

Instructions for Use Code 21359





1. Introduction

These instructions are intended to assist you with the use and maintenance of the split leg positioner accessory. It is important that these instructions are read thoroughly before using the equipment. The device will be adversely affected, and its life expectancy reduced, if the following instructions are not observed.

We also recommend that the user familiarise themselves with the QA4 Powered Mobile Surgery System instructions for use, document no. 992010.

NOTE:

If any part of the split leg positioners are damaged or faulty, the device <u>must</u> be taken out of use with immediate effect and the fault reported to Anetic Aid, your authorised dealer or maintenance department. The split leg positioners <u>must not</u> be used until the damage or fault has been repaired.

1.1. Warnings & Cautions

Various warnings and cautions are made throughout these operating instructions.



A **WARNING** is given when the personal safety of the patient or user may be affected and when disregarding this information could result in injury.



A **CAUTION** is given when special instructions must be followed. Disregarding this information could result in permanent damage being caused to the device.

1.2. Intended Use & Contraindications

The split leg positioner accessory is intended for use within a theatre environment to aid with the positioning and abducting of patients legs during operative procedures.

1.3. Equipment Classification

The equipment referenced in this document has been classified as a Class 1 Medical Device, and is both CE and UKCA marked under the scope of the Medical Devices Regulation 2017/745 and the UK Medical Devices Regulations 2002.





EU-UK Authorised Representative Ltd. Unit 591, Moat House, 54 Bloomfield Avenue, Belfast, BT5 5AD, Northern Ireland



OZG OneZurich Group Ltd., Mülibodenstrasse 3, 8172 Niederglatt ZH, Switzerland

1.4. Putting the Split Leg Positioner into Service

It is important that the split leg positioner sections are cleaned and disinfected before being put into service. Use this manual to check all the functions and refer to the 'Cleaning and Disinfecting' instructions.

2. Product Specifications



Key	Key to Fig. 1				
1.	Mounting blade				
2.	wist-to-release handle				
3.	side bar for accessory mounting				
Dimensions:					
Product size, per section		L1000mm x W420mm			
Mattress area, per section		L650mm x W350mm			
Product weight, per section		7.5kg			
Abduction angle, per section		25° out from stretcher mid-line			
Adduction angle, per section		10° in from stretcher mid-line			
Elevation angle, per section		30° up from horizontal			
Articulation angle, per section		50° down from horizontal			
Weight Limits:					
Maximum patient weight limit		160kg (353lbs)			
Safe working load		180kg (397lbs)			
<u>\(\frac{1}{2} \)</u>		WARNING: Exceeding the maximum specified patient weight limit could result in failure of the split leg positioner and injury to the user.			

The split leg positioner should be used in conjunction with the following Anetic Aid side bar clamp: Item No. 10250, Clamp - Universal (Socket & Rail) - Handwheel - for UK

Side Bar Clamp Accessory:

& EU Side Bar.

3. Setting Up and Using the Split Leg Positioner

As illustrated in fig. 3, the split legs must be abducted prior to attaching to the stretcher; this ensures they sit outside of the patients' legs on the leg section. Each split leg is adjusted using the twist-to-release adjustment handle (fig. 1, item 2).

As shown in fig. 2, insert the mounting blade (A) of the split leg into the side bar clamp (B); see fig. 1 for details of the clamp required. **Note**; ensure the leg section release buttons are accessible (C).



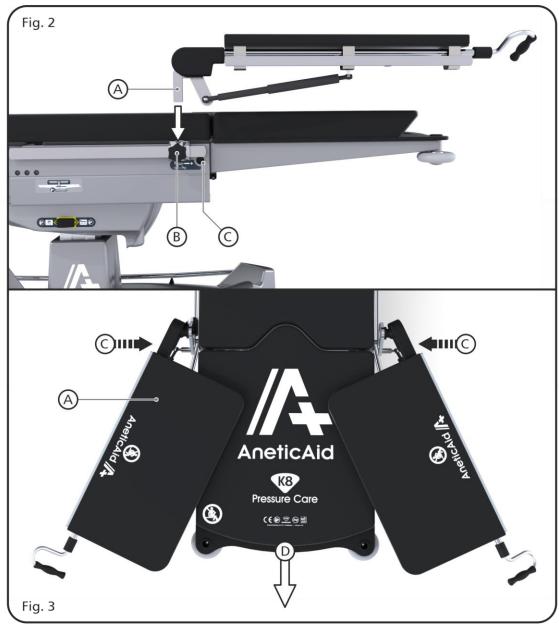
WARNING: Ensure the side bar clamps are firmly tightened to prevent any movement of the leg section positioners during use.

When the splits legs are securely affixed, lift the patients legs off the leg section, and onto each split leg. Next, depress the leg section release buttons (C), and remove the stretcher leg section (D); the split legs can now be positioned as required.

Following the procedure, the split legs should be abducted to allow the leg section to be refitted; align the spigots of the leg section into the mating female sockets on the stretcher and push home firmly until the leg section is fully engaged.



WARNING: Ensure that the leg section is fully engaged and securely locked in position.



4. Cleaning and Disinfecting

It is recommended that only CE marked cleaning products are used in the cleaning of this device. Cleaning and Disinfection should be carried out by hand only.

Clean the device with warm water and neutral detergent and dry the surfaces thoroughly using a soft cloth. Suitable disinfectants are: quaternary ammonium compounds, isopropyl alcohol & chlorine bleach up to 1% (10,000 ppm). Apply disinfectant by cloth, spray or disinfectant wipe. Following disinfection, wash off the all surfaces with clean warm water and dry thoroughly using a soft cloth.

The product will be adversely affected and its life expectancy reduced if the following cautions are not observed;

CAUTION:

- Do not steam clean or jet wash any area of this device.
- Do not soak or immerse the device.



- Do not use concentrated bleaching disinfectant solutions, organic solvent or abrasive powders in the cleaning or disinfection of this product.
- Dilute all disinfectants in accordance with the manufacturer's guidelines.
- Disinfectant products are corrosive in nature; failure to properly wash and dry the product surface could leave a corrosive residue which may cause damage to the product.

5. Product Maintenance

The split leg positioner does not require servicing. However, before use, visually inspect the device for any loose or damaged parts.

NOTE:

If any part of the split leg positioners are damaged or faulty, the device <u>must</u> be taken out of use with immediate effect and the fault reported to Anetic Aid, your authorised dealer or maintenance department. The split leg positioners <u>must not</u> be used until the damage or fault has been repaired.



CAUTION: In line with the MHRA Device Bulletin DB2006(5), maintenance work should only be conducted by suitably trained personnel following manufacturer's guidelines.

6. Product Warranty

The product, when new, is guaranteed to be free from defects in materials and workmanship and to perform in accordance with the manufacturer's specification for a period of 12 months from the date of purchase from Anetic Aid Ltd or their approved Distributor. Anetic Aid Ltd will repair or replace, at their discretion, any components found to be defective or at variance with the manufacturer's specification within this time at no cost to the purchaser. The warranty will take effect from the date of purchase, subject to the purchaser registering the product with Anetic Aid to confirm its receipt, installation date and product details.

The warranty does not provide cover for breakage or failure due to tampering, misuse, neglect, accidents, modifications or shipping. The warranty is also void if the product is not used in accordance with the manufacturer's instructions or is repaired during the warranty period by any persons other than Anetic Aid or its appointed agent. No other expressed or implied warranty is given.

For details of our extended warranty packages please contact Anetic Aid or your authorised dealer.

7. Label Identification

The following list is a description of all the labels used on the device;

Label indicating maximum patient weight and the safe working load for the device.



Anetic Aid CE product label.



Anetic Aid operating table screen print.



Do Not Sit; indicates that neither of the split leg positioner sections should be sat upon.



For more information on any of our products or service contracts, call:

sales@aneticaid.com +44 (0)1943 878647 aneticaid.com











