GOODTEC Y-CONNECTOR SET

ENGLISH

Warning
1. Only use this device after air has been completely removed from lumen. Complications such as air embolism may occur.
2. The fixed valve should be in the closed position when negative pressure is applied to the Y-connector to prevent air from being drawn into the device. Complications such as air embolism may occur.
3. Both hemostatic valve and fixed valve should be completely open when inserting or removing catheters or other medical devices. Damage may occur to Y-connector and/or catheter, etc.
4. Ensure that air has been entirely removed from catheter, etc. prior to insertion into Y-connector. Complications such as air embolism may occur.

Contraindications
1. Contraindications for use
   (1) This product is sterilized, is not reusable and must not be re-sterilized. Re-sterilization could lead to infection of patient or degradation of the material characteristics of the device.
   (2) This product should only be used in facilities which are capable of performing emergency coronary artery bypass grafting (CABG) as a provision against complications that may cause injury and serious complications that could prove life threatening.
   (3) This product is a medical device and should only be used by physicians who are trained in the procedures of coronary angiography (CAG) and percutaneous transluminal coronary angioplasty (PTCA).
   (4) If any resistance is felt when opening the fixed valve, immediately stop rotating valve. Damage to Y-connector may occur.

2. Prohibition of combination use with medicine, medical equipment
   (1) Not to be used with products comprising of organic solvent, fat emulsion, or oil-based components. It may incur damage to product.
   (2) Injection pressures of greater than 3448kPa (500psi) should not be performed when infusing contrast media. Excessive pressure may cause damage to product.

Shape/Construction
YOK0A includes a combination of Y-connector, inserter and torque device and YOK0E includes a combination of Y-connector, inserter, torque device and extension tube.

1. Product Summary
   (1) Y-connector
   The Y-connector is attached to a device such as a guiding catheter for the purposes of reducing blood leakage and for fixation of devices inserted into the vasculature. Simultaneously, a channel is provided for obtaining blood pressure measurement or the introduction of drug solution/contrast media.
   (2) Inserter
   The inserter facilitates smooth introduction of guide wires into the Y-connector without causing damage to the tip shape.
   (3) Torque device
   The torque device is attached appropriately to the proximal section of the guide wire in order to assist in delivery of guide wire to target lesion. The torque device provides for easy gripping when rotating or manipulating the guide wire.
   (4) Extension tube
   The extension tube is attached to the sideport and other devices used for passing contrast media and other solutions used in CAG and PTCA procedures.

2. Construction
   (1) GOODTEC Y-connector
   (2) Inserter
   (3) Torque Device
   (4) Extension tube

3. Principles of operation
   (1) Hemostatic valve
   Pushing the opener in the direction of the hemostatic valve opens the device and pulling it in the other direction closes it. Pushing the opener and turning in a clockwise direction locks the device in an open position. While the hemostatic valve is closed, blood loss during catheter manipulation is kept to a minimum.
   (2) Fixed valve
   Rotating the screw in a right direction closes the valve while rotating in a left direction opens it. With the fixed valve in a closed position, catheter positioning can be fixed and introduction of contrast media or drug solution is possible.

Purpose
This product is designed to work in conjunction with guiding catheters, etc. to reduce blood loss while assisting in manipulation of catheters, etc., injection of contrast solution from a side port, injection of medicine or saline solution, and measurement of blood pressure.

Specifications
1. Inserter tensile strength: >19.6N
2. Torque device guide wire fixation strength: >9.8N
3. Main Branch ID: 3.33mm/10Fr (The ID of the valve segments are less than 3.33mm/10Fr.)

1/2
Method of use

1. All equipment and devices to be used should be carefully inspected and proper functionality confirmed prior to use.
2. A line is attached to the Y-connector side port for the purpose of obtaining blood pressure measurement, introduction of contrast media, or medication.
3. In order to eliminate air from within the Y-connector, the hemostatic valve and fixed valve should be in the open position, a finger placed across the rotator opening and heparinized saline flushed through the side port.
4. In order to avoid the introduction of air after emission, flushing should be performed while closing the hemostatic valve, and the Y-connector should be filled with heparinized saline.
5. The Y-connector rotator section is attached to the guiding catheter hub.
6. When introducing a guide wire into the Y-connector, the tip of the guide wire should be placed within the inserter, the hemostatic valve opened and the inserter placed deep within the Y-connector.
7. After insertion, the inserter should be removed while leaving the guide wire in place and the hemostatic valve closed.
8. The torque device is attached to an appropriate position on the guide wire, the guide wire advanced to the target lesion and the torque device removed from the guide wire.
9. For introducing catheters after being placed on the guide wire, the Y-connector hemostatic valve should be opened and the catheter inserted. After insertion of the main catheter component, the hemostatic valve should be closed and catheter delivered to target location.
10. When catheter, etc. reaches target location, the fixed valve may be closed to fixate the catheter.

Precautions for use

1. Precautions prior to use
   (1) Be sure to reference IFU's accompanying all medical devices or products to be used jointly with this device.
   (2) Confirm the compatibility of this device and other medical devices to be used in regards to the procedure.
   (3) If the package or product is damaged or contaminated, do not use the product.
   (4) All devices, use should be undertaken in a sterile environment.

2. Precautions during use
   (1) The hemostatic valve is designed to facilitate catheter delivery, and will not completely eliminate blood loss, but is instead designed to minimize it. Conditions of use will determine volume of blood loss.
   (2) Introduction of contrast media or drug solution through the Y-connector should be performed with the fixed valve in a closed position and within the provisions of infusion pressure. Exceeding infusion pressure may result in the leakage of contrast media or drug solution.
   (3) Do not over tighten the fixed valve when fixing catheters into position. Damage to catheter may occur.
   (4) If resistance is felt when introducing catheters through the Y-connector, immediately cease insertion and confirm the cause of the resistance. Damage to catheter may occur.
   (5) The hemostatic valve of the OKAY II type product is not constructed to close automatically. The opener must be pulled to the proper position by hand when closing the hemostatic valve.
   (6) The inner lumen and outer casing of the Y-connector should be regularly flushed with heparinized saline. Contrast media and/or blood may adhere to device, affecting closing functionality of the hemostatic valve and/or the fixed valve.
   (7) Should the hemostatic valve closing function be affected by contrast media or blood adherence, blood loss can be controlled through manipulation of the fixed valve when inserting catheters.
   (8) When an extension tube is utilized, do not over tighten connection. Damage to y-connector extension tube may result.

3. Precautions post use
   Dispose of this product as medical waste, while considering the prevention of infection.

4. Adverse event
   - Hypotension/hypertension
   - Hemorrhagic complications
   - Infection
   - Air embolism

Storage method, shelf life and Other

1. Storage method
   (1) Store the product in a room temperature location not exposed to high temperature and humidity or direct sunlight and take proper precautions to ensure product does not contact water.
   (2) Avoid inclinations, vibrations and impacts (including during transportation) and store in a safe, stable environment.
   (3) Do not store near chemicals or in areas where the device may be exposed to gases.

2. Shelf-life
   Use this product before the "expiration date" shown on the package label.

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