø 2.4
	EA-S24A21	2100 mm	Ø 2.4
	EA-S24A23	2300 mm	Ø 2.4
Disposable alligator cups Biopsy Forceps (coated)	EA-S18AC10	1000 mm	Ø 1.8
	EA-S18AC12	1200 mm	Ø 1.8
	EA-S18AC15	1500 mm	Ø 1.8
	EA-S24AC16	1600 mm	Ø 2.4
	EA-S24AC18	1800 mm	Ø 2.4
	EA-S24AC21	2100 mm	Ø 2.4
	EA-S24AC23	2300 mm	Ø 2.4
Disposable alligator cups with needle Biopsy Forceps	EA-S18AW10	1000 mm	Ø 1.8
	EA-S18AW10	1000mm	Ø 1.8
	EA-S18AW12	1200 mm	Ø 1.8
	EA-S18AW15	1500 mm	Ø 1.8
	EA-S24AW16	1600 mm	Ø 2.4
	EA-S24AW18	1800 mm	Ø 2.4
	EA-S24AW21	2100 mm	Ø 2.4
	EA-S24AW23	2300 mm	Ø 2.4
Disposable alligator cups with needle Biopsy Forceps (coated)	EA-S18WA10	1000 mm	Ø 1.8
	EA-S18WA12	1200 mm	Ø 1.8
	EA-S18WA15	1500 mm	Ø 1.8

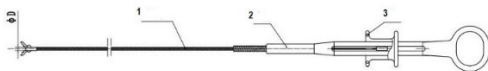
Instructions for use

	EA-S24WA16	1600 mm	Ø 2.4
	EA-S24WA18	1800 mm	Ø 2.4
	EA-S24WA21	2100 mm	Ø 2.4
	EA-S24WA23	2300 mm	Ø 2.4
Disposable oval cups Biopsy Forceps (coated) - Jumbo	EA-S30OC23	2300 mm	Ø 3,0
Disposable oval cups Biopsy Forceps - Jumbo	EA-S30C23	2300 mm	Ø 3,0

6.3 Structure

The disposable biopsy forceps is composed of head, tube and handle.

The head of the disposable biopsy forceps varies as listed in the table under 6.2



1. Components of forceps body
2. Bend protection
3. Clamp ring

Raw materials			
No	Part	Material	Body contact (Yes/No)
1	Head (forceps jaw)	Stainless steel	Yes
2	Tube	Inner:Stainless steel	No
		Outer:Stainless steel or Stainless stell & PE coating	Yes
3	Bend protection	PTFE	No
4	Handle	ABS	No

6.4 Before use

- Check the content of the package: Instruction for use; product qualification and product
- Check the sealing of the package
- Check for damages. Do not use damaged products
- To be disinfected and disposed of.
- According to the relevant national regulations, aseptic medical devices that have been disinfected and destroyed or not destroyed, must be handed over to legally authorized medical waste disposal companies for centralized disposal

6.5 Biopsy

- Place the biopsy forceps in front of the target area
- Push the clamp ring gently forward to open the jaws of the forceps
- Introduce the forceps into the tissue, pull back the clamp ring to close the forceps and carefully remove the tissue sample.
- Hold the forceps jaws in the closed position and slowly withdraw the entire instrument from the endoscope. The tissue sample thus obtained may now be prepared for further examination.

7. Cleaning/Sterilization

Disposable biopsy forceps are delivered sterilized by ETO gas.

Do not re-sterilize. For single use only. To be disposed of after use according to hospital guidelines.

8. Repairing and maintenance

Do not use after sterilization date (see label) has expired

Single use items must not be repaired

9. Working environment

Recommended environment: 0°C -40 °C, humidity range: 30% - 85%, Air pressure: 50.0-106.0KPa

10. Storage and transport conditions

Allow a 20 cm diameter for the coiled instrument when stored

- do not store or deliver under heavy pressure to avoid distortion
- store in clean and dry environment
- avoid direct or indirect sunlight or other ultra-violet rays
- protect from shocks and vibrations during transport, must not be exposed to rain or snow
- do not put any objects on instruments or packaging
- do not store close to aggressive chemical substances

Incorrect storage of the instruments invalidates any claims.

11. Period of validity

Three years after sterilization date.

12. User

The user of the instruments of Endoaccess GmbH must be specialized in the field of endoscopy. He or she should have special training in handling and reprocessing of flexible endoscopy instruments.

13. Dispatches for repair and claims

In the interest of our employees' health, only sterilized or disinfected instruments will be accepted as returns. They should be labelled as such; otherwise they cannot be handled further.

14. Legal foundation

The Law of the European Union is applied

15. Product Support

In case of questions or difficulties concerning our instruments please contact your distributor or Endoaccess GmbH directly during regular working hours.

Address: Endoaccess GmbH, Feldriethe 1, 30826 Garbsen, Germany

16. Symbols

	Do not reuse		EO-Gas sterilized
	Expiration date		Lot number
	Manufacturer		Date of manufacture
	Keep dry		Do not use if package is damaged
	Give attention to IFU		Product code
	Do not re-sterilize		Do not expose to direct sunlight
			Medical Device

17. Disposal

After use, dispose the instrument and packaging according to the regulations of the hospital, or local waste law!



info@endoaccess.de

www.endoaccess.de

