

Push-Click Y Connector Kit

Instructions for use

Revision History:

Rev.	Revised contents	Release data
A/0	Initial release.	2023.11.29
A/1	Delete the specification table	2024 -05- 3 0

Push-Click Y Connector Kit Instructions For Use

Please read instructions carefully before use.

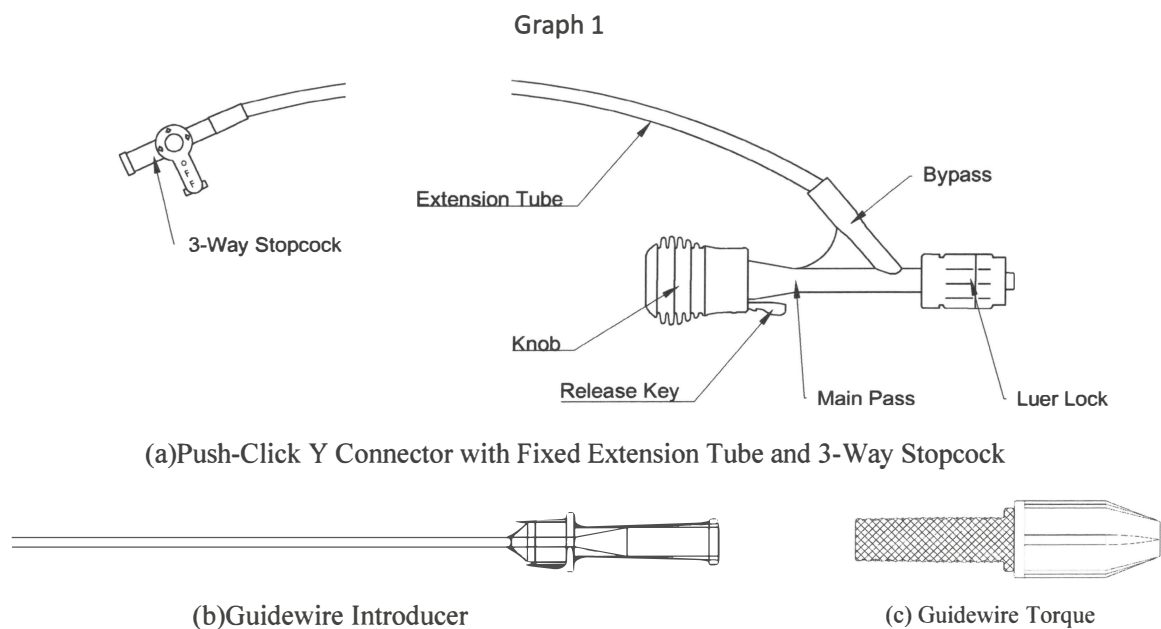
Product Description

Push-Click Y Connector Kit intends to provide two tunnels into the blood vessel, this can introduce the contrast agent and guidewire or catheters during the interventional surgery. Push-Click Y Connector Kit consists of Push-Click Y Connector, Guidewire Torque Device, Guidewire Insertion Tools.

Performance Characteristics

Push-Click Y Connector Kit consists of Push-Click Y Connector, Guidewire Torque Device, Guidewire Insertion Tools. Push-Click Y Connector's inner diameter is $\phi 2.7 \pm 0.1 \text{mm}$. Guidewire Insertion Tools' diameter is 0.021", effective length is $103 \pm 5 \text{mm}$. Guidewire Torque Device can hold and move guidewire which diameter is 0.014"~0.035".

Product Diagram



Indications for Use

Stenosis of coronary and peripheral arteries, etc.



Target Population

Push-Click Y Connector Kit is intended for patients who need for vascular intervention.

Intended Purpose

Push-Click Y connector Kit intends to provide two tunnels into the blood vessel, this can introduce the contrast agent and guidewire or catheters during the interventional surgery. Y connector valve intends to prevent blood loss. Guidewire Introducer inserts the valve of Y connector, making a tunnel for guidewire to get through and protecting guidewire tip. Guidewire Torquer holds guidewire and makes torque guidewire move easier.

Intended User

Push-Click Y Connector Kit is meant to be used by experienced physicians trained. It is solely the hospital/clinic's responsibility to assign qualified users to the product.

Clinical Benefits

Push-click Y connector kit is an auxiliary equipment in vascular intervention operation, it's mainly used in coronary balloon dilatation surgery and PCI operation. It can help guide wire and other similar devices into the vascular in vitro; also can reduce bleeding during surgery, use of Push-click Y connector kit is benefit for surgery which with long operation time and large amount of bleeding. Especially for younger children, reducing the amount of bleeding is to increase the safety and smoothness of the operation.

Products/devices to be used together with the Twist Y Connector Kit

Guiding Catheter, Manifolds, Balloon In-deflation Devices.

Contraindications

Not found.

Possible Complications

Hypotension/hypertension

Hemorrhagic complications

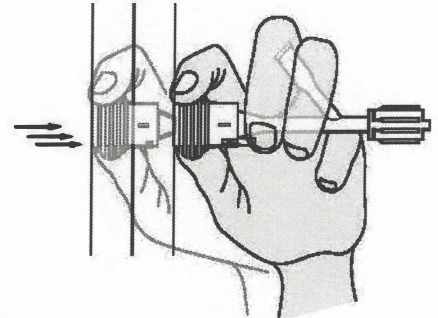
Air embolism

Drug reaction-sallergic reaction to contrast medium or drug solution

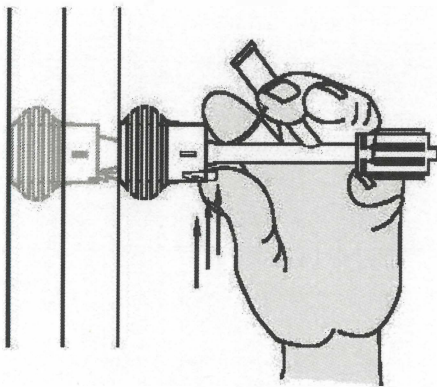
Infection

Instruction for use (Push-Click Y Connector Kit)

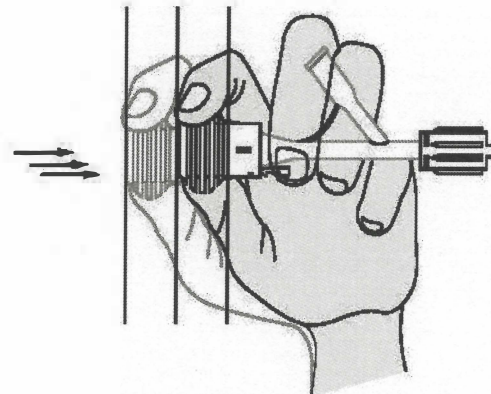
1. Check the package and products prior to use to verify that no damage or contamination.
2. Flush the devices with normal saline before use.
3. Connect the removable 3-way stopcock with bypass if necessary.
4. Securely connect the distal luer lock with catheter or other devices.
5. Press the knob to the end to keep the valve in "Open" position.
("click" sound should be heard) (see Graph 2)
6. When the valve is in fully "Open" position, operator can put through the operating device such as guidewire, balloon catheter. Do not try to put any devices through the Y connector, when valve is in "Close" position.
7. Press the release key (small blue key) will reset the valve to "Close" position.
(see Graph 3)



Graph 2



Graph 3



Graph 4

8. Press knob by fingers between "Open" and "Close" can adjust the valve from full open to full close which may help the device through with minimum blood loss. (see Graph 4)
9. If try to decrease bleeding, operator can try not push knob to fully open position and make the Y connector's valve half open. But in this way, operator must be strongly careful to make sure that the device is not damaged.
10. After put the device in the catheter through the Y connector valve, operator can close the Y connector's valve, but the device still can be pushed and rotated.
11. Guidewire Introducer can help the insertion of guidewire.
12. Using Guidewire Torquer is recommended to help controlling guidewire.



Precaution:

Push-Click Y Connector Kit consists of Push-Click Y Connector, Guidewire Torque Device, Guidewire Insertion Tools. Inspect all products prior to use.

Luer connector must be well connected, and the valve must be closed. Incorrect connection, loose connection or the valve not being closed properly may cause leaking or air getting into blood vessel.

Refer to the instructions for use before use.

Use immediately after opening the single package.

Do not attempt to use a guidewire over maximum diameter.

Warnings

1. Read the instructions before use.
2. The device is designed for single use only. Do not desterilize and /or reuse.
3. Use the product prior to the "Use By" date specified on the package.
4. Do not use if the single package or the product has been damaged or soiled.
5. The persons perform this device should be professional and trained.
6. Do not inject air into the blood vessel.
7. Suggested working pressure is under 180psi.
8. For qualified physicians use only.
9. Please dispose the device after use, according to the local legislation.
10. The intactness of the content should be inspected after opening.
11. Strict aseptic operation should be carried out during use to avoid bacterial contamination.
12. It is important to make that the valve of the push-pull Y-connector is open before using it to connect any device.
13. It is recommended to use the full set of PTCA accessories manufactured by our company, as mixing with products of other brands may cause poor mismatch. The company bears no responsibility for any problems arising therefrom.
14. Potential biological hazards shall be aware. Please dispose products according to medical practice, local regulation and laws.

Note: any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.



Caution: Please dispose the device after use according to local laws and regulations.

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Symbols

DO NOT REUSE



CONTENTS



CAUTION



KEEP AWAY FROM SUNLIGHT



USE BY DATE



KEEP DRY



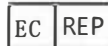
DATE OF MANUFACTURE



MANUFACTURER



BATCH CODE

AUTHORISED REPRESENTATIVE
IN THE EUROPEAN COMMUNITY

CATALOGUE NUMBER

CE MARKING OF
CONFORMITYSTERILIZED USING
ETHYLENE OXIDE

Medical device

DO NOT USE IF
PACKAGE IS DAMAGEDSingle Sterile Barrier System With Protective
Packaging Inside & Sterilized Using Ethylene
Oxide

Consult Instruction For Use



DO NOT RESTERILIZE



Prescription Use Only



Unique device identifier

How supplied**Contents:**

One (1) Push-Click Y Connector
One (1) Guidewire Torque Device
One (1) Guidewire Insertion Tools



Sterile

Sterilized with ethylene oxide gas. Non-pyrogenic.

Storage

Store in a dry, dark, cool place. The temperature is 10°C ~30°C. The humidity is less than 80%.

The use before date (expiry date) see label.

Transportation condition

Keep away from heavy and sunshine, keep dry

Temperature limit:-18°C ~55°C

Humidity limitation: 0~85%



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