



sartorius stedim
biotech

BioSealer® TC For robust and consistent sealing



turning science **into solutions**



Extended wide range of sealing possibilities in a single device

A single device contains pre-installed standard parameters to seal up to 6 sizes of the 5 most used TPE tubings in the industry such as TuFlux® TPE, C-Flex® 374, AdvantaFlex™, Sanipure™ BDF and Pharmed™ BPT.

The extended flexibility allows you, especially in product development phase, to shift tubing material and/or tubing dimension using the same device.

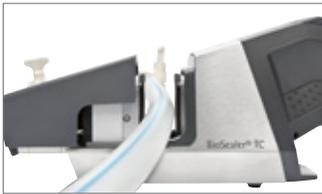
This is reducing your capital investment compared to other solutions that are limited to only a portion of the tubing dimensions or materials used in your manufacturing processes, thereby imposing the purchase of several devices to cover all your needs.



BioSealer® TC – Sterile disconnection of thermoplastic tubing up to 1" OD

The BioSealer® TC is the new device intended to disconnect thermoplastic tubing (TPE), such as TuFlux® TPE or C-Flex® 374 for example, on disposable assemblies used in biopharmaceutical manufacturing processes.

The disconnection can be performed on dry, wet or liquid filled tubing in a non-sterile environment while maintaining sterility of the product flow path.



Enhanced sealing possibilities for larger tubing dimensions

The BioSealer® TC is capable of sealing up to 6 sizes of TPE tubings from 1/8" x 1/4" up to 3/4" x 1" (ID x OD) including liquid filled conditions, without any accessory.



Increased stability of thermal sealings

The BioSealer® TC provides to the user a wider sealing of 20 mm for a more robust disconnection operation. In addition, a cutting guide-line embedded into the seal ensures a proper and clean cut with scissors by the operator.



Enhanced portability

Due to its reasonably low weight and possibility to be operated on a table or when hung, the BioSealer® TC is portable and can be moved the closest to the process area where the sterile disconnection is desired.



Intuitive user interface

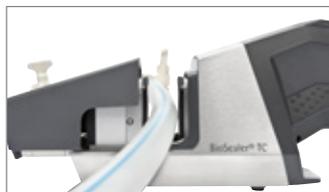
Selecting the tubing material and size to be sealed is very easy using BioSealer® TC touch screen. All key instructions such as setting and closing the pinch clamps at the right time, are displayed on the screen and need to be acknowledged by the user securing consistent sealing quality.

BioSealer® TC benefits as well from an integrated flip function of the display that guarantees adequate text orientation for the user to read in all operating situations.



Four easy steps to a strong sealing

It is very easy to operate the fully automated BioSealer® TC and to perform sterile disconnections in 4 simple steps.



Step 1
Insert the TPE tubing inside the device where the sterile disconnection is wanted.



Step 2
One click in the touch screen is sufficient to start the sealing process. Just follow the instructions displayed.



Step 3
When sealing process is completed the lid automatically reopens.



Step 4
After visual inspection of the sealing use scissors to cut through the guideline on the sealed tubing. Done!

Service

The Installation Qualification and Operational Qualification is recommended and should only be performed by Sartorius Stedim Biotech Service.

Other services are available for BioSealer® TC upon request such as device installation, temperature calibration, preventive maintenance and several levels of maintenance contracts.

Our Confidence® validation services scientists can also establish protocols and conduct customer specific studies based – but not only – on the BioSealer® TC testing that are compiled into the Validation Guide. Such analysis could be performed using actual process fluid or drug formulation in a specific single-use system. This work is performed under full production scale conditions or under scale down conditions that mimic the manufacturing process.

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