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 dysfunction of cruor
- 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

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Product code</th>
<th>Working Length</th>
<th>Instrument Diameter in mm</th>
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<tbody>
<tr>
<td>Disposable oval cups Biopsy Forceps</td>
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<td>1000 mm</td>
<td>Ø 1.8</td>
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<tr>
<td></td>
<td>EA-S18C12</td>
<td>1200 mm</td>
<td>Ø 1.8</td>
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<td>EA-S18C15</td>
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<tr>
<td></td>
<td>EA-S18C16</td>
<td>1600 mm</td>
<td>Ø 1.8</td>
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Disposable Biopsy Forceps

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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

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

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

Endoaccess GmbH, Feldstrüethe 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
- Sterile
- Medical Device

17. Disposal
info@endoaccess.de   www.endoaccess.de

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