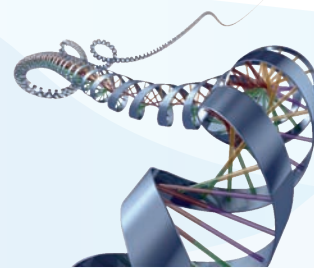


Single-Use Assemblies



Single-Use Assemblies for ultraclean production

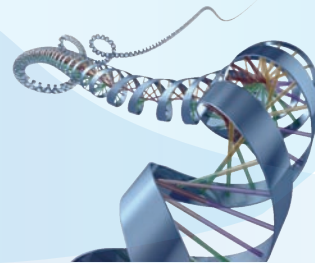
The use of single-use devices has emerged in all pharma-biotech fluid transfers productions. Providing an attractive alternative to conventional stainless steel appliances CIP / SIP cumbersome procedures, this technology eliminates the risk of cross contamination, reduces downtime and size of equipment.

The implementation of gamma irradiated pre-assembled and pre-sterilized complete disposable assemblies, improves the availability and integration of these devices in bioproduction.

These assemblies are made of bags, connectors, tubings, sensors, filter cartridges, needles, downstream processes, or any other component.

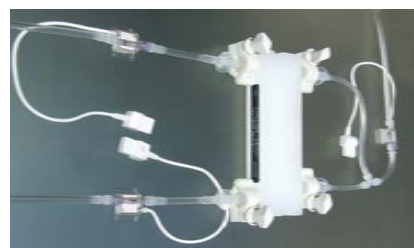
Advantages

- Lot traceability documentation
- Better production flexibility
- Reduction of cross-contamination
- Optimized logistics by reducing components inventories
- Assembly time and maintenance reduction.



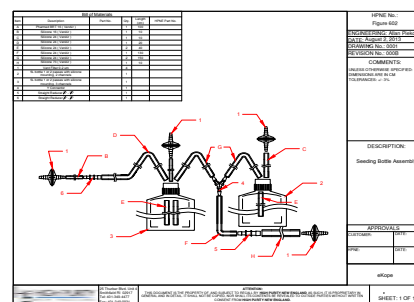
◆ Production

U.S. production site - ISO 7 clean room, cGMP
Custom assembly of all brand and product
(bags, connectors, tubings, sensors, downstream processes, filter capsules, needles, ...)
Short production time
Secure packaging for air express transport
Complete production documentation (registration batch, analysis certificates, γ -sterilization ...)
Possible production of hybrid systems incorporating stainless steel.



◆ Services

Qualification-validation for each product is possible
Product compatibility and sterility assurance according to USP /
EMA / BPSA / ISO 11137
Replacement study of your stainless steel process by single use devices
Logistics organization for a "just in time" delivery.



◆ Quality & Guarantees

Certificates (USP, class VI, EDQM compliance, calibration, TOC, animal free, BSE / TSE, γ -irradiation sterilization, ...)
E&L risk analysis according to BPSA and ICH Q9 guide.

