Instruction manual of Swan knee joint

Multi Axial Swaying Type Safety Knee

Swan

M0780

CE

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■ Foreword

We would like to thank you for using our products.

This manual describes product handling, adjustments, precautions, etc. in order to ensure safe use for the lifetime of the product.

Before use, be sure to read the manual thoroughly in order to use the product safely and appropriately.

After reading the manual, remember to store it in a place easily accessible to the user. If there are problems during normal use, be sure to check the manual for confirmation.

Contents

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Safety precautions

- Before use, read the "Safety precautions" carefully for proper use.
- What is given here shows important instructions on safety. Be sure to follow them.
- Symbols and their meanings are as follows:

⚠ WARNING

In the event of a failure or anomaly:

No repair, modification, or disassembly should be carried out.

This may cause trouble.

A request for inspections or repairs should be made to our company.

When used:

Make sure that a user firmly maintains stability of prosthetic knee by sitting on a chair or holding on to parallel bars before the hydraulic cylinder is adjusted.

When the instability of prosthetic knee causes the knee joint to be bent while the hydraulic cylinder is being adjusted, fingers could get caught between the hydraulic cylinder and the knee frame, causing serious injury.

Make sure that a user firmly maintains stability of the prosthetic knee before an adjustment is made.

⚠ CAUTION

Do not use parts beyond their useful life.

This may result in damage to parts.

For the parts that are beyond their useful life, advise users to contact an orthotist for consultation.

All adjustments should be carried out by an orthotist.

An incorrect adjustment may cause trouble.

This instruction should be given to users as well.

Tighten individual bolts to the specified torque.

Tighten bolts to the specified torque using a torque wrench.

Avoid contact with water, sea water or other liquids.

This is to prevent trouble that may be caused by rust formation on parts.

This instruction should be given to users as well.

Before use, check to breakage of part, loosen of bolts.

This is to prevent the trouble during use.
If the trouble found, stop the use, and guide to talk to orthotist immediately.

If the breakage of part or the bolts loosen or abnormality, stop the use immediately.
If the trouble found or felt, stop to use, and guide to talk to orthotist immediately.

With the knee joint bent, never put hands between the knee joint and the vicinity of the extension stopper or the backward of the socket.
This is to prevent injury that may occur to fingers when they are caught.
This instruction should be given to users as well.

When stored:

Avoid contact with water, sea water or other liquids.
This is to prevent trouble that may be caused by rust formation on parts.
This instruction should be given to users as well.

In the event of a failure or anomaly:

When there is an anomaly such as looseness, abnormal noises, and/or oil leakage, immediately contact an orthotist for consultation.
Neglecting looseness, abnormal noises, oil leakage, etc. may cause bodily injury or damage to parts, etc.
In the event of such problems, advise users to contact an orthotist for consultation

⚠ CAUTION

1. Don't loose M8 screw (situated at behind of the knee). Before shipping, the screw is set as 2 full turns from the minimum compression.
2. Too much bouncing movement may damage dynamic stabilizing mechanism, especially in case of active patients who are able to stabilize the prosthetic knee joint voluntarily.
3. Use of very soft heel bumper or too small step length may not actuate dynamic stabilizing mechanism of the knee.
4. Heel Contact without full extension of the knee joint may cause knee-buckling.
5. If patient usually load on his prosthesis in maximum flexed position, put a shock reducing soft pads between socket and the knee (Fig. 7).

In case of maximum flexion of long stump, posterior end part of the socket may hit and damage the posterior link or hydraulic cylinder (Fig. 8-a). If it is inevitable, please change the hitting point to distal part of the knee to reduce moment force. Use softer material and make a new hitting point at more proximal part of the socket (Fig. 8-b).

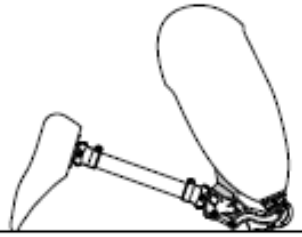
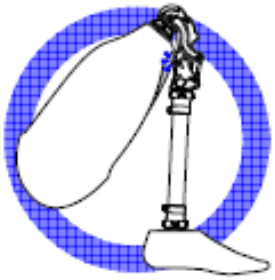


Fig.7

< Fig. 8-a Bad >

Fig. 8



< Fig. 8-b Good >

Indication

The knee is applicable for following patients.

	body weight	activity level
M0780 Swan	up to 75 kg(165 lbs)	low to moderate

Features

Dynamic stabilizing mechanism to prevent knee buckling

At heel contact, the lower part of the knee joint bends slightly to minimize the shock of floor reaction force. In this process, the two vertical links (front & rear) become nearly parallel and the instantaneous center of rotation (I.C.R.) of the knee joint shifts upward and backward of the hip joint instantly preventing knee buckling.

After mid-stance, the knee returns to basic four bar linkage and allows knee flexion at final stage of stance-phase.

Bouncing mechanism for easy stance phase

The slight knee flexion before mid-stance (= stance flexion) in bipedal walking reduces up-and-down fluctuation of C.G. of the body. It absorbs floor shock, helping smooth forward movement of the body. The result is natural gait and smaller energy consumption. In case of Swan, the angle between the center line of socket and the shank tube become smaller at the early stage of stance phase. The amount of bouncing movement can be altered by tilting the knee joint in A-P plane as well as by adjustment of the hardness of bouncing bumper.

Compact hydraulic cylinder for easy swing phase

In general, it is considered that the hydraulic knees are heavier to swing than pneumatic knees, thus, the acceptance of inactive patients is poor. The hydraulic cylinder of Swan, however, is designed as to minimize the flexion resistance and not to inhibit the knee flexion at final stage of stance phase, as well as by small flexion moment in swing phase due to slow walking. On the other hand, the cylinder shows preferable cadence adaptability for different walking speed, up to cadence 105/min.

Weight and Dimensions

	M0780 Swan
weight	670g(1.476lbs)
overall length	194mm
overall width	63mm
maximum flexion	150deg.

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■ Link mechanism of Swan

Swan has five links in total, combining two sets of four bar linkage. The one is "basic set" and the other is "bouncing set" (Fig. 1). At the first stage of stance-phase, only the bouncing set is actuated by loading (Fig. 2-a), because the instantaneous center of rotation (I.C.R.) of basic set is situated behind to the vector of floor reaction force and resulted extension moment cannot extend the link as the movement is inhibited by extension stop.

The floor reaction force of heel-contact push the anterior link of bouncing set backward, and shifts the I.C.R. of basic set instantly, high and posterior position of the hip joint, because the anterior link of basic set become parallel to the posterior one (Fig. 2-b).

After mid-stance, the I.C.R. of bouncing set shifts backward to the vector of floor reaction force and the resultant force allows the bouncing set (as well as the basic one) to the alignment of non loading (Fig. 2-c).

At the push-off stage, I.C.R. of basic set is returned to original alignment and allows knee flexion for swing-phase (Fig. 2-d).

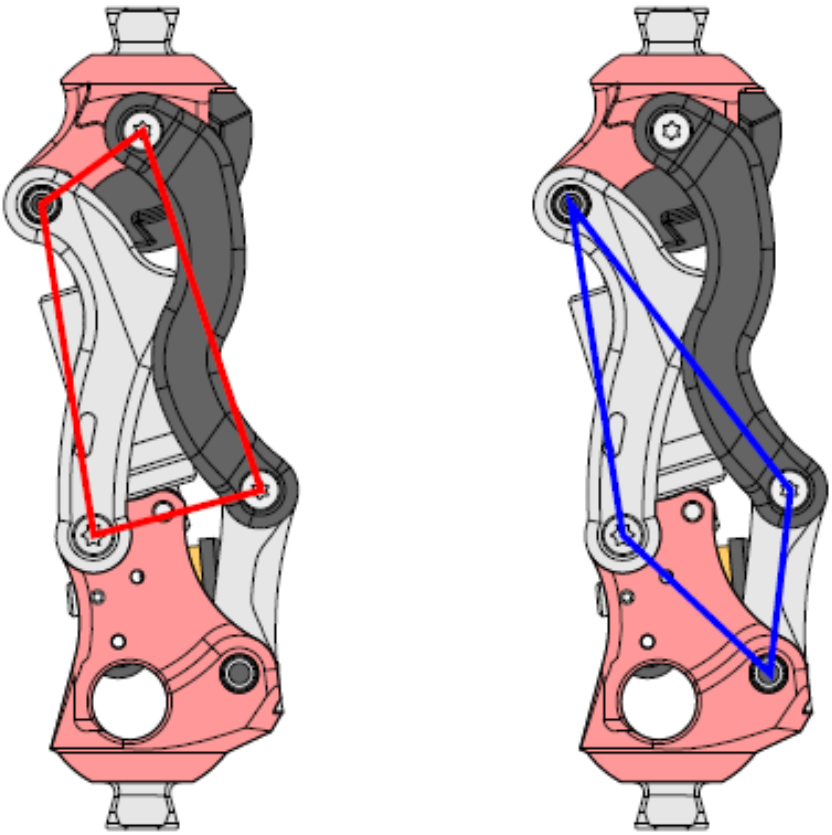
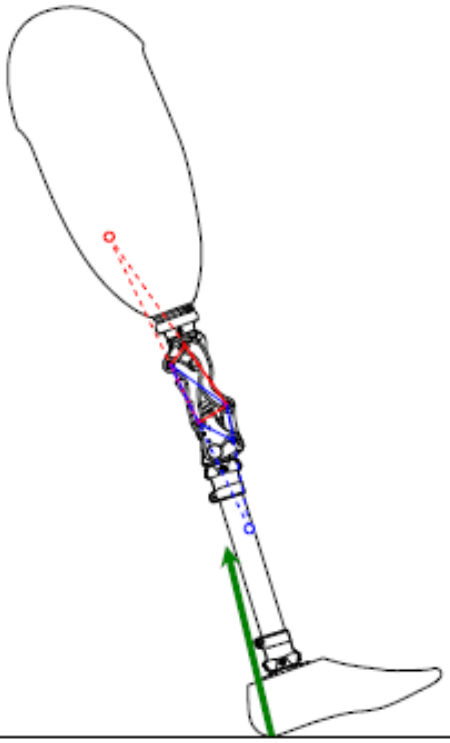
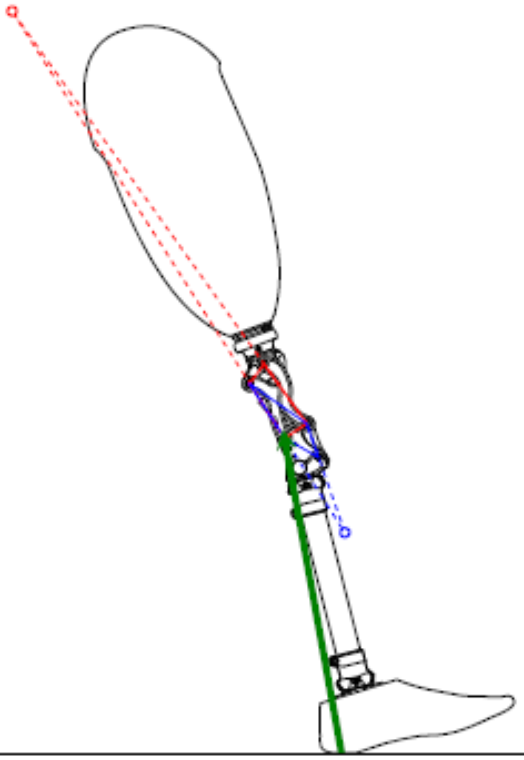


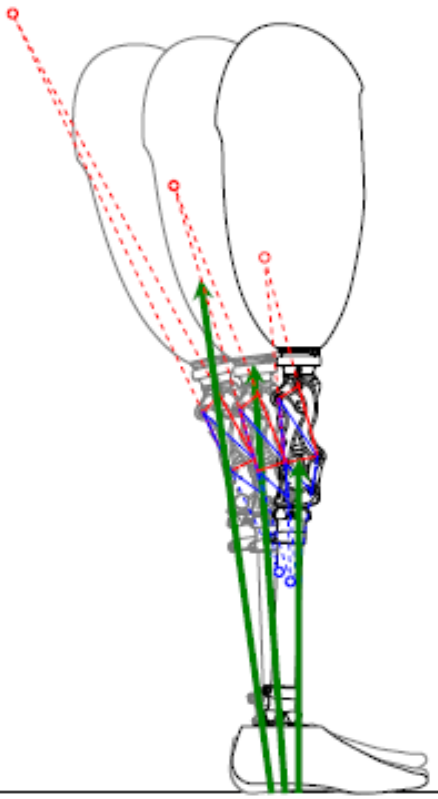
Fig. 1 Link mechanism of Swan



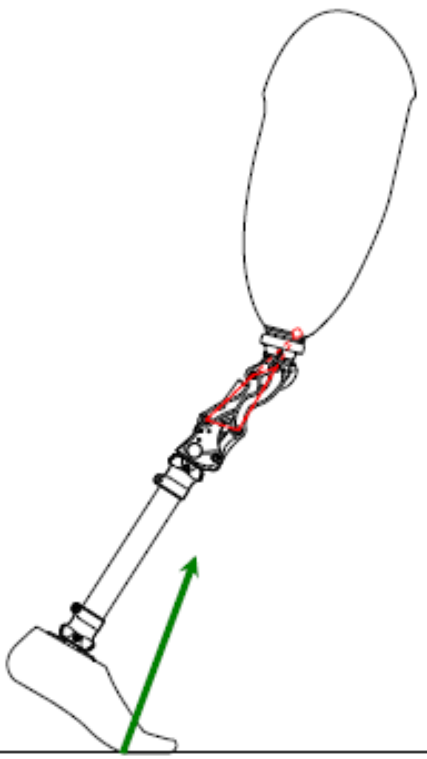
< Fig. 2-a just after Heel-Contact >



< Fig. 2-b between H.C. and Foot-Flat >



< Fig. 2-c between Mid-Stance to Heel-Off >



< Fig. 2-d Push-Off stage>

Fig. 2. Displacement of configuration of Swan links by loading

■ Bench alignment

In order to fulfill the proposed function of the knee, we recommend you to set up the prosthesis under following bench alignment.

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

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 vertical link, lower attachment axis of hydraulic cylinder, reaching to mid of toe-break and heel edge (Fig. 3).

■ 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.

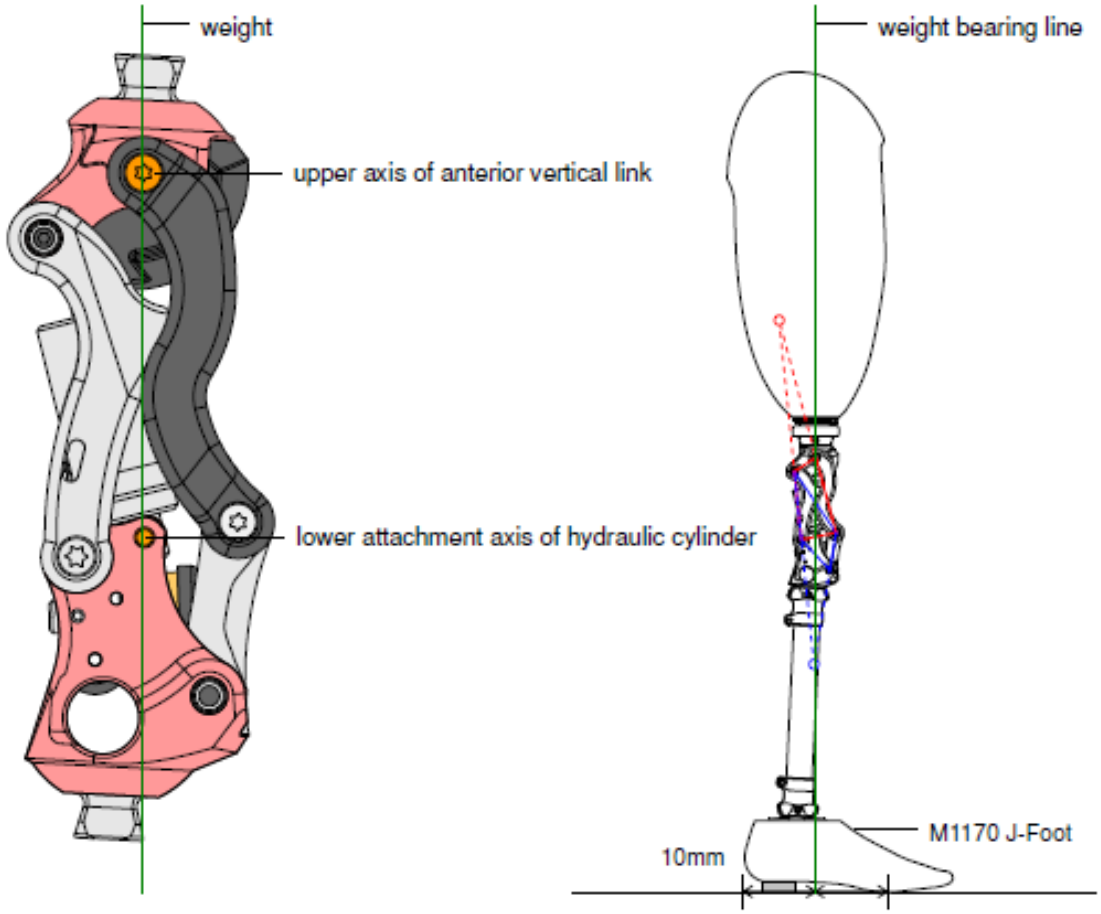


Fig. 3 Bench alignment

■ Dynamic alignment

■ Adjustment of knee stability in stance-phase

A-P stability of fully extended knee at H.C. is affected by the position of knee axis.

In case of Swan, the position of I.C.R. of extended knee is changed dramatically just after loading, and become safety. The problem is in the difficulty to decide "how much and how soon" the loading should be applied on a specified case. Series of trial walk including a kind of trial and error based adjustments are required.

To minimize the difficulty, we recommend you following procedure.

☐ The first step (Controlling the knee stability by "tilting the knee module in A-P plane")

When the knee seems too much stable,

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

too much bouncing with mechanical noise,

natural knee flexion after heel-off seems difficult,

→ increase the forward tilt of the knee module (Fig. 4-a)

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

(I.C.R. of basic set shifts forward)

(I.C.R. of bouncing set shifts backward)

When the knee seems instable

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

patient feels (shows) instability at heel contact,

no bouncing movement in down slope walking,

→ decrease the forward tilt of the knee module (Fig. 4-b)

(weight bearing line passes behind the lower attachment axis of hydraulic cylinder)

(I.C.R. of basic set shifts backward)

(I.C.R. of bouncing set shifts forward)

☐ The second step (Adjustment of the hardness of bouncing bumper)

In case of trial walking, patient may claim that the knee is not solid enough, thus, not reliable. Those instable feeling are usually caused by bouncing movement of the knee joint. If forward tilt of the knee is already enough and if there is no fear for knee buckling, increase of bouncing bumper hardness (i.e. increase of initial compression rate of the bumper) might be helpful to reduce those unfavorable feeling (Fig. 5).

① Loosen M4 screw (situated below of anterior vertical link, R side) using 2mm wrench.
② Rotate clockwise M8 screw (situated at behind of the knee) by **1/4 rotation (90 degrees)** using 4mm wrench.
③ Retighten M4 screw and repeat trial walk.
④ When the result found to be insufficient, repeat same procedure.

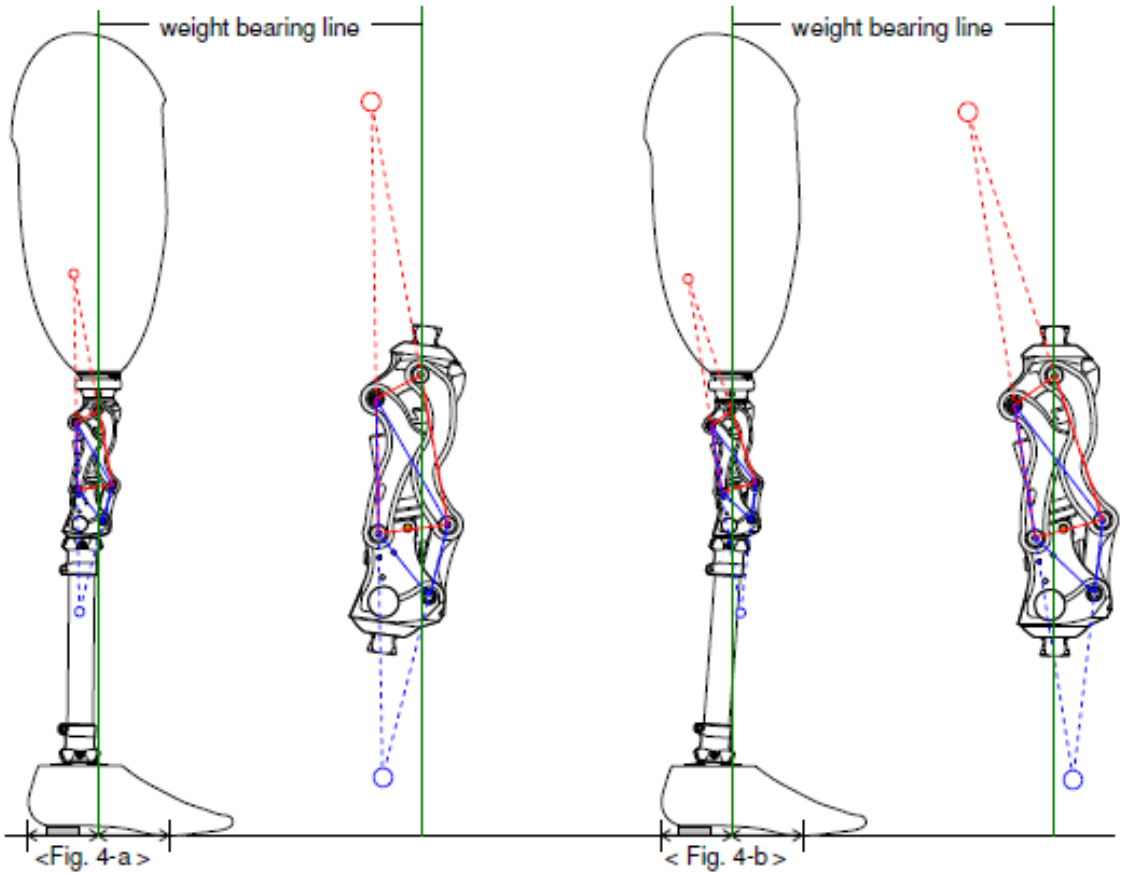


Fig. 4 Adjustment of knee stability in stance-phase

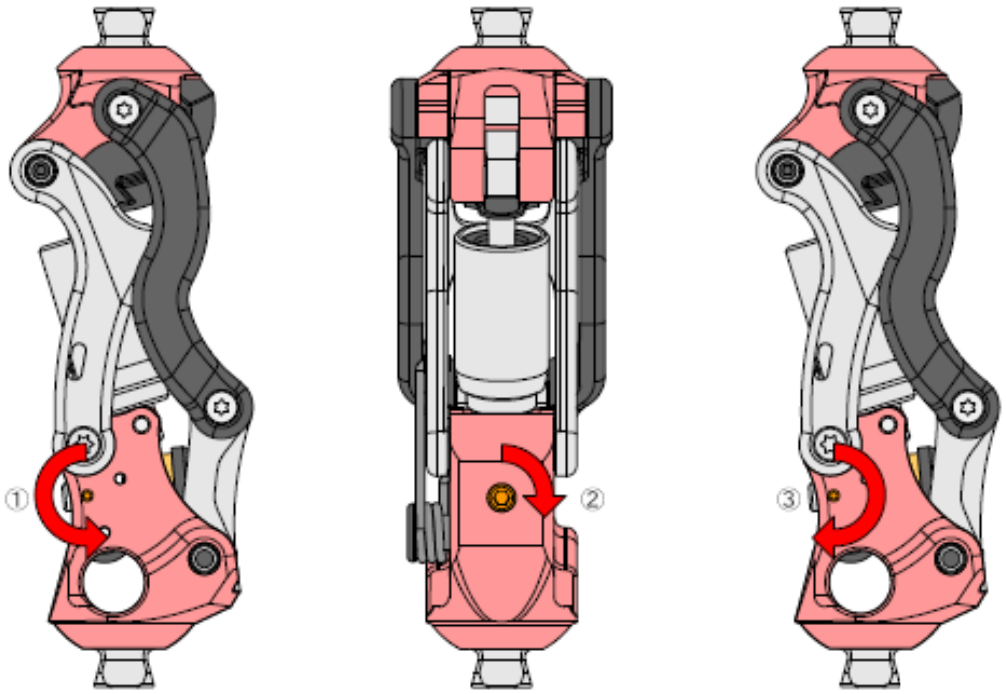


Fig. 5 Adjustment of the hardness of bouncing bumper

■ Adjustment of hydraulic cylinder for swing phase control

Adjustment of hydraulic resistance is possible for flexion only. Extension resistance is generated in accordance to extension velocity of the shank. Soon after the maximum flexion in swing-phase, the knee extends smoothly and reaches to full extension without terminal impact.

Counter clockwise rotation of the cylinder increases flexion resistance of the knee joint and vice versa. Hydraulic resistance will be changed from minimum to maximum by **1 and 1/4 rotation of the cylinder.** **The device is set in minimum resistance at the time of shipping.**

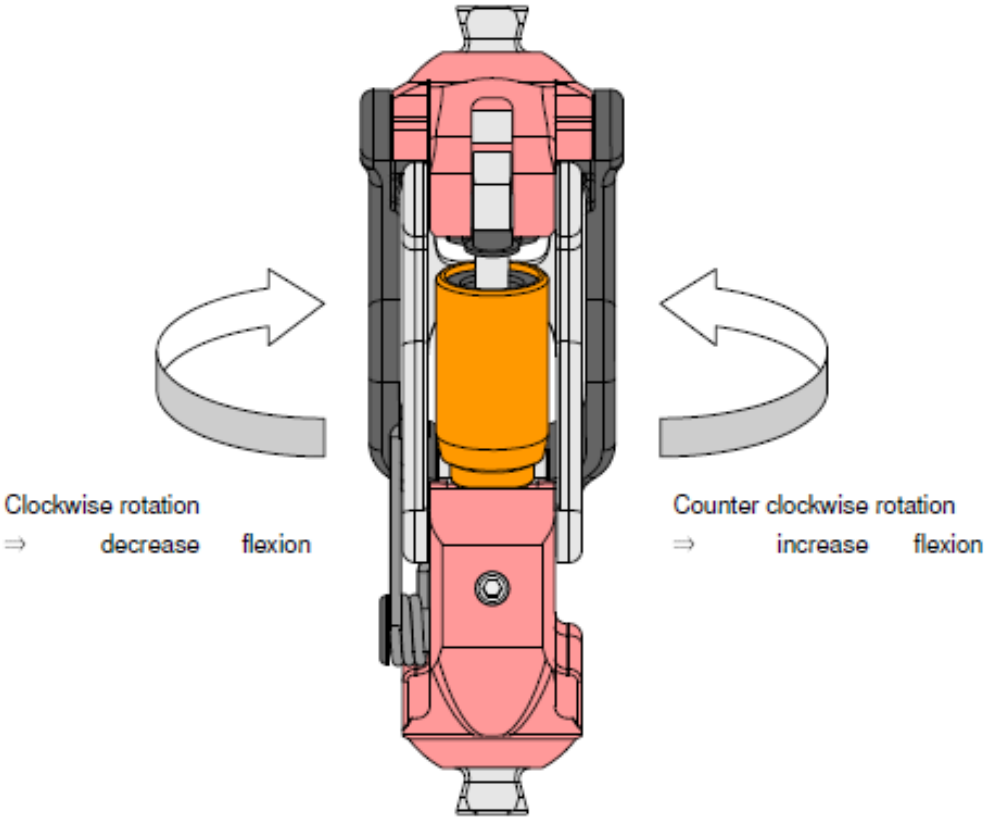


Fig. 6 Adjustment of hydraulic cylinder for swing phase control

In case of high velocity walking, higher hydraulic resistance is required.
In such cases, extension aid spring at the side will disturb the swing of the shank, and better results will be attained by the elimination of the spring.

M07-001 Extension Assist Spring Kit (Swan)

Features

The M07-001 kit comes with "firm & weak" springs for the right side of the Swan and a "weak" spring for the left side. This allows the clinician to adjust the extension assist on the Swan 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 original default.

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

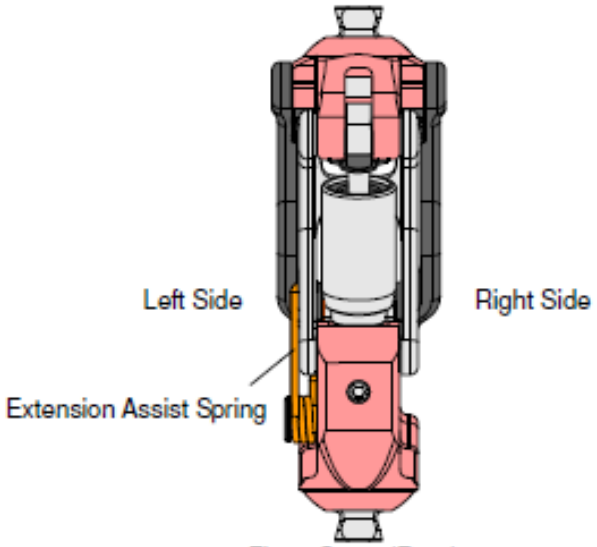


Fig. 1 Swan (Rear)

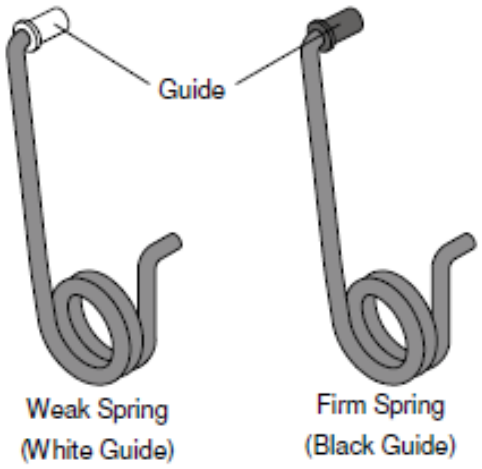


Fig. 2 Spring Guide

The Swan knee comes fitted with a firm spring on the left side and no spring on the right. This is the default setting number 3. The strength of the extension assist is changed higher or lower by altering the spring combination.

For both the left and right side springs the strength is indicated by the color of the guide as shown in Fig. 2. The white guide is on the weak spring and the black guide is on the firm spring.

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■ Procedure for Spring Alteration

When the spring is required to be changed the following procedure is used.

Step 1 Removal of spring.

① Use a Phillips –head screwdriver to loosen the screw as shown in Fig. 3.

② The spring may then be gently removed from the mounting holes.

Step 2 Preparation of spring to be inserted.

① Place the retainer through the coil section and position the spacer at the forward end of the retainer.

② When the weak spring (White Guide) is used, combine with the white retainer.
When the firm spring (Black Guide) is used, combine with the black retainer.

③ Apply grease to the periphery of the retainer, both ends of the guide and the spring, and inside of the spring. Fig. 4.

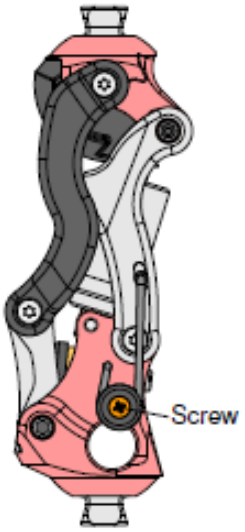
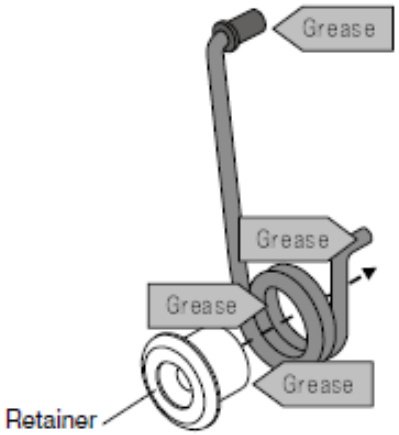


Fig. 3



Black retainer
Firm spring (Black guide in use)

Fig. 4

Step 3 Mounting of springs.

① Mount a weak or firm spring on the mounting hole indicated by the arrow in Fig. 5-a and Fig. 5-b.

② Push the spring with a finger so that the retainer hole may be matched to the spring mounting hole of the Swan body (as shown by the arrow in Fig.6).

③ Then tighten the attached set screw for fixation.

Step 4 Loctite Set Screw

After determining the optimum strength of the extension assist, apply Loctite to the set screw, and tighten it for fixation (Fig.7).

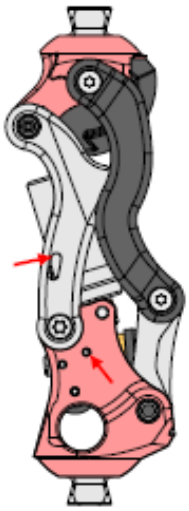


Fig. 5-a

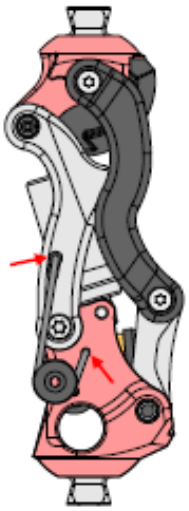


Fig. 5-b

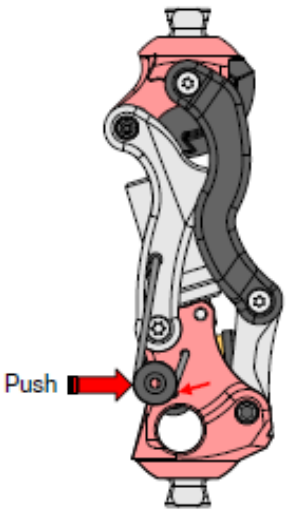


Fig. 6

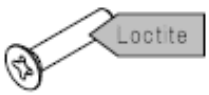


Fig. 7