

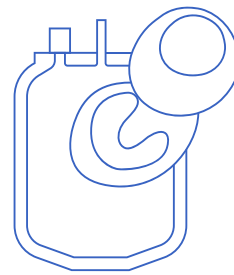
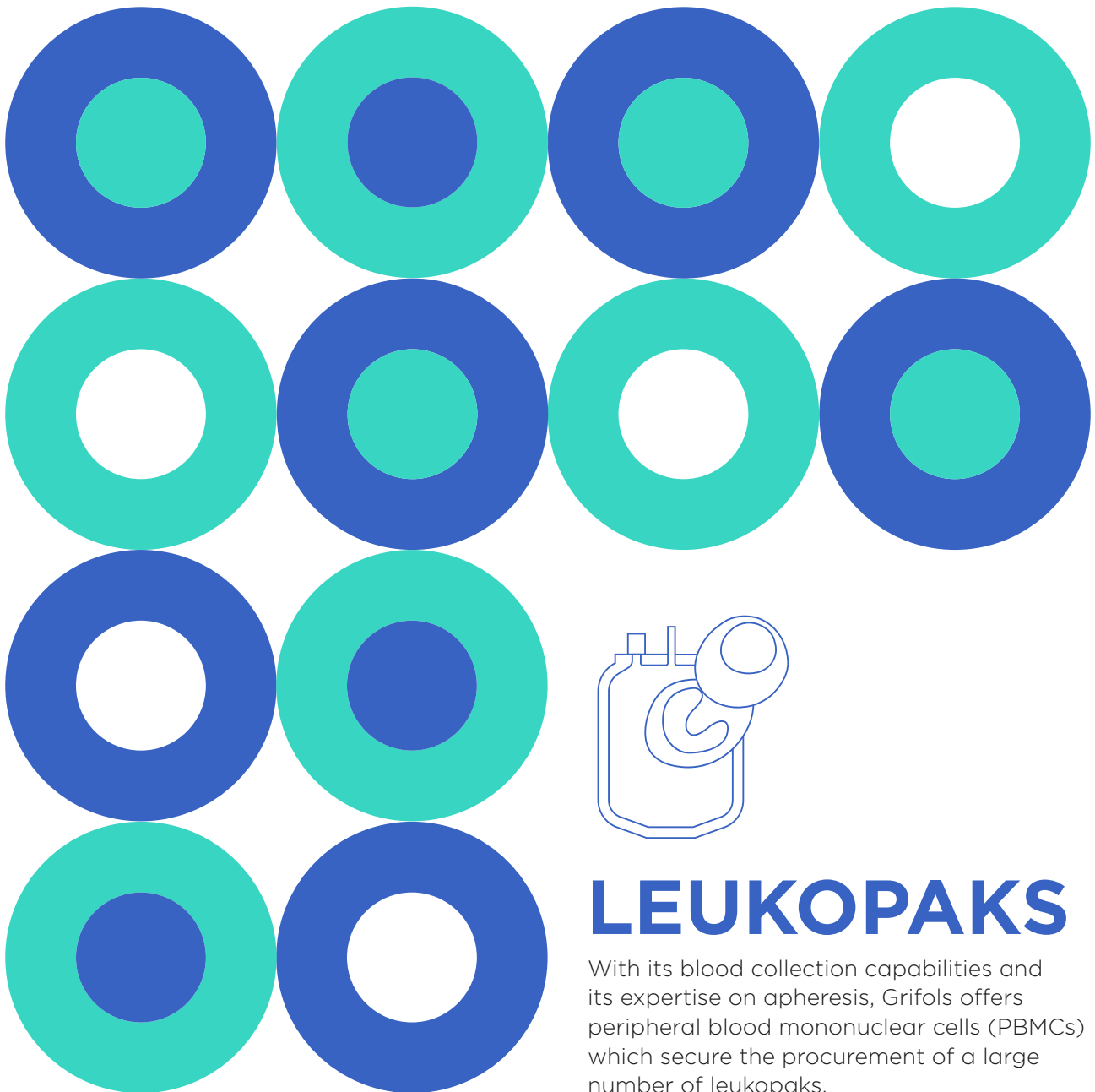
Cell Therapy: Sourcing Materials from USA

BioSupplies

Biological material solutions

Cell Therapy

Leukopaks



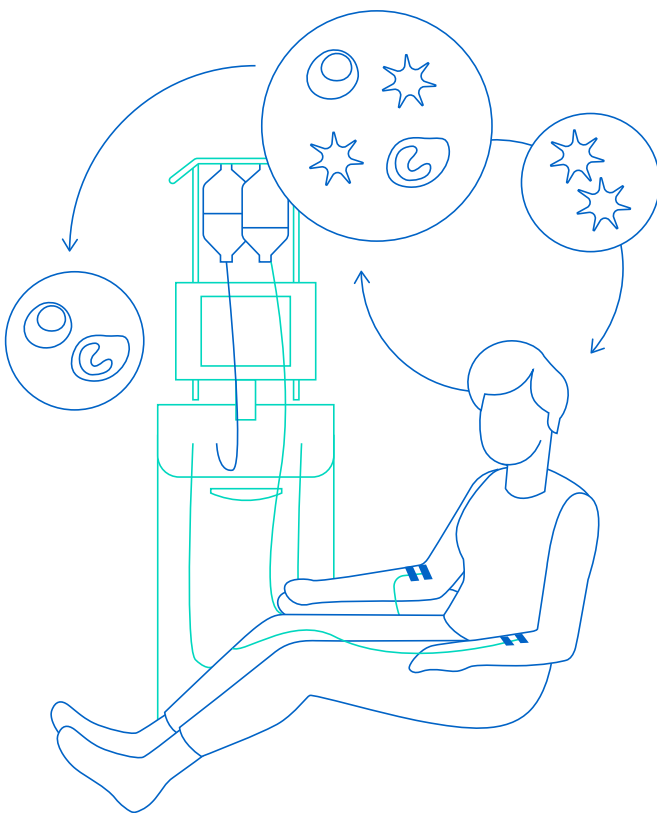
LEUKOPAKS

With its blood collection capabilities and its expertise on apheresis, Grifols offers peripheral blood mononuclear cells (PBMCs) which secure the procurement of a large number of leukopaks.

GRIFOLS

Leukopak is a blood-derived product generated from apheresis, rich in mononuclear leukocytes (ie, lymphocytes and monocytes)¹ and is used by researchers and manufacturers as a starting material in the field of cell therapy.

Grifols Bio Supplies offers fresh leukopaks for research use only and GMP grade. The high collection capabilities of Grifols and its expertise on apheresis secure the procurement of a large number of starting material.



THE LEUKOPAKS AVAILABLE ARE:



FRESH LEUKOPAKS

Our fresh leukopaks collected from healthy donors from USA without any further manufacturing steps. Fresh leukopaks are shipped within 24 hours within the USA territory for Immediate use.

Leukapheresis Process

Leukapheresis is a procedure where donors can donate their leukocytes. Donors are connected to the leukapheresis device with both arms. During the donation, the blood is removed from the donors' body and the leukapheresis machine separates the leukocytes from other cellular components and blood plasma. Those cellular components as well as the plasma are returned to the donors. The process takes approximately 3 hours.

LEUKOPAKS APHERESIS PROCESS



Collection Services in the USA

Grifols collection services program has been designed by our experienced donor recruiters to address the specific donor attributes that our customer needs. From the Grifols donor network in the USA, donors fulfilling the requirements for leukapheresis donations are approached to be enrolled within the Leukopak Donation Program.

All collections are done according to the FDA guidelines for Collection and Processing of Blood and Blood Components and internal SOPs.

Collection services

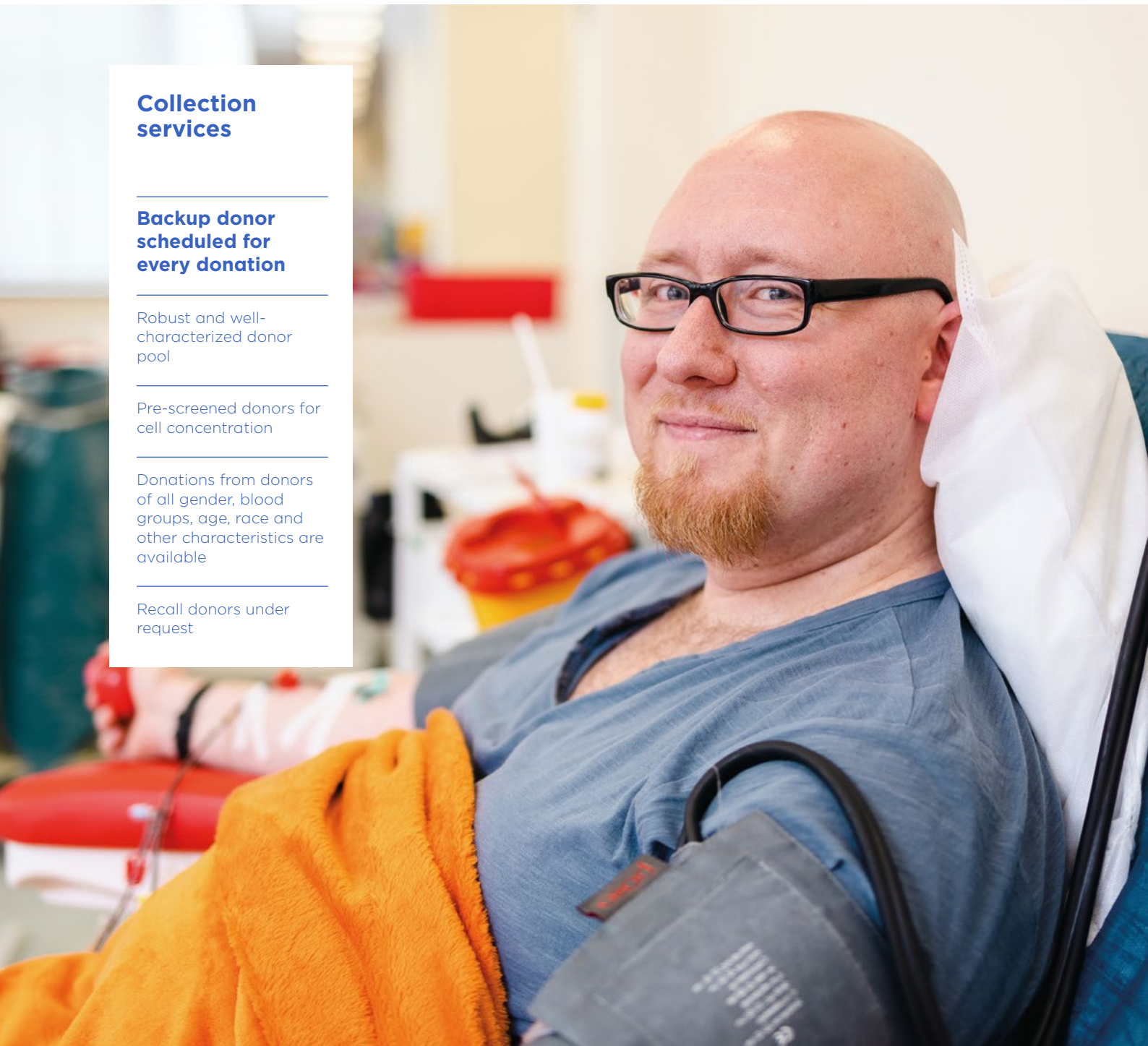
Backup donor scheduled for every donation

Robust and well-characterized donor pool

Pre-screened donors for cell concentration

Donations from donors of all gender, blood groups, age, race and other characteristics are available

Recall donors under request



Qualified technology, process, and people you can trust

LEUKAPHERESIS TECHNOLOGY AND PROCESS

Leukopak donations are done via leukapheresis using ACD-A as anticoagulant. The leukapheresis is an automated method for collecting mononuclear cells which allows the collection of:

- Different amounts of cells (1/2 leukopaks or full leukopaks)
- Different amounts of plasma either within the plasma bag or the collection bag

For all Leukopaks multiple lab testing analysis are performed being also able to be customized according to each project need. The parameters included in the testing are:

- Viral testing (following requirements of FDA)
- Blood count analysis for: the total amount of hemoglobin, whole blood cell count, platelet count, lymphocyte count and monocyte count

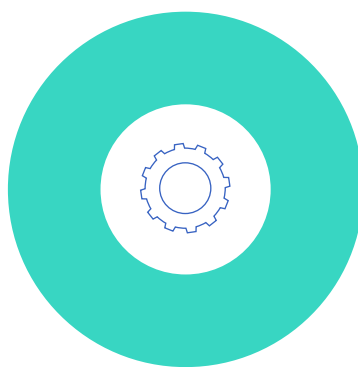
QUALIFIED AND TRAINED PERSONNEL

Our personnel have long-term experience on apheresis collections.



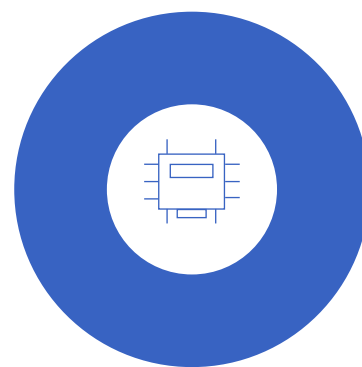
PEOPLE

Experienced personnel



PROCESS

Flexible and efficient processes



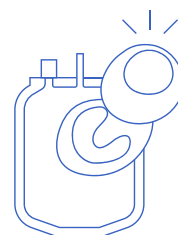
TECHNOLOGY

State-of-the-art devices used for manufacturing

Fresh Leukopaks Specifications

Fresh leukopaks provided by Grifols are collected from our robust and well-characterized USA donor pool with a backup donor system which secures the availability of the leukopak on the scheduled day.

Grifols offers fresh leukopaks with a high concentration of leukocytes ($\geq 40 \times 10^9$ cells/L) which helps to cover large scale needs.



SPECIFICATIONS

Origin of leukopaks	USA
Donor criteria	Donors have an approved consent for donating blood. All donors are screened to ensure that each of them is in good health condition and that products are not collected from a high-risk population for blood-borne infections.
Donor data provided	Age, gender, race, blood group and other
Viral testing	Each donor is tested for the standard FDA viral markers and found negative for Anti-HIV Ag/Ab, HBsAg, Anti-HCV, HTLV I/II, Treponema Pallidum Antibodies, Anti-HBc, Atypical Antibody, HIV-1 RNA/HBV DNA/HCV RNA, West Nile Virus RNA, Chagas (donor level)
Format	>170 mL
Anticoagulant	ACD-A
Obtention method	Leukapheresis
Leukocyte concentration	$\geq 40 \times 10^9$ cells/L
Hemoglobin concentration	≤ 0.5 mmol/L
Monocyte concentration	$\geq 5 \times 10^9$ cells/L
Lymphocyte concentration	$\geq 28 \times 10^9$ cells/L
Use	R&D cell therapy Source of PBMCs
Grade	Research use only (RUO) and GMP



GRIFOLS

For ordering information,
contact us here:



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