Leukocyte depleting filters used to implement Total Leukocyte Control (TLC). The collection of filters shown here provides high efficiency leukocyte depletion of homologous blood transfusion products. They may be separated into products that will remove leukocytes normally found in packed red blood cell preparations and other products that remove white cells found in preparations of platelets. Within these two major types of homologous blood transfusion product leukocyte depleting filters, some are designed for use in the blood bank, some for use in the OR and others still for use at the bedside or in the ICU.

Background History

Pall Biomedical Products Company is a division of Pall Corporation, the international leader in the design, manufacture and marketing of filters and other fluid clarification devices for the health care, aeropower and fluid processing markets. Pall Corporation was founded in 1946 to develop and market one of Dr. David Pall's early inventions, a porous stainless steel filter which provided the marketplace with a more durable filter medium capable of withstanding extreme temperatures, high pressure and corrosion.

In its early days, the '50s and '60s, Pall Corporation was a supplier of filters principally for aircraft and chemical process industry use. The philosophy of providing solutions to customers' problems is epitomized by Pall Corporation's most recent introduction into the health care industry. Pall Corporation has been referred to as one of corporate America's best kept secrets for Pall filtration products are employed in such diversified industrial settings that it is entirely possible that each of us has, without our knowledge, used a product processed with a Pall filter.

If you travel by plane, you probably fly with a Pall product on board. A dramatic episode in Pall's history in the late '50s is the story of the maiden flights of Boeing's 707 aircraft. The landing gear of the new airplanes would not go down on arrival of the planes at destinations. American Airlines urgently appealed to Pall for help. On extremely short notice, Pall responded to the customer with sufficient quantities of high performance filters which alleviated the grounding of Boeing 707 aircraft, by removing contamination from the hydraulic landing gear.

Environmental safety was a Pall concern before it was fashionable. Product lines were added in the '60s and '70s to service the electronics, power generation, food processing and pharmaceutical industries. As nuclear energy gained ground during the '60s and '70s numerous applications for a variety of Pall filters appeared. Once again, through the company's constant readiness to recognize industrial needs, Pall developed a sintered metal filter to help in the cleanup of the crippled Three Mile Island nuclear reactor.
Improving the quality of life has been of no less concern for Pall innovators. If you enjoy filtered beer and crystal clear wines it is entirely possible you are enjoying a product that has passed through a Pall filter. The memories of days gone by and loving moments shared are captured for us in film. Here, too, a strong presence of Pall filtration technology in the photochemical processing industry is how you may have been using Pall technology without even knowing it.

Pall filtration for health care is relatively new. In the late '60s and early '70s, Pall was called upon again to solve problems with filtration technology but this time it was in the health care marketplace. Physicians identified the presence of clumps or microaggregates in blood used for transfusions. Microaggregates were recognized as being harmful to patients receiving transfusions. Pall Corporation satisfied the medical community’s requirements by developing a filter to remove particles during blood transfusion.

Around the same time, cardiac surgeons were growing more convinced that filtration was required for patients undergoing cardiopulmonary bypass. The threat of a massive air accident with a high probability of mortality prompted Pall Corporation, which was by this time a major presence in filtration innovation, to respond to the need for a device to reduce the severe consequences of massive air emboli in the open heart arena. Massive air issues combined with expanding awareness of the clinical sequelae associated with particulate and gaseous microemboli prompted the introduction of the world’s first extracorporeal blood filter, EC3840, for open heart surgery. Within several years, patents for the extracorporeal filter were issued. The EC3840 filter was accepted worldwide as the filter of choice for cardiac surgery to remove gas and particulate microemboli which can cause severe brain damage from the blood during open heart surgery. The same filter also provides a significant level of protection against the threat of massive air accidents.

The Birth of a Dedicated Health Care Company

Numerous problems to be solved using filtration technology in health care prompted the development of Pall Biomedical Products Company. By the '70s Pall was well diversified in a broad array of markets. Increased emphasis was placed on filters for patient protection and in 1975, Pall Biomedical Products was incorporated. Throughout the '70s and '80s, Pall added an extensive line of medical devices which are now in use in thousands of hospitals around the world. These biomedical products are used in the extracorporeal blood oxygenation circuit during open heart surgery and are familiar to most perfusionists. Perhaps less known to perfusionists and cardiac surgeons are filters for intravenous fluids, for purifying and humidifying breathing gases in respiratory therapy, and for gases used in anesthesia.

Pall Biomedical had its origin with blood filters and retains a strong commitment to help make blood and blood products as safe as they can be. Success with the extracorporeal blood filters has led to other configurations of arterial line filters and other filtration products used in open heart surgery. The first generation arterial line filter has been improved to provide maximal protection against rare but costly inadvertent massive air embolic events. The second generation arterial line filter provides the unique feature of automatic air venting. By eliminating the vent line, restriction to the flow of air that rapidly accumulates and must escape the arterial line filter during a massive air accident is reduced.

Leukocyte depletion of transfused blood products provided by Pall represents another major innovation in filtration technology. In 1988, a series of leukocyte depletion filters were developed to protect patients from leukocytes present in transfused blood. Although the deleterious effects of leukocytes present in transfusion products were first identified as early as 1957, their contribution to morbidity and the cost of providing health care is now well-appreciated.

White blood cells are contaminants of a component blood product and can cause serious side effects. The herpes virus, cytomegalovirus, employs the leukocyte as its home and can be transmitted by the transfusion of a blood product prepared from an individual once infected but asymptomatic at the time of donation. CMV dramatically affects certain patients, particularly immunocompromised individuals, and leukocyte depletion can provide a safer blood product.
Other adverse reactions to transfused blood products derived from someone other than the recipient include febrile reactions, alloimmunization that could lead to platelet refractoriness, graft versus host disease and immunosuppressive effects that may be responsible for increased frequencies of post-operative infections. Most of these adverse reactions can now be addressed with leukocyte depletion filtration technology. Pall blood transfusion filters have established the standard for safe and effective blood transfusion therapies at the bedside and in the blood bank.

**Pall has responded to an identified need for leukocyte depleting blood in the extracorporeal circuit.** Late in 1991, Pall Biomedical Products Company introduced the third generation of arterial line filtration technology by adding leukocyte depletion capability to its automatic air venting arterial line filter. While the deleterious effects of someone else’s leukocytes transfused into a recipient have been known for some time, the adverse reactions associated with one’s own leukocytes that become activated during extracorporeal circulation is a problem only recently appreciated. Pall Biomedical once again responded to the needs of the health care community by providing the capability of leukocyte depletion in the extracorporeal circuit. While a reasonable measure of skepticism of the potential for clinical efficacy and cost-effectiveness surrounded the introduction of this technology, discussions of clinical safety, efficacy and cost effectiveness are now appearing in print.  

Undaunted by the slow conservative acceptance of new concepts and products designed around them, Pall used its tireless adherence to the axiom of providing filtration solutions to customer problems to launch its newest product, the leukocyte depleting blood cardioplegia filter. Several papers in the medical literature have appeared since 1992 that suggest leukocyte depletion of blood cardioplegia reduces cellular damage to the myocardium and improves overall heart performance. Pall proudly introduced the world’s first leukocyte depleting blood cardioplegia filter confident that the idea was a good one, based upon principles in medicine. While we all await the practitioners’ assessment of the value of Pall technologies in this particular application, the commitment to patient safety with innovative quality filtration products remains affirmed and consistent with the history of Pall Corporation.

**TLC now means Total Leukocyte Control.** Cardiovascular surgery represents the only area of medicine in which the burden of leukocytes presented to the surgical patient is multifaceted and extensive. These patients receive homologous blood products for which the application of leukocyte depletion technology may be considered prudent. They are also exposed to their own activated leukocytes that may be controlled with leukocyte depletion within the extracorporeal circuit and the blood cardioplegia line. Controlling this patient’s exposure to leukocytes from the variety of sources discussed is the underlying principle Pall Biomedical refers to as Total Leukocyte Control (TLC). The products now available to implement TLC are depicted in Figures 1 & 2 and their positioning within the conduct of cardiopulmonary bypass is illustrated in Figure 3. In theory, and it is our strong impression, TLC will provide tender loving care to the cardiac surgery patient at a total lower cost to the health care system.

![Figure 3](image_url)

A simplified illustration of an extracorporeal circuit shown with a patient on cardiopulmonary bypass depicting the position of Pall filters that combine to provide Total Leukocyte Control. The change in color intensity from light red to a darker red depict leukocyte removal across each of the leukocyte depleting filters. LG represents the LeukoGuard-6® filter and BC is the blood cardioplegia (BC1B) filter.

**The world recognizes Pall Corporation’s success.** In 1990, Pall Corporation joined the ranks of the Fortune 500. Representation and sales of Pall Biomedical Products Company is worldwide including Canada, Europe, South America, Asia and the Pacific Rim. In 1991, Dr. Pall was awarded the National Medal of Technology by President Bush for patenting and commercializing over 100 filtration products that have contributed significantly to safety in flight, upgrading of industrial processes and improved safety of blood transfusions. The National Medal of Technology honors individuals or companies that have made exceptional contributions to the well-being of the nation through the development or
application of technology. Dr. Pall's contributions have indeed pressed the limits of filtration technology and have spanned five decades.

The formula for success continues with our commitment to the American Society of Extracorporeal Technology (AmSECT) and others in the perfusion community. Pall is proud to sponsor AmSECT and believes the close relationship it fosters is important for mutual success. Pall recognizes the technology of perfusion has advanced to unprecedented academic heights and perfusionists can identify the need for new filtration products. Pall has made efforts to strengthen this relationship by supporting education. Particularly noteworthy is the Pall Professional Scientist Lecturers Program which details, in a non-commercial format, scientific issues related to leukocyte depletion, infection control in anesthesia and respiratory care as well as intravenous infusion.

Solving customer’s problems has repeatedly been the driving force behind Dr. Pall’s work and Pall Biomedical's success. The company avoids markets where filters are thought of as commodities and concentrates its research and development efforts on areas where technologically advanced filters will out-perform competition and result in commercial success. This approach has made Pall Biomedical the unquestioned leader in many profitable niche markets. This commitment to make a real difference will continue with the help of perfusion technology professionals and we thank you for your support.

References


Published with the Permission of the American Society of Extra-Corporeal Technology; All Rights Reserved.

For more information...