The RAMP™ Knee Positioning System

User manual

Innovative Orthopedic Technologies

Manufacturer

Innovative Orthopedic Technologies (IOT) AG
Schochenmühlestrasse 4
CH-6340 Baar
Switzerland
Phone: +41 41-749-4099
Fax: +41 41-511-2248
Email: info@iotiot.com

Distributor
(US and Canada)

Innovative Orthopedic Technologies (IOT), LLC
1115 Hwy 124
Winnie, Texas 77665
U.S.A.
Phone: +1 409-658-1017
Fax: +1 409-753-2020
Email: info@iotiot.com

▶ Please carefully preserve these operating instructions!

Product The RAMP™ Knee Positioning System
Order number 9811000
GTIN 3701602300037
Document number RD-PT-9811000-01en_V02_instruction_for_use_US
Version V02
Publication date: September 12th, 2023
Author Innovative Orthopedic Technologies (IOT) AG

Table of Contents

List of Figures

1. Notes for users

1.1. Using this user manual

This user manual should make it possible for you to work safely with the device.

- ▶ Use this product only in accordance with the safety instructions and warnings in this user manual.
- ▶ If you have questions regarding the operation of the product and the accessories, please contact the manufacturer.

1.2. Instructions are part of the product

The following instructions belong to the product:

- User Manual RD-PT-9811000-01en

They promote the intended use of the product and contain important information to install, operate and maintain the device safely and efficiently.

- ▶ Keep these instructions complete, legible, and accessible to personnel at all times.
- ▶ Read these instructions and especially all safety instructions and warnings with care before you place the device into operation for the first time.
- ▶ These instructions contribute to reducing the risk of injury or illness to people, and risks of damage, malfunction, or inefficient operation of the product.
- ▶ If you transfer the device to third parties, include these instructions with it.
- ▶ If you lose these instructions, please order a replacement from your distributor.

1.3. Warning and danger symbols

DANGER

Danger of death or serious bodily injury

Failure to observe WILL lead to death or serious bodily injury.

WARNING

Danger of death or serious bodily injury

Failure to observe CAN lead to death or serious bodily injury.

CAUTION

Danger of slight bodily injury

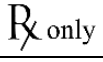
A hazard which CAN lead to slight bodily injury.

ATTENTION

Warning of damage to components

A hazard that CAN cause damage to or malfunctions of the product, equipment, other devices, etc.

1.4. Warning signs and symbols on the device and the packaging

Symbol	Meaning
	Serial number
	Catalog number
	Manufacturer
	Unique Device Identifier
	Prescription Only
	Non-Sterile Device
	CAUTION: SEE INSTRUCTION MANUAL
	READ THE INSTRUCTIONS

	Medical Device
	Date of manufacture and country of origin
	Body Weight

Symbols on the packaging	
	This side up
	Fragile; treat with the required care
	Keep dry

1.5. Typographical conventions and symbols

Symbol	Meaning
	Notice with especially useful information and tips
▶	Request for action
▷	Result of a request for action
□	Listing 1
○	Listing 2

1.6. Acronyms and abbreviations

Acronym/Abbreviation	Meaning
OR	Operating room

1.7. Figures in this user manual

Some of the figures in this user manual are schematics where the colors do not necessarily correspond to the final product.

2. Product description

2.1. Overall illustration

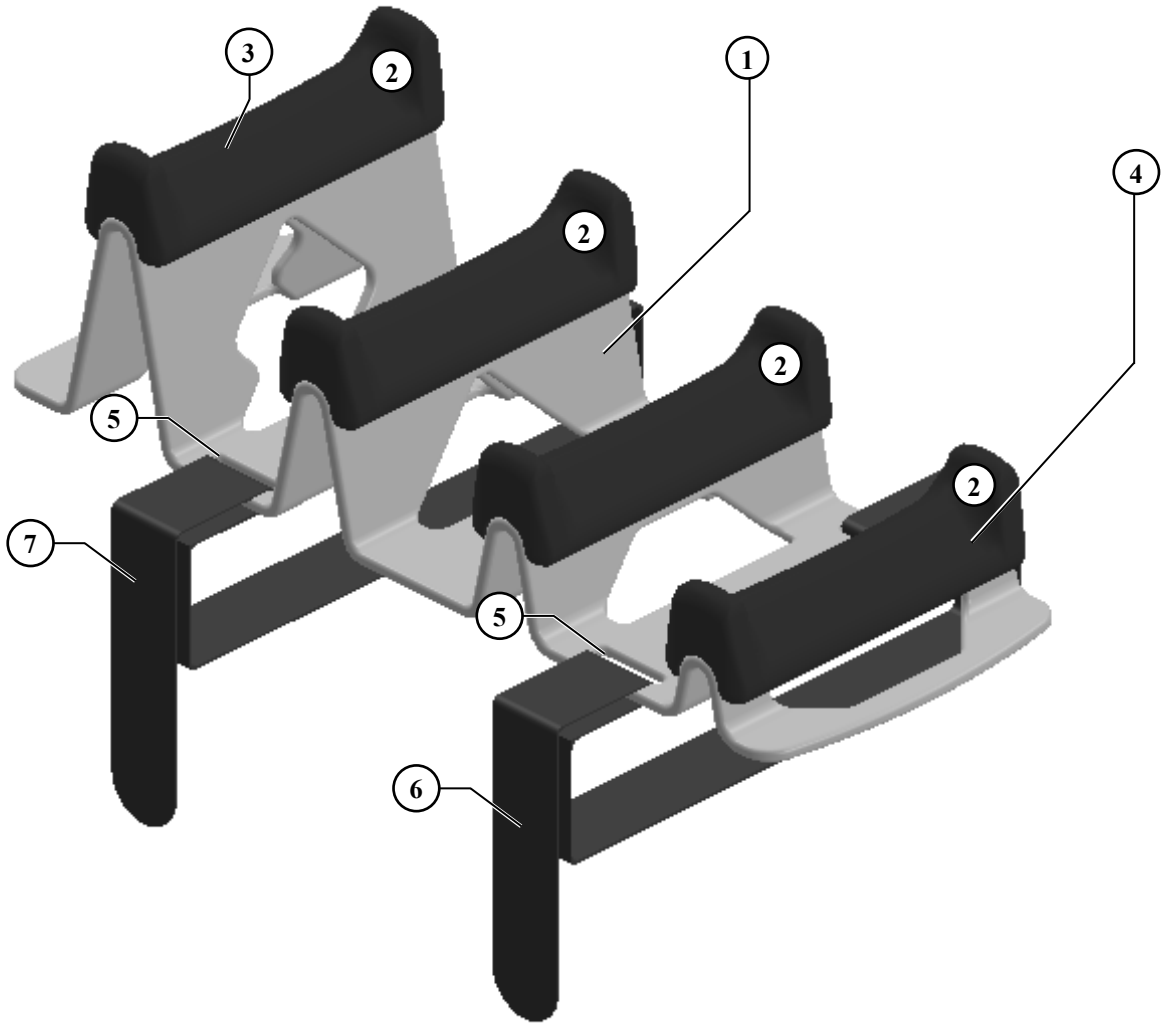


Fig. 2-1: The RAMP Top View

1 Ramp body
2 Footrest (qty 4)
3 Tallest footrest
4 Shortest footrest
5 Belt slots (qty 4)
6 First belt
7 Second belt

2.2. Scope of delivery

The RAMP Knee Positioning System is delivered in a box with the following items:

- The RAMP
- Belts (qty 2)
- User manual

▶ For more details, please see chapter "Preparing the product for operation".

2.3. Check upon receipt

▶ Immediately upon delivery check to see that the components are complete and undamaged.

▶ Report any damage during transport to the distributor immediately.

WARNING

Risk of contamination

This device is not sent in sterile condition. There is a danger of contamination.

▶ Please clean and disinfect the device according to the procedures approved by your organization.

2.4. Device properties

The device is intended to position the foot of the leg to be operated on during knee surgery.

2.5. Product service life

The device was developed for an expected service life of 5 years.

After these 5 years of operation, the manufacturer will only be responsible for the safe and correct performance of the device, if a complete inspection, normally covered by a warranty agreement, has been carried out and documented.

2.6. Warranty and Guarantee

The warranty provisions form a part of the manufacturer's General Terms and Conditions.

If you use unauthorized replacement parts, you void the manufacturer's warranty.

3. General Safety Notes

3.1. Intended use

The RAMP is designed for knee surgery. The product is used as an accessory for operating tables. It has been designed exclusively for positioning of the patient's leg during operation.

The product is to be used in accordance with the documentation supplied with it.

The product is designed exclusively for indoor use.

Operation / installation is done by specialized surgical staff familiar with patient positioning and have made themselves familiar with the product from the user manual.

The period of use of the product is about 1 to 4 hours per procedure / surgery.

The product may be used on patients who have a body weight of up to 227 kg (500 lb.). Should, however, the safe working load of the operating table be lower than this, the table load has priority.

Cleaning and disinfection are required.

Maintenance shall be performed in accordance with the instructions for use.

The product has a lifespan of 5 years.

Medical Device Class

The RAMP is classified as: Class I general, non-sterile, no measuring function.

3.2. Use in contradiction to intended use

The device may not be used for any other purpose than as it is indicated in section "Intended use".

WARNING

Hazard from use in contradiction to the intended use

Use of the device in contradiction to the intended use can lead to dangerous situations. The following are in particular regarded as contradictions to intended use:

- Use of the device outside spaces that have been created according to instruction as per the valid provisions and guidelines for erection of medical spaces
- Use of a damaged device
- Use of an incorrectly installed device
- Allowing unqualified personnel to use the device
- Modification of the device without permission from the manufacturer

3.3. Hazards when used according to intended use

WARNING

Risk of injury from long fixation of the leg

Holding the leg in the same position for a long period of time during a surgery can give rise to blood clots in the veins (thrombosis).

▶ The physician must take countermeasures during longer surgeries.

WARNING

Risk of contamination from the device

This device is not shipped in sterile condition. There is a risk of contamination.

▶ Please clean and disinfect the product according to the procedures approved by your organization.

▶ The product must be positioned under the sterile drape during the surgery.

▶ Avoid direct contact with the patient.

WARNING

Risk of injury through radiation

When using the RAMP in connection with an X-ray system, the high-frequency electromagnetic radiation may cause radiation hazards.

▶ Observe the operating instructions for the X-ray system.

▶ Only to be operated by trained personnel.

CAUTION

Danger of injuries

In operations which last several hours, pressure sores can occur – especially with patients who are slimly built or have sensitive skin. The treating doctor is in charge for the correct positioning and padding of the patient.

- ▶ Ensure sufficient padding and correct positioning of patient.

CAUTION

Danger of injury for osteoporotic patients

Leg fractures may occur if excessive mechanical force is applied to the bones of osteoporotic patients, e.g. by manipulation of the leg.

- ▶ Do not use the device for osteoporotic patients or use the device with caution.
- ▶ The operating surgeon is responsible to check the patient's bone quality and to avoid excessive load to the bones and joints.
- ▶ Be careful when manipulating the patient’s leg.

CAUTION

Risk of injury from defective components

Defective components pose a risk of injury.

- ▶ Stop using the device.
- ▶ Replace defective components only with original spare parts.
- ▶ Observe the liability information concerning the use of non-original spare parts.

CAUTION

Risk of injury due to incorrect belt fastening

The RAMP may move during surgery if the belts are not properly fastened.

- ▶ Ensure both belts are properly attached to the operating table and tightened before use.

CAUTION

Risk of injury due to leg manipulation

Stress can be applied to the leg, foot, knee, and/or ankle joints by incorrect positioning of the foot on and/or around the footrests of the RAMP. Not all patient leg positions the RAMP is capable of facilitating are safe for all patients.

- Only place the foot in one of the 6 positions described in section 5.2.3. Do not use any other positions.
- Take caution when positioning the foot, especially if the foot is positioned proximal of the shortest footrest (e.g., during hyperflexion of the knee joint).
- Do not apply excessive force on the leg if the leg or ankle is immobilized by placement on, under, or around any portion of the RAMP.
- The operating surgeon must decide and advise on exact RAMP positioning on the OR table and patient leg positioning.
- Only the operating surgeon or qualified medical personnel should manipulate the leg during the operation.

CAUTION

Risk of injury from the RAMP breaking

The RAMP may break in case of heavy patients over 227 kg (500lb.).

- Use product only for patients of max 227 kg (500 lb.).
- No portion of the patient's body should be placed on the RAMP other than the lower portion of the leg.

ATTENTION

Risk of Damaging The RAMP

The RAMP is not designed to be put through sterilization.

- Do not put the RAMP or the belts through sterile processing.

3.4. Qualifications of operating, assembly and maintenance personnel

This device may only be assembled, operated and maintained by properly trained technical personnel.

▶ Before assembly, use, and maintenance, carefully read the operating instruction and become familiar with the device.

3.5. Original replacement parts

The manufacturer shall only be liable for the safety of the device if the device is maintained by authorized maintenance personnel, and original replacement parts are used. This is true for maintenance, repairs and for modifications.

3.6. Notes on product liability

Manufacturer's liability

IOT AG shall only be liable for safe operation, reliability and performance of the device if:

- operating and assembly of the device is carried out in accordance with this manual.
- the product is used within the scope of application described here.
- no unauthorized modifications are made to the product.

3.7. Materials compatibility

ATTENTION

Corrosive substances could damage the device

During cleaning, use of corrosive substances could damage the device.

▶ Observe the cleaning instructions.

3.8. Conformity

3.8.1. Guidelines and international standards used

ISO 14971	Medical Devices – Application of risk management to medical devices
ISO 15223-1	Medical Devices. Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Medical Device Class The RAMP is classified as: Class I general, non-sterile, no measuring function.

4. Preparing the device for operation

4.1. Required tools, equipment and staff

Tools	• The device can be unpacked and assembled without tools.
Personnel	• 1 person
Required time	• 5 minutes

Note: Packaging
Please note that the packaging is reusable.

4.2. Unpacking the RAMP

▶ Open the package.

▶ Successively withdraw The RAMP and the two fastening belts.

▷ Now the components can be placed and attached to the operating table (see chapter 5.2)

4.3. Final examination

Before use, perform a control:

- Check that the product is not damaged.
- Make sure the belts are in good condition.
- Make sure the footrests are in good condition.

WARNING

Risk of contamination from the device

This device is not shipped in sterile condition. There is a risk of contamination.

- Please clean and disinfect the product according to the procedures approved by your organization.
- The product must be positioned under the sterile drape during the surgery.
- Avoid direct contact with the patient.

CAUTION

Risk of injury from the RAMP breaking

The RAMP may break in case of heavy patients over 227 kg (500lb.).

- Use product only for patients of max 227 kg (500 lb.).
- No portion of the patient's body should be placed on the RAMP other than the lower portion of the leg.

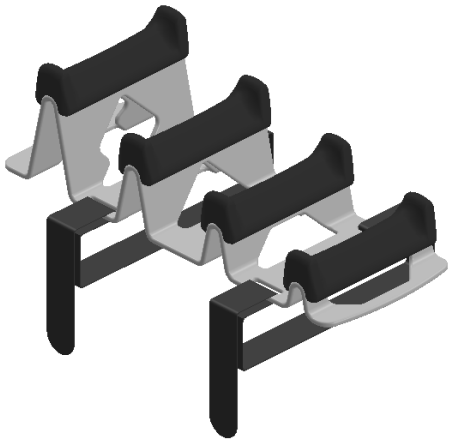


Fig. 4-1: The RAMP with belts

5. Setup and Operation

5.1. General operational steps

- Check the functionality of the product before each use.
- Install the product as described in sections 5.2.1 and 5.2.2.
- Before the surgery, cover the RAMP with drapes. Ensure the patient never comes into direct contact with the RAMP.
- Position the patient as described in section 5.2.3.

CAUTION

Danger of injury for osteoporotic patients

Leg fractures may occur if excessive mechanical force is applied to the bones of osteoporotic patients, e.g. by manipulation of the leg.

- Do not use the device for osteoporotic patients or use the device with caution.
- The operating surgeon is responsible to check the patient's bone quality and to avoid excessive load to the bones and joints.
- Be careful when manipulating the patient’s leg.

CAUTION

Danger of injuries

In operations which last several hours, pressure sores can occur – especially with patients who are slimly built or have sensitive skin. The treating doctor is in charge for the correct positioning and padding of the patient.

- Ensure sufficient padding and correct positioning of patient.

5.2. RAMP Setup

5.2.1. Ramp Positioning

Note: Use with Split Leg Sections
These steps show positioning and installing the RAMP on an OR table without a split leg section. However, the RAMP can also be used on OR tables with split leg sections.

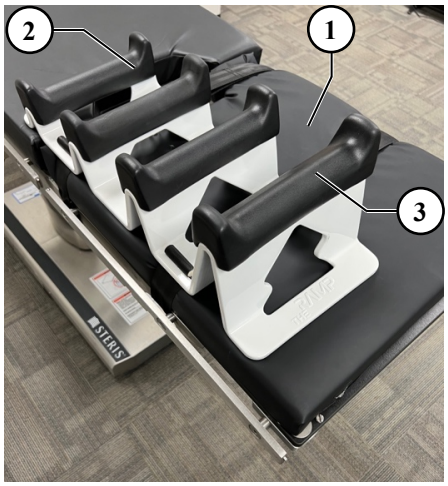


Fig. 5-1: Initial Positioning (shown for a right knee operation)

1 OR table leg section
2 Shortest footrest
3 Tallest footrest

- ▶ Place the RAMP longitudinally on the OR table leg section (1), with the shortest footrest (2) situated proximal of the tallest footrest (3).
- ▶ Position the RAMP so that it will be situated under the operative leg.
- ▶ Align the operative side edge of the RAMP with the operative side edge of the OR table.

Note: OR Table Pads
It is recommended to keep the OR table pads on the table and place the RAMP on top of the OR table leg section pad(s).

5.2.2. Installing the Belts

CAUTION

Risk of injury due to incorrect belt fastening

The RAMP may move during surgery if the belts are not properly fastened.

- ▶ Ensure both belts are properly attached to the operating table and tightened before use.

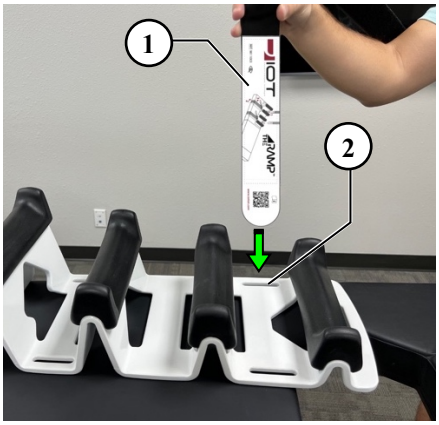


Fig. 5-2: Inserting belt

1 Belt

2 Operative Side Belt Slot

- ▶ Ensure the belt (1) is oriented so that the white label is facing inwards (medially) as shown in Figures 5-2 and 5-3.
- ▶ Insert the belt (1) vertically downward through the operative side belt slot (2).

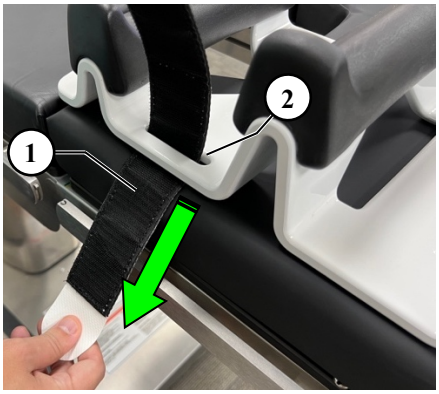


Fig. 5-3: Installing belt

1 Velcro

2 Operative side belt slot

- ▶ Ensure the belt is oriented as shown with the Velcro (1) facing outward (laterally).
- ▶ Continue feeding the belt through the operative side belt slot (2).

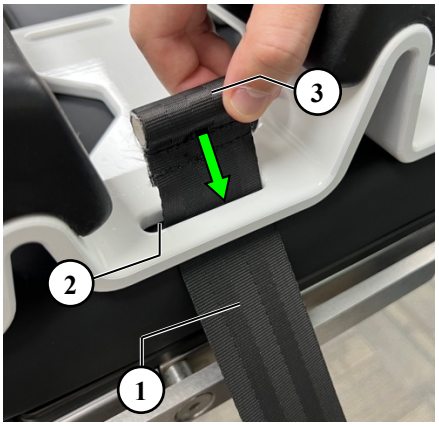


Fig. 5-4: Advancing belt

1 Belt
2 Belt slot
3 Dowel

▶ Continue feeding the belt (1) downward through the belt slot (2) until the dowel (3) stops the belt from advancing.

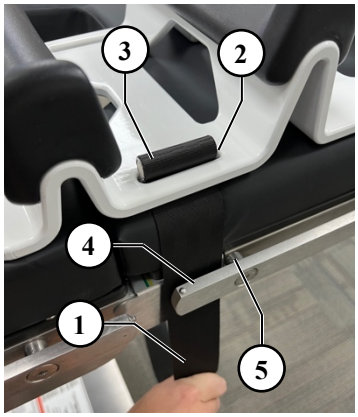


Fig. 5-5: Positioning belt

1 Belt
2 Belt slot
3 Dowel
4 OR table siderail
5 Siderail standoff

▶ Ensure the belt (1) is fully pulled down so the dowel (3) is firmly secured into the belt slot (2) from above.

▶ For maximum stability, position the belt behind (medial of) the OR table siderail (4) and proximal of the siderail standoff (5).

Note: Belt Positioning
It is recommended to position the belts proximal of the siderail standoffs to reduce the chance of the RAMP sliding distally during the operation.

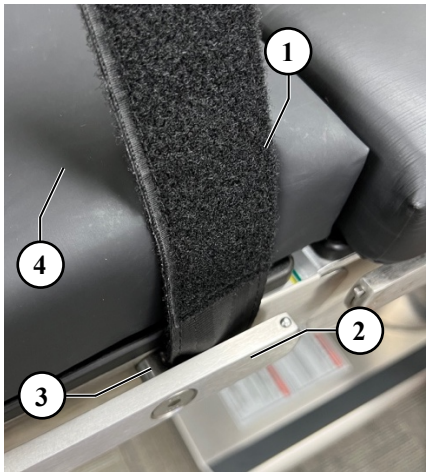


Fig. 5-6: Belt positioning, non-operative side

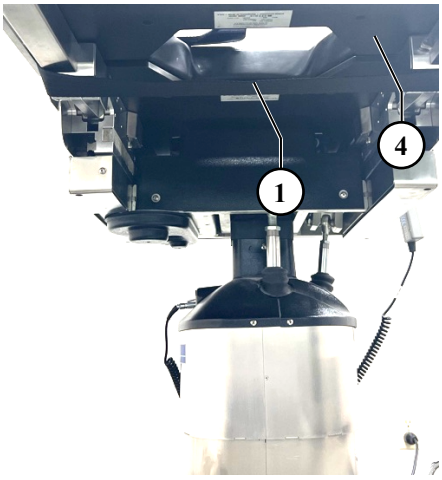


Fig. 5-7: Underside of OR table leg section

1 Belt
2 OR table siderail (non-operative side)
3 Siderail standoff
4 OR table leg section

- ▶ Bring the belt (1) under the OR table leg section (4) and up around the non-operative side.
- ▶ Ensure the belt is not twisted.
- ▶ Ensure the belt is securely routed under the OR table leg section (4) so that it will not slip during the operation due to any components on the underside of the OR table leg section as shown in Figure 5-7.
- ▶ Keep pressure on the belt while feeding it under the OR table leg section and up around the non-operative side.
- ▶ For maximum stability, position the belt behind (medial of) the OR table siderail (2) and proximal of the siderail standoff (3).

Note: OR Table Differences
Different OR tables have different geometries on the underside of the leg section(s). The belts may need to be situated slightly differently depending on the exact OR table used.

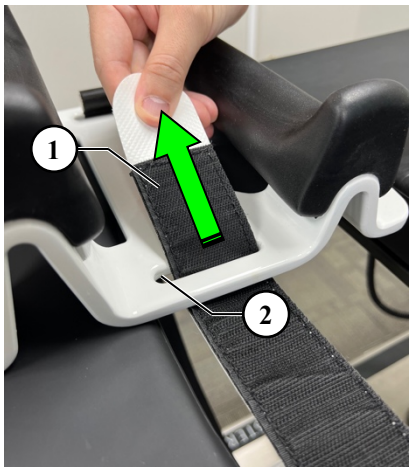


Fig. 5-8: Inserting belt, non-operative side

1 Belt
2 Non-operative side belt slot

- ▶ Ensure the belt (1) is not twisted.
- ▶ Feed the belt (1) upwards through the non-operative side belt slot (2).

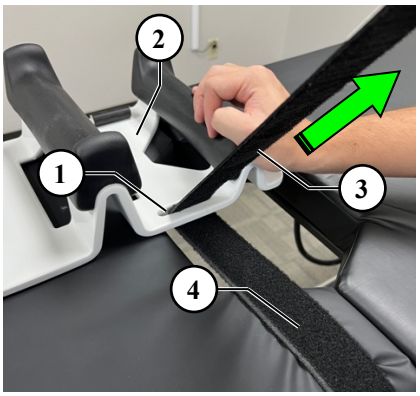


Fig. 5-9: Advancing belt, non-operative side

1 Non-operative side belt slot
2 The RAMP body
3 Male Velcro
4 Female Velcro

- ▶ Continue feeding the belt thought the non-operative side belt slot (1) until all slack is removed from the belt.
- ▶ Firmly hold the RAMP body (2) in position with one hand. Ensure the RAMP remains aligned with edge of the operative side of the OR table.

Fig. 5-10: Securing belt

- ▶ Pull the belt tightly, then move the belt downward to secure the male Velcro (3) onto the female Velcro (4).
- ▶ Visually inspect the strap to ensure it is not twisted, not caught on any components underneath the OR table, and the Velcro is firmly secured.

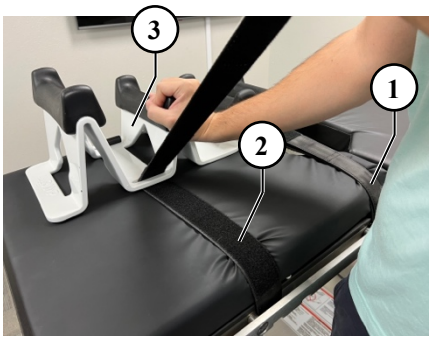


Fig. 5-11: Tightening second belt

Fig. 5-12: Securing second belt

Fig. 5-13: RAMP Installed

1 First belt
2 Second belt
3 The RAMP body

- ▶ Repeat the process described in the previous steps for the second belt (2).
- ▶ Ensure the RAMP body (3) stays aligned with the operative side edge of the OR table as shown in Figure 5-13.
- ▶ Test the stability of the device by applying a force similar to the force that will be applied by the patient's leg during the operation.
- ▶ Tighten belts as needed.
- ▷ Both belts are now properly installed.

Note: Use with Split Leg Sections
The RAMP can also be installed on OR table beds with split leg sections. The belts have Velcro on both sides to facilitate this.

5.2.3. Patient Positioning

WARNING

Risk of contamination from the device

This device is not shipped in sterile condition. There is a risk of contamination.

- Please clean and disinfect the product according to the procedures approved by your organization.
- The product must be positioned under the sterile drape during the surgery.
- Avoid direct contact with the patient.

CAUTION

Risk of injury due to leg manipulation

Stress can be applied to the leg, foot, knee, and/or ankle joints by incorrect positioning of the foot on and/or around the footrests of the RAMP. Not all patient leg positions the RAMP is capable of facilitating are safe for all patients.

- Only place the foot in one of the 6 positions described in section 5.2.3. Do not use any other positions.
- Take caution when positioning the foot, especially if the foot is positioned proximal of the shortest footrest (e.g., during hyperflexion of the knee joint).
- Do not apply excessive force on the leg if the leg or ankle is immobilized by placement on, under, or around any portion of the RAMP.
- The operating surgeon must decide and advise on exact RAMP positioning on the OR table and patient leg positioning.
- Only the operating surgeon or qualified medical personnel should manipulate the leg during the operation.

CAUTION

Risk of injury from the RAMP breaking

The RAMP may break in case of heavy patients over 227 kg (500lb.).

- Use product only for patients of max 227 kg (500 lb.).
- No portion of the patient's body should be placed on the RAMP other than the lower portion of the leg.

ATTENTION

Risk of Damaging The RAMP

The RAMP is not designed to be put through sterilization.

- Do not put the RAMP or the belts through sterile processing.

Note: No Drape Shown

Figures 5-14 through 5-15 below do not show the drape for better visualization. The patient should never come in to contact with any portion of the RAMP, including the belts.

Note: No Lateral Support Shown

The RAMP is intended to be used with a lateral support. A lateral support can help prevent the knee and leg from falling laterally. Figures 5-14 through 5-20 below do not show this support for better visualization.

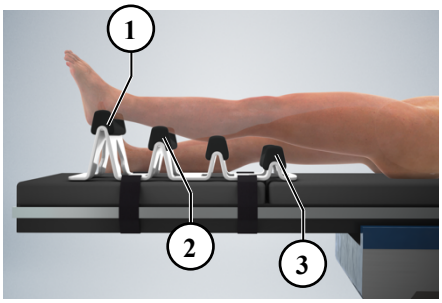


Fig. 5-14: Position 1. Knee in extended position, with the heel resting on the tallest footrest.

1 Tallest footrest

2 Second tallest footrest

3 Shortest footrest

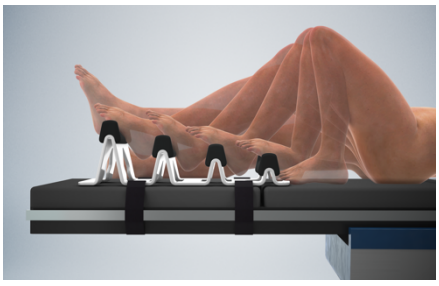


Fig. 5-15: Various possible patient positioning options

- ▶ Add sterile drape(s) over the RAMP.
- ▶ Position the patient so the heel is resting on the tallest footrest (1). This will enable a multitude of positions used during various operations as shown in Figure 5-15. This is a good starting point; however, the surgeon must decide and advise on proper RAMP and patient positioning. Another common technique is to set the device up so the patient's knee flexion is as close to 90 degrees as possible on the second highest footrest (exact angles vary based on patient anatomy).

Note: No Measuring Function

The RAMP is not a measuring tool. The measurements shown on the following page are approximate and are to be used for rough estimation of knee flexion angles only. These knee flexion angles vary based on individual patient anatomy and the exact patient position relative to the RAMP on the OR table.

Fig. 5-16: Position 2

Fig. 5-17: Position 3

Fig. 5-18: Position 4

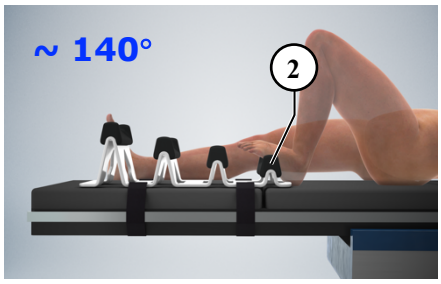


Fig. 5-19: Position 5

Fig. 5-20: Position 6

1 Tallest footrest

2 Shortest footrest

▷ The following 6 positions are now possible. These measurements are only approximations and may be different for different patients.

Position 1: Full Extension

Position 2: ~55° Knee Flexion (foot sole on highest footrest)

Position 3: ~90° Knee Flexion

Position 4: ~115° Knee Flexion

Position 5: ~140° Knee Flexion (foot sole on shortest footrest)

Position 6: ~150° Knee Flexion

▶ To change the amount of knee flexion in various positions, position the patient more proximal or distal than what is shown in Figures 5-14 through 5-20.

▶ Use cation when changing the position of the leg. Additional stress can be applied to the knee joint, especially in positions 5 and/or 6. Positions 5 and 6 may not be safely attainable for all patients.

6. Maintenance and service operation

6.1. Important information

Like every technical device, this device also requires:

- proper operation in accordance with these operating instructions
- regular checks by the operator
- regular maintenance

Through these precautionary measures, you will keep the device in an operationally capable and safe state. For this, you, as the operator, are obligated to comply with rules to prevent accidents and the Medical Products Act.

Maintenance consists of:

- Checks which the operator can carry out.
- Cleaning by personnel assigned by the operator.
- Disinfecting tasks by personnel assigned by the operator.

6.2. Checks by the operator

As the operator, you must check the device for obvious defects. If functional defects or other deviations from normal operating behavior occur, you may no longer operate the device and you must inform customer service. Put the device back into operation only after repair is complete. Operation using defective components can result in increased safety risks.

6.3. Maintenance and service

The device contains the following components that are subject to operational wear:

- belts
- footrests
- The RAMP body

CAUTION

Danger due to defective components

Defective parts may cause a risk of injury.

- ▶ Replace defective parts immediately.
- ▶ Use only original spare parts.
- ▶ Do not use the RAMP if any defects are detected.

6.4. Maintenance plan

The following sections describe tasks which are required for the device to be operated optimally and free of malfunctions.

If regular checks reveal increased wear, shorten the required maintenance intervals to be in accord with the de facto appearance of wear. If you have questions about maintenance tasks and intervals, contact the manufacturer; see the contact data on page 2.

Interval	Maintenance task
As needed	Replace belts
Before each use	Check for defects: - Ensure the belts are in good condition and show no deterioration. - Ensure the Velcro portions function as intended. - Ensure the footrests are firmly attached to the RAMP body. - Ensure no part(s) of the footrest(s) are damaged or missing. - Ensure the RAMP body is mechanically sound and is not cracked or damaged.
	Clean and disinfect the device.

6.5. Maintenance

6.5.1. Cleaning

WARNING

Danger of contamination

This device is not sent in sterile condition.

- ▶ Please clean and disinfect the device according to the procedures prescribed by your organization.

WARNING

Explosion hazard

The use of cleaning agents containing alcohol can lead to the formation of explosive mixtures.

- ▶ Do not use cleaning agents containing alcohol in high-frequency applications.

Please take care in your selection of a cleaning agent:

- ▶ No corrosives, solvents or grinding agents to be used for cleaning or polishing.

ATTENTION

Risk of Damaging The RAMP

Some cleaning agents (e.g. betadine) may stain the RAMP body if left on for long periods of time.

- ▶ Wipe off cleaning agents after use.

6.5.2. Disinfection

The methods used for disinfecting have to comply with the valid legal provisions and guidelines for disinfecting and for explosion protection.

The following disinfectants have been approved for use. Disinfectants not listed may cause discoloration or deterioration of pad surface. If these recommended cleaning products are not available in your area, use a neutral disinfectant or a disinfectant with a sodium hypochlorite solution (0.1% or 1000 parts per million available chlorine).

- Disinfecting/Deodorizing/Cleaning Wipes
- Quaternary Ammonium Compound (Quats) with Ethanol solvent
- Quaternary Ammonium Compound (Quats) with Isopropyl Alcohol (IPA) solvent
- Quaternary Ammonium Compound (Quats) with IPA + 2-Butoxyethanol solvent
- Quaternary Ammonium Compound (Quats) + Biguanide
- Neutral Cleaners

▶ Avoid direct contact with the patient.

7. Transport, storage and disposal

7.1. Decontamination before sending

WARNING

Danger of contamination

After usage, medical devices can contain germs and represent a contamination hazard.

▶ Prior to transport, the operator must clean and disinfect the device according to the procedures authorized by his organization.

7.2. Transport

The product may be transported only in the following approved transport containers:

- Original transport box (item no. 9811004)

A suitable transportation box must be used at any time to prevent possible structural damage to the RAMP during transportation by e.g. truck, plane, or ship.

▶ Make sure that the RAMP and all components are firmly secured.

ATTENTION

Danger of damage

Failure to use an approved transportation box can damage THE RAMP due to the sometimes severe and continued vibrations during transportation.

▶ Use only approved transportation box for transport.

▶ After transportation of the device execute a preventive visual inspection.

7.3. Storage

ATTENTION

Danger of damage if not properly stored

- ▶ Store the device as per the storage conditions – see section "Technical Data".

7.4. Disposal

Please take care to properly dispose of or recycle the device and/or that the pertinent legal requirements are taken into account. For this reason, this product may not be disposed of with ordinary industrial or household waste. Dispose of the individual component parts separately.

IOT AG will, if necessary, will provide support to you regarding proper disposal.

8. Technical data

8.1. Technical data of The RAMP Knee Positioning System

	Designation or name	The RAMP System Overview
General information	Service life, years	5
	Length, mm / in.	600/55.91
	Width, mm/in.	230/32.28
	Height, mm/in.	185/63.78
	Weight, kg/lb.	3/200
Operating conditions	Temperature range, °C	10...40
	Relative humidity, %	5...85
	Atmospheric pressure, kPa	70...106
Storage conditions	Temperature range, °C	-10...+60
	Relative humidity, %	5...85
	Atmospheric pressure, kPa	70...106
Transport conditions	Temperature range, °C	-10...+60
	Relative humidity, %	5...85
	Atmospheric pressure, kPa	70...106
Medical device; class		Class I

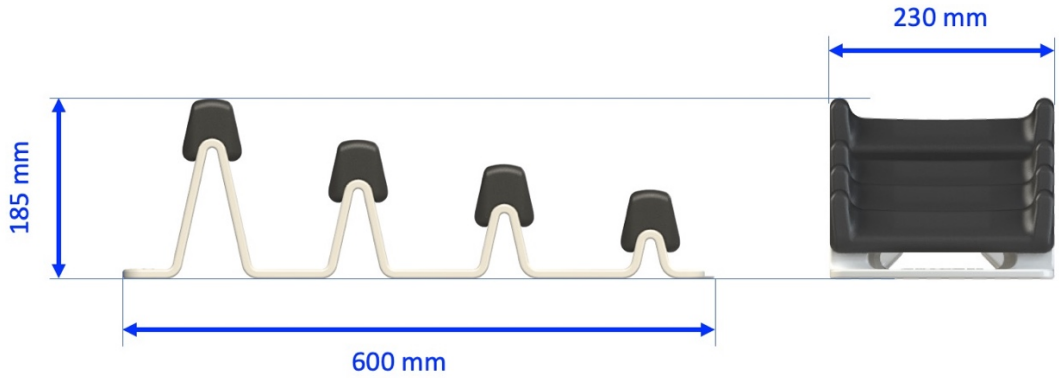


Fig. 8-1: Dimensions of The RAMP

9. Information for ordering

9.1. Spare parts

Only use spare parts with The RAMP that have been officially approved by IOT AG.

Order number	Description
9811003	Belt (qty 1)

10. Revision

Version	Release Date	Company	Reason for Change
V01	June 22nd, 2023	IOT AG	First version
V02	September 12th, 2023	IOT AG	Updated images and other minor updates to section 5.2.2. Updates to sections 5.2.3 and 9.1. Minor updates throughout.