

# NIPRO SAFETOUCH TULIP™

## SAFETY AV Fistula Needle Set with Anti-Stick Needle Protector

### CAUTIONS AND WARNINGS:

- Accidental needle dislodgement from patient's access site or disconnection of AV Fistula Needle Set ("AVF") from blood tubing set may result in significant blood loss, which may cause patient injury or death. Accidental needle dislodgements or blood tubing set disconnections MAY NOT be detected by hemodialysis machine's alarm systems. To minimize possible dislodgement or disconnection: Ensure SafeTouch TULIP is safely secured to patient during treatment as suggested in figure 1 or by other physician-validated securement method.
  - Monitor patient's access site and all connections continuously during treatment for evidence of needle dislodgement, blood leakage around access, loose tape, loose connections, air in tubing or leaking from blood tubing set/AVF connections. Take immediate action to prevent any blood leaks or air incursion.
  - Do not obstruct view of patient's access sites or blood tubing set/AVF connections at any time during treatment and maintain visual monitoring continuously throughout treatment.
  - DO NOT cover vascular access or connections with blanket or clothing during treatment.
  - Ensure AVF female luer is securely tightened to blood tubing set male luer. Make connection "finger tight"; do not use hemostats, pliers, or other mechanical means to further tighten connection.
  - Do not use any disinfectant directly on SafeTouch TULIP. Disinfectant use on AVF female luer connector may cause loosening of connection with blood tubing set connector, or may cause leakage due to device damage.
- Do not use SafeTouch TULIP if protective sterility caps are damaged or not in place. Aseptic technique is required during use. DO NOT touch cannula surface at any time. Fluid path and exterior area under cannula tip protector are sterile and non-pyrogenic.
- Do not use if tubing is kinked or if cannula is dented or damaged. These conditions may result in hemolysis.
- Do not use SafeTouch TULIP for any purpose other than cannulating a patient.
- Single use only. DO NOT REUSE.
- SafeTouch TULIP female connectors must be connected to single use blood tubing sets equipped with male locking connectors compatible with ISO 594 part 1. Failure to connect AVF to ISO compliant male luer lock connector may result in unsecured connection, air/blood leakage, or subsequent disconnection.
- Ensure that all connectors on SafeTouch TULIP and any mating connectors (e.g. on blood tubing sets) are free of blood or any other lubricious fluids before connection. Such lubricious fluids include blood, silicone, Betadine, etc. Some medical connectors (e.g. some needleless valves may contain lubricant fluid in their mechanism. Lubricant fluids in such devices can be transferred to other devices when mated and re-transferred to subsequently mated products. Blood or lubricious fluids will compromise mated luer connections and may significantly increase the chance for accidental disconnect.
  - DO NOT allow blood or other lubricious fluids on mating luer surfaces of this AVF or on the male luers on devices, which will be attached to this set.
  - DO NOT use any other medical device in the dialysis procedure that may be attached to this AVF's luer connector or its mated luer connectors unless such device is known to be free of lubricant fluids. Contact the manufacturer of such devices to determine if lubricious fluids are used.
  - DO NOT reverse the arterial and venous patient connectors on the blood tubing set with the female luer connectors of this AVF during dialysis unless all blood is completely removed from this AVF's luer connectors and those of the blood tubing set prior to reconnection. Failure to heed these warnings may result in spontaneous, undetected disconnection of the blood tubing set from this AVF.
- To prevent air emboli ensure all air has been expelled from AVF

- prior to any medical treatment with this device.
- Check vascular access whenever excessive pressures are noted. Stenosis of access and/or improper placement of AVF may cause reduced blood flow resulting in excess positive or negative pressures. Excessive pressures may cause hemolysis. Hemolysis may result in patient injury or death.
- Do not use SafeTouch TULIP to access established constant-site or "Buttonhole" cannulation sites. Use only NIPRO BioHole® Needle Sets for this purpose.
- The needle is extremely sharp. Use extreme caution when handling SafeTouch TULIP to avoid needlestick injuries. DO NOT touch any part of the cannula or attempt to recap.
- When withdrawing AVF from patient, always engage TULIP needle protector according to enclosed instructions.
- TULIP needle protector activates correctly only by a healthcare worker following enclosed instructions. For example, TULIP needle protector does not automatically activate upon accidental needle dislodgment.
- After TULIP needle protector engagement, visually confirm TULIP needle protector is locked over needle and wings are securely held behind locking prongs. Do not attempt to remove needle from TULIP needle protector once it has been locked into place.
- Applying pressure to access site before completely withdrawing needle may result in needlepoint causing intimal damage to vascular access.
- High blood flows through small cross sectional areas may result in hemolysis. Do not exceed positive or negative pressure. Selection of needle gauge and blood flow rates the responsibility of the treating physician.
- Do not use SafeTouch TULIP beyond expiration date printed on package.
- Store SafeTouch TULIP in dry environment at temperatures between 32°F (0°C) and 104°F (40°C).
- Take precautions at all times to prevent exposure to or transmission of infectious agents. Employ universal precautions during patient use and when disposing of SafeTouch TULIP.
- Rx Only. SafeTouch TULIP should be used only as prescribed by a physician.
- Do not cannulate any site that has not been adequately cleansed with appropriate antibacterial agent using physician prescribed/approved skin preparation technique. If this step is omitted, incomplete or inadequate, severe patient infection and/or loss of blood access can result.
- NIPRO provides cannula lengths of 1 inch and 1.25 inches. The depth and diameter of the patient's access must be evaluated in order to choose the correct cannula length. Failure to use the correct cannula length may result in damage to the patient's access and/or injury to the patient.
- Needle must be bevel up for proper TULIP activation.

### INDICATIONS FOR USE:

The NIPRO SafeTouch Tulip is intended for use as a blood access device for blood purification and for other treatments requiring an extracorporeal circuit of larger volumes of blood. Secondly, it is designed with an anti-stick needle protector requiring physical action by the clinician to aid in the prevention of accidental needlesticks. The compatibility of available configurations is the responsibility of the physician in charge.

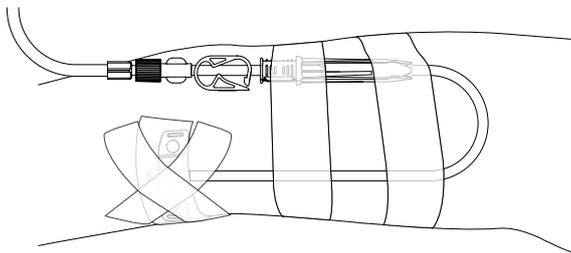
### DIRECTIONS FOR USE:

#### *Cannulation with SafeTouch TULIP:*

- Choose needle gauge and length, rotatable hub or backeye options depending on physician's prescription.
- Remove SafeTouch TULIP from package. Close supplied clamp, or clamp with suitable hemostat ensuring tubing is not damaged by hemostat use. Ensure TULIP needle protector is positioned at luer connector end of AVF so it does not interfere with cannulation procedure.
- To prevent patient infection, follow physician's cleansing prescription, validated facility procedures and antibacterial agent's instructions-for-use to clean patient's access site to be cannulated.
- Follow facility's procedure to prime AVF with physiologic solution (or blood if post-cannulation) to ensure all air is expelled from tubing.
- Inspect patient access according to physician's prescription to determine proper sites for needle cannulation:

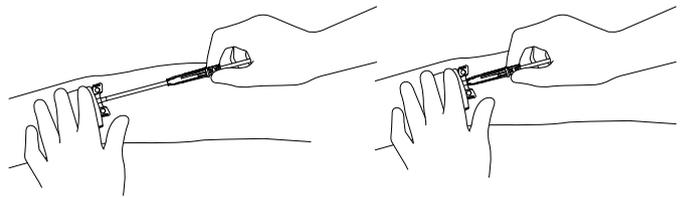
- a. Cannulation with SafeTouch TULIP should assure appropriate site rotation at  $\frac{1}{4}$ " -  $\frac{1}{2}$ " (6 mm -13 mm) distance from previous cannulation sites.
  - b. Determine access blood flow for proper arterial and venous needle placement.
  - c. Listen for bruit and feel for thrill. Do not cannulate if bruit and thrill are not present.
  - d. Arterial needle can be placed pointing either upstream or down stream; venous needle must point in the direction of flow.
  - e. Do not cannulate aneurysms, pseudoaneurysms, or infected areas.
6. Pinch wings together while holding hub between forefinger and thumb. Carefully remove the cannula tip protector by twisting  $\frac{1}{4}$  turn and pulling straight off. Immediately cannulate patient per facility's procedure. Note: To prevent damage to patient's access after inserting needle, do not flip needle bevel within access. If rotation is required, NIPRO offers a rotating hub model.
  7. Securely tape SafeTouch TULIP to patient and initiate treatment per facility's procedure. Tape only using dry tape on clean and dry skin. Monitor continuously for tape's adhesion to device and patient's skin.
  8. During patient treatment, TULIP needle protector should be taped in position as shown in Figure 1.

Removal of AVF from patient and engagement of TULIP needle protector:



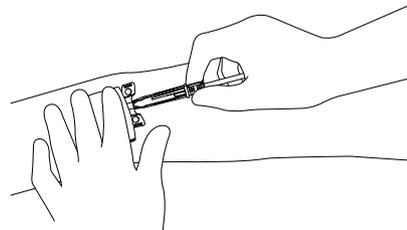
\*\*\*\*Figure 1

1. Upon completion of dialysis, close the clamp, and remove all tape except last piece securing wings. Straighten tubing.
2. Remove last piece of tape and pull needle back slightly to expose cannulation site. Place hemostasis dressing over site and gently hold in place.
3. Slide TULIP needle protector forward until three petals of the TULIP needle protector tip are positioned over the flattened wings. See Figure 2.



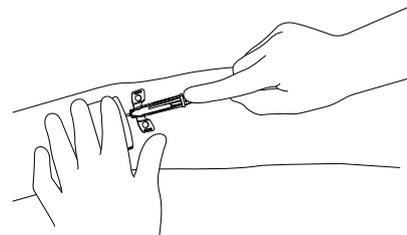
\*\*\*\*Figure 2

4. With one hand grasp the tubing directly behind TULIP needle protector, keeping other hand on hemostasis dressing over cannulation site. See figure 3.



\*\*\*\*Figure 3

5. To withdraw AVF from patient, pull on tubing while pushing TULIP needle protector forward completely covering the needle (keeping needle angle constant) until wings are secured with audible or tactile "Click". Maintain finger pressure on hemostasis dressing. See figure 4.



\*\*\*\*Figure 4

6. Dispose of SafeTouch TULIP in approved biohazard sharp container.

**DISCLAIMER:** NIPRO Corporation is not responsible or liable for any failure of the AVF where such failure is due, in whole or in part, to any misuse or modification of the set or its operation, including, without limitation:

- Failure to have all operating procedures performed by a fully trained and qualified person;
- Failure to use the set with compatible hemodialysis blood tubing sets or other medical equipment;
- Failure to operate at all times in accordance with the warnings, precautions, and instructions contained in this document;
- AVF reuse or use with a reused bloodline.



**NIPRO**

**NIPRO CORPORATION**

3-9-3 Honjo-Nishi, Kitaku, Osaka 531-8510, Japan

Distributed by: **NIPRO MEDICAL CORPORATION**

3150 N.W. 107 Ave, Miami, Florida 33172 US

TEL: (305) 599-7174

MADE IN THAILAND