

Fabrication of lower extremity orthoses

with the UL joint system using the lamination technique

Technical information 5.9.1



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1 Introduction

The fabrication of lower extremity orthoses with a unilateral joint bar is an alternative to traditional orthotic fitting practice. In some applications, the bilateral joint bars with corresponding pairs of joints typically used in lower extremity orthoses can be replaced by a unilateral (UL) joint system. The UL joint system is positioned on the lateral side of the leg and is designed such that medial bars are not required.

The UL joint system is intended for the ankle and knee. The special construction and modular design of the UL joints combine multiple functions with easy-to-handle components. Different joint inserts, for example, can be used to limit the range of movement of the UL ankle joint. Its multifunctional construction also pro-

vides for adaptation of the knee joint function as required.

For a more detailed functional description of the UL ankle joint and UL knee joint, please see the IFU 647G975, UL knee joint, and 647G864, UL ankle joint.

To verify the fit, we recommend fabricating a test orthosis (not illustrated) using 616T83=1250×1025×6 ThermoLyn clear.

2 General information regarding the lamination technique

This technical information demonstrates the fabrication of an individual lower extremity orthosis with a unilateral joint design using the lamination technique. The processing and assembly of a UL joint system, size 16 mm, is illustrated using the example of an orthopaedic fitting. Extra-long PVA bags in a length of 1.30 m are available for fabricating lower extremity orthoses using the lamination technique.

The joints themselves are not laminated, but are replaced by dummies made of lamination resin-repelling plastic or by multi-purpose steel dummies. This facilitates the removal of the orthosis from the model later on.

In order to achieve both the required rigidity and flexibility for the support surfaces (bands), special unidirectional (UD) carbon fibre materials and carbon woven hoses are used. Partial layers of carbon fibre cloth are used to reinforce the orthosis in the closure system zones and the forefoot.

Combining the lamination technique with the UL joint system has the benefit of allowing biomechanical requirements and construction principles (3-point holding system) to be maximised and allows the patient to benefit from the dynamic properties of the entire orthosis.



Note:

We recommend using the same reinforcement thickness as that shown here (carbon fibre and stockinette). The number of layers of the reinforcement may vary depending on the load, body weight, forefoot lever load, etc. It is your responsibility to use your judgement and experience to ensure that the fabrication process provides the orthosis with the appropriate level of strength and stability.

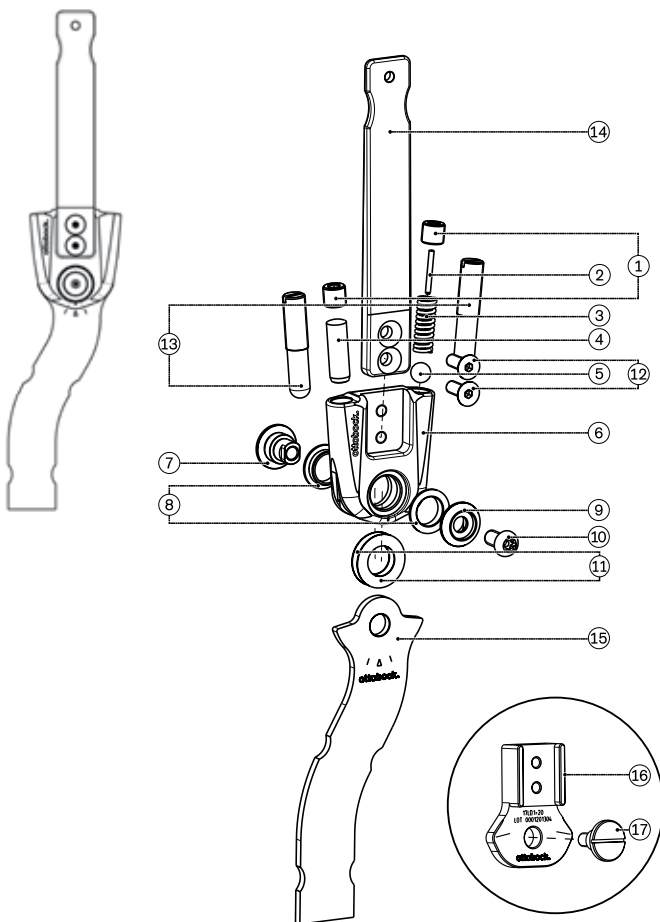
3 Tools and materials for orthosis fabrication

Knee pivot gauge	743A8	Carbon fibre cloth	616G12 (bidirectional)
Foot casting aid	743A9	C-Orthocryl lamination resin	617H55
Orthotic alignment aid	746A6		
Pivot point adjustment aid	743A7		
Orthotic joint adjustment set	743R6	Plastaband	636K8=20×2×10
ThermoLyn clear	616T83=1250×1025×6	Pigment paste, white	617Z4
PVA bag	99B81=130×19×5	Terry cloth padding	623P3
	99B81=130×22×5	Space-Tex	623F62
	99B81=130×26×5	Micro hook-and-loop	623Z4=50-6
Carbon-fibreglass webbing	616B2 (unidirectional)	Padding tape	623P5=*
		PE adhesive tape	627B4

For socket decors, please see our 646K1 materials catalogue.

4 Components

4.1 Ankle joint components and accessories



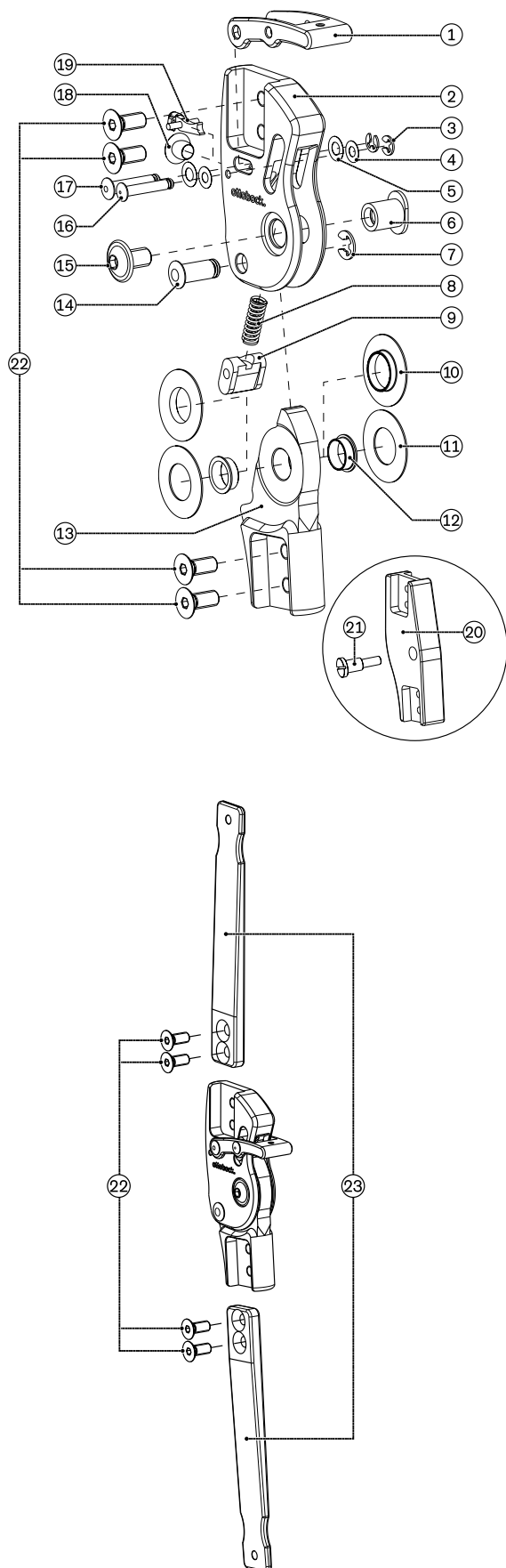
Delivery includes:

Item	Component	Quantity
1	Set screw	2
2	Stop pin (small)	2
3	Compression spring	2
	Compression spring set (17LA3=16/=20 only)	2
4	Stop pin	2
5	Bearing ball	2
6	Joint body	1
7	Nut	1
8	Bushing with collar	2
9	Screw	1
10	Flat head screw (TORX®)	1
11	Washer	2
12	Flat head screw (Allen screw)	2
13	Stop dummy	2

Delivery does NOT include:

Item	Component	Article no.
14	Lamination bar	17LS3=12/-T, =14/-T, =16/-T, =20/-T
15	Foot stirrup	17LF3=12, =14, =16, =20
16	Lamination dummy	17LD1=12, =14, =16, =20
17	Shoulder screw (included in scope of delivery of 17LD1=*)	

4.2 Knee joint components and accessories



Delivery includes:

Item	Component	Joint	Art. No.
1	Knee lever		30Y265=*
2	Knee joint upper part		
3	Lock washer		507S96=2.3
4	Washer		30Y267=3.3
5	Washer		30Y267=4.2
6	Bearing nut	(17LK3=12/=14) (17LK3=16) (17LK3=20)	17Y93=9x9.2xM6 17Y93=9x10.75xM6 17Y93=9x11.75xM6
7	Lock washer	(17LK3=12/=14) (17LK3=16/=20)	507S96=3.2 507S96=4
8	Compression spring	(17LK3=12) (17LK3=14/=16/=20)	513D83=0.75x4.3x19 513D83=0.75x4.6x20
9	Lock wedge	(17LK3=12/=14) (17LK3=16) (17LK3=20)	17Y156=* 17Y157=* 17Y158=*
10	Bushing	(17LK3=12/=14)	30Y87=3
11	Bearing washer	(17LK3=16/=20)	170Z93=1
12	Bushing	(17LK3=16/=20)	30Y87=1
13	Knee joint lower part		
14	Axle	(17LK3=12/=14) (17LK3=16) (17LK3=20)	4A101=5x10.6 4A101=6x12.7 4A101=6x13.7
15	Screw with flat-tened half-round head	(17LK3=12/=14) (17LK3=16/=20)	501F7=M6x8 501F7=M6x10
16	Axle	(17LK3=12/=14) (17LK3=16) (17LK3=20)	4A101=3.2x15.1 4A101=3.2x17.1 4A101=3.2x18.1
17	Axle	(17LK3=12/=14) (17LK3=16) (17LK3=20)	4A101=4x15.1 4A101=4x17.1 4A101=4x18.1
18	Protective plug	(17LK3=12/=14) (17LK3=16/=20)	30Y91=3 30Y91=1
19	Temporary switch		170Y162=*
20	Joint dummy		30Y268=*
21	Shoulder screw (part of 743R6 adjustment set)		30Y89
22	Flat head screw (Allen screw)	(17LK3=12/=14) (17LK3=16/=20)	501S41=M4x10 501S41=M5x12

Delivery does NOT include:

Item	Component	Joint	Art. No.
23	Joint bar		17LS3=*

5 Lower extremity orthosis fabrication

5.1 Selecting joint components

The UK joint system can be used in a number of different indications, such as cerebral palsy, post-polio syndrome, frontal and sagittal ankle/knee deviations, spina bifida, or traumatic paraplegia, or for general nerve lesions, failure or weakness in the dorsiflexor and/or plantar flexor muscles, failure or weakness of the knee extensors.

The UL ankle joint can be used for Ankle Foot Orthoses (AFO) and the UL knee joint for Knee Ankle Foot Orthoses (KAFO), potentially in combination with the UL ankle joint, respectively. Combination with the RGO hip joint system is also possible.

A guide is available for selecting the joint components. When used as a bilateral fitting, the maximum patient body weight allowable is 160 kg.

Alignment instructions



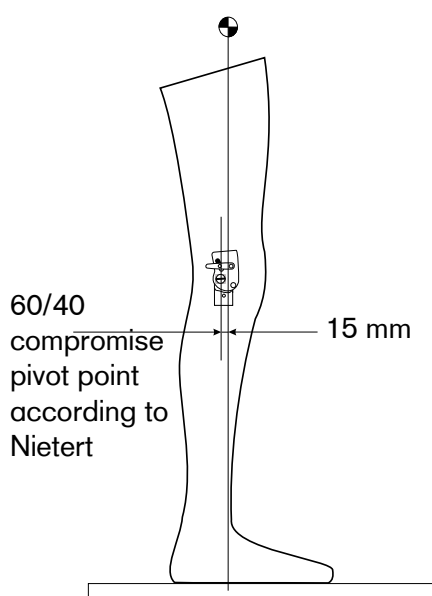
CAUTION!

The following applies to sagittal alignment (assessment using the L.A.S.A.R. Posture, art. no. 743L100): For all three joint sizes, the load line must not run more than 3 cm behind the compromise pivot point according to Nietert (60/40) or behind the mechanical pivot point, as the function and stability of the orthosis and thus patient safety, would otherwise be compromised (see illustration below).

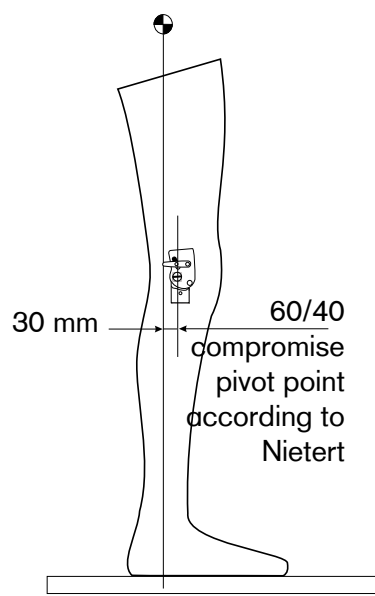
When used as a unilateral joint, the frontal axis deviation (valgus, varus deviation) in the knee joint must not measure more than 10°. A medial support joint (e.g. 17B205=*) should be used as the medial joint if necessary, as the function and stability of the orthosis and thus the patient's safety would otherwise be compromised.

Maximum patient weight [kg]

	17LK3=12	17LK3=14	17LK3=16	17LK3=20	17LA3=12/-T	17LA3=14/-T	17LA3=16/-T	17LA3=20/-T
Unilateral use (lateral or medial)	20	50	85	110	20	50	85	110
Bilateral use (lateral and medial)	40	80	120	160	40	80	120	160



Recommended (physiological) course of the load line in the orthosis (measurement with the L.A.S.A.R. Posture).



Maximal posterior course of the load line in the orthosis (measurement with the L.A.S.A.R. Posture).

5.2 Preparing the plaster model



Note

The 743A9 foot casting aid is used to ensure secure foot support and correct axial alignment of the plaster cast (see adjacent illustration). We recommend using suitable orthotic alignment tools such as the 743A6 orthotic alignment aid to locate the alignment axes for the later positioning of the joint.

Any padding material should be taken into consideration before shaping the bars. Depending on the padding material used later, spacer material is applied to the cast. This could be 617S3 Pedilin, for example, or several layers of stockinette. If compressing the spacer material is not an option, we recommend gluing 620P3 rubber cork to the model. Remove the spacer material in the area of the alignment adapter.



Determine the position of the alignment axes in the plaster negative, secure them with plaster bandages and prepare the model for casting.

We recommend using the 746A6 orthotic alignment aid for positioning the axes (see adjacent illustration). The square channels which later emerge in the plaster positive may be closed on the medial side if necessary.

5.3 Shaping the bars

This section describes how to use the joint dummies and process the UL bars.

Further information can be found in the respective instructions for use (IFU) 647G975, UL knee joint, and 647G864, UL ankle joint.



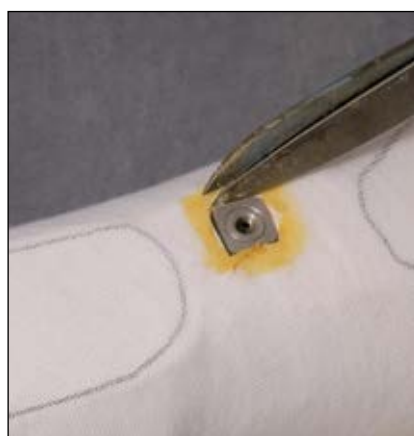
Do not shape the bar in the ankle joint area or the knee joint connection plug, or damage it by notching it with bending irons, as the notch effect could otherwise cause the lamination bar to break. For this reason, mark the position on the joint dummy before shaping the tibial bar.



Proceed in the same manner for the UL lamination bar of the knee joint.



Mount the knee joint dummy to the 743Y56=4 alignment adapter using the 30Y89 shoulder screw. Secure the lamination bars with the flat head screws provided, by screwing them directly into the plastic dummy; the screws cut a thread into the plastic. The joint dummies can be used on the left or right side.



If using stockinette as spacer material (as in our fitting example), apply 636N9 Ottobock contact adhesive to the surface over the adapter, let the adhesive dry and use scissors to remove the stockinette above the adapter.



Secure the ankle joint dummy with the shaped foot stirrup and the lamination bar.

Observe the markings on the dummy for the neutral positioning of the foot stirrup:



The knee joint dummy is screwed with the shaped lamination bars and the appropriate flat head screws. Depending on the thickness of the reinforcement material, ensure that there is a distance of approx. 2 mm between the plaster model and bar, to allow saturation of the matrix.



Grind away any grooves and burrs caused by shaping, as notches could cause the bar to break. For fine surface finishing, we recommend using the 649Z10 polishing sanding drum.



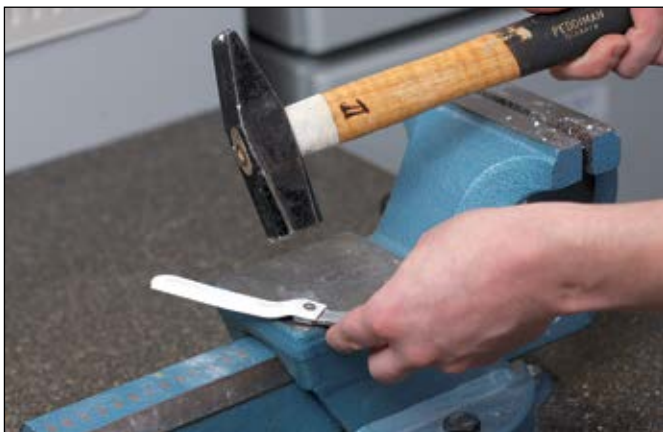
Finished, shaped lamination bars with joint dummies.



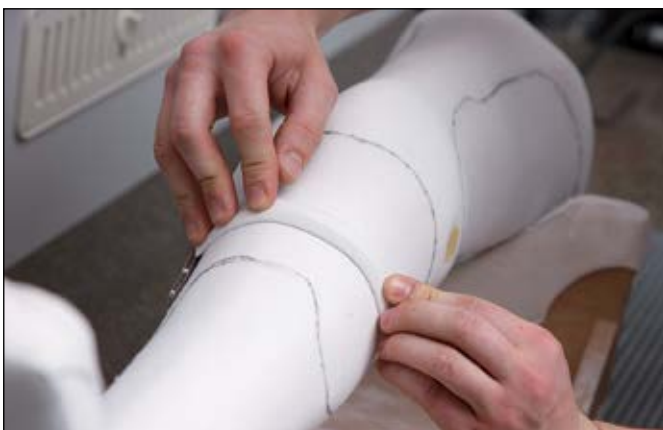
Mark up the plaster of the definitive orthosis as a guide for the fitting of the PVC bar profiles and the carbon reinforcements.



The PVC profile (17Y106) connects and/or lengthens the lamination bars and is used instead of continuous bars.



Use small hollow rivets (504H1=7) to join the profile to the lamination bar.



Bands of carbon fibre-reinforced PVC profile (17Y106) are used to reinforce the support surfaces. Use a hot-air gun to heat the PVC profile. A limited amount of cold forming is also possible.

5.4 Reinforcing the PVC profiles on bars and bands



To counteract the loads in the side bars and orthosis, the bars with the profile material are interposed and riveted and reinforced with 616G15 carbon fibre woven hose. The number of layers varies from 1–3 pc.



The band reinforcements are lengthened with unidirectional cloth before being covered with woven hose.



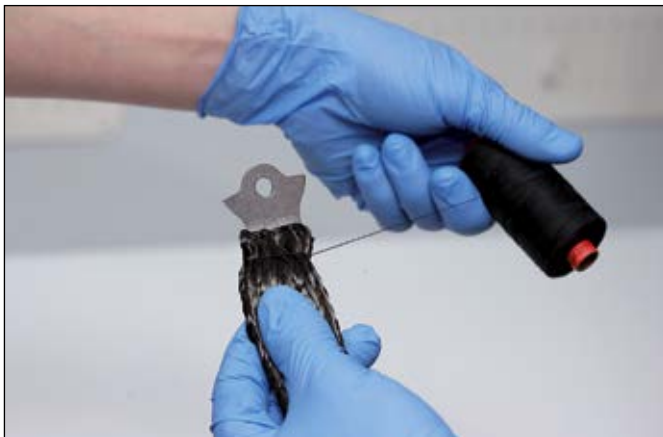
We recommend always using 2 layers of woven carbon fibre stockinette around the joining area of the reinforced band and side bar (= 30-40 mm in front of and 50 mm above the band), in order to achieve sufficient stability in this area.



Proceed with the foot stirrup in the same way as with the profile reinforcements for the bands. Use 616B2=25X5 unidirectional carbon webbing on the foot stirrup and to lengthen the band connection.



Guide the carbon fibre woven hose over the bars and the PVC profile material and make sure that the fibres are taut.



Wrapping the carbon fibre woven hose with normal sewing thread (waxed thread must not be used) helps it fit more closely to the core material.

5.5 Applying the reinforcement



Insulate the plaster model with a PVA bag (e.g. 99B81=130×19×5) and apply a piece of 627B4 PE adhesive tape to the surfaces above the alignment adapter to protect them against tearing.



Pull 1 layer of Perlon stockinette tightly over the model.



Apply a small amount of 636N9 Ottobock contact adhesive to the stockinette above the alignment adapter. After drying, cut into the stockinette.



Tape down the 616B2 unidirectional (UD) carbon webbing with a bit of 616F10=6 double-sided adhesive tape. Use as little adhesive tape as possible. If too much tape is used, it can prevent saturation of the carbon fibres. During lamination, always ensure the material is well soaked in lamination resin.



To reinforce the foot part, add 1 layer in the transverse plane from medial to lateral, passing in the direction of the lateral ankle, under the heel, to medial ankle. Do the same in the frontal plane, passing from lateral ankle to the medial ankle when viewed from the back or coronal plane. Laterally, there should be a **minimum of a 20 mm** gap between the carbon fibre material and the lower edge of the ankle joint.



Apply 1 circular layer of UD carbon webbing to the supports of the bars and bands.



Apply 1 layer of UD carbon webbing in the medial area of the contact surface above and below the knee joint.



The plastic knee joint dummy can be used on the left or right side. For this reason, please seal the free connection plugs which are not required with Plastaband.



Apply a bit of Plastaband above the alignment adapters around the thread and then prick the PVA bag.



Secure the prepared, carbon fibre-reinforced ankle/knee joint combination to the model.



Insulate the screw connections on the stainless steel dummy of the ankle joint with Plastaband.



Then join the band reinforcements to the bars using the carbon webbing extensions. Cover the screw connections of the knee joint dummy with Plastaband as well.



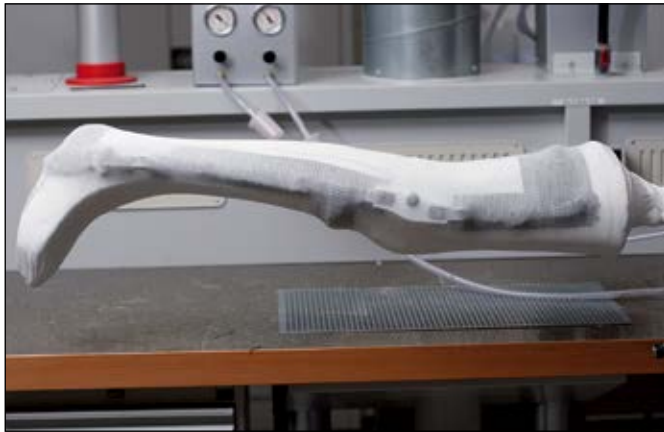
Lateral view of the tibial band.



Then apply a layer of carbon webbing for stability.



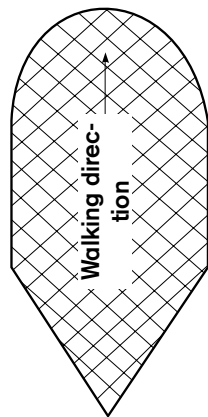
Finally, secure the reinforcement of the foot stirrup with carbon webbing and attach it to the long-soled fore-foot part as in the illustration.



Pull 1 layer of Perlon stockinette over the model. A Nylglas stockinette can be used as an alternative.



This is followed by the next layer of unidirectional carbon webbing.



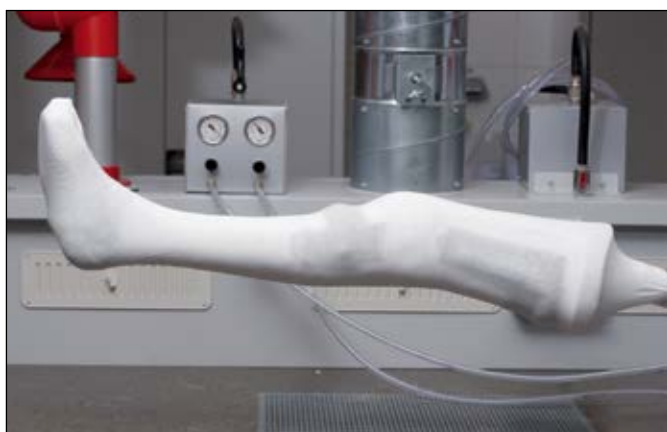
For the long-soled foot part of the orthosis we recommend using a cut piece of 2 layers of 616G12 carbon fibre cloth with 45° alignment of the fibres (see sketch).



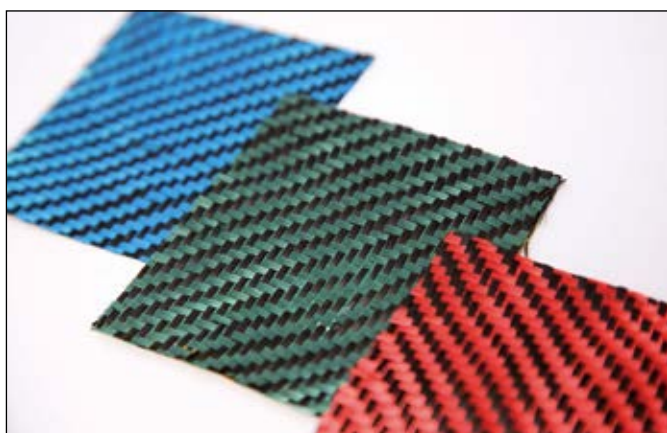
Again, apply 1 lengthways and 1 crossways layer of the same width of UD carbon webbing to the foot part.



Apply 1 layer of UD carbon webbing lengthways in the medial area of the contact surfaces.



Pull over 1 layer of Perlon stockinette.



Finally, 1 layer of decorative fabric is applied (please see our 646K1 materials catalogue for selection). Optionally, the decorative fabric can also be replaced by a Perlon stockinette.



Verify the position of the bands, pull over a PVA bag, vacuum the model and make sure that there are no leaks in the PVA bag. Apply talcum powder to the PVA bag.



Please only use 617H55 C-Orthocryl from Ottobock. This is specially designed for the carbon fibre material. To avoid overheating during curing, an additional 1.5% of hardener should be added.

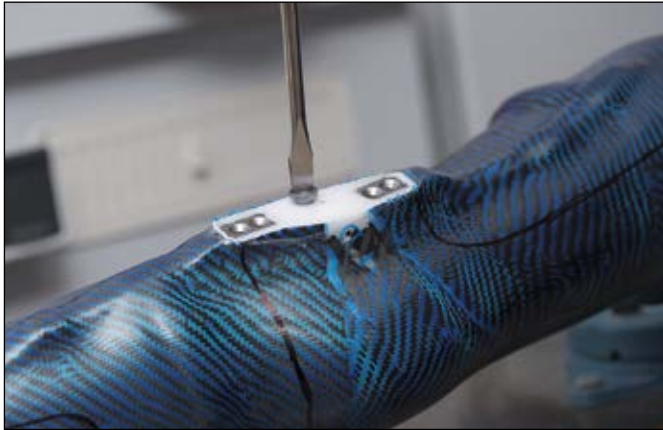


During lamination, distribute the lamination resin slowly and evenly in the cast and make sure that the material is properly saturated.

5.6 Demoulding



Prior to demoulding, mark the edge course on the orthosis and then cut the joint dummies free.



Remove the screws from the knee joint dummy and ankle joint dummy.



Separate the thigh part from the tibial part.



Carefully cut along the separation edge using an oscillating saw. Uncover the dummy and carefully cut the foot stirrup free.



Separate the foot part from the tibial part.



Grind the orthosis components.



Caution:

The UL bar must not be damaged by grinding, since this would compromise the function and stability of the orthosis and thus put patient safety at risk.

5.7 Finishing the orthosis



To finish the orthosis for trial fitting or delivery, you will need an Allen key size 4 and a torque wrench.



For the trial fitting, the joints do not have to be secured with Loctite® on the screws. However, it is essential that the recommended torque from IFU 647G975, UL knee joint, or IFU 647G864, UL ankle joint is applied without exception.

Torque values [Nm]

	17LK3=12	17LK3=14	17LK3=16	17LK3=20
UL knee joint				
Screw with flattened half-round head (item 15)*	8	8	8	8
Flat head screw (item 22)*	3.6	3.6	7.1	7.1
UL ankle joint				
Torx screw (item 10)**	4	8	8	12
Flat head screw (item 12)**	3.6	3.6	7.1	7.1

* See illustration p. 5

** See illustration p. 4



Mount the ankle joint.



During installation of the bearing washers, make sure they do not interfere with the free movement of the joint.

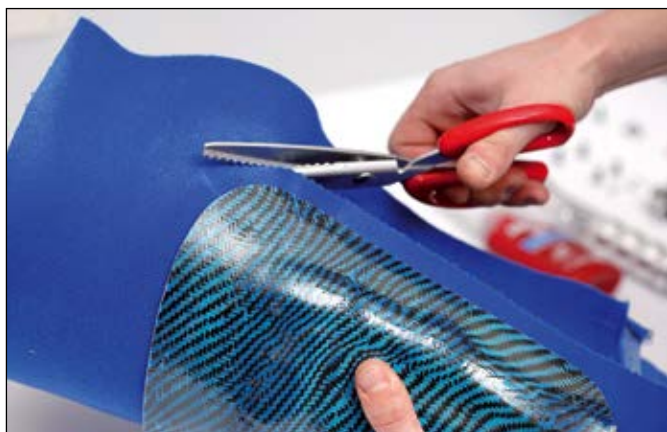


The bearing washers must not be visible when the axles are inserted!



During final assembly, be sure to apply Loctite® 241 to the joint screw and tighten it to the specified torque as per IFU 647G864.

If it is difficult to move the joint, please check whether the bearing washers have been correctly inserted (located between the foot stirrup and the body of the joint).



In addition to various padding materials for the lining, exchangeable padding fabrics can also be used (e.g. 623P3 terry cloth padding fabric). These can be removed by the patient for washing and afterwards reattached by hook and loop closure. For the hook and loop fastening we recommend self-adhesive 623Z4=50-6 micro hook-and-loop. For optimal adhesion of the micro hook-and-loop, apply a small amount of 636N9 Ottobock contact adhesive to the orthotic surfaces to which the strip will be attached.



To finish the orthosis, it is essential that you apply Loctite® no. 241 to the joint and bar screw connections and tighten them using the appropriate torque as per IFU 647G975, UL knee joint, or IFU 647G864, UL ankle joint.



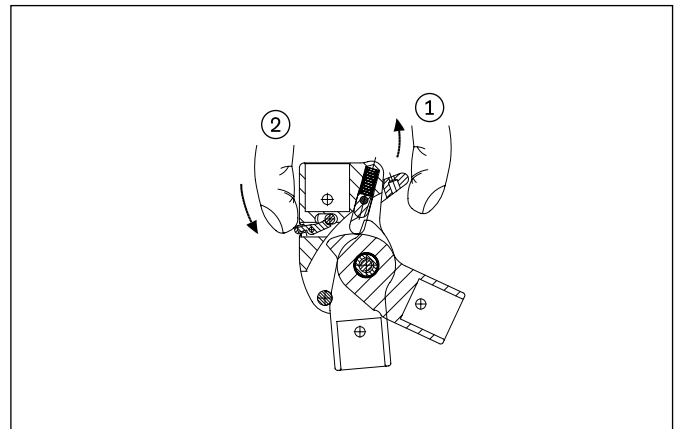
To assess the sagittal alignment, we recommend monitoring the patient on the L.A.S.A.R. Posture while wearing the orthosis. The load line projected by the laser onto the leg should ideally fall 15 mm in front of the compromise pivot point according to Nietert (please also refer to the alignment instructions in the IFU 647G975, UL knee joint).



Final fitting and assessment of the orthosis' functionality on the patient.

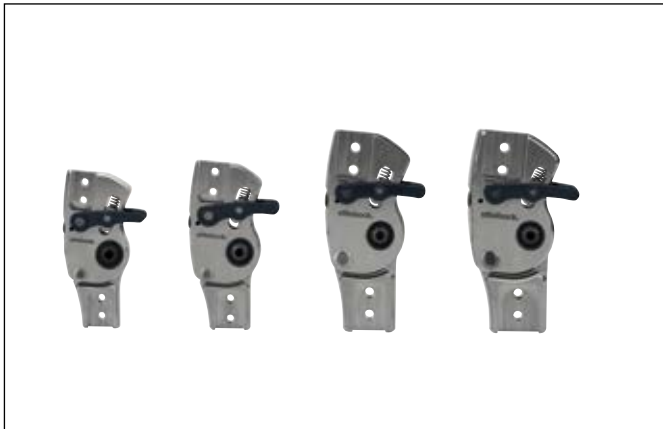


Switching the joint to cycle mode.





17LA3 ankle joint



17LK3 knee joint



Fitting examples with the UL joint system.

Unilateral Joint System

Fax Order form

Company	<input type="text"/>	Date	<input type="text"/>
Technician	<input type="text"/>	Signature	<input type="text"/>
Customer no.	<input type="text"/>		

User information

Surname, first name Weight

Age Indication

Side Left Right Bilateral

The size chosen depends on the patient's weight and the conditions of use.

1 17LS3=* Lamination bar

Steel version	Titanium version
<input type="checkbox"/> 17LS3=12	<input type="checkbox"/> 17LS3=12-T
<input type="checkbox"/> 17LS3=14	<input type="checkbox"/> 17LS3=14-T
<input type="checkbox"/> 17LS3=16	<input type="checkbox"/> 17LS3=16-T
<input type="checkbox"/> 17LS3=20	<input type="checkbox"/> 17LS3=20-T

2 17LK3=* Unilateral Knee Joint

Steel version	Titanium version	(A) Shoulder screw*		
<input type="checkbox"/> 17LK3=12	<input type="checkbox"/> 17LK3=12-T	<input type="checkbox"/> L	<input type="checkbox"/> R	<input type="checkbox"/> 30Y89
<input type="checkbox"/> 17LK3=14	<input type="checkbox"/> 17LK3=14-T	<input type="checkbox"/> L	<input type="checkbox"/> R	<input type="checkbox"/> 30Y89
<input type="checkbox"/> 17LK3=16	<input type="checkbox"/> 17LK3=16-T	<input type="checkbox"/> L	<input type="checkbox"/> R	<input type="checkbox"/> 30Y89
<input type="checkbox"/> 17LK3=20	<input type="checkbox"/> 17LK3=20-T	<input type="checkbox"/> L	<input type="checkbox"/> R	<input type="checkbox"/> 30Y89

3 17LS3=* Lamination bar

Steel version	Titanium version
<input type="checkbox"/> 17LS3=12	<input type="checkbox"/> 17LS3=12-T
<input type="checkbox"/> 17LS3=14	<input type="checkbox"/> 17LS3=14-T
<input type="checkbox"/> 17LS3=16	<input type="checkbox"/> 17LS3=16-T
<input type="checkbox"/> 17LS3=20	<input type="checkbox"/> 17LS3=20-T

4 17LS3=* Lamination bar

Steel version	Titanium version
<input type="checkbox"/> 17LS3=12	<input type="checkbox"/> 17LS3=12-T
<input type="checkbox"/> 17LS3=14	<input type="checkbox"/> 17LS3=14-T
<input type="checkbox"/> 17LS3=16	<input type="checkbox"/> 17LS3=16-T
<input type="checkbox"/> 17LS3=20	<input type="checkbox"/> 17LS3=20-T

5 17LA3=* Unilateral Ankle Joint

Steel version	Titanium version	(B) Optional lamination dummy with shoulder screw
<input type="checkbox"/> 17LA3=12	<input type="checkbox"/> 17LA3=12-T	<input type="checkbox"/> 17LD1=12
<input type="checkbox"/> 17LA3=14	<input type="checkbox"/> 17LA3=14-T	<input type="checkbox"/> 17LD1=14
<input type="checkbox"/> 17LA3=16	<input type="checkbox"/> 17LA3=16-T	<input type="checkbox"/> 17LD1=16
<input type="checkbox"/> 17LA3=20	<input type="checkbox"/> 17LA3=20-T	<input type="checkbox"/> 17LD1=20

6 17LF3=* Foot stirrup

<input type="checkbox"/> 17LF3=12	<input type="checkbox"/> 17LF3=16
<input type="checkbox"/> 17LF3=14	<input type="checkbox"/> 17LF3=20

* (A) The 30Y89 shoulder screw is not included in the scope of delivery of 17LK3. It is part of the 743R6 orthotic joint alignment fixture.

Kundenservice/Customer Service

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