

For medical practitioners

k Pacific Supply
Think Possibility!

GAIT INNOVATION

Knee Ankle Foot Orthosis Gait Innovation

Instruction Manual



Thank you for purchasing our knee ankle foot orthosis “Gait Innovation.” This Instruction Manual provides easy-to-understand explanations so even a first-time user of Gait Innovation can use it with ease. Carefully read this Instruction Manual before use. In addition, store this Manual so that it remains in good condition in a location that is accessible whenever necessary.

*For inquiries concerning our products, please refer to the last page of this Instruction Manual.

*The contents of this Instruction Manual may be subject to change without prior notice due to changes in specifications, etc.

Make sure to check the Instruction Manual that was enclosed together with the product you purchased.

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1 What is Gait Innovation?

Gait Innovation (hereinafter, referred to as the product) is a Knee Ankle Foot Orthosis equipped with a simple adjustment function.

By simplifying height and circumference adjustment of the thigh area, which is very troublesome with a conventional orthosis, rehabilitation can be started without loss of time.

In addition, with Gait Innovation, we aim to enhance motivation for rehabilitation by enhancing designability in comparison with a conventional Knee Ankle Foot Orthosis.

2 Product features

The product has the following features.

① Height Adjustment System

Stepless adjustment of the height of the lower thigh cuff, knee and thigh cuff can be performed within the adjustment range by operating the lever mounted on the cuff.

② Center Fix System

Stepless adjustment of the circumferential diameter can be performed with the dial in addition to belt adjustment. A high fixing force can be achieved because tightening in the left and right direction is possible in addition to tightening in the front and rear direction when adjusting with the dial.

③ Holding of the foot region

The heel is held by tightening the belt for the ankle.

④ Cleanliness

Materials that allow cleaning with water and the use of sterilizing agents have been adopted for parts that come in contact with the human body. We made maintenance of Gait Innovation easy because orthoses are apparatuses to be used by many people.

*Do not put under water (wash the entire orthosis).



3 For safe use

3-1 Symbols

Various symbols are used in this Instruction Manual. These symbols are intended to be indications for safe and correct use of the product and to prevent hazards or injury to the user or other persons before they happen.

Symbols and their meanings are as follows. Fully understand the contents and read the text.

The kinds of contents that we ask you to observe are classified with the following symbols.

Symbol	Meaning
 WARNING	Indicates contents in which ignoring this symbol and handling improperly may result in trouble during operation that could possibly result in a serious injury or death.
 CAUTION	Indicates contents in which ignoring this symbol and handling improperly may result in trouble during operation that could result in injury or damage to property.

3-2 Matters concerning Warnings



WARNING

Indicates contents in which ignoring this symbol and handling improperly may result in trouble during operation, and could result in death or serious injury.

- The product should be fit to the user's body, and adjustments to the movable range of the plantar/dorsal flexion and plantar flexion braking force should be performed by a person with expert knowledge such as a physical therapist or prosthetist under the direction of a physician.
- Do not repair, disassemble or modify the orthosis. This may result in a malfunction. Should you require repair, disassembly or modification, please contact our distributor.
- The product has a body weight limit of **70kg** (common to all sizes). Persons exceeding this body weight limit should not use the product. This may result in injury.
- The product is intended to be used as a knee ankle foot orthosis or ankle foot orthosis in order to improve the gait of the user. Do not use the product for any other purpose. Also, do not apply any force different from that of the actual use method. This may result in breakage.
- Should you detect any abnormal sound, or breakage in any part during operation, or should water, etc., get inside the orthosis, immediately cease use and contact our distributor.
- Make sure to observe the instructions related to safety in this Instruction Manual.
- The following persons should not use the product. It could result in breakage.
 - Persons who require an orthosis for both legs
 - Persons who would apply an excessive burden on the orthosis due to significant hyperextension of the knee or strong ankle valgus.
 - Persons whose gait generates an excessive burden to the extent that the support column bends, or whose body weight exceeds the body weight limit above.
- Do not use the product until you understand the adjustment method and cautions for handling.
- The user, caretaker or health care professional should perform maintenance and inspection once a day before wearing/fitting the product. Do not use the product unless maintenance and inspection are performed. Refer to "6. Daily inspection" for how to perform maintenance and inspection.

The following are warning items when Gait Solution is used for the ankle joint.

- Do not use the product with the plantar flexion braking force set at a value of 3.5 or more. This may result in breakage.
- Do not insert fingers or foreign objects between the rod cap and the cam. This may result in an injury.
- Clean dust and foreign matter on the adjustment shaft part and rotation shaft part once a month. This may result in breakage.

3-3 Caution



CAUTION

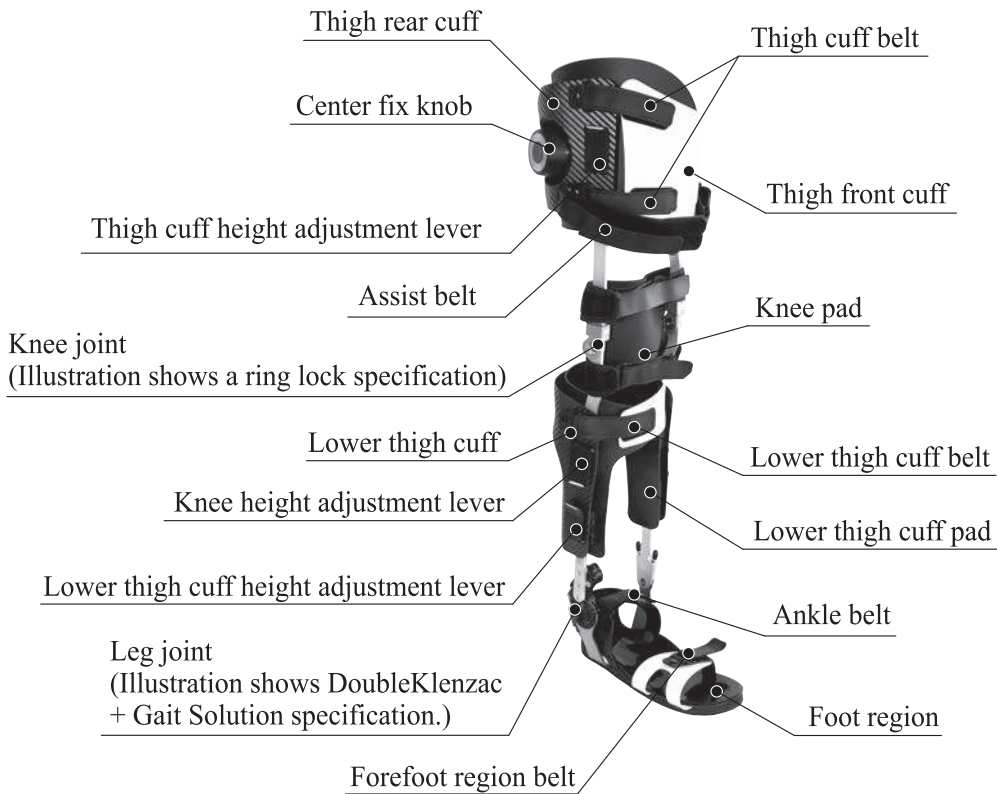
Indicates contents in which ignoring this symbol and handling improperly may result in trouble during operation that could result in injury or damage to property.

- Do not excessively tighten the cuff in the center fix system. Adjust to an extent that a finger can be inserted between the cuff and your body.
- Be careful to prevent fingers from getting caught in the levers of each part when adjusting the height.
- The height adjustment lever and center fix knob protrude from the cuff. Be careful to prevent the lever from catching onto your body or surrounding objects.
- Check that each lever for height adjustment is locked before use.
- Check that the heights of the cuff and knee joint on both sides are the same before use and after adjustment.

- Should your body make contact with the support column or knee/ankle joint, adjust the height and circumference so that they do not make contact. Do not use the product when your body makes contact with the support column or the knee/ankle joint cannot be resolved even with adjustment.
- When folding the knee joint, be careful to prevent fingers or a part of your body from getting caught.
- Check that the lock of the knee joint is in the appropriate state according to the operating conditions.
- Do not use the product with the knee joint locked only on one side. This may result in deformation or breakage of the support column, or the user falling over.
- Check that the front, rear, left and right sides of each part are correct when assembling.
- Use the same left or right side orthosis of the leg to be used.
- Do not use any parts other than optional parts (sold separately) that are compatible with the product.
- Check that a cap is installed on the screw part of the Double Klenzac before use.
- Check that a blind rivet and cuff in the lower thigh are installed.
- Do not insert or drop metals or foreign matter such as easily combustible substances inside the orthosis from the gap of the hydraulic unit.
- Do not wipe the orthosis with benzine, thinner, or alcohol. This may result in discoloration or deformation of the material.
- Do not drop or apply a strong impact to the product. This may result in malfunction.
- Do not use the product in an environment where powder dust, contaminants or water may adhere to it.
- Do not apply silicon spray, etc., to the hydraulic unit part of this orthosis.
- Do not dispose of the product by throwing it into a fire. If the product is disposed of by throwing it into a fire, the oil may ignite, resulting in injury.
- Since the product is not of waterproof specifications, it cannot be used in the following places. In addition, should it be exposed to water droplets, wipe the droplets off with a dry cloth as quickly as possible. Malfunction or rust may result if the product is left with water droplets on it.
 - ◎ A place where the product is directly exposed to rain
 - ◎ Bathrooms or submerged in water
- Use the product in a temperature range from -5°C to 50°C. Use outside of this temperature range may result in a reduction in lifespan or breakage. In addition, do not leave the product in a wet state in a place where the temperature falls below 5°C.
- Do not leave the product in a place where it will be exposed to direct sunlight or in a vehicle under a blazing sun for a long time. In addition, do not use the product near heating equipment (such as stoves). This may result in breakage.
- Should you experience any redness of the skin, rash or pain while using the product, immediately cease use and consult a doctor.
- When the product is deformed, worn, or generates any noise, immediately cease use and contact our distributor.
- When wiping off dirt, use a cloth dampened with water and tightly wrung out or SAPOSTE (made by SARAYA) or an equivalent product (that does not contain methanol).
- The actual product may be different from the contents in this Instruction Manual due to continuous improvement of the product. Contact our distributor if you have any questions.
- The specifications of the product may be subject to change without prior notice due to improvements.
- While we take all possible measures with regard to the contents of this Instruction Manual, please contact our distributor if you find any questionable points, errors, incorrect collation, missing pages or omissions.
- Safety cannot be guaranteed for any methods other than the methods specified in this Instruction Manual.
- Keep this Instruction Manual in an easy to access location with the product, and refer to it again as necessary.
- Some of the illustrations in this Instruction Manual have partial omissions or abstracted expressions.
- Should this Instruction Manual be lost or damaged, immediately contact our distributor.
- Reproduction or copying of this Instruction Manual, in whole or in part, is strictly forbidden without permission.

4 Names of each part, accessories

The names of each part are as follows. (Right leg pictured)



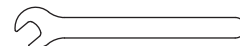
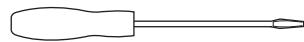
The following parts are included with the product. Check that no part is missing.

Common parts

Main body ... 1

Flat-blade screwdriver ... 1

Spanner ... 1



Assist belt ... 1

Knee pad ... 1

Instruction Manual (this booklet) ... 1

Only for ankle joint Double Klenzac + Gait Solution specifications

Rod cap 5 degrees ... 1

Hexagon wrench for M2 ... 1



Only for knee joint dial lock specifications

Hexagon wrench for M4 ... 1



5 Product lineup


Sizes of products and types of joints are as follows. (There are left and right versions of the orthosis)

Size	S size	M size
Circumference (inner dimension)	Thigh region 340 to 450 [mm] Lower thigh region ... 290 to 350 [mm]	Thigh region 450 to 570 [mm] Lower thigh region ... 320 to 420 [mm]
Total height	650 to 770 [mm]	730 to 860 [mm]
Knee joint	Ring lock/dial lock	
Ankle joint	Double Klenzac + Double Klenzac / Double Klenzac + Gait Solution	
Foot length	24 [cm]	26[cm] / 28[cm]

Knee joints other than the above are also available (made-to-order). Please contact our distributor.

6 Daily inspection method

Make sure to inspect the following items once a day before using the product.

 CAUTION	Should any breakage or abnormality occur or should you find any breakage or abnormality, do not use it as is and make sure to contact our distributor for repair/replacement.
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- Do the joints move smoothly?
- Are the belts free of any abnormality?
- Is there any breakage in the support column, plastic, metal or cloth?
- Does any part rattle?
- Is there any abnormal sound?
- Is there any abnormality with the screws or rivets?
- Is there any deformation?
- Is there any peeling of adhered parts?

The following are inspection items when Gait Solution is used for the ankle joint.

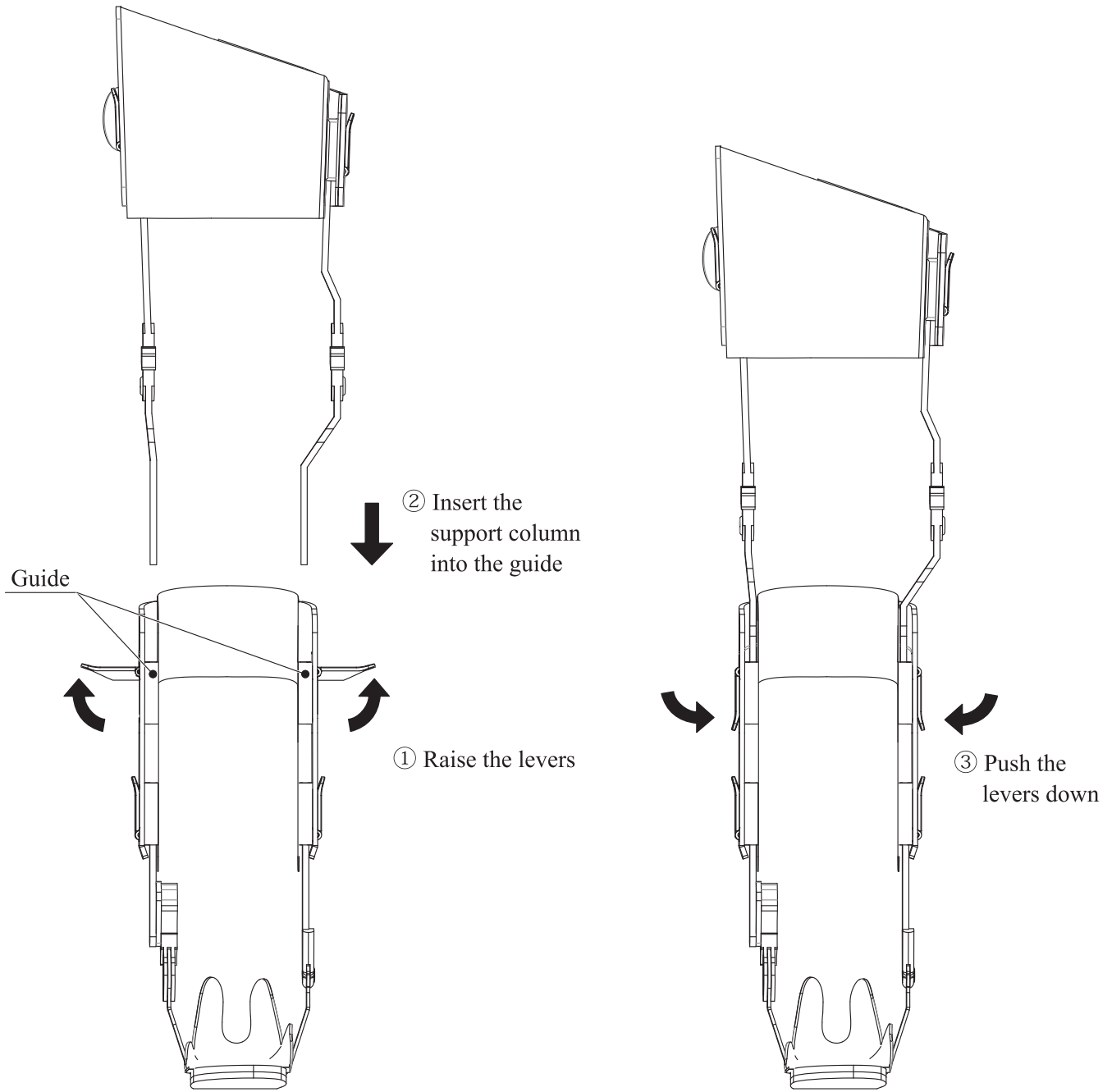
- Are any rod caps removed?
- Are contaminants or dust adhered around the rod caps or around the adjustment shaft.

7 Before use

The product is disassembled as below at the time of packing.

Assemble the product by the following procedure before use. (First time only)

- ① Raise the left and right knee height adjustment levers to a 90° angle.
- ② Insert the support column into the guide for the lower thigh cuff.
- ③ Push the knee height adjustment levers down to lock.



Before inserting the support column

After inserting the support column

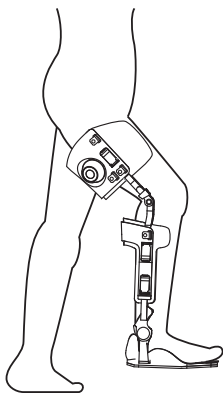


CAUTION

Check that the front, rear, left and right sides of each part are correct after assembly. Do not use the product with the front, rear, left and right sides of each part in an incorrect state. This may result in injury or breakage of the orthosis.

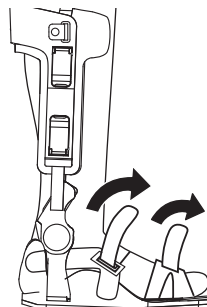
8 How to wear

- ① Align the product with the lower leg while the user is in a stable position such as sitting down.

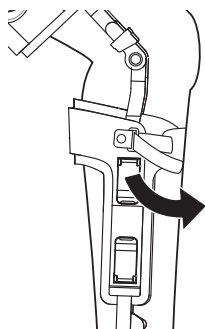


- ② Set the heel of the foot region to the heel of the user. Then, tighten the ankle belt, and forefoot region belt in this order.

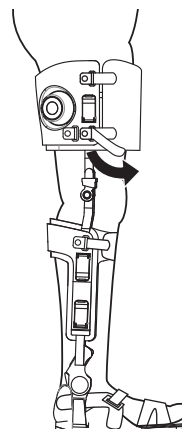
*Check that the heel of the user is covered by the heel of the foot region.



- ③ Check that the lower thigh rear surface makes contact with the lower thigh cuff pad, and then tighten the lower thigh cuff belt.



- ④ Check that the thigh rear surface makes contact with the thigh rear cuff, then tighten the two thigh cuff belts.



CAUTION

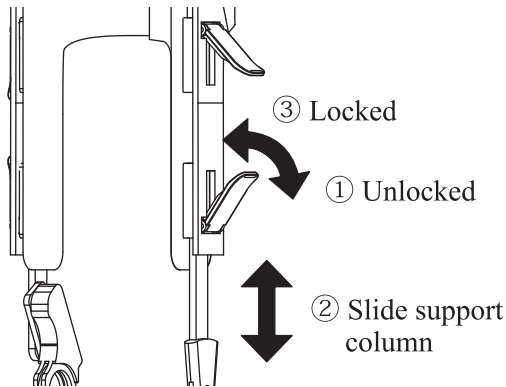
- The surface fastener used for the belt is fastened by firmly pressing. Firmly press the belt to use. When the belt is insufficiently pressed, a fastening force is not obtained, and the user may fall over.
- Do not excessively tighten the belt. This may result in injury or breakage of the orthosis.

9 Adjustment

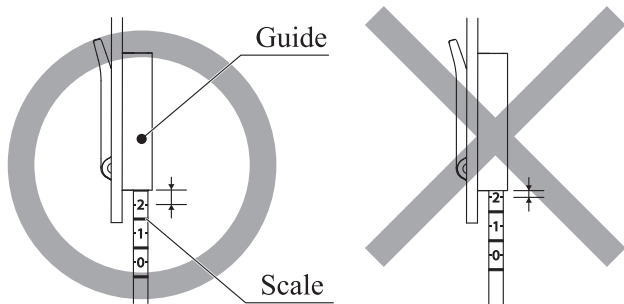
Perform the following adjustment to allow the product to assist the user's gait more easily.

9-1 Adjusting height (Height Adjustment System) *Right leg shown in the illustration

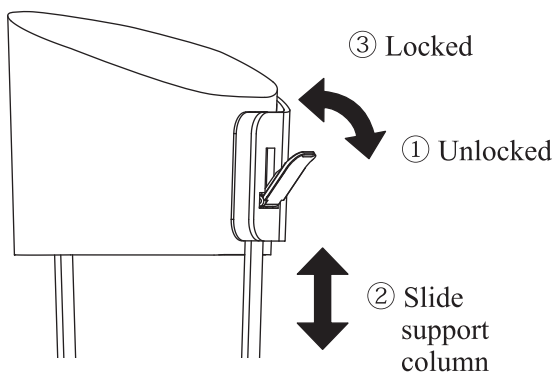
- ① Raise the left and right lower thigh cuff height adjustment lever to a 90° angle to adjust the height of the lower thigh cuff. Return the lever to its original position after adjustment to lock.



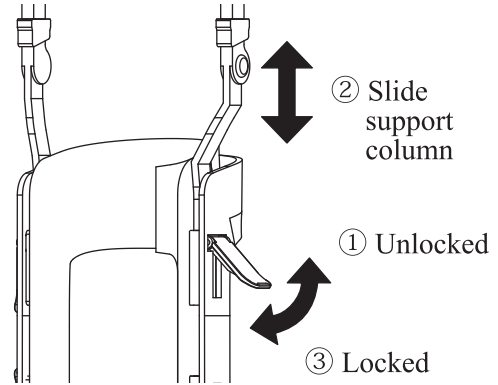
*When adjusting the lower thigh cuff height and knee height, set the scale on the front of the support column to the end surface of the guide. In addition, make sure to set the scales of both the left and right support columns.



- ③ Raise the left and right thigh cuff height adjustment lever to a 90° angle to adjust the height of the thigh cuff. Return the lever to its original position after adjustment to lock.

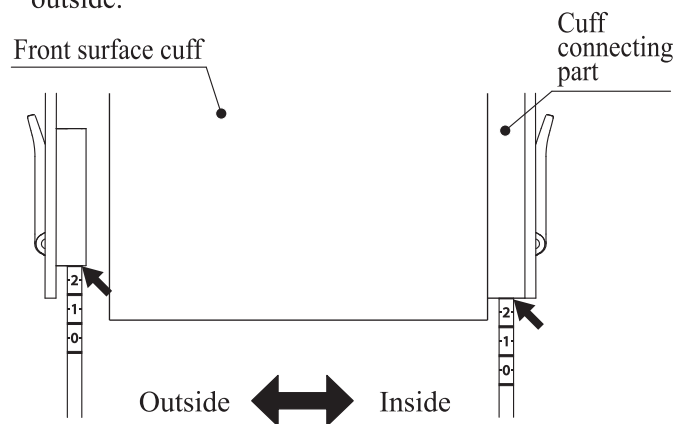


- ② Raise the left and right knee height adjustment lever to a 90° angle to adjust the height of the knee. Return the lever to its original position after adjustment to lock.



*When the lever operation while locked is stiff, shift the support column slightly (approx. 1 to 2 mm) and operate the lever again.

*When adjusting the thigh cuff height, set the scale on the front surface of the support column to the end surface of the cuff connecting part for the inside and set the scale to the end surface of the guide for the outside.



CAUTION

- Push the lever down after height adjustment and make sure that it is locked. Otherwise, the orthosis may become unstable while walking and the user may fall over.
- When adjusting the height, set the heights on the left and right support columns with reference to the scale on the front surface of the support column. Otherwise, this may result in instability while walking or breakage of the orthosis.

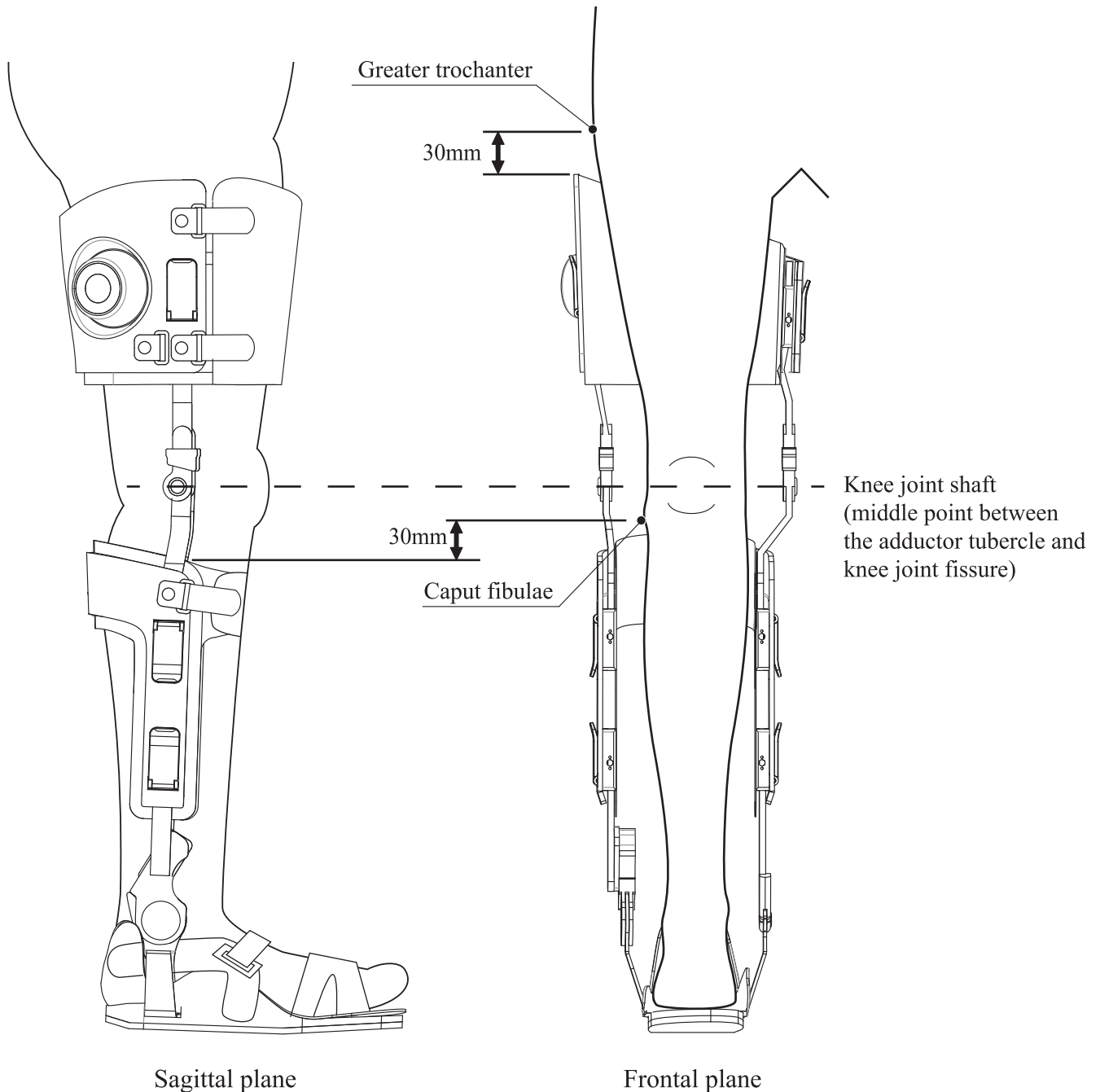
<Height reference>


Adjust so that the height of the upper edge of the lower thigh is located approximately 30mm below the lower end of the caput fibulae.

Adjust the height of the knee joint shaft with reference to the middle point between the adductor tubercle and knee joint fissure.

Adjust the height of the thigh cuff upper end so that the outside upper end of the thigh cuff is located approximately 30mm below the greater trochanter.

*The above is one example. Adjust the height after observing the user's gait and body condition.

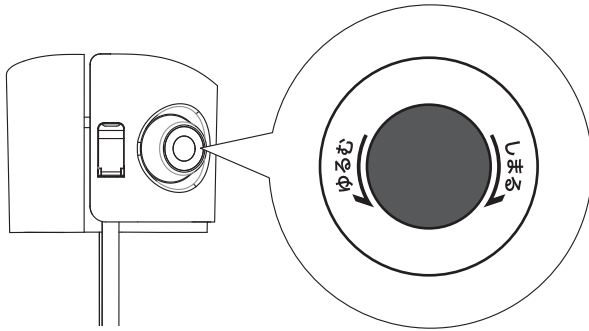


 CAUTION	Do not extend the support column beyond the range without a scale. The support column may come out from the cuff. In addition, the lever may not be able to be completely locked.
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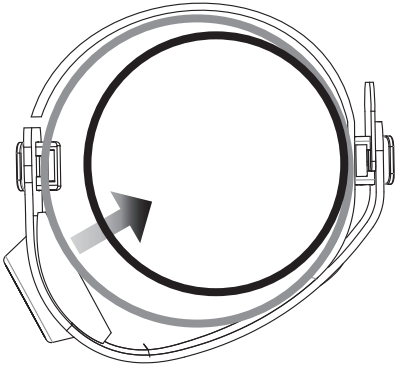
9-2 Adjusting thigh circumference (Center Fix System)

After tightening the thigh cuff belt, adjust by the following method when circumference adjustment in the left and right directions is required.

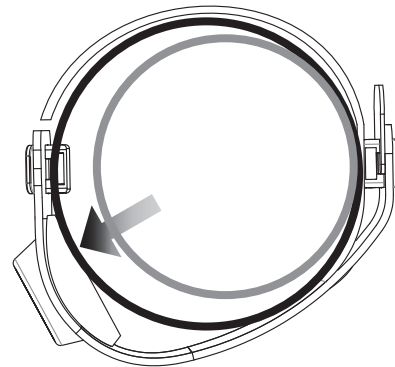
- Turn the center fix knob for the thigh part to adjust the circumference.
[The circumference becomes smaller by turning the knob in the tightening direction (clockwise) and becomes larger by turning the knob in the loosening direction (counterclockwise)]



- When turning in the tightening direction (clockwise)



- When turning in the loosening direction (counterclockwise)



- Do not excessively tighten the cuff. This may result in injury or breakage of the orthosis.
- Do not turn the center fix knob beyond the position where you feel it latch. This may result in breakage of the orthosis.

9-3 Adjusting the plantar flexion braking force (when Gait Solution ankle joint is used)

Plantar flexion braking force can be changed by turning the adjustment shaft of the hydraulic unit and adjusting the opening and closing amount of the hydraulic valve.



WARNING

The user of the orthosis must never adjust the plantar flexion braking force on their own. This may result in the user being unable to walk stably. Should adjustment of the plantar flexion braking force be required, it should be performed by a person with expert knowledge such as a physical therapist or prosthetist under the direction of a physician.

- ① Loosen the set screw for the adjustment shaft with the included M12 hexagon wrench so that the adjustment shaft can be turned.



Plantar flexion braking force can be arbitrarily set from a state of no resistance (soft) to a semi-fixed state.

The adjustment shaft is designed to change the opening and closing amount of the valve in one rotation. Therefore, it is unnecessary to keep the number of rotations in mind while making adjustments as with a spindle type.

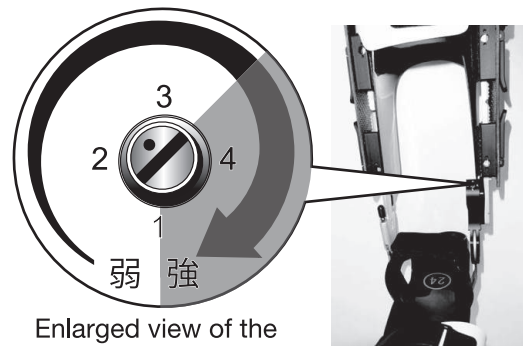
- ③ Tighten the set screw for the adjustment shaft to fix the adjustment shaft.

- ② Turn the adjustment shaft with a flat-blade screwdriver to set the appropriate plantar flexion braking force.

Marks of 1 to 4 are engraved on the upper part of the hydraulic unit.

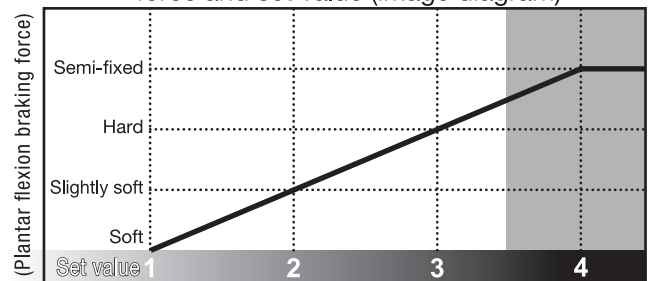
Make adjustments with reference to the mark.

(Detailed settings such as 2.3 and 2.45 are possible)



Enlarged view of the adjustment shaft part

Relationship between the plantar flexion braking force and set value (image diagram)



WARNING

- The plantar flexion braking force depends on the user's training method, body weight, body condition and gait. Set the appropriate plantar flexion braking force while observing the user's gait as prescribed by a physician and during training.
- Do not use a hydraulic braking force beyond the set value of 3.5 (the shaded range in the illustration)



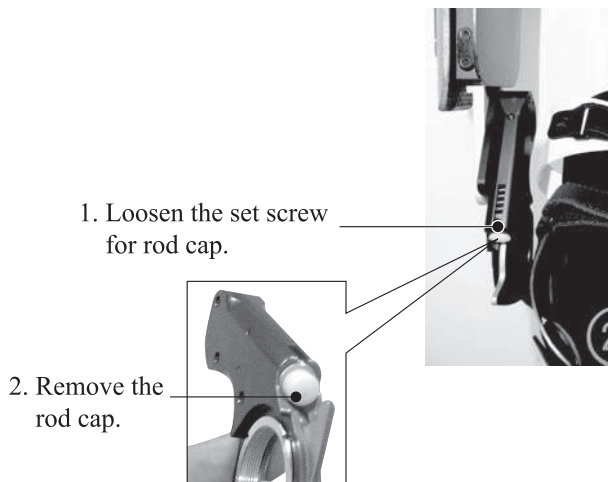
CAUTION

Do not excessively tighten the set screw for the adjustment shaft. Excessive tightening may cause the thread to break.

9-4 Adjusting initial angle (when Gait Solution ankle joint is used)

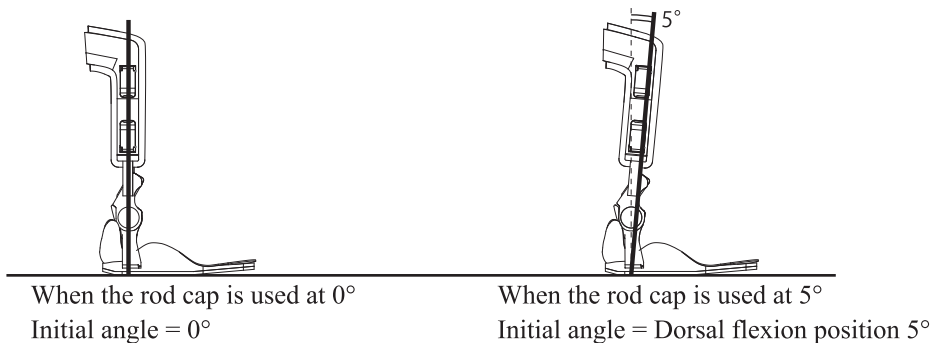
The initial angle can be changed to 0° and 5° by replacing the rod cap of the hydraulic unit.

- ① Loosen the set screw for the rod cap on the hydraulic unit with the included M2 hexagon wrench to remove the rod cap.





- ② Replace the rod cap with one of the appropriate height.

*Assume a stationary position and adjust to the extent that the rod cap and the cam make contact with each other.



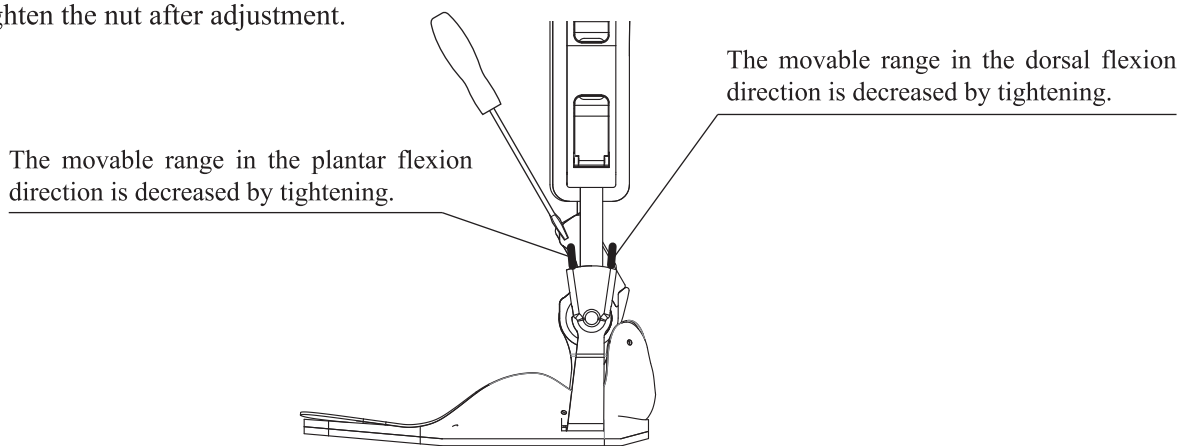
- ③ Tighten the set screw for the rod cap by following the procedure in ① in the reverse order.

 WARNING	<ul style="list-style-type: none">• The user of the orthosis must never adjust the initial angle on their own. This may result in the user being unable to walk stably. Should adjustment of the initial angle be required, it should be performed by a person with expert knowledge such as a physical therapist or prosthetist under the direction of a physician.• The plantar flexion movable range of the hydraulic unit is 18° from the state in which the rod cap makes contact with the cam. Set the initial angle to an angle where it does not exceed the plantar flexion movable range during use of the orthosis.
 CAUTION	<ul style="list-style-type: none">• Do not excessively tighten the set screw for the rod cap. Excessive tightening may cause the thread to break.• Check that the rod cap is completely fixed. The rod cap may come off while walking, resulting in injury.

9-5 Adjusting ankle braking range

Loosen the nut, and turn the screw for the joint with a flat-blade screwdriver to adjust the movable range of the plantar flexion and dorsal flexion.

Tighten the nut after adjustment.



10 Installing accessories

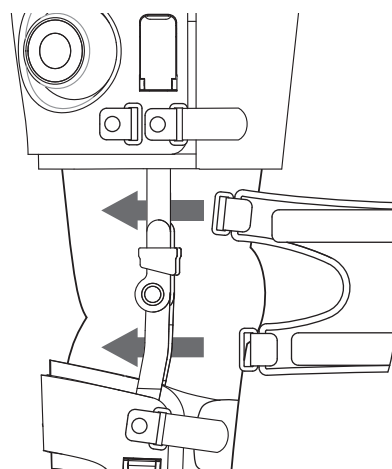
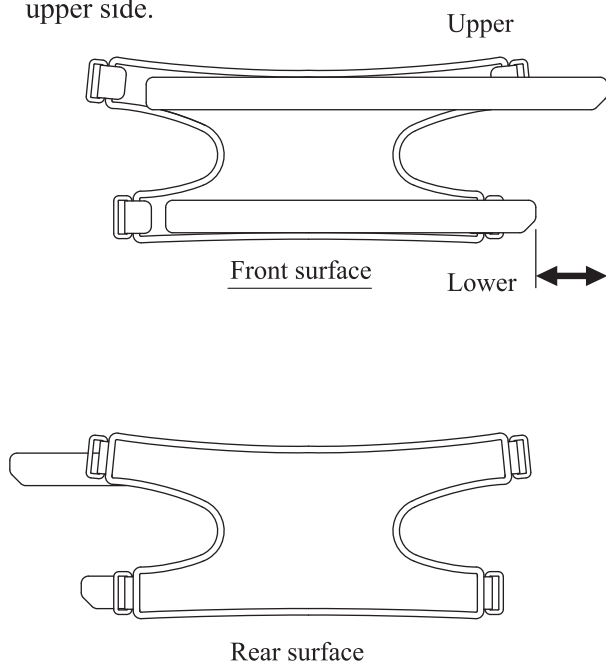
Install a knee pad and assist belt as necessary.

10-1 Installing knee pad

① Check the front, rear, upper and lower sides of the knee pad.

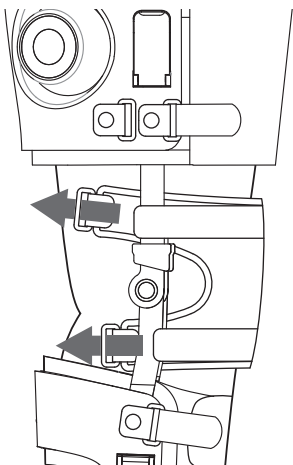
*The side where the longer belt is installed is the upper side.

② Pass the buckle of the knee pad through the inside of the support column.



- ③ Pass the belt of the knee pad through the buckle and tighten the belt.
- *Pass the belt on the outside of the support column.

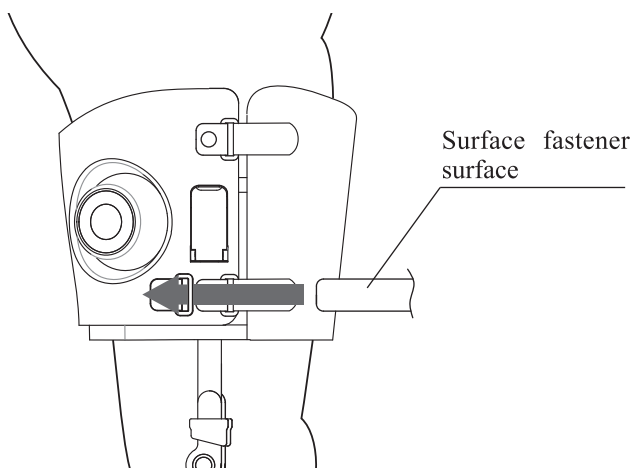
- ④ Also tighten the belt on the opposite side by the same procedure



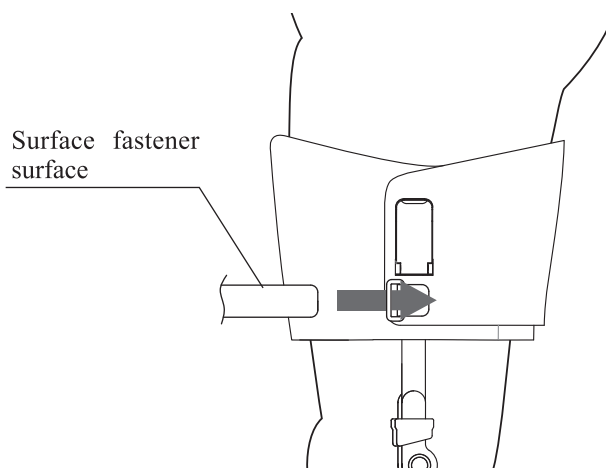
10-2 Installing assist belt

- ① Pass the assist belt through the buckle on the lower rear side of the side where the center fix knob for the thigh cuff is installed.

- ② Pass the assist belt through the buckle on the opposite side of the thigh cuff, and adjust the assist belt to the appropriate length.



Sagittal plane (outside)



Sagittal plane (inside)



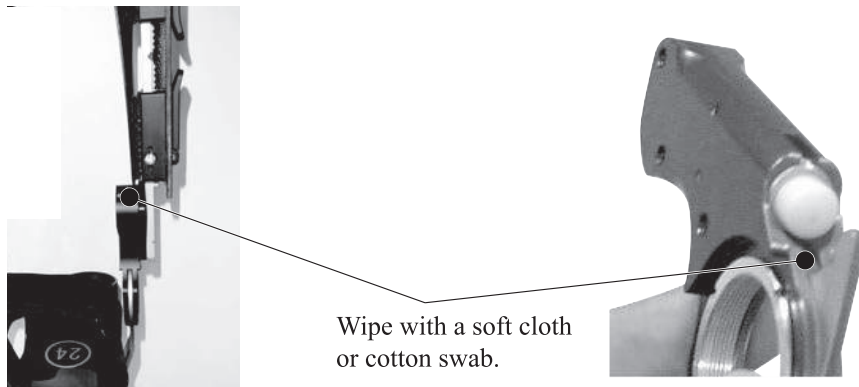
CAUTION

- The surface fastener used for the belt is fastened by firmly pressing. Firmly press the belt to use. When the belt is insufficiently pressed, a fastening force is not obtained, and the user may fall over.
- Do not excessively tighten the belt. This may result in injury or breakage of the orthosis.

11 Performing maintenance

Perform the following maintenance monthly.

- ① Should dirt adhere to the orthosis, wipe it off with a cloth dampened with water and tightly wrung out, or a cloth including SAPOSTE (made by SARAYA) or an equivalent product (that does not contain methanol).
- ② Clean dust and foreign matter adhering to the support column and joints.
- ③ Clean dust and foreign matter adhering to the sole of the shoe.
- ④ Clean dust and foreign matter on the adjustment shaft part and rotation shaft part of Gait Solution.
(When Gait Solution ankle joint is used)



12 Storage method

Avoid moisture and direct sunlight and store in a place without light.

13 Disposal method

Follow the instructions of your municipality when disposing of the orthosis.

- Hydraulic unit/rotation shaft/support column/other metallic parts: Aluminum
- Stirrup: Stainless steel
- Cuff: FRP, EVA, ABS
- Belt: Polyester, urethane
- Foot region: PVC, EVA, rubber

Warranty Card

We perform strict quality controls and inspection before delivery of each of our products. However, should any malfunction occur, we will repair the product free of charge based on the warranty items. When requesting repair, please submit this warranty card together with the product.

Product name	Knee Ankle Foot Orthosis “Gait Innovation”		
Address	〒	TEL	
Customer name			
Date of purchase	Year/	month/	day/
Distributor			

- ① This warranty card is not valid when the date of purchase, customer name and distributor are not filled in. Make sure to check that these items are filled in. If they are not filled in, immediately contact the distributor.
- ② Since we do not reissue warranty cards, please make sure to carefully store it.
- ③ This warranty card promises free repair within a certain period and under the conditions specified on the warranty card and in the warranty provisions, and does not restrict the legal rights of customers.
- ④ Contact the distributor if you have any questions regarding repair after the warranty period has expired.

Warranty items

<Warranty provisions>

- (1) The warranty period is for one year from the invoice date that pacific supply issues to the distributor. We will repair any malfunction that occurs within the warranty period free of charge.
- (2) The warranty covers the entire set of the product. However, this excludes malfunction or damage due to deterioration of each part such as belts and the slip guard.
- (3) Submission of the warranty card is required for free repair.
- (4) While the following are not covered under warranty, we will perform a charged repair if requested by the customer.
 - ① When the warranty card is lost
 - ② Malfunction or damage caused by improper use methods or improper repair/modification
 - ③ Malfunction or damage caused by natural disaster such as fire or earthquake
 - ④ When the date of purchase, customer name and distributor are not filled in in the warranty card, or they are changed without a justifiable reason
 - ⑤ Malfunction or damage caused by transportation, relocation or dropping after purchase
- (5) We will repair any malfunction or damage not covered by warranty free of charge regardless of the warranty period when the cause of such malfunction or damage is attributable to us.
- (6) Miscellaneous
 - ① The warranty card is valid.
 - ② We do not reissue warranty cards.

Pacific Supply

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