

White Paper

Process Contamination Control for Polyester Depth Filter Components used in Cardiotomy Reservoirs for Intraoperative Blood Salvage Procedures.

Peggy Niston

Product Manager



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Polyester depth filter components have been used for intraoperative blood salvage for many years. During the development cycle of these filters, which began in earnest in the early 1970s', much attention was given to cleanliness, biocompatibility of materials, as well as filtration efficiency and longevity.

Over time the designs evolved into more complex systems providing different levels of filtration depending on the end users' preference. Industry demand for components has remained fairly constant, while cost reduction programs have steadily demanded component manufacturers and supply chain management look for savings opportunities wherever possible. Multiple manufacturers produce polyester depth filter components, either alone, or in conjunction with a secondary source to the equipment manufacturers, who incorporate these components into their finished medical device. Some manufacturers who produce various products to serve multiple applications often offer lower cost solutions, however they may not necessarily offer assurance as to the purity of the polyester product. Title 21 of the CFR Subpart G- Production and Process Controls 820.70 states that manufacturers must have procedures in place to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

This article discusses the challenges of contamination control faced by manufacturers of non-woven polyester filter components. Production of filter material used for fiber-based polyester depth filters is a multiple step process and includes steps to open the fiber, card the fiber, cross-lap and needle the fiber. Figures 1-4 represent a typical non-woven set up for manufacture of a needle punched roll good. By necessity the enormous systems used for filter material manufacturing are typically located in a warehouse setting and are designed for high speed delivery and volume.

To mitigate cost, typical non-woven manufacturers produce roll goods from multiple types of fiber for various applications that may or may not be visibly distinct from a qualified polyester fiber used in medical applications. While they may not be visible or even present in significant quantities, non-specified fibers can be chemically distinct. Rayon (a wood or cellulose based fiber), nylon (a polyamide), orlon (acrylic) and polypropylene (thermoplastic) are all very different fibers compared to polyester. All are widely used in non-wovens produced for the clothing, furniture, and automotive industries.

The annual requirement of polyester roll goods to support manufacture and conversion of the depth filter components used in cardiotomy reservoirs for roughly 1.2M open heart surgeries can be produced by a typical non-woven manufacturer in less than one week. As a result, polyester roll goods may be consolidated into a single annual manufacturing run where the product is produced and stored by either the non-woven manufacturer or the converter until conversion into individual components.

Figure 1: Fiber Staging/Opening



Photos courtesy of BMP Worldwide

Figure 2: Fiber Blending



Figure 3: Carding Process

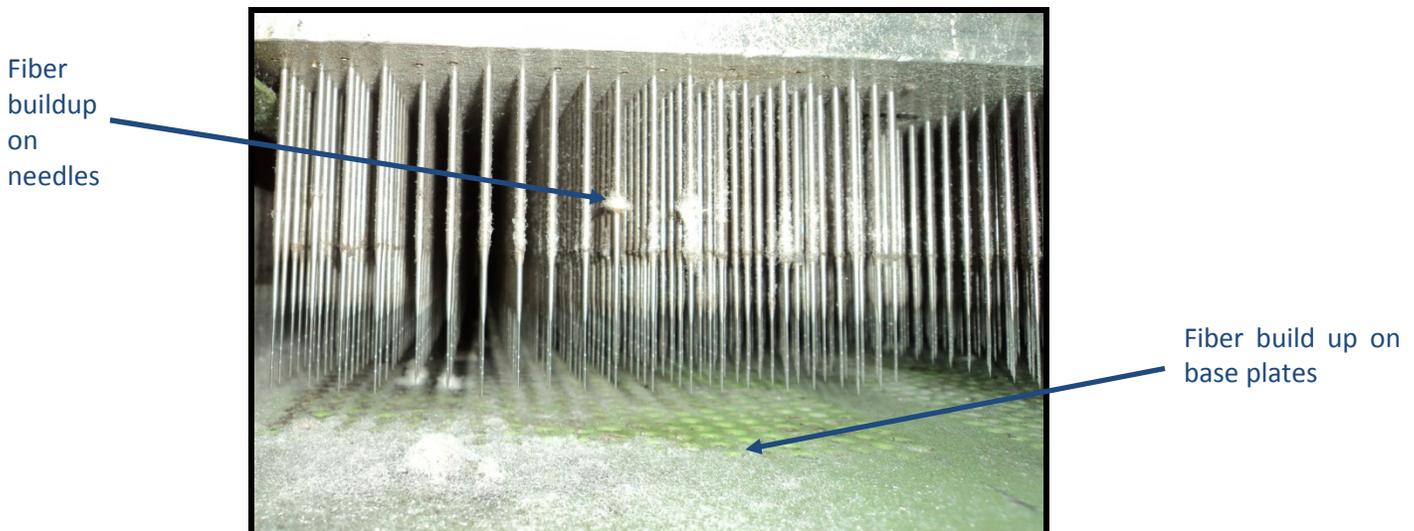


Figure 4: Needlepunch Process



The process presents multiple risk opportunities for contamination that must be addressed or mitigated. Rigorous cleaning, visual inspection, and a robust maintenance schedule may eliminate obvious contaminants however, non-visible contaminants are much more of a challenge to avoid or detect. There are many moving parts in the process equipment as well as many areas for raw fiber to temporarily lodge undetected as is demonstrated in the needleboard area shown in figure 5 below. The nature of the manufacturing practice for a typical non-woven manufacturer makes it impossible to guarantee the roll good produced by commodity based suppliers is “free of foreign material” or that sporadic cross contamination does not occur following a fiber type change over.

Figure 5



Charter Medical recently evaluated three potential suppliers in a “make vs buy” approach for cost containment. The manufacturers considered as potential suppliers provided details of the methods used for a fiber change over. In all cases a clean out run of a similar polyester product for non-medical applications would precede the production of a medical grade product. This would reduce the potential for cross contamination but does not provide adequate assurance that previously processed unapproved fibers are eliminated. As a result of our analysis Charter Medical concluded that the risk for cross contamination by other fiber types is a significant concern. Due to

the severity of the potential impact, it was also concluded that outsourcing the manufacture of the polyester base web from a typical non-woven manufacturer would introduce unacceptable risk.

Charter Medical elected to continue to manufacture the base polyester web in-house. **Charter's unique ability to dedicate equipment exclusively for qualified polyester fiber production ensures our polyester base web is free of foreign materials commonly found in polyester base web produced by typical nonwoven manufacturers.**

This fiber type has been approved through rigorous biocompatibility testing to support medical applications. Charter Medical supplies Class II medical device customers a level of control in their supply chain that does not exist in products provided by companies that source polyester roll goods from multi-industry non-woven manufacturers.

To further ensure cleanliness once the 100% polyester roll good is produced, our depth filter components are processed in a ISO Class 8 Cleanroom where they are welded, washed and certified to meet the rigorous requirements of a medical device component. Figures 6–9 represent a typical depth filter component in preparation for final assembly.

Figure 6: Inverting Weld Seam



Figure 7: Bottom Weld Shaping



Figure 8: Corner Weld Shaping



Figure 9: Multi-Component Assembly



For more information on Charter Medical's manufacturing capabilities visit us on our website www.chartermedical.com or call our customer care center at 866-458-3116

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