M·C·T

Meta Cell Technology

MCT® Kit Manual

Ver: 2023-04

CLINIPRO SL
Manel Farres, 101
08173 Sant Cugat del Vallès
España

CE
0051

Intended Use: MCT Kit is a sterile, single-use container specifically intended for storing body fluids such as blood, plasma and liquid fat that is to be subsequently re-administered to the patient within 24 hours. It is intended to provide the specific environment necessary to condition the fluid according to the physician's requirements before it is administered to the patient.
Specific clinical applications include the conditioning of platelet-rich-plasma (PRP), serums, cell concentrations (Stromal-vascular-fraction) or fat-derived concentrates to enhance cell regeneration results when administrated to the patient.

Indications:
Aesthetic surgery and medicine

Contraindications:
Such associated to the medical procedure

Specifications:
Volume: The volume of the container is the standard volume of an extraction syringe (10ml) plus small extra volume (0,5ml) for minor fluctuations (temperature, etc..).

Shape: The extra flat shape of the container is to guarantee that, if cells are physically conditioned by light:

1- All the liquid will be exposed to the light
2- Exposure will be homogeneous for the whole volume.

Ports: The 2 ports allow the pressure equalization while loaded and unloaded. With only one port negative pressure (while unloaded) would narrow the space and might squeeze/stress the liquid.

Transparence: The specific Terlux® medical polymer guarantees the reflection and diffraction of the light is less than 0,1%. This means that all the amount of light emitted will reach all the liquid in the same way.

Interactions: MCT Kit interacts only with syringes (Luer Lock® or standard) for load-unload purposes.

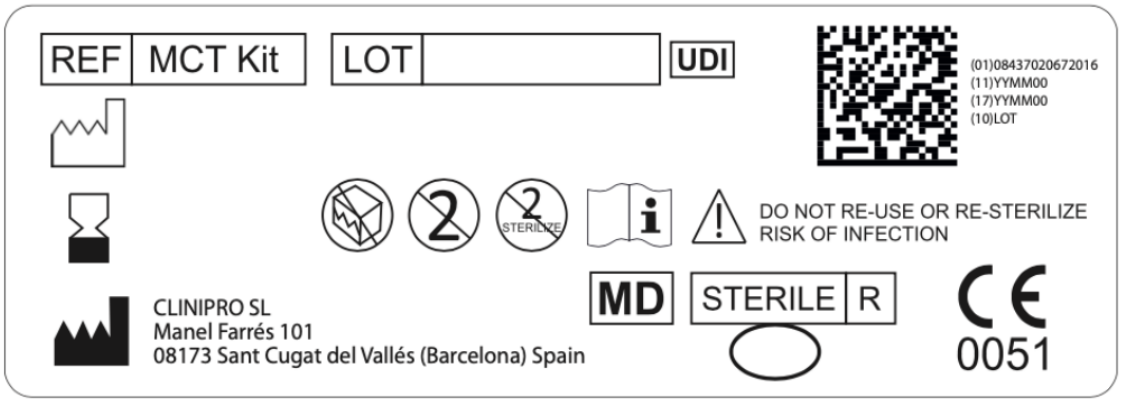
Presentation:
MCT kit is composed of:

- a 10 ml capacity flat rectangular medical grade plastic container with 2 filling / extraction holes
- wrap of soft plastic of medical grade that incorporates the plugs for the 2 holes of the kit
- Each box /secondary packaging) contains 10 units MCT Kits

The MCT Kit is presented sterile into a pouch (primary packaging) hermetically sealed.

Identification:

Each kit is identified with the following information:



REF	Product identification reference
LOT	Manufacturing batch code
VER:	Labelling version
	Do not use if package is damaged
	USE BY (AAAA-MM)
	Product for single use Do not reuse. The reuse of the device can produce a cross infection
STERILE R	Sterilized with gamma radiation
	Do not re-sterilize. The device does not support their correct cleaning and sterilization after used
	CAUTION - Place a 20 or 25 micras filter coupled to the Luer-Lock syringe before application to the patient - Once used, get rid of the MCT Kit in a special biological waste container
	Consult instructions for use
MD	Medical Device
UDI	Unique Device Identifier
	MANUFACTURER. This symbol is accompanied by the name and the address of the manufacturer
CE 0051	CE symbol with the intervention of a Notified Body

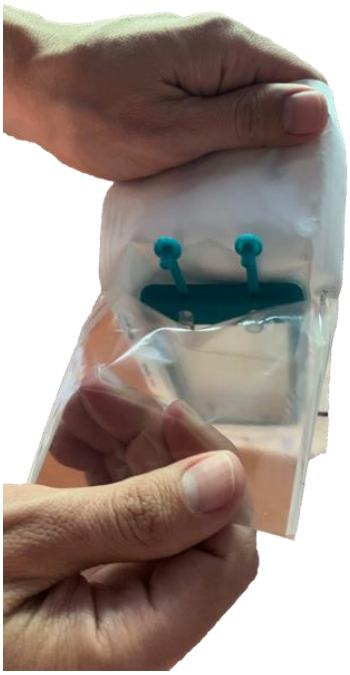
Instructions for use:

1) Open the secondary packaging and remove the kit

2) Check that the primary packaging has not been damaged

3) Check that the product is not fractured or cracked

4) While another person opens the primary packaging, remove the kit equipped with sterile gloves

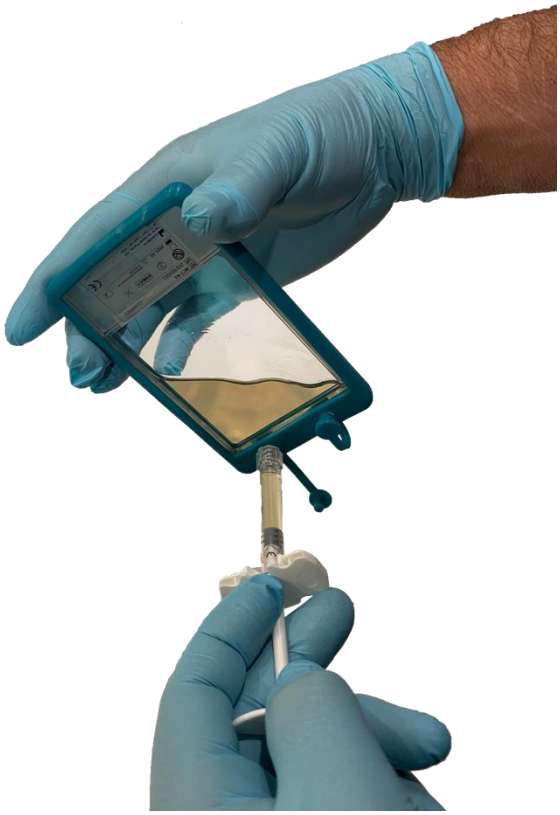


4) Place the Luer-Lock syringe in one of the connectors and lock it

5) Fill the kit with the filler face tilted up so that it is higher than the bottom face (see photo)
The filling capacity is 10ml maximun

6) Close the 2 connectors with the 2 plugs included in the soft plastic wrap

7) To extract the contents of the kit, remove one of the plugs, place the Luer-Lock syringe in the connector, block it and extract the desired amount by tilting the Kit.



Warnings:

- Place a 20 or 25 micras filter coupled to the Luer-Lock syringe before application to the patient
- The sterile MCT Kit is for single use
- Do not use if the product is fractured or cracked
- Do not re-sterilize. The device does not support their correct cleaning and sterilization after used
- Do not reuse. The reuse of the device can produce a cross infection
- Once used, get rid of the MCT Kit in a special biological waste container

CLINIPRO®

DECLARACIÓN DE CONFORMIDAD UE
UE DECLARATION OF CONFORMITY

de acuerdo con el anexo IV de la MDR (EU) 2017/745 /
according to annex IV of the MDR (EU) 2017/745

N° 2022-12-12

FABRICANTE: *MANUFACTURER:*	CLINIPRO SL
DIRECCIÓN: *ADDRESS*	Carrer de Manel Farres, 101 08173 Sant Cugat del Vallès España
SRN:	ES-MF-000000946

DECLARAN BAJO SU EXCLUSIVA RESPONSABILIDAD QUE EL/LOS PRODUCTO(s) FABRICADO(S):
DECLARE UNDER THEIR SOLE RESPONSIBILITY THAT THE MANUFACTURED PRODUCT(s):

Nombre *Name*	**[MCT KIT]** **REF** MCT KIT *REF*
Tipo *Type*	Producto de un solo uso Single use device
fabricado a partir de fecha: *manufactured from date:*	24-09-2021 *2021-09-24*
UDI-DI Básico *Basic UDI-DI*	8437020672MCT01ZT
Código GMDN/ *GMDN Code*	44904 Recipiente para almacenamiento de sangre y cultivo/ *Blood/tissue storage/culture container*
Código CND/ *CND Code*	A080299 BOLSAS Y ENVASES, INFUSIÓN – OTROS/ *BAGS AND CONTAINERS, INFUSION – OTHERS*
Finalidad Prevista *Intended Use*	MCT Kit es un contenedor estéril específico de un solo uso para almacenar fluidos biológicos, como por ejemplo, plasma, para posterior re-administración al paciente en menos de 24 horas. Su finalidad es de permitir un entorno específico necesario para acondicionar el fluido biológico conforme a los requerimientos físicos previamente a su administración al paciente/ *MCT Kit is a sterile, single-use container specifically intended for storing body fluids such as blood, plasma that is to be subsequently re-administered to the patient within 24 hours. It is intended to provide the specific environment necessary to condition the fluid according to the physician's requirements before it is administered to the patient.*
Clasificación: *Classification:*	**IIa** (anexo VIII regla 2) *(annex VIII rule 2)*

CUMPLE LOS REQUISITOS GENERALES DE SEGURIDAD Y FUNCIONAMIENTO Y DISPOSICIONES DE:
CONFORMS WITH THE GENERAL SAFETY AND PERFORMANCE REQUIREMENTS & PROVISIONS OF:

(EU) 2017/745 **y sus modificaciones / as amended**	**Reglamento Productos Sanitarios,** ***Medical Devices Regulation,*** y las legislaciones nacionales adicionales *and the aditional national laws*
Ruta evaluación conformidad: *Conformity assessment route*	Anexo IX (I) Annex IX (I)
Expediente Técnico: **Technical documentation**	TD01-01 ver 09
Organismo Notificado: *Notified Body*	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A / NB n° 0051 Via Quintiliano, 4320138–MILANO *cert. n° 009/MDR* con validez hasta / *valid until*: 2026-09-23
Normas específicas: *Specific standards*	EN ISO 10993-1:2020 EN ISO 11137:2015
Sistema de Calidad según: *Quality System according:*	EN ISO 13485:2016+/AC:2018+/A11:2021

Nombre y Firma *Name and Signature*	PLAN DALMAU EDUARDO DAVID - 53293795N Digitally signed by PLAN DALMAU EDUARDO DAVID - 53293795N Date: 2022.12.12 12:57:00 +01'00' **Eduard Plan** **Date 2022/12/12**	PLAN PHILIPPE - X0762496T Firmado digitalmente por PLAN PHILIPPE - X0762496T Fecha: 2022.12.12 16:07:26 +01'00' **Philippe Plan** **Date 2022/12/12**
	Persona Responsable Cumplimiento Normativo (PRCN) *Person Responsible for Regulatory Compliance (PRRC)*	**Director General** *General Manager*