

Liver transplantation with the OrganOx *metra*

**Patient information:
A guide for you and your family**



MedStar Health

MEDSTAR GEORGETOWN
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About this brochure

This brochure is for patients who need a liver transplant and are listed on the U.S. liver transplant waiting list. It contains information that will help you and your family learn more about a new way to preserve livers before transplantation using the OrganOx *metra* normothermic perfusion system.

Please discuss any questions you have with your doctor.

The OrganOx® metra®

The OrganOx® metra® (referred to as OrganOx metra) is an FDA approved **normothermic liver machine perfusion (NMP)** system:

- **Normothermic** means at normal body temperature, around 99°F;
- **Machine** means a piece of equipment that performs a task, in this case the OrganOx metra;
- **Perfusion** means the passage of fluid through an organ

The OrganOx metra is a **piece of equipment that moves fluid through an organ** (in this case, the liver) at **normal body temperature**.

Your doctor is the best person to explain your treatment options to you. Your doctor will also be able to tell you about the benefits and risks associated with this treatment. If you have questions about the OrganOx metra system that are not answered in this brochure, please ask your doctor.

This brochure is intended to provide some general information about the OrganOx metra. It is not intended to tell you more broadly about a liver transplant. For any questions about your health, your condition, and your treatment options please talk to your doctor.

When should the OrganOx metra be used?

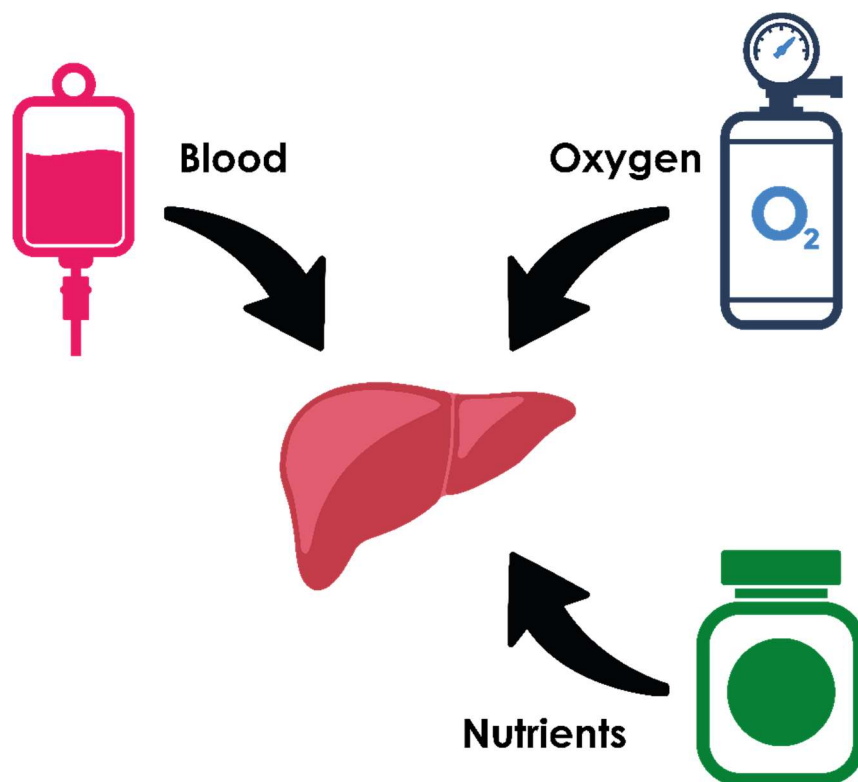
The OrganOx metra is intended to support livers from donors over the age of 16 years. There are various *types* of organ donors, and you should discuss these different types with your doctor.

The intended recipients are people over 18 years of age on the U.S. waiting list for liver transplantation.

How does the OrganOx *metra* work?

The OrganOx *metra* is a method of preserving a liver once it has been removed from a donor.

Instead of being placed on ice in a cooler or organ transportation box, the liver is placed in the OrganOx *metra*, which keeps it warm similar to the human body. The OrganOx *metra* circulates warm blood through the liver and provides oxygen and nutrients to keep it healthy and functioning like in the human body.



Because the liver receives warm blood, oxygen, and nutrients, it is able to function inside the OrganOx *metra* like in the human body. Livers perfused on the OrganOx *metra* have been shown to suffer less injury than those livers that are stored in an ice box.

In order to achieve FDA approval for clinical use, the OrganOx *metra* was evaluated in a randomized clinical trial of 266 subjects at 14 US liver transplant hospitals. The results of this study demonstrated an improvement shown by a reduction in the incidence of Early Allograft Dysfunction (a measure of the amount of damage sustained by a liver during the process of transplanting it)

from 25% with ice box storage to 19% with the OrganOx *metra*. Livers were also stored for 75% longer on the OrganOx *metra* compared to ice box storage.

Maintaining the liver in this way allows your doctor to assess the quality of the liver before transplantation.

When should the OrganOx *metra* be used? (Indications)

The OrganOx *metra* is a transportable device intended to be used to sustain donor livers for a total preservation time of up to 12 hours.

The OrganOx *metra* device is suitable for liver grafts from donors after brain death (DBD), or liver grafts from donors after circulatory death (DCD) ≤ 40 years old, with ≤ 20 mins of functional warm ischemic time (time from donor systolic blood pressure < 50 mmHg until in situ cold flush), and macrosteatosis $\leq 15\%$, in a near-physiologic, normothermic and functioning state intended for a potential transplant recipient.

When shouldn't the OrganOx *metra* be used? (Contraindications)

Living donor liver

Liver intended for split transplant

Lack of trained personnel

Donor liver trauma

DCD donors age > 40 years old, > 20 mins of functional warm ischemic time, and macrosteatosis $> 15\%$.

What are the risks of using the OrganOx *metra*?

All surgical procedures have potential risks. The risks of having a transplant after using the OrganOx *metra* are the same as using an ice box. General risks of surgical procedures include:

- Infection
- Bleeding
- Fluid build-up in abdomen or lungs
- Kidney problems

- Liver problems or failure
- Heart problems
- Lung problems
- Hypotension
- Leukopenia
- Anemia
- Gastrointestinal problems
- Altered mental status
- Death

It is possible that after perfusion on the OrganOx *metra*, your doctor may decide that the donor liver is not of sufficient quality to be transplanted.

Should your doctor decide that a liver inside the OrganOx *metra* is not suitable for transplantation, your transplant may be cancelled or postponed, and you will have to wait for another liver to become available.

The OrganOx *metra* is robust, safe, and reliable, however it is possible that a malfunction may cause the OrganOx *metra* to not work properly. It is also possible that user error could lead to damage of the liver or conversion to ice box storage. In order to reduce these risks, the OrganOx *metra* is always monitored to reduce the risk of malfunction as much as possible and your doctors have been fully trained to use the OrganOx *metra* by experts from OrganOx. The OrganOx *metra* is serviced and maintained regularly.

What are the benefits of using the OrganOx *metra*?

There are several potential benefits to using the OrganOx *metra* instead of an ice box.

- Prolonged cold storage may cause damage to the liver when it is transplanted.
- The liver can be safely stored in the OrganOx *metra* for a longer time than in the ice box. The OrganOx *metra* can prolong storage for approximately two extra hours with comparable results to static cold storage.

- This longer storage time can give your doctor more time to arrange and perform your transplant.
- Your doctor can carefully examine and assess the function of the liver while in the OrganOx *metra*, allowing a more thorough assessment.

To date, the OrganOx *metra* has supported more than 1,200 liver transplants worldwide. In a recent clinical trial in the U.S., the OrganOx *metra* demonstrated a comparable safety profile to cold storage.

What to expect if your doctor decides to use the OrganOx *metra*

If your doctor decides to use the OrganOx *metra* for your transplant, you do not have to do anything differently. Your doctor will explain what you need to do before and after your transplant.

Precautions

The safety and effectiveness of the OrganOx *metra* is based upon clinical evaluations. Longer term outcomes (greater than 5 years) are unknown. Short-term patient and graft survival using the OrganOx *metra* are comparable to static cold storage.

Your doctor has been advised to carefully review all available information when considering using the OrganOx *metra*.

Contact information

For more information about the OrganOx *metra*, please contact OrganOx Inc. by phone or online.

By phone: 855-ORGANOX (855-674-2669)

Online: www.organox.com

See instructions for use for indications, contraindications, warnings, precautions, and adverse events.

CAUTION: Federal law (USA) restricts use of this device by or on order of a physician.

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