

Instructions for use

Disposable Cleaning Brush



Intended Use

The disposable cleaning brush is a commonly used instrument for endoscopy. It is used for cleaning the working channel of the endoscope and to ensure and improve the visibility of the equipment for clinical diagnosis and application.

The instruments can only be used with an endoscope or an instrument that is equipped with a working channel.

These instruments are not meant for any other purpose! Do not work with damaged instruments!

This instruction is intended to assist the user in using the disposable cleaning brush as intended, to describe their use and thus provide a higher degree of safety for the operation.

2.

Endoaccess GmbH supplies various designs of disposable cleaning brushes. Information on the range of sizes available may be obtained directly from us or the

Before use

Please study these instructions carefully before using the disposable cleaning brush. Inspect the instrument for defects and damages after removing it from the pouch. If damages or defects are detected in this inspection, the instrument must not be used on the endoscope and must immediately be returned to Endoaccess GmbH for inspection by an expert.

- Cleaning brushes are not sterilized by manufacturer
- For single use only
- To be disposed of after use

Handling

4.1 Inserting the disposable cleaning brush into the endoscope:

Consider the appropriate diameters of disposable cleaning brush and working channels (see "Table 1").

4.2 Types

Endoaccess GmbH offers disposable cleaning brushes in two different models of 2.4 and 1.8 to match with corresponding endoscope model.

Table 1: Model list

Table 1: Meder list						
		EA-S10DB10	Ф1.0*1000mm			
	Disposable Cleaning Brush (double ended)	EA-S10DB12	Ф1.0*1200mm			
		EA-S10DB22	Ф1.0*2200mm			
1		EA-S18DB18	Ф1.8*1800mm			
		EA-S18DB10	Ф1.8*1000mm			
		EA-S18DB12	Ф1.8*1200mm			
		EA-S24DB16	Ф2.4*1600mm			
		EA-S24DB22	Ф2.4*2300mm			
2	Disposable	EA-S18DB18A34	Ф1.8*1800mm:3mm/4mm			
	Cleaning Brush	EA-S18DB22A35	Ф1.8*1800mm:3mm/5mm			
	(double ended,	EA-S24DB23A35	Ф2.4*2300mm:3mm/5mm			
	asymmetrical)	EA-S24DB22A510	Ф2.4*2200mm:5mm/10mm			

For further information regarding dimensions please refer to the Endoaccess GmbH main catalogue.

4.3 Products structure

Disposable cleaning brushes consist of four components: head, tube, bend protection and handle. Please refer to illustration 1.

- Brush head
- 2 Tube
- 3 Bend protection



No.	Product components	Material	Materials of body contact (Yes/No)
1	Head	Stainless steel and Nylon	No
2	Tube	Inner: Stainless steel	No
	Tube	Outer: PTFE	No
3	Bend protection	PTFE	No

Contraindication

- To be used by professional operators only
- Do not use on patients if the surgery endangers the patient's life
- Avoid any unsafe situations such as connecting to rated high frequency voltage.

6. Cautions

- To be used by professional operators only
- Be aware of type, function and working channel diameter of the disposable cleaning brush. The diameter of the working channel must be bigger than the outer diameter of the brush head.

Example: Diameter of the disposable cleaning brush model of EA-S24DB22, the outer diameter of the tube is 2.4mm. Diameter of the working channel must be 2.8mm or bigger. Length 2200 mm. Refer to the product specifications in table 2.

Table 2: Specifications

Model	Scope range	Note
EA-S24DB22	Working channel diameter > or = 2.8mm	24 D 22 Working length (x100mm) External diameter of brush head (x0,1mm)

- Cleaning brushes are not sterilized by manufacturer
- For single use only, to be disposed of after use
- Reprocessing or reuse of the products cannot guarantee the quality of the sterilization or the tolerance of the products. This may result in infections or injuries to patients. For single use only.
- The product must be used with endoscope, cannot be used alone
- Keep away from moisture.

Rev. Date 12/21 Rev.05



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7. Operation

7.1 Check before use

- The sealing of the packaging
- Open the packaging and check the instrument for damages. Do not use the item if damaged. Contact Endoaccess or your distributor for exchange

7.2 Operation

- Open the packaging and use device according to IFU
- Insert the disposable cleaning brush to clean the working channel of the endoscope
- When finished pull out slowly to avoid damages of the equipment

8. Sterilization/Cleaning

- Disposable cleaning brushes are delivered non-sterilized
- Device does not have to be sterilized before use
- For single use only

9. Period of use

Ten years

10. Storage

- To be stored indoors and kept in clean and dry environment
- Avoid direct sunlight.

11. User

To be used by professional operators only

12. Repairing and complaints

Disposable devices are

- · are not to be used if expiration date has been exceeded
- not to be repaired

13. Legal Foundation

The Law of the European Union is applied.

14. Product Support

In case of questions or difficulties concerning our instruments please contact the local distributors distributors or the **Endoaccess GmbH** directly during regular working hours.

Adress: Feldriethe 1, 30826 Garbsen, Germany Phone +49 5131 4422 610, Fax +49 5131 4422 622

15. Symbols

NOM STERILE	Non-Sterile	*	Keep away from sunlight
><	Use by	LOT	Lot number
***	Manufacturer	~	Date of manufacture
*	Keep dry	®	Do not use if package is damaged
Ţi	Give attention to IFU	REF	Item number
STEER STEER	Do not resterilize	\otimes	Do not reuse
MD	Medical Device		

16. Disposal

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





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