**INSTRUCTIONS FOR USE**

1. **Prepare the PTCA catheter for use:**
   - Make sure the plunger is secured to the syringe.
   - Disconnect the balloon from the catheter.

2. **Insertion:**
   - Insert the PTCA catheter over the guidewire and into the lesion.
   - Advance the dilatation catheter until the appropriate proximal marker marks the hemostatic valve hub. This indicates that the dilatation catheter tip has reached the guiding catheter tip.

3. **Advance the balloon catheter over the guidewire into the lesion:**
   - During the procedure, appropriate anticoagulant and coronary vasodilator drugs should be provided to the patient as needed. After the procedure, the anticoagulant therapy should be continued for a period of time as determined by the physician.

4. **Discard all disposable devices used during this procedure per local requirements for medical device waste disposal.**

5. **Use only the recommended balloon inflation medium.**

6. **Operate under high resolution fluoroscopy.**

7. **Discard the dilatation catheter out of the hemostatic valve, and tighten valve onto the guidewire to hold it securely in place.**

8. **Prepare the next dilatation catheter to be used, as previously described under the Instructions for Use Section, Step 4, and continue the procedure accordingly.**

**REFERENCES:**

1. The physician should consult recent literature on current medical practice on balloon dilation, such as that published by ACC/AHA.

2. **DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY:**

   - OrbusNeich Medical is not responsible for any direct, incidental, or consequential damages resulting from the misuse of the device.

   - **Manufacturer:**
   - **EU Authorized Representative:**
   - **Quality First International Limited**
   - **Sapphire is a registered trademark of OrbusNeich Medical**

**EXPLANATION OF SYMBOLS**

- **Description**
- **Catalog Number**
- **Lot Number**
- **Balloont Diameter**
- **Balloont Length**
- **Sterilized Using Ethylene Oxide**
- **Use By**
- **Do Not Reuse**
- **Consult Instructions For Use**
- **Do Not Resterilize**

**Conformity to the Council Directive 93/42/EEC**

- **Concerning Medical Devices**

- **www.OrbusNeich.com**

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