LAPOC

M0790 MCK (Motion Control Knee)

INSTRUCTION MANUAL

MD

■ Foreword

We would like to thank you for using our products.

This prosthetic knee joint is developed for patients with lower limb deficiency above the knee. This product should be fitted on the patients by prosthetists following this instruction manual.

Before use, read this manual in order to use the product safely and appropriately.

After reading this manual, remember to store it in a place easily accessible. If there are any questions and concerns, check this manual for confirmation.

This manual is downloadable from our company official website below.

IMASEN ENGINEERING CORPORATION official website https://www.imasengiken.co.jp/en/

■ Contents

■Symbols

SYMBOLS	MEANINGS
	Indicates the medical device manufacturer
	Indicates the date when the medical device was manufactured
	Indicates the Authorized representative in the European Community
	Indicates the item is a medical device
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates the manufacturer's serial number so that a specific medical device can be identified
	Indicates a barcode as containing Unique Device Identification
	Indicates the need for the user to consult the instructions for use
	Indicates the temperature limits to which the medical device can be safely stored.
	Indicates the packaging box is recyclable.
	Indicates the packaging plastic is recyclable.
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions.
	Indicates a medical device that needs to be protected from moisture.
	Indicates a medical device that can be broken or damaged if not handled carefully.
	Indicates the way is up when the medical device is carried and stored.

■Safety precautions

- Read the "Safety precautions" carefully before usage.
- If the product was not handled following this instruction, there are risks to cause safety issues and malfunctions of the knee joint.

Marking	MEANINGS
⚠ CAUTION	**Caution regarding possible risks of accident or injury.**
NOTICE	**Notice regarding possible technical damage.**

⚠ CAUTION
When used
Never be used when doctors or prosthetists assess the device is inappropriate for the patient. The improper prescription can cause safety issues.
All fitting and adjustments should be carried out by a prosthetist. Incorrect setting may cause safety issues and malfunctions.
All setting and adjustments should be carried out following this instruction manual. Malalignment setting and incorrect adjustment may cause safety issues and malfunctions. The details of the adjustments are described at page 9-12 “Procedure of application and adjustment”.
Confirm the knee is prescribed for the user with the recommended activity levels. Recommended activity levels for M0790 MCK are K1-3 If the device is used for K4 patients, the device might have safety issues and malfunctions.
Never be used when the patient weight is beyond the weight limit of the products. Weight limit of the products for M0790 is 100kg/220lbs. If the patient weight beyond the limit, the device might have safety issues and malfunctions.
Avoid loading onto the prosthetic knee joint in the maximum flexed position. In case of maximum flexion, posterior part of the socket or other components may hit and damage the knee device and the socket (Fig. 1-a). If it is inevitable, make a new hitting point on the distal part of the knee to reduce moment force (Fig. 1-b).
When the knee joint is bent, never put hands around the device. Insertion of fingers between knee components or the knee device and another prosthetic component could cause severe injury such as laceration or fracture. This instruction should be given to users as well.
Do not use parts beyond their useful life (3 years).

This may result in danger from the malfunction or brakeage of the device.
If the knee has been used for their useful life period, contact a prosthetist for consultation

In the event of a malfunction or anomaly:

No repair, modification, or disassembly should be carried out.
This may cause safety issues and malfunction of the device.
Any inspections or repairs must be conducted by IMASEN Engineering Corporation.

NOTICE

When used

Avoid any liquids such as water, sea water, sweat and urine.
It might cause rush formation causing noise, malfunctions and breakage.
This instruction should be given to users as well.

Use the knee within the recommended temperature range.
If the temperature is below -10℃ or more than 60℃, it can cause malfunction of the hydraulic cylinder.

Keep away from fire.
If the user touches the device with high temperature heat storage from fire, it may cause burns.

Tight 4 piece of screws on female pyramid adaptors with the specified torque to connect the proximal and distal pyramids of the device.
Improper connection may result in loosening of the adaptors.

Connect with the adaptors with female pyramid which meet ISO 24562:2022(E).
If the inappropriate adaptors are connected, the connection may result in loosening of the adaptors and limiting the adjustment range.

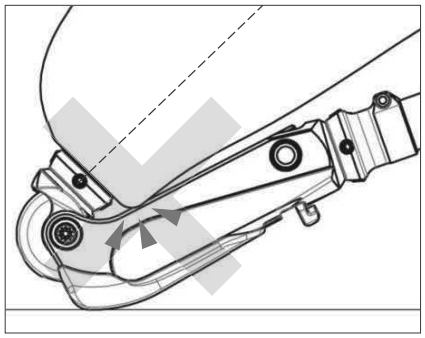
Do not use water and alcohol for cleaning of the knee device.
This may result in rush formation causing noise, malfunctions and breakage. When the cleaning of the knee is needed, wipe it with a piece of dry soft cloth to remove stain and dust.

In the event of a malfunction or anomaly:

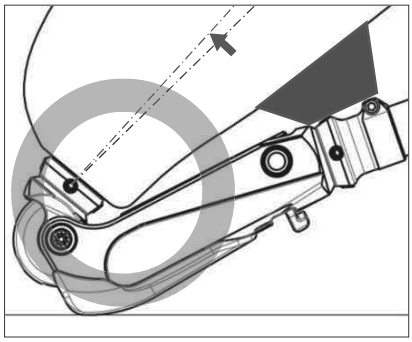
If the any abnormalities such as rattling, noise, malfunction and brakeage of components are found, stop the usage and consult a prosthetist immediately.
If the trouble found or felt, stop using the device and ask a prosthetist to check the condition immediately.

Report any serious incidents occurred in relation to the device to the manufacturer and the competent authorities.
A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
This instruction should be given to lay users as well.

When stored:
Avoid contact with liquids such as water. It can cause rush formation causing noise or malfunctions.
Keep away from fire. If the user touches the device with high temperature heat storage from fire, it may cause burns.
Avoid store in the environment less than -10℃ and more than 60℃. It can cause malfunctions of the hydraulic cylinder.



< Fig. 1-a >



< Fig. 1-b >

■Product General Information

Manufacturer: IMASEN ENGINEERING CORPORATION

Address: 3-1-8 Techno Plaza Kakamigahara Gifu JAPAN 509-0109

Tel: (81)58-379-2714/ Fax:(81)58-379-2712

Homepage: www.imasengiken.co.jp

Brand name: LAPOC

Product Category：Prosthetic Knee Joint

Product Number: M0790

Product Name: MCK (Motion Control Knee)

■ Product Specification

Product Number	M0790
Product name	MCK (Motion Control Knee)
Weight	940g (2.072lbs)
Overall length	210mm
Overall width	45mm
Maximum flexion	180deg.
Swing Control	Hydraulic resistance
Structural material	Aluminum
Weight limit	100kg (220lbs)
Activity level	K1-3

Indication

Product description

This is the mechanical knee joint to replace the knee joint of the patient with above knee lower limb deficiency.

Intended outcome

This prosthetic knee joint is designed to provide the amputees standing and walking.

1. high stability from initial contact to midstance
2. smooth pendulum movement of the below knee section during swing phase
3. adequate knee flexion angle when seated.

Intended user:

Patient with lower limb deficiency and Prosthetists

This knee has to be assembled, adjusted and fitted on patients by prosthetists

This prosthetic knee joint is developed for patients with above knee lower limb deficiency such as patients experienced 1) Transfemoral amputation 2) Knee disarticulation 3) Hip disarticulation. and 4) congenital limb deficiency.

⚠ CAUTION	**All adjustments should be carried out by a prosthetist following this instruction manual.** An incorrect adjustment may cause safety issues and malfunctions.

Contraindication

The prescription of M0790 has to be abundant in the cases below

- The patient is over 100kg (220lbs) and/or K4.
- The doctor decides the prescription of M0790 is inappropriate.

⚠ CAUTION	**Confirm the knee is prescribed for the user with K1-3** If the device is used for K4 patients, the device might have safety issues and malfunctions.
	Never be used when the patient weight is beyond 100kg/220lbs. The device might have safety issues and malfunctions.
	Never be used when doctors or prosthetists assess the device is inappropriate for the patient. The improper prescription can cause safety issues.

Safety of Connection

The proximal and distal male pyramid adaptors must be connected with female adaptors which meet Operational principals of M0790 MCK are following,

Support of loadings

This knee joint is able to support loading of patients with the weight below 100kg while standing and

walking

- **Stance phase control**
  - **Yielding function**

    The hydraulic cylinder “Damper” provides high resistance to support body weight from initial contact to midstance unless the knee is tilted backward. This prevents the knee from collapsing at early stance phase. This mode is called “Standard mode”.
  - **Constant Yeilding function**

    The hydraulic cylinder “Damper” provides high resistance to support body weight at stance phase regardless the knee angle. This prevents the knee from collapsing during stance phase. This mode is called “Constant yielding mode”.
  - **Locking function**

    The knee is able to be locked mechanically at fully extended position. This provides the highest stability. This mode is called “Lock mode”.
  - **Free swing function**

    The knee is able to be unlocked during swing phase. This requires stability by alignment setting and voluntary control by patient. This mode is called “cycling mode”.

- **Swing phase control**
  - **Damping device at swing phase**

    At the swing phase, hydraulic resistance produced by hydraulic cylinder “Damper” controls the knee flexion and extension angle according to walking speed. This hydraulic resistance of the damper is easily adjustable.

NOTICE	**Tight 4 piece of screws on female pyramid adaptors with the specified torque to connect the proximal and distal male pyramids of the device.** Improper connection may result in loosening of the adaptors.
	Connect the adaptors with female pyramid which meet ISO24562:2022(E). If the inappropriate adaptors are connected, the connection may result in loosening of the adaptors and limitation of the adjustment range.

■Operational principals

- **Extension assist mechanism**

  Extension assist spring creates knee extension moment at the late swing phase. It prevents loading on the flexed knee at the heel contact which results knee buckling.

■ Procedure of application and adjustment

● Bench alignment and static alignment

In order to fulfill the proposed function of the knee, follow this instruction to set up the prosthesis following bench alignment and static alignment.

⚠ **CAUTION**	**Set the alignment following this instruction.** An incorrect alignment may cause instability and malfunctions.
NOTICE	**Tight 4 piece of screws on female pyramid adaptors with the specified torque to connect the proximal and distal male pyramids of the device.** An adaptor with female pyramid has to meet the standard, ISO 24562:2022(E). Improper connection may result in loosening of the adaptor.

◆ Bench alignment

The knee is assembled with proximal and distal pyramid adaptors. The proximal pyramid adaptor will be connected above knee section including prosthetic socket. The distal pyramid adaptor will be connected to below knee section including foot.

Before fitting the prosthesis on the patient, check the prosthetic alignment is set in the recommended alignment.

■ in A-P plane (viewing from the side)

The weight bearing line (the plumb line from the mid-point of interior wall of the socket) has to pass along the vertical line on the knee frame. (Fig.2)

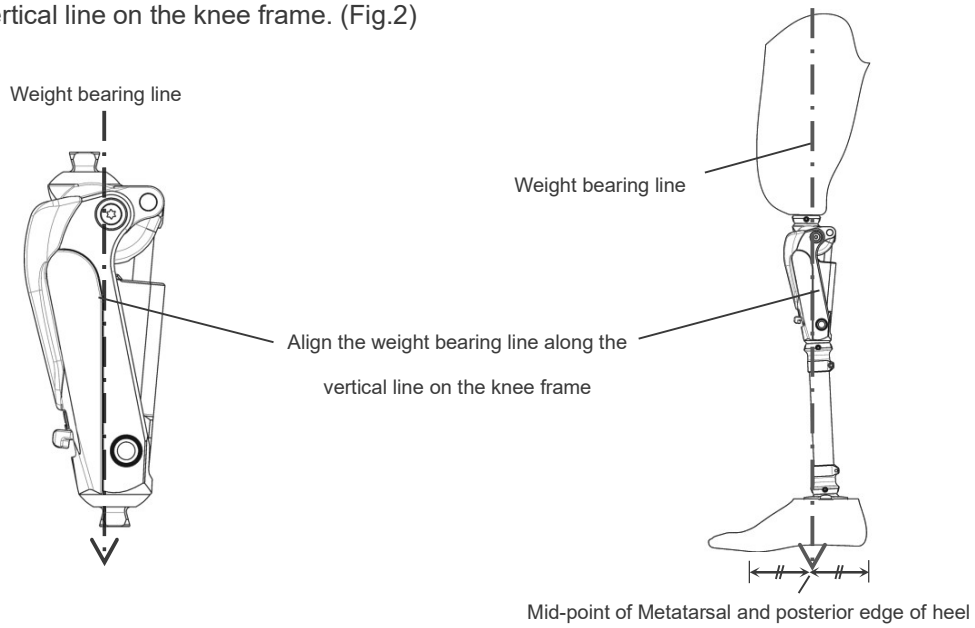


Fig. 2 Bench alignment

■ in M-L plane (viewing from behind)

The weight bearing line (the plumb line from the mid-point of posterior wall of the socket) has to pass the M-L center of the knee and the foot.

◆ Static alignment

After confirmation of the bench alignment is set appropriately, ask the patient put the prosthesis on his residual limb and stand straight between the parallel bars. Then, check the alignment is located in the recommended alignment. Also, confirm the length is correct and the prosthesis is stable without any discomfort.

If it is not aligned appropriately or user complains any discomfort, adjust the alignment or review the socket fitting before dynamic alignment assessment is started.

● Dynamic alignment

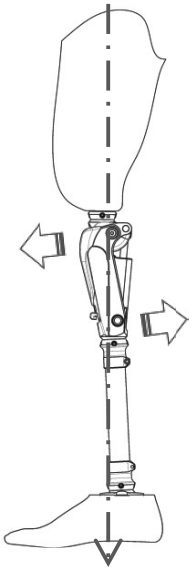
If there are stability issues, please use parallel bars or walking aid devices such as clutches and canes. Ask patient to walk 10 meters to check gait patterns.

After this gait assessment, optimize the gait patterns by adjusting the knee alignment for stance phase stability and damper for swing phase control.

◆ Alignment adjustment for knee stability in stance-phase

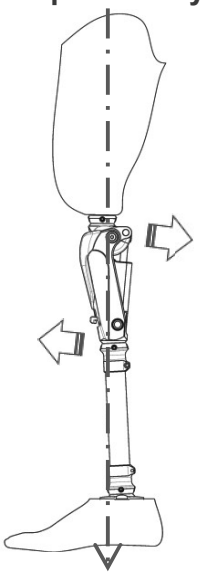
When the knee seems too stable.
When the difficulty to shift into swing phase is observed.

Tilt the knee anteriorly slightly.



When the knee seems unstable.
When the difficulty to activate yielding function is observed.

Tilt the knee posteriorly slightly.

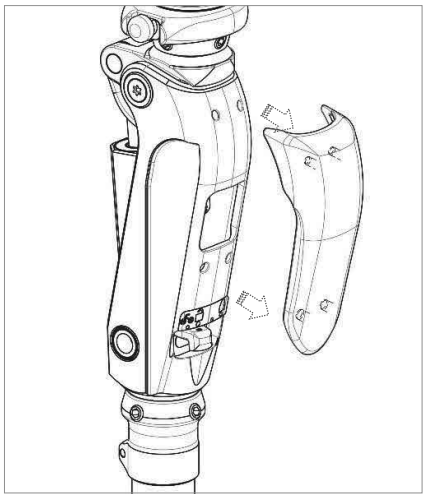


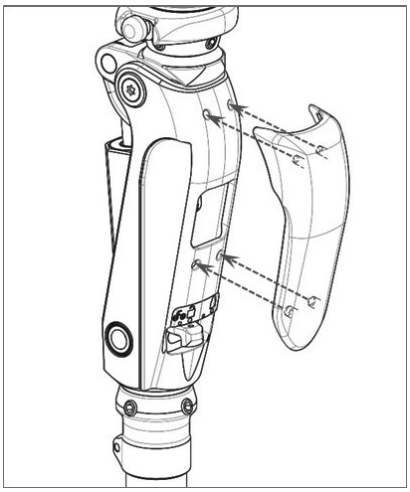
◆ Hydraulic resistance adjustment procedure.

The hydraulic resistance adjustment dials are located anterior part of the damper. It is covered by a front cover. Please pull the cover forward to take the cover out.

After taking off the cover, please bend the knee. The adjustment dials appear inside of the anteriorly located window of the knee frame.

The hydraulic resistance adjustment is finished, put the cover back to the knee frame.





◆ **Yielding resistance adjustment in stance-phase**

Yeilding resistance for stance phase is adjusted by turning adjustment screw marked as S. S stands for stance. The yielding resistance strength has to be adjusted for each user's requirements regarding to body weight, activity level and life style. **The adjustment screw can be turned 180 degrees in counter clockwise from the maximum resistance setting. The yielding resistance is in maximum as the product default setting.**

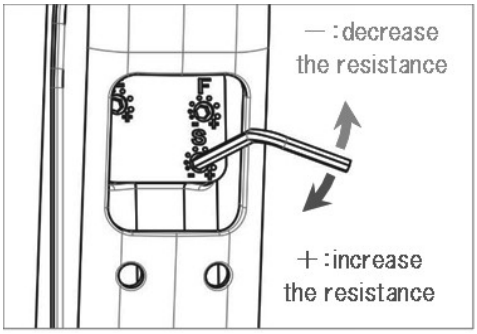
When the knee seems too stable,

Decrease the yielding resistance by turning the screw into counter clockwise).

When the knee seems unstable

Increase the yielding resistance (turning the screw into clockwise)

Yeilding resistance adjustment (S)

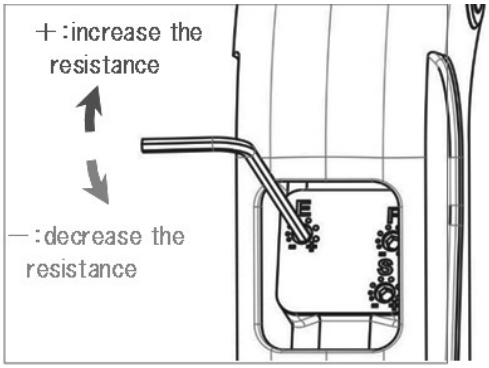


◆ **Adjustment of hydraulic resistance for swing phase control**

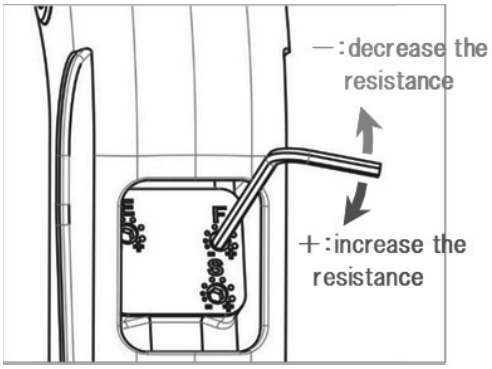
Hydraulic resistance for swing phase is manually adjustable by turning screws on the front of the damper. Extension resistance is adjustable by turning an adjustment screw (E) located on the front of the damper. Flexion resistance is also adjustable by turning an adjustment screw (F) next to the extension adjustment screw. The swing resistance adjustment screws (E) and (F) is able to be turned 180 degrees in clockwise from the minimum resistance setting. The extension and flexion resistance are in minimum as the product default setting.

Please don't turn the screws beyond the range. It might cause damage on the Damper.

Extension resistance adjustment screw (E) :Extension.



Flexion resistance adjustment screw (F) :Flexion.

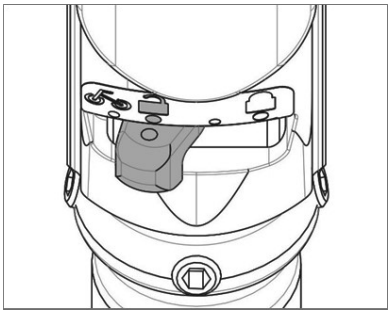


■ Procedure of changing the modes

◆ Yielding resistance adjustment in stance-phase

The four modes can be shifted by sliding the lever on the front of the knee frame.

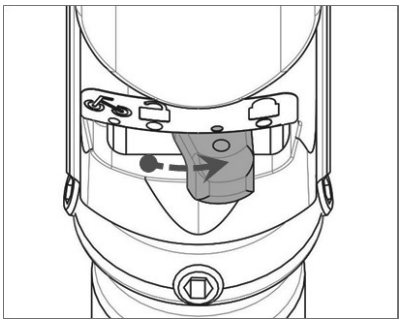
① Standard mode



The pendulum inside of Damper detects the tilting angle of the knee. The yielding function works when the knee is tilted backward.

- Backward tilt: Yeilding is【ON】.
- Forward tilt: Yeilding is【OFF】.

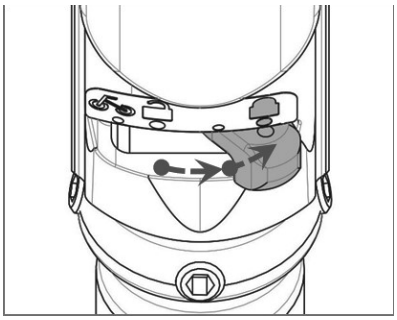
② Constant yielding mode



The yielding function works regardless the tilting angle.

- Backward tilt: Yeilding is【ON】.
- Forward tilt: Yeilding is【ON】.

③ **Lock mode**



The knee is mechanically locked in fully extended position.

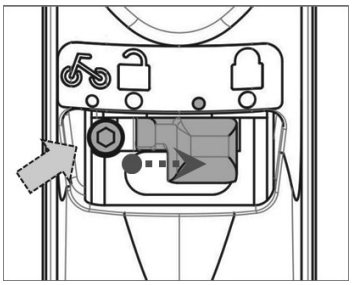
④ **Cycling mode**

※The lever cannot be shifted into Cycling mode when the knee is in default setting for safety purpose.

The cycling mode can be used after the stopper is removed by the following procedure.

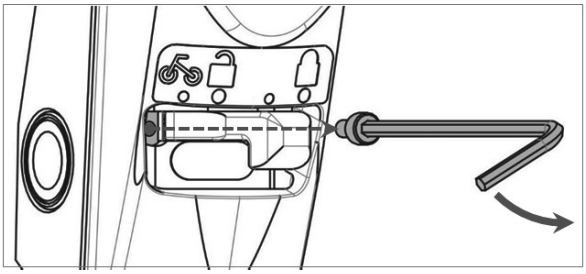
◆Cycling mode stopper removal procedure

1) Side the lever into constant yielding mode.

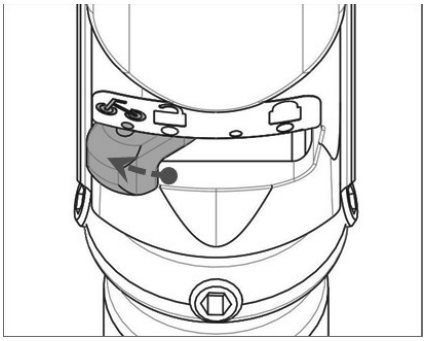


2) Take off a screw (M3x4) on the right side of the lever bottom.

※ Please store the screw if the limit is needed in future.



3) Shift the lever into cycling mode.



The hydraulic yielding resistance will be off unless the knee is tilted backward and forward.

4) To stop the lever shift into the cycling mode for safety reasons, please put the screw back to the original hold.

⚠ CAUTION	**Adjust the flexion resistance within the adjustment range of Damper (1/2 rotations).** Inappropriate adjustment of the flexion resistance may cause unnatural gait pattern and instability.
	Adjust the extension resistance within the adjustment range of Damper (1/2 rotations). Inappropriate adjustment of the extension resistance may cause unnatural gait pattern and instability.

■ Delivery of prosthetic limb

When handing over a prosthetic leg, please explain the following to the user.

(1) After wearing the prosthesis, be sure to check that the knee joint is functioning properly before starting walking.

(2) If an abnormality occurs in the yielding function at the start of use, switch the mode switching lever to "(2) Constant yielding mode" (see P9) and bend the knee joint deeply multiple times. After that, switch to normal mode and make sure the yielding works.

(3) If the yielding function does not function properly in the above procedure, explain that the mode selector switch lever should be safely set to "(3) Lock Mode" (see P9) and then contact the prosthetist.

(4) Perform regular inspections at least once a year.

■Maintenance/Repairment instruction

Any inspections or repairs should be conducted by IMASEN Engineering Corporation.

⚠ CAUTION	**No repair, modification, or disassembly should be carried out.** This may cause safety issues and malfunction of the device. Any inspections or repairs should be conducted by IMASEN Engineering Corporation.
NOTICE	**If the any abnormalities such as rattling, noise, malfunction and brakeage of components are found, stop the usage and consult a prosthetist immediately.** If the trouble found or felt, stop using the device and ask a prosthetist to check the condition immediately.

■ Warranty

Warranty period: 2 years after the delivery

If the product is used inappropriately or against this instruction manual, any incidences are out of our warranty. Once products are disassembled outside of IMASEN Engineering Corporation, the product is not acceptable for our service and any incidents are out of manufacturer's quality control responsibility.

NOTICE	**Report any serious incidents occurred in relation to the device to the manufacturer and the competent authorities.** A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. This instruction should be given to lay users as well.

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