



The more often you give,  
the better we all feel.

# WORKING TOGETHER...



# TO SAVE LIVES.

## **OUR MISSION**

To provide the highest quality plasma services, ensuring a consistent supply of life-saving therapies to patients.



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## WHO WE ARE

BioLife Plasma Services is an industry leader in the collection of high quality plasma that is processed into life-saving plasma-based therapies.

BioLife operates and maintains numerous state-of-the-art plasma collection facilities throughout the United States and collects nearly 3 million liters of plasma per year.

In order to provide high quality service and a high level of safety to our donors, as well as the patients who receive life-saving plasma-based therapeutics, BioLife is committed to safety. The company is licensed by and/or complies with requirements from the Plasma Protein Therapeutics Association (PPTA), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Department of Transportation (DOT), Centers for Medicare and Medicaid Services (CMS), Federal Aviation Administration (FAA) and other state and local regulations.

Each BioLife center is a vital part of its community. The donors not only contribute the source of life-saving therapeutics, but also contribute to the commercial vitality of their immediate neighborhoods. The fees donors receive for their commitment to the BioLife program are used to support church, civic and charitable organizations and activities, or for their families. These dollars are then spent and re-spent in the community, multiplying their impact and the benefits to the donors, neighboring businesses and the community at large.

BioLife Plasma Services is part of Baxter Healthcare Corporation, the principal domestic operating subsidiary of Baxter International Inc. (NYSE: BAX). Baxter International Inc., through its subsidiaries, assists health-care professionals and their patients with treatment of complex medical conditions, including cancer, hemophilia, immune disorders, kidney disease and trauma. The company applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives.

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- Plasma is the pale yellow liquid portion of the blood that can be easily replaced by the body.
- Plasma functions as an aid in the circulation of red and white blood cells and platelets.
- Source Plasma is collected through a process called plasmapheresis.
- According to the Plasma Protein Therapeutics Association, a global organization dedicated to important issues relating to the quality, safety and efficacy of plasma therapeutics, over 22 million liters of plasma are used worldwide in producing life-saving medicines. From these 22 million liters, more than 1 million people worldwide receive plasma therapeutics every year.

**Plasma makes up approximately 57 percent of whole blood.**



#### **Plasma Processing**

Plasma is processed into a wide variety of life-saving therapeutics, including blood clotting proteins to treat hemophilia, immune support therapies, blood volume replacements and surgical sealants that benefit thousands of people everyday.





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## WHAT IS PLASMA?

Plasma is the yellow liquid portion of whole blood that can be easily replaced by the body. Plasma makes up approximately 57 percent of whole blood and consists primarily of water and proteins that help the body control bleeding and infection. Plasma functions as an aid in the circulation of red and white blood cells and platelets. It also makes possible natural chemical communication among different parts of the body by carrying minerals, hormones, vitamins and antibodies. Important plasma proteins include coagulation factors and globulins, as well as albumin.

Plasma used in plasma-based therapies is obtained through two different donation processes; Recovered and Source plasma.

Recovered plasma is obtained from whole blood donations. In the United States, approximately 250 milliliters of plasma are obtained per whole blood donation.

Source Plasma is collected through the use of an automated plasmapheresis process. During plasmapheresis, the plasma component of whole blood is collected through the use of an automated machine, returning the cellular blood components, such as red blood cells and platelets, back to the donor. Approximately 600-800 milliliters of plasma can be safely obtained during each donation.

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## HOW IS DONATING PLASMA DIFFERENT FROM DONATING WHOLE BLOOD?

### WHOLE BLOOD DONATION

Whole blood is collected manually into a container approved for the collection of human blood. During a whole blood donation, all components of the blood are collected. The actual blood donation procedure only takes about 10-15 minutes, at which time approximately one pint has been collected. Because all of the blood's components are collected, whole blood donors are only allowed to donate once every eight weeks in order to replenish the body's blood supply.

### PLASMA DONATION

Plasma is collected through a process called plasmapheresis. When donating plasma, whole blood is withdrawn from the body. The whole blood is then separated into plasma and the other whole blood elements using a sterile system. The plasma is retained and other whole blood elements – red blood cells, white blood cells and platelets – are returned to the donor during the plasmapheresis process. The plasmapheresis process takes about 20-40 minutes longer than a whole blood donation, but because the cellular components are returned, a donor can donate as often as twice in a seven-day period, with at least one day between donations.

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The plasma collected at BioLife Plasma Services is processed into a wide variety of life-saving therapeutics that benefit thousands of people everyday. Five main therapies are derived from the plasma:

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#### **HEMOPHILIA THERAPIES**

Hemophilia is a genetic bleeding disorder that prevents blood from forming an effective clot. A disorder that primarily affects males, people living with hemophilia do not have enough of, or are missing, one of the blood clotting proteins naturally found in blood. Individuals with hemophilia A (also called classic hemophilia) lack a sufficient amount of a protein called clotting factor VIII, while individuals with hemophilia B (also called Christmas disease) lack a sufficient amount of clotting factor IX.

The plasma donated at BioLife Plasma Services is processed into Factor VIII and Factor IX replacement therapies and infused intravenously to temporarily replace a missing or nonfunctioning factor in people living with hemophilia. These plasma-based factor concentrates help individuals who suffer from hemophilia lead more active and healthy lives. For more information on hemophilia therapies produced by Baxter, please visit [www.hemophiliagalaxy.com](http://www.hemophiliagalaxy.com).

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#### **BLOOD VOLUME REPLACEMENT**

A loss of blood volume affects patients in a variety of trauma conditions. Restoration of this lost blood is often a key factor in emergency situations with a long-term favorable outcome.

The therapeutic protein albumin, derived from plasma donated at BioLife Plasma Services, is used in hospitals across the United States to treat trauma and burn victims, as well as patients suffering from shock. For more information on blood volume replacements produced by Baxter, please visit [www.albumintherapy.com](http://www.albumintherapy.com).

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#### **IMMUNE SUPPORT**

Once classified as fatal disorders, more than 80 primary immune deficiency disorders affect approximately 500,000 people in the United States. These disorders occur when a part of the body's immune system is missing or does not function properly. Today, advances in medicine and our understanding of these deficiencies have resulted in the development of immunoglobulins (antibodies) that assist the patient's immune system in fighting off infection.

Immune Globulin Intravenous (IGIV) is a therapeutic derived from plasma donated at BioLife Plasma Services for use in primary immune deficiencies, as well as B-cell Chronic Lymphocytic Leukemia and Idiopathic Thrombocytopenic Purpura. For more information on immunoglobulin therapies produced by Baxter, please visit [www.immunedisease.com](http://www.immunedisease.com).

### **SURGICAL HEMOSTASIS & TISSUE SEALING**

During surgery, the ability to control bleeding quickly helps reduce complications and improve a patient's outcome. Increasingly, surgeons are turning to a solution called fibrin sealant, comprised of human fibrinogen and human thrombin, two components derived from plasma donated at BioLife Plasma Services.

Fibrin sealant is used to replicate the natural blood clotting process to stop bleeding in a variety of surgical procedures. For more information on fibrin sealant technologies produced by Baxter, please visit [www.tissuesealing.com](http://www.tissuesealing.com).

### **RH IMMUNIZATION PREVENTION**

Rh Immunization can occur when a Rh negative woman and an Rh positive man conceive a baby that is Rh positive. Throughout the pregnancy and especially during delivery, blood from the mother and baby can intermingle, producing antibodies in the mother that attack the baby's foreign red blood cells. Subsequent pregnancies can result in jaundice, anemia or even death to the fetus.

Certain individuals with Rh negative blood are eligible to participate in BioLife's Anti-D donation program, which helps provide the plasma-based antibodies to create a life-saving therapy called Rh immune-globulin. Rh immune-globulin is an injection administered to women with Rh negative blood during and after pregnancy to prevent the development of these Rh positive antibodies. It is estimated that over a quarter of a million infants' lives have been saved in the United States alone since the introduction of Rh immune-globulin in 1968.



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# PLASMA COLLECTION PROCESS



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Source Plasma is collected through an automated process called “plasmapheresis.” The procedure requires the use of an automated device and disposable single-use kit in which the donor’s blood is collected and processed to separate the plasma from the other blood components.

A needle is placed in the donor’s vein and blood is pumped into a specialized spinning device that separates the plasma from the cellular components of the blood, such as red and white blood cells and platelets. While the plasma is collected, the other blood components are pumped into a reservoir. Once the reservoir is full, the red and white blood cells and platelets are returned to the donor’s body. Throughout the process, the system automatically alternates between collection and reinfusion until the predetermined amount of plasma is obtained.

Each donation procedure uses sterile and disposable collection materials. Once the donation is complete, the disposable equipment is discarded and replaced with new materials for the next donation.

On each donor’s initial visit, and at least annually, the donor undergoes a physical examination and his/her medical history is recorded. During each subsequent visit, a staff member checks the donor’s vital signs and donors answer questions about their medical history. In addition, the donor’s hematocrit (the percentage of blood volume occupied by red blood cells) and plasma protein levels are checked. Once the plasma is collected, samples from each donation are sent to a BioLife laboratory and tested for indicators of viral infections including hepatitis and human immunodeficiency virus (HIV). Additionally, periodic tests, including syphilis, are performed on each donor to help ensure donor health and acceptability for the plasmapheresis process.

For new donors, the entire plasma donation process, including a physical examination, donor screening and the plasmapheresis process, usually takes about two hours. Repeat donors can expect to spend approximately an hour and a half in the center, with the average plasmapheresis process taking around 45 minutes.

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A safe product starts with a safe supply of plasma. While the risks associated with plasma cannot be totally eliminated, Baxter and BioLife Plasma Services are committed to the highest standards of safety and employ numerous measures to ensure the safety of its donors and its products. Baxter and BioLife Plasma Services rely on three key processes to assure product safety; donor selection and screening, plasma screening and inventory hold, and virus inactivation and removal.

## From Donor To Patient...

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### DONOR SELECTION AND SCREENING

Before a donor is accepted into the BioLife Plasma Services donor program, he or she must pass a medical examination and survey of their medical history. **A donor must return to provide a second donation within six months of the first donation before the plasma from that donor may be considered for use. If the applicant donor successfully completes a secondary round of screening interviews and laboratory tests, the donor becomes a “qualified donor” and his or her plasma may be considered for use. These steps help ensure the safety of the donor and protect the recipients of the therapies processed from their plasma.** The donor screening process is required every time an individual returns to donate plasma and is intended to identify a variety of infectious diseases, including human immunodeficiency virus (HIV) and hepatitis.

All BioLife plasmapheresis centers voluntarily comply with the quality and safety standards defined by the International Quality Plasma Program (iQPP) of the Plasma Protein Therapeutics Association (PPTA), a global organization dedicated to important issues relating to the quality, safety and efficacy of plasma therapeutics.

BioLife Plasma Services is also licensed by the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS). In addition, each facility is expected to comply with the regulations set forth by the Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Department of Transportation (DOT), Federal Aviation Administration (FAA) and other state and local regulatory organizations.

### NATIONAL DONOR DEFERRAL REGISTRY

The National Donor Deferral Registry (NDDR) is a computerized safety network that allows plasma collection facilities to check all applicant donors against a list of permanently deferred donors in the U.S.

Baxter accepts plasma for processing only after verification that the applicant donor is not in the NDDR. Should BioLife Plasma Services identify a donor as ineligible for further donations after a laboratory sample testing for viral markers, the NDDR is notified and the donor is listed as a deferred donor.

### **PLASMA SCREENING AND INVENTORY HOLD**

Once the plasma is collected, samples from each donation are sent to a BioLife Plasma Services laboratory and tested for indicators of viral infections including hepatitis and human immunodeficiency

virus (HIV). Additionally, periodic tests, including syphilis, are performed on each donor to help ensure donor health and acceptability for the plasmapheresis process.

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In addition to the screening of individual plasma donations, the plasma is also screened for viruses such as hepatitis and HIV using PCR (polymerase chain reaction) technology, one of the most sensitive tests available for detecting viruses. With PCR testing, it is not necessary to wait until the body has produced antibodies in order to detect the presence of a virus. Instead, the technique reduces the time from initial infection to laboratory detection. PCR testing can therefore increase the safety margin significantly by earlier detection of a virus that might enter the process.

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Plasma donations from qualified donors are held for 60 days (inventory hold) prior to further processing. This measure allows for the retrieval, prior to processing, of plasma units from previously qualified donors who are later found to have unacceptable results. The primary goal of plasma screening and inventory hold is to ensure safe plasma for further processing into therapeutics.

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### **THE PLASMA FRACTIONATION PROCESS**

After the plasma is collected and tested, it is frozen and shipped to a fractionation facility where it is processed into life-saving therapeutics and distributed.

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Cryoprecipitation, filtration and solvent/detergent treatments isolate and purify the plasma proteins.

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### **VIRUS INACTIVATION AND REMOVAL**

Using the latest technologies to screen plasma is a highly effective way to reduce the risk of viral transmission. However, any screening procedure has a detection limit and can only test for known viruses. Moreover, unknown and/or emerging pathogens may also be present in the plasma. These potential contaminants can be reduced and sometimes eliminated by a process of virus inactivation and removal.

Virus inactivation steps are treatments that are able to inactivate virus infectivity through steps such as solvent/detergent treatment, heating or chromatography. Baxter manufacturing processes utilize one or more virus inactivation processes to help assure the safety of the finished product.



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# FACILITY INFORMATION



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BioLife Plasma Services operates numerous plasma collection centers throughout the United States. The following data represents the per center statistics of our newer facilities, which are mainly stand-alone buildings:

<b>AVERAGE SQUARE FEET</b> . . . . .	15,000
<b>NUMBER OF DONOR BEDS</b> . . . . .	60
<b>NUMBER OF EMPLOYEES</b> . . . . .	25 – 50
<b>DONATIONS PER WEEK</b> . . . . .	1,000 – 2,300
<b>NUMBER OF DONORS PER YEAR</b> . . . . .	4,500 – 6,000
<b>AVERAGE ANNUAL DONATIONS PER DONOR</b> . . . . .	36 – 48

Economic impact on the community:

<b>CAPITAL INVESTMENT (BUILDING, LAND)</b> . . . . .	\$3 – 6 million
<b>DONOR REIMBURSEMENT</b> . . . . .	\$1.5 – 2 million/year

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**DEMOGRAPHICS OF OUR PLASMA DONORS**

BioLife plasma donors mirror the demographics of the different communities in which its centers are located. The majority of donors come from within a seven-mile radius of the center and range between 20-35 years old. In general, the gender ratio is fairly equal. Depending on location, students make up between 15 percent - 60 percent of a center’s donor base. In regards to occupation, BioLife centers attract a wide mix of individuals: blue and white collar workers, stay-at-home parents, professionals and individuals in the military...people from all walks of life.

Donors have varying reasons for giving, including the self-fulfillment of knowing they are helping others and the opportunity to receive extra money, as well as the social aspects of donating. Many BioLife donors come in to donate twice a week and see their time spent donating as a chance to socialize with friends.

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## EVIN



"I had spent 12 years in and out of hospitals and missed most of elementary school due to a disorder called Immune Thrombocytopenic Purpura (ITP), which attacks the platelets of the blood and destroys them. My life was completely at the whim

of my illnesses. Then came Gammagard S/D IGIV. My fevers abated, my infections became less frequent and most amazingly, I began to grow.

The ability to carry on a healthy, happy life and my being one of many who receive products made from donated plasma is not a coincidence. My health is the direct result of the generosity of others.

There is not a simple way to express my gratitude to the staff of BioLife Plasma Services and to all the caring donors who give of themselves to keep me alive.

Thank you from the bottom of my heart."

—Evin, recipient of Gammagard S/D IGIV, a Baxter-produced plasma-based therapeutic

## ISAAC



"I was born on September 13, 1991. I was really small as a baby. The doctor put me in a special bed. In fact, I was so small that I had to wear socks from my sister's doll. My head was as big as my mom's fist.

I'm the youngest one in my family. I have an older brother and an older sister... and, of course, my mom and dad.

Sports have always been important to me. My dad has coached sports such as basketball, football, and baseball for over 15 years. My brother played football in school. So, I've grown up surrounded by sports.

Since I was a little kid I've liked playing basketball. I've had a ball in my hands ever since I can remember. But what I really liked to do was lay on the couch because I was always sick, and nobody could find out why. Even though I went outside I didn't stay out long. I didn't eat much either.

Then one day my life would be changed forever. Finally, after five and a half years of suffering we found a certain doctor who I still see today. His name is Dr. Shapiro. He told my parents and me that I had Common

Variable Immune Deficiency Disease or CVID. It's one of over 120 primary immune deficiency diseases. So, we joined the Immune Deficiency Foundation which helps people like me. My mom and I have traveled to many places to speak about primary immune deficiency diseases. We've even been to Capitol Hill.

In my case the treatment for CVID is gamma globulin infusions every 14 days. Gamma globulin is made from plasma. Without this drug I would be sick all the time.

My life is much better now that I receive infusions. I'm able to do whatever I want to do. I am able to eat all types of foods. I can be outside playing sports as much as I want.

My dream for the future is to start my own business or have a good paying job. I want to go to college, but no matter what happens to me in the future I'll be happy with whatever I do. It doesn't matter whether I end up making lots of money or working in a gas station. I'll be fine however I end up in the future as long as I can continue receiving my infusions.

Thank you to everyone who donates plasma and works at plasma collection centers. You have helped to change my life and the lives of others."

—Isaac, recipient of Gammagard S/D IGIV, a Baxter-produced plasma-based therapeutic

# FREQUENTLY ASKED QUESTIONS



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**Q: WHO IS ELIGIBLE TO DONATE PLASMA?**

**A:** To donate plasma, an individual must be at least 18 years of age, weigh at least 110 pounds and pass all other required donor eligibility criteria.

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**Q: IS IT SAFE TO DONATE PLASMA?**

**A:** Yes. Donating plasma is a low risk procedure with minimal or no side effects. Before a donor is accepted into the BioLife Plasma Services donor program, he or she must pass a medical examination and a survey of their medical history performed by a member of BioLife's professional medical staff. During each subsequent visit, a staff member checks the donor's vital signs and the donor answers questions about their medical history.

In addition, the donor's hematocrit (the percentage of blood volume occupied by red blood cells) and plasma protein levels are checked. These steps help ensure the safety of the donor and protect the recipients of the therapies processed from their plasma. Each donation procedure uses sterile and disposable collection materials. Once the donation is complete, the disposable equipment is discarded and replaced with new materials for the next donation.

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**Q: HOW OFTEN CAN I DONATE PLASMA?**

**A:** The body replaces the plasma removed during the donation process quickly; therefore, healthy

individuals can donate as often as twice in a seven-day period, with at least one day between donations.

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**Q: HOW LONG DOES IT TAKE TO DONATE?**

**A:** On a donor's first visit, the whole process, including a physical examination, medical screening and the plasma donation, usually takes about two hours.

Repeat donors generally spend approximately an hour and a half in the center, with the average plasmapheresis process taking around 45 minutes.

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**Q: DO YOU TEST THE PLASMA EVERY TIME?**

**A:** Yes. Once the plasma is collected, samples from each donation are sent to a BioLife Plasma Services laboratory and tested for indicators of viral infections including hepatitis and human immunodeficiency

virus (HIV). Additionally, periodic tests, including syphilis, are performed on each donor to help ensure donor health and acceptability for the plasmapheresis process.

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Continued on back

Donating plasma is a low risk procedure with minimal or no side effects.

## Frequently Asked Questions Continued

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**Q: HOW IS THE COLLECTED PLASMA USED?**

**A:** Plasma is processed into a wide variety of life-saving therapies that benefit thousands of people everyday. Plasma-based therapeutics are used in the treatment of serious disorders such as hemophilia and immune system deficiencies, and to treat victims of shock and burn. For example, those who suffer from certain forms of hemophilia lack the natural clotting factors that help stop bleeding after sustaining acute or other injuries. Plasma-based therapeutics are used to treat

people with this disorder so that they may lead normal, active lives. In addition, hospitals and emergency rooms all over the world use plasma derived albumin in the treatment of traumatic injuries such as shock and severe burns. It is important to remember that plasma is not a substance that can be produced in a laboratory or some other artificial environment. It can only be obtained from healthy adults. Plasma donors help save lives.

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**Q: HOW DOES A PLASMA CENTER AFFECT THE COMMUNITY BLOOD SUPPLY?**

**A:** It can often enhance a community's whole blood donations if BioLife comes to a new location since the general awareness of the need for blood and

plasma donations is increased through BioLife's marketing efforts.

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**Q: WHY DO PLASMA DONORS RECEIVE MONEY FOR DONATING?**

**A:** Plasma donors spend up to two hours, as often as twice a week, in our centers to help save someone's life or improve the quality of it. In addition, plasma donors must undergo physical examinations at least annually and a medical history questioning every

time they come in to donate. All of these measures help to guarantee a healthy donor population. We merely offer compensation to our donors for their commitment to the program.

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**ADDITIONAL RESOURCES**

For more information about plasma and the life-saving therapies it provides, please take a look at the following Websites:

**BIOLIFE PLASMA SERVICES**  
[www.biolifeplasma.com](http://www.biolifeplasma.com)

**PPTA: PLASMA PROTEIN THERAPEUTICS ASSOCIATION**  
[www.plasmatherapeutics.org](http://www.plasmatherapeutics.org)

**NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)**  
[www.nhlbi.org](http://www.nhlbi.org)

**AMERICAN SOCIETY OF HEMATOLOGY**  
[www.hematology.org](http://www.hematology.org)

**BAXTER HEALTHCARE CORPORATION**  
[www.baxter.com](http://www.baxter.com)

**NATIONAL HEMOPHILIA FOUNDATION**  
[www.hemophilia.org](http://www.hemophilia.org)

**WORLD FEDERATION OF HEMOPHILIA**  
[www.wfh.org](http://www.wfh.org)

**IMMUNE DEFICIENCY FOUNDATION**  
[www.primaryimmune.org](http://www.primaryimmune.org)

**IMMUNE DISEASE**  
[www.immunedisease.com](http://www.immunedisease.com)

**ALBUMIN THERAPY**  
[www.albumintherapy.com](http://www.albumintherapy.com)

**TISSUE SEALING**  
[www.tissuesealing.com](http://www.tissuesealing.com)

**HEMOPHILIA FEDERATION OF AMERICA**  
[www.hemophiliafed.org](http://www.hemophiliafed.org)



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