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iFIX

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Instructions for use

ENGLISH

iFIX Products

iFIX Fleece

REF	PRODUCT NAME	SPECIFICATIONS
31618	iFIX Fleece 5	Qty: 1 Dim: 5 cm x 30 m
16304	iFIX Fleece 15	Qty: 1 Dim: 15 cm x 200 m
17674	iFIX Fleece 50	Qty: 1 Dim: 50cm x 30 m

iFIX Spider Fleece

REF	PRODUCT NAME	SPECIFICATIONS
40286	iFIX Spider Fleece Arm M	Qty: 1 Dim: 50 x 45 cm
40287	iFIX Spider Fleece Leg M	Qty: 1 Dim: 75 x 75 cm
40288	iFIX Spider Fleece Body S	Qty: 1 Dim: 100 x 90 cm
40289	iFIX Spider Fleece Body M	Qty: 1 Dim: 125 x 90 cm
40290	iFIX Spider Fleece Body L	Qty: 1 Dim: 150 x 90 cm
40291	iFIX Spider Fleece Body XL	Qty: 1 Dim: 175 x 90 cm

iFIX Head Mask

REF	PRODUCT NAME	SPECIFICATIONS
26102	iFIX Head Mask XS	Qty: 10 Dim: 33 x 41 cm

26105	iFIX Head Mask S	Qty: 10 Dim: 33 x 43 cm
26104	iFIX Head Mask M	Qty: 10 Dim: 33 x 45 cm
26103	iFIX Head Mask L	Qty: 10 Dim: 33 x 47 cm
29341	iFIX Head Mask XL	Qty: 10 Dim: 33 x 49cm
35080	iFIX Head Mask L elongated	Qty: 10 Dim: 58 x 62 cm

iFIX Patch

REF	PRODUCT NAME	SPECIFICATIONS
16180L001	iFIX Patch 15	Qty: 8 Dim: 15 x 10 cm
16180L002	iFIX Patch 25	Qty: 6 Dim: 25 x 10 cm
16180L005	iFIX Patch 50	Qty: 4 Dim: 50 x 10 cm
16180L007	iFIX Patch 75	Qty: 4 Dim: 75 x 10 cm
32982	iFIX Patch 15X6	Qty: 3 Dim: 15 x 6 cm

iFIX Patch Adapter

REF	PRODUCT NAME	SPECIFICATIONS
16179L001	iFIX Patch Adapter 50	Qty: 4 Dim: 50 x 15 cm

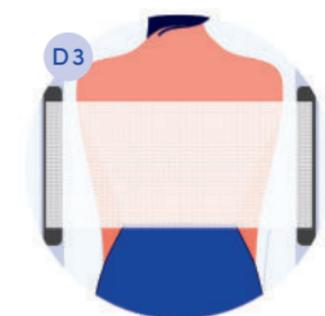
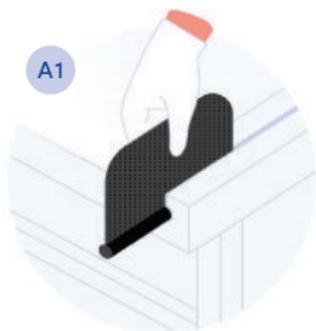
iFIX Slot Adapter

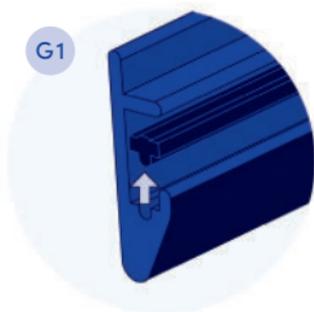
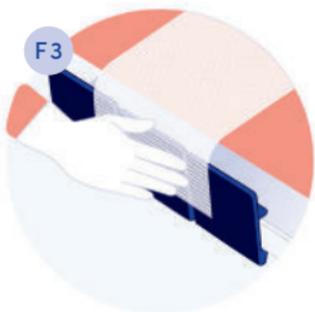
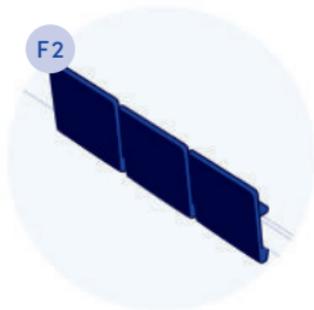
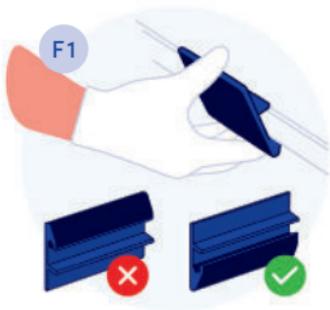
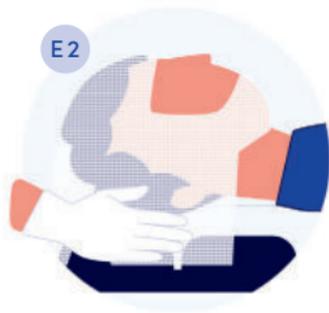
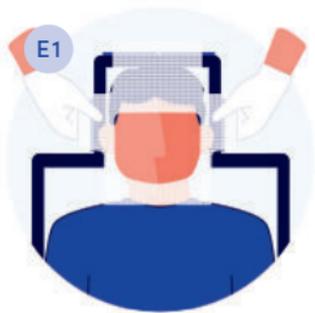
REF	PRODUCT NAME	SPECIFICATIONS
38037	iFIX Slot Adapter 2.0/30	Qty: 4 Dim: 30 x 12 cm, Ø 3.0 mm
17622L003	iFIX Slot Adapter 3.0/30	Qty: 4 Dim: 30 x 12 cm, Ø 4.0 mm
16192L003	iFIX Slot Adapter 8.0/30	Qty: 4 Dim: 30 x 12 cm, Ø 9.5 mm
33224	iFIX Slot Adapter 10.0/30	Qty: 4 Dim: 30 x 12 cm, Ø 11.5 mm
35193	iFIX Slot Adapter Trapezoid 12.0/9	Qty: 8 Dim: 9 x 14 cm, Ø 13.3 mm
39775	iFIX Slot Adapter Wing 3.0/30	Qty: 4 Dim: 30 x 13,5 cm Ø 4.0 mm, wing-shaped rod

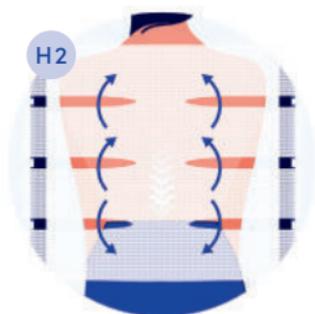
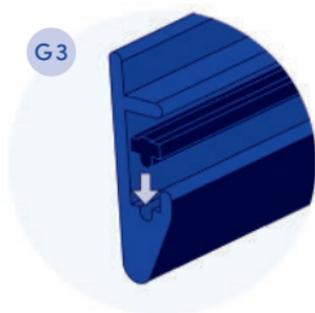
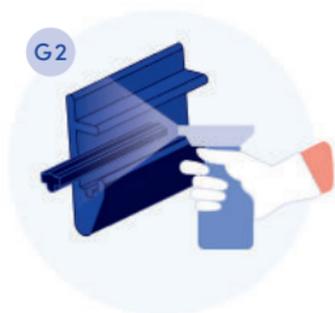
iFIX Side Rail Adapter

REF	PRODUCT NAME	SPECIFICATIONS
42642-EU	iFIX Side Rail Adapter	Qty: 4 Dim: 12,5 x 8 x 2 cm
42642-JP	iFIX Side Rail Adapter JP	Qty: 4 Dim: 12,5 x 8 x 2 cm
42642-US	iFIX Side Rail Adapter US	Qty: 4 Dim: 12,5 x 8 x 2 cm
44824	iFIX Side Rail Adapter Spare Patch	Qty: 10 Dim: 12 x 10,5 cm

iFIX Product Illustrations







Instructions for Use

Intended Use

The iFIX Product Line is a non-sterile product, intended to stabilize patients, during invasive and non-invasive procedures, by securing the position of body parts with intact skin outside the sterile field.

Description

iFIX is indicated for medical procedures during which the patient's body parts is required to maintain a specific position over a short period of time. No known contraindications. The stretchy fleece is intended for single patient use and, as a single use component, lowers the risk of cross-contamination. It contours to the patient's anatomy and secures them in the desired position through its connection to the reusable iFIX anchor products. Depending on the table design, an iFIX Patch that adheres to the table surface, an iFIX Slot Adapter that slides into the channels or an iFIX Patch Adapter which

connects to standard hook fasteners can be chosen.

The micro anchors of the iFIX Patches and Adapters strongly secure the iFIX Fleece and iFIX Spider Fleece to ensure optimal patient stabilization and minimizing motion artifacts.

Warnings and Precautions

Warning: The system may only be used by medical professionals.

Warning: iFIX Fleece, iFIX Spider Fleece and iFIX Head Mask are products for single patient use only. Do not reuse iFIX Fleece, iFIX Spider Fleece and iFIX Head Masks.

Selection of the anchor product

IFIX SLOT ADAPTER

In case the table contains channels:

1. Select an appropriate iFIX Slot Adapter size and shape.

2. Slide the iFIX Slot Adapters to the area of the patient's anatomy to be stabilized (See **A1**, p. 6). While positioning, make sure that no collisions with the existing equipment take place during use.
3. Use additional iFIX Slot Adapters if required.

IFIX SIDE RAIL ADAPTER (SRA)

In case the table is equipped with a side rail:

1. Hook in the SRA on the bottom edge of the rail first (See **F1**, p. 7).
2. Push the SRA towards the table till it clicks on the rail and the patch surface becomes parallel to the rail's surface (See **F2**, p. 7).
3. Attach the iFIX Fleece using its textured side to the SRA (See **F3**, p. 7).

IFIX PATCH

In case there is a flat surface available:

1. Remove the liner from the iFIX Patch.

2. Adhere the iFIX Patches to the lateral sides of the patient support device, table or another desired surface (See **B1**, p. 6).
3. Expose the anchor side of the iFIX Patch by removing the white cover (See **C1**, p. 6).
4. Adhere additional iFIX Patches if required.

IFIX PATCH ADAPTER

In case the table contains a standard hook fastener:

1. Attach the loop side of the iFIX Patch Adapter to the existing hook fastener on both sides of the patient table.
2. Expose the anchor side of the iFIX Patch Adapter by removing the white cover (See **C1**, p. 6).
3. Add additional iFIX Patch Adapters and/or cut iFIX Patch Adapters if required.

Patient stabilization

IFIX FLEECE AND IFIX SPIDER FLEECE

1. Estimate the required length of iFIX Fleece and cut or select an

appropriate iFIX Spider Fleece size for the patient, place it in the middle of the patient and unfold the iFIX Spider Fleece. (See **H1-H2**, p. 8).

2. Attach the iFIX Fleece / iFIX Spider Fleece using its textured side to an anchor product on the opposite side of the table (See **D1**, p. 6 and **H3**, p. 8).

Warning: iFIX Fleece has a plain side facing upwards when pulled out of the fleece dispenser, and a textured one on the opposite side. Only the latter can be used for the connection to the anchor products. Using the wrong surface of the fleece may lead to patient injury.

3. Pull the iFIX Fleece / iFIX Spider Fleece tightly, up and over the patient (See **D2**, p. 6 and **H3**, p. 8).

Warning: Do not apply the iFIX Fleece / iFIX Spider Fleece too tight, or it can restrict the blood circulation and the patient's breathing.

4. Adhere the iFIX Fleece / iFIX Spider Fleece to the anchor product on the other side of

the table. If necessary, adjust the iFIX Fleece / Spider Fleece to increase or decrease stabilization level. (See **D3**, p. 6 and **H4**, p. 8).

Warning: Confirm the stability of the setup before conducting the procedure and readjust if necessary. Forgetting it may lead to patient injury.

5. If necessary, repeat this procedure with additional iFIX Fleece layers to increase stabilization.

iFIX HEAD MASK

1. Select an appropriate iFIX Head Mask size for the patient.

Warning: Using the wrong Head Mask size may lead to patient injury.

2. Place the mask over the patient's face ensuring eyes, nose, and mouth are exposed (See **E1**, p. 7).

Warning: Do not apply the iFIX Head Mask too tight, or it can restrict the blood circulation and the patient's breathing.

3. Attach the iFIX Head Mask

flaps to an anchor product.
Warning: Confirm the stability of the setup before conducting the procedure and readjust if necessary. Forgetting it may lead to patient injury.

4. If necessary, adjust iFIX Head Mask to increase or decrease stabilization (See **E2**, p. 7).

Cleaning, refurbishing and disposal

1. After use, dispose of the iFIX Fleece / iFIX Spider Fleece or the iFIX Head Mask.

Warning: Reusing an iFIX Fleece / iFIX Spider Fleece or an iFIX Head Mask may lead to cross-infection.

2. Clean all reusable anchor products after use. Residues of iFIX Fleece / iFIX Spider Fleece can be removed using commercially available lint roller.
3. Apply a disinfection agent to the reusable products. Make sure there is complete wetting of the anchor

surfaces with disinfection agent. Recommended agents: alcoholic (e. g. Incidin Liquid or Mikrozid AF Liquid) or quaternary ammonium (e.g. Meliseptol) surface disinfectants.

When disinfecting the Side Rail Adapter: take care to disassemble the adapter prior to disinfection (See **G1**, p. 7) and only use alcoholic surface disinfectants as a spray in order to treat adequately all surfaces, holes, lumen and edges (See **G2**, p. 8). Allow agent to take effect during at least 5 minutes before reassembling the anchor (See **G3**, p. 8).

4. In case iFIX Fleece does not attach to the Side Rail Adapter anymore, remove the Patch and replace it by a new Side Rail Adapter Spare Patch.

Product Information

- iFIX is not made with natural rubber latex.
- iFIX is hypoallergenic.
- iFIX is safe for use in MRI environment.
- iFIX anchor products are not

intended to come in contact with patient skin.

Symbol Definitions



The device is safe for use in MRI Environment



The device is not safe for use in MRI Environment



Quantity



Medical Device



Manufacturer



Catalogue number



Use by date



Caution



The device is compliant with applicable directives and regulations for CE-Marking



or

Consult instructions for use



Unique Device Identifier



Do not re-use



Do not use if
package is
damaged



Batch code

Contact Information

If a serious incident occurs in relation to the use of this system, report it to Interventional Systems using any of the methods listed below. Technical service personnel will either assist to solve the problem immediately or inform you about the procedure for a replacement of the affected component. No corrective maintenance will be provided during patient treatment.

Provide the following information when escalating a problem:

- Serial number of the system.
- Batch code of the affected item, if applicable.

- Name, email address, and phone number.
- Installation site (hospital name and address).

Contact at the hospital for shipment:

Name

iSYS Medizintechnik GmbH

Address

Bergwerksweg 21, 6370 Kitzbühel,
Austria

E-mail

info@interventional-systems.com

Phone

+49 (8232) 99 41 956

Website

www.interventional-systems.com

If a serious incident occurs in the European Union, also report it to the competent authority in the Member State where the incident occurred.

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Interventional Systems is a registered trademark.

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iFIX is a registered trademark.

iFIX is a patented technology.



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