LAPOC

Instruction manual of M0786 Swan100

Swan100

M0786 Multi Axial Bouncing Type Safety 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 10-15 “Procedure of the application and adjustment”
Confirm the knee is prescribed for the user with the recommended activity levels. Recommended activity levels for M0786 Swan are K2-3 If the device is used for K1 and 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 M0786 is 125kg/275lbs. 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, place a soft pad between socket and the knee for shock reduction (Fig. 1-b) and make a new hitting point to distal part of the knee to reduce moment force (Fig. 1-c).
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 and distal male pyramids of the device.

Improper connection may result in loosening of the adaptors.

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 or hydrolysis 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.

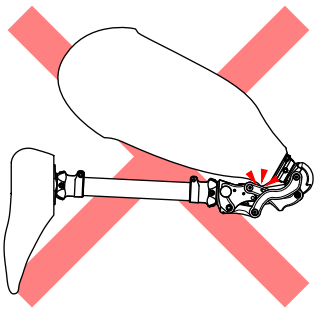
This instruction should be given to lay users as well.

When stored:

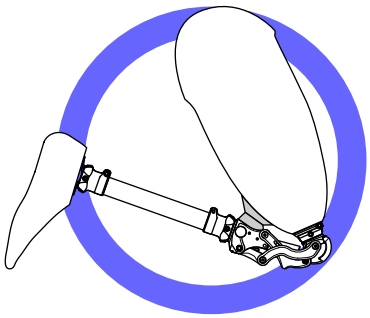
Avoid contact with liquids such as water.

It can cause rush formation causing noise or malfunctions.

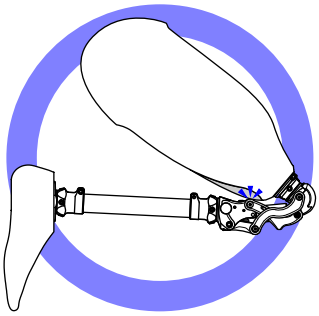
Keep away from fire. If the user touches the device with high temperature heat storage from fire, it may cause burns.
Avoid store in the environment less than -20℃ and more than 80℃. It can cause malfunctions of the hydraulic cylinder.



< Fig. 1-a >



< Fig. 1-b >



< Fig. 1-c >

■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: M0786

Product Name: Swan100

■ Product Specification

Product Number	M0786
Product name	Swan100
Weight	935g (2.061lbs)
Overall length	198mm
Overall width	76mm
Maximum flexion	150deg.
Stance Control	Bouncing
Swing Control	Hydraulic resistance Extension spring assistance
Structural material	Aluminum
Weight limit	125kg (275lbs)
Activity level	K2-3

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 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 M0786 has to be abundant in the cases below

- The patient is over 125kg (275lbs) and/or K1 and K4.
- The doctor decides the prescription of M0786 is inappropriate.

⚠ **CAUTION**	**Confirm the knee is prescribed for the user with K2-3** If the device is used for K1 and K4 patients, the device might have safety issues and malfunctions.
	Never be used when the patient weight is beyond 125kg/275lbs. 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 ISO/DIS 24562:2021(E) standardized by ISO/TC168 with specified torque of the female adaptors.

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 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 limitation of the adjustment range.

■ Operational principals

Operational principals of M0786 Swan100 are following,

● Support of loadings

This knee joint is able to support the loading of patients with the weight under 125kg while standing and walking

● Stance phase control

◆ Bouncing mechanism at stance phase

At heel contact with full knee extension (Fig.3-a), the lower 4 bar linkage described (Fig.2) is displaced which results in 3° flexion of the knee joint (Fig.3-b). While the displacement, the bouncing bumper absorbs the shock and the anterior and posterior links become closer to parallel. In this process, the instantaneous center of rotation (I.C.R.) of the knee joint shifts upward and backward of the hip joint instantly. This prevents knee buckling.

After mid-stance, according to the weight shift, the knee returns to the original four bar linkage position and allows knee flexion at final stage of stance-phase (Fig.3-c & 3-d). The slight knee flexion reduces vertical fluctuation of center of body gravity. It absorbs ground reaction force, helping smooth forward progression. This results in natural gait and reduction of energy consumption. The sensitivity and amount of bouncing movement can be adjusted by the alignment and hardness of bouncing bumper.

Fig.2 Lower four bar linkage for bouncing mechanism

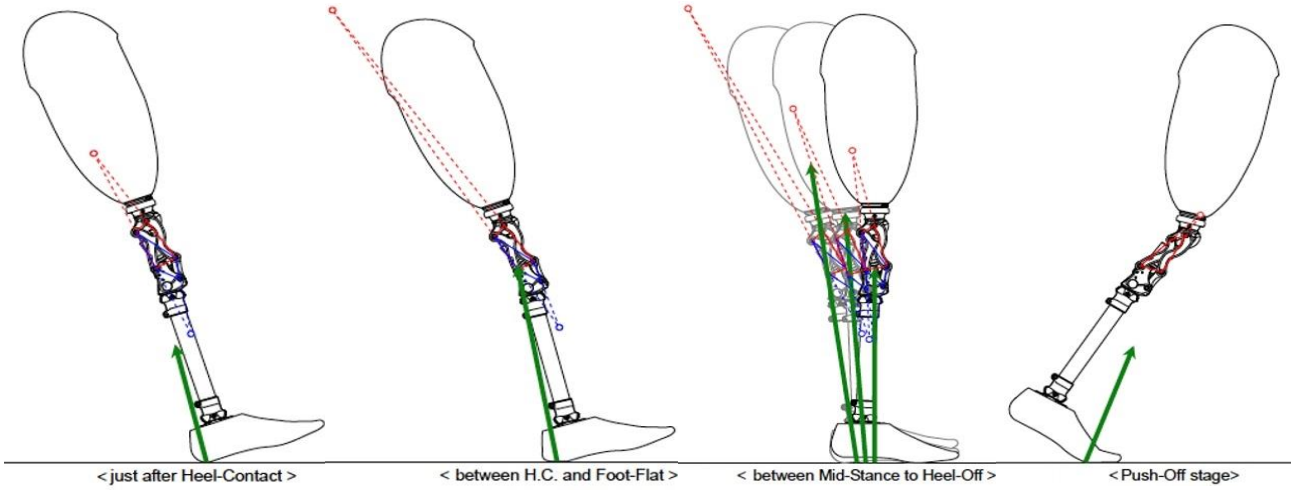


Fig.3 Displacement of configuration of Swan100 links by loading

● Swing phase control

◆ Multiaxial linkage mechanism

At the swing phase, the upper four bar linkage mechanism (Fig.4) enables clearance between the foot and floor bigger which prevents the toe from catching the floor during swing phase.

Fig.4 Upper four bar linkage for swing phase

◆ 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 for low to moderate active users. 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 proximal and distal pyramid adaptors. The proximal adaptor will be connected above knee section including prosthetic socket. The distal pyramid adaptor will be connected to below knee section including foot.

Before put 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 the center of upper axis of anterior link and lower attachment axis of hydraulic cylinder and mid-point of Metatarsal and posterior edge of heel (Fig. 5).

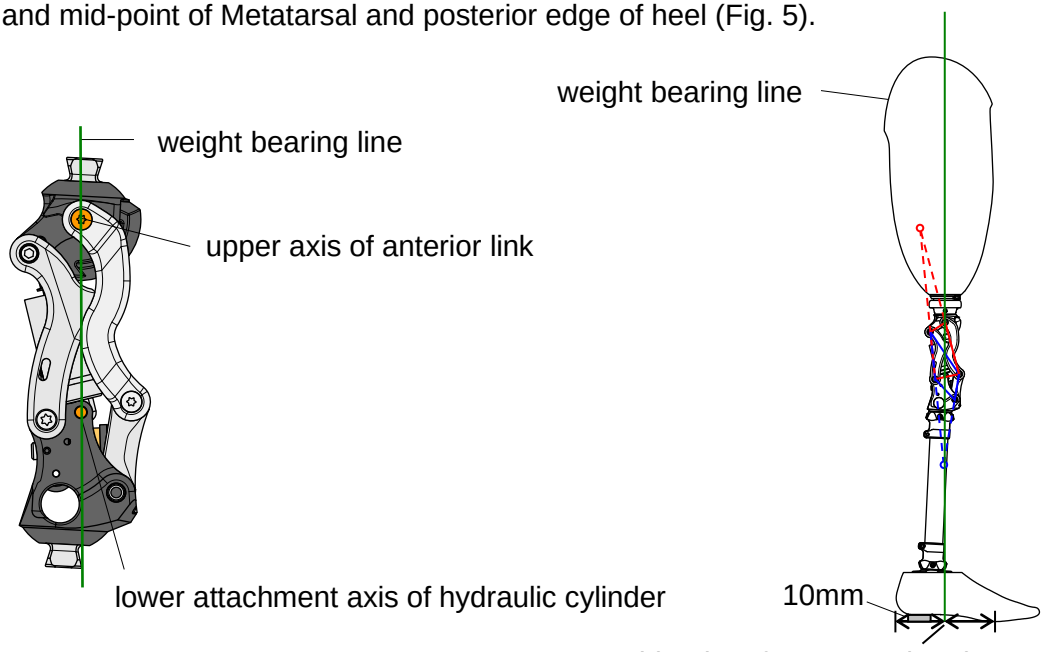


Fig. 5 Bench alignment

■ 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.

● 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 and hardness of the bouncing bumper for stance phase stability and damper and extension assist springs for swing phase control.

◆ Alignment adjustment for knee stability in stance-phase

■ First step (Controlling the knee stability by “tilting the knee in A-P plane”)

When the knee seems too stable,

During dynamic alignment setting, if you aware following set of signals, such as

Too deep bouncing with mechanical noise with difficulty of knee flexion after heel-off

→ increase the forward tilt of the knee (Fig.6-a)

(Shift weight bearing line anterior to the lower attachment of hydraulic cylinder)

When the knee seems unstable

During trial walking, if you aware following set of signals, such as

instability with no bouncing movement at heel contact,

→ decrease the forward tilt of the knee (Fig. 6-b)

(Shift weight bearing line posterior to the lower attachment axis of hydraulic cylinder)

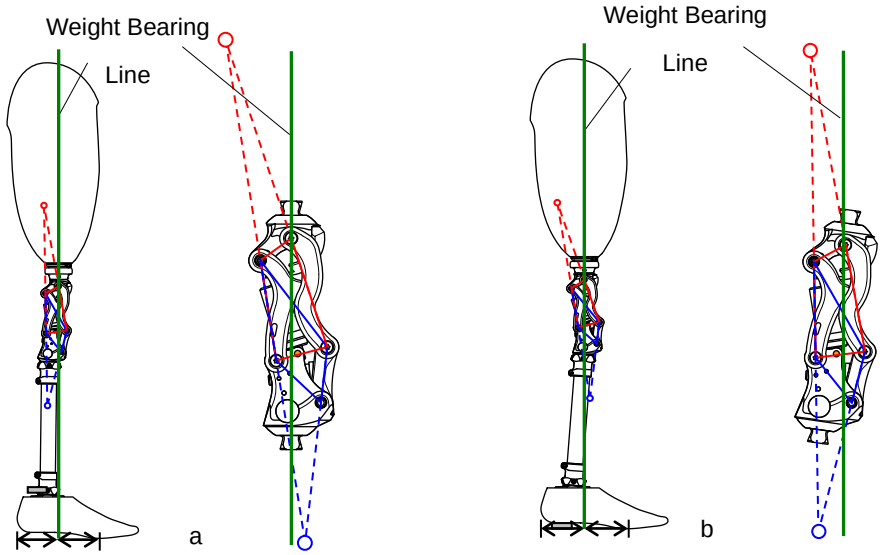


Fig. 6 Adjustment of knee stability in stance-phase

■ Second step (Adjustment of the hardness of bouncing bumper)

In case of trial walking, patient may claim that the knee stance phase movement is so soft and not reliable. Those instable feeling could be caused by too soft bouncing setting. If forward tilt of the knee is already enough and there is no fear for knee buckling, increase bouncing bumper hardness (increase of initial compression rate of the bumper) can reduce those unfavorable feeling.

Procedure (Fig. 7)

① Loosen M4 screw situated below right-side anterior link using 2mm wrench.
② Turn M8 screw on the posterior part of the knee clockwise using 4mm wrench.
③ If the user still feels instability even the bouncing works, rotate the M8 screw further.
④ After the adjustment is finished, please tight M4 screw back.
※Do not rotate M8 screw counter clockwise further than the default setting.

⚠ **CAUTION**	**Adjust the bouncing bumper within the specified adjustment range.** Inappropriate adjustment of the bumper could cause instability and malfunction.

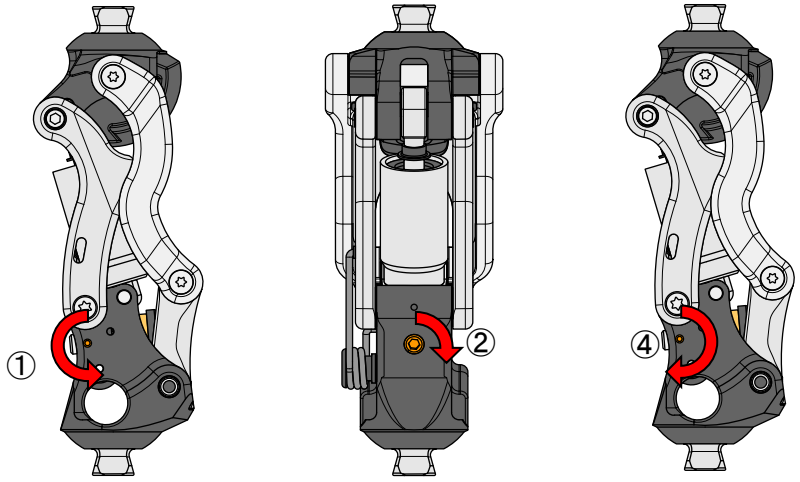


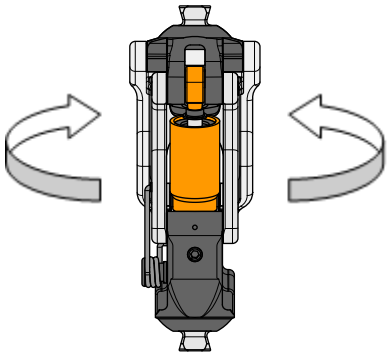
Fig. 7. Adjustment of the hardness of bouncing

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

Hydraulic knee flexion resistance is manually adjustable by turning Damper. Extension resistance is adjusted in accordance to extension velocity of the below knee section.

Counter clockwise rotation of the cylinder increases flexion resistance of the knee device. Clockwise rotation of the cylinder decreases flexion resistance (Fig. 8). Hydraulic resistance will be changed from minimum to maximum by **1 and 1/4 rotations of the cylinder. The device is set in minimum resistance at the time of shipping.**

Clockwise rotation
⇒decrease flexion resistance



Counter clockwise rotation
⇒increase flexion resistance

Fig. 8 Adjustment of hydraulic cylinder for swing phase

⚠ **CAUTION**	**Adjust the flexion resistance within the rotation range of Damper (1 and 1/4 rotations).** Inappropriate adjustment of the flexion resistance may cause unnatural gait pattern and instability.

◆ **Adjustment of extension assist strength for swing phase control**

The swing phase is enabled to be adjusted by using M07-001 extension assist spring kit.

The M07-001 kit comes with right side “firm & weak” springs and a left side “weak” spring. This allows the clinician to adjust the extension assist on the Swan100 for an amputee’s gait with 6 different settings as shown in Table 1.

Strength		Left side	Right side
Weak	1	None	None
	2	Weak spring	None
	3	**Firm spring**	**None**
	4	Weak spring	Weak spring
	5	Firm spring	Weak spring
Firm	6	Firm spring	Firm spring

Setting 3 is the default setting.

Table. 1 Combination of springs, and strength of extension assist control

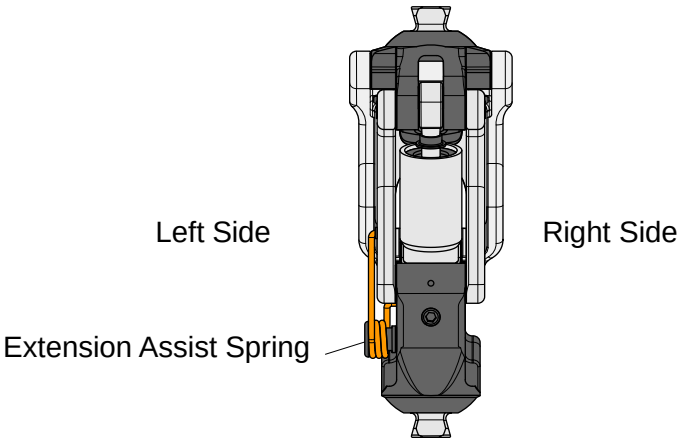


Fig. 9 Swan100 (Posterior View)

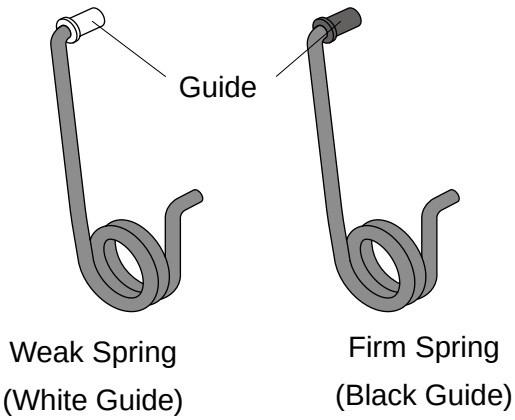


Fig. 10 Spring

M0786 Swa100 comes with a left side firm spring as the default setting (Fig. 9.). The extension assist strength is adjustable by altering the spring combination.

Each spring strength is indicated by the color of the guide as shown in Fig. 10. The white guide is installed on weak springs and the black guide is installed on the firm spring.

◆ **Procedure for Spring Alteration**

When the spring is required to be changed, follow the procedure below.

Step 1 Removal of spring.

1. Use a Phillips –head screwdriver to loosen the screw shown in Fig. 11.

2. Remove the spring from the knee.

Step 2 Preparation of spring to be inserted.

1. Place the retainer through the coil section.
2. When the weak spring (White Guide) is installed, use the white retainer. When the firm spring (Black Guide) is installed, use the black retainer.
3. Apply grease to the periphery of the retainer and the guide on spring (Fig. 12).

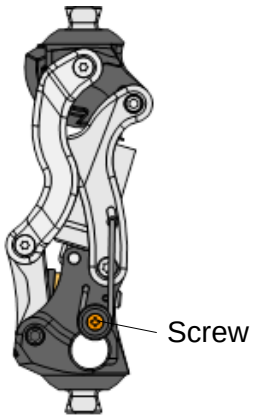


Fig. 11

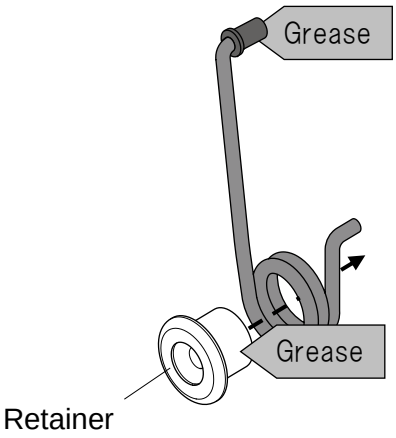


Fig. 12

Step 3 Installing springs.

1. Mount weak or firm springs on the mounting hole indicated by the arrow in Fig. 13-a and Fig. 13-b.
2. Push the spring with a finger so that the retainer hole may be matched to the spring mounting hole of the Swan100 body (as shown by the arrow in Fig.13-c).
3. Then tighten the attached set screw for fixation.
4. After determining the optimum strength of the extension assist, apply anti-loosening agent to the screw and tighten it for fixation.

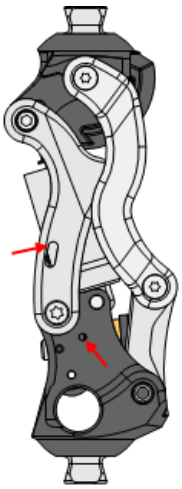


Fig. 13-a

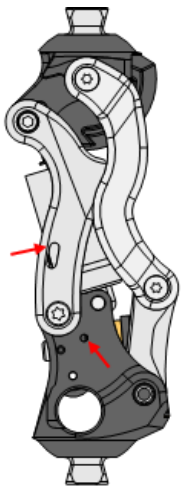


Fig. 13-b

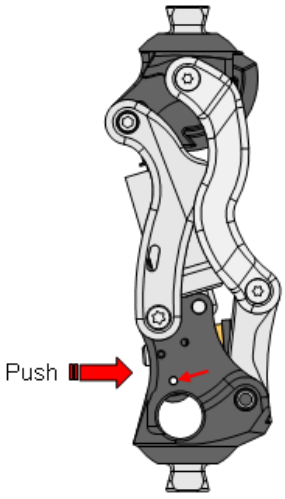


Fig. 13-c

⚠ **CAUTION**	**Adjust the spring extension strength following the procedure above.** Inappropriate spring setting may cause malfunction and the safety issues.
NOTICE	**Apply grease on Guide and Retainer.** If grease is not applied, Guide and Retainer can be planed due to friction.
NOTICE	**Apply anti-loosening agent on the screw.** If anti-loosing agent is not applied, the screw can be loosened.

■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 incidence 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.

EC REP MedNet EC-REP GmbH,
Borkstrasse 10,
48163 Münster,
Germany

IMASEN ENGINEERING CORPORATION
3-1-8 Techno Plaza Kakamigahara Gifu JAPAN 509-0109
Tel: (81)58-379-2714/ Fax:(81)58-379-2712
www.imasengiken.co.jp
lapoc@imasengiken.co.jp