

NIPRO BIOHOLE™ NEEDLE WITH CAPICK™ SCAB REMOVER

For Constant-Site (buttonhole) Access

CAUTIONS AND WARNINGS

1. DO NOT USE BioHole Needle TO ESTABLISH CONSTANT-SITES (also known as buttonhole access sites) OR USE FOR CANNULATING THROUGH INTACT SKIN. BioHole Needle is only for use with mature AV fistula constant-sites. Needle dullness is unsuitable for such use and could cause permanent damage to patient's blood access. Use only sharp needles such as NIPRO AV Fistula Needles to establish a constant-site access.
2. Accidental needle dislodgement from patient's access site or disconnection of BioHole Needle from blood tubing set may result in significant blood loss which may cause patient injury or death. Accidental needle dislodgements or bloodline disconnections may not be detected by hemodialysis machine's alarm systems. To minimize possible dislodgement or disconnection:
 - a. Ensure BioHole Needle is safely secured to patient during treatment.
 - b. Monitor patient's access site and all connections continuously during treatment for evidence of needle dislodgement, blood leakage around access, loose tape, loose connections, and air in tubing or leaking from bloodline/needle connections. Take immediate action to prevent any blood leaks or air incursion.
 - c. Do not obstruct view of patient's access sites or bloodline/needle 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.
 - d. Ensure BioHole Needle 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.
 - e. Use only aqueous-based solutions such as povidone-iodine solution if required to wipe this device. The use of an alcohol or solvent-based solution may adversely affect the device tightness (connector integrity) resulting in leakage.
3. Do not use BioHole Needle 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 protective sterility caps of cannula are sterile and non-pyrogenic.
4. Do not use if tubing is kinked or if cannula is dented or damaged. These conditions may result in hemolysis.
5. Do not use BioHole Needle for any purpose other than cannulating a patient.
6. Single use only. DO NOT REUSE.
7. BioHole Needle female connectors must be connected to single use blood tubing sets equipped with male locking connectors compatible with ISO 594-2. Failure to connect BioHole Needle to ISO compliant male luer lock connector may result in unsecured connection, air/blood leakage, or subsequent disconnection.
8. To prevent air emboli ensure all air has been expelled from BioHole Needle prior to any medical treatment with this device.
9. Check vascular access whenever excessive pressures are noted. Stenosis of access and/or improper placement of BioHole Needle 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.
10. Use caution when handling BioHole Needle. DO NOT touch any part of the needle or attempt to recap.
11. Applying pressure to access site before completely

- withdrawing needle may result in the needle's point causing intimal damage to vascular access.
12. High blood flow through small cross sectional areas may result in hemolysis. Do not exceed positive or negative pressures.
13. Store product in a cool, dry environment (5° C/41° F to 40° C/104° F, 20% to 80% humidity) away from direct sunlight, extreme temperature and humidity.
14. Take precautions at all times to prevent exposure to or transmission of infectious agents. Employ universal precautions during patient use and when disposing of BioHole Needle.
15. Rx Only. BioHole Needle should be used only as instructed by a physician.
16. Selection of needle gauge and blood flow rate is the responsibility of treating physician.
17. 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.

INDICATIONS:

The NIPRO BioHole Needle is indicated for use as an access device for dialysis procedures using a constant-site technique of needle insertion with an established, mature constant-site also known as a buttonhole access site.

CONTRAINDICATIONS:

Do not use with AV Grafts.

DIRECTIONS FOR USE:

The BioHole Needle is to be used for dialysis procedures using the constant-site (buttonhole) technique of needle insertion. The term constant-site refers to the technique of needle insertion in which a scar tissue tunnel track is formed to allow repeated access to the exact same site. The constant-site (buttonhole) is initially created by approximately six cannulations using a sharp needle, such as NIPRO AV Fistula Needle. Since the BioHole Needle features an antistick dull bevel; it is used only for cannulations through the established constant site.

It is important to cannulate the developing constant-site in the exact same place using the same insertion angle and depth of penetration each time. This requires that a single cannulator perform all cannulations until the sites are well established. Once the sites are well established anyone familiar with the constant-site (buttonhole) technique should be able to perform the cannulations.

1. Choose needle gauge and length, rotatable hub or backeye options depending on physician's prescription.
2. Remove BioHole Needle from package. Close supplied clamp or clamp with suitable hemostat ensuring tubing is not damaged by hemostat use.
3. 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.
4. Follow facility's procedure to prime BioHole Needle with physiologic solution (or blood if post-cannulations) to ensure all air is expelled from tubing.
5. Inspect patient constant-site access sites according to physician's prescription.
Evaluate the fistula:
 - a. Determine access blood flow for proper arterial and venous needle placement.

- b. Listen for bruit and feel for thrill. Do not cannulate if bruit and thrill are not present.
 - c. Arterial needle can be placed pointing either upstream or downstream; venous needle must point in direction of flow.
 - d. Do not cannulate aneurysms, pseudoaneurysms, and infected areas.
6. Remove any scab that has developed over constant-site prior to accessing with BioHole Needle
 - Scab removal may be easier if scabs are softened with lotion, isopropyl alcohol wipes, or saline soaked gauze prior to removal.
 - Stretch skin in all directions around scab to loosen edges.
 - Remove CAPICK Scab Remover from the BioHole Needle Tip Protector using aseptic technique.
 - Slide either slanted edge of CAPICK BioHole Scab Remover under loosened scab edge and lift scab up and off.
 - Complete scab removal is imperative to decrease the risk of infection and for proper BioHole Needle/ scar tissue tunnel alignment.
 - Use one CAPICK Scab Remover per constant-site.
 - Cleanse constant-site after scab removal and before cannulation.
 7. Pinch wings together while holding hub between forefinger and thumb, carefully remove needle tip protector by twisting 1/4 turn and pulling straight off.
 8. Align BioHole Needle cannula, with bevel facing up, over constant-site and pull the skin taut.
 9. Carefully insert BioHole Needle into established constant-site. Ensure the same angle and depth of insertion is used consistently during each cannulation.
 10. Advance BioHole Needle along scar tissue tunnel track. If mild to moderate resistance is met, rotate needle as you advance it using gentle pressure.
 11. "Flashback" of blood will appear in tubing when needle is in access. Lower angle of insertion. Continue to advance BioHole Needle in AV fistula until appropriately positioned within vessel.

Note: to prevent damage to patient's access after inserting BioHole Needle, do not flip needle bevel within access. If rotation is required NIPRO offers a rotating hub BioHole Needle.

- a. Backeye Bevel Type: Backeye hole functions as additional flow path to permit sufficient flow rate.
 - b. Rotating hub Type: Black dot on needle hub indicates bevel facing up and red dot indicates bevel facing down.
12. Securely tape BioHole Needle to patient and initiate treatment per facility's procedure. Use only dry tape on clean and dry skin. Monitor continuously for tape's adhesion to BioHole Needle and patient's skin.
 13. Upon completion of dialysis, close clamp and remove all tape except last piece securing wings. Straighten tubing.
 14. Remove last piece of tape and pull needle back slightly to expose cannulations site. Place hemostasis dressing over site and gently hold in place.
 15. To withdraw BioHole Needle from patient, grasp tubing and pull smoothly and continuously while keeping needle angle constant.
 16. Maintain double finger pressure on hemostasis dressing per facility's procedure.
 17. Dispose of BioHole Needle in approved biohazard sharps container.

DISCLAIMER

Nipro Medical Corporation is not responsible or liable for any failure of the BioHole Needle 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;
- BioHole Needle reuses or use with a reused bloodline.



NIPRO CORPORATION
3-9-3, Honjo-Nishi, Kita-Ku, Osaka, Japan



NIPRO EUROPE N.V.
Weihoek 3H, B-1930 Zaventem, Belgium

Distributed in North America by :

NIPRO MEDICAL CORPORATION
3150 N.W. 107th Ave, Miami FL33172 USA TEL (305) 599-7174

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

MADE IN THAILAND

Questions? Comments? Call 1-888-647-7698

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