LAPOC

M0703 Dolphin

INSTRUCTION MANUAL

Dolphin
M0703 Compact Hydraulic Single Axis Knee

CE 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
	Signifies European technical conformity
	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 alignment 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 9-11 “Procedure of the application and adjustment”
Confirm the knee is prescribed for the user with the recommended activity levels. Recommended activity levels for M0703 Dolphin are K3-4 If the device is used for K1 and K2 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 M0703 is 100kg/220lbs. 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 -20℃ 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 pyramids of the device.

Improper connection may result in loosening of the adaptors.

Tight the screw with the specified torque to connect a tube distal to the device.

Improper connection may result in loosening of the tube.

Connect with the adaptors with female pyramid which meet ISO/DIS 24562:2021(E) standardized by ISO/TC168.

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.

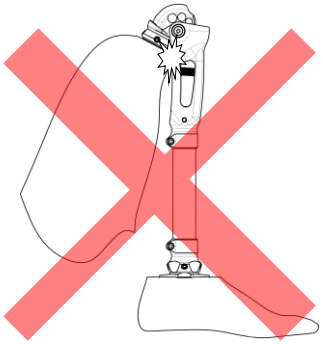
Report any serious incidents occurred in relation to the device to the manufacturer and the competent authorities.

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.

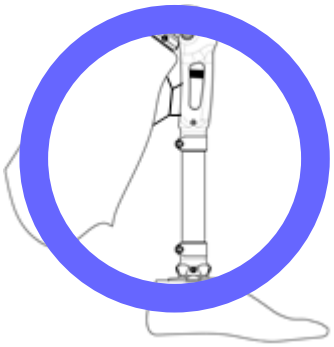
This instruction should be given to lay users as well.

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 -20℃ and more than 80℃. 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: M0703

Product Name: Dolphin

■ Product Specification

Product Number	M0703
Product name	Dolphin
Weight	495g (1.091lbs)
Overall length	187mm
Overall width	54mm
Maximum flexion	180deg.
Swing Control	Hydraulic resistance
Structural material	Aluminum
Weight limit	100kg (220lbs)
Activity level	K3-4

Indication

Product description

This is the mechanical knee joint to replace the knee joint for 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 with fully extended knee position during the stance phase
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 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 M0703 has to be abundant in the cases below

- The patient is over 100kg (220lbs) and/or K1-2.
- The doctor decides the prescription of M0703 is inappropriate.

⚠ **CAUTION**	**Confirm the knee is prescribed for the user with K3-4** If the device is used for K1-2 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 male pyramid adaptors must be connected with female adaptors which meet ISO/DIS 24562:2021(E) standardized by ISO/TC168 with specified torque of the female adaptors.

The distal tube connecter on the knee must be connected with 300mm tube with specified torque below.

○**Tightening Torque**

Screw type	Tightening Torque	Device Used
M5 Allen Hex Socket Screw	7.8～8.0Nm	4 mm Hexagon Wrench

NOTICE	**Tight 4 piece of screws on female pyramid adaptor 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 ISO/DIS 24562:2021(E) standardized by ISO/TC168. If the inappropriate adaptors are connected, the connection may result in loosening of the adaptors and limitation of the adjustment range.
	Connect a tube with the distal tube connector on the knee with specified torque, 7.8～8.0Nm. If the inappropriate tubes are connected, the connection may result in loosening of the tube and disengagement.

■ Operational principals

Operational principals of M0703 Dolphin are following,

● Support of loadings

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

● Stance phase control

◆ Extremely stabile knee axial position

As compared with conventional single axial knees, Dolphin has set up a knee axis position posterior. This provides excellent stability at stance phase. Dolphin can be used by those who can control the knee voluntarily.

● Swing phase control

◆ Damping device at swing phase

At the swing phase, hydraulic resistance produced by hydraulic cylinder “Damper” controls the knee flexion angle according to walking speed. At the late stance phase, knee flexion resistance is low. This setting allows the transit from the stance phase to swing phase easily. This hydraulic resistance of the damper is easily adjustable.

◆ 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 the 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/DIS 24562:2021(E) standardized by ISO/TC168. Improper connection may result in loosening of the adaptor.

◆ Bench alignment

The knee is assembled with a pyramid adaptor proximally and tube distally. The proximal adaptor will be connected above knee section including prosthetic socket. The distal tube 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 10-15mm anterior to the knee center. (Fig.2)

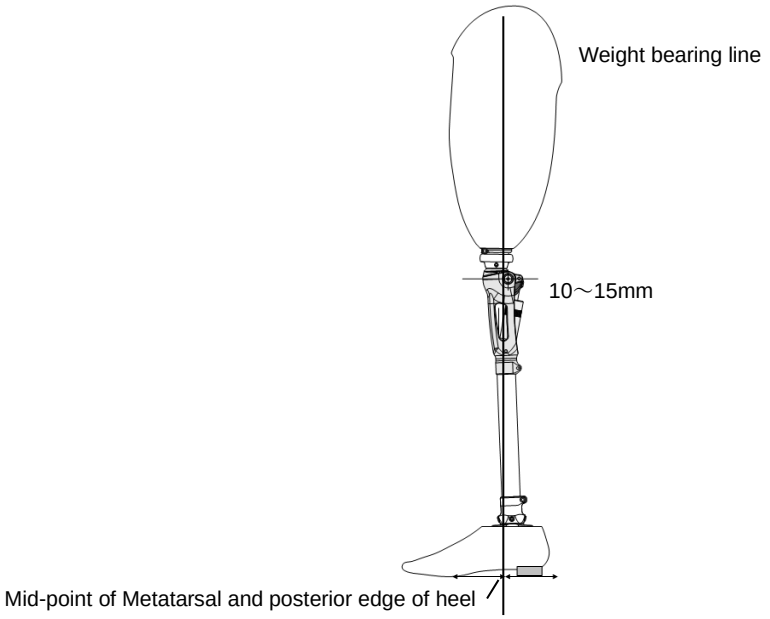


Fig. 2 Bench alignment

■ 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 start dynamic alignment assessment.

● 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,

Shift weight bearing line further anterior to the knee axis

When the knee seems unstable

Shift weight bearing line posterior and closer to the knee axis

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

Hydraulic knee flexion resistance is manually adjustable by turning Damper. Extension resistance is manually adjustable by turning an adjustment screw on the proximal section of the damper.

○Adjustment of flexion resistance for swing phase control

・ Counter clockwise rotation of the cylinder increases flexion resistance of the knee device. Clockwise rotation of the cylinder decreases flexion resistance (Fig.3). Hydraulic resistance will be changed from minimum to maximum by **2 rotations of the cylinder. Flexion resistance is in the intermediate state as the product's default setting.**

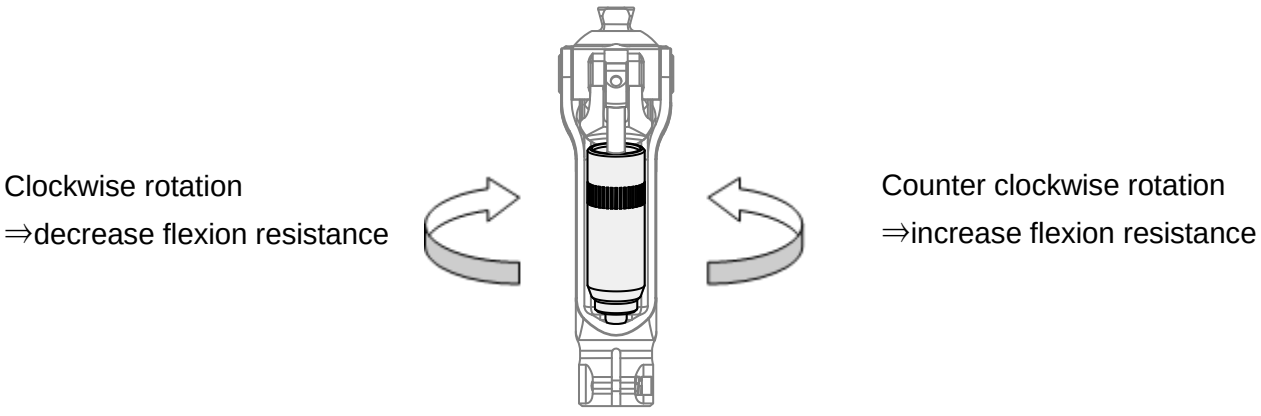


Fig. 3 Flexion resistance adjustment of hydraulic cylinder for swing phase control

○Adjustment of extension resistance for swing phase control

・ Turn an adjustment screw on the proximal section of the damper using a hexagon wrench for adjustment (Fig.4). The range of adjustment is approximately 2 rotations from the condition where the adjustment screw is tightened completely (maximum resistance to the extension). Extension resistance is set in the middle state in the products default setting.

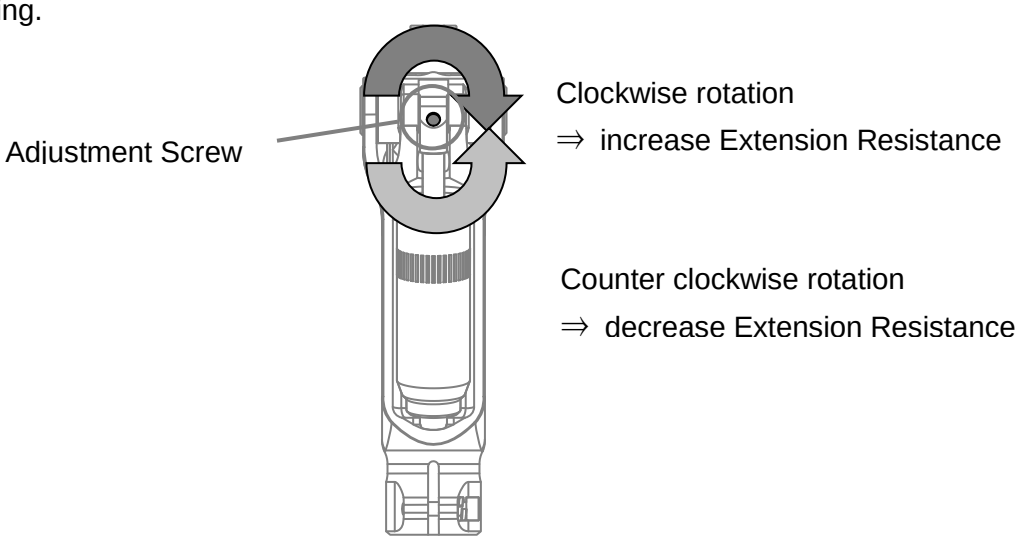


Fig. 4 Flexion resistance adjustment of hydraulic cylinder for swing phase control

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

■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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