

Dear donor,

A while ago you donated stem cells for a sick patient. The cells were successfully transplanted. Unfortunately, another problem has arisen with the patient in the meantime, which is why we are approaching you today and asking for a second donation. Unlike the first donation, however, this time lymphocytes will be collected instead of stem cells.

Lymphocytes are part of the white blood cells which are responsible for the body's defense system and identify substances that are foreign to the body. Your lymphocytes will be given to the patient in an attempt to target and destroy leukemia cells or other malignant cells. This strengthens the patient's immune system so that a recurrence of the malignant disease can be treated. Lymphocytes are a normal component of the peripheral blood, which means that unlike stem cells, they can be found throughout the body.

As a result, this time **mobilization treatment with the growth factor filgrastim / lenograstim (Neupogen® / Granocyte®) is not necessary**. If you consent to donating lymphocytes, you will be hooked up to the blood cell separator once again. In terms of the process and the technology involved, it is not different than what you are already familiar with from donating stem cells. The notes below are to remind you about some of the key points.

The cell separators used here are tested and approved devices which only take certain components of the blood and then return the rest of the blood to your body immediately. These devices primarily consist of pumps which lead the blood into a centrifuge, where the blood is separated into its individual components. During the blood-separating process, you are connected to the blood-cell separator via two infusion tubes. The common procedure here is to insert **two venous catheters (one each into your left and right arm)**. If the veins in your arms are not strong enough, in individual cases it may be necessary to insert the catheter into a larger vein around the neck or the groin (a central venous catheter [CVC]).

For each donor, a new **single-use tube kit** is used; it is closed so that there is no risk of potentially transmitting an infection via the blood of someone else previously treated on the separator. The tube kit is first filled with saline solution, which also forces out all of the air. Then you are hooked up to the tube kit and your blood passes into the separator. During the process, some 160-280 milliliters (approximately 6-9 oz.) of your blood will be in the tube, depending on the type of the separator. At the same time, saline solution is fed back into the other catheter, followed by your blood. When the separation process is over, the kit is rinsed with saline, so only a very small amount of your blood remains in the separator. All in all, the procedure lasts 3-4 hours, and around 3-4 times the amount of your total blood volume passes through the cell separator.

To make sure your blood does not clot in the machine, an anticoagulant is added. The substance is called ACD and is derived from citric acid. The anticoagulant functions by binding with calcium, a mineral which is important for muscle and nerve function. As a result, you may feel some tingling and unusual sensations during the donation process, especially in the fingertips and around the mouth. These sensations can be quickly corrected by administering calcium as a tablet or an infusion. Furthermore, heparin is also given as an additional anticoagulant. When used on a long-term basis, this medication can lead to

a reduction of platelets in very rare cases. In the short term, however, the medication does not cause any subjective complaints.

The **blood cell separator** is designed in such a way that any risk to the donor is ruled out as much as possible. As is the case any time blood is donated, people with a certain constitution may experience dizziness, fainting, vomiting or hyperventilation. Loss of consciousness due to blood loss is a rare occurrence, since adding the saline solution means there is no net decrease in blood volume. At the site where the catheter is inserted, a bruise can form, and in very rare cases there can be damage to other blood vessels or nerves.

A decrease in platelets (thrombocytes) usually occurs when blood cells are donated. However, the related occurrence of hemorrhaging is very rare and platelet levels return to normal within approximately 3 weeks. Since your platelet count is lower, you need to avoid taking painkillers which contain acetylsalicylic acid (such as Aspirin®, Thomapyrin®, etc.) for around one week before and one week after cell collection.

Any changes in the blood's mineral and salt (electrolyte) levels caused by apheresis are corrected by taking the appropriate tablets or infusions. Complications such as blood loss, hemolysis, embolism, allergic reactions or an excessive loss of fluid are not to be expected and can only occur if there has been an error in treatment or in handling the device.

With your signature, you confirm the following: I have now read this information sheet. All questions and unclear issues were properly answered in a manner I could understand. I have no further questions about the procedure and side effects involved in the planned donation.