

INSTRUCTIONS FOR USE

You can request a printed copy of these instructions by emailing info@hso-solutions.at and they will be sent to you free of charge.

PRODUCT NAME

HSO SafeFix

PRODUCT DESCRIPTION

SafeFix is a Class I medical device in accordance with the requirements of Regulation (EU) 2017/745.

SafeFix is a padded hand and finger restraint and is fastened to the wrist using a hook and loop (Velcro) closure.

SafeFix is available in two versions:

Basic F-1.1

Basic: Features individual finger compartments for defined positioning of the fingers.



- A Padded body with mesh
- B Finger placement
- C Plastic buckles
- D Loop (strap guide)
- E Velcro strap for adjusting the fit around the wrist

Light | Mini F-1.2

Mini & Light: Feature a fold over fabric flap at the fingertips that can be secured with a hook and loop fastener (F1-2 B). In addition, the Mini version has an elastic cuff around the wrist.



- A Padded mitten body
- B Fabric flap, including Velcro fastening
- C Plastic buckles
- D Loop (strap guide)
- E Velcro strap for adjusting the fit around the wrist

The Mini version also features an elastic strap around the wrist.

All items have soft padding.

The product is intended for single use only.

Intended purpose and indications

SafeFix is used to prevent manipulation or unintentional removal of infusions, catheters, drains, or medical devices with the fingers,

and to protect against self injury in patients with markedly agitated behavior.

Intended users and treatment setting

SafeFix is intended exclusively for use by healthcare professionals (physicians, qualified nursing staff, and trained assistant personnel) who are trained in the use of fixation products and are familiar with the relevant legal and clinical requirements.

Intended patient population

- SafeFix Child: Paediatric patients or patients with small hand sizes, according to the specified sizes (see T 1).
- SafeFix Basic and Light: Adolescent and adult patients with medium to large hand sizes, according to the specified sizes (see T 1).

Selection of the appropriate size is carried out by the user based on the patient's hand length.

T-1



	L (cm)
HSOSAFIX1000	9
HSOSAFIX2000	10
HSOSAFIX3000	14
HSOSAFIX4000	15
HSOSAFIX5000	18
HSOSAFIX5000L	18

Use environment and compatibilities

SafeFix is intended for use in clinical environments.

In the case of SafeFix Light and SafeFix Mini, the fabric flap at the fingertips allows sensors to be attached to the fingers.

In combination with the HSO Fix Band (Art. HSOFIXBAND6000), SafeFix offers additional protection for patients. The range of motion can thereby be restricted, if necessary.

SAFETY INFORMATION

Contraindications

No contraindications are known.

Warnings and safety notes

- SafeFix may only be applied by healthcare professionals.
- Apply SafeFix so that it does not constrict: blood circulation in the fingers must always be maintained; a flat finger should fit between the cuff and the wrist.
- Check product and packaging before each use. Use SafeFix only in perfect condition.
- SafeFix is a single use product for one patient. After use, dispose of it appropriately and do not reuse in order to avoid cross contamination.
- Regularly observe the skin, comfort, and movement of the affected hand. In case of abnormalities (e.g. severe pain, discoloration, marked restlessness), check the application and adjust or remove as necessary.

- Do not attach the fixation strap to moving parts in order to avoid injuries.

Procedure in case of product defects

In the event of product defects or complaints, please contact the exclusive distribution partner Rudolf Heintel Gesellschaft m.b.H at info@hso-solutions.at.

In the case of serious incidents (e.g. deterioration in state of health, prolongation of hospital stay), these must be reported both to Rudolf Heintel Gesellschaft m.b.H and to the manufacturer as well as to the competent authority of the Member State in which the user and/or the patient is established.

APPLICATION

Preparation

Ensure that the correct size is selected to provide the most secure fit of SafeFix. Hand lengths can be found in Table T 1.

Operation and use

Pull SafeFix over the hand (F 2), ensuring that the back of the hand faces the strap loop (F 1.1 D & F1.2 D). For the Basic version, make sure that the fingers are correctly positioned individually in the designated compartments (F 3).

F-2



F-3



For the Mini & Light version, pull the fabric flap (F 1.2 B) over the fingertips and secure it with the hook and loop fastener (F 4).

F-4



Pass the wrist hook and loop strap (F 1.1 E & F 1.2 E) through the loop (F 1.1 D & F 1.2 D), then through the plastic buckle (F 1.1 C & F 1.2 C) and fasten the hook and loop strap. Optionally, the strap can be passed through the loop again or laid over it.

To secure the extremity, attach the fixation strap to the plastic buckles and fasten it at a suitable location with sufficient stability (F 5 Basic | F 6 Light / Mini).

F-5



F-6



Maintenance and care

No maintenance is required. Store unopened products in a dark, cool and dry place. Protect the products from moisture and excessive heat.

Disposal

Dispose of the product and packaging in accordance with hospital policies and/or local regulations.

SYMBOLS

	Manufacturer		Packaging unit
	Catalogue number		Medical device
	Batch code		Keep away from sunlight
	Keep away from rain		Date of manufacture
	Do not use if package is damaged		Unique Device Identification
	Electronic instructions for use		General symbol for recovery/recyclable
	CE mark		Do not re-use

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