





Imaxeon Pty Ltd Unit 1, 38-46 South St Rydalmere NSW 2116 AUSTRALIA Ph: 61 2 8845 4999 Fx: 61 2 8845 4998 support@imaxeon.com





LATEX FREE

Catalog Numbers

ZY6021	Klikfit 150mL Syringe and QFT (pouch)
ZY6022	Klikfit 150mL Syringe, QFT, 75cm LPCT (pouch)
ZY6023	Klikfit 150mL Syringe, QFT, 150cm LPCT (pouch)

Symbols

Symbol	Description
\triangle	Attention, consult accompanying instructions
NON-PYROGENIC	Non Pyrogenic
DO NOT USE IF PACKAGE IS OPENED OR DAMAGED	Do not use if package is opened or damaged
2	Single Use Only
\sim	Date of Manufacture/Sterilisation
	Use By
LOT	Lot Number
REF	Catalog Number
STERILE EO	Sterilized with Ethylene Oxide
LATEX FREE	Latex Free
€0086	Indicates the device conforms to the requirements of the European Medical Device Directive 93/42/ EEC
Warning	Warning - Advises you of circumstances that could result in injury or death to the patient or operator.
Caution	Caution - Advises you of circumstances that could result in damage to the device.

1 REF: MN051001-03

Important safety notice: These devices are intended to be used by individuals with adequate training and experience in diagnostic imaging studies.

Indications for use: These devices are intended to be used for the delivery of contrast media. These devices are indicated for single-use only with Imaxeon injectors.

Contraindications: These devices are not intended for multiple-use, drug infusion, chemotherapy, or any other use for which the devices are not indicated.

WARNINGS

- Air embolization can cause serious patient injury or death. Do not connect a patient to the injector until all trapped air has been cleared from the syringe, connector tubing and catheter. Operator vigilance and care, coupled with a set procedure is essential for the avoidance of air embolism.
- Refilling increases the risk of biological contamination.
 Do not use disposable devices on more than one patient.
 Discard disposable devices immediately after use.
- Patient infection may result from the use of non-sterile components. Do not remove plunger to fill syringe.
 Maintain sterility of all disposable components. Check for damaged packaging or components before opening.
- Patient or operator injury may result from contrast media leaks or tubing ruptures. Ensure that the fluid path is open; do not exceed pressures identified on the front of the package. Use of greater pressures or occlusions in the fluid path may result in leaks or ruptures to the connector tube.
- Filled syringes, which are stored, can promote bacterial growth. Imaxeon syringes are designed to be filled just prior to the procedure. Discard unused filled syringes.

CAUTIONS

Component damage may occur if not installed properly.
 Assure all connections are secure; do not overtighten.
 This will help to minimize leaks, disconnection and component damage.

General information

The KLIKFIT syringe is a sterile, single use device.

The syringe packages contain a single assembled syringe and a curved filling tube (QFT) for drawing up contrast.

The packages ZY6022 and ZY6023 also include a low-pressure connecting tube (LPCT) for connecting the syringe to the patient. The tubes are 75cm and 150cm in length, respectively.

The syringe, QFT, and LPCT have been gas sterilised, and whilst in the unopened package, retain their sterility until the USE BY date printed on the label.

The syringe is designed for use only with the VISIMAX CT Contrast Injector - do not substitute any other type of syringe or a syringe manufactured by any alternate supplier. The syringe has been designed and tested to withstand the pressures and flow rates achievable by the VISIMAX CT Contrast Injector.

Labelling information

The label of the syringe package contains important information. This will allow you to decide if the syringe is acceptable for use or should be discarded.

PLEASE CHECK THE FOLLOWING INFORMATION ON THE SYRINGE PACKAGING BEFORE USE:

- Check for use only with the VISIMAX CT Contrast Injector, the catalog number must be ZY6021, ZY6022, or ZY6023.
- Check the packaging for ANY signs of damage, if in doubt discard packaging and contents.
- Check the USE BY date discard immediately if date is exceeded.

Use information

For comprehensive use instructions, please refer to the VISIMAX CT Contrast Injector Operation Manual provided with the injector.

To remove the contents from the packaging, tear the lid away from the peel-apart the pouch (ZY6021, ZY6022, ZY6023). Remove the syringe and curved fill tube, being careful not to touch the luer lock fittings or the fill tube ends. Inspect the syringe for any signs of damage or visible contamination, and load the syringe into the pressure jacket located at the front of the injector head.

Refer to the Operation Manual for comprehensive filling instructions.

Expelling air and attaching the LPCT (ZY6022, ZY6023)

- After filling the syringe, expel all air from the syringe and connector tube.
- 2. Remove the filling device and expel air by manually advancing the injector piston so that the contrast is visible in the tip of the syringe.
- 3. Gently tap the pressure jacket to dislodge air bubbles and expel remaining air.
- Attach the connector tube (if used) and advance the injector piston so that contrast flows into the connector tube and is visible at the connector tip.
- 5. Verify that all air is expelled before connecting to the vascular entry device.

2 REF: MN051001-03