



Secure. Convenient. Cost-Effective.



User Manual

SuperClip™ Model 4600

Securement Clasp

For managing guidewires,
catheters and drapes.



ADVANCED VASCULAR DYNAMICS

A Semler Technologies Company

Intended Use

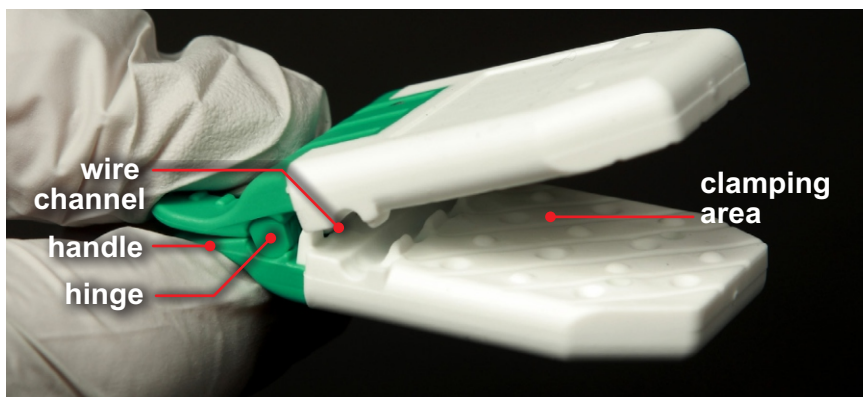
The SuperClip™ Model 4600 devices are intended for use by clinicians in securing and managing guidewires, catheters and drapes before and during interventional vascular procedures.



- Secures the distal end of a guidewire during deployment, while enabling easy manipulation of the wire through the sheath.
- Secures and identifies coiled guidewires or catheters when not in use.
- Attaches the medial edges of radial or brachial drapes to the patient's body drape to prevent unwanted movement.

Description

The SuperClip clasp is a sterile, single-use clip that can be used to secure drapes, guidewires or catheters during a vascular procedure. Ridges on the ergonomically curved handles enable secure handling and the elastomeric pads provide a secure grip on the drapes, wires and catheters while avoiding damage.



Directions

CAUTION: Do not use if the sealed pouch is broken, torn or punctured. Use sterile technique when opening and handling the SuperClip.

Controlling the distal end of a guidewire during deployment.

- i) Remove the SuperClip from its pouch using sterile technique.
- ii) Place the distal end of the guidewire into the wire channel next to the SuperClip hinge.
- iii) Insert a fold of the body drape into the open SuperClip.
- iv) Allow SuperClip to close. The guidewire may be torqued and moved back and forth through the sheath while its distal end is secured on top of the drape.



After use, dispose of SuperClip following institutional protocols.

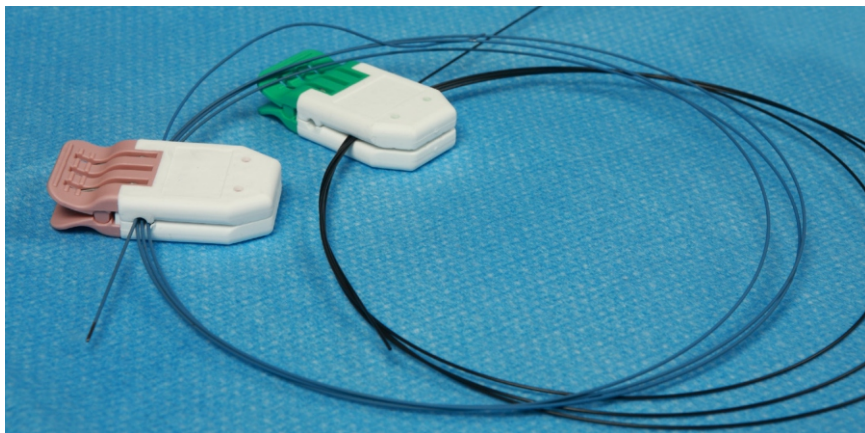
Holding unused guidewires and catheters.

Stiff wires should be placed in the wire channel. Smaller wires may be held in the clamping area.

- i) Remove the SuperClip from its pouch using sterile technique.
- ii) Loop the wire or catheter.
- iii) Open SuperClip and insert the loop into the wire channel next to the SuperClip hinge or in the clamping area.
- iv) Allow SuperClip to close.
- v) The wire or catheter, with SuperClip, may then be placed onto a sterile surface or bowl of saline.



Only one wire or catheter should be secured with each SuperClip. It may be helpful to use different colored SuperClips to help identify different wires.



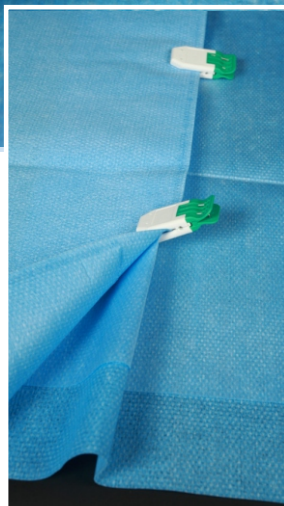
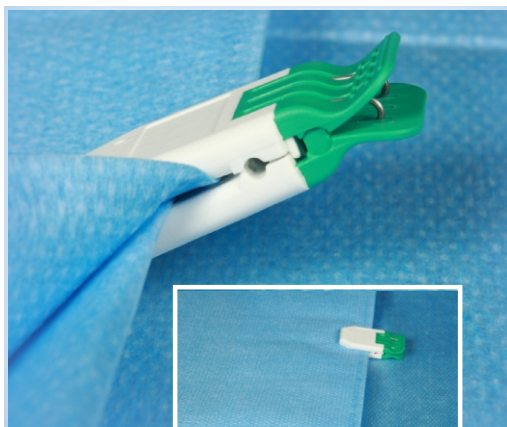
Note: open SuperClip before removing the wire or catheter.
After use, dispose of SuperClip following institutional protocols.

Attaching drapes.

- i) Remove the SuperClip from its pouch.
- ii) To attach a radial or brachial drape to a body drape, open the SuperClip and insert the edge of the radial or brachial drape into the opening together with an edge or fold of the body drape.
- iii) Allow the SuperClip to close.

At least 2 SuperClips should be used to secure a radial or brachial drape.

After use, dispose of SuperClip following institutional protocols.



Dimensions: 1.13"W x 2.3" L x 0.5" H.

Weight: 0.6 oz.

Packaged one sterile unit per pouch. Available in four colors:

4600-00 - Grey; 4600-10 - Pink; 4600-20 - Yellow; 4600-30 - Green.

The SuperClip device contains no user-repairable parts. Contact Advanced Vascular Dynamics for service and support and to report issues .

SuperClip™ LIMITED WARRANTY

The Advanced Vascular Dynamics SuperClip Devices are warranted against defective material and workmanship for one year following delivery of the product to the original purchaser. If any Device or part thereof, in the judgment of Advanced Vascular Dynamics (AVD), is proven to be defective in material or workmanship during the limited warranty period, such defects will be repaired or component or product replaced (at AVD's option) free of charge for parts or labor. Any replacement part may be new or refurbished and like-new.

This limited warranty shall not apply to any product which has not been used in accordance with the manual, been misused, abused, altered or repaired by anyone other than AVD or its authorized representatives. This limited warranty does not cover SuperClip Devices which have been reprocessed or re-used in any way. Use of anything other than new SuperClip Devices in previously unopened factory sterile packaging immediately and permanently voids all warranties and AVD shall not be liable to any person for any indirect or direct consequential damages resulting from or caused by any defect, failure, or malfunction of such Devices or any component thereof.

This limited warranty is in lieu of, and AVD specifically disclaims, all other warranties, express or implied, including any implied warranty of merchantability or fitness for a particular purpose, and AVD shall in no event be liable to any person for indirect, direct, incidental, special or consequential damages of any kind or character. No person is authorized to assume for AVD any other liability in connection with the sale of this Device or its components. Some states or countries do not allow the exclusion or limitation of incidental or consequential damages or allow limitations on how long a limited warranty lasts, so the above limitations or exclusions may not apply to you. This limited warranty gives you specific legal rights, and you may also have other rights that vary from state to state or country to country.

To obtain factory service, contact AVD request a Returned Goods Authorization, shipping instructions, and the ship-to address. The SuperClip is to be shipped, freight pre-paid. Inwarranty products will be returned to the sender, postage pre-paid.



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



Instruction symbol. This indicates that you must read the instructions for use.



Sterile symbol. This indicates that the SuperClip is sterilized using ethylene oxide.



No re-use symbol. This indicates that the SuperClip is for single use only and is not intended to be re-used. Injury or infection may result if devices are re-used.



Do not re-sterilize. This indicates that the SuperClip is not to be re-sterilized. Injury or infection may result if devices are re-sterilized or re-used.



Do not use if the package is damaged or open.

This product is not made with natural rubber latex or phthalates.



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SuperClip Directions For Use

SuperClip devices are made in the USA.

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