

KEOFITT® THREE60 SAMPLING BAG

GENERAL



The Keofitt Three60 is an easy to secure, easy to use disposable device for removing up to 4 samples per batch from a closed sterile tank, pipe or bioreactor 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 is unnecessary to safely remove the sample from your system.

Three60 is simply compatible with either a NA port, or a 1 1/2" sanitary connector. There is no longer a need to have specific hardware or expensive porting machined to your vessel.

The Keofitt Three60 is fitted to the production line just prior to the initial SIP process and stays there throughout the production batch.



The samples are contained in laminated plastic bags made from medical grade material. Disconnecting your sample bag from the device is equally simple using the ingenious single-use Pinch & Cut component, which, when compressed, provides a sterile disconnect (a "cut and seal" action).

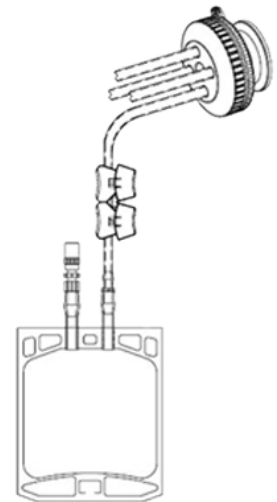


The THREE60 Sampling Bag is a single use product.

The product to be sampled must be a low viscosity liquid (about 100cP max.) with no visible particles.

FEATURES

- Simplified and cost-effective sampling
- Supplied sterilized by Gamma irradiation in a thermoformed transparent box with a Tyvek® seal
- Single use product
- Stays in place throughout the production batch and is discarded afterwards
- Fits an NA port or a 1 1/2" sanitary connector
- Takes up to 4 individual samples
- Apply 2 or 3 devices for up to 8 or 12 samples per batch
- Easy sterile disconnect of sample bag
- Secondary port with septum for extracting a sample of the sample or for injecting a substance into the sample. Secondary port also fitted with luer lock fittings (male and female) for secure and sterile connection to relevant equipment in a Laminar Air Flow (LAF) bench.



TECHNICAL DATA

STEAMING:

Once fixed to a port the Keofitt Three60 is sterilized in place (SIP) using steam (up to 135C/275F) and/or normal SIP liquids. The Keofitt Three60 flange is resistant to mineral acids, alkali and salt solutions, detergents and hydrocarbon oils, but the flange will be attacked by polar solvents such as ketones, chlorinated hydrocarbons and aromatic hydrocarbons.

SAMPLING/FILLING:

Read the enclosed manual carefully before use!

You move from a sampling position to the next by turning the main body clockwise (anti-clockwise motion is blocked to avoid cross contamination between samples).

During sampling support the bag by holding it in your hand (in particular the larger volumes).

Note, that the speed by which the bag is filled increases with the internal pressure of the production line (max. pressure = 6 bar(g))

Never exceed the nominal volume of the bag, as it will eventually blast (safety margin = approx. 3 x nominal volume).

STERILITY AND ENDOTOXIN TESTING:

The Three60 is sterilized via gamma irradiation at doses of 27.5 - 45 kGy.

A select number of complete assemblies are irradiated and tested for endotoxins using the LAL method per USP <85>. The entire lot of product is not released by quality assurance until verification of the endotoxin level is completed and determined to be acceptable.

MICROBIAL INGRESS TESTING:

The design has been tested for the ability to prevent entry of the contaminating organism into the sample bags before, during, and after sampling. In the simulation of a bioreactor, no contamination was able to enter into the bioreactor through



the contaminated valve.

Documented tests have verified that bacterial contaminants present on the surface of the tubing and pinch and cut clamps cannot enter the sample bags during the operation of the clamps, which afterwards are capable maintaining sample bag sterility.

SAMPLE TEMPERATURE:

Sample liquid must be within the temperature 2-60 °C (36-140 °F).

STORAGE AND SHELF LIFE:

The Keofitt Three60 sampling bag unit is packed in a thermoformed transparent box with Tyvek® seal and delivered in a carton box containing 8 units. Shelf life is the 3 years following product date printed on the individual packs. Store in original packaging at 10 – 34 °C (50 – 94 °F) and less than 80% humidity.

CERTIFICATES::

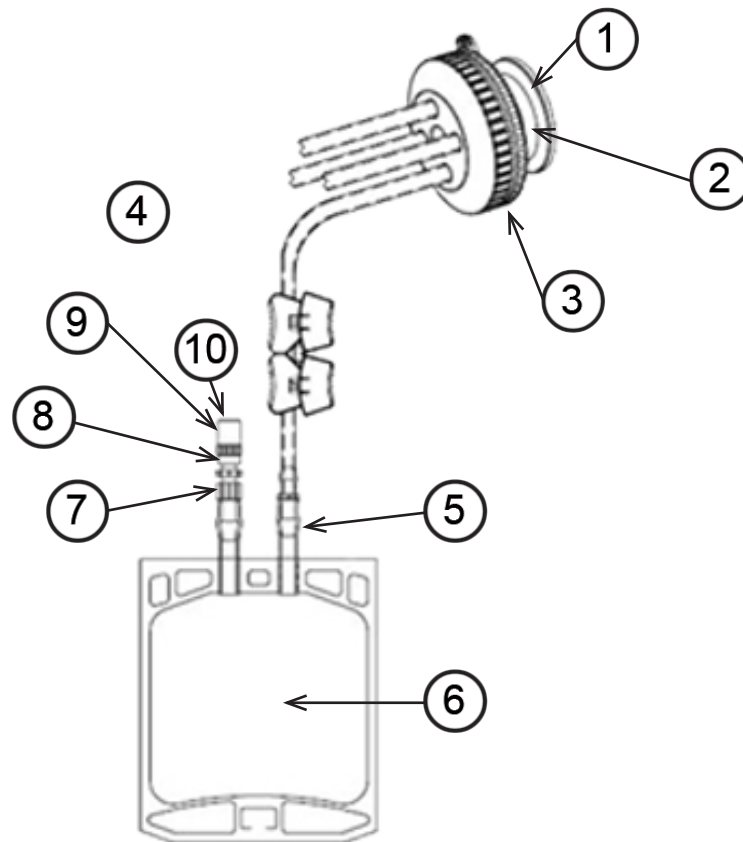
The Keofitt Three60 is manufactured in clean rooms (class 10,000 or class C) under the scrutiny of a quality system approved by ISO 13485 and the FDA.

Each delivery is accompanied with a Certificate of Conformity (CoC) covering Sterility, Product conformity, Gamma Irradiation, GMP, FDA regulations 21 CFR part 820, ISO 13485:2003 Quality Standards etc. For the bag film in constant contact with the sample the CoC covers USP 88 Class VI Biocompatibility, USP 87 Cytotoxicity test, Physiochemical test for Plastic USP 661, Endotoxine test (USP 85) and Extractables test.

SIZES::

The bags are available in the following sizes (part number): 50 ml (140050), 100 ml (140100), 250 ml (140250), 500 ml (140500), 1000 ml (141000) and 2000 ml (142000).

MATERIAL SPECIFICATIONS:



The numbers in the table refer to the assembly drawing of the Three60.

#	Designation	Material	Material properties	Process contact
1	Base	Polysulfone (PSU)	Machanically stable, rigid, high-strength termoplastic suitable for continous use up to 149 °C (300 °F). High resistance to oxydation and hydrolysis and withstand prolonged exposure to high temperatures and repeated sterilization. Highly resistant to mineral acids, alkali and salt solutions. Good resistance to detergents and hydrocarbon oils. Will be attacked by polar solvents such as ketones and clorinated and aromatic hydrocarbons. FDA, USDA and 3-A Dairy compliant.	Permanent. The base is attached to your fluid holding vessel or transfer line and is Sterilized-In-Place (SIP) with the entire production equipment.
2	Gasket	Silicone (LSR)	Liquid silicone rubber is a high purity platinum-cured silicone. USP Class VI and FDA 21CFR177.2600 compliant.	Permanent, but surface area < 24 mm2 (0.04 in2)
3	Cover (Housing)	Polycarbonate	High-impact resistant polymer suitable for steam sterilization. Biocompatible with ISO10993-1 and USP Class VI compliant.	Permanent contact limited to 4.2 mm2 (0.0064 in2) Part of the flowpath during sampling.
4	Tubing	ThermoPlastic Elastomer (TPE)	Biocompatible polymer compliant with USP Class VI. Does not contain PVC or latex rubber.	Part of the flowpath during sampling.
5	Reduction Tube Fitting	Polycarbonate (PC)		Part of the flowpath during sampling.
6	Sampling bag	Co-extruded LLDPE-EVOH-PA film.	This film is Class VI, non-animal origin and is supported by a complete documentation package. Inner fluid contact layer = LLDPE	No process contact. Container for the sample.



7	Male Luer Lock Ring	Polycarbonate (PC)		Part of the flowpath when emptying the bag using the luer connector.
8	Female Luer Thread Style Coupler	Polycarbonate (PC)		Part of the flowpath when emptying the bag using the luer connector.
9	Luer Cap with inj. site (septum)	Acrylonitrile Butadiene Styrene (ABS)	Compliant with ISO-594. Latex free.	Part of the flowpath when emptying the bag using the luer connector.
10	Septum material	Polyisoprene	Compliant with ISO-594. Latex free.	Liquid contact when emptying the bag using the luer connector.