Role of Small Chamber Eto Sterilizers in Medical Device Processing

The Eto Sterilization Industry has long been predicated on the premise that larger is better. The industry as it is today is based on chamber capacities based on pallets of product, not units of product. As a result, with recent Eto Plant closures, large amounts of capacity have quickly disappeared and placed in jeopardy the overall ability of the current Eto Facilities to handle the needed market volume of product.

These large chambers that handle pallet loads of medical products are largely inefficient. While the goal of performing the Eto Sterilization is to sterilize the sterile barrier system and contained medical product, the pallet load scenario requires that folding cartons, corrugated cases and even the pallets themselves to be included in the sterilization load, creating unnecessary density that requires a longer overall cycle and more Eto Sterilant Gas to effect sterile processing.

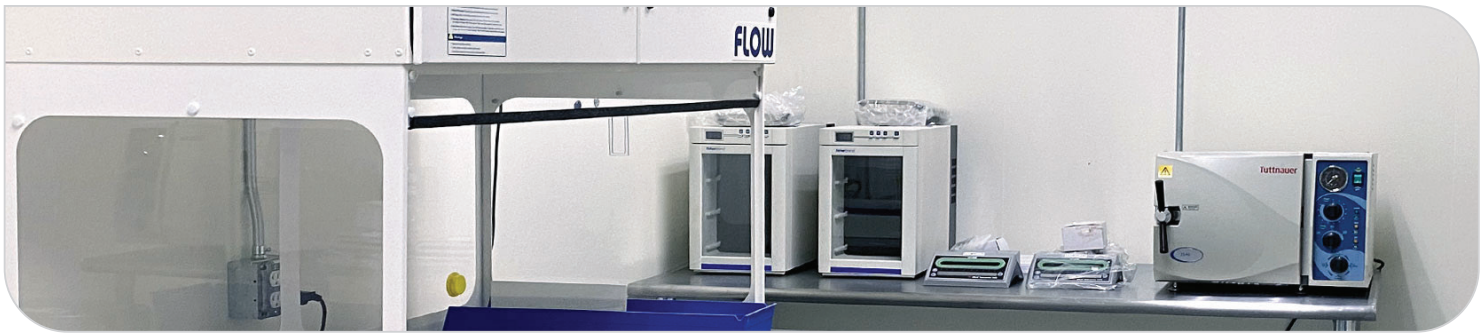
Additionally, and especially in the current capacity constrained market, medical device companies seeking capacity will access any available chamber size in order to get needed products to market. This can result in small amounts of product being processed through chambers that are oversized for the load, requiring longer sterilization times and greater use of Eto Sterilant than should be required. This scenario is common with routinely sterilized smaller volume products, as well as new products.

Recent events have given rise to a need to complete medical device sterilization using appropriately sized chambers and a minimum of Eto Sterilant Gas in the process. Removal of unnecessary density from the load, and right sizing the load to the chamber are easily accomplished with some rethinking of historical preconditions.

A relatively new approach to meeting these objectives is available through the use of smaller chamber Eto Sterilizers. These sterilizers have been used for years in hospitals to sterilize devices and equipment on demand, and most recently are being used by OEM's and Contract Service Houses to provide terminally sterilized sterile, disposable medical products.

The use of these units is especially beneficial with small to mid-volume products where the sterilization can be performed in-process immediately following creation of the sterile barrier system, as opposed to at finished goods. With only the sterile barrier system and medical product being included in the sterilization cycle, the following benefits result:

- Loads are a higher density containing only target materials (no folding cartons, IFU's Corrugated Shippers or Pallets).
- Cycles are shorter because of the reduced chamber size and focused density.
- Eto Sterilant Density may be run at a lower level compared to the traditional finished goods sterilization approach.
- In-process sterilization precludes the need for shipment of "non-sterile product that is labelled as sterile" to and from a contract facility.
- Improved usage of sterilization capacity



These small chamber sterilizers may not meet the needs for all products, but definitely offer advantages where product size and volumes avail themselves to the approach. Cycles typically range from 8-12 hours, and can easily be accommodated within a product as an intermediate step prior to secondary packaging. The production planning inclusive of sterilization becomes one focused on internal flow rather than building larger volumes of products to finished goods that are subsequently shipped off site for sterilization processing.

This scenario is especially advantageous in the processing of resorbable polymer products requiring barrier packaging post Eto processing. The "Open Time" between Eto Exposure and creation of the barrier package can be greatly reduced with in-process in-house sterilization compared to remote processing. The scenario also lends itself to the incorporation of past-Eto vacuum drying of the product followed in rapid succession by barrier packaging, an optimal approach to this type of packaging.

This is a different thought process than is typical for Eto Sterilization today, but one that can bring benefits in the capacity constrained Eto Market that we are dealing with today.