





Product Picture

Trading Name

Product Code

MCT-A30SP00000

Composed of:

MTK02650/HTA-03	INFUSION PROCEDURES SET
FL40/D27	FILTER FOR OBTAINING MONONUCLEATE CELLS
4010005000	BLOOD COMPONENT SAMPLING BAG 300 ML
401000000	BAG FOR COLLECTING MONONUCLEATE CELLS 50 ML

Uso Previsto

MONOCYTES is a peripheral blood selective filtration system from which it is possible to obtain mononuclear cells. MONOCYTES works by gravity filtration, exploiting the force of gravity, avoiding any act that alters or stresses the cells themselves (centrifugation, cutting, etc.). The heart of the system is a membrane that selectively holds cells by size, and is capable of completely eliminating the inflammatory cell component.

CODICE	DESCRIZIONE	CE	CND	RDM
MCT-A30SP00000	KIT MONOCYTES	//	//	132880

Composition Kit Monocytes

CODICE	DESCRIZIONE	CE	CND	RDM
MTK02650/HTA-03	INFUSION PROCEDURES SET	0373	T0202	2138622
FL40/D27	FILTER FOR OBTAINING MONONUCLEATE CELLS	0425	B06	1556515/R
4010005000	BLOOD COMPONENT SAMPLING BAG 300 ML	0476	B019004	2142764/R
4010000000	BAG FOR COLLECTING MONONUCLEATE CELLS 50ML	0476	B019004	2142764/R

MONOCYTES (MCT-A30SP00000) IS AN ASSEMBLED KIT, THE CE AND THE CND OF REFERENCE ARE THOSE OF THE INDIVIDUAL CODES THAT COMPOSE IT (MTK02650/HTA-03, FL40 / D27, 4010005000, 4010000000).



Description of the individual devices

MTK02650/HTA-03 Description Disposable sterile complete kit for infusion procedures

INFUSION

PROCEDURES SET

Content N ° 1 cloth 100x100 cm

N ° 1 tray 14x24x2.5 cm

N $^{\circ}$ 2 hypodermic needles of 22 g 30 mm N $^{\circ}$ 1 18g 2-way cannula needle L. 45 mm

N° 2 10 ml luer lock syringes N° 2 syringes of 60 ml luer lock N° 10 syringes of 3 ml luer lock

Materials All devices are CE marked. The technical specifications of the medical

devices included in the kit are

available on request.

Packaging With peel open bag in paper / PE suitable for sterilization.

Sterilization Ethylene oxide - validity 60 months

CE Class IIa sterile

Produced by BETATEX S.P.A. – Loc. Venella, Terentola di Cortona (AR)

FL40/D27 Description System for the preparation of concentrated mononuclear cells

FILTER FOR OBTAINING

MONONUCLEATE

CELLS

Content Male L / L connector and protective cap

L / L female connector with bi-directional safety valve and protective

cap

NO DOP PVC pipe Sliding clamp in PE Y-piece in PVC

Filter for the separation of mononuclear cells.

Materials All devices are CE marked. The technical specifications of the medical

devices included in the kit are available upon request.

Packaging Medical paper bag suitable for sterilization

Sterilization Ethylene oxide - validity 60 months

CE Class IIa

Produced by MACROPHARM Srl – Caltanissetta (CL)



Technical Sheet

4010005000 Description System for the preparation of concentrated mononuclear cells

BLOOD COMPONENT SAMPLING BAG 300 MI Content 300 ML blood bag

Materials 2 blood bags of 300 ML

All devices are CE marked. The technical specifications of the medical

devices included in the kit are

Packaging available on request.

Sterilization With peel open bag in paper / PE suitable for sterilization.

CE Class Ethylene oxide - validity 60 months

Produced by IIb

4010000000 Description 50 ML blood bag

BAG FOR COLLECTING MONONUCLEATE CELLS 50 ML Content 1 50 ML blood bags

Materials All devices are CE marked. The technical specifications of the medical

devices included in the kit are

available on request.

Packaging With peel open bag in paper / PE suitable for sterilization.

Sterilization Ethylene oxide - validity 60 months

CE Class IIb

Produced by MEDITALIA INDUSTRIALE Srl – Lovero V. (SO)

Packaging

Monocytes System

Each box contains:

- 1 SET OF INFUSION PROCEDURES (MTK02650/HTA-03)
- 1 FILTER TO OBTAIN MONONUCLEATE CELLS (FL40 / D27)
- 2 BLOOD COMPONENT SAMPLING BAG 300 ML (4010005000)
- 1 BAG FOR COLLECTING MONONUCLEATE CELLS 50 ML (4010000000).

Each device inside the box is packaged in a double sterile, single-use bag.

Packaging labeling compliant with current regulations.

4 adhesive labels for traceability

The MONOCYTES Kit does not undergo any alterations whatsoever to normal storage conditions.

Warnings and Precautions

MONOCYTES contains single use sterile packaged products. Do not resterilize. Discard open, unused or damaged packages. Do not use in case of loss of sterility of the devices.

Keep the kit away from excessive heat sources. Keep at room temperature, away from direct heat sources, including sunlight.

The product must be stored in a cool and dry place.



Technical Sheet

Mod 7.01.2 / Rev.01 / 25/03/2021

Quality Monocytes Kit All the components of the assembly are manufactured according to quality systems

compliant with UNI EN ISO 9001: 2015 and UNI CEI EN ISO 13485: 2016 and Directive

93/42/CEE.

Assembler data CLOVER ORTHOPEDICS SRL - Via Gadames 57/7 - 20151 Milano (MI)

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