

Instructions for use

1. Intended Use

The flexible disposable injection needle is an accessory for digestive endoscopy used with an endoscope. It is intended to inject an agent to a target lesion, and generally used for treatment of variceal bleeding.

- **Only to be used with an endoscope!**
- **These instruments are not designed for other applications!**
- **Damaged instruments must not be used!**

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

Patient population: for adults only

2. Models and Specification

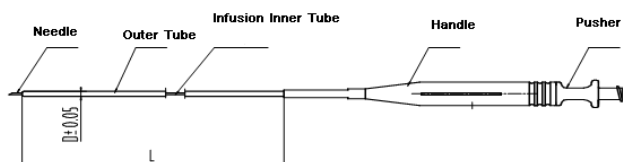
Endoaccess GmbH offers disposable injection needles in various sizes. Further information regarding the different types may be obtained from the main catalog of Endoaccess GmbH.

2.1 Article number composition

Company Code	Disposable	Outer tube external diameter (x0.1mm)	Working length in mm	Product code	Needle Diameter in G	Needle length in mm
EA-	S	18	10	NJ	23	04

2.2 Key Material and structure

Structure of the disposable injection needle



Raw materials			
No	Part	Material	Body contact (Yes/No)
1	Head	stainless steel 304	Yes
2	Tube inner	PTFE	Yes
3	Bend protection	PTFE	No
4	Handle	ABS	No

2.3 Models and Specification.

Product Name	Product Code	Instrument Diameter in mm
Disposable Injection needle	EA-S18xxNJxxxx	Ø 1.8
	EA-S24xxNJxxxx	Ø 2.4

Please refer to catalogue for complete listing of sizes

3. Contraindications

Please do not use on patients who suffer from:

- Severe dysfunction of crur
- Systemic hemorrhage disease
- Severe hypertension and diabetes
- Serious heart and lung disease(s) that do not permit endoscopic examination
- Neurological diseases
- Acute inflammation in upper digestive tract and/or ulcer
- Narrow in upper digestive tract making endoscopical access impossible
- Patients allergic to this product or the agent
- Patients not suitable for the procedure according to diagnosis

Disposable Injection Needle

4. Cautions

- Only to be used by trained and specialized surgeons.
- Users should be aware of model, characteristics and diameter of endoscopic forceps and the corresponding working channel of the endoscope. The diameter of the working channel of the endoscope must be larger than the external diameter of the disposable injection needle's outer tube. Please refer to table 4 for reference.
- All disposable injection needles produced by Endoaccess GmbH are delivered sterilized and can thus be used directly.
- The product must be used with an endoscope and cannot be used alone. It must not be arbitrarily modified, repaired or used in any other way. Otherwise, patients and users may be harmed and other medical equipment may be damaged.

Table 4 . Models and corresponding working channels

REF	Suitable working channel diameter in mm
EA-S1810NJxxxx	Endoscopic forceps Ø 2.0 ~ Ø 2.4
EA-S2416NJxxxx	Endoscopic forceps ≥ Ø 2.8

5. Before Use

- Check the content in the package.
- Check the sealing of the package.
- Check for damages of the instrument. Do not use it in case of damages. In case of damages please contact Endoaccess GmbH or your supplier immediately for exchange.
- After use, dispose of products and packaging in accordance with hospital, administrative and/or local government policies

6. Operation

- Wear personal protective equipment when operating the equipment to protect against infection from blood, mucosa, and other potential hazards. Appropriate personal protective equipment helps to ensure that skin exposure is reduced to a minimum risk.
- The instruments must only be used if the visible part of the endoscope or a significant part of the distal end is clearly visible. Otherwise, injuries to the patient or damage to the endoscope may occur
- Keep the head of the needle retracted in the tube during insertion into the endoscopic working channel. Insert the needle through the valve. Insertion should be smooth and light without force using short strokes. Keep your hands close to the entrance of the working channel to avoid bending of the instrument.
- When the disposable injection needle passes through the endoscopic angulation part, make sure that this can be done without any problems, as the injection needle could otherwise be damaged.
- Please extract the needle head carefully to apply agent or medicine to avoid injuries of the mucosal tissue
- After the procedure extract the needle slowly and carefully through the working channel completely retracted into the tube

7. Instructions for Storage

- Do not store under heavy pressure
 - To be stored in clean and dry environment
 - The instrument must not be exposed to direct sunlight
- Allow a 20 cm diameter for the coiled instrument.

Improper storage voids all warranty claims

8. Cleaning/Sterilization

Disposable injection needles are delivered sterilized by ETO gas. Do not re-sterilize! For single use only!

9. Period of sterilization validity is three years

10. User

The user of the instruments of Endoaccess GmbH must be specialized in the field of endoscopy.

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11. Legal foundation

The Law of the European Union is applied














12. 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

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13. 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 the IfU		Product code
	Do not resterilize		Do not expose to direct sunlight
	Medical Device		

14. Disposal

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



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