

Instructions for Use

KEOFITT
WORLD LEADERS IN STERILE SAMPLING™

THREE 60 SAMPLING SYSTEM

Three 60 is a completely disposable method of removing a sample from a closed sterile system. There are no parts which must be disassembled, cleaned, and reassembled. The entire set can be applied to your fluid holding vessel or transfer line, used, and discarded. The use of secondary tools are unnecessary to safely remove the sample from your system.

Three 60 is simply compatible with either a NA port, or a 1 ½" sanitary connector. There is no longer a need to have specific hardware or expensive porting machined to your vessel.

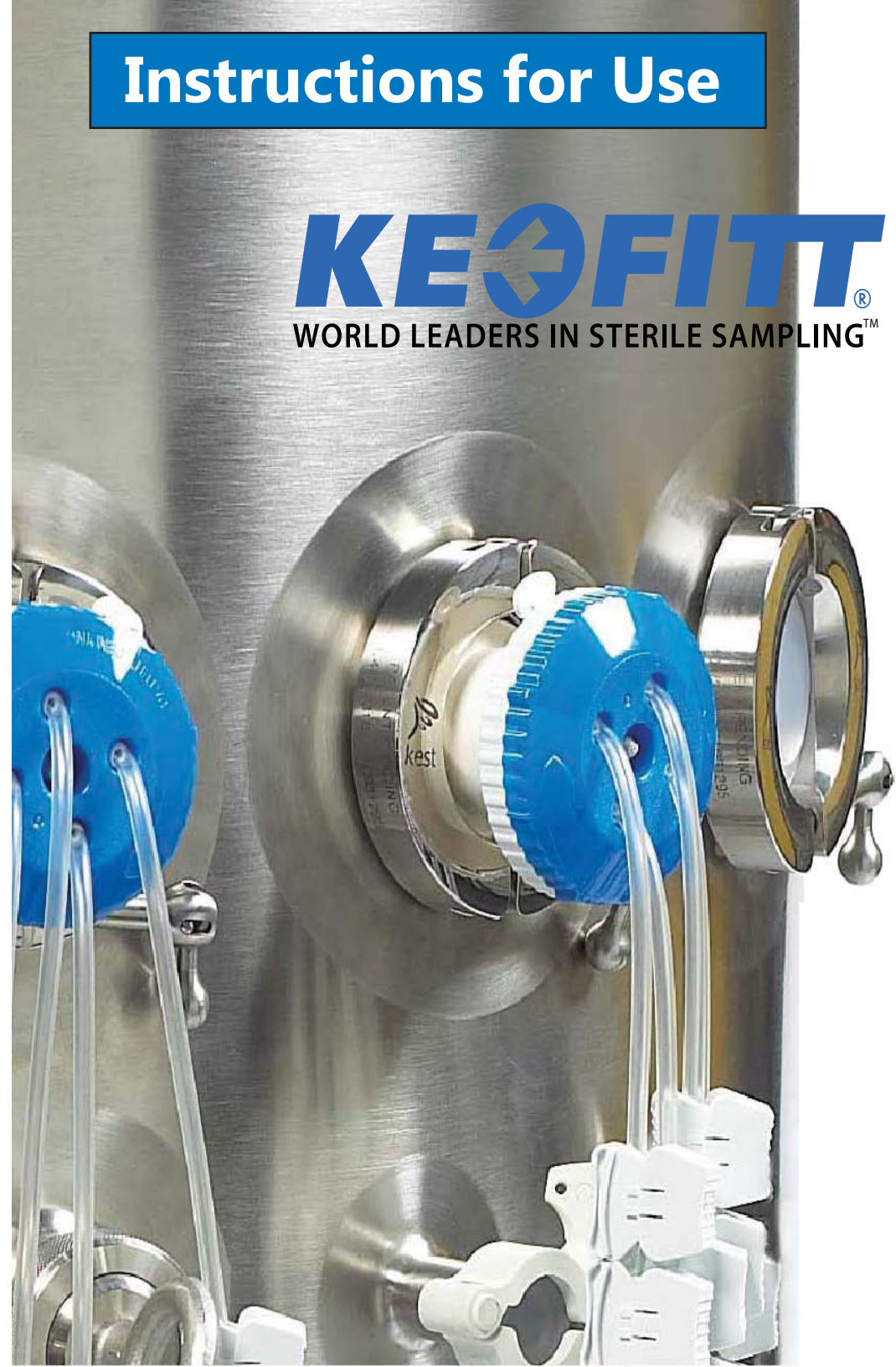
Disconnecting your sample from the device is equally simple. The Three 60 was developed with a disposable disconnect which makes a "cut and seal" action.

The Three 60 devices are produced in a FDA Registered facility and comply to the requirements of our ISO 13485 certified Quality Management System. All Bag manufacturing occurs in an ISO Class 7 clean room and all final assemblies are 100% inspected to assure conformity to product specifications and compliance to CGMP as prescribed by ISO standards and FDA 21 CFR 820 guidelines.

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PLEASE READ THIS INSTRUCTION CAREFULLY BEFORE USE

Check clamps to ensure they are not pinching the tubing and cutting off the flow path by gently pulling each clamp upward but not disconnecting them. It is now ready for fluid transfer.

Check that the luer septum has not come loose and that it is firmly fastened.



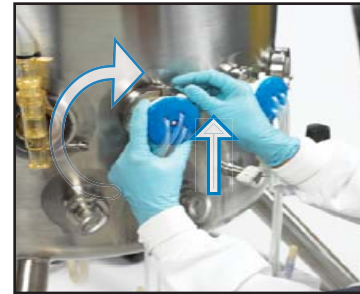
STEP 1 INSTALLATION OF UNIT

- Remove sample system from sterile package.
- Apply a gasket, Three 60 unit and clamp to flange interface of your vessel (1 ½").
- Position unit with finger tab pointing upwards or in any other convenient position.
- Complete your "steam in place" or "clean in place" process.

STEP 2 START SAMPLING



- When ready to take a sample, slightly depress finger tab feature while turning main body clock-wise. **Caution: Excessive pressure on the finger tab may cause it to be permanently deformed, thus compromising locking action.**
- **Immediately** release finger tab, as the tab will lock when the open flow position is reached **Caution: Holding tab as you turn may allow turning past the flow opening.**
- Fill product to the volume desired. For 250ml or heavier samples, support the bag with your hand. **Caution: Observe the speed of filling to avoid overfilling.**



STEP 3 STOP SAMPLING

- When sample fill is complete, press finger tab and again grip and advance body clock-wise.
- Release tab **immediately** as you turn as this will assure you lock into the next closed position.



STEP 4 DISCONNECT THE SAMPLE BAG

- First, grip with both hands the cutting clamp closest to the sample bag and press down until an audible click is heard, and the top rests on the lip.
- Second, repeat this same action as step one with the clamp closest to the valve.
- When you are sure the lock has engaged grip the clamps with both hands and the "V" facing you.
- Press thumbs towards each other. This action will break the clamps to allow separation.
- Continue the motion until the tube separates.
- The clamp is permanently closed and integrally sealed.

