



RM4[®]

Pulsatile Perfusion Solution

FDA-cleared device

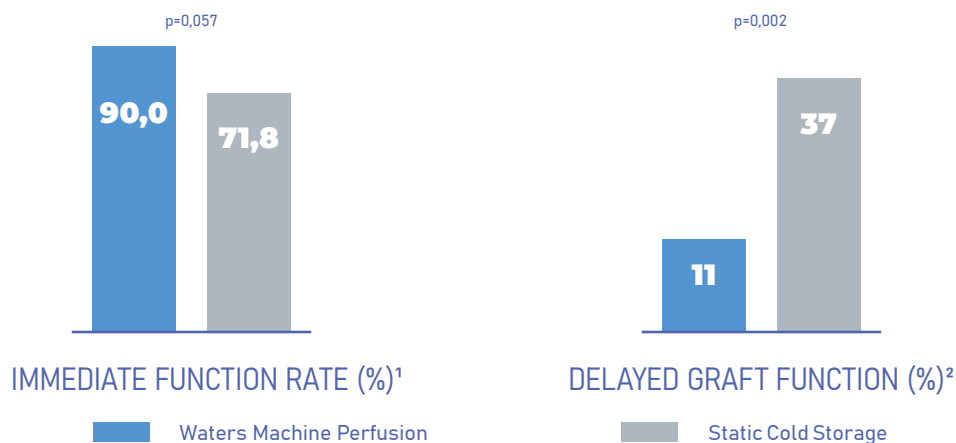
DESCRIPTION

RM4 is used for the pulsatile hypothermic machine perfusion of either one or two kidneys from the same donor for preservation and eventual transplantation into a recipient.

The system monitors perfusate flow, temperature, pressure, and renal resistance during preservation, and continually circulates a cooled solution (Waters IGL® Pulsatile Perfusion System or PERF-GEN®) through the vascular vessels of the organs. The solution removes cell fragments and enables unbroken delivery of oxygen and substrates to the organs. The ion-pump activity as well as the metabolism, including adenosine triphosphate (ATP) synthesis, are thereby maintained during the perfusion. The hypothermic conditions slow down the metabolism and then decrease the cellular degradation of the organs.

CLINICAL BENEFITS

RM4 inherits the Waters Hypothermic Machine Perfusion technology which has been shown to be beneficial to marginal donor kidneys, leading to more favorable immediate graft function and delayed graft function compared to static cold storage. Immediate graft function is defined by serum creatinine falls of more than 20% in the first 24 hours post-transplant. Serum creatinine is an important indicator of renal health because it is an easily measured byproduct of muscle metabolism that is excreted unchanged by the kidneys. Delayed graft function is defined as the need for dialysis within 7 days of transplantation.



1. Light JA Clinical Transplantation June 1996; 10(3):233-6.

2. Stratta RJ J American College of Surgeons May 2007; 204(5):873-82; discussion 882-4.

ACCESSORIES FOR CANNULATION

Kidneys are cannulated by the renal artery. Different types of cannula are provided with the RM4 system in order to suit all anatomies.

- Clamp for organ recovered with aortic patch
- Straight cannula for organ recovered without aortic patch
- Trident cannula for organ with multiple arteries

SPECIFICATIONS

SIZE AND WEIGHT

- 51 cm (20") x 37.8 cm (15") x 21.9 cm (8") control unit
- 36.8 cm (14") x 26.6 cm (10") x 26.7 cm (11") cassette
- 13 kg (26 lb) dry control unit
- 2 kg (4 lb) dry cassette
- 22 kg (44 lb) system fully loaded

COOLING

- Perfusate temperature regulation through heat exchanger
- Water-and-ice slush in detachable reservoir

PUMP

- Pulsatile pump with systolic pressure range user settable from 10 to 70 mmHg
- Fixed pulse repetition rate, 60 beats per minute (BPM)

FLOW

- Ultrasonic flowmeter, range 0 to 250 mL/min

INTERFACE

- Set pressure
- Prime
- Organ information (organ ID, kidney side, clamp time)
- Device information (time, date, device ID, battery status, language selection, network status)
- Pressure display
- Flow rate display
- Renal resistance display
- Perfusate temperature display
- Ice temperature display

TEMPERATURE

- Temperature sensor 1: Fluid in Bubble Trap
- Temperature sensor 2: Ice Container

BATTERIES

- 1-4 lithium ion batteries
- Drop-in, hot swappable
- Rapid recharge via mains
- Battery life 5 hr

POWER

- 100-240V AC; 50-60Hz

CONNECTION

- Mains power
- USB type-A
- Ethernet
- Wi-Fi
- Flash drive (setpoints, calculated and displayed values, sensor readings and events)
- Unit memory fifteen 48h data files
- FCC Compliant

PERFORMANCE

- Constant pressure regulation to maintain user-set pressure
- Maintain organ temperature at 2°C to 8°C

ORGAN CASSETTE

- Organ capacity, two human kidneys ≤ 10 cm x 20 cm x 5 cm
- 1 liter perfusate, Waters IGL® Pulsatile Perfusion Solution, PERF-GEN®
- EtO sterilized, single-use
- Bubble trap integrated to perfusion circuit

BENEFITS OF RM4 RENAL PERFUSION SYSTEM :

- **PHYSIOLOGIC SYSTEM**
Pulsatile arterial pressure and oxygenation of the perfusate to simulate human physiology
- **CONVENIENT INTERFACE**
Equipped with a large touchscreen interface to walk the user, minimizing significant setup and training time
- **DUAL PERFUSION**
An obvious cost saving and convenient procedure for centers with any number of transplant



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