NIPRO

EN

BIOHOLE™

BUTTONHOLE DEVICE

<Instructions for Use>

Prior to use, please read the Instructions for Use carefully.

Indications

The device is used to form a fixed puncture route (buttonhole) for devices that require vascular access for hemodialysis, etc., as required for renal patients.
The device must be used by a healthcare professional licensed or qualified to indwell or remove the device.

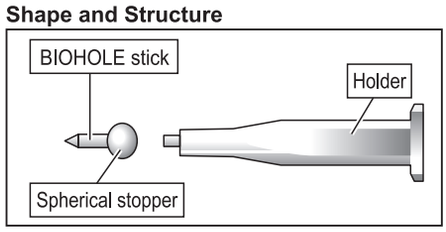
Contraindications

- Do not re-use.
- This device must not be used if the outside packaging is damaged or if the product inside shows damage or irregularities.

Clinical Benefits

The artificial fixed puncture route (buttonhole) mitigates pain for the dialysis patient and simplifies preparations for vascular access, thus improving the quality of life of the renal patient.

Shape and Structure



Cautions

1. Re-use of the device may lead to infection by contamination.
2. Take care to avoid adhesion of medicine containing organic solvent such as alcohol. (It may result in deformation or cracks.)
3. Wear gloves and eye protection to reduce the risk of coming into contact with blood as there is always a possibility that blood will leak from the product when inserting or removing the product.
4. While the BIOHOLE stick is indwelling refrain from activities in which the BIOHOLE stick could get wet, such as taking a bath, entering a sauna, or swimming. Wear a plastic bag or sheet on the arm while taking showers when the BIOHOLE stick is in place.
5. If swelling, redness or throbbing subsequently develops at the puncture site and/or if a fever results those could be a sign of infection and a physician or appropriate medical person should be immediately contacted.
6. Dispose of the device in an approved biohazard container as per facility protocol.
7. Any incidents shall be reported to the manufacturer and the competent authority of your State.
8. Do not use if package is damaged.
9. If the device is exposed to abnormal conditions (for example, high temperature and humidity) or if it is unintentionally opened before use, do not use the device.

Performance and Specification

Product code	BIOHOLE stick outer diameter (mm)	BIOHOLE stick total length (mm)
BH KIT S3MM CE GA	1.65	3.00
BH KIT S5MM CE GA	1.65	5.18
BH KIT S8MM CE GA	1.65	8.00

Instructions for Use

1. First, perform a standard dialysis treatment.
2. After completing the dialysis treatment, remove the fistula needle, stop the bleeding and then wait at least five minutes.
3. Remove a BIOHOLE stick and holder from its packaging.
4. Ensure that the BIOHOLE stick is securely loaded into the holder.
5. Thoroughly disinfect the puncture area with an alcoholic cotton swab and then apply povidone-iodine solution.
6. Insert the BIOHOLE stick connected to its holder into the puncture site left by the fistula needle on the skin surface.
7. After inserting the BIOHOLE stick into the puncture site, grip the spherical stopper on the BIOHOLE stick (using forceps or similar equipment if required), and remove the holder from the BIOHOLE stick.
8. Place a waterproof adhesive plaster with pad over the spherical stopper of the BIOHOLE stick to fix the stick in place. To ensure that the inserted puncture site does not get wet, place another waterproof adhesive plaster over the first. The patient can then be sent home.
   Because the tip of the BIOHOLE stick does not penetrate the blood vessel, the possibility of infection is low and so the patient can lead a normal daily life with the BIOHOLE stick. If a physician judges that there is a risk of infection, the arm should be covered with a plastic bag or similar. If the adhesive plasters start to peel at any time, the patient must seek medical advice. Patients should be instructed that if swelling, redness or throbbing subsequently develops at the puncture site and/or if a fever results those could be a sign of infection and the physician or appropriate medical person should be immediately contacted.
9. Patients must be instructed while the BIOHOLE stick is indwelling to refrain from activities in which the BIOHOLE stick could get wet, such as taking a bath, entering a sauna, or swimming and to wear a plastic bag or sheet on the arm while taking showers while the BIOHOLE stick is in place.
10. At the time of the next dialysis treatment, remove the BIOHOLE stick first. After removing the BIOHOLE stick and performing dialysis, check to make sure there is no bleeding, and disinfect the puncture area with an alcoholic cotton swab and one after each dialysis treatment. BIOHOLE stick is inserted into the puncture tunnel left by the removed stick.
    During the BIOHOLE stick indwelling period, two methods can be used to puncture an access blood vessel. One is to puncture the access flood vessel using a standard fistula needle at puncture sites away from the indwelling site of the BIOHOLE stick. Another method is to puncture the access blood vessel using a dull fistula needle (the initial and final punctures in a new area are always made using a standard fistula needle), through the puncture tunnel left by the removed BIOHOLE stick. Perform the dialysis treatment as usual and after bleeding has stopped insert a new stick in accordance with the replacement procedure detailed above. This method is used for patients with whom it has been difficult to find a suitable puncture site other than the indwelling site of the BIOHOLE stick. In this method the puncture tunnel is not yet firmly established so the puncture tunnel can be easily damaged causing blood leakage from between the dull fistula needle and the skin during the dialysis treatment. In this case we recommend the former method for forming the buttonhole using the BIOHOLE stick. In both methods, the BIOHOLE stick should be replaced with a new BIOHOLE stick after each dialysis treatment. We recommend that BIOHOLE sticks are left in place from 10 to 30 days in total. In general it takes 14 days to form the buttonhole using the BIOHOLE stick.
11. The puncture of the access blood vessel following completion of the BIOHOLE stick indwelling period is then via the buttonhole using a dull fistula needle.

Guarantee

This device is manufactured under strict quality controls. In no event shall Nipro be responsible for damages resulting from death or injury to a patient or any other person or damage to any object attributable to the transportation, storage and manner of insertion or removal of the device. Furthermore, Nipro shall not be responsible nor liable for any damages arising out of injury or death to patients if this device is used after the expiry date printed on the packages. Nor shall Nipro be responsible for damages arising out of injury or death if said injury or death is caused by the utilization of this device.

Symbols used for labeling

STERILE R Sterilized using irradiation

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MADE IN JAPAN CE 0123

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