Subcutaneous Guidewire™

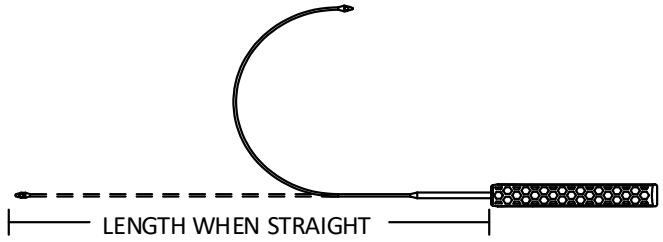
Subcutaneous Tunneling Instrument

Catalog Numbers:

Size	Individual Instrument	Box of 5 Instruments
Small	41.240.101	41.240.501
Medium	41.240.102	41.240.502
Large	41.240.103	41.240.503

Description of the Subcutaneous Guidewire

The Subcutaneous Guidewire consists of a preformed, stainless steel guidewire with a plastic handle.



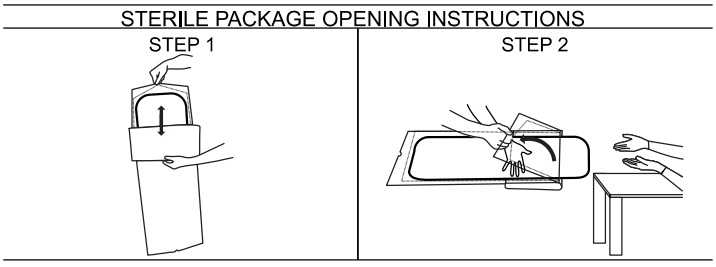
Kit Size	Guidewire Length (when Fully Straightened)
Small	30 cm (11.6”)
Medium	34 cm (13.3”)
Large	38 cm (14.8”)

Indications for Use

The Subcutaneous Guidewire is designed to facilitate the subcutaneous passage of tubing, suture, ribbons, and/or bands between two skin incisions. It is also designed to facilitate the subcutaneous passage of shunt tubing when implanting a ventricular or lumbar cerebrospinal fluid (CSF) shunting system or externalized CSF drain.

Instructions for Use for the Subcutaneous Guidewire

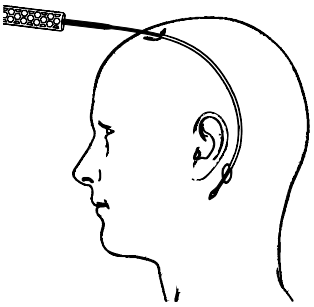
Before use, visually inspect the structural integrity of the packaging and product. Open and remove instruments only from the chevron end, as shown, and be cautious of any loose instruments.



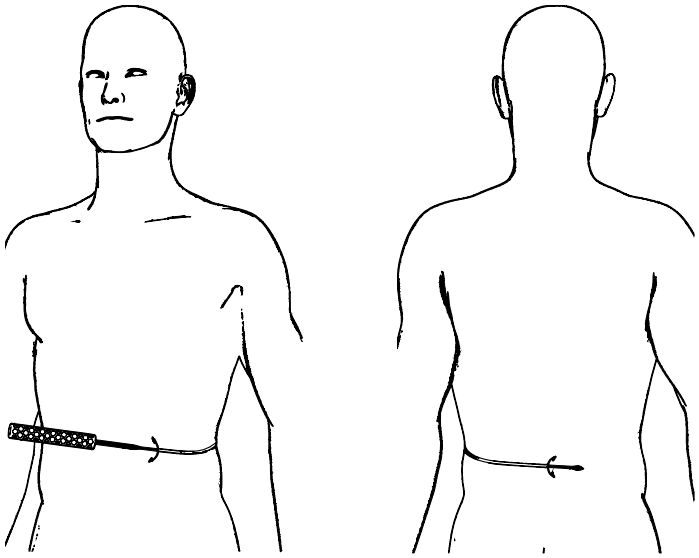
The following procedure assumes that tubing, suture, ribbons, and/or bands is to be passed in a subcutaneous manner between two skin incisions. Incision site size and location, the selection of non-absorbable suture material, etc. should be performed per the surgeon's experience and preference. The procedure may be varied per the surgeon's clinical judgment.

1. The Subcutaneous Guidewire may be contoured to facilitate subcutaneous passage based on the patient’s anatomy.

2. Insert the Subcutaneous Guidewire tip into a subcutaneous plane at the first incision and pass the device subcutaneously to the second incision.



OR



3. A suture, ribbon, band, or tubing may be attached to the eyelet and passed subcutaneously by withdrawing the Subcutaneous Guidewire from the second to the first incision. Alternatively, a suture may be tied to the eyelet and passed subcutaneous to the first incision. The suture may then be used to subcutaneously pass a tube, ribbon, or band. If tubing to be implanted is tied to the Subcutaneous Guidewire’s eyelet or to a suture, the tied portion of the tubing should cut off and discarded after passage.

Contraindications

This device is not designed, sold, nor intended for use except as indicated.

The Subcutaneous Guidewire is contraindicated in patients with abnormally fragile skin.

When tunneling beneath the scalp, the Subcutaneous Guidewire is contraindicated in patients with abnormally fragile skull bone structure and in children with incompletely developed skulls or unfused bone sutures.

Warnings and Precautions

This is a pre-shaped device and is intended for use only by a qualified surgeon.

When tunneling on the torso care should be taken to maintain the tip in the subcutaneous tissue. Penetration into the pleural, peritoneal, or retroperitoneal space could cause serious or life-threatening injury to organs or blood vessels.

How the Subcutaneous Guidewire is Supplied

The Subcutaneous Guidewire is provided sterile. The Subcutaneous Guidewire is packaged in a double barrier package consisting of an inner and an outer sealed pouch. Do not use if package is damaged or open. Do not use if past the use-by date indicated on the individual package label.

Do Not Reuse or Re-sterilize

The Subcutaneous Guidewire is designed to be single-use a disposable device. Do not reuse or re-sterilize any Subcutaneous Guidewire. If bending, breaking, or cutting instruments for disposal, be cautious of broken edges, debris, or sharp edges. Arkis BioSciences will not be liable for any direct, indirect, incidental, or consequential damages resulting from or related to re-sterilization or reshaping of the Subcutaneous Guidewire.

Returned Goods Policy for the Subcutaneous Guidewire

Products must be returned in undamaged, unopened packages, with manufacturer's seals intact to be accepted for replacement or credit, unless the products are returned due to a complaint of product defect or mislabeling. Determination of a product defect or mislabeling will be made solely by Arkis BioSciences.

Products will not be accepted for replacement if they have been in the possession of the customer for more than 30 days.

Product Order Information

Kit Size	Product No. (Box of 5 Instruments)	Guidewire Length (when Fully Straightened)
Small	41.240.501	30 cm (11.6")
Medium	41.240.502	34 cm (13.3")
Large	41.240.503	38 cm (14.8")

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

All products can be ordered through your Arkis BioSciences customer service representative.

Arkis BioSciences Inc.
1059 N. Cedar Bluff Rd. #157
Knoxville, TN 37923
info@arkisbiosciences.com
Telephone: 1-844-247-5383
Fax: 1-844-247-5383

Warranty Disclaimer and Limitation of Liability

ARKIS BIOSCIENCES INC. ("ARKIS") MAKES NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY, EITHER EXPRESS OR IMPLIED, ON ANY OF ITS PRODUCTS DESCRIBED IN THESE INSTRUCTIONS FOR USE ("IFUs"). UNDER NO CIRCUMSTANCES SHALL ARKIS BE LIABLE FOR MEDICAL EXPENSES OR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OTHER THAN THOSE FOR WHICH SPECIFIC APPLICABLE LAW EXPRESSLY PROVIDES. ARKIS MAY ONLY BE BOUND TO ANY REPRESENTATION OR WARRANTY CONCERNING ITS PRODUCTS AS SPECIFICALLY SET FORTH HEREIN, AND NO PERSON HAS ANY AUTHORITY TO OTHERWISE BIND ARKIS TO ANY OTHER REPRESENTATIONS OR WARRANTIES CONCERNING ITS PRODUCTS.

Descriptions and specifications appearing in Arkis BioSciences' printed matter, including this publication, serve the sole purpose of generally describing the product at the time of manufacture and do not constitute any express warranties.

Symbols used in Labeling

	Catalog number
	Batch code
	Use-by date
	Sterilized using irradiation
	Do not reuse
	Do not use if package is damaged
	Magnetic resonance unsafe
	Consult instructions for use
	Manufacturer
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician.

Patents Pending.

Arkis Document 04100004 – Rev A