

GAITSOLUTION

Design R1

Technical manual

Ankle foot orthosis GAITSOLUTION Design R1



We explain in this technical manual how to adjust “GAITSOLUTION Design R1” properly and easily. Please read this technical manual thoroughly before you adopt GSD-R1 to patients. Please keep this technical manual carefully and read this repeatedly, for example when you maintenance GSD-R1.

Please see the information in catalogue or instruction manual for customers when you need to know about features of this product.

This product is developed by Kawamura Gishi Co, Ltd. in conjunction with Professor Sumiko Yamamoto from the International University of Health and Welfare. GK Dynamics Inc. designed it.

This “GAITSOLUTION Design R1” is developed under subsidy for development of welfare equipment applications of NEDO (New Energy and Industrial Technology Development Organizaion).

(※)Please see the information in last page when you have any enquiry about this product.

(※)All contents in this assembly manual may be changed from deviation of this product without notice. Please confirm that you read an assembly manual packed in your own product.

Contents

Page	
02	1. What is GAITSOLUTION Design R1 (GSD-R1)?
02	2. Safety information (Overview of safety instructions)
04	3. Structure and parts of GSD-R1
06	4. Tools and parts (Tools for assembly or maintenance)
07	5. Adjustments for body fitting (Adjustments of flame width, belt length.)
08	6. How to adjust settings
11	7. Maintenance
18	8. When you find any trouble...
19	9. Attachments (Pattern for belts cutting and tracing form for GSD-R1)
26	10. Customer information
26	11. Periodic inspection
26	12. Explanation of Label

1. What is GAITSOLUTION Design R1 (GSD-R1)?

GAITSOLUTION Design R1 is one of the products which has features for hemiplegia or peroneal paraplegia patients to control plantar flexion of the paralyzed side in the early stance phase. This product is one of the ankle foot orthosis that realizes not only smooth walking and easy to don structure but also designability.

GSD-R1 is endowed with the functions required for AFO, which have been derived from the result of gait analysis. This GAITSOLUTION Design R1 is available in three colors to suit your taste: Standard, Urban, and Sport.






2. Safety information

Safety instruction symbols

There are many safety instruction symbols in this technical manual. These are the symbols to show you how you can use this product safely and avoid possible injury or damage. Symbols and their meanings are listed below. Please read this thoroughly and move to other contents.

We divide safety instructions into these groups.

Symbol	Meaning
 WARNING	Important information about a possible dangerous situation which, if not avoided, leads to serious injuries.
 CAUTION	Important information about a possible dangerous situation which, if not avoided, leads to injuries or property damage.
	This symbol means prohibition that you should never do. Important information about a possible dangerous situation which, if not avoided.

1-1 Warnings



Important information about a possible dangerous situation which, if not avoided, leads to serious injuries.

- Please hand the instruction manual in this kit certainly to your customer.
- A physical therapist or CPO should fit this product or adjust braking force under the guidance of a doctor.
- Weight limit of GAITSOLUTION Design R1 is 90kg. Weight limit is the same in any size of this product. Do not use this product if you weigh over weight limit. There is the possibility of getting hurt.
- This product is designed as an ankle foot orthosis to improve your gait. Do not use this product in other purposes. Do not apply force unlike actual usage. It may cause destruction.
- Do not set the set point for planter flexion braking force over 3.5. If you set it over 3.5, you may cause destruction.
- Do not use this product for the customer like listed below: There is possibility to damage this product.
 - Bilateral orthosis user.
 - A user who has hyper extension of knee joint or strong varus or valgus foot.
 - Gait pattern of a user is not proper and puts severe strain to the frame.
 - A user who has severe malalignment needs remarkable frame bending.
- Clean up dust or foreign substance around adjustment joint and rotation joint once a month. If not, it may cause destruction.
- Do not put your finger or foreign substance between Rod cap and Cam. It may cause destruction.
- Do not assemble this product unless you can understand how to assemble or safety precautions of this product.
- Follow the safety precautions in this technical manual.

1-2 Cautions



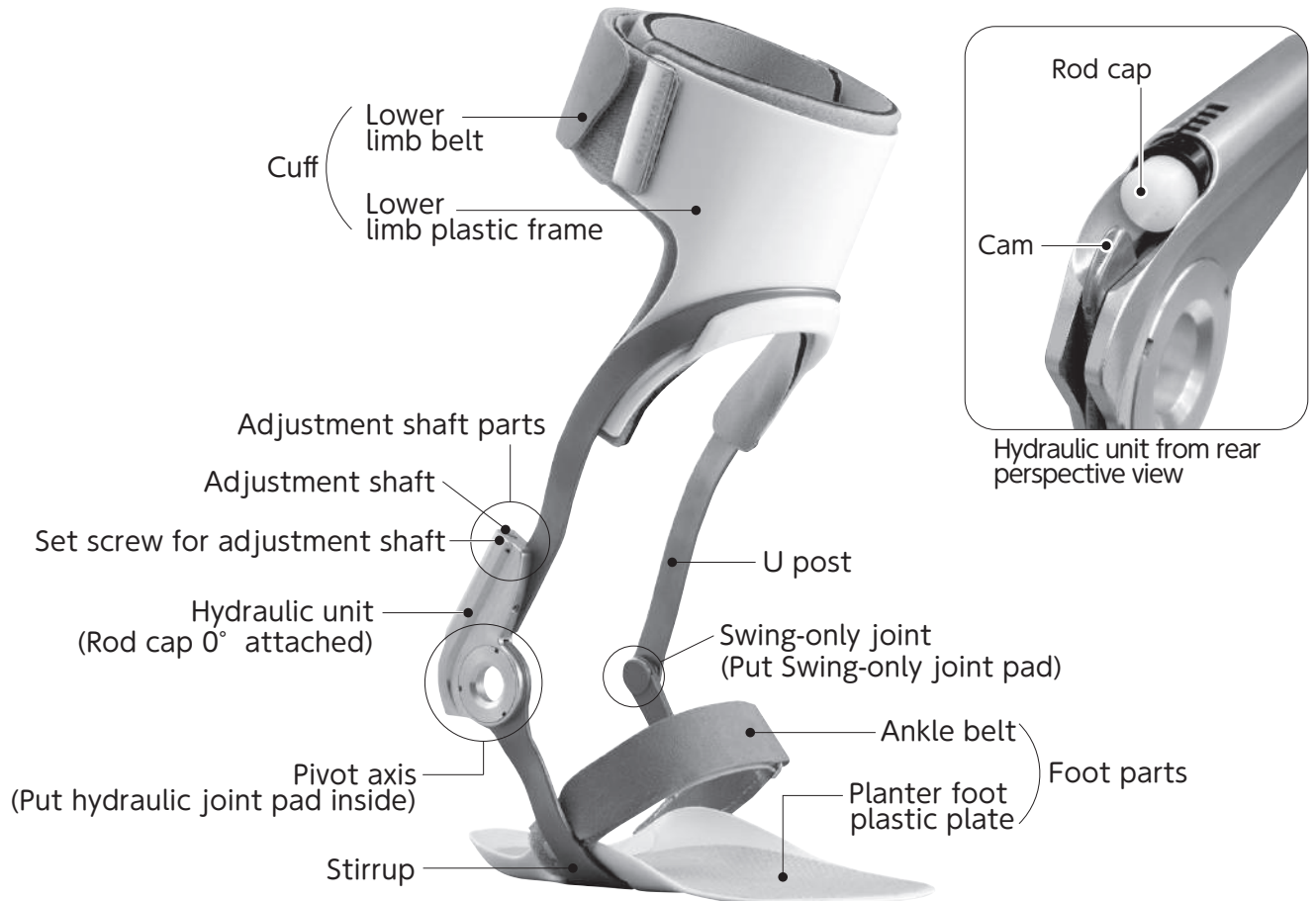
Important information about a possible dangerous situation which, if not avoided, leads to injuries or property damage.

- Do not insert or drop any metals or flammables in slits on hydraulic unit.
- Do not wipe this product with benzene, solvent or alcohol. It may cause discoloration or deformation.
- Do not drop GSD-R1 and avoid impact to this product. Damage to this product may cause product malfunction.
- Hydraulic unit in this product is maintenance free. Do not put silicon spray on this product.
- Do not use GSD-R1 in dust, waste or water drop. It may cause oil leakage from damage to packing and may cause product malfunction.
- Operating temperature of GSD-R1 is -5°C to 50°C. Usage out of this range may impact on packing and accumulator and cause product malfunction. Also do not keep this product below 0°C while wet with water.
- Please use hexagon wrenches provided. Not doing so may render the product unusable.
- Do not put GSD-R1 into flame. It may set fire to oil in hydraulic unit and hurt anyone around.
- Please contact your distributor whenever you find mistake, incorrect collating, missing pages or omission in this assembly manual.
- Some figures shown in this assembly manual may have omitted or abstracted expression.
- Unauthorized reproduction and copying from all or a part of this assembly manual is prohibited.
- Note that the unit for hexagon wrenches and screws are always “mm”, not “inch” in this assembly manual.

3. Structure and parts of GSD-R1

This GAITSOLUTION Design R1 is available in three colors to suit your taste: Standard, Urban, and Sport. We can provide “Parts set” for you to use it for maintenance or repairing.

Finished picture (This picture is for right foot)



● GAITSOLUTION Design R1

“Semi ready-made type” for you can adjust it at any site.

Part#	Description
69500031	GSD-R1 Assembled Standard Left S
69500032	GSD-R1 Assembled Standard Right S
69500051	GSD-R1 Assembled Standard Left M
69500052	GSD-R1 Assembled Standard Right M
69500041	GSD-R1 Assembled Standard Left L
69500042	GSD-R1 Assembled Standard Right L
69500033	GSD-R1 Assembled Urban Left S
69500034	GSD-R1 Assembled Urban Right S
69500037	GSD-R1 Assembled Urban Left M

Part#	Description
69500038	GSD-R1 Assembled Urban Right M
69500043	GSD-R1 Assembled Urban Left L
69500044	GSD-R1 Assembled Urban Right L
69500035	GSD-R1 Assembled Sport Left S
69500036	GSD-R1 Assembled Sport Right S
69500039	GSD-R1 Assembled Sport Left M
69500040	GSD-R1 Assembled Sport Right M
69500045	GSD-R1 Assembled Sport Left L
69500046	GSD-R1 Assembled Sport Right L

●“Parts set” for you can use it for maintenance.

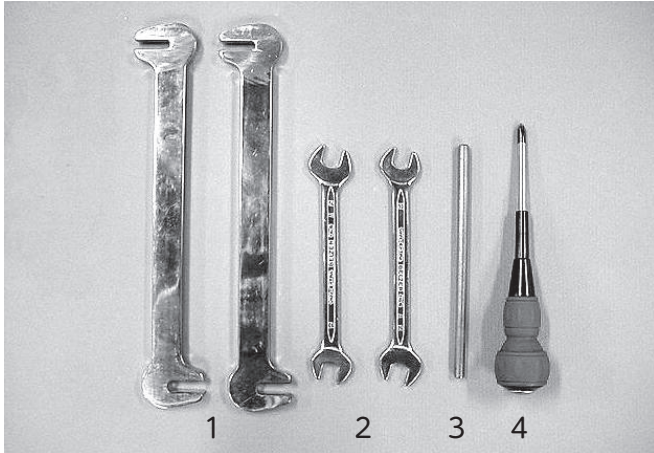
Part#	Description
69500311	Cuff set for Standard Left S
69500312	Cuff set for Standard Right S
69500107	Cuff set for Standard Left M
69500108	Cuff set for Standard Right M
69500313	Cuff set for Standard Left L
69500314	Cuff set for Standard Right L
69500315	Foot part set for Standard Left S
69500316	Foot part set for Standard Right S
69500109	Foot part set for Standard Left M
69500110	Foot part set for Standard Right M
69500317	Foot part set for Standard Left L
69500318	Foot part set for Standard Right L
69500319	Cuff pad set for Standard S
69500111	Cuff pad set for Standard M
69500320	Cuff pad set for Standard L
69500112	Swing-only joint set for Standard
69500321	Cuff set for Urban Left S
69500322	Cuff set for Urban Right S
69500113	Cuff set for Urban Left M
69500114	Cuff set for Urban Right M
69500323	Cuff set for Urban Left L
69500324	Cuff set for Urban Right L
69500325	Foot part set for Urban Left S
69500326	Foot part set for Urban Right S
69500115	Foot part set for Urban Left M
69500116	Foot part set for Urban Right M
69500327	Foot part set for Urban Left L
69500328	Foot part set for Urban Right L
69500329	Cuff pad set for Urban/Sport S
69500117	Cuff pad set for Urban/Sport M
69500330	Cuff pad set for Urban/Sport L
69500118	Swing-only joint set for Urban
69500331	Cuff set for Sport Left S
69500332	Cuff set for Sport Right S
69500119	Cuff set for Sport Left M
69500120	Cuff set for Sport Right M
69500333	Cuff set for Sport Left L
69500334	Cuff set for Sport Right L
69500335	Foot part set for Sport Left S
69500336	Foot part set for Sport Right S

Part#	Description
69500121	Foot part set for Sport Left M
69500122	Foot part set for Sport Right M
69500337	Foot part set for Sport Left L
69500338	Foot part set for Sport Right L
69500123	Swing-only joint set for Sport
69500124	Special tools set for
69500339	Planter foot seat for Standard 5 sheets Left S
69500340	Planter foot seat for Standard 5 sheets Right S
69500125	Planter foot seat for Standard 5 sheets Left M
69500126	Planter foot seat for Standard 5 sheets Right M
69500341	Planter foot seat for Standard 5 sheets Left L
69500342	Planter foot seat for Standard 5 sheets Right L
69500307	Swing-only joint set for-R1 Standard
69500308	Swing-only joint set for-R1 Urban
69500309	Swing-only joint set for-R1 Sport
69500343	Planter foot seat for Urban/Sport 5 sheets Left S
69500344	Planter foot seat for Urban/Sport 5 sheets Right S
69500127	Planter foot seat for Urban/Sport 5 sheets Left M
69500128	Planter foot seat for Urban/Sport 5 sheets Right M
69500345	Planter foot seat for Urban/Sport 5 sheets Left L
69500346	Planter foot seat for Urban/Sport 5 sheets Right L
69500129	Swing-only joint pads 20 sheets
69500130	Hydraulic joint pads 20 sheets
69500131	Pivot axis washer 20 sheets
69500132	M8 washer set 4 kinds (5 washers each)
69500133	Protection seals 15(White) 16seals in 1 seat (5 seats)
69500134	Protection seals 15(Orange) 16seals in 1 seat (5 seats)
69500310	SUS Round flat-head screw M4×4 50 screws
69500135	SUS Round flat-head screw M4×5 50 screws
69500136	SUS Round flat-head screw M4×6.5 50 screws
69500137	SUS Countersunk screw M4×5 50 screws
69500138	Set screw for adjustment shaft 20 screws
69500139	Set screw for rod cap 20 screws
69500140	Hexagon wrench M1.6 (for adjustment shaft) 4 wrenches
69500141	Hexagon wrench M2 (for rod cap) 4 wrenches
69500142	Carton for (one for every size) with partition 10 sheets
69500143	Nonwoven fabric bag for 5 bags
69500144	Screwdriver for 4 pieces
69500145	Rod caps for adjusting initial angle of 0° 5 pieces
69500146	Rod caps for adjusting initial angle of 5° 5 pieces

4. Tools and parts

Tools shown below are for assembly or maintenance of GSD-R1.

1) Tools for assembly or maintenance

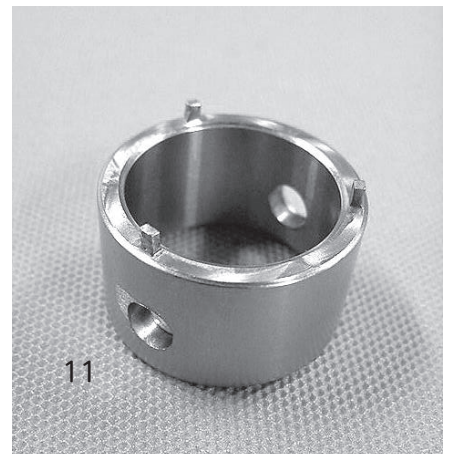


1	Hacker(Bender) ... 2
2	Spanner(13mm) ... 2
3	φ8 Shaft (length over 200mm)
4	Phillips head screwdriver (#2)



5	Screw locking agent(Low strength) / Recommendation:LOCTITE221
6	Screw locking agent(Middle strength) / Recommendation:LOCTITE241
7	Grease / Recommendation : G-30M (Shin-Etsu Silicone)
8	Cloth (To prevent scratches)

2) Special tools set (Part#:69500124)



9	Dummy for pivot axis A (Dummy to find right shaft center for Hydraulic unit. Use with pivot axis.)
10	Dummy for pivot axis B(Dummy to find right shaft center for Hydraulic unit. Use without pivot axis.)
11	Jig to rotate pivot axis (It has 3 picks to remove pivot axis on Hydraulic unit.)

3) Tools to modify plastics

12	Heat gun ... 1
13	Working gloves ... 1 pair

※You should also prepare some tools like hacker fixer or vice if you need them.

5. Adjustments for body fitting

You can get better fitting of this product when you apply small adjustments below:


5-1 Adjustments for medial and lateral malleolus

You can adjust medial and lateral malleolus width by bending flame.

1) Check how much adjustment you should apply


Check medial and lateral malleolus clearance in standing position when a user dons this product.

In case of inadequate clearance (distance between Hydraulic joint pad or Swing-only joint pad and lateral or medial malleolus are below 5mm), determine adjustment width and bend flame to follow the process below:

 CAUTION	You should consult a medical doctor or a physical therapist when you decide adjustment width. When you put width adjustment over 5mm on one side, you may lose proper alignment. When you need to adjust over 5 mm on one side, you should put width adjustment on the other side not to lose proper alignment. You should adjust within 15mm on one side.
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2) Adjustments for medial and lateral malleolus

- ① Remove Hydraulic unit and SUS Round flat-head screw M4×5 that fixes U post.
- ② Put Dummy for pivot axis A to Hydraulic unit on lateral malleolus side and insert $\phi 8$ Shaft in joints to check shaft position. Bend flame with Hacker and adjust medial and lateral malleolus width.
- ③ We recommend that you should remove Cuff or foot parts and adjust in condition of only flame when you adjust medial and lateral malleolus part. Remove Cuff and foot parts and put Dummy for pivot axis A and insert $\phi 8$ Shaft to adjust.
- ④ After you adjust width, please check torsion in flame. Please keep small distance about 2mm between U post and Stirrup on the pivot axis side to put Washer.
- ⑤ Check movements towards plantar and dorsal flexion and confirm that you can set proper alignment. After that, assemble every part in reverse order when you remove it. Apply proper quantity of Screw locking agent (Low strength) on the tip of SUS Round flat-head screws M4×5 and fix Hydraulic unit and U post with these screws.

 CAUTION	Burr might come out from AL or BS swing-only joints when you cannot remove or attach Swing-only joint properly. At that time, please replace them to new one and never leave this product as it is. It might leads to injuries. In case you damage pads when you remove it, you should replace it with new ones.
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5-2 Adjustments of foot parts and Cuff

1) Checking foot longitudinal arch

Check the height of user's foot longitudinal arch. When a user has long foot length, his foot might be on the edge of foot parts. For that case, you should modify and widen arch on foot parts. Also if necessary, you should put a pad on foot parts.

2) Adjustments of foot parts

- ① Remove Planter foot seat completely.
- ② Take working gloves on and modify to adjust longitudinal arch by softening foot parts with Heat gun.
- ③ Put Planter foot seat again.

3) Adjustments of Cuff

Adjust Cuff by softening it with Heat gun.


 CAUTION	Do not soften resin parts again and again. Resin may deteriorate and this may cause damage to parts.
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6. How to adjust settings

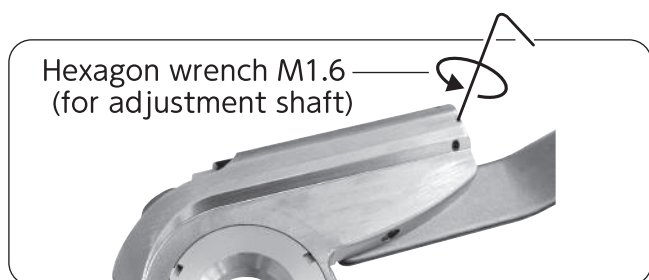
This product has 2 adjustment mechanisms. One is adjustment mechanism of planter flexion braking force and the other one is adjustment mechanism of initial angle. You can set proper setting of this product for each user by adjusting these 2 mechanisms.

6-1 Adjustment of planter flexion braking force

You can change planter flexion braking force by rotating Adjustment shaft in Hydraulic unit and adjust open and close volume of Hydraulic valve.

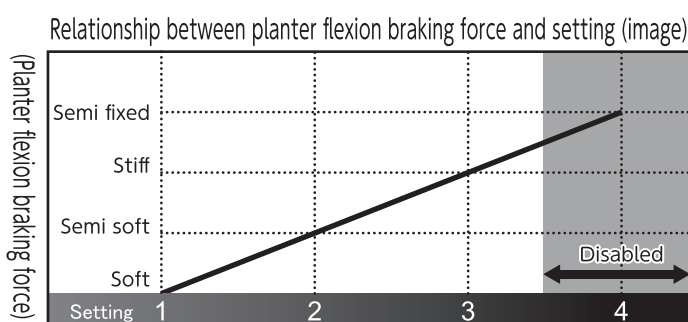
 WARNING	<p>The user should never adjust planter flexion braking force! The user might not be able to walk stably. Please consult a medical doctor or a physical therapist or an orthotist when planter flexion braking force needs to be adjusted.</p>
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1) Loosen Set screw for Adjustment shaft with Hexagon wrench M1.6 in accessory and make Adjustment shaft can rotate.

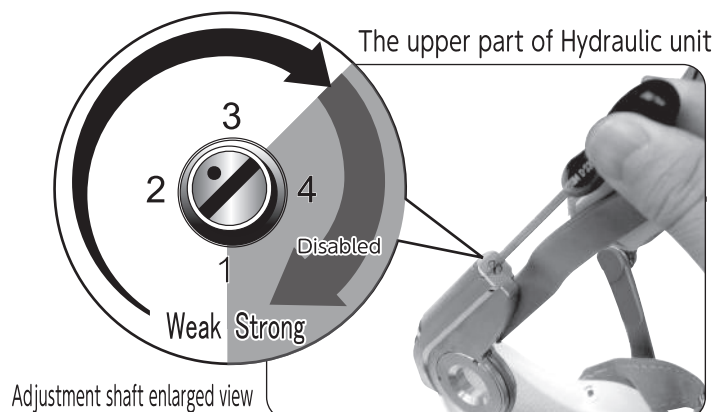


2) Rotate Adjustment shaft with Flathead screwdriver to set proper planter flexion braking force.

- You can set planter flexion braking force voluntarily from weak (soft) to strong (semi fixed).
- Markings from 1 to 4 are in the upper part of Hydraulic unit. You can adjust the braking force by using those markings for indication. (You can set detailed setting like 2.3 or 2.45)
- You don't need to count the number of rotations like spindle system because this adjustment shaft can change open and close volume of Hydraulic valve in single rotation.
- The planter flexion braking force should be deferent from each user's weight, body condition and gait or rehabilitation procedure. You should set proper planter flexion braking force from medical doctor's prescription or observation of user's gait in rehabilitation program.



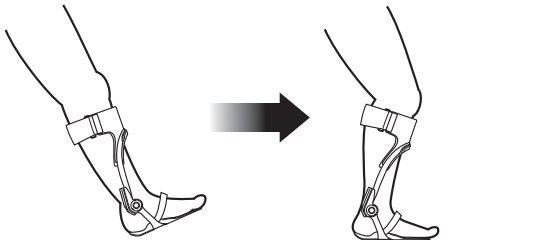
 WARNING	<p>Do not use set point for planter flexion braking force over 3.5. If you set it over 3.5, it may cause destruction.</p>
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<Reference> Indications to set planter flexion braking force

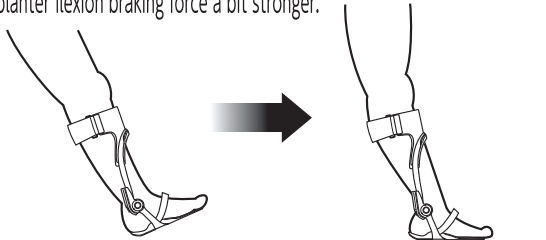
When the planter flexion braking force is too strong...

It's not easy for a user to move ankle joint from heel contact to foot flat. You can observe unstable knee movement or knee bending in heel contact. To prevent this knee bending, some user abducts lower limb too much. In these cases, you should set the planter flexion braking force a bit weaker.



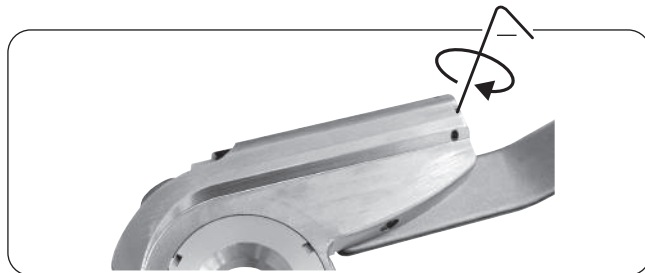
When the planter flexion braking force is too weak...

The ankle joint moves toward planter flexion rapidly just after heel contact and the knee joint moves toward hyper extension. When a user keeps this situation from mid to terminal stance, knee hyper extension may increase. It is difficult for healthy side (swing side) to move forward and also it is difficult for paralyzed side to lift toe off in this situation. In these cases, you should set the planter flexion braking force a bit stronger.



3) Tighten Set screw for Adjustment shaft and fix Adjustment shaft.

CAUTION	Do not tighten Set screw too tight. When you tighten Set screw too tight, you may damage screw thread.
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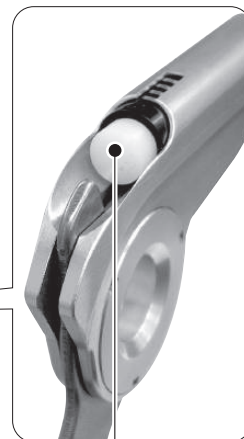
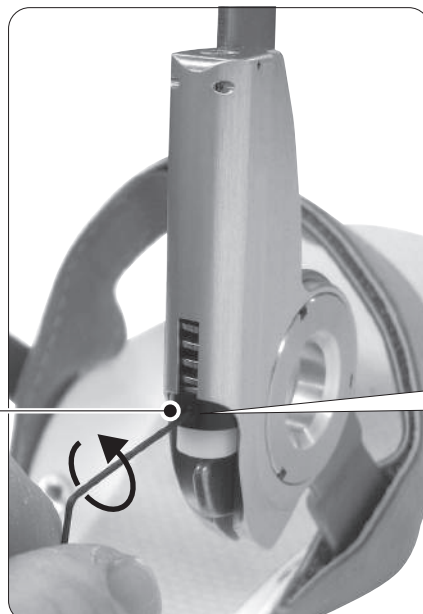
6-2 Adjustment of initial flexion

You can set initial flexion angle in 0 and 5 degree by replacing Rod cap in Hydraulic unit. You can also set initial flexion angle toward planter flexion by carving Cam.

WARNING	The user should never adjust initial flexion angle! The user might not be able to walk stably. Please consult a medical doctor or a physical therapist or an orthotist when initial flexion angle needs to be adjusted.
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1) Loosen Set screw for Rod cap on Hydraulic unit with Hexagon wrench M2 (for Rod cap) and remove Rod cap.

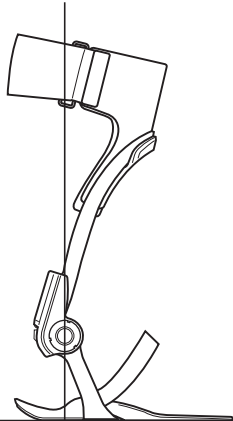
① Loosen Set screw for Rod cap



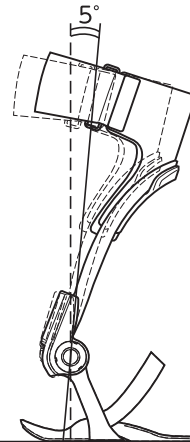
② Remove Rod cap

2) Replace Rod cap to the one with proper height

※ You should adjust the initial flexion angle after checking toe clearance during swing phase while walking with shoes.



When you use Rod cap 0°
Initial flexion angle = 0°



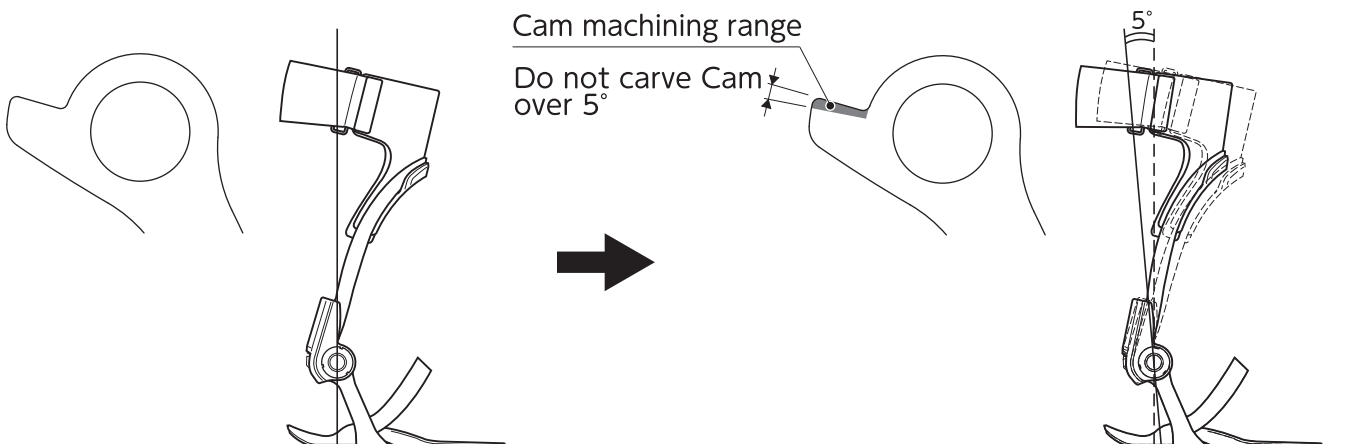
When you use Rod cap 5°
Initial flexion angle = Dorsal flexion 5°

3) Tighten Set screw for Rod cap in reverse order of 1 and fix Rod cap

CAUTION

Do not tighten Set screw too tight. When you tighten Set screw too tight, you may damage screw thread. Confirm that Rod cap is fixed completely. When Rod cap is not fixed properly, Rod cap may come out while walking and it may leads to injuries.

4) Confirm initial flexion in standing position with shoes. In case that you observe strong pushing to Cam, you should carve Cam and set proper initial flexion angle.



When you carve Cam to 5°
Initial flexion angle = Planter flexion 5°

CAUTION

Do not carve Cam over 5°. When you carve Cam too much, you may damage the Cam. When you carve Cam, you should check that it doesn't have burrs.

7. Maintenance

You can use this product longer if it is maintained properly. Please perform the replacement of a part, if necessary.

7.1 Replacement of hydraulic unit or Swing only joint

1) Removal of hydraulic unit

Remove Pivot Axis by Jig To Rotate GSD-R1 Pivot Axis (see page 6) (Fig. 1) . Loosen 2 screws inside to remove Hydraulic Unit (Fig. 2 and 3).



Fig. 1 Removal by Jig



Fig. 2 Screws loosening



Fig. 3 Removal of Hydraulic unit

2) Attachment of Hydraulic unit

Take 2 Washers for pivot axis out and apply proper quantity of grease on both sides of Washers. Hold pivot axis part on Stirrup between Washers over Resin ring (small) (Fig.4) and attach Hydraulic unit. (Fig.5) Adjust the center of pivot axis to Stirrup and attach rectangular pivot axis from inside. Apply proper quantity of Screw locking agent (Low strength) on around pivot axis (Fig.6) and attach circular pivot axis from outside by using jig to rotate GSD pivot axis. (Fig.7)



CAUTION Do not place Washer for pivot axis completely upon Resin ring. In case of complete overlapping, Washer for pivot axis may be worn away soon and cause trouble.



Fig.4 Application of Washer for pivot axis

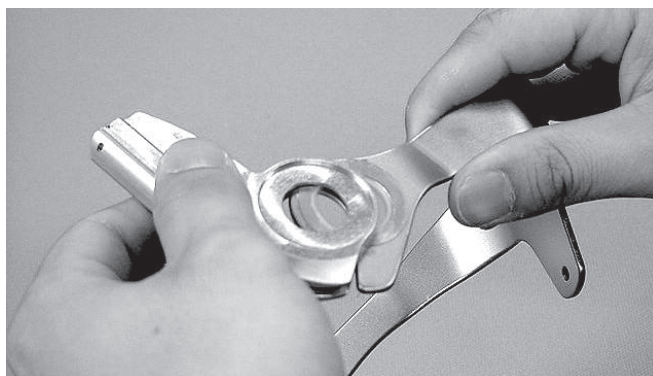


Fig.5 Application of Hydraulic unit



Fig.6 Attachment of Rectangular pivot axis/
Application of Screw locking agent

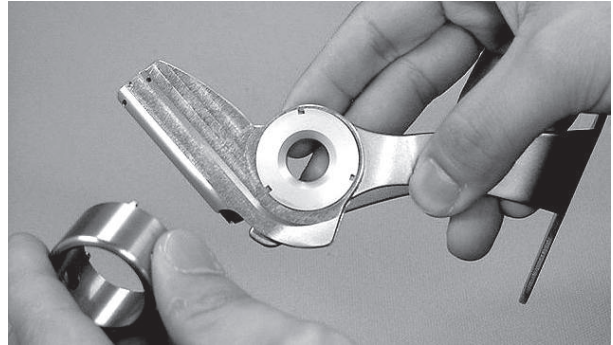


Fig.7 Attachment of Circular pivot axis

3) Attachment of U post

Take 2 SUS Round flat-head screws M4×5 out from the box. Apply proper quantity of Screw locking agent (Low strength) on the tip of SUS Round flat-head screws and fix Hydraulic unit and U post with these screws. (Fig.8)

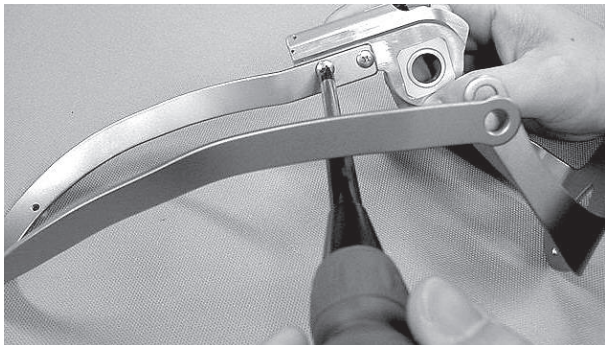


Fig.8 Attachment of U post

7.2 Washer replacement/Grease up

1) Removal of AL/BS Swing only axis

Remove AL Swing only axis and BS Swing only axis by Spanner (see page 6) (Fig. 9) . Loosen 2 screws inside to remove Hydraulic Unit (Fig. 10).



Fig 9 Removal by Spanner



Fig. 10 Removal of Swing only axis

2) Attachment of BS swing-only joint

Attach BS swing-only joint on U post as a guide to washer, put M8 washer 0.25 (sticky) on U post. (Fig.9) After that, apply proper quantity of grease on washer and take BS swing-only joint out from U post. Take 2 M8 washers 0.25 and a M8 washer 0.15 out and apply proper quantity of grease on these washers. Attach parts to BS swing-only joint from Stirrup → M8 washer 0.25 → SUS disc spring → M8 washer 0.15 (only for standard GSD) → M8 washer 0.25 → U post. (Fig.10)



Fig.9 Application of M8 washer 0.25 (sticky)

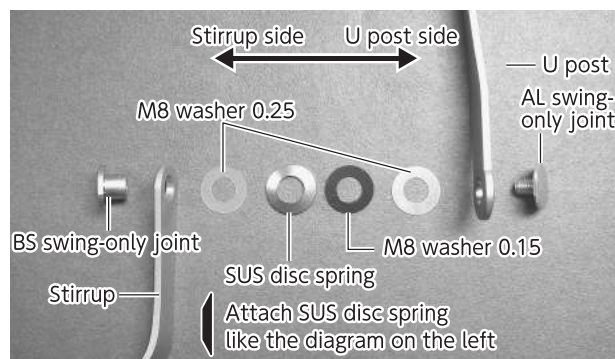


Fig.10 Sequence of attachment

3) Adjustments for braking force to planter flexion

The SUS disc spring inside of Swing-only joint gives braking force to ankle planter flexion. When you increase the number of washer, you can increase braking force and when you decrease the number of washer, you can decrease braking force. The braking force to dorsal and planter flexion is mainly necessary not to drop Cuff when a user wears this product. When you set the braking force to dorsal and planter flexion too strong, the setting makes supporting force to dorsal flexion weaker and makes difficult for a user to take toe clearance in swing phase. You should observe a user gait and how to wear footwear to select proper setting for each user. When you need to adjust the braking force to dorsal and planter flexion strong, you can purchase GSD M8 washer set 4 kinds (5 washers each). 5 M8 washers 0.25 and 5 M8 washers 0.15 are included in this set.

4) Attachment of AL swing-only joint

Apply proper quantity of Screw locking agent (Middle strength) on AL swing-only joint. Put Spanner on BS swing-only joint (Fig.13) and hold the spanner and U post in one hand. After that, tighten AL swing-only joint with another spanner. (Fig.14)



Fig.13 Holding BS swing-only joint



Fig.14 Tightening AL swing-only joint



Burrs might come out from AL or BS swing-only joint when you attach Swing-only joint. At that time, please replace them to new one and never leave this product as it is. It might leads to injuries.

5) Validation

Move joint to plantar side and dorsal side and verify movements. Please check if grease is on around pivot axis or not. When you find excess of grease, wipe it out with cloth.

7.3 Replacement of foot part and cuff

1) Removal of Foot part

Remove Planter foot sheet (Fig. 15). Loosen 4 screws to remove Foot Part from Stirrup (Fig. 16).



Fig. 15 Removal of Planter foot sheet



Fig. 16 Removal of Foot part

2) Attachment of foot parts

Apply proper quantity of Screw locking agent (Middle strength) on around screw part of a SUS Round flat-head screw M4×5 (M4×4 for Small size) and 3 SUS Round flat-head screws M4×6.5 (M4×5 for Small size). Put foot parts on Stirrup and adjust 4 holes on foot parts to the holes on Stirrup. Put a SUS Round flat-head screw M4×5 (M4×4 for Small size) on a hole near heel and tighten the screw with Phillips head screwdriver.(Fig.17)

Put 3 SUS Round flat-head screws M4×6.5 (M4×5 for Small size) on the residual holes and tighten the screw with Phillips head screwdriver.(Fig.18) Tighten 4 screws again after you finished to tighten screws.



Fig.17 Attachment of SUS Round flat-head screw M4×5 (M4×4 for Small size) 1



Fig.18 Attachment of SUS Round flat-head screws M4×6.5 (M4×5 for Small size) 3

3) Removal of Cuff

Remove Pads and loosen 3 screws to remove the cuff from U post (Fig. 19 and Fig. 20).



Fig. 19 Screw loosening



Fig. 20 Removal of cuff

4) Attachment of Cuff

Put the Cuff on U post in frame (Fig.21) and adjust 3 holes on Cuff to the holes on U post. Apply proper quantity of Screw locking agent (Low strength) on SUS Countersunk screw M4×5 and fix the Cuff from inside with those screws. (Fig.22)



Fig.21 Attachment of the Cuff

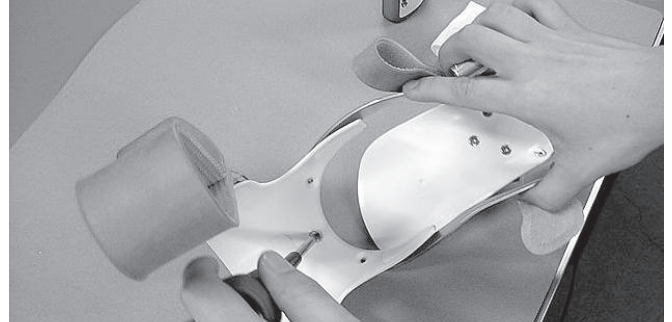


Fig.22 Fixing the Cuff



Take care not to scratch around center of the Cuff when you attach it. You may spoil the appearance.

7.4 Replacement of Protection seals and Planter foot sheet

1) Removal of Protection seals

Remove Protection seals on the metal fixture with Ankle Belt and Planter foot sheet on the insole.
※Remove stains like grease out from the product after Planter foot sheet is removed.

1) Sticking protection seals and planter foot sheet

Stick protection seals on the rivets which are inside and outside of foot parts. (Fig.23) Stick planter foot sheet on the foot parts. (Fig.24)

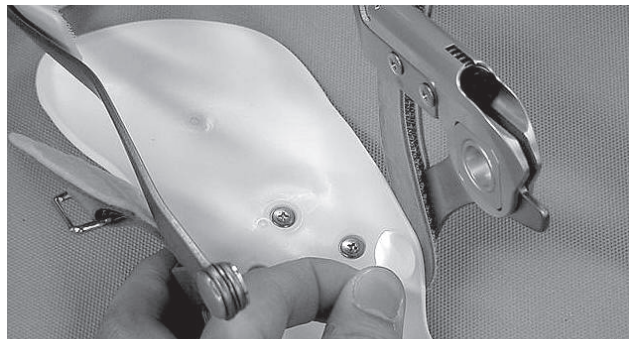


Fig.23 Sticking protection seals



Fig.24 Sticking planter foot seat (Match the toes)

7.5 Replacement of Swing only joint and Hydraulic joint pad

1) Removal of Swing only joint and Hydraulic joint pad

Remove Swing only joint and Hydraulic joint pad (Fig. 25 and 26)



Fig.25 Sticking protection seals



Fig.26 Sticking planter foot seat (Match the toes)

2) Attachment of Swing only joint and Hydraulic joint pad

Stick Swing-only joint pad on the joint like a picture below: (Fig.27) Stick Hydraulic joint pad on the inside of rotation axis in Hydraulic unit. (Fig.28) You can stick Hydraulic joint pad without a gap by using Dummy for pivot axis A as a guide.



Fig.27 Sticking swing-only joint pad

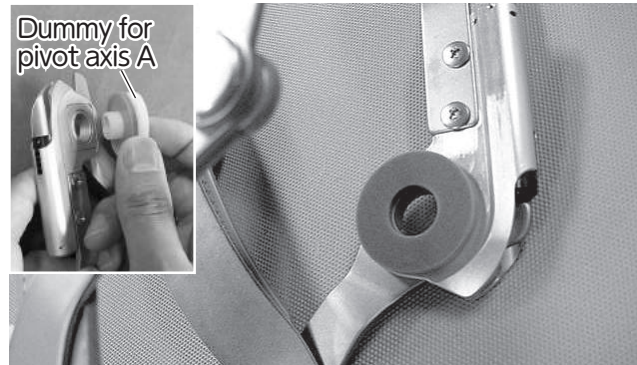


Fig.28 Sticking Hydraulic joint pad

7.7 Replacement of Frontal Cuff Pad

1) Removal of Frontal Cuff Pad

Remove Frontal Cuff Pad and Back Pad (Fig. 29).

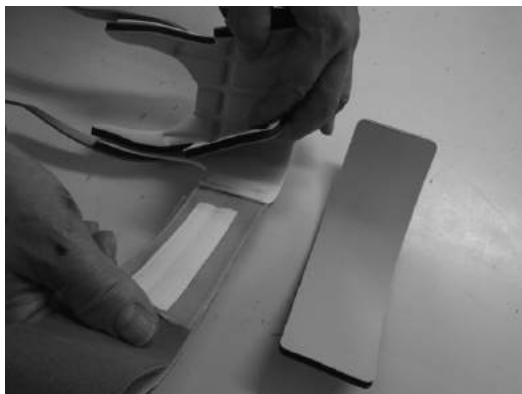


Fig.29 Removal of Frontal Cuff Pad

2) Attachment of Frontal cuff pad

Attach Frontal cuff pad on the Cuff where the pad comes outside of the edge about 3mm. The pad should come outside evenly on the left and the right side. (Fig.30) Attach Back pad on the belt where the pad comes outside of the edge about 3mm. (Fig.31)

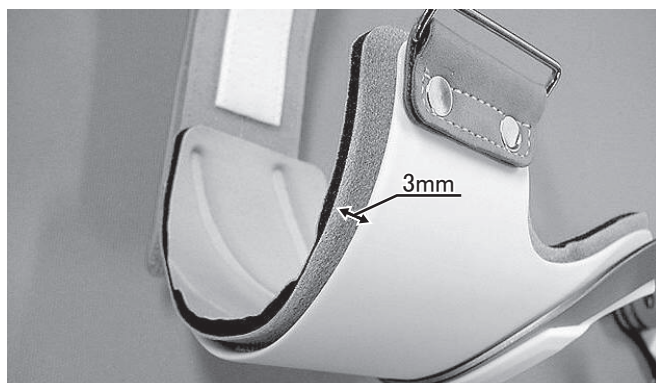


Fig.30 Attachment of Frontal cuff pad

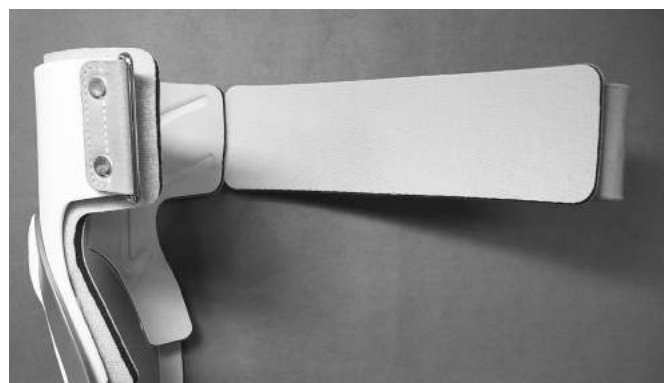


Fig.31 Attachment of Back pad

7.8 Check after maintenance

1) Validation for dorsal flexion

Move ankle joints towards dorsal flexion to find if any noise comes out or not.

Check if dorsal flexion braking force is proper or not. (Fig.32)

If you find any problem, adjust Swing-only joint again. (See page 13)

! CAUTION

You may find something like fiber from Swing-only joint side in an early stage, but this is not abnormal thing. In this case, move joints until you cannot find any fiber and wipe it away. You may spoil the appearance when you keep this fiber on.

2) Validation for Adjustment shaft

Confirm that the Adjustment shaft is not fixed with Set screw for Adjustment shaft and set the Adjustment shaft to setting1. Move ankle joints towards dorsal flexion to find if these joints move smoothly or not. (Fig.32)

Next, set the Adjustment shaft to setting4. Move ankle joints towards dorsal flexion to find if joint movements are limited (almost fixed) or not.

! CAUTION

When you confirm movements in setting4 you may find that there is a little play until the limitation of joint movements starts. This comes from the property of hydraulic shock absorber in hydraulic unit, and this is not a malfunction. Please contact us, when you find that the play is over 1.2mm in setting4. In case you keep using it, you may damage the hydraulic unit.

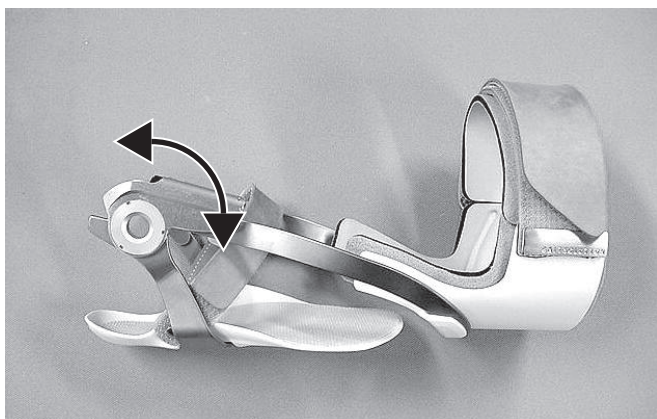


Fig.32 Validation towards dorsal and planter flexion

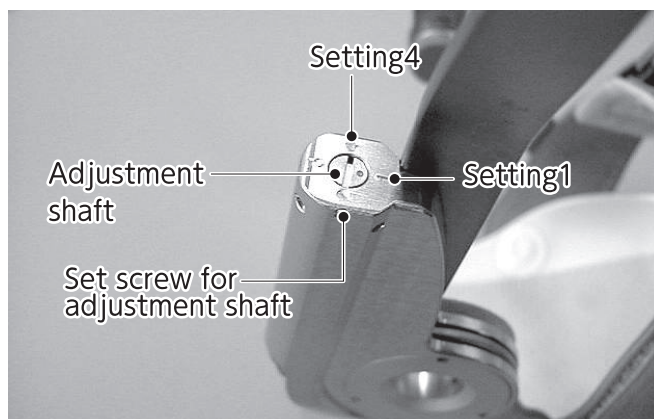


Fig.33 Confirmation for Adjustment shaft

3) Confirmation for parts

Check below again, if you forgot to put these parts or not.

- 2 protection seals on the rivets of the foot parts
- Planter foot seat on the foot parts
- Hydraulic joint pad on Hydraulic unit
- Swing-only joint pad on swing-only joint
- Frontal cuff pad and Back pad on the Cuff

8. When you find any trouble...

①Noise

The noise may come from shortage of grease. Please check page 12 '7.2 Washer replacement/Grease up' and apply grease on each parts.

The noise may come from torsion force to this product by serious varus foot or excess of loading towards planter flexion (like going up the stairs with locked ankle and the knee is in hyper extended position). You cannot use this product under this kind of high loading to orthosis. You should consider about application of orthosis again.

②Adjustment shaft in Hydraulic unit doesn't rotate

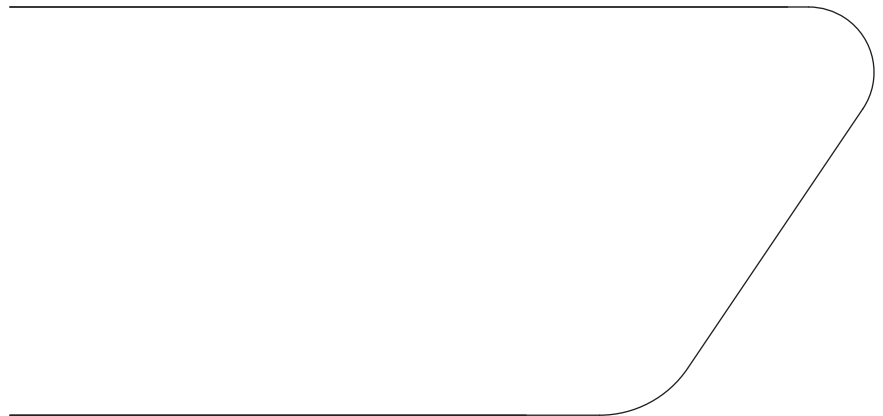
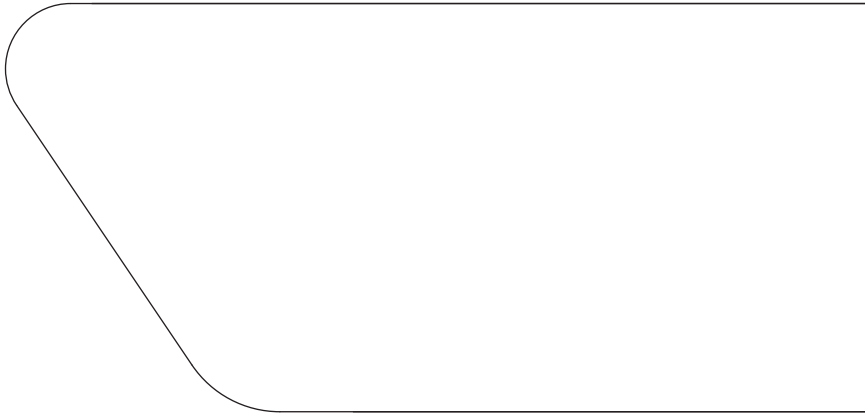
It may come from completely tightened Set screw for adjustment beside Adjustment shaft in Hydraulic unit or scratch in Adjustment shaft when you tighten it forcibly with Set screw tightened(Fig.33). When you loosen Set screw and still you cannot rotate Adjustment screw, please contact your distributor.

When you find any other problem, please contact your distributor.

9. Attachments

9-1 Pattern for belt cutting (Scale 1:1)

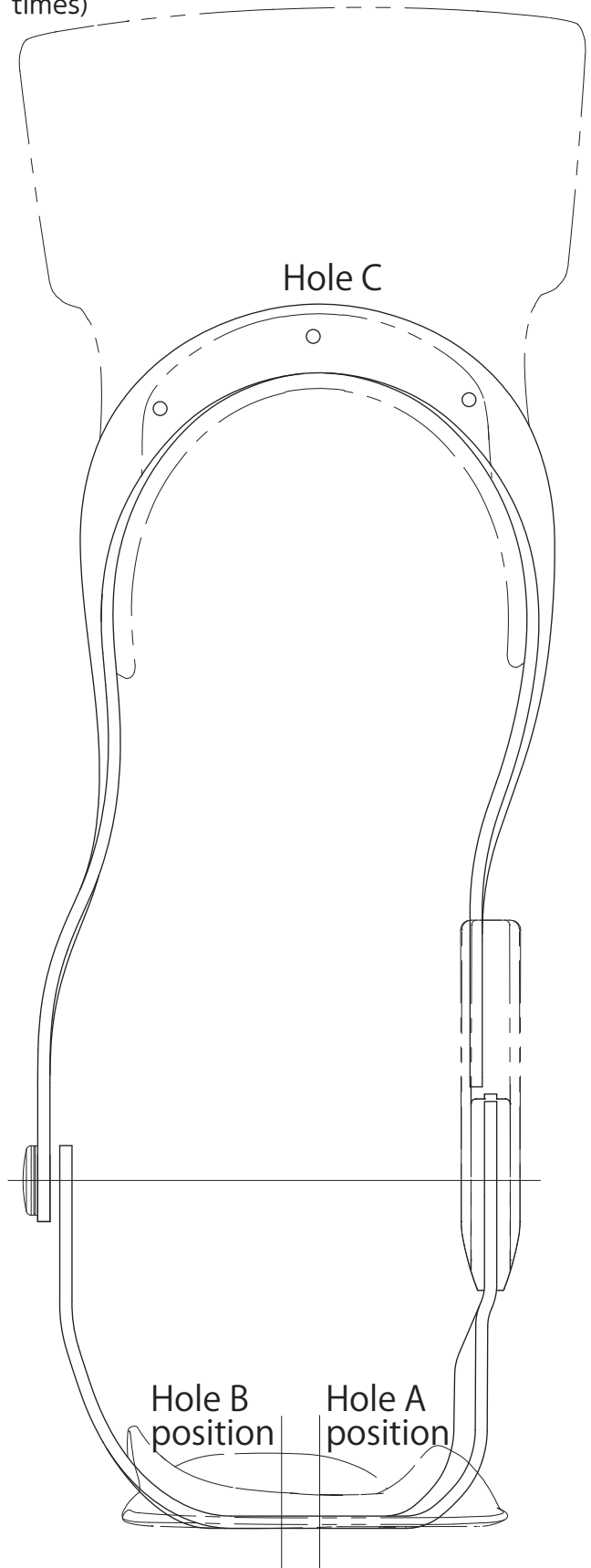
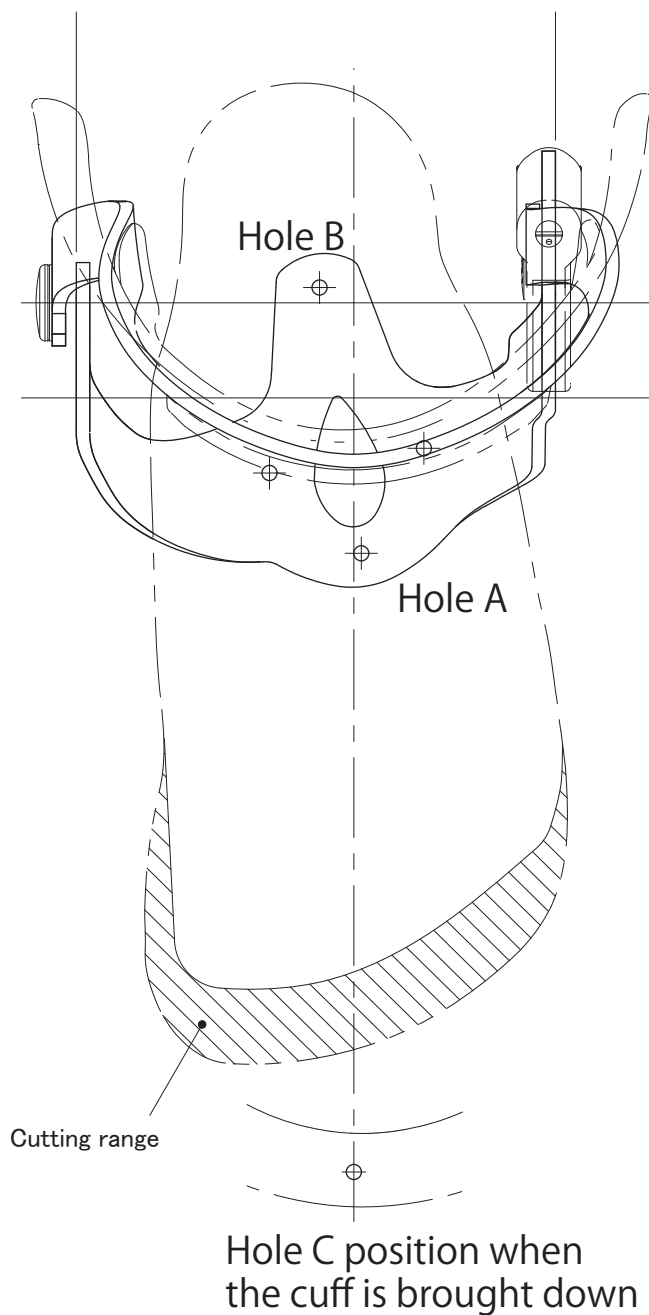
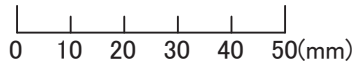
Please use this pattern when you cut belts.



9-2 Tracing form for GSD-R1 (For Left S)

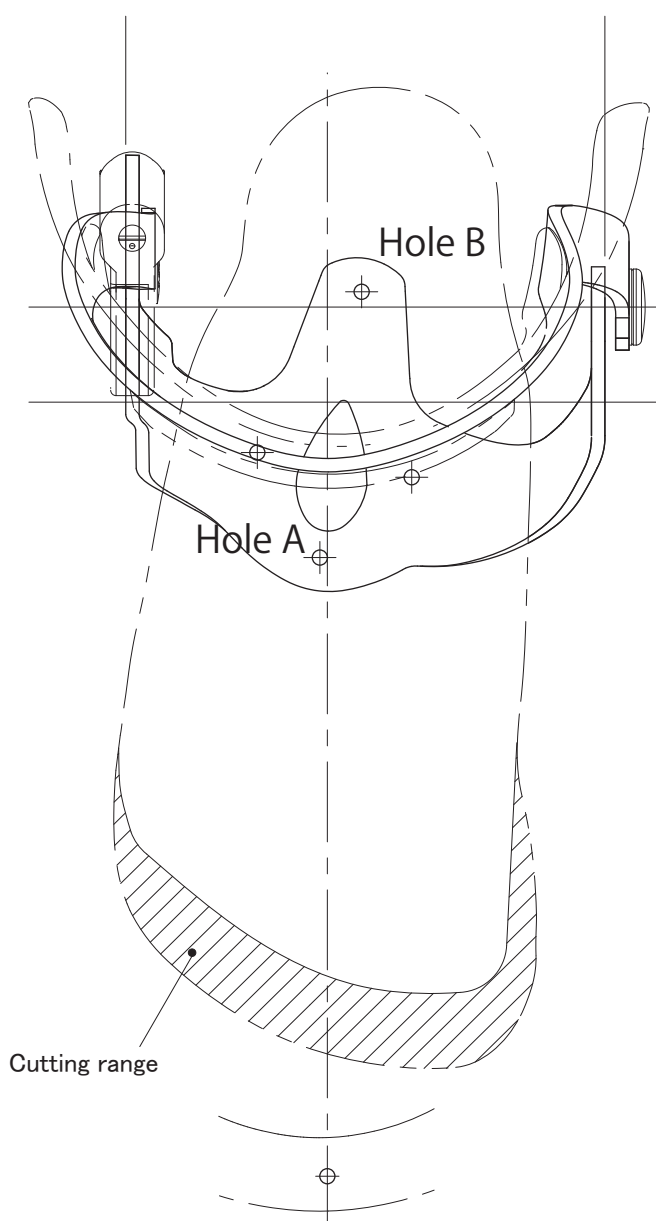
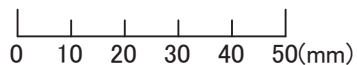
Here is tracing form for this product

Please magnify this form to A3 size (by 1.41 times)
and use it.

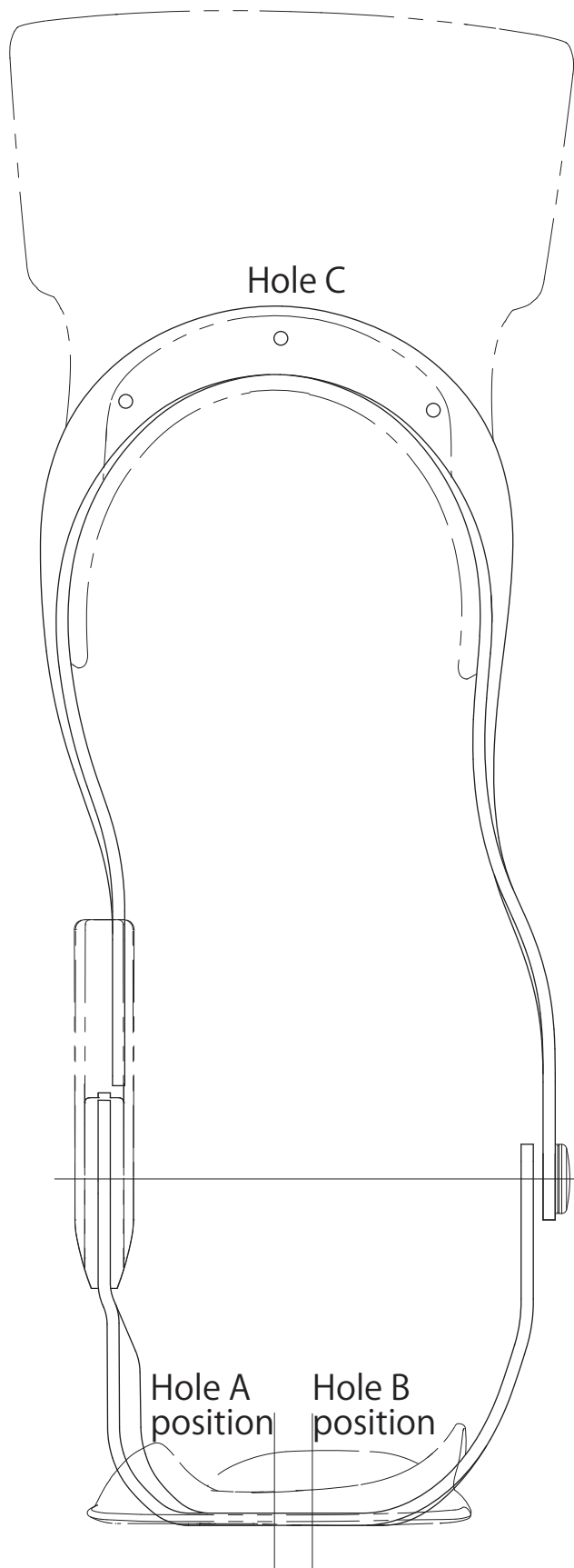


9-3 Tracing form for GSD-R1 (For Right S)

Here is tracing form for this product
Please magnify this form to A3 size
(by 1.41 times) and use it.

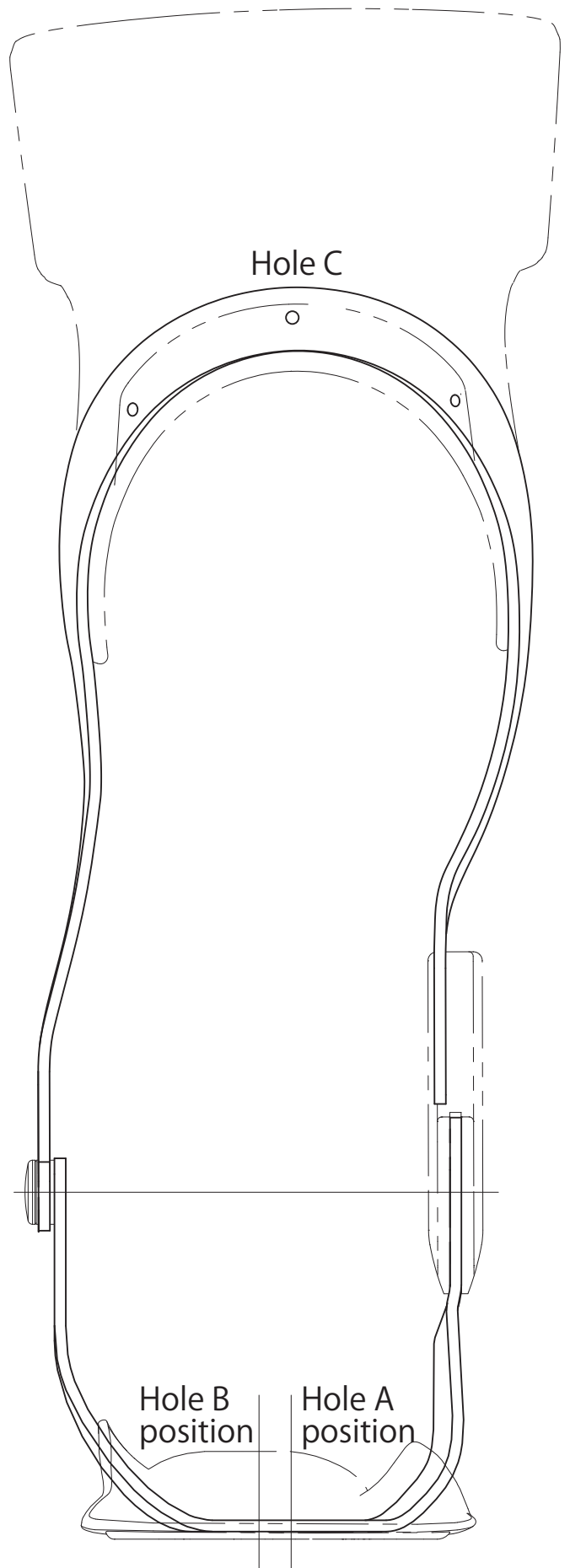
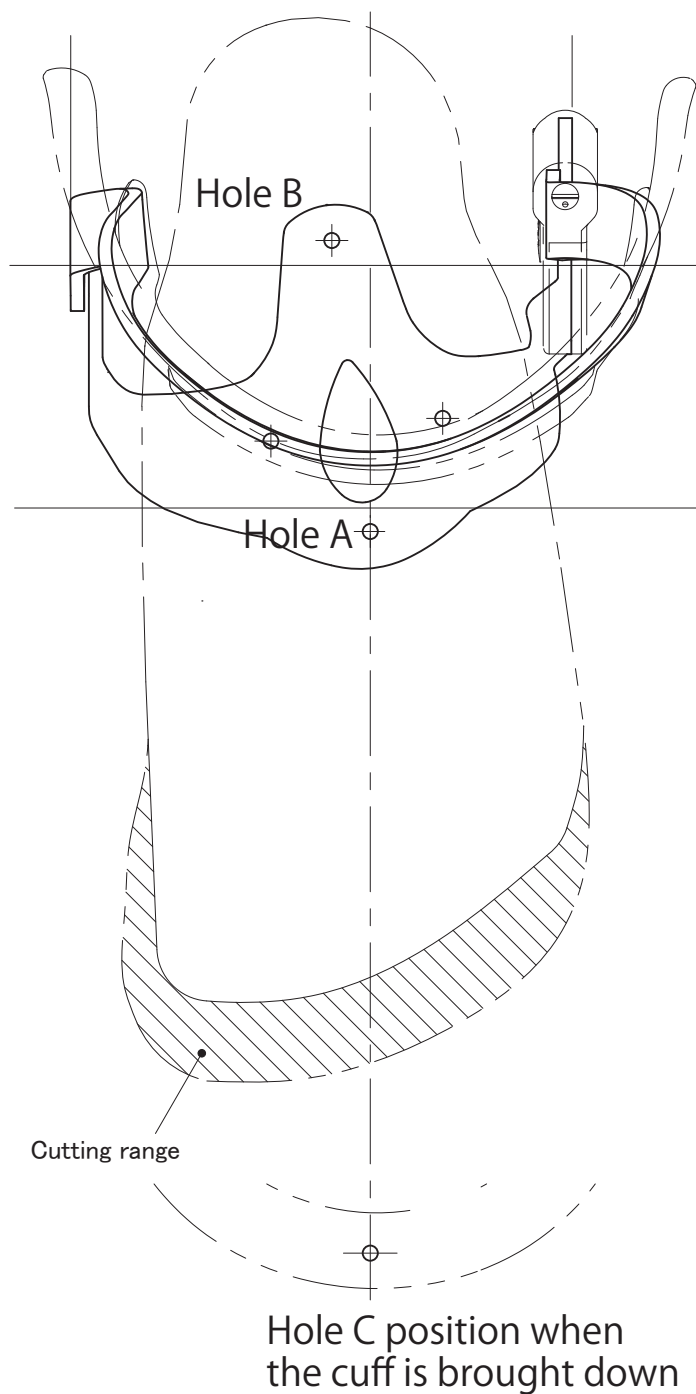
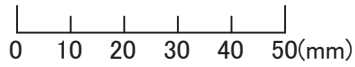


Hole C position when
the cuff is brought down



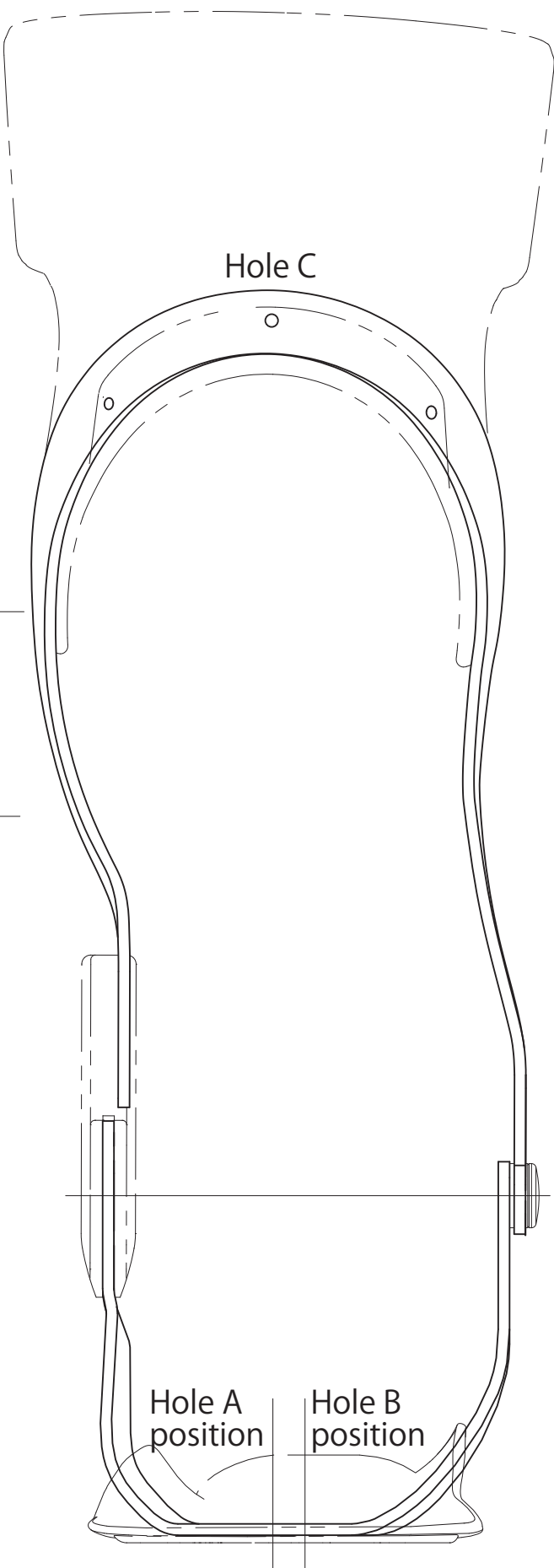
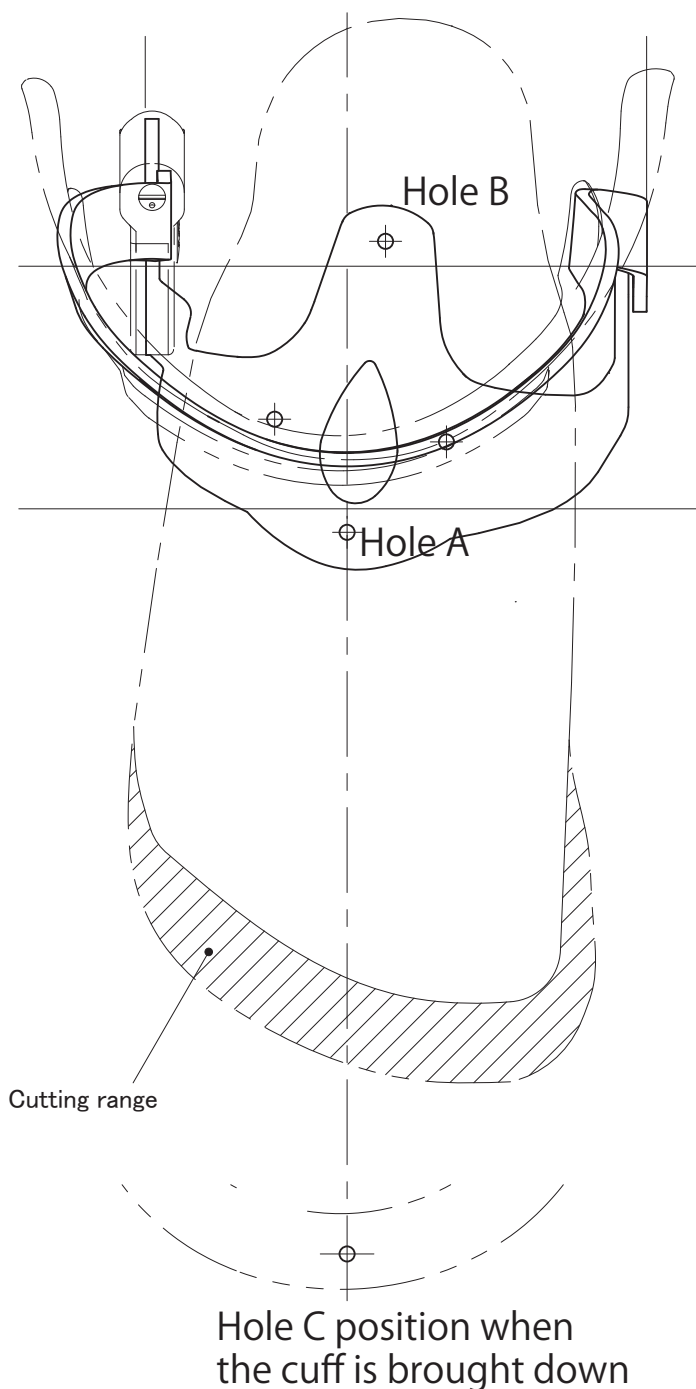
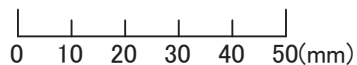
9-4 Tracing form for GSD-R1 (For Left M)

Here is tracing form for this product
Please magnify this form to A3 size
(by 1.41 times) and use it.



9-5 Tracing form for GSD-R1(For Right M)

Here is tracing form for this product
Please magnify this form to A3 size
(by 1.41 times) and use it.

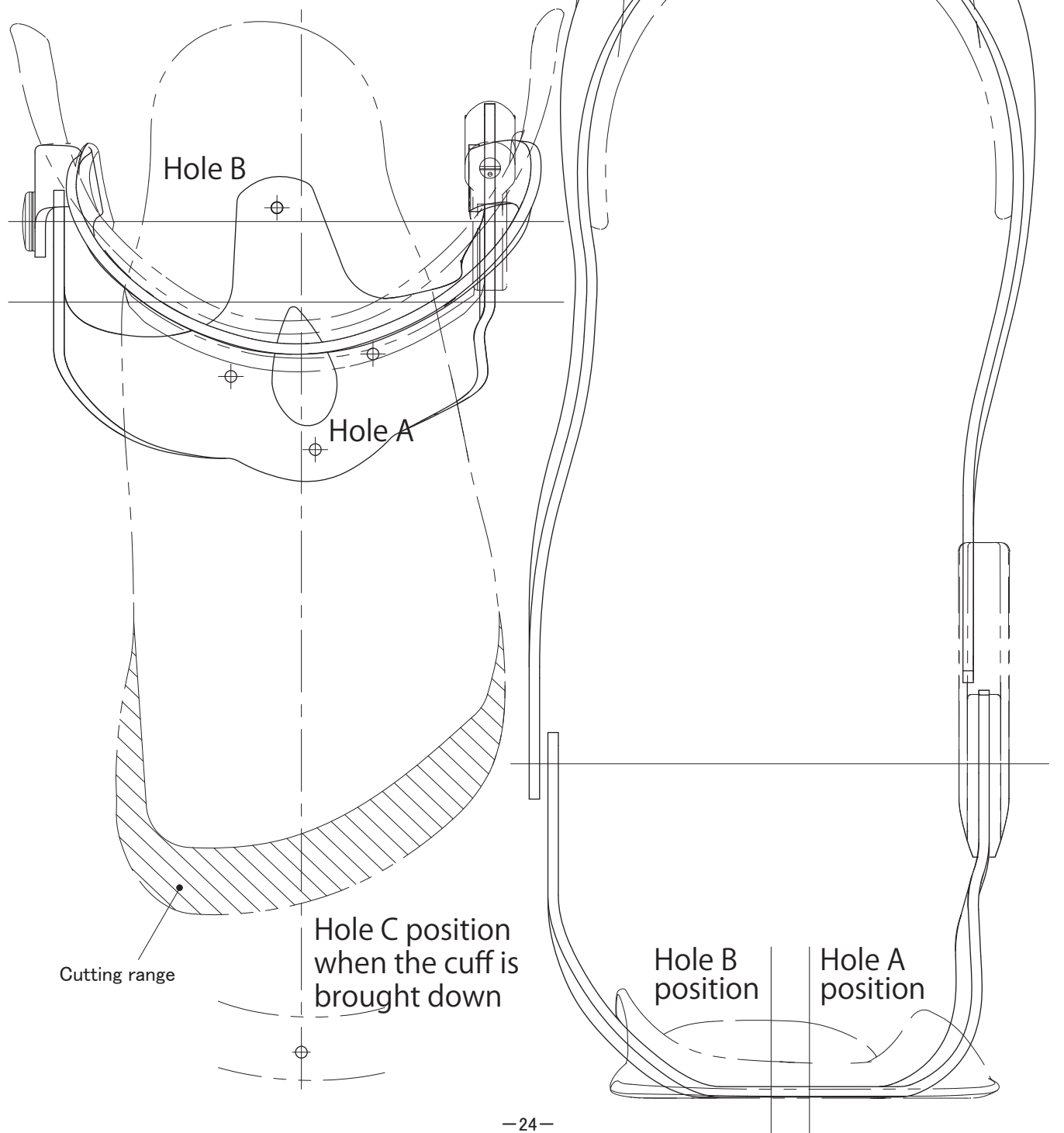
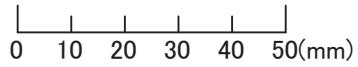


9-6 Tracing form for GSDR-1(For Left L)

Here is tracing form for this product

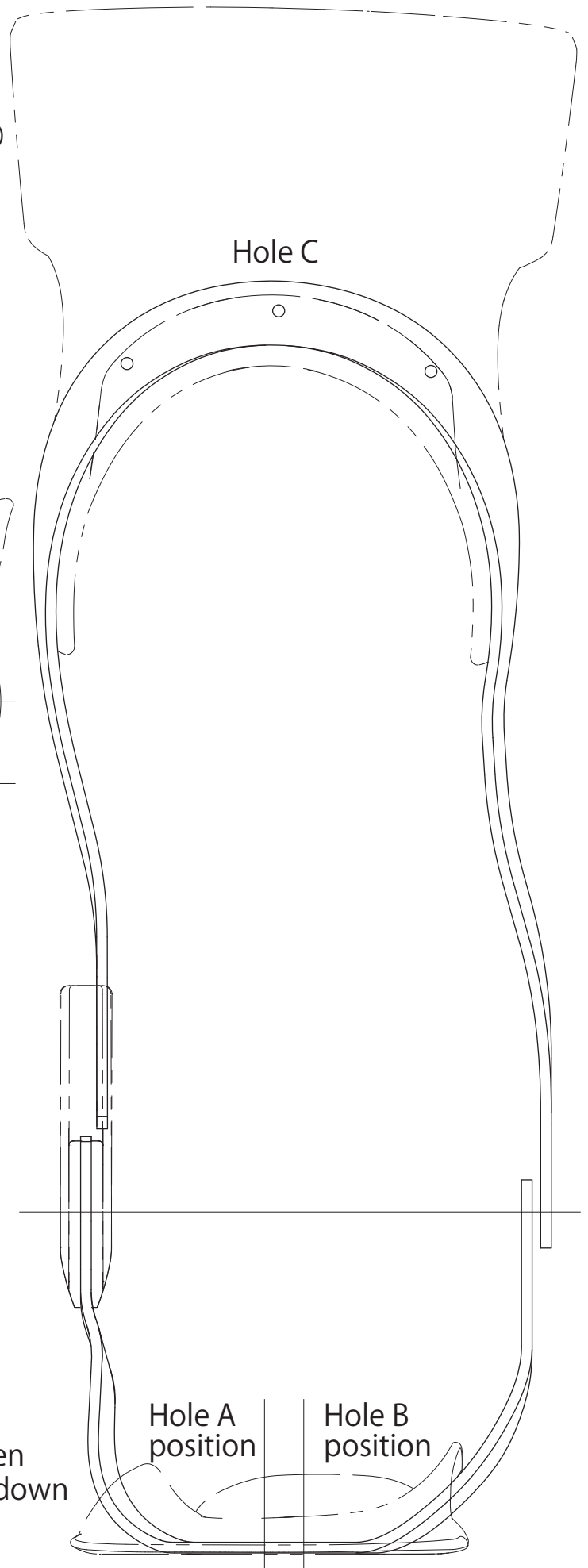
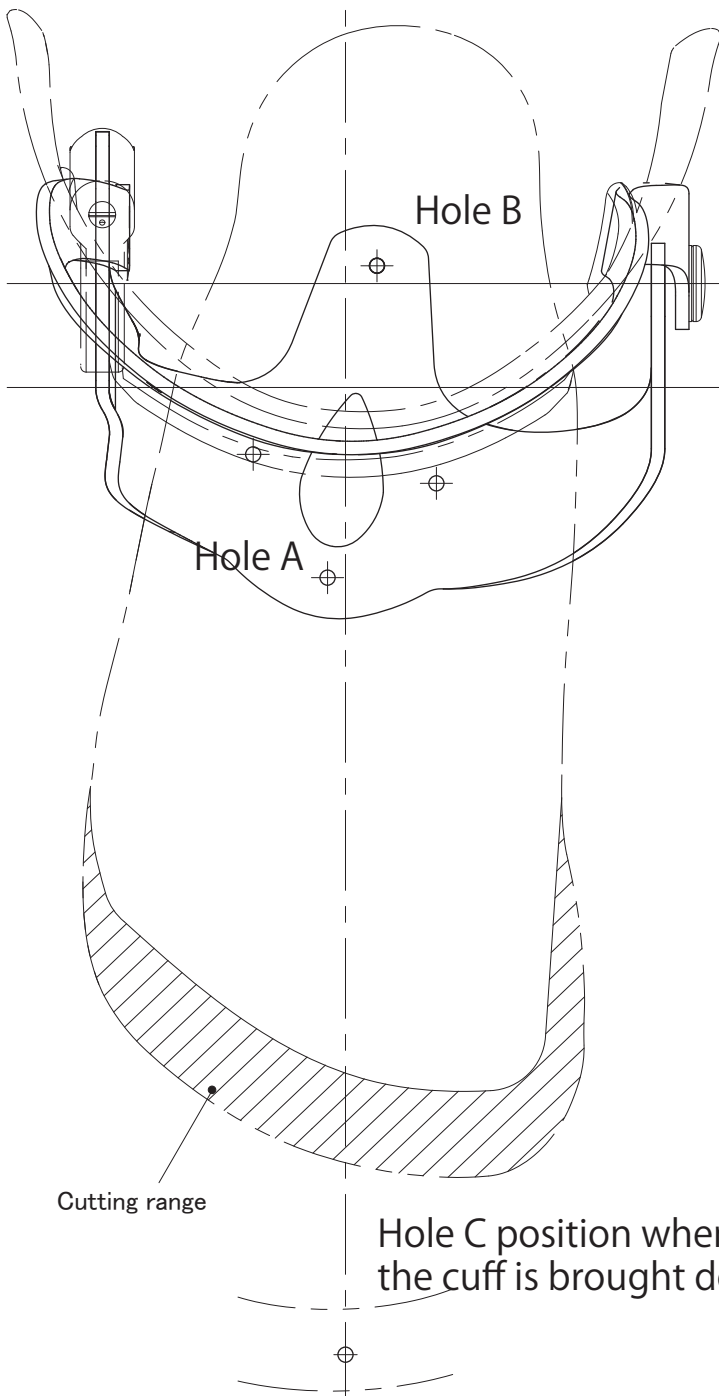
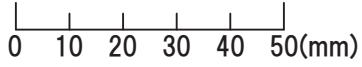
Please magnify this form to A3

size (by 1.41 times) and use it.



9-7 Tracing form for GSD-R1(For Right L)

Here is tracing form for this product
Please magnify this form to A3 size
(by 1.41 times) and use it.



10. Customer information

Product name/Model/Size : _____

Serial No. : _____

Delivery Date(dd/mm/yy) : _____

Foot Length : _____

Customer weight : _____

Initial hydraulic unit setting : _____

11. Periodic inspection

The warranty period is one year after the delivery date. The durable period on this product is two years when regular inspections and necessary part replacement are performed every 6 months.

The components except U post and Stirrup are consumables which are not covered under the warranty.

Please perform regular inspections and systematically replace worn parts during regular inspections.

Item	Time of Replacement	Check for	Result
Hydraulic unit	Every 1 year	Range of play	
Washer	Every 6 months	Noise/Play	
Swing only joint	Every 6 months	Stability	
Sponge pad	Every 6 months	Wear and Tear	
Cuff belt	Every 6 months	Adhesion	
Ankle belt	Every 6 months	Adhesion	
Protection seals Planter foot seal	Every 6 months	Peeling / Stains	

Replaced parts : _____

Inspection date : _____

Inspection person : _____

Over 90 kg of customer's weight? No / Yes.

If yes, please stop using this product. Nothing doing so may cause you injuries.

12. Explanation of Label

GAITSOLUTION Design R1 is labeled as follows:

1. 
2. GAITSOLUTION Design R1
3. Standard Urban Sport
4. S M L
5. Left Right
6. Pacific Supply Co., Ltd.
7. Made in Japan
8. Lot No. _____
9. MFG. _____

- 1 CE mark
- 2 Product Name
- 3 Model Name
- 4 Size
- 5 Left or Right
- 6 Manufacturer
- 7 Origin of product
- 8 Lot No.
- 9 Manufacturing Date

-Original-

**EC Declaration of Conformity
for Medical device Directive 93/42/EEC, 27 Oct. 1998**


1. Business name and full address of the manufacturer;
Pacific Supply Co., Ltd.
1-12-1, Goryo, Daito-Shi, Osaka, 574-0064 JAPAN
Telephone: +81-72-875-0813, Fax: +81-72-875-0817

2. Name and address of the person authorized to compile the technical file;
CRESTEC EUROPE B.V.
Teleportboulevard 110, Amsterdam, The Netherlands, 1043 EJ

3. Description and identification of the medical device
Ankle foot orthosis, GaitSolutionDesign R1

4. We hereby declare that the product identified above confirms to the relevant essential health and safety requirements of Annex VII of directive COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.

5. Classification according to ANNEX IX of directive 93/42/EEC
This device is classified as "Class I".

6. Date/Manufacturer signature: 1-May 2015 
Position of the signatory

Kei Kawamura
President and CEO



Pacific Supply Co., Ltd.

1-12-1, Goryo, Daito-Shi, Osaka, 574-0064 JAPAN

TEL: +81-72-875-8013

FAX: +81-72-875-8017

URL: <http://www.p-supply.co.jp/>

Authorized Distributor:



CRESTEC EUROPE B.V.

Teleportboulevard 110, Amsterdam, The Netherlands, 1043 EJ

TEL: +31 (0)20 585 46 40

FAX: +31 (0)20 585 46 60

URL: www.crestec.eu

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