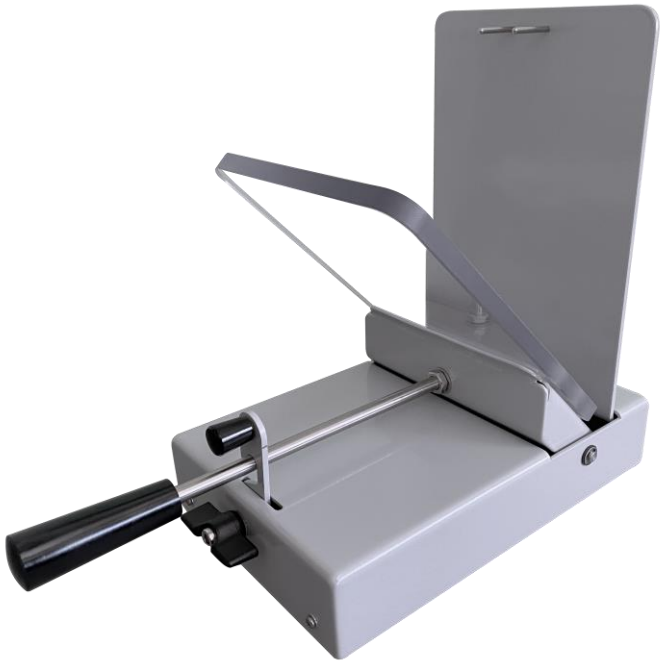
VASINI STRUMENTI S.r.l.
MEDICAL DIVISION

GLOBE CERTIFICAZIONI N. 1141 UNI EN ISO 9001:2015

DESIGN, MANUFACTURING , MARKETING & QUALITY CONTROL OF MEDICAL DEVICES
Via Faentina 207/Q 48124 Fornace Zarattini (RA) - **ITALY** TEL. +39-0544-464048 FAX +39-0544-501617
E-mail: commerciale@vasinistrumenti.it Website: www.vasinistrumenti.it

MANUAL PLASMA EXTRACTOR MOD. EPM



FUNCTIONS

The manual plasma extractor mod. EPM is a medical device inteded for the easy separation of blood components that are inside bags. Thanks to the transparent polycarbonate panel, it allows the operator, in a precise and safe way, to divide the blood components from the primary bag to the satellite bags.

The plasma extractor mod. EPM is suitable for the production, starting from whole blood, of: Concentrated Red Blood Cells (CRBC), Platelet-Poor Plasma (PPP), Platelet-Rich Plasma (PRP), Buffy-Coat (BC) and Platelets (PLT) from Plasma.

FEATURES

- Delicate and adjustable pressure during blood components separation.
- Support to hang the bag, in order to facilitate the manual breaking of the cannula.
- Extremely silent functioning thanks to the springs' high quality.
- Easy to clean and sanitize design.
- Pressure plate in unbreakable transparent polycarbonate.
- Material: painted stainless steel.
- Weight: about 4Kg
- Dimensions: Breadth 170mm, Depth 240 mm, Height 264mm.
- Packed device weight and dimensions: 200x300x300 mm – 4,5 kg

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- CND: B99 RDM: 2253794 CLASS I

USE

1. PREPARATION (Fig.1)

Completely open the extraction system through the central lever and lock it with the specific hook.

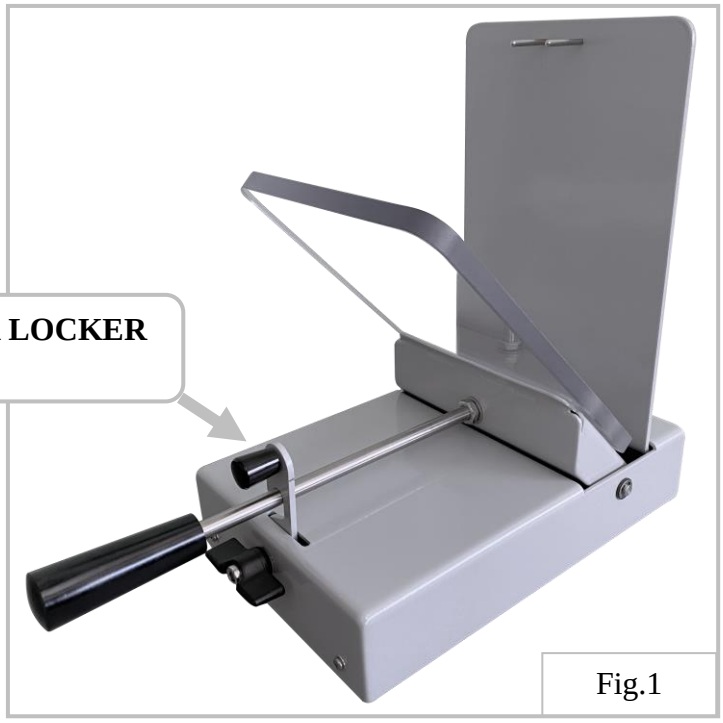

Fig.1

2. PLASMA EXTRACTION (Fig.2)

Place the bag onto the two supports, unlock the lever and move the transparent plate against the bag.

3. EXTRACTION SPEED REGULATION (Fig.2)

To increase/decrease the extraction speed, it suffice to rotate the regulation knob clock wisely to increase the speed or anti-clock wisely to decrease it.

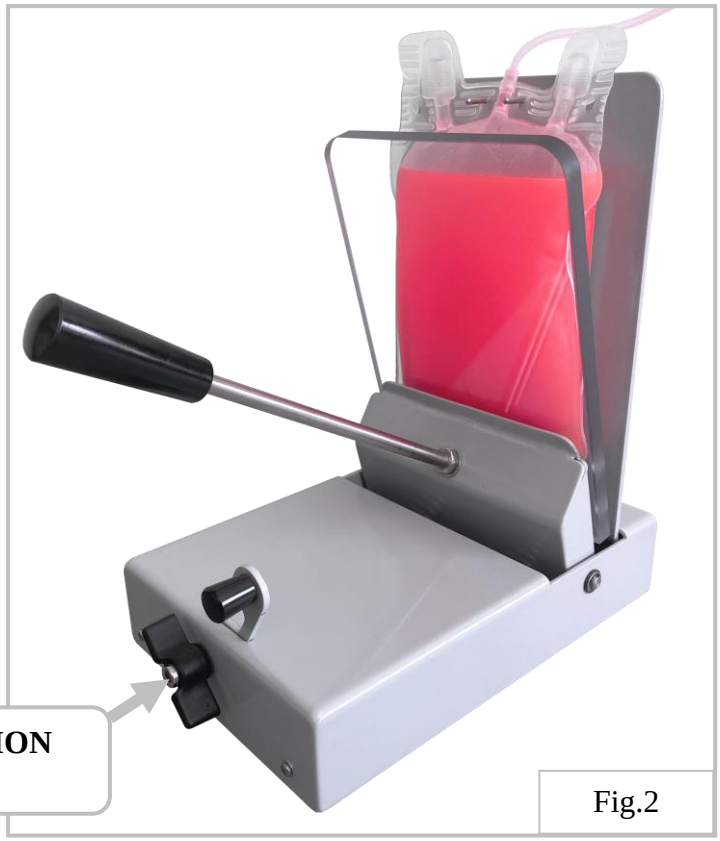

Fig.2

4. BAG REMOVAL (Fig.1)

Once the extraction is completed, lower the main lever, lock it with the proper locker and then remove the bag.

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CLEANING PROCEDURE

Clean the device with a soft cloth soaked in isopropyl alcohol. Then wipe with a soft, dry cloth. Do not use corrosive or abrasive cleaners.

SIMBOLI E DEFINIZIONI

Informazione contenuta	Descrizione
 VASINI STRUMENTI S.r.l. Via Faentina 207/Q Fornace Zarattini (RA) e-mail info@vasinistrumenti.it	Medical device's manufacturer
	**MODEL/TYPE** The model identifies the product's family, the type identifies the device inside the family.
	Device's serial number
	Production date
	CE Marking
	Medical Device

IN COMPLIANCE WITH THE EEC DIRECTIVES IN FORCE MDR 2017/745

The company reserves the right to make changes and / or improvements without notice at any time

Designed and manufactured in Italy.

WARRANTY

The manufacturer guarantees the device and all its components for 12 months since the delivery date. During this period, Vasini Instruments srl undertakes the responsibility to repair or replace the device for free when there are manufacturing defects, only if the found defect is communicated in advance**.**

Shipment costs that come with goods repair are at the client's charge, both in case of goods delivery and pick-up. Replaced parts remain a Vasini Instruments property.

Warranty cannot be considered valid when the followings occur: tampering with, modification, inappropriate use with respect to the use instructions, wrong power supply, repairs done by unathorized personnel, accidental breakages due to transport or falls; lack, cancellation or alteration of the serial number. In case of repairs not covered by warranty, Vasini Instruments Srl or one of its representatives will draw up an estimate and will arrange for the repair with the prior written consent of the customer.

Each return must be authorized in advance by Vasini Instruments Srl.

In any case, the warranty excludes any compensation for damages.

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CONFORMITY DECLARATION

CE

The Manufacturer:

Vasini Strumenti Srl
Via Faentina 207/Q
FORNACE ZARATTINI (RA)
SRN: **IT-MF-000012098**

DECLARES under its full responsibility

that the medical device defined as

ESTRATTORE DI PLASMA MANUALE
MODELLO **EPM**

UDI di BASE: **8057502560000EPMGU**

is a Class I non-invasive medical device as per rule 1, att. VIII of the MDR 2017/745.
Such device is compliant with the safety essential requirements listed in the att. I and follows the provision of the MDR2017/745.
Certification procedure as per attachments II and III of the MDR2017/745.

Ravenna, 16/05/2022

Yours faithfully

DT. EPM.11 rev oo