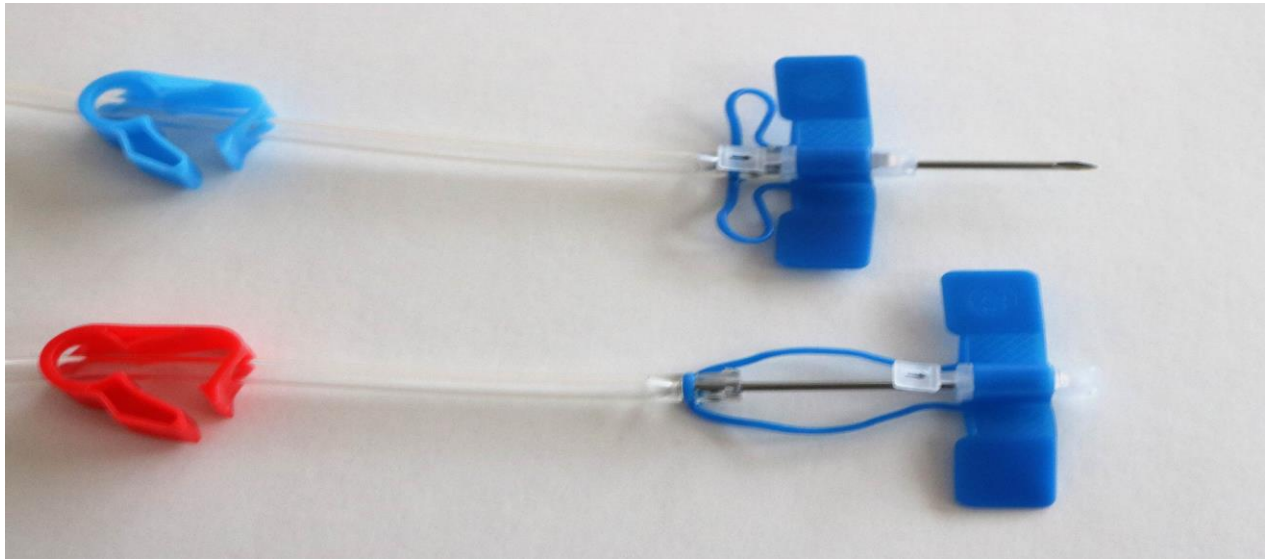


# Summit International Medical Technologies, Inc.

## AngelTip Safety Fistula



**Introducing a new safety fistula designed to meet the safety standards of the Dialysis workplace**

➤ **AngelTip Benefits:**

- ✓ A fully integrated, automatic safety mechanism encompasses needle tip upon removal from the skin
- ✓ Simple, safe, and intuitive one-handed needle removal
- ✓ Automatically encloses AVF needle tip upon removal
- ✓ Does not alter existing protocols
- ✓ Wide wings for superior gripping and taping
- ✓ The AngelTip Safety Fistula safety mechanism is a completely closed housing for the needle and is the most efficient design for preventing blood splatter.

*Does your current safety fistula meet the rationale for needle stick prevention in the Dialysis work place?*

**The AngelTip Safety Fistula meets all the required rational. Please see reverse side for details.**

### Percutaneous Injuries in the Dialysis Setting

Published by the International Health Care Worker Safety Center at the University of Virginia in 2001

- The Dialysis fistula needles are the most dangerous because they are blood filled
- The concern for needle stick injuries were not only with the use of the needle but also with the removal of the needle, post removal of the needle, and with the disposal of the needle.

### Evaluation Criteria for Guarded Fistula Needles for Hemodialysis

Published by the FDA in 2002

- The AVF needle removal requires a double finger hemostasis pressure due to the high pressure of the procedure. Failure to hold double finger pressure can cause life threatening blood loss to the patient and blood exposure to the Health Care Worker and other patients.
- Safety mechanisms that do not activate until after AVF needle removal do not protect the HCW fingers supplying hemostasis pressure.

### Further recommended in the white paper that the safety mechanism should:

- Completely enclose the needle upon removal and subsequent disposal
- Be a one-step locking mechanism ensuring immediate, simple, and complete protection.
- Upon deployment the guard should completely house the blood-filled needle
- The safety design should not allow the sharp tip of the needle to extend past the base of the guard.
- Initial safety designs developed sheaths that slid up the tubing rather than creating engineering controls to modify the AVF needle itself.

### Further recommendations of the white paper stated that the safety mechanism should also work as follows:

- ✓ The safety device should not interfere with standard protocols of taping of the needle set.
- ✓ Automatic needle protection in the Hemodialysis setting calls for the safety mechanism to be activated during the normal course of needle removal.
- ✓ Subsequently, if the Dialysis Health Care Worker finds a device to be difficult or awkward to use they may fail to activate the mechanism correctly or they may choose not to use the safety device at all.

### In Summary:

- The safety mechanism should activate during the normal course of AVF removal
- The safety mechanism is an integral part of the needle set.
- The safety mechanism provides one step locking to ensure automatic protection during needle removal.

### The AngelTip Safety Fistula Needle is designed to meet all of the above criteria and recommendations.

For inquiries please call Summit International Medical Technologies, Inc.