EN

Instructions For Use

CE

Please read these instructions in full and observe them.

1. Intended use – important information for the user

These instructions for use contain general instructions on the application and use of k-wire accessories from MK medical GmbH & Co. KG.
⚠ The products are non-sterile reuseable medical devices. Before use, the accessories must be reprocessed in accordance with the specifications defined in these IFU.

Item name: K-Wire accessories:
- Containers
- Storage Racks
- Dispensers
- Gauges

Dimensions/specifications: See table below

Item number	Item name	UMDNS code	Dimensions
BS1164	DISPENSER FOR K-WIRES	16-767	**For K-Wires up to a length of 150 mm.** Classification: Ø 0.8 / 1.0 / 1.2 / 1.3 / 1.4 mm Measurement: 162 x 74 x 40 mm
BS1162	DISPENSER FOR K-WIRES	16-767	**For K-Wires up to a length of 150 mm.** Classification: Ø 1.4 / 1.5 / 1.6 / 1.8 / 2.0 / 2.5 / 3.0 mm Measurement: 162 x 96 x 40 mm
BS1168	DISPENSER FOR K-WIRES	16-767	**For K-Wires up to a length of 310 mm.** Classification: Ø 0.8 / 1.0 / 1.2 / 1.3 / 1.4 mm Measurement: 326 x 74 x 40 mm
BS1166	DISPENSER FOR K-WIRES	16-767	**For K-Wires up to a length of 310 mm.** Classification: Ø 1.4 / 1.5 / 1.6 / 1.8 / 2.0 / 2.5 / 3.0 mm Measurement: 326 x 96 x 40 mm
BS1170	FLEXIBLE DISPENSER FOR K-WIRES	16-767	**For K-Wires up to a length of 310 mm.** Classification: Ø 1.4 / 1.5 / 1.6 / 1.8 / 2.0 / 2.5 / 3.0 mm Measurement: (flexible) x 96 x 40 mm
BS7600	K-WIRE DISPENSER SET CONSISTING OF: BS8016 Sieve Tray BS8015 Lid BS1160 Wire Dispenser Insert	16-767	**For K-Wires up to a length of 150 mm.** Classification: Ø 0.8 / 1.0 / 1.2 / 1.4 / 1.6 / 1.8 / 2.0 / 2.2 / 2.5 / 3.0 mm Measurement: 236 x 74 x 38 mm
BS1500	STORAGE RACK FOR KIRSCHNER WIRES	16-767	**For K-Wires up to a length of 150 mm.** Classification: Ø 1.0 / 1.2 / 1.4 / 1.6 / 1.8 / 2.0 / 2.5 / 3.0 mm
BS3100	STORAGE RACK FOR KIRSCHNER WIRES	16-767	**For K-Wires up to a length of 310 mm.** Classification: Ø 1.0 / 1.2 / 1.4 / 1.6 / 1.8 / 2.0 / 2.5 / 3.0 mm
MK-19## **MK-20##** **MK-25##**	CONTAINERS	16-767	**For K-Wires various sizes**
MK-1950	CALIPER FOR KIRSCHNER WIRES	No MD	**To check k-wires diameters from 0.7mm to 3.0mm**

Before using an MK medical product, the user must carefully read the following instructions for use and comply with its recommendations, warnings and instructions.
MK medical cannot be held liable for complications arising due to the use of MK medical products outside of the control of MK medical, including but not limited to product selection and deviations from use/handling and surgical technique.

2. Intended purpose

- Kirschner wire Containers, Dispensers and Storage Racks are intended for protected storing and reprocessing (cleaning and sterilization) protection of Kirschner wires. The containers as well as the dispensers and storage racks are intended for sterilization INSIDE a sterilization container.

⚠ The Kirschner wire Containers as well as the dispensers and storage racks are NO sterilization containers with a sterile barrier system.

⚠
- Calipers for K-wires are intended for quick-checking the diameters of K-wires.

The calipers for k-wire are NOT a calibrated measuring equipment and no medical Device.

Selection of the correct type and size:

Choosing the proper container, dispenser or storage rack depends on storage environment and the specific needs of the end user or hospital.

⚠ The containers, dispensers and storage racks are just made for the use of the Kirschner wire dimensions according to the table in chapter 1 of this instruction for use.

3. Indications

Protected storing and reprocessing protection of k-wires.

4. Contraindications

Currently there are no known contraindications.

5. Compatibility:

MK medical does not recommend the combination of MK medical products with those of other manufacturers since the designs, materials, mechanics and construction are not mutually harmonized. MK medical assumes no liability for any complications arising from combining components or from using third-party medical devices in combination.

⚠ ***Warning:***
- Before use, the user must check the product for visible damage.
- The products must be handled exclusively by trained staff.

6. Product reprocessing

MK medical products are supplied in non-sterile condition and must be cleaned, disinfected and steam sterilized prior to first use.

MK medical recommends machine reprocessing with a standard cleaning program using a washer-disinfector in accordance with ISO 15883-2.
Manual reprocessing methods are unsuitable due to the product design and have therefore not been validated.

7. Validated machine reprocessing methods

Validated machine reprocessing methods include:

a) Machine cleaning, disinfection and drying in the washer-disinfector
b) Visual check
c) Packaging
d) Validated sterilization method

a) Machine cleaning, disinfection and drying in the washer-disinfector

The validated cleaning and disinfection method refers to the Miele standard program “DES-VAR-TD” in the Miele G7835 CD washer-disinfector.

The specifications of the washer-disinfector manufacturer regarding appropriate and professional operation and loading as well as maintenance of the washer-disinfector must be strictly observed.

Procedure:

- Prerinsing with cold water for 1 minute
- Cleaning using water and the alkaline cleaner “Neodisher Mediclean forte, 0.5%” for 5 minutes at 55°C ± 5°C
- Neutralisation with the “Neodisher Z” neutraliser for 2 minutes
- Rinsing with deionised water for at least 1 minute
- Disinfection at 55°C ± 5°C for 5 minutes
- Drying at 60°C ± 5°C for 30 minutes

b) Visual inspection

After cleaning, articles must be visually inspected for cleanliness and damage. Articles that are obviously not clean or damaged must be separated out and discarded.

c) Packaging

The articles must be packaged for sterilization in accordance with 11607-1. The validated sterilization method applies to double foil bags.

⚠ • The k-wire containers should be placed bottom down into the sterilization container to avoid accumulation of condensation water in the top of the k-wire container

d) Validated sterilization method

The validated sterilization method applies to the autoclave Tuttnauer Type B 3870 EHS.

Sterilization:

- 2 fractionated pre-vacuum phases
- Holding time: min. 5 minutes, max. 7 minutes at 134°C
- Drying for at least 10 minutes

The unit manufacturer's operating instructions as well as instructions for use and maintenance must be strictly followed.

8. Symbols for labelling

Symbol	Description	Symbol	Description
	Medical device accord. To VO (EU) 2017/745, Chapter 2,1.		Manufacturer accord. to VO (EU) 2017/745, Chapter 2,30.
	Unique Device Identifier - UDI		Hint: protect from moisture
	Manufacturing date		Hint: protect from direct sunlight
	LOT number		Hint: storage conditions
	Article reference		CE-mark
	Please cunsult the instructions für use		Hint: NON STERILE
	Caution: please pay attention on the hints		

9. Storage

Must be stored at room temperature in a clean and dry location and protected from humidity and direct sunlight.

10. Guarantee policy

MK medical GmbH & Co. KG is responsible for each individual product being produced, inspected and packaged with the utmost care. Since ***MK medical*** has no influence or control over correct and professional application, ***MK medical*** cannot be held responsible for complications or the failure of an application. ***MK medical*** sets and individual products are mutually compatible. Users are responsible for verifying the mutual compatibility of the products before use.
MK medical employees are not authorized to change the above conditions or extend liability or enter into additional product-related commitments.

11. Bibliography

"Hygiene requirements for the reprocessing of medical devices", RKI (Robert Koch Institute)

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