INFLATION DEVICE

Instruction for use

Sterile (sterilized with ethylene oxide). Do not re-sterilize. For single use if the packaging is opened or damaged. Use before the expiry date shown on the packaging. Use with balloon dilatation catheters. Read the instructions before use. Store away from light in a cool and dry place.

Caution

Federal (U.S.A) law restricts this device to use or on the order of a physician.

Reuse of the Flamingo is strictly prohibited. If a product is reused its functionality would be entirely altered. In addition, the iatrogenic risk from inter-patient cross-transmission would be high.

Description

Flamingo is an inflation device for single use. It's consisting of a 20 cc syringe body with a plunger which may be engaged by a control button, a rotatory handle, a manometer and a high pressure connector with a rotating male luer lock. The manometer is graduated between vacuum and 30 atm with an equivalent scale in PSI. There are two gripping choices by changing manometer's position.

Indication

Flamingo inflation device is intended for use during cardiovascular procedure to create, maintain and monitor pressure in the balloon catheter.

Operation

The plunger is free to move when the control button is rocked towards the back of the device (opposite point of manometer). To lock the plunger, push completely on the control button towards the manometer. Turn the handle clockwise to inject the mixture of contrast media. The estimated pressure is indicated on the manometer.

Preparation

1. Prepare the mixture of contrast media for balloon catheter following the manufacture's recommendations for the contrast media.
2. Check the plunger is unlocked
3. Hold the Flamingo with its manometer downwards and insert the end of connector into the contrast solution to fill the syringe
4. Hold the device with the manometer upards to purge the air contained in the syringe and in the connector.
5. Connect the Flamingo to the balloon catheter.
6. To inflate the balloon catheter, point the manometer downwards and slowly the handle clockwise up to posting of desired pressure. This pressure is kept thanks to the locking system.
7. To deflate the balloon catheter, unlock the plunger and pull completely the handle.

Precautions for use

The Flamingo must be used by doctor. Before each inflation, confirm the needle of the manometer is set to the zero position +/-1 atm. When releasing the deflation, it is recommended to go with the handle. If the control knob can't return in unlocked position, turn the handle anticlockwise to deflate the balloon catheter. Refer to the balloon catheter instructions for use (precaution for use, maximum pressure, ect.)

If the key is difficult to clock, do not force it as this could damage the plunger. Turn the handle gently and re-engage the key.

Kflow® Epic® SHORT TERM HAEMODIALYSIS CATHETER KIT

INSTRUCTION FOR USE

Warning

The implantation technique has a significant influence on the complications and outcome of the device. Implantation must be performed by a competent and experienced catheter insertion team. Inexperienced personnel should not be permitted to perform the implantation except under the direct supervision of an experienced physician or surgeon.

Intended use

Sterile single use device indicated for use in attaining short term access for Hemodialysis or aphaeresis.

Caution

Federal law (USA) restricts this device to sale by or on the order of a physician

How supplied

The device is sterilized by Ethylene Oxide. Contents are sterile and non-pyrogenic in unopened undamaged package. Do not use catheter if package has been damaged or has been opened.

Storage

Store at room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet lights, rotate inventory so that catheter are used prior to expiration date on package label.

Contraindication

The devices are contraindication as follows:

- The catheter should not be place in patient with bleeding disorders
- When the presence of the other device related infection, bacteraemia or septicemia is known suspected.
- If sever chronic obstructive lung disease exists
- Post irradiation of prospective insertion site
- Previous episode of venous thrombosis or vascular surgical procedure at the prospective placement site have occurred.
- Local tissue factors will prevent proper devices stabilization and/or access.

Device description

The short term Hemodialysis catheter are radiopaque and made from polyurethane catheter. The catheters are semi rigid but become softer at body temperature. Catheters tube profile can be single, dual or triple lumen. The catheter is tapered tipped with softer material. Catheter shape can be with both straight tube and extension, straight tube and J shape extension or pre-cur