

Trans-PTCA Kit
PTCA 'Y' Connector Kit
Instructions for use

Manufacturing Facility



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PRODUCT DESCRIPTION

The 'Trans-PTCA Kit' is a PTCA 'Y' Connector Kit.

DEVICE COMPONENT DESCRIPTION

Trans-PTCA Kit is a set of accessorial devices, which is mainly used to help the guide wire enter into the patient's body in angiography diagnosis and many other procedures.

The disposable Trans-PTCA Kit is composed of single Y connector, insertion tool and torquer. Among them, the single Y connector is used to assist the guide wire to enter into patient's body. The single Y connector has two different structures: one is that whose Y branch is with spiral luer lock of 6:100 through which the liquid medicine can be transferred; another is that whose Y branch is extended by the pressure tube and a stopcock which can perform the function of extending the device and transfusing more than one kind of liquid medicine. The insertion tool help straighten guide wire in various shapes. The torquer is fixed at the end of the guide wire and facilitates entry of guide wire into patient's body.

TRANS PTCA KIT: Product Matrix with product reference No.

Ref No.	Type	Size	Extension Tube
PTIT37233	Push/Pull Type	7F(2.33mm)-0.092"	with Removable Extn
PTIT38267	Screw Type	8F(2.67mm)0.105"	with Removable Extn
PTIT39300	Push/Click Type	9F(3.00mm) 0.118"	with Removable Extn
PTIT27233	Push/Pull Type	7F(2.33mm)0.092"	with Fixed Extn
PTIT28267	Screw Type	8F(2.67mm) 0.105"	with Fixed Extn
PTIT29300	Push/Click Type	9F(3.00mm) 0.118"	with Fixed Extn

INDICATIONS

- Procedure in which needing entry of guide wire into patient's body.
- Angiography diagnosis that needs entry of guide wire into patient's body.

CONTRAINDICATIONS

None

WARNINGS

- This product is ETO sterilized. The package must be inspected on its status and it shall not be used if the package is broken;
- This product is disposable and it shall be used immediately after being unfolded and must not be used again;
- This product must be used within its validity period. Check the validity period before use and no use when it is beyond validity period;
- This product is of various specifications and that proper specification shall be chosen.

NOTICES BEFORE USING

- This product must be used by professional doctors who must be familiar with instruction for use of this product;
- Before applying this product, the single Y connector and torque device shall be sealed well, the insertion needle and torquer shall be smooth and the guide wire shall be able to pass through them freely.

INSTRUCTION FOR USE

Preparation before using

- Connect a manifold to sidearm of a single Y connector by connective tubing.
- Fill and flush the single Y with normal saline.
- Prepare interventional devices (balloon catheter and guide wire) according to the manufacturer's instructions.

Operating haemostatic valve (Screw Y Connector)

- Connect male luer of a single Y connector to female luer of a guiding catheter.
- Aspirate the system to remove any trapped air and flush thoroughly with saline.
- Rotate bore clockwise to open condition.
- Insert guide wire through open bore (if desired and possible, insert insertion tool and advance it through bore).
- Remove insertion tool, if it was inserted before.

- Rotate top cap of a torquer to open, insert the end of guide wire into torquer's hole.
- Rotate bore counter clockwise to a position that balloon catheter and guide wire can move into blood vessels without blood leaking.
- Once balloon catheter and guide wire are in place, if desired, rotate bore counter clockwise to allow for liquid injection from sidearm and/or secure the interventional devices in position.

Operating haemostatic valve (Push –pull YConnector)

- Connect male luer of single Y connector to female luer of guiding catheter.
- Aspirate the system to remove any trapped air and flush thoroughly with saline.
- Push bore in open condition.
- Insert guide wire through an open bore (if desired and possible, insert insertion tool and advance it through bore).
- Remove insertion tool, if it was inserted before.
- Rotate the top cap of torquer to open, insert the end of guide wire into torquer's hole.
- Pull bore to close valve. Move balloon catheter and guide wire in blood vessels when valve is in close position, which also allow for liquid injection from sidearm.

Operating haemostatic valves (Y clickConnector)

- Connect male luer of single Y connector to female luer of guiding catheter.
- Aspirate the system to remove any trapped air and flush thoroughly with saline.
- Press bore to open condition.
- Insert guide wire through an open bore. (If desired and advance it through the bore).
- Remove insertion tool, if it was inserted before.
- Insert guide wire through an open bore1. (If desired and possible, insert insertion tool and advance it through bore).
- Remove insertion tool, if it was inserted before.
- Rotate bore2 clockwise in open condition.
- Insert guide wire through an open bore2. (If desired and possible, insert insertion tool and advance it through bore).
- Remove insertion tool, if it was inserted before.
- Rotate the top cap of torquer to open, insert the end of guide wire into torquer's hole.
- Rotate bore1 and bore2 counter clockwise to a position that balloon catheter and guide wire can move into blood vessels without blood leaking.
- Once the interventional devices are in place, if desired, close bore1 and/or bore 2 counter clockwise to allow for liquid injection from sidearm and/or secure the interventional devices in position.

Operating homeostatic valve (Double Screw YConnector)









- Connect male luer of single Y to female luer of guiding catheter.
- Aspirate the system to remove any trapped air and flush thoroughly with saline.
- Rotate Bore1 clockwise in open condition.
- Insert guide wire through an open bore1. (If desired and possible, insert insertion tool and advance it through bore).
- Remove insertion tool, if it was inserted before.
- Rotate bore2 clockwise in open condition.
- Insert guide wire through an open bore2. (If desired and possible, insert insertion tool and advance it through bore).
- Remove insertion tool, if it was inserted before.
- Rotate the top cap of torquer to open, insert the end of guide wire into torquer's hole.
- Rotate bore1 and bore2 counter clockwise to a position that balloon catheter and guide wire can move into blood vessels without blood leaking.
- Once the interventional devices are in place, if desired, close bore1 and/or bore2 counter clockwise to allow for liquid injection from sidearm and/or secure the interventional devices in position.









Note: Hemostatic valves with two bores allow easier manipulation and control of interventional devices during “kissing balloon” or “kissing stent” procedures.

PACKAGING

- **Sterile:** The device is sterilized with ETO gas.
- **Contents:** Trans –PTCA Kit – PTCA ‘Y’ connector kit
- **Storage:** Store in a cool, Dark, dry place below 40°C

SYMBOL

Description	Symbol
Reference No.	
Batch No.	
Type	XXXX-XXXX Type
Manufactured Date	 YYYY MM
Use By	 YYYY MM
Sterile and Method of sterilization	
Single use only & do not re-sterile	
Storage condition	
Medical Device	

Description	Symbol
Name of Manufacturer	
Content : Trans-PTCA Kit	
Size	XX FR
Do not use if package open or damaged	
Keep away from direct sun light	
Keep dry	
Warning / Attention: See Instructions for Use	
Pyrogen free	
Single Sterile barrier system	

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