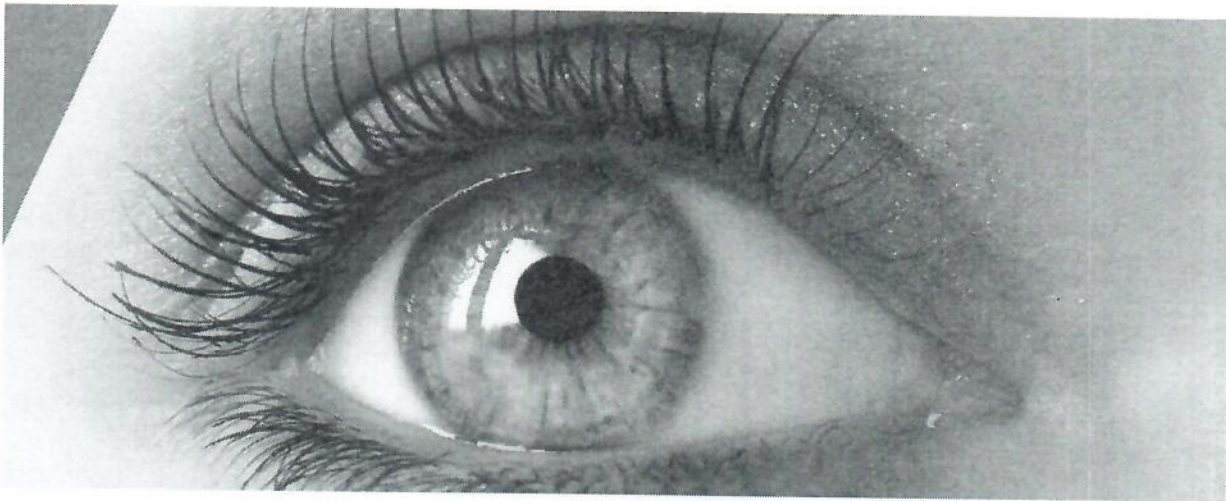


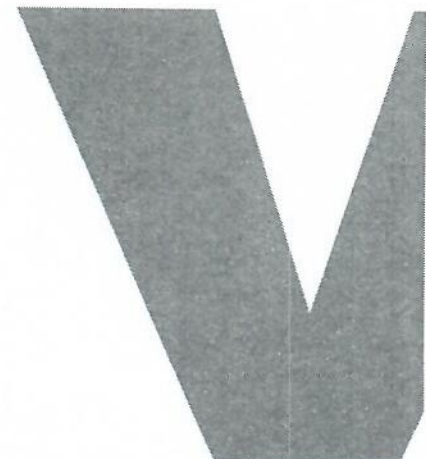


Medizintechnik GmbH



# WingSTEP

## Instructions for Use



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**Follow these instructions for proper and safe use. Keep for later reference.**

## 1. INTRODUCTION

### 1.1 Hazard warnings and signal words



#### **WARNING**

Denotes a potentially imminent danger. If not avoided, death or serious injury may result.





#### **CAUTION**

Denotes a potentially imminent danger. If not avoided, minor or moderate injuries may result.

#### **NOTICE**

Indicates a possibly harmful situation. If it is not avoided, the device or something in its vicinity can be damaged.

### 1.2 Labeling

Symbol	Description
 YYYY-MM-DD	Indicates the medical device manufacturer and the production date.
R <sub>x</sub> Only	Indicates that the product is a medical device as defined in 21 CFR 820.3(l) and Federal Law (USA) restricts this device to sale by or on the order of a physician (21 CFR 801.109).
<b>LOT</b>	Batch code
<b>SN</b>	Serial number
<b>REF</b>	Catalogue number
<b>MD</b>	Medical device
<b>MR</b>	MR safe. A product that does not pose a known risk in an MRI environment.
	MR conditional. A product that is considered safe in an MRI environment under certain conditions.

### 1.3 Intended user

All STEP products are for professional use only. Users shall have adequate education or training in relevant clinical settings.

### 1.4 Intended use

The WingSTEP is intended for positioning of the lung- and thorax area of the patient during radiotherapy and diagnostics.

### 1.5 Product lifetime

The product lifespan is limited to 10 years. For consumables, please note the respective expiration date.

### 1.6 Compatibility

The product may only be used in combination with other equipment or components, if these have expressly been recognized by the manufacturer as compatible. Consult the manufacturer for advice on compatibility before using any equipment or components not supplied by the manufacturer. Changes and/or additions to the equipment shall only be performed by persons expressly authorized to do so by the manufacturer. Such changes must comply with best engineering practice, all applicable laws, and all regulations that have the force of law within the jurisdiction where the equipment will be used.

### 1.7 Safety instructions



**CAUTION** - To avoid possible damage, read and follow the following safety information.

- Changes, additions or maintenance to the product may only be carried out with the explicit approval of IT-V GmbH. Changes to the product can lead to personal injury and / or damage to the device.
- Do not use defective or incorrectly adjusted devices. This could expose users and / or patients to radiation or other hazards.
- The product may only be installed and maintained by trained and authorized personnel according to the provided instructions.
- The WingSTEP system may only be used in accordance with the manufacturer's intended purpose (see chapter 1.4).
- Use of the product for purposes other than those intended and expressly stated by the manufacturer, as well as incorrect use or operation, may relieve the manufacturer (or distributor) from all or some responsibility for resultant noncompliance, damage or injury.

Nothing stated in this user manual shall reduce the operator's responsibility for sound clinical judgement and best clinical practice.

## 2. COMPONENTS AND ACCESSORIES

Photo	Art.-Nr.	Product name	Size [mm]
	P10107-740 P10107-742	System WingSTEP Low – Pin Joint System WingSTEP Low – Ball Joint	500x585x250 500x585x250
	P10107-741 P10107-743	System WingSTEP High – Pin Joint System WingSTEP High – Ball Joint	500x585x300 500x585x300
	P10107-747 P10107-750	System WingSTEP Carbon High – Ball Joint System WingSTEP Carbon High – Pin Joint	500x585x300 500x585x300
	P10107-749 P10107-751	System WingSTEP Carbon Low – Ball Joint System WingSTEP Carbon Low – Pin Joint	500x585x250 500x585x250
	P10107-744	System WingSTEP High – HS IMRT	535x585x300
	P10107-745 P10107-746	System WingSTEP High for Varian – Ball Joint System WingSTEP Low for Varian – Ball Joint	500x585x300 500x585x250
	P10107-753 P10107-754	System WingSTEP MR Low – Ball Joint System WingSTEP MR High – Ball Joint	500x585x250 500x585x300
	P10107-756	System WingSTEP MR High VR – Ball Joint	500x585x300
	P10107-240	Pillow A – Standard	253x120x75
	P10107-241	Pillow B – High	253x120x95

	P10107-255 P10107-256	Pillow Standard A – MR Pillow High B – MR	253x120x75 253x120x100
	P10107-232	Pillow - Fix	254x235x105
	P10107-267 P10107-268	Pillow Wide A Pillow Tilt Wide G	260x133x102 256x133x91
	P10107-242 P10107-243	PU Cover for Arm Support (2 pcs.) PU Cover for Wrist Support (2 pcs.)	220x130x3 170x120x3
	P10107-440 P10107-512 P10107-513	MCT Wedge 10° MCT Wedge 5° MCT Wedge 15°	880x460x100 880x460x65 880x460x130
	P10107-441 P10107-442	Arm Support – Pin Joint – Small (2 pcs.) Arm Support – Pin Joint – Large (2 pcs.)	170x120x120 200x120x120
	P10107-443	Wrist Support – Ball Joint (2 pcs.)	120x120x90
	P10107-444 P10107-445	Arm Support – Ball Joint – Small (2 pcs.) Arm Support – Ball Joint – Large (2 pcs.)	170x120x120 200x120x120
	P10107-446	Wall Holder for WS	400x60x33
	P10107-467	HeadSTEP upper plate for WingSTEP	400x210x25
	P10107-334	iCAST Chin Double 4mm	300x325x10

	P10107-452	WingSTEP Elevation Block ABS	410x410x60
	P10107-474	MCT Wedge Indexing Adapter	530x120x50
	P10107-475 P10107-476 P10107-477	MCT Wedge Indexing Bar for Elekta MCT Wedge Indexing Bar for Varian MCT Wedge Indexing Bar for Pin Indexing	530x20x42 530x20x42 530x20x42
	P10107-478	MCT Wedge evo Indexed	840x470x100
	P10107-488	WingSTEP Arm Support Elevation Barrel	H 70, Ø 50
	P10107-487	WingSTEP Pole Bar	L 220, Ø 50
	P10107-522	WingSTEP Pole Bridge Bar	225x390x155

### 3. HANDLING INSTRUCTIONS



**WARNING** – Make sure that no body part, clothing or other objects can get caught by the treatment table or the product. This could lead to injuries or damage to the device.

#### 3.1 Integrated indexing system

Indexing systems add reference points to the devices and thus allow reproducible positioning of the patient in relation to the treatment table.

1. Place the device-specific indexing bars in the holes provided on the couch top (Fig. 1). The positions are marked with numbers and letters. Write down the positions for later treatments.



Fig. 1. Positioning of Indexing Bars

2. Place the indexing holes on the bottom of the device on the indexing bar (Fig. 2)



Fig. 2. Place the device on the indexing bar.

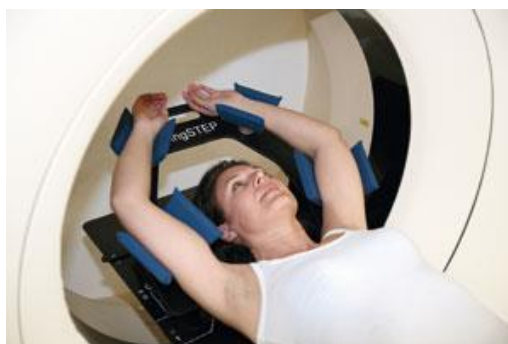
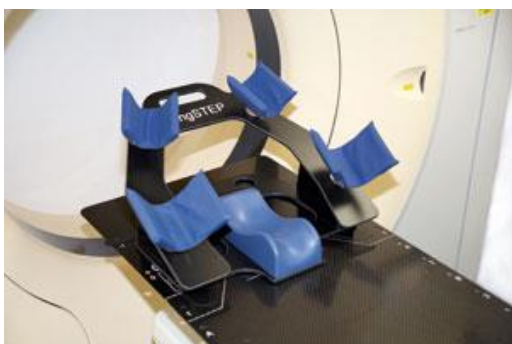


## 3.2 WingSTEP

1. Place the WingSTEP on the treatment table.



2. Select a pillow that is suitable for the patient and place it on the WingSTEP. Before using for the first time, attach the upper and lower arm rests to the ball joints of the baseplate.



3. Align the patient's head. Place the patient's arms overhead in the upper and lower arm rests.

## 4. INSPECTION

Check all components before and after each use to ensure that they have not been damaged in transit or use and that the device is securely positioned on the table.



**CAUTION** – Inspect the product daily before using. If you detect any kind of damage or decreasing performance, take the product out of service and contact the manufacturer.

## 5. CLEANING AND DISINFECTION

**NOTICE – Do not use any corrosive or abrasive cleaning agents or bleach-based cleaners (such as chlorine). This could damage the surface of the devices.**

All surfaces that come into contact with the patient should be wiped with a mild detergent solution and then dried with a clean, lint-free cloth.

## 6. STORAGE

Store in dry places without direct sunlight.

## 7. DISPOSAL

No special requirements. Follow the local laws and regulations.

## 8. MANUFACTURER CONTACT

**IT-V Medizintechnik GmbH**  
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**All serious incidents in connection with this product must immediately be reported to the manufacturer and the responsible authorities!**



This product is CE-marked in accordance with the Medical Device Regulation (EU) 2017/745. Classification according to this regulation: Class I.