SPL2 Product Manual

The most popular stance control orthotic knee joint **just got better**





Jillauer LLC

U.S. Patent 6979304

STOP! Quick Reference Tips / Troubleshooting

Warranty could be void if SPL2 Guidelines are not followed, read your manual carefully to ensure correct installation and usage of the SPL2. This quick reference DOES NOT replace the manual.

Tips for Success



When casting, add 5° of knee flexion to the patient's full range of knee extension.



DO NOT compensate for flexion by unlocking the SPL2 joint.



Remote Control must be set in LOCK MODE before making cable adjustments.

- Read the SPL2 manual for Patient Assessment Recommendations, Casting and Fabrication Guidelines, Adjustment and Maintenance Instructions, and Fitting Procedure / Evaluation.
- When casting, add 5° of knee flexion to the patient's full range of knee extension; this will allow proper locking and unlocking in the SPL2. This casting method will ensure the SPL2 always locks at full extension BEFORE the leg comes to full extension.

During Fabrication, DO NOT compensate for flexion by unlocking the SPL2 joint.

• The joint should be locked and set exactly parallel to the plumb line. This will keep the pendulum balanced and prevent the SPL2 joint from locking or unlocking inadvertently. Bend the upper bar in standard 5° of flexion or as otherwise indicated.

NEVER LUBRICATE THE SPL2.

- Use of lubricants will void warranty.
- The joints have Teflon[®] self lubricating surfaces. Under no circumstances should the joint be lubricated.

Remote Control must be set in LOCK MODE before making cable adjustments.

• Adjustments to the cable must be made in the Lock Mode to avoid an incorrect cable length.

Avoiding Noise in SPL2 Joint

- (Popping and Cracking in Laminated Fabrication)
- ALL the resin must be cleaned from the extension stop and bushings.
- Lock Plate must be free from burrs.

Troubleshooting Locking and Unlocking



The lock mechanism is position dependant.



Remote Control must be in LOCK MODE to adjust cable. Insert cable into End Block at desired length, leave approximately 3/16" beyond end block.



Position of Lever Arm when Satellite Slide Lever is properly adjusted in Automatic Lock Position.



Function Unit Pendulum Adjustment

The lock mechanism is position dependent.

• During gait, the device LOCKS just prior to heel strike when the correct ANGLE of the pendulum is achieved at FULL knee extension.

• The device will UNLOCK when the correct ANGLE of the pendulum is achieved at heel off and the flexion load is released by FULL knee extension moment.

SPL2 locks when off, but not when on patient.

• A working SPL2 that will not lock on the patient can be caused by improper upper bar alignment. Upper bar must be retroverted at Terminal Swing to allow pendulum to fall (see tips for success above).

• Fair or Better (Grade 3) Hip Flexors are required to achieve swing-through.

Patient unable to lock SPL2 in full extension.

Cable may be too short forcing slide lever out of proper adjustment or if extreme, into unlock mode.
Additional flexion to the upper bar may be necessary to achieve locking on some patients (patient w/fleshy limb).

Patient unable to unlock SPL2.

• Make sure patient is Indicated for the SPL2. Patients with spasms, central paralysis, hip flexion contracture, or knee flexion contracture more than 10° will be unable to achieve the extension moment required to unlock the SPL2.

• If the Cable is cut or comes loose the SPL2 will remain locked, this is a Safety feature.

• Cable may be too long, forcing slide lever out of proper adjustment, or if extreme, into lock mode. Make sure Remote Control is in automatic lock mode and shorten Cable Length.

• Applying a dorsiflexion stop is suggested where there may be an insufficient extension moment due to poor hip extensors or poor plantar flexors.

• Moving the pendulum ANTERIOR (FORWARD) in the function unit, allows the SPL2 to unlock sooner in gait and will also require greater hip flexion to lock.

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Features and Benefits

- Automatic Locking Prior To Heel Strike
- Closely Mimics Normal Gait Pattern
- Free Flexion During Swing Phase
- Minimizes Energy Consumption
- Eliminates Circumduction and Vaulting
- Facilitates Toe Clearance During Swing Phase
- Added Patient Security
- Increased Range of Motion to 151°
- 2 Locking Positions at 0° and 15°
- Extended Wear Bumper
- Teflon Bushings for Sideloading
- High Load PEEK Bushing
- 4 Modes of Control
- No Cables or Special Heel Connections
- Easy Fabrication

Warranty

Fillauer orthotic components are warranted for 12 months from the date of shipment from the Fillauer warehouse or from an authorized Fillauer distributor. Items under warranty will be replaced or repaired (at Fillauer's discretion) at no charge. The warranty will be void if the item has been fabricated or installed outside Fillauer's recommendations, if the item has been exposed to a corrosive environment, or if the item has been used in extremely abusive activities that could result in injury.

Indications:

- Post-Polio
- Spinal Involvement
- Cerebral Vascular Accident
- Peripheral Paresis/Paralysis
- Nerve Inflammations

- Neurological Failures
- Myopathies
- Multiple Sclerosis (or similar diseases)

Contraindications:

- Knee Flexion Contracture greater than 10°
- Central Paralysis
- Hip Flexion Contracture
- Hip Musculature Involvement
- Poor Balance or Coordination
- Knee Hyperextension greater than 10°

Introduction to Swing Phase Lock 2



Welcome to the next generation of orthotic knee design known as the "Swing Phase Lock 2" or "SPL2"

Developed by Basko Healthcare, a Fillauer affiliate in the Netherlands, the SPL2 uses a simple internal pendulum mechanism to lock and unlock the knee depending on the angle of the joint in the sagittal plane. During gait, the device locks just prior to heel strike for support during stance and unlocks the knee at heel off in preparation for swing. This action is intended to mimic the normal physiologic action of the knee extensors. Because the mechanism is position dependent, it does not rely on heel loading or cabling as in other designs. This allows for a more normal gait pattern and prevents circumduction or hip hiking commonly seen in standard KAFOs.

The SPL2 has four modes of operation controlled by a proximal remote push-button switch:

- 1) Automatic Lock/ Unlock
- 2) Manual Unlock
- 3) Manual Lock
- 4) Free Motion

The different modes allow the patient to select automatic lock for walking, unlock for sitting, lock for standing or free motion for driving in a car or riding a bicycle.

The SPL2 must be used with the Swing Phase Control (SPC) Joint which uses friction and a spring to regulate knee flexion during swing phase. The SPL2 is designed to be mounted laterally and the SPC medially. Both use standard 3/4" (20mm) sidebars.

Frequently Asked Questions and Answers

Can the SPL2 joint be used with Spastic Patients? No.

Can the SPL2 joint be retrofit to an existing KAFO? In most thermoplastic applications the SPL2 Joint can be retrofit by repositioning the uprights to accommodate the 5° of flexion needed to lock and unlock the SPL2. (Not recommended for Lamination.)

- Is a pediatric size available? Not at the present time, but may be in the future.
- Is an ankle section required for the use with the SPL2 joint? If the patient has good control of the ankle, an ankle section is not required.

Can I (the patient) adjust the SPL2 joint myself? No. This MUST ONLY be done by a properly trained Orthotist.

Can ANY Fabrication method be used for the SPL2? Yes. Conventional, Plastic and Laminated fabrication processes can be used.

Can the SPL2 joint be lubricated? NEVER. The joints have Teflon self lubricating surfaces. Under no circumstances should the joint be lubricated.

Can the SPC Joint be Lubricated to reduce noise? Yes. If after loosening the spring adjustment screw on the SPC clicking or squeaking still occur, then a small amount of lubricating oil may be applied

Can the SPL2 Joint be used in combination with a joint other than the SPC on the medial side?

to the spring inside the SPC Joint. NEVER LUBRICATE THE SPL2.

No, the SPL2 is designed to be used with the SPC joint. When used without the SPC joint, the manufacturer's warranty is void.

Is it possible to use the SPL2 Joint (single sided) without the use of a medial sided joint?

Yes, this must be laminated and made very strong to ensure no tension for the SPL2 joint. Proper fabrication is a must for this application.

Frequently Asked Questions and Answers

Can the satellite (remote control) be connected to the orthosis? Yes, the SPL2 Kit includes the Satellite Connector assembly which can be used as an alternative attachment method.

- Am I required to attend a seminar to be able to work with the joint? No, but the SPL2 system is a new component to orthotics and has unique casting, alignment and adjustments. Seminar attendance is strongly advised.
- Can the SPL2 joint be used both laterally (as intended) and medially? No, the SPL2 is intended to be only used laterally, it would be difficult to achieve lock at the same time. Also, the SPC provides swing phase control to insure extension.
- Can the SPL2 joint be used in a weight bearing orthosis? No, the joint was not designed for the high degree of mechanical load. The joint is designed for construction in a supporting device, not for a weightbearing.
- Is there a weight limit for the SPL2 Orthosis? No, the SPL2 orthotic knee system has been designed only as an orthotic support and should not be used for weight bearing orthotic applications.

Can the SPL2 be used during cycling?

Yes. With the new "free motion" mode for the satellite (remote control) this can easily be achieved.

Patient Assessment

Indications:

- Post-Polio
- Spinal Involvement
- Cerebral Vascular Accident
- Peripheral Paresis/ Paralysis
- Nerve Inflammations
- Neurological Failures
- Myopathies
- Multiple Sclerosis (or similar diseases)

Contraindications:

- Knee Flexion Contracture greater than 10°
- Central Paralysis
- Hip Flexion Contracture
- Hip Musculature
 Involvement
- Poor Balance/ Coordination
- Knee Hyperextension greater than 10°

The SPL2 is intended for patients with partial or total paralysis of the knee extensors and can be used as a KO or KAFO, with or without articulating ankle joints. It is not recommended for those with more proximal impairment of the hip musculature.

To use the SPL2, the patient must be able to initiate swing thru. If there is no active hip extensor at heel strike, (hip extensor failure, foot flexor failure) a dorsiflexion stop may be used to help unlock the knee. Users must have fair or better (grade 3) hip flexor strength to use the SPL2. Also, the SPL2 orthotic knee system has been designed only as a non-weight bearing joint and should not be used in any weight bearing orthoses.

Any use, other than described in this manual, with respect to patient indications or orthotic fabrication will void any product warranties and liability. For example, lubrication of the joint is NOT necessary and will void the warranty.

The SPL2 may be used in a unilateral application, but must be laminated to ensure proper strength.

Casting



Figure 1

Casting Requirements

Fillauer recommends a segmental casting technique with footboard. (Figure 1)1 Cast Foot and Ankle correcting varus/valgus.2. Cast Knee and Thigh correcting genu varum or valgum.

Casting



Figure 2



Figure 3



Figure 4

When casting, add 5° of knee flexion to the patient's full range of knee extension; this will allow proper locking and unlocking in the SPL2. This casting method will ensure the SPL2 always comes to full extension BEFORE the leg comes to full extension.

EXAMPLE:

Full extension at 0°-Provide Cast at 5° Flexion Full extension at 5°-Provide Cast at 10° Flexion Hyperextension at 5°-Provide Cast at 0° Flexion

The knee joint axis, approximately half the distance between the adductor tubercle and the medial tibial plateau, should also be marked. (Figure 2)

Sagittal Alignment

A sagittal plumb line is crucial to determine the neutral alignment of the joint. Balancing the pendulum prevents the lock from locking or unlocking inadvertently. Setting the joint to the plumb line allows the pendulum to be set within adjustment range. (Figure 3)

When filling the mold, the SPL2-Alignment Kit, (P/N IQ150) perpendicular to the frontal plane bisection line, should be used to keep the joint axis straight. (Figure 4)

When fabricated, the SPC should be parallel in all planes with the SPL2. The performance of the mechanism is highly dependent on the sagittal plane alignment. The SPL2 Unit Bumper should always be contacted first to allow for easy automatic unlock. If the joint is set incorrectly, the joint may engage prematurely or not at all, which may cause a fall.

Fabrication Requirements



Swing Phase Lamination Dummy Kit P/N 029840

Rigid thermoplastics such as Polypropylene should be used as opposed to more flexible plastics like TPE or Polyethylene. Carbon reinforcement such as carbon composite bands (available from Fillauer) or aluminum bands attached to the thigh and calf section is highly recommended to increase structural stiffness.

Applying a dorsiflexion stop is suggested where there may be an insufficient extension moment due to poor hip extensors, knee flexors, or plantar flexors.

If the recommended SPL2 Lamination Dummy Kit (available from Fillauer) is used during lamination, it is not necessary to disassemble the SPL2 or SPC. If lamination kit is not used, the SPL2 and SPC should be disassembled along with the Proximal Satellite (Remote Control).

The SPL2 should NOT be greased, oiled, or lubricated in anyway. To clean use a solvent or de-greaser and wipe clean. If Lamination Kit is not used, all joint adjustments and screw openings in the SPC and SPL2 should be filled with Stick Wax(P/N 990035) prior to lamination to prevent improper resin flow. Composite reinforcement such as unidirectional carbon tape should be laid in a "figure 8" manner in three layers above and below the knee to increase structural rigidity and torsional resistance.

Plastic Fabrication Using Fillauer Double Action Ankle Joints



Figure 5



Figure 6



Figure 7

- Apply Nylon hosiery over mold.
- Heat and form Carbon Composite Bands or TFC to the thigh and calf section of the mold unless using aluminum bands for reinforcement. (Figure 5)
- There should be a 45° bevel applied to the carbon to ensure encapsulation. Bevel side should be against the mold (Figure 6).
- From paper or Pe-Lite, make a pattern the same size as the PolyCar-C[™] and outline on the mold. Apply Poly-Adhesive to the area.
- To attain proper bonding of the metal Joints and PolyCar-C[™], both should be cleaned thoroughly and the metal should be roughened.
- Place the Polypropylene and ankle joints in a 400° oven until the plastic is clear.
- Next, place the PolyCar-C[™] into the oven for 2-3 minutes, or until pliable.
- Place the PolyCar-C[™] on the ankle joint assembly and place back into the oven for approximately 1 minute. (Figure 7)
- Immediately place the heated PolyCar-C[™] reinforcements and the heated ankle joint on the cast where it has been outlined. (Figure 8)

NOTE: Aluminum bands may be used instead of carbon bands for strength.

Plastic Fabrication Using Fillauer Double Action Ankle Joints



Figure 8



Figure 9

- Vacuum-form the Polypropylene rapidly to assure good bonding and encapsulation of the Carbon Composite Bands and the PolyCar-C[™].
- Trim the excess Polypropylene and cool with air. (Figure 9)
- Trim the orthosis and assemble as usual.
- The technician should follow standard orthotic fabrication practice using 3/4"(20 mm) sidebars/uprights with special attention to torsion rigidity and knee flexion.
- Contour the uprights.
- In both the SPL2 and the SPC joints, the IQ internal hexagonal joint screw must be tightened using a 3mm internal hex key.
- Secure the SPL2 bar screws using Loctite.
- In the final assembly all upright connections must be secured.
- Attach uprights and finish the orthosis.

Adjustments and Maintenance of the Satellite (Remote Control)



IQ140 IQ SPL2 Satellite (Remote Control) IQ SPL2 Satellite A. IQ140 IQ SPL2 Satellite Includes: C. IQ140/03 IQ Satellite Shrink Wrap D. IQ140/04 IQ Satellite Cable End Block E. IQ140/05 IQ Satellite Coupling Kit F. IQ140/06 IQ Satellite Insert Kit SPL2 G. IQ140/08 IQ Satellite Outer Cable I. IQ140/10 IQ Satellite Screw $2.5 \times 6(2x)$ IQ Satellite Screw J. IQ140/11 $2.5 \times 8 (4x)$ IQ Satellite Crater K. IQ140/12 Set Screw for Cable End Block L. IQ140/13 IQ Satellite Cable Connector M. IQ140/14 IQ Satellite Spring N. IQ140/15 IQ Satellite Pull Reliever Cable with End Bullet O. IQ140/16 IQ Satellite Screw M3 x 25 (2x) P. IQ140/17 IQ Satellite Latch Pin Knob Q.IQ140/18 IQ Satellite Clip R. IQ140/19 IQ Satellite Orthosis Connector

IMPORTANT: Satellite Pull-Relieve Cable

• To prevent stretching of the outer cable, mount the Pull-Relieve Cable (L) as close as possible to the top side of the joint on the orthosis using the cable connectors supplied. Use the cable clamps, that are also supplied to connect the cable to the orthosis.

Shortening the SPL2 Satellite Cable

- Put the Remote Control in Lock Mode assuring the knee is in full extension.
- Make sure SPL2 is in full extension and locked.
- Remove the joint cover on the medial side of the SPL2 joint.
- Slide the Functional Unit Lever Arm proximal. This releases the cable tension and allows the cable end to be removed from the lever arm.
- Loosen the Set Screw from the Coupling Nut/Outside Cable Adjustment Screw and unscrew from SPL2.
- Unscrew the Adjustment Screw from the Outside Plastic Cable Housing (the cable housing is threaded on the Adjustment Screw).
- Remove Satellite (Remote Control) and Cable from the SPL2 Joint.
- Carefully open the Satellite by removing the 6 screws from the back.
- Loosen the set screw from the end block and remove the cable.
- Decide how long you want the cable (remember it will lengthen as it is re-screwed into the adjustment screw) and shorten the Outside Cable housing using a sharp knife (be careful not to cut the internal cable).
- Insert inside cable into the end block. Leave approximately 3/16" of cable beyond the end block and tighten the set screw.
- Re-assemble the Satellite (Remote Control).

Adjustments and Maintenance of the Satellite (Remote Control)



IQ SPL2 Satellite Connector A. IQ140/16 Screw M3x25 (2x) B. IQ140/19 Orthosis Connector

C. IQ140/17 Latch Pin Knob



IQ140 IQ SPL2 Satellite (Remote Control) Top View

Re-Assembly of the Satellite

- Make sure the spring, cable, end block, and slide lever (pg. 14) are positioned correctly.
- Screw Outside Cable Housing into the Outside Cable Adjustment Screw, tighten until snug.
- Screw the Coupling Nut (E) and the internal cable with the remote switch into the joint housing until tight. Then back it out 3 turns for adjustment range.
- Lift up the Lever Arm on the Functional Unit and press the Cable Stop Bead into the slot.
- Check the various modes of the Satellite (Remote Control). Be sure lever arm of the function unit (pg. 14) lines up at all three marks correctly in each satellite mode.
- Assemble satellite (remote control) face plates. Do not overtighten screws.

Check of all Functions

- Check all functions of the satellite (remote control) once again to assure all four modes switch reliably.
- Make sure a reliable locking can be achieved with free swing through, and that locking is sufficient. The satellite cable should be the right length, and the lever arm in the function unit in a neutral 0° position.
- Make sure the joint unlocks reliably after back swing, and the stops re-position correctly.
- The joint should swing smoothly without play.

Clinical Adjustments of the Swing Phase Lock 2



Position of Lever Arm when Satellite Slide Lever is in Automatic Lock Position



Position of Lever Arm when Satellite Slide Lever is in Manual Unlock Position



Position of Lever Arm when Satellite Slide Lever is in Manual Lock Position

IMPORTANT! Proximal Satellite (Remote Control)

The four different modes of operation are controlled with a Proximal Remote Switch that connects to a slide lever and button. The automatic lock position is achieved when the slide lever is even with the top of the switch. When pulled up (manual unlock), the lock is immediately free for sitting and returns to the automatic lock position when released. When the button is pushed (manual lock), the slide lever snaps into the lower position which locks the knee at all times. To achieve free motion the slide lever must be pulled past the unlock position until an audible click is heard.

Swing Phase Control

The Swing Phase Control extension spring may be adjusted by tightening the set screw to increase spring load. This decreases the amount of heel rise and also controls the amount of knee flexion during swing.

Static Adjustment

Before Dynamic Fitting, Static Balance of the pendulum must be checked.

- The IQ SPL2 Functional Unit lever should remain in a neutral 0° position.
- All four modes of the Remote Switch should work reliably.
- In Automatic Lock mode, the SPL2 should be locked with forward swinging.

The function of the joint is influenced by different factors: muscle strength, joint contractures, weight, and orthotic construction.

Clinical Adjustments of the Swing Phase Lock 2



Function Unit Pendulum Adjustment

Adjustment of Function Unit

(Automatic Knee Lock Release)

Before making adjustments, the patient should apply a flexion load to secure pendulum or the Remote must be in locked mode. The timing of the release pendulum mechanism can be adjusted to compensate for any variance in the functional alignment of the orthosis. This adjustment should be made with small increments during dynamic fitting by presetting the pendulum more anterior or posterior. The pendulum is adjusted by loosening the small set screw and moving the pendulum with small iterations more anterior (forward) or posterior (backward).

- Moving the pendulum ANTERIOR (Forward), INCREASES the tendency to unlock, because its weight line is shifted forward and the pawl disengages the lower lock earlier in gait for a shorter step. Moving the pendulum anterior will also require greater hip flexion to lock the SPL2 functional unit.
- Moving the pendulum POSTERIOR (Backward), DECREASES the tendency to unlock because its weight line is shifted backward and the pawl disengages the lower lock later in gait for a longer step. Moving the pendulum posterior will also make the SPL2 functional unit lock earlier in gait.

After the pendulum is adjusted, tighten the set screw until pendulum remains in desired position. DO NOT OVERTIGHTEN.

Adjustments and Maintenance of the SPL2



IQ2 B	IQ110/03	IQ Joint
		SPL2
B1	IQ110/03/01	IQ Screws for Joint Cover
B ²	IQ110/03/02	IQ Medial Cover Plate SPL2
B³	IQ110/03/03	IQ Lateral Cover Plate SPL2
С	IQ110/04	IQ Joint Screw and Nut SPL2
C¹	IQ110/04/01	IQ Female Ax SPL2
C ²	IQ110/04/02	IQ Male Ax SPL2
D	IQ110/05	IQ Set Screw Cone Point SPL2
Е	IQ210/07	IQ Bumper Kit SPL2
G	IQ110/08	IQ Bearing Kit SPL2
Н	IQ130L or R	IQ SPL2 Function Unit L or R
I	IQ130/01	IQ Spring Pin for SPL2 Function Unit

The patient should frequently inspect the orthosis for wear and function and the orthotist should be seen every 6 months for routine follow-up appointments. Wear and tear, joint play and damage should be evaluated. If the joint is no longer running freely, a thorough service is recommended. Regular maintenance of a dynamic joint is considered normal and is required.

SPL2 Locking Cam

• If the locking cam becomes too loud or worn it can be replaced by disassembling the SPL2 joint and pressing the Locking Insert (G) out sideways from the lower part of the joint. The new Locking Insert (G) can now be pushed in and secured.

SPL2 Front End Stop

- If the Front Stop becomes worn or terminal impact too loud it may need to be replaced by disassembling the SPL2 joint and pressing the Bumper Insert (I) out sideways from the lower part of the joint. The new IQ bumper insert SPL2 (I) can then be pushed in and secured.
- The Rubber Insert is used to provide a cushioned front end stop for the upper part of the joint to eliminate noise and wear.

Vertical play in SPL2

• Vertical play can be corrected by disassembling the SPL2 joint and replacing the Sleeve Bearing (L) and Joint Nut (E).

Horizontal play in SPL2

• Horizontal play can be corrected by replacing the Bearing Discs and the Sleeve bearing (L).

Adjustments and Maintenance of the SPC



IQ1 B	20 IQ SPC Jo IQ120/03	oint IQ Joint Cover Kit SPC
B¹	IQ110/03/01	IQ Cover Plate Screws
B ²	IQ120/03/02	IQ Medial Cover Plate SPC
С	IQ120/04	IQ Joint Screw and Nut SPC
C¹	IQ120/04/01	IQ Axis Set SPC
C ²	IQ120/04/02	IQ Female Ax SPC
D	IQ120/08	IQ Bumper Kit SPC
E	IQ120/09	IQ Flexion Control Set SPC
E1	IQ120/09/01	IQ Flexion Control Bumper Pin SPC
E ²	IQ120/09/02	IQ Flexion Control Spring Nut SPC
E ³	IQ120/09/03	IQ Flexion Control Spring SPC

Swing Phase Control (SPC)

 If the swing phase control becomes too loose, the Spring Adjustment Screw should be tightened. The Extension Spring and / or the Flexion Control can be replaced by first removing the Spring Adjustment Screw and pulling the spring out. The Pressure Pin should also be pressed out from the joint and inspected for wear (F).

Vertical Play in the SPC

• Vertical play in the SPC can be corrected by disassembling the SPC Joint and replacing the SPC Sleeve Bearing and Joint Nut (D).

Horizontal Play in the SPC

• Horizontal play can be corrected by disassembling the SPC Joint and replacing the Sleeve Bearing (E).

Noise From the SPC

 If after loosening the spring adjustment screw on the SPC clicking or squeaking still occur, then a small amount of lubricating oil may be applied to the spring inside the SPC Joint. NEVER LUBRICATE THE SPL2.

Disassembly and Maintenance of the SPL2



IQ110 IQ Swing Phase Lock 2 Kit



IQ120 IQ Swing Phase Control

Disassembly of SPL2 Joint

Remove the round Cover Plates and slide the cable from the bracket arm of the Functional Unit. The joint can then be disassembled by unscrewing the 3 mm Joint Screw and pushing out the Joint Nut. This exposes the Bumper Kit, IQ110/07, Locking Insert, Sleeve Bearing, and Bearing Discs, IQ110/08.

Disassembly of the SPC Joint

Remove the Round Joint Cover Plate, IQ120/03, and then unscrew the 3 mm joint screw. Remove Joint Nut IQ110/04. This exposes the SPC Bearings, IQ120/08. The Flexion Control Spring IQ120/09 can be removed by unscrewing the adjustment screw.

Disassembly and Maintenance of the SPL2



IQ130 IQ SPL2 Function Unit



IQ140 IQ SPL2 Satellite (Remote Control)

Replacing the Functional Unit

The Functional Unit should be checked periodically. The pendulum weight must move freely by tilting in the sagittal plane when the joint is in full extension. If the pawl is worn or the locking play cannot be eliminated by replacement of the Locking Cam, the whole Functional Unit must be replaced. To replace the Functional unit unscrew the lower set screw from the SPL2. The SPL2 should then be disassembled, the satellite (remote control) switch cable should be removed, and the Functional Unit pressed out. CAUTION:

Reassemble Function Unit carefully. Pendulum may not work consistently if the Function Unit Set Screw is overtightened during assembly.

Removal of the SPL2 Satellite (Remote)

Remove the round Cover Plates, and slide the cable from the slotted arm of the Functional Unit. The knurled cable Fine Adjustment Screw is then removed by first unscrewing the upper Set Screw, IQ110/05 and sliding the cable out.

Clinical Fitting of the Swing Phase Lock 2



Evaluation of Fit

Fitting begins with a standard check of loading comfort, relieving any pressure points, and checking joint placement. The first steps should first be made in the locked mode then in automatic locking mode. Torsional and overall rigidity must be inspected before dynamic testing.

Knee Lock

Within parallel bars, the orthotist should check if the patient can bring the leg into full extension with the orthosis on. If not, the alignment of the joint must be examined to see whether there is any twisting or interference to prevent full extension. The position of the joint may also need to be corrected.

If the patient cannot achieve full extension due to a knee flexion contracture, the preflexion of 5° may need to be increased. Patients with soft or fleshy limbs may have difficulty achieving full extension of the orthosis to lock the joint because of the pliable nature of their limbs. In these cases the joint must be adjusted to achieve full extension to lock consistently at the end of the swing phase.

Knee Unlock

A sufficient knee extension moment can usually be achieved with active hip extensors or dorsiflexors. Patient training and therapy may be required to achieve this function. For patients unable to initiate a knee extension moment, a dorsiflexion stop may be necessary. It is crucial that the SPL2 knee joint be adjusted to achieve proper knee joint release during the correct moment of stance.

The joint cannot be unlocked if it is loaded in flexion. A flexion load will prevent it from disengaging.

Clinical Fitting of the Swing Phase Lock 2

Dynamic Evaluation

The patient may walk with ambulatory aids with their normal stride length using their hip musculature to achieve full knee extension. If the patient is unable to achieve full knee extension additional therapy, alignment changes, or a dorsiflexion stop may be required. If heel rise is excessive, causing a timing delay pattern, the SPC joint should be tightened for a greater extension bias.

Also, the Automatic Lock should be adjusted until there is sufficient locking just before heel contact and unlocking at heel off. Additional patient training is important to achieve this balance in gait. Often orthotic ankle control must be adjusted to allow foot flat and provide a dorsiflexion stop late in stance. A double action ankle joint (P/N 020882) may be required.

Once all the adjustment/maintenance work has been done, the opening on the functional unit must be re-sealed using the IQ sticker. This reduces the likelihood of dirt and clothing fibers getting into the opening.

Usage and Limitations of the Orthosis

The SPL2 orthosis is a custom orthopedic device especially fabricated and aligned for the patient's needs. The orthosis will enable the patient to stand, ambulate, or to overcome other challenges attributable to disease or limb stability. It is essential that the patient follow all of the instructions, verbal and written, given by you the orthotist regarding use, adjustment, operation, and maintenance.

The orthosis should not be used in water or other corrosive environments and contact with acids or solvents should be avoided. It should not be exposed to temperatures above 122°F (50°C) since this may cause a change in the operation of the orthosis. The adjustment cable from the knee joint to the remote control should have some slack to prevent the plastic cable from cracking and breaking.

Care and Maintenance

The patient should frequently inspect the orthosis for wear and function and the orthotist should be seen every 6 months for routine follow-up appointments. Any changes in skin condition or function of the orthosis should be communicated to the orthotist immediately. The patient should also be aware of the structural strength of the orthosis and not use the device above functional load limits. Although the orthosis is intended for active ambulation the patient should use their best judgment to assess stability on uneven or inclined surfaces. An interface sock such as the SmartKnit interface sock (with Coolmax[®]/ Lycra[®] and antimicrobial fabric that inhibits bacteria, fungus, and odor) is recommended for limb protection and comfort.

Patient Instructions



The patient must be instructed on the four different control modes for the Proximal Satellite:

- Automatic Lock
 Manual Unlock
 Manual Lock
 Free Motion
- Automatic locking and unlocking is used during active ambulation to mimic normal gait, and should be adjusted by the orthotist to lock just before the heel contacts the ground and unlock during swing thru. If the orthosis does not function in this manner smoothly, the orthotist should be seen for an adjustment as soon as possible. Only the orthotist should make these adjustments. The opening for the functional unit (pendulum) should be sealed with the IQ sticker; this protects the mechanism from dirt or dust.
- Manual Unlock is usually only necessary for sitting or when the automatic unlock feature did not disengage. To manually unlock the knee, the remote control switch is pulled up to the highest position. (This must be done in full extension or there could be breakage in the cable.) When the switch is released, it retracts to automatic lock and unlock mode to insure the knee lock is not disengaged at all times.



Automatic Mode



Manual Unlock Mode

Patient Instructions



Manual Lock Mode



Free Motion Mode

- Manual Lock engages the knee lock at all times for maximum standing stability. This mode is activated by straightening the leg and pushing the lower button. It is important to note that the lock will not engage until the orthosis is fully extended or straightened out. The manual lock is disengaged by pulling the upper switch back to automatic lock mode.
- Free Motion mode can be used for cycling or driving. This mode is activated by pulling the remote switch past the unlock mode until you hear an audible click. The switch will stay in the unlocked or free motion mode until the lower button is pushed.

If the remote control cable should break, the SPL2 will revert to manual lock mode to insure safety.

NOTE: If the mode switch is pressed when in Free Motion Mode, the satellite will drop into the Lock Mode. The Automatic Lock must be re-engaged with the slide lever.

Swing Phase Lock 2 Order Information



Swing Phase Lock 2 Kits

- IQ Swing Phase Lock 2 Kit includes the SPL2 Joint, SPC Joint, and Satellite (Remote Control).
- Many Other Accessories also available for the IQ Swing Phase Lock 2 Including:

Upright Bars and Alignment Kits Fabrication Kits and Tools Remote Control Auxiliary Bracket Carbon Composite and PolyCar-C[™] Ankle Joints and Insert Stirrups

IQ200L IQ Swing Phase Lock 2 Kit, Left

SPL2 Kit Includes:

IQ250L	IQ SPL2 Joint, Left
IQ120L	IQ SPC Joint, Left
IQ140	IQ SPL2 Satellite (Remote Control)

IQ200R IQ Swing Phase Lock 2 Kit, Right

SPL2 Kit Includes:

IQ250R	IQ SPL2 Joint, Right
IQ120R	IQ SPC Joint, Right
IQ140	IQ SPL2 Satellite (Remote Control)

IQ050R Unilateral, Right IQ050L Unilateral, Left

Swing Phase Lock 2 Order Information





IQ Swing Phase Lock 2 Joints

IQ2	250L	IQ SF	L2 Joint, Left
IQ2	250R	IQ SF	L2 Joint, Right
			-
IQ	SPL2 Joir	nt Incl	udes:
В	IQ110/03	10	Q Joint Cover Kit SPL2
B1	IQ110/03/	01 10	Q Screws for Joint Cover
B ²	IQ110/03/	02 10	Q Medial Cover Plate SPL2
B ³	IQ110/03/	03 10	Q Lateral Cover Plate SPL2
С	IQ110/04	10	Q Joint Screw and Nut SPL2
C¹	IQ110/04/	01 10	Q Female Ax SPL2
C^2	IQ110/04/	02 10	Q Male Ax SPL2
D	IQ110/05	10	Q Set Screw Cone Point
		S	PL2
Е	IQ210/07	10	Q Bumper Kit SPL2
G	IQ110/08	10	Q Bearing Kit SPL2
Η	IQ130L or	RI	Q SPL2 Function Unit L or R
I	IQ130/01	10	Q Spring Pin for SPL2
		F	unction Unit





IQ Swing Phase Control Joints

IQ120L/R IQ Swing Phase Control Joint

IQ SPC Joint Includes:

В	IQ120/03	IQ Joint Cover Kit SPC
B^1	IQ110/03/01	IQ Cover Plate Screws
B^2	IQ120/03/02	IQ Medial Cover Plate SPC
С	IQ120/04	IQ Joint Screw and Nut SPC
C^1	IQ120/04/01	IQ Axis Set SPC
C^2	IQ120/04/02	IQ Female Ax SPC
D	IQ120/08	IQ Bumper Kit SPC
Е	IQ120/09	IQ Flexion Control Set SPC
E^1	IQ120/09/01	IQ Flexion Control Bumper Pin
		SPC
E^2	IQ120/09/02	IQ Flexion Control Spring Nut
		SPC
E^3	IQ120/09/03	IQ Flexion Control Spring SPC

Swing Phase Lock 2 Order Information





IQ SPL2 Satellite Connector Assembly (Alternate Attachment)

IQ Satellite SPL2 (Remote control)

A. IQ140 IQ SPL2 Satellite

IQ SPL2 Satellite (Remote Control) Includes:

- C. IQ140/03 IQ Satellite Shrink Wrap
- D. IQ140/04 IQ Satellite Cable End Block
- E. IQ140/05 IQ Satellite Coupling Kit
- F. IQ140/06 IQ Satellite Insert Kit SPL2
- G. IQ140/08 IQ Satellite Outer Cable
- I. IQ140/10 IQ Satellite Screw 2.5 x 6 (2x)
- J. IQ140/11 IQ Satellite Screw 2.5 x 8 (4x)
- K. IQ140/12 IQ Satellite Crater Set Screw for Cable End Block
- L. IQ140/13 IQ Satellite Cable Connector
- M. IQ140/14 IQ Satellite Spring
- N. IQ140/15 IQ Satellite Pull Reliever Cable with End Bullet
- O. IQ140/16 IQ Satellite Screw M3 x 25 (2x)
- P. IQ140/17 IQ Satellite Latch Pin Knob
- Q. IQ140/18 IQ Satellite Clip
- R. IQ140/19 IQ Satellite Orthosis Connector

IQ SPL2 Satellite Connector Assembly Includes:

- A. IQ140/16 Screws, M3x25 (2x)
- B. IQ140/19 Orthosis Connector
- C. IQ140/17 Latch Pin Knob (T-Nut)





SPL2 Remote Auxiliary Bracket

029850 SPL2 Remote Auxiliary Bracket, Al



Swing Lock Upright Kits

023516	Swing Lock Upright Kit,AL 3/16x3/4
023514	SPL2 Lower Bar, AL 3/16 x 3/4, each
023515	SPL2 Upper Bar, AL 3/16 x 3/4, each
882509	Bar Screws, M5x.8x10MM FHSC, SS
023616	Swing Lock Upright Kit, SS 3/16x3/4
023614	SPL2 Lower Bar, SS 3/16 x 3/4, each
023615	ODI O LINN DAN CC O/40 O/4
	SPL2 Upper Bar, SS 3/16 x 3/4, each
882509	SPL2 Opper Bar, SS 3/16 x 3/4, each Bar Screws, M5x.8x10MM FHSC, SS



SPL2 Fabrication Kits

IQ150 Alignment Kit



029840 SPL2 Lamination Dummy Kit 882509 Bar Screws, M5x.8x10MM FHSC, SS



Hex Key

885859 SPL2 Hex Driver, 1.25mm



PolyCar-C[™] Ankle Inserts

- High performance reinforcing composite
- Easy to mold, High carbon content
- Thermobonds to polypropylene, copolymer, metal

076630	PolyCar-C™ Insert, .060 Small,
	pair
076632	PolyCar-C™ Insert, .090 Med, pair
076634	PolyCar-C™ Insert, .090 Large, pair
076636	PolyCar-C™ Insert 125 XI pair
0.0000	



Comfil® TFC Ankle Inserts

700100	Comfil® TFC Insert, .060 Small, pair
700110	Comfil® TFC Insert, .100 Med, pair
700120	Comfil® TFC Insert, .100 Large,
700130	Comfil® TFC Insert, .100 XL, pair



Double Action Ankle Joint

020882 Double Action, SS, Large 020884 Double Action w/Positioning Pins, SS, Large



Insert Stirrups for Plastic Orthotics

• 1-1/8" Head Size

Stainless Steel

- For plastic laminations
- Sold per pair, medial and lateral

020099	Insert Stirrup, Limited Motion, 2-5/16"
020115	Insert Stirrup, Limited Motion, 2-3/4"
020123	Insert Stirrup, Toe Lift, 2-5/16"
020149	Insert Stirrup, Toe Lift, 2-3/4"
020094	Insert Stirrup, Double Action, 2-3/4"



- 1-1/8" Head Size
- Sold per pair, medial and lateral

020016	Offset Stirrup, Limited, 2-1/4"x3/8"
020024	Offset Stirrup, Limited, 2-1/4"x1/2"
020032	Offset Stirrup, Limited, 2-1/2"x3/8"
020040	Offset Stirrup, Limited, 2-1/2"x1/2"
020057	Offset Stirrup, Toe Lift, 2-1/4"x3/8"
020065	Offset Stirrup, Toe Lift, 2-1/4"x1/2"
020073	Offset Stirrup, Toe Lift,
	2-1/2"x3/8"
020081	Offset Stirrup, Toe Lift, 2-1/2"x1/2"



Pre Cut PolyCar-C™

020803 Pre Cut PolyCar-C[™], Large



Carbon Composite Bands

- Very short fabrication time
- Ideal fatigue resistance
- True joint alignment maintained

1-1/4	inches	1-1/2 inches		2 in	2 inches	
part#	length	part#	length	part#	length	
07635	6 8"	07639	8 8"	07644	8 8"	
076364	4 9"	07652	1 9"	07645	5 9"	
076372	2 10"	07640	6 10"	07646	3 10"	
		076414	4 11 "	07647	1 11"	
		07642	2 12"	07648	9 12"	
		07643	0 13"	07649	7 13"	
				07650	5 1 4"	
				07651	3 15"	

L-Code Recommendations for the Swing Phase Lock 2, SPL2

Confidential Reference for Orthotists Only

The following L-Codes may be applicable for billing a Knee Ankle Foot Orthotic (KAFO) that includes the Swing Phase Lock 2 (SPL2) orthotic knee joint.

- Each code should be reviewed for appropriateness and functional equivalency.
- The L-Codes listed below cover a wide variety of KAFO designs.
- Additional L-Codes may be appropriate when other componentry or modifications are added to an orthosis.
- Not all L-Codes listed apply to each custom orthosis.
- Accurate L-Code reporting to the third party payor remains the responsibility of the orthotic service provider. The manufacturer and distributor of the Swing Phase Lock 2 do not assume any liability for L-Code recommendations.

L-Code Recommendations for the Swing Phase Lock 2, SPL2

CHOOSE A BASE CODE:

Stance Control KAFO

L2005 - KNEE ANKLE FOOT ORTHOSIS, ANY MATERIAL, SINGLE OR DOUBLE UPRIGHT, STANCE CONTROL, AUTOMATIC LOCK AND SWING PHASE RELEASE, ANY TYPE ACTIVA-TION, INCLUDES ANKLE JOINT, ANY TYPE, CUSTOM FABRICATED.

Knee Orthosis Only

When incorporated into a device that will be used as a Knee Orthosis, consider using the following miscellaneous code and verbal description:

L2999 – SAME AS L2005 EXCLUDING ANKLE, FOOT SECTIONS.

ADDITIONS THAT MAY APPLY USING CURRENT L-CODES:

L2385 -- ADDITION TO LOWER EXTREMITY, STRAIGHT KNEE JOINT, HEAVY DUTY, EACH JOINT

The SPL2 is built with increased ruggedness and resistance to wear. It also has a high strength spring loaded flexion resist that may be easily replaced for longer product life.

L2755 - ADDITION TO LOWER EXTREMITY ORTHOSIS, HIGH STRENGTH, LIGHTWEIGHT MATERIAL, ALL HYBRID LAMINATION/PREPREG COMPOSITE, PER SEGMENT

This code can be utilized where composites are employed in thigh, calf, ankle or foot sections as needed to strengthen plastic sections for greater activity or load bearing capacity. Carbon bands may be appropriate to provide greater torsional stability when fabricating the SPL2 into a plastic KAFO and or KO as indicated in the fabrication instructions.

L2250* – ADDITION TO LOWER EXTREMITY, FOOT PLATE MOLDED TO PATIENT MODEL, STIRRUP ATTACHMENT

This code may be appropriate as indicated by patient need and can be incorporated into a KAFO using the SPL2.

* Depending on type of attachment provider might alternatively consider using L2230, L2240, L2260 or L2265.

L2820/L2830 - SOFT INTERFACE FOR MOLDED PLASTIC, BELOW KNEE/ABOVE KNEE SECTION

This code may be appropriate as indicated by patient need and can be incorporated into a KAFO or KO using the SPL2.

Other Codes to consider:

L2270, L2275, L2795 or L2800 – As indicated for correction of Varus or Valgus.

L2320 or L2330 - ADDITIONS TO LOWER EXTREMITY, NON-MOLDED OR MOLDED LACER ... as indicated when constructed using metal and leather in a traditional long leg brace.



Fillauer LLC • www.fillauer.com/Orthotics/SPL2.html 800-251-6398 • 423-624-0946 • Fax: 423-629-7936 2710 Amnicola Hwy • Chattanooga, TN 37406

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