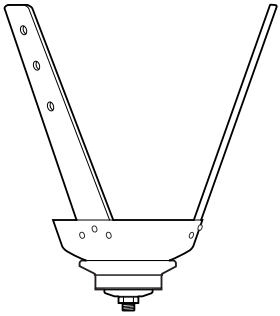
Cup and Strut Kit
for ESK Chassis
Instructions for Use

189118



Contents

1 Description and Intended Purpose

These Instructions for Use are intended for the practitioner and user, unless otherwise stated.

The term *device* is used throughout to refer to a Cup and Strut Kit.

Please read and ensure you understand these instructions, in particular all safety information and maintenance instructions.

Application

This device is to be used exclusively for lower limb prosthetic fittings, intended for a single user.

The device is used to permanently connect a prosthetic socket to an ESK chassis, and to provide structural support and adjustability between these components. Sockets must have Blatchford single bolt alignment. The device allows optimal alignment to be achieved when using a socket manufactured with single bolt construction.

Features

- Choice between two build height options.
- Allows connectivity to open ended or closed, polypropylene-GRP or metal prosthetic sockets.

Blatchford

Activity Level

This device is suitable for Activity Levels 1-4 (weight limits apply, see Section 8 Technical Data).

Activity Level 1

Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.

Activity Level 2

Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.

Activity Level 3

Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

Activity Level 4

Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

Contraindications

There are no known contraindications if used in accordance with these instructions.

Clinical Benefits

- Aids in setting correct prosthetic alignment during prosthetic socket manufacture.

2 Safety Information

This warning symbol highlights important safety information which must be followed carefully.

Any changes in the performance or function of the limb, e.g. excessive play or unusual noises, should be immediately reported to your service provider.

Always use a hand rail when descending stairs and at any other time if available.

The device is designed for prolonged submersion and suitable for immersion in fresh water only. Ensure any use of the device in water complies with the conditions given in Limitations on Use.

The user must not adjust or tamper with the setup of the device.

The user is advised to contact their practitioner if their condition changes.

Always use Loctite and apply the specified torque value to the bolts. Never use an alternative bolt.

To reduce the risk of injury due to failure or loosening of the bolt connections, ensure the bolt threads are cleaned thoroughly before each installation.

To ensure safety during assembly, drilling and riveting, use appropriate Personal Protective Equipment (PPE), which includes but not limited to, safety glasses, gloves and sufficient ventilation when using adhesives.

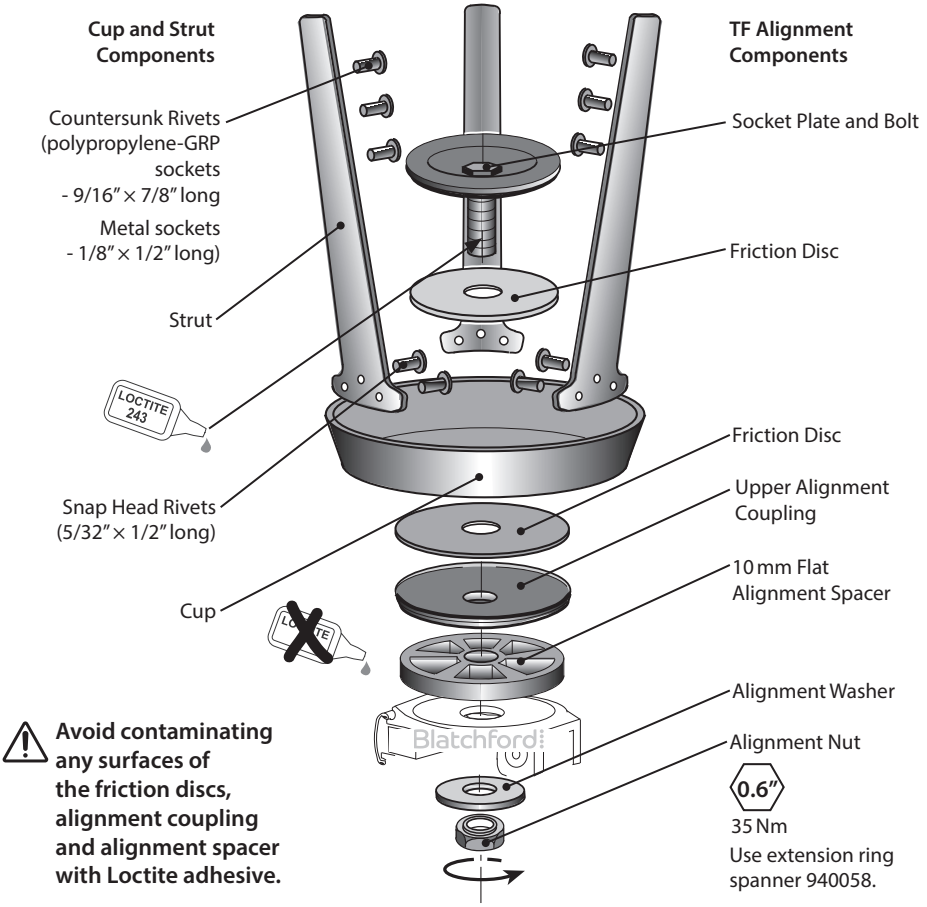
Only use components and combinations of components specified in these Instruction for Use. Use of unauthorized parts and unapproved combinations may compromise the integrity of the prosthesis and lead to failure and injury.

3 Construction

Principal Parts

- Cup & Struts — Aluminum alloy
- TF Alignment Components — Aluminum alloy, synthetic rubber, st. steel, polyarylamide
- Rivets — Aluminum alloy/copper

Component Identification



Avoid contaminating any surfaces of the friction discs, alignment coupling and alignment spacer with Loctite adhesive.

4 Function

The device enables transfemoral polypropylene-GRP or metal prosthetic sockets to be fitted to a single-bolt 115 mm diameter cup and a range of TF alignment components. The cup and the struts are permanently riveted to the socket wall. When attached to a prosthetic knee, the TF alignment components offer secure connection and the ability to make angular shift and rotational adjustments.

5 Maintenance

Visually check the device regularly. Report any changes in performance of this device to the practitioner/service provider e.g. unusual movement, noises or significant wear. Inform the practitioner/service provider of any changes in body weight and/or activity level.

Cleaning

Use a damp cloth and mild soap to clean outside surfaces. DO NOT use aggressive cleansers.

This maintenance must be carried out only by competent personnel (practitioner or suitable trained technician).

The following routine maintenance is to be carried out at least annually:

- Check rivets for tightness. Replace if necessary.
- Check the screws and bolts for tightness. Reapply Loctite adhesive and retighten if necessary.
- Check for defects that could affect proper function.
- Check for corrosion.

Ensure the user has read and understood all safety and user-level maintenance information.

Advise the user that a regular visual check of the device is recommended and signs of wear that may affect function should be reported to their service provider.

Advise the user to inform the practitioner/service provider of any changes in body weight and/or activity level.

If this device is used for extreme activity, the maintenance level and interval should be reviewed and if required advice and technical support sought to plan a new maintenance schedule dependent upon the frequency and nature of the activity. This should be determined by a local risk assessment carried out by a suitably qualified individual.

Storage and Handling

When storing for prolonged periods, ensure the product is free from moisture and stored at room temperature.

6 Limitations on Use

Intended Life

A local risk assessment should be carried out based upon activity and usage.

Lifting Loads

User weight and activity is governed by the stated limits. Load carrying by the user should be based on a local risk assessment.

Environment

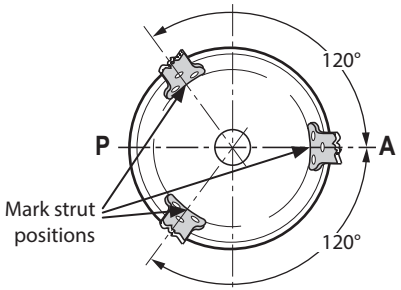
This device is waterproof to a maximum depth of 1 meter. Thoroughly rinse with fresh water after use in abrasive environments such as those that may contain sand or grit, for example, to prevent wear or damage to moving parts. Thoroughly rinse with fresh water after use in salt or chlorinated water.

Exclusively for use between -15 °C and 50 °C (5 °F to 122 °F).

Suitable for submersion

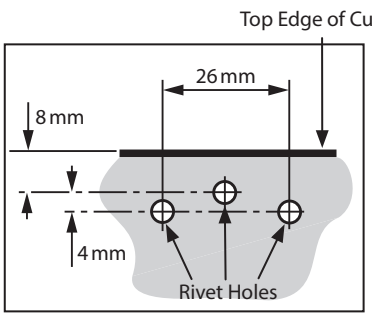
7 Fitting Advice

1 Set struts individually to suit socket alignment and curvature of socket.



Mark the position of the struts relative to the A-P direction around the inside edge of the cup as shown.

2

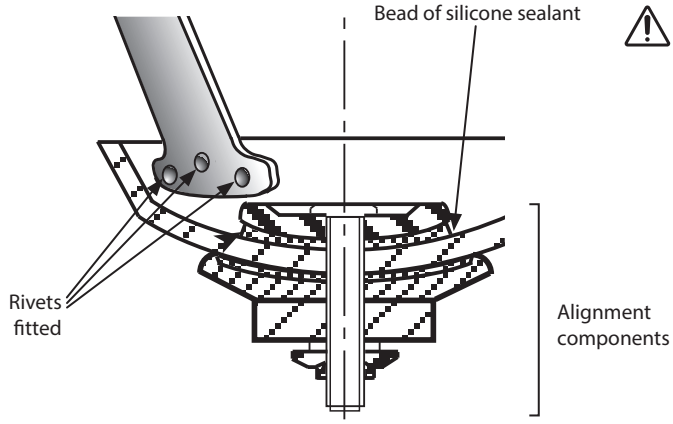


Mark rivet holes for drilling as shown above. Using a 4.1 mm diameter drill bit, drill 3 holes per strut normal to the surface.

3 Using 3 snap head rivets per strut, fasten each strut to the cup. Loosely assemble alignment components into the cup, following the order shown on the Construction image.

Do not apply Loctite adhesive to the end of the socket bolt at this stage.

If a closed-end socket is used, fitting and removal of the socket plate, socket bolt and friction disc may not be possible later.



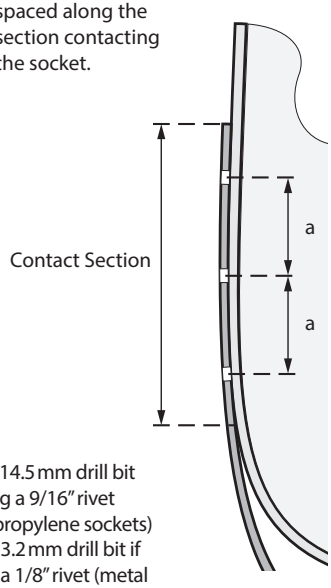
Only during final assembly should a bead of silicone sealant be applied all around the socket plate to form a seal. (See Full Alignment Kit Instructions for Use, 938456.)

938456

4 Bend struts individually using a bending tool to suit the alignment and curvature of socket.

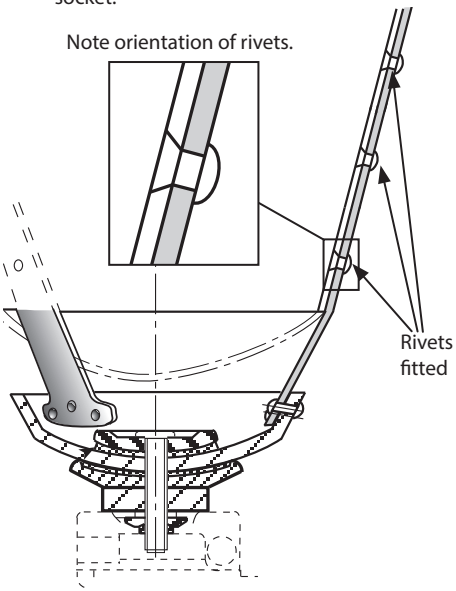
DO NOT repeatedly bend the struts in opposite directions. This will weaken the material and could cause it to break.

5 Drill strut holes evenly spaced along the section contacting the socket.



Use a 14.5 mm drill bit if using a 9/16" rivet (polypropylene sockets) and a 3.2 mm drill bit if using a 1/8" rivet (metal sockets).
Mark strut hole positions against the socket surface and drill rivet holes using the same drill bit as above.

6 Countersink each hole on the inside of the socket.



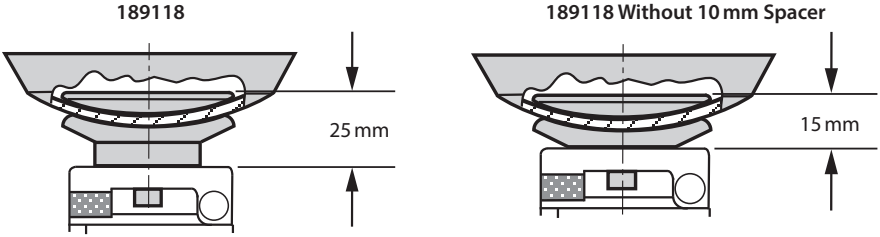
Using 7/8" long countersunk rivets for polypropylene-GRP sockets and 1/2" long countersunk rivets for metal sockets, fasten each strut to socket.

Symptom	Solution
A recurring noise occurs between the socket and the knee.	Ensure that the socket interface has been correctly formed and is the correct thickness. The Alignment Nut must be tightened. Apply Loctite and tighten to the correct torque setting.
The adapter moves out of position.	User must not use the device until adjusted, repaired or replaced.

8 Technical Data

Operating & Storage Temperature Range:		-15 °C to 50 °C (5 °F to 122 °F)
Component Weight:		825 g (1 lb 13 oz)
Activity Level:		1–4
Maximum User Weight:	Activity level 1-3	125 kg (276 lb)
	Activity level 4	100 kg (220 lb)
Attachment Type:		Single Bolt
Range of Adjustment:		360 ° axial rotation, ±7 ° tilt from vertical
Length:		25 mm/15 mm

Fitting Length



The 15 mm build height setup requires precisely 10 mm shortening of the socket bolt. A long socket bolt protruding past the alignment nut may interfere with the operation of the chassis, while a short socket bolt may not engage all threads inside the alignment nut and will not provide a secure connection.

938456

Assemble and align alignment components according to Full Alignment Kit Instructions for Use, 938456.

9 Ordering Information

Order Example

189118 115 mm diameter cup with standard alignment kit and 10 mm spacer.

Tooling

Part	Part Number
Extension Ring Spanner 3/8" BS	940058

Manufacturer's Declarations and Legal Information

Liability

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use supplied with the device. The manufacturer is not liable for any adverse outcome caused by any component combinations that were not authorized by them.

CE Conformity

This product meets the requirements of the European Regulation EU 2017/745 for medical devices. This product has been classified as a class I device according to the classification rules outlined in Annex VIII of the regulation. The EU declaration of conformity certificate is available at the following internet address: **www.blatchfordmobility.com**

MD Medical Device

Single Patient – multiple use

Compatibility

Combination with Blatchford branded products is approved based on testing in accordance with relevant standards and the MDR including structural test, dimensional compatibility and monitored field performance.

Combination with alternative CE marked products must be carried out in view of a documented local risk assessment carried out by a Practitioner.

Warranty

This device is warranted for 24 months.

The user should be aware that changes or modifications not expressly approved could void the warranty, operating licenses and exemptions.

See the Blatchford website for the current full warranty statement.

Reporting of Serious Incidents

In the unlikely event of a serious incident occurring in relation to this device it should be reported to the manufacturer and your national competent authority.

Environmental Aspects

This product is made from a recyclable material. Where possible, the components should be recycled in accordance with local waste handling regulations.

Retaining the Packaging Label

The practitioner is advised to keep the packaging label as a record of the device supplied.

Trademark Acknowledgements

Blatchford is a registered trademark of Blatchford Products Limited.

https://www.blatchfordmobility.com/locations/distributors

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