

# Y-Connector Set

## A CAUTION

This device should be used only by physicians trained in angiography and Percutaneous Coronary Intervention (PCI), and/or Percutaneous Transluminal Angioplasty (PTA). Carefully read all instructions prior to use. Failure to observe all warnings and precautions may result in complications. Refer to the instructions supplied with any diagnostic / interventional devices to be used in conjunction with the Y-Connector set for intended uses, contraindications, and potential complications.

## B DEVICE DESCRIPTION

The Y-Connector sets have 3.33mm (GYC-A) and 2.44mm (GYC-B) two kinds inside diameters. This device has two seals that operate independently: the fixed valve and the hemostatic valve. The fixed valve can be opened or closed by rotating the screw. Closing of the fixed valve allows for pressure injections up to 30atm (441 psi) and also secures the diagnostic / interventional device in position within the vasculature.

The hemostatic valve is a diaphragm seal that forms around diagnostic / interventional devices as they move into and out of the vasculature. This valve provides minimal fluid loss without restricting device movement.

### GYC-A

The hemostatic valve is open when the opener is pressed down, and locked in an open position when the opener is pressed down and turn in a clockwise direction. The hemostatic valve is closed when the opener is released. An open hemostatic valve allows air to be purged from the device and allows the insertion/withdrawal of diagnostic / interventional devices.

### GYC-B

The hemostatic valve is open when the opener is pressed down, and closed when the opener is released. An open hemostatic valve allows air to be purged from the device and allows the insertion / withdrawal of diagnostic / interventional devices.

## C HOW SUPPLIED

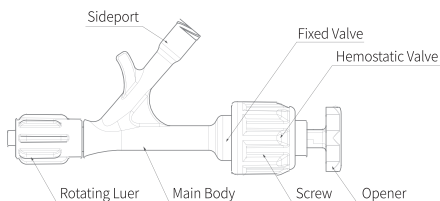
**Sterile.** Sterilized with Ethylene oxide gas. Non-pyrogenic. Do not use if package is open or damaged.

This single use device cannot be reused on another patient, as it is not designed to perform as intended after the first usage. Changes in mechanical, physical, and/or chemical characteristics introduced under conditions of repeated use, cleaning, and/or resterilization may compromise the integrity of the design and/or materials, leading to contamination due to narrow gaps and/or spaces and diminished safety and/or performance of the device. Absence of original labeling may lead to misuse and eliminate traceability. Absence of original packaging may lead to device damage, loss of sterility, and risk of injury to the patient and/or user.

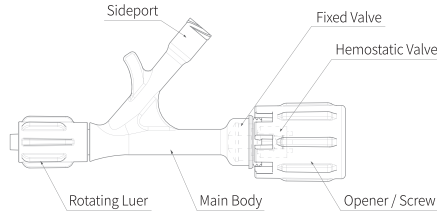
### Contents.

Catalogue No.	Contents
GYC-A19	Y-Connector, Introducer Needle(19G), Torque Device
GYC-A20	Y-Connector, Introducer Needle(20G), Torque Device
GYC-B19	Y-Connector, Introducer Needle(19G), Torque Device
GYC-B20	Y-Connector, Introducer Needle(20G), Torque Device

### GYC-A



### GYC-B

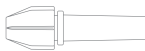


## Accessories

### 1. Introducer Needle(19G/20G)



### 2. Torque Device



**Storage.** Store in a dry, dark, cool place.

## D INTENDED USE

The Y-Connector set is intended to maintain hemostasis during the introduction / withdrawal and use of diagnostic / interventional devices.

## E INDICATIONS

The Y-Connector set is indicated for maintaining a valve around diagnostic / interventional devices with an outside diameter < 3.33mm (GYC-A) / 2.44mm (GYC-B) during interventional procedures.

## F CONTRAINDICATIONS

The Y-Connector set is not intended for use with pressure injections > 30atm (441psi)

## G WARNINGS

This device is intended for single-use only. Do not resterilize and/or reuse. Do not inject any fluid if air bubbles are visible within the Y-Connector set.

To prevent damage to a balloon, it must be completely deflated during advancement/withdrawal through the Y-Connector set. Failure to depress the opener prior to inserting a guide wire introducer could cause valve damage resulting in leakage and/or particulate embolization.

Failure to open the hemostatic valve and the fixed valve prior to inserting / withdrawing a diagnostic / interventional device could cause damage to the diagnostic/interventional device. Power injection at pressures greater than 30atm (441psi) could result in leakage or detachment of components.

Care should be taken to avoid overtightening the fixed valve, as this may compromise the integrity of the diagnostic / interventional device lumen.

## H PRECAUTIONS

Prior to use, inspect the Y-Connector set for any damage. Do not use a damaged Y-Connector set.

## I STORAGE

Store at room temperature (1°C~30°C) in dry and dark places.

## J PREPARATION FOR USE

1. Prior to the interventional procedure, all equipment to be used, including the diagnostic / interventional devices should be examined carefully for defects. Do not use any defective equipment.
2. Attach connective tubing to a manifold and the sideport of the Y-Connector set.
3. Fill and flush the assembly with normal saline. Open the fixed valve and hemostatic valve, place one finger over the luer fitting, and fill the assembly.
4. Prepare diagnostic / interventional device according to the manufacturer's instructions.

## K DIRECTION FOR USE

1. Connect the Y-Connector set to the guiding catheter.
2. Aspirate the system to remove any trapped air before introducing devices.
3. Insert the Introducer Needle and guide wire through an open hemostatic valve and an open fixed valve.
4. Remove the Introducer Needle.
  - 4.1 Insert the rapid exchange (rail) dilatation catheter through an open hemostatic valve and an open fixed valve.
  - 4.2 Insert the over-the-wire dilatation catheter and guide wire through an open hemostatic valve and an open fixed valve.
5. Advance the diagnostic / interventional device through an open fixed valve.
6. Once the diagnostic / interventional device is in place, if desired, close the Fixed valve to allow for pressure injections up to 30atm (441 psi) and / or secure the diagnostic / interventional device in position.
7. Remove the diagnostic / interventional device through an open fixed valve. If resistance is felt, open the hemostatic valve as well.

## L SYMBOLS

Y-Connector set is a trademark of the GENOSS Co., Ltd.  
Graphical Symbols for Medical Device Labeling

REF	Catalogue number	LOT	Batch code
	Do not reuse		Caution
	Do not use if package is damaged		Temperature limitation
	Sterilized using ethylene oxide		Keep away from sunlight
	Use by		Date of manufacture
	Consult instructions for use		Manufacturer
	Do not resterilize		Keep Dry