

SPL2

Product Manual

Fillauer®

Package Contents

IQ SPL2 Set

- 1 SPL2 Joint
- 1 SPC Joint
- 1 Satellite and Cable
- 1 Inner Hexagonal Wrench
- 2 Stickers
- 2 Cable Clamps
- 2 Nyloplex Stud with Header
- 1 Manual

IQ SPL2 Joint

- 1 SPL2 Joint
- 1 Inner Hexagonal Wrench
- 2 Stickers
- 2 Cable Clamps
- 2 Nyloplex Stud with Header
- 1 Manual

IQ Satellite

- 1 Satellite and Cable

IQ SPL2 Unilateral

- 1 SPL2 Joint
- 1 Satellite and Cable
- 1 Inner Hexagonal Wrench
- 2 Stickers
- 2 Cable Clamps
- 2 Nyloplex Stud with Header
- 1 Manual

IQ SPC Joint

- 1 SPC Joint
- 1 Inner Hexagonal Wrench
- 1 Manual

- 1 Manual

Overview Parts

SPL2 Joint Parts

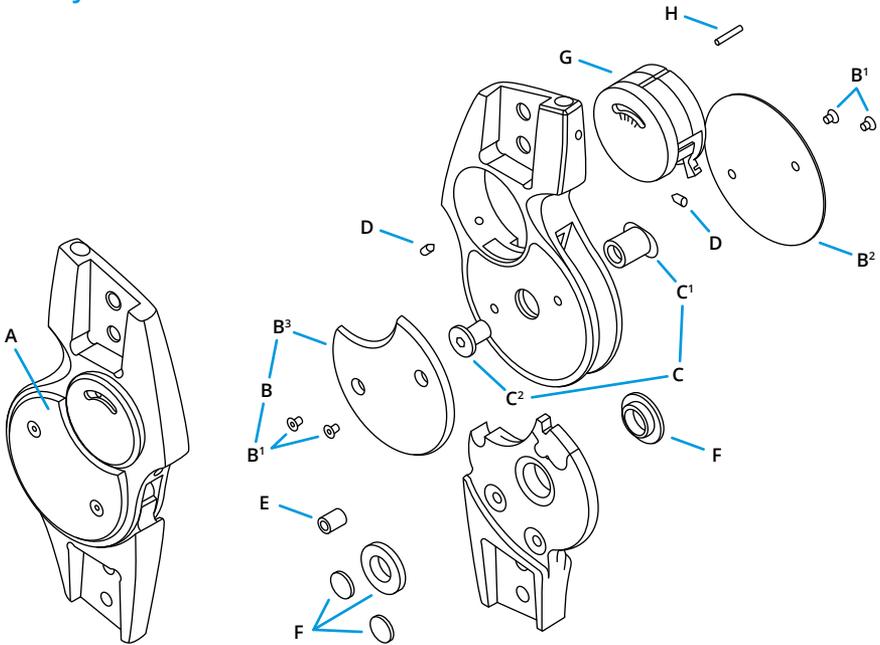


Fig.	Part Number	Unit	Description
A	IQ210L or R	1x	Swing Phase Lock 2 Joint
B	IQ110/03	1x	Joint Cover Plate Set
B ¹	IQ110/03/01	4x	Cover Plate Screws
B ²	IQ110/03/02	1x	Medial Cover Plate
B ³	IQ110/03/03	1x	Lateral Cover Plate
C	IQ110/04	1x	Joint Screw and Nut Kit
C ¹	IQ110/04/01	1x	Joint Screw
C ²	IQ110/04/02	1x	Joint Nut
D	IQ110/05	1x	Set Screw
E	IQ210/07	1x	Bumper
F	IQ110/08	1x	Teflon Bushing Set
G	IQ130L or R	1x	Function Unit
H	IQ130/01	1x	Function Unit Spring Pin

SPC Joint Parts

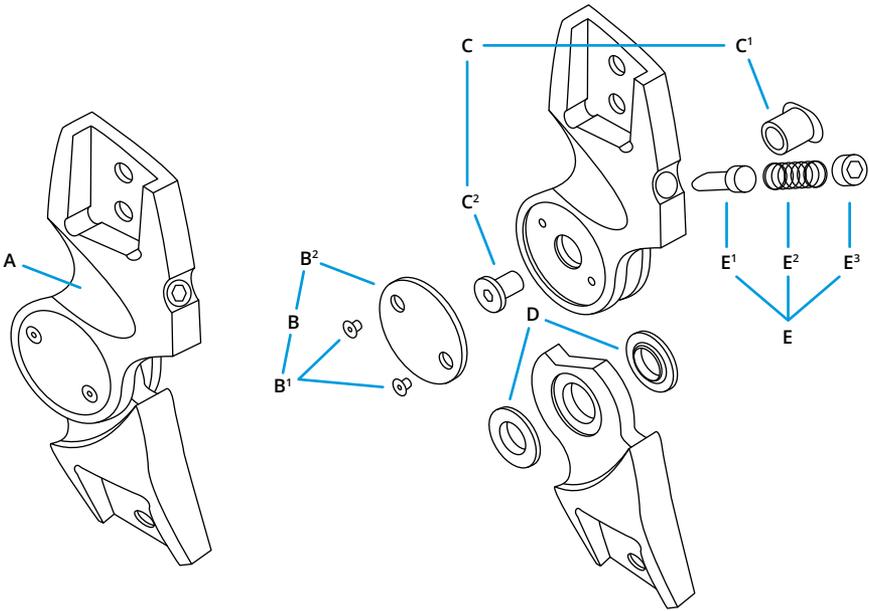


Fig.	Part Number	Unit	Description
A	IQ120L/R	1x	Swing Phase Control Joint
B	IQ120/03	1x	Joint Cover Plate Set
B ¹	IQ110/03/01	2x	Cover Plate Screws
B ²	IQ120/03/02	1x	Lateral Cover Plate
C	IQ120/04	1x	Joint Screw and Nut Kit
C ¹	IQ120/04/01	1x	Joint Nut
C ²	IQ120/04/02	1x	Joint Screw
D	IQ120/08	1x	Teflon Bushing Set
E	IQ120/09	1x	Flexion Control Set
E ¹	IQ120/09/01	1x	Flexion Control Bumper Pin
E ²	IQ120/09/02	1x	Flexion Control Spring Nut
E ³	IQ120/09/03	1x	Flexion Control Spring

Satellite Parts

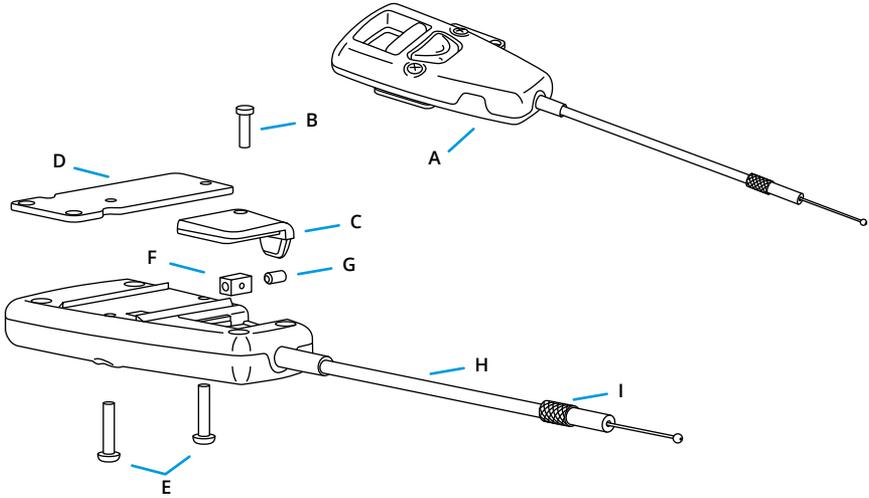


Fig.	Part Number	Unit	Description
A	IQ141	1x	IQ SPL Satellite Complete
B	IQ141/01	1x	IQ SPL Satellite Service Hatch Screw 2.2 x 8 mm
C	IQ141/02	1x	IQ SPL Satellite Service Hatch
D	IQ141/03	1x	IQ SPL Satellite Mounting Bracket
E	IQ141/04	1x	IQ SPL Satellite Mounting Plate Screws 2.5 x 12 mm
F	IQ140/04	1x	IQ SPL Satellite Cable End Block
G	IQ140/12	1x	IQ Satellite Set Screw for Cable End Block
H	IQ141/05	1x	IQ SPL Satellite Cable Set
I	IQ140/06	1x	IQ SPL Satellite Set Screw

Product Specifications

Usage of the SPL2 knee joint system provides optimum care for patients with paresis/paralysis (e.g. polio) and contributes to a successful therapeutic treatment. This articulating system is meant to compensate weakened or complete failure of the knee extension function. The joint is available in two different versions: **a.** unilateral joint or **b.** bilateral joint.

Indications

SPL2 Orthotic Knee Joint Bilateral and Unilateral

- Apoplexy (CVA) (ICD10: I64)
- Multiple sclerosis (ICD10: G35)
- Myopathy (ICD10: G72.9)
- Paralysis (ICD10: G83.9)
- Paresis (peripheral) (ICD10: G83.9)
- Poliomyelitis (ICD10: A80)

Contraindications

SPL2 Orthotic Knee Joint Bilateral

- Flexion Contracture > 10° (ICD10: M24.59)
- Spasm
- Hip Contracture
- Weight bearing Orthosis (e.g. quad brim)

SPL2 Orthotic Knee Joint Unilateral

- Patient weight > 100 kg
- Varus > 10° (ICD10: M21.10/Q74.9)
- Valgus >10° (ICD10: M21.00/Q74.9)
- Flexion Contracture > 5°
- Spasm
- Hip Contracture
- Weight bearing Orthosis

Warranty Period

12 months from date of patient fitting

Note: The satellite/remote control is not covered under warranty. 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.

Important Terms and Usages

The SPL2 joint offers knee stability during stance and offers free movement of the knee during swing. This feature is fully automatically activated with each step. It is prohibited to be used in water or exposed to temperatures exceeding 122 °F (50 °C).

Correct application, in combination with the satellite in the orthosis, is mandatory. The joint system has been designed only as a non-weight bearing joint (KAFO/KO) and should not be used in any weight bearing orthoses. Non-observance of these regulations excludes any liability claims.

Important: The patient must be well informed concerning the functions and possibilities of the knee joint system, including the satellite/remote control.

Function

SPL2 Technical Features

The technique of the SPL2 (Swing Phase Lock) joint is based on a simple internal pendulum mechanism, which locks and unlocks the knee depending on the angle of the knee joint in the sagittal plane. During gait, the device locks at the end of swing phase, just prior to heel strike, and unlocks the knee at heel off in preparation for swing. The joint cannot be unlocked if it is loaded in flexion.

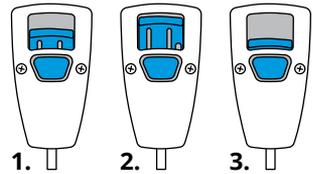
SPC Technical Features

The technique of the SPC (Swing Phase Control) joint uses friction to regulate or influence excessive knee flexion. The moment to full flexion is somewhat shortened and slightly variable.

The SPC joint is always to be mounted on the medial side and is suitable for ¾ in. (19 mm) uprights. The joint weight is 6.7 oz. (190 grams).

Satellite Technical Features

The SPL2 joint is controlled by a proximal remote push-button switch. The satellite is mounted to the thigh part of the orthosis with the mounting bracket that is supplied in the packaging.



The three modes to manually control the SPL2 joint are:

1. Automatic locking/unlocking
2. Permanent unlocking/free motion
3. Permanent locking

By deactivating the permanent unlocking/free motion mode the satellite switches into the permanent locking mode and needs to be raised into the automatic function (Mode 1).

Cleaning & Disinfection Instructions

The SPL2 joint may not be greased, oiled, or lubricated in any way. To clean, use naphtha or similar cleaning fluid or compressed air. Do not use acetone, dilutions or turpentine, etc.

Maintenance Instructions

Maintenance cycles depend strongly on the patient's activity level. At a moderate activity level, the joints must be checked or serviced every six months. When doing this, attention must be paid to wear and tear, joint play, and damages. If the joint is no longer working freely, a thorough service is recommended.

If the joint has been heavily loaded in a flexed position, e.g. with stumbling, tripping, or walking (falling) down the staircase, the joint has to be inspected by the orthotist. If the patient walks constantly with a slightly flexed knee or regularly uses the safety stops, adjustment of the extension position towards flexion is absolutely necessary.

Casting and Fabrication Instructions

Component Construction

- SPL2 Joint:** Housing: stainless steel
Function unit: brass
Cover plates: ABS plastic
- SPC Joint:** Housing: stainless steel
Cover plates and bumper pin: ABS plastic
- Satellite:** Housing: ABS, POM plastic
Cable: Teflon

Measuring

Casting must be done with a fully neutral extended leg. Stretching, however, should be possible without too much effort to allow full extension (needed to unlock the joint) once the orthosis is worn.

When the alignment unit is used (IQ150) to construct the orthosis, make sure the square with the T-bar is placed horizontal in the frontal plane to keep the axis straight. Alignment should be based on the plumb line to create a neutral baseline for the function unit.

Orthosis Construction

Any type of construction is suitable, as long as sufficient torsion rigidity and possibility of changing the flexion position during the initial fitting is taken into account.

When the joint is used in a carbon fiber-reinforced construction, the SPL2 should be disassembled by removing the satellite. Disconnect the cable within the function unit (G) and loosen the IQ set screws (D), loosen the adjustment screw, and gently pull the cable from the housing. Now the function unit (G) can be pushed inside and removed.

The SPC flexion Control Unit must be removed (E) and sealed with stick wax to prevent improper resin flow. In this case, the upright spacer (029860) can be used and aligned, allowing the joints to be mounted in a later stage.

Joint Alignment

The alignment unit must be parallel to the plumb line. The SPC joint should not be aligned in full extension. If the joint is aligned without using the unit, the cover plates (B) may be removed allowing the joint axis to be used for parallel alignment.

Dynamic Initial Fitting

Function Check

Prior to the initial fitting, the proper setting of the joint needs to be checked.

- The slotted arm of the function unit (G) must be set in neutral 0 position (Fig. A) when the satellite is in Mode 1. Adjust the proximal adjustment screw (F) on the SPL2 as necessary.
- Check to see if the SPL2 joint lock after swing with the satellite in Mode 1. If it cannot lock,...

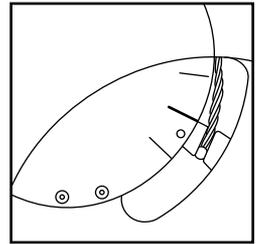


Figure A

Adjusting Locking and Unlocking

Timing settings to lock or unlock can be read or adjusted by moving the pendulum weight of the function unit.

- Moving the pendulum ANTERIOR (forward), DECREASES the tendency to lock, because its weight is shifted forward.
- Moving the pendulum POSTERIOR (backward), INCREASES the tendency to lock because its weight is shifted backward.

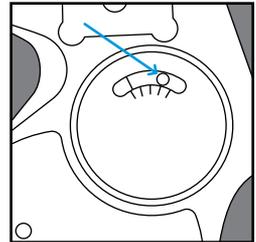


Figure B

Satellite Control

The patient needs to be instructed on functionality and how to operate the satellite.

Mode 1—Automatic Locking and Unlocking

The slider on the satellite is positioned in the middle. This is the normal position by which the SPL2 joint automatically locks and unlocks during walking. In this mode, the joint can also be unlocked once, by slightly pushing the switch upwards. The automatic mode is activated again when the joint is fully extended.



Mode 2—Permanently Unlocked

The slider on the satellite is slid upward from the center. In this mode the SPL2 joint is permanently unlocked. NOTE: When deactivating the permanent unlocking (by pushing the central button), the satellite automatically shifts into the permanent locking mode and thus needs to be slid up into the automatic locking/unlocking mode.



Mode 3—Permanently Locked

For this purpose the central button on the satellite is to be pressed for the slider to slid fully down. This is a safety mode in which the SPL2 joint is constantly locked when in full extension (e.g. at home, making many turns, etc.).



Shortening the Satellite Cable

First determine the position where the satellite will be mounted on the thigh cuff of the orthosis in order to establish the correct cable length. Bear in mind that the cable should have a slight S-shape.

1. Position the joint in full extension and set the satellite in Mode 3 by pressing the button on the satellite. Make sure the joint is indeed locked.
2. Use the supplied hex screwdriver to loosen the two screws on the medial (stainless steel) cover plate and remove it (see Fig. 1).
3. After removal of the cover plate check if the upper side of the lever arm (holding the satellite cable) is parallel to the lower of the three markers on the function unit (see Fig. 2).
4. Using a Phillips screwdriver, loosen the screw of the service hatch at the back of the satellite and remove the cover and screw.
5. Use the hex screwdriver to loosen the cone point safety screw two to three turns and slide the cable end block off the inner cable (see Fig. 3).
6. Twist the Teflon outer cable from the swivel connector at the bottom of the satellite. Place the swivel in one hand between your thumb and forefinger and the Teflon outer cable in the other hand between the thumb and forefinger and unscrew (counterclockwise) the outer cable from the Swivel Connector. Retract the inner cable outwards through the swivel.
7. Loosen the cone point safety screw on the side of the joint two turns (see Fig. 4). Do not remove the screw from the joint.
8. Turn the satellite set screw (which connects the Teflon cable to the joint) completely in the joint, followed by two complete turns up again. Trim the Teflon outer cable with a sharp knife to the desired length and remove

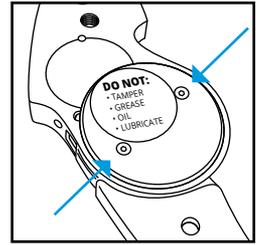


Figure 1

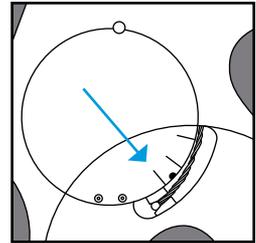


Figure 2

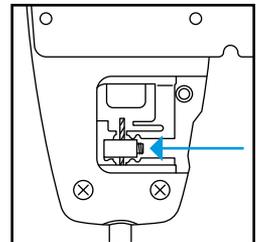


Figure 3

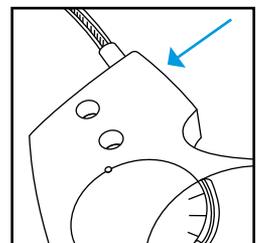


Figure 4

the excess outer cable. The inner steel cable will be shortened in step 13.

9. Now slide the inner cable through the bottom of the swivel connector into the satellite housing and screw the Teflon outer cable onto the swivel. Place the swivel in one hand between your thumb and forefinger and the Teflon cable in the other hand between the thumb and forefinger. Press and turn (clockwise) the two parts firmly together (the swivel is self-tapping).
10. Slide the cable end block back over the steel inner cable and position the end block back into the corresponding slot in the satellite (see Fig. 5).
11. Recheck the correct position (Mode 3) of the lever arm in the function unit of the joint (see Fig. 2).
12. Tighten the cone point safety screw of the cable end block firmly on the inner cable.
13. Use wire cutters to cut off the excess inner cable at ± 5 mm above the cable end block.
14. Install the service hatch back on the back of the satellite and reattach the screw.
15. Slide the satellite switch into the automatic position (Mode 1) and check within the functional unit of the joint if the top of the lever arm has moved and now is parallel with the center marker (see Fig. 6).
16. Use the satellite set screw (which connects the Teflon cable to the joint) to fine tune and adjust the position described in step 16.
17. Tighten the cone point Safety screw back in the joint (see Fig. 4).
18. Mount the medial cover plate back onto the joint and tighten the screws.
19. Loosen both screws on the front side of the satellite housing and remove the mounting bracket.

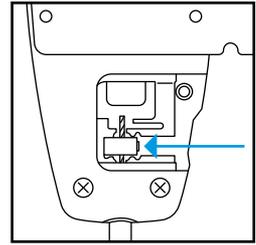


Figure 5

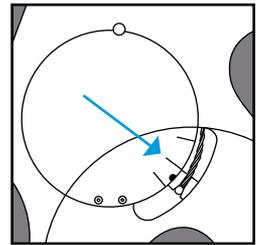


Figure 6

20. Determine the exact position where the satellite is to be mounted on the thigh cuff and contour the bracket if necessary. Mount the mounting bracket on the brace and reattach the satellite using the screws at the front again.
21. Use the provided cable clamps to attach the satellite cable in order to ensure an optimal, flat resting cable run against the thigh cuff of the orthosis.

Once all the adjustments are done, the opening on **the function unit must be resealed using the IQ sticker**. This reduces the likelihood of dirt and clothing fibers getting in.

Checking All Functions

All functions must be checked once again.

1. Do all three modes on the satellite switch reliably?
2. Can reliable locking be achieved with free swing, and is the locking sufficient (is the cable to the satellite on the right length, is the inner cable in a neutral position, in the 0 position)?
3. Does the joint unlock reliably after the posterior swing?
4. Are the stops all again in position, and does the joint run without play and smoothly?

Fillauer®

www.fillauer.com

Fillauer LLC

2710 Amnicola Highway
Chattanooga, TN 37406
423.624.0946
Fax 423.629.7936



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