A PATIENT’S GUIDE ON HOW SICKLE CELL DISEASE IS MANAGED WITH RED BLOOD CELL EXCHANGE.
RED BLOOD CELL EXCHANGE AND SICKLE CELL DISEASE

If you or someone you care for has sickle cell disease, this educational brochure can help you better understand automated red blood cell exchange, a medical procedure used for transfusion management (removal and replacement of blood) in sickle cell disease patients.

WHAT ARE RED BLOOD CELLS AND HEMOGLOBIN?

A red blood cell is a component of the blood that carries oxygen from the lungs to all parts of the body. Hemoglobin is the part of the red blood cell that is responsible for carrying oxygen.

HOW DOES SICKLE CELL DISEASE AFFECT RED BLOOD CELLS?

Red blood cells containing hemoglobin flow freely throughout the body. In sickle cell disease, red blood cells contain a form of abnormal hemoglobin called hemoglobin S. The presence of hemoglobin S can cause red blood cells to change shape and become sticky, making it difficult for them to pass through small blood vessels. As a result, the body’s tissues and organs are deprived of the oxygen they need to function properly.

NORMAL RED BLOOD CELLS
LIVE 120 DAYS

SICKLE CELL DISEASE-AFFECTED RED BLOOD CELLS
LIVE 15 TO 20 DAYS
WHAT HAPPENS DURING THE RED BLOOD CELL EXCHANGE PROCEDURE

A qualified medical professional is responsible for operating a medical device called a blood cell separator, for example the Spectra Optia Apheresis System, and monitoring the patient throughout the procedure.

1 PREPARE
The single-use sterile tubing set, which holds the patient’s blood during the procedure, is placed on the Spectra Optia system.

2 CONNECT
Next, a tubing set is connected to the patient. Options include needles placed in the patient’s arm or arms. Depending on the length of treatment, more permanent options may be used.

3 REMOVE
Once the tubing set is connected to the patient, blood is removed from the patient and mixed with a fluid called anticoagulant, which prevents the blood from clotting. Very little blood, less than a cup, is in the tubing set at any point during the procedure.

4 SEPARATE
Next, the patient’s blood is sent to the centrifuge, where the red blood cells are separated and removed from the other blood components.

5 REPLACE
The healthy donor red blood cells are returned to the patient.

6 FINISH
When the procedure is complete, the tubing set and the red blood cells removed from the patient are properly thrown away.
WHAT HAPPENS DURING THE RED BLOOD CELL EXCHANGE PROCEDURE

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**WHAT IS AN AUTOMATED RED BLOOD CELL EXCHANGE PROCEDURE?**

Red blood cell exchange is an automated procedure that removes the patient’s red blood cells and replaces them with healthy red blood cells from a blood donor at the same time. The blood donor is someone who donated his or her blood for procedures like red blood cell exchange.

The system uses a centrifuge that spins the blood and separates it into red blood cells and other blood components.

Automated red blood cell exchange may help manage iron overload, which can be a challenge with simple transfusion or manual exchange procedures. With these types of procedures, medication is often required to manage iron overload.

**WHAT ARE THE POTENTIAL RISKS AND SIDE EFFECTS?**

Some patients may experience side effects.

- Patient anxiety may result in side effects such as headache, light-headedness, rapid breathing, shortness of breath, chills, nausea, vomiting or fainting.
- Other rare side effects may include tingling around the lips or fingers, fever, hives, itching, shock, or high or low blood pressure.
- Serious problems, such as allergic reactions to transfused red blood cells and infections due to viruses such as hepatitis and HIV, are extremely rare.

CLINICAL TRIAL RESULTS

A U.S. clinical trial was conducted on the red blood cell exchange procedure on the Spectra Optia system with the following results:

- The Spectra Optia system was able to decrease the patient’s hemoglobin S to the level that was requested by the physician.
- No serious adverse events were reported in 72 investigational patients tested in the clinical study.
- Thirteen of the 72 patients experienced at least one apheresis-related adverse event; of these adverse events, mild to moderate dizziness and nausea were reported in 10 of the 13 cases. The remaining three cases reported low platelet counts following the red blood cell exchange procedure however no platelet transfusions were required. A decrease in platelet count is typical for a red blood cell exchange procedure.
- There was no difference in the types or severity of adverse events reported for adult and pediatric participants.

To learn more about the procedure, benefits, potential risks and side effects of red blood cell exchange for the transfusion management of sickle cell disease, talk to your doctor.
FREQUENTLY ASKED QUESTIONS

Q: How long does the red blood cell exchange procedure take to complete?
A: The length of the procedure varies from patient to patient but can often be completed in two hours or less. Red blood cell exchange generally takes less time than a blood transfusion procedure.

Q: How often should a red blood cell exchange procedure be performed?
A: A doctor determines the recommended frequency of a red blood cell exchange.

Q: Is red blood cell exchange a common medical procedure?
A: Thousands of red blood cell exchange procedures are performed worldwide each year with few problems.

Q: Is a red blood cell exchange procedure painful?
A: While patients may experience slight discomfort when the tubing set is connected, the procedure itself is not painful. Bruising may occur depending on how the patient is connected to the device.

Q: Are visitors allowed during the procedure?
A: Once the procedure is underway, the medical staff will determine if the patient can have visitors. Most of the time visitors are allowed to be present.

Q: What can patients do during a procedure?
A: Generally, patients can eat and drink during the procedure and are allowed to participate in various activities like watching a movie or reading. The medical staff will provide specific instructions prior to the procedure.
Patients should always ask their doctors for medical advice about adverse events. You may report an adverse event related to Terumo BCT products by calling 1.877.339.4228 (U.S. only) or by email at customersupport@terumobct.com. If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly. The FDA has established a reporting service known as MedWatch where health care professionals and consumers can report serious problems they suspect may be associated with drugs and medical devices. Visit MedWatch or call 1.800.FDA.1088.

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