



CELL DIVIDER®

Instructions for use

Euromi 

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1. Medical device presentation

1.1 General information

These instructions describe the procedures to be followed for the safe use of the Cell Divider®. The device must only be used by duly qualified healthcare professionals.

The Cell Divider® is a class IIa short-term non-invasive medical device.

The Cell Divider® is sold sterile and for single use and single patient. It must not be re-used or re-sterilized under any circumstances.

The Cell Divider® is packaged in a single-use double package to ensure a double microbiological barrier and guarantee its sterility until use. The cardboard packaging provides additional mechanical protection to the double packaging.

1.2 Composition

The Cell Divider® is composed of: Polycarbonate and inox.

1.3 Description

The Cell Divider® is designed to provide a progressive and optimized separation of adipocytes in order to obtain fat fractions adapted to the different applications requiring a volume increase.

Below are the Cell Divider® filter sizes:

- 100 µm: ultra-fine filtration for advanced regenerative medicine (treatment of skin lesions, post-surgical regeneration).
- 200 µm: preparation of nanofat rich in stromal cells (treatment of scars, stretch marks, skin rejuvenation).
- 400 µm: production of microfat (correction of deep wrinkles, volumization of the lip and eyelid contour).
- 800 µm: intermediate fraction for precise and homogeneous lipofilling (lipofilling of the face, hands, correction of tissue depressions).
- 1250 µm: selection of large adipocytes for structuring lipofilling (breast and buttock augmentation by lipofilling, volume reconstruction).
- 1400 µm: filter for clearing large fat clusters, used for initial separation of fat clusters (removal of fibrous deposits, initial preparation before fine separation).

The cascade use of filters provides progressive and controlled adipocyte size reduction, minimizing mechanical stress to preserve cell viability and enabling efficient fat cluster reduction and separation.

2. Medical purpose / Indications / Benefits

The Cell Divider® has no standalone medical purpose, indications and benefits and shall be used in accordance with the instructions for use of the corresponding EUROMI device.

3. Contraindications

No specific contraindications are associated with the Cell Divider® when used as intended; the contraindications of the EUROMI devices and the related procedure remain applicable. For complete information, please refer to the instructions for use of the corresponding EUROMI devices.

4. Possible complications

No specific complications are associated with the Cell Divider® when used as intended; complications, if any, are related to the EUROMI devices and the associated procedure. Please refer to the instructions for use of the corresponding EUROMI devices for further information.

5. Use of the medical device

5.1 Warnings

Competence and training

- The device should be used by medically qualified and appropriately trained healthcare professionals.
- Users must be trained in safe and effective use.

Usage and sterility

- The Cell Divider® is for single use only.
- The Cell Divider® is a sterile product: it must not be cleaned or sterilized by the surgeon.
- Any reuse of the Cell Divider® is strictly forbidden because it may result in serious clinical complications, including death. Similarly, any re-sterilization of the Cell Divider® is formally forbidden, as it may cause a significant deterioration in its properties.
- The Cell Divider® is to be used only once and for a single patient.
- The fat must be transferred to the patient directly after the collect.
- The expiration date of the Cell Divider® must be respected.
- The validated lifetime of the Cell Divider® is 3 hours.
- The Cell Divider® must be decontaminated before disposal.
- The user must leave at least 6 weeks between two operations.

Handling and checks

- Do not use the Cell Divider® if the sterile packaging is damaged or unintentionally opened before use.
- The Cell Divider® must be unpacked from its sterile packaging and handled under sterile conditions.
- The Cell Divider® must be handled with care and caution.
- Do not use the Cell Divider® if it has been dropped or knocked.
- The graduations on the Cell Divider® are given for informational purposes only.

Connectivity and accessories

- The Cell Divider® must only be connected to another Euromi medical device.
- The user is responsible for the use of accessories other than those supplied by Euromi S.A.

Restrictions and responsibilities

- The Cell Divider® must not be modified.
- It is forbidden to resell a Euromi device for reasons of traceability.
- EUROMI S.A. is not responsible for the use of any air source that does not supply medical or compressed air.
- Euromi S.A. is not responsible for any use of the device other than the one foreseen in these instructions for use.

5.2 Devices used in combination with the Cell Divider®

Description	Class
Adipcontrol®	IIb
Adipclean®	IIb
Infiltration kit®	IIa
Reusable and single-use cannulas	IIa
Adipmaster®	IIb

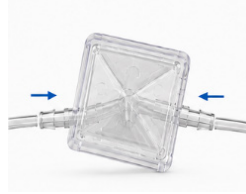
5.3 Installation and use of the Cell Divider®

The Cell Divider® is intended for use in a sterile area.

1. Locate the duckbill (non-return valve) on the infiltration kit at the outlet of the syringe pump. The direction of flow is indicated by an arrow on the duckbill.
2. Using a sterile scalpel, cut the tubing downstream of the duckbill.



3. Connect the two cut ends of the tubing to the splined connectors of the Cell Divider® by securely pushing the tubing onto the connectors.



4. Cell Divider® units may be installed in cascade according to the desired filtration configuration. When multiple Cell Divider® units are used, they shall be installed in descending order of filter size, from the largest filter size to the smallest. Available filter sizes are 1400 µm, 1250 µm, 800 µm, 400 µm, 200 µm and 100 µm. To add another Cell Divider®, cut the tubing downstream of the previously installed Cell Divider® using a sterile scalpel, then connect the two resulting tubing ends to the splined connectors of the next Cell Divider®.

5. Repeat this procedure for each additional Cell Divider® to be installed in cascade, ensuring that each successive Cell Divider® has a smaller filter size than the preceding one.



6. The Adipclean® and Adipcontrol® can then be used to process the adipose tissue through the Cell Divider® filters.

6. Disposal

Dispose of each type of waste according to the appropriate channel:

- **Non-Infectious Clinical Waste:** such waste includes packaging, unused and noncontaminated medical devices.
- **Infectious and Medical Waste:** such waste includes tubing, contaminated cannulas, contaminated devices. This waste is to be disposed of according to the appropriate channel to prevent any contamination.

The Cell Divider® must not be disposed of with public or communal waste.

The device must be disposed of in accordance with current national legislation.

7. Transport and storage of the medical device

The Cell Divider® must be transported and stored in its original double packaging, away from light, in a dry place, protected from dust and pests.

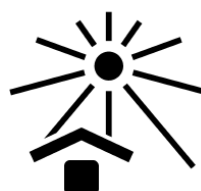
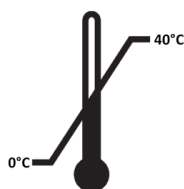
To prevent condensation from developing on the Cell Divider®, large temperature fluctuations should be avoided during storage.

To avoid any risk of chemical contamination, the storage of chemicals with the Cell Divider® is prohibited.

The shelf-life of the Cell Divider® is 1 year.

It is imperative to check the expiration date of the device on the traceability label before use.

Storage conditions:



8. Resterilization and reuse

The Cell Divider® is supplied sterile and for single use only. Any reuse of a Cell Divider® is strictly forbidden.

Any reuse of a Cell Divider® may result in serious clinical complications, including death. Similarly, any re-sterilization of a Cell Divider® is formally forbidden, as it causes a significant deterioration in its mechanical properties.

9. Labels, patient card and surgeon's certificate

Not applicable.

10. Materiovigilance case

Any incident or risk of a serious incident which has led or could lead to the death or serious deterioration of the state of health of a patient, a user or a third party involving the Cell Divider® must be reported without delay to the competent authorities and to Euromi S.A. at the email address materiovigilance@euromi.com.

11. Handling returns

Products that are the subject of a complaint or that have caused an incident or risk of a serious incident must be reported and returned to the local Euromi S.A. material vigilance representative. Before returning the product to the manufacturer, it must first be decontaminated and disinfected (according to the procedures in force at the health care facility). The product should not be returned to Euromi S.A. if the patient is infected with HIV, hepatitis or if he/she is a known or suspected carrier of another infectious agent.

12. Guarantees and limits of guarantees

Euromi S.A. guarantees the Cell Divider® for a maximum of two years from the invoice date, or up to the product's expiration date, whichever comes first.

Euromi S.A. guarantees that all products are supplied without any defects or malfunction. If our product is defective, despite the meticulous manufacturing process, please contact the technical department.

The warranty applies if the defective product is presented during the guarantee period and if it is a defect coming directly from the manufacturer Euromi.

For more information, please contact the technical department at Euromi S.A. or consult our general sales conditions on our website:

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Medical device



Read the user instructions carefully



Name and address of the manufacturer



Batch number



Commercial reference



Indication of notified body responsible



Warning



Single use product, do not use a second time



Do not sterilize a second time



Expiration. Do not use after the date indicated



Date of manufacture



Sterilised using dry heat / Double sterile barrier system



Keep away from light



Do not use if packaging is damaged



Keep dry



The product must be stored between 0°C minimum and 40°C maximum



UDI Code



Fragile, handle with care



Vertical orientation



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