ANGIOGRAPHIC CATHETERS

INSTRUCTION FOR USE

U.S. Federal Law restricts the sale of the device to use under physician's prescription only.

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ANGIOGRAPHIC CATHETERS is intended for single use. The reprocessing and reuse of single-use products pose the risk of bacterial growth, contamination, patient injuries and could lead to death. Faulty clean, re-sterilization and tests may allow the transmission of infectious disease between patients; may alter device’s mechanical properties and thus risk product failure. It is the end user’s responsibility to read and understand the important warnings and to ensure the single use of medical devices. Do not reuse. ANGIOGRAPHIC CATHETERS is single patient use only and MUST be replaced for each patient.

The BIOTEQ ANGIOGRAPHIC CATHETERS are intended for use in the delivery of radiopaque contrast media to the selected sites, such as Coronary Arteries or Peripheral vascular systems. The use of those catheters for the neurovasculature is not included.

This medical device is used only by Trained doctors and nurses.

1. With the puncture needle to puncture the blood vessel.
2. Inserted the guide wire (recommended max. size: 0.038") into the puncture the blood vessel.
3. To remove the puncture needle.
4. Inserted the sheath introducer (recommended max. size: 6Fr) into the guide wire.
5. Leave sheath and pull out introducer.
6. Inserted the catheter forward into the blood vessel go along with the guide wire.
7. The catheter tip will take shape in the main artery or the main artery difference department.
8. Confirmed the catheter into the purpose blood vessel.
9. To remove the guide wire.
10. Inject streams of contrast agents into the area of interest using catheters to create detailed images of the blood vessels, in order to the angiographic procedure.

For single use. Do not reuse and resterilize. Use prior to the “Use Before” date. Refer to accompanying Instruction for use.
Cautions

- Store in a dark, dry and cool place.
- Avoid extended exposure to light
- Non-pyrogenic

Warnings

1. Operating pressure don’t exceed products max flow rate that show at the label.
2. Please pay attention to during push and pull out while operating the catheter. When meet the strength of resisting, please stop the operation of the catheter temporarily, operate again after excluding from resisting the strength reason.
3. Don’t be used in the operation of the artificial blood vessel as much as possible may cause the infection or hurt the artificial blood vessel.
4. Extreme care must be exercised during manipulation and withdrawal to prevent pulling catheter apart.

Precautions

1. While using a product, please with operate while being aseptic, it is prevent possibility produced pollute.
2. Please leave going on in the X-rays while using a product.
3. Please carry on the step of washing of the standard of a product before using.
4. This product front should not contact the vapor temperature, prevent being out of shape.
5. Please choose the tip configuration of a product in accordance with the disease.
6. Forcible insertion of the catheter may cause tissue damage. If insertion is difficult, discontinue the use and take appropriate measures.
7. If abnormalities are noted discontinue the use immediately and take appropriate measures.
8. Forcible insertion or extraction may cause damage on the product. Attention should be fully paid for performing the procedures.

Contraindications

1. Store in a cool dry place.
2. Protect from ultraviolet light.
3. Do not use the product if its package has been damage or if abnormalities of the product are noted.
4. Avoid wetting and store the product cleanly protecting from direct sunlight, high temperature, high humidity, radiation, etc.
5. This is a single use product sterilized with ethylene oxide. Do not reuse it.
6. Handle the product carefully and avoid forceful stretching etc.
7. Use this product immediately after opening the package. After use, deposit it in a safe manner.
8. The effective period of this product is 3 years when stored appropriately.
9. Do not modify this product.