



Instructions for Use

REF A-Line Positioner with Straps 800-0143

INTENDED USE

Intended use is to securely position the hand and forearm for a-line insertions. The intended users of this device are medical professionals within hospitals and surgery centers.



GENERAL INFORMATION

- *Product not made with Natural Rubber Latex*
- *Product warranty covers product from manufacturing defects for period of 2 years*
- *If damaged in shipping, call Customer Service at (888) 724-8763 or (781) 982-7000 to obtain Return Material Authorization number. For product warranty issues, contact Customer Service.*
- *CE marked medical device according to MDR (EU) 2017/745*
- *Life of device is 5 years under normal use*
- *Store device between -4°F to $+86^{\circ}\text{F}$ (-20°C to 30°C)*

COMPONENT OVERVIEW

Easy-to-use patient positioning device for all A-line insertions. Anatomically formed base with two, exclusive 1"W x 17"L (2 cm x 43 cm) soft-edge straps. Straps reduce risk of skin ulceration in patients. Base provides best angle for hand, wrist and forearm positioning. Keeps skin taut for optimal needle insertion. 12/cs.

INSTRUCTIONS

Become familiar with the features of patient positioning device before use with a patient. Always practice use on a nurse, physician or appropriate volunteer prior to using clinically.

1. *Place support under patient's hand and forearm*
2. *Attach one end of each strap across forearm and palm*
3. *Secure free end of strap to hook on support underside*
4. *Strap should be snug but not so tight to restrict circulation*
5. *Incorporated slot in A-Line Positioner can be used to secure device to armboard*
6. *To facilitate a-line insertion, wrist may be temporarily placed in hyper-extension by wrapping hand strap around thumb and attaching strap in position across palm*
7. *Once insertion is completed, hand strap must be unwrapped from thumb and reattached to hook under support*

GENERAL SPECIFICATIONS

Device Dimensions (maximum)

- *Length: 10.5" +/- 0.5" (27 cm +/- 1 cm)*
- *Width: 3" +/- 0.5" (8 cm +/- 1 cm)*
- *Device Weight: .5 +/- 0.5 lbs. (.22 +/- .22 kg)*

DISPOSAL

- **General** - *Prevent infection by cleaning and disinfecting product before disposal*
- **Packaging** - *Dispose packaging material via household waste according to national requirements*
- *SchureMed accepts back used or retired products - or dispose of product in accordance with national requirements*



PRODUCT USE WARNINGS

WARNING! *Hazard resulting from incorrect use.*



WARNING! *Strap should be snug but not so tight to restrict circulation.*



WARNING! *Do not reuse device if there are obvious signs of damage or functional issues. Consult manufacturer before reusing.*

USER NOTICE

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.














SINGLE PATIENT USE – Please dispose after each use.

UDI Basic UDI-DI: 081001560F0046ET

eIFU Language Versions

To download and print the Instructions for Use, please go to <http://www.schuremed.com/schuremed-eifu>.

Symbol Glossary

Symbol	Title	Symbol Description
	Manufacturer	Indicates the medical device manufacturer.
	Authorized Representative in the European Community	Indicates the authorized representative in the european community.
	Use-by Date	Indicates the date after which the medical device is not to be used.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue or Item Number	Indicates the manufacturer's catalogue or item number so that the medical device can be identified.
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Medical Device	Indicates the item is a medical device.
	Unique Device Identifier	Indicates a barcode as containing unique device identifier information.
	CE Marking	European Conformity.
	Single Patient Use	Indicates the item is a single patient use medical device.



Manufacturer

SchureMed (081001460)

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 **Authorized Representative**

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