ENGLISH

USER MANUAL

Concentrate Growth Factors

MEDIFUGE CGF Kit
MEDIFUGE CGF Kit-M

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1 INFORMATION FOR USERS

1.1 IMPORTANT

The English version of this manual is a translation of the original Italian version. In the event of discrepancies between the versions, refer to the original Italian.

We recommend reading these installation, use, and maintenance instructions of MEDIFUGE CGF Kit or MEDIFUGE CGF Kit-M components carefully before use, to prevent improper use or damage of any kind.

1.2 SYMBOLS

Both the KIT packaging and this manual have symbols:


Caution / refer to the documentation


Follow the instructions in the manual

Can be steam sterilised at 135°C

Non-sterile device. Clean and sterilise before use.

Ethylene Oxide sterilised

Radiation sterilised


This symbol is applied to the packaging of components that cannot be reused


Use by: This symbol, accompanied by the expiry date, is applied to the packaging of devices with an expiry date.


Manufacturer's identification data: next to or under this symbol there are manufacturer's data


Manufacturing date: the manufacturing date (which can be in different formats) is placed next to or under this symbol.

The production lot number is inserted next to this symbol.

The code is added next to this symbol.


Read the instruction for use


Do not dispose of as unsorted municipal waste. Refer to a special waste collection centre.


CE marking (European Union) A product with this symbol complies with the applicable EC Directive.

1.3 INTENDED USE

The MEDIFUGE CGF with its accessories is a kit available in two versions, depending on the different intended use.
The MEDIFUGE CGF K1 is the kit to be used in dentistry.
The MEDIFUGE CGF K1-M kit is intended to cosmetic and general surgery, and in the treatment of wounds and ulcers.

1.4 WARNINGS

Below, you will find some preliminary instructions helping you through the initial stages of contact with the product. It is important to ensure that the warranty certificate is in the packaging and that the aforementioned has been completed and stamped by the retailer.

Carefully remove all MEDIFUGE CGF Kit or MEDIFUGE CGF Kit-M components from the package and check that no damage has been caused during transportation; if so, contact the retailer immediately. SILFRADENT SRL has compiled this manual to help user of the MEDIFUGE CGF Kit or MEDIFUGE CGF Kit-M.

SILFRADENT SRL cannot be held liable for damage to third parties or alterations to the MEDIFUGE CGF Kit or MEDIFUGE CGF Kit-M caused by its improper use or storage.

Each kit is supplied with a copy of this manual. Compliance with the instructions contained in this technical document ensures the proper use of the MEDIFUGE CGF Kit or MEDIFUGE CGF Kit-M.

This kit has been made for the use it is intended for. Some individual components may also have other possible uses.

Failure to comply with the instructions included in this booklet will make the warranty null and void.

For any request, please provide the purchase date and the lot number of the MEDIFUGE CGF Kit or MEDIFUGE CGF Kit-M located on the data plate.

CAUTION!

Always check the expiry date of the disposable components included in MEDIFUGE CGF Kit or MEDIFUGE CGF Kit-M before use.

1.5 SAFETY

Before each use, check the condition of all the components of the kit and the expiration dates that are indicated on the packages of components.

Do not use parts that are not in a perfect state or after their due date.

1.6 PRECAUTIONS

The technical data, information, and product specifications described in these instructions correspond to the current specifications at the time of publication of this manual.

The product may be modified following technical innovations; however, this does not give users the right to demand such modifications for KITS that have already been purchased.

SILFRADENT SRL is not liable for damage caused by:

- Improper storage of the KIT components
- Non-compliant use of the KIT.

1.7 WASTE DISPOSAL

Hazardous medical waste

Hazardous medical waste means any material contaminated by:

- human or animal blood;
- microorganisms, even if genetically modified, and cell cultures that could cause infections, allergies, intoxications, and other damage to the human body;
- human or animal tissues;
- human or animal fluids;
- Carcasses of animals used for experimental or other scientific purposes.

No hazardous waste must be disposed of in the sewer or together with municipal waste.

Each person who uses, handles, or removes hazardous biological waste must be informed on the proper methods to dispose of it.

It is the responsibility of each user to follow established procedures and comply with the applicable national laws and regulations.

Disposable components of this kit should be disposed of as hazardous medical waste.

Reusable components (container or metal tools) must be disposed of only after being made safe.

1.8 GUARANTEE

SILFRADENT S.r.l. guarantees the repair or, at its discretion, the replacement of any part which proves to have manufacturing or material defects under normal conditions of use for a period of one year. In the event of a return, package the product correctly using, where possible, the original packaging. It is advisable to insure the package.

The customer has full responsibility for damages arising from unsuitable packaging.

Please note.
The guarantee is provided ex-factory SILFRADENT SRL.
The guarantee does not cover defects or damage arising from:
- Use not in compliance with the instructions of this manual.
- Incorrect or unsuitable maintenance by the user.
- Unauthorized tampering or changes.
- Cleaning with unsuitable products.

1.9 TRANSPORT AND STORAGE

The equipment MUST BE TRANSPORTED AND STORED in an environment whose temperature ranges between -40 °C and +70 °C, relative humidity between 10 and 90%, and pressure between 500 and 1060 HPA.

2 DESCRIPTION

2.1 DESCRIPTION OF THE CGF

It is every surgeon's wish to have material that heals wounds and prevents all the secondary effects of surgical procedures (oedema, dehiscence, infection, haematoma, etc.). Growth Factors are molecules that can certainly activate these processes.

They can be natural or synthetic.

The distinctive feature of GFs (Growth Factors) is the excellent reactivity even at very low concentrations. In fact, we are in the order of µg.

It is certainly better to extract GFs directly from the patient's tissue. Blood is the donor tissue that is the easiest to handle.

The best known GF extraction techniques are:
- Fibrin Sealant (Tissucol Baxter)
- cPRP platelet concentrate (Marx 1998)
- Platelet rich plasma (PRP)
- Plasma rich in growth factors (PRGF E. Anitua)
- Fibrin rich plasma (2001 J. Choukroun)
- CGF (Concentrated Growth Factors 2006, IAIO)

CGF (Concentrated Growth Factors) is a reparative biomaterial similar to platelet and fibrin concentrate, which enhances the features of this technique.

The autologous matrix consists of a block of Fibrin and a platelet concentrate with a large amount of:
- Plasma cytokines
- Platelets: thrombocytes
- Activated fibrin
- Leukocytes
- GF
- Antibodies

Special biological properties of CGF
- Blood coagulation with the formation of a flexible and elastic fibrin network.
- Neoangiogenesis (promoting vascularisation and graft survival)
- Plasma cytokine activation
- Local immune system activation
- Release of GFs from Platelet disaggregation and fibrin concentrate.
- CGF-induced processes
- Angiogenesis
- Immunisation
- Proliferation of fibroblasts and osteoblasts.
- Repair stimulation and modulation

Structural and mechanical properties of CGF

The slow and natural polymerisation leads to a concentration of physiological thrombin

Trimolecular and multiple fibrin monomer junctions

The thin, soft, elastic, and permeable network allows for the colonisation of reparative cells, red blood cells, white blood cells, platelets, and antibodies.

CGF is prepared by drawing the patient's blood into 9 ml tubes, which are centrifuged immediately with SILFRADENT MEDIFUGE.

You can draw up to 8 tubes simultaneously. Simple centrifugation without adding any other substance gives 3 fractions for each tube. A lower part where all the red blood cells are located, an upper part with the platelet poor plasma (PPP), and a fibrin clot between these two fractions, which will be removed from the tube and separated from the red fraction using scissors. The clot can be used in the form of a membrane by pressing it or crushed into smaller fragments

2.2 SCOPE OF APPLICATION

MEDIFUGE CGF Kit o MEDIFUGE CGF Kit-M has been designed to process the blood and obtain CGFs in a sterile environment, thereby preventing any contamination of the material to be implanted. The use of MEDIFUGE blood phase separator, whose separation time and speed are suitable for the process, ensures even better results.

2.3 STANDARD EQUIPMENT

2.3.1 DISPOSABLE PARTS

Table 1

Material with a expiry date:

The materials listed in the following table have the expiry date indicated on the packaging. Always check the date before use.

These materials have been sterilised by the manufacturer; therefore, the packaging also shows the symbol of the sterilisation method.

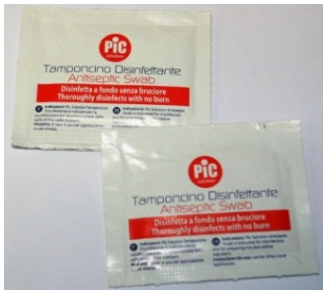
Do not dispose of as unsorted municipal waste. Refer to a special waste collection centre.

This symbol is applied to the packaging of components that cannot be reused, i.e. all the items with due date contained in the table.

The due date is indicated next to or under this symbol on the packaging of devices with a due date.

STERILE | EO — Ethylene Oxide sterilised

STERILE | R — Radiation sterilised

No.	Quantity	Code	Description	Image
1	50	**CGF K1 TMP01**	Disinfectant swab : Swab soaked of disinfectant liquid to be used on the patient's blood sampling point.	
2	25	**CGF K1 LCE**	Latex free disposable tourniquets	
3	24	**CGF K1 AGO**	The SAFETY Blood Collection Set is a single-use, sterile, butterfly blood collection needle G21 bonded to flexible tubing with a luer connector and a holder. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately following veni-puncture to aid in the protec-tion against accidental needlestick injury.	

4	30	**CGF K1 CER01**	Haemostatic plasters for after-sampling dressing.	
5	100 pcs. in MEDIFUGE CGF K1 50 pcs. in MEDIFUGE CGF K1-M	**CGF K1 PRO**	Vacuette 9 ml tubes red cap.	
9	30	**CGF K1 FSL**	10ml vials of saline. Each vial should be used for one application.	
20	25	**CGF K1 GAR**	Garza topper	

2.3.2 STERILISABLE CONTAINERS

Table 2

The containers in the following list have been chosen for their shape and size, in order to ensure maximum ergonomics during the process.

NON STERILE

The materials of the next table are supplied non-sterile; therefore, they must be cleaned and sterilised before use.

135°C

Can be steam sterilised at 135°C

N°	Quantità	Codice	Descrizione	Immagine
7	1	**CGF K1 SPF**	Fibrin separator: Stainless steel container used to separate the liquid part from the fibrin clot, in combination with the grid CGF K1 GSP	

10	1	**CGF K1 DFD**	Dappen for fibrin: Stainless steel container that facilitates the formation of the fibrin clot combined with the saline.	
11	1	**CGF K1 DPC**	Dappen for platelet: Cylindrical stainless steel container intended to contain red blood clots by preventing the oxidation	
12	1	**CGF K1 DPT**	Dappen for particulate: stainless steel container intended to keep the fibrin clot cut into particles.	

2.3.3 COMMERCIAL TOOLS

Table 3

Some components of this KIT are commercial devices already used in the medical field, which have been chosen for their features and shape.
They are listed in the following table

The tools listed below are supplied non-sterile; therefore, they must be cleaned and sterilised before use.

Can be steam sterilised at 135°C

N°	Quantità	Codice	Descrizione	Immagine
13	1	CGF K1 FPS	Blunt scissors	
14	1	CGF K1 PAD	Straight anatomic pliers	
15	1	CGF K1 SPD	Straight spatula	

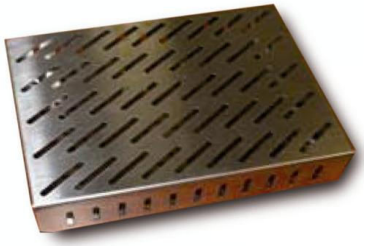
2.3.4 INSTRUMENTS SPECIALLY DESIGNED FOR THE KITS

Table 4

The components of the kits listed in this table, have been specially designed to facilitate the operations necessary to prepare and use the CGF

Non-sterile device: before use it must be sterilised.

Steam sterilizable up to 135°C.

N°	Quantità	Codice	Descrizione	Immagine
16	1	**CGF K1 FMP**	Membrane shaping pliers: stainless steel tool designed to form membranes by pressing fibrin clot	
19	1	**CGF K1 PMS**	Spatula applicator for membrane: Stainless steel tool designed to ease handling fibrin clots or membranes	
6	1	**CGF K1 PPR**	Stainless steel tube holder: this base contains the tubes while preparing CGF	
8	1	**CGF K1 GSP**	Grid for fibrin separator: Stainless steel grid, designed to separate the liquid part from the fibrin clot in combination with the Dappen for fibrin separation.	
21	1	**CGF K1 TRA**	Tray for tools: this is the container for tools to be sterilised.	

2.3.5 DISPOSABLE DEVICES INCLUDED ONLY IN MEDIFUGE CGF K1-M

Table 5

Material with a expiry date:

The materials listed in the following table have the expiry date indicated on the packaging. Always check the date before use.

These materials have been sterilised by the manufacturer; therefore, the packaging also shows the symbol of the sterilisation method.

Do not dispose of as unsorted municipal waste. Refer to a special waste collection centre.

	This symbol is applied to the packaging of components that cannot be reused, i.e. all the items with due date contained in the table.
	The due date is indicated next to or under this symbol on the packaging of devices with a due date.
STERILE EO	Ethylene Oxide sterilised
STERILE R	Radiation sterilised

N°	Quantità	Codice	Descrizione	Immagine
22	50	**CGF K1 P50B**	Vacuette 9 ml tubes white cap, no additives.	
23	100	**CGF K1 P50V**	Vacuette 9 ml tubes green cap, with sodium heparin.	

2.3.6 PARTS INCLUDED ONLY IN MEDIFUGE CGF K1

Table 6

	**Components specially included in MEDIFUGE CGF K1, the compactor is a commercial tool, the fibrin injector is designed for kit.**
	The materials listed below are supplied non-sterile; therefore, they must be cleaned and sterilised before use.
	Can be steam sterilised at 135°C

N°	Quantità	Codice	Descrizione	Immagine
17	1	**CGF K1 COM**	Compactor	
18	1	**CGF K1 INF**	Fibrin injector: Stainless steel tool designed to inject the fibrin particulate in the site of application, divided into two parts. Specially designed for MEDIFUGE CGF K1.	

Caution!
All the operations to obtain the fibrin clots must be carried out in an environ-ment with a controlled temperature ranging between 21 and 23 °C.
The machines and materials used must be kept at room temperature.

2.4 GENERAL PROCESS DESCRIPTION

1 - Make sure that all the instruments and containers of the KIT are clean and sterile.
2 - Apply the tourniquet **CGF K1 LCE**; the stasis should not cause pain to the patient.
3 - Carefully disinfect the puncture site with a disinfectant swab **CGF K1 TMP01.** Leave to dry after cleaning.
4 - Collect blood using the safety blood collection set **CGF K1 AGO** and the tube according to procedure used (**CGF K1 PRO**, **CGF K1 P50B, CGF K1 P50V**) until the blood stops entering due to the negative pressure Fig. 1 shows the correct filling level
5 - Insert the tubes in the MEDIFUGE rotor (always in pairs opposite each other as shown in the manual of the machine) within two minutes from the blood collection and start the machine

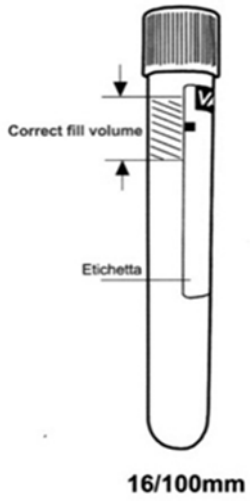


Fig. 1 filling level of tubes

6 - When MEDIFUGE has completed its cycle and opens the lid, remove the tubes and place them in the tube holder **CGF K1 PPR**.

Caution!
Do not shake the tube before inserting it in the centrifuge.

We recommend preparing at least 4 tubes.

7 - Open a tube and gently pour the serum into the particulate Dappen dish **CGF K1 DPC**
8 - Place the Fibrin separator grid **CGF K1 GSP** onto the Fibrin separator **CGF K1 SPF** and empty the tube.
9 - Take the fibrin clot using the straight anatomic pliers **CGF K1 PAD** cut out 2 mm in the red part using the scissors **CGF K1 FPS** leaving them on the grid **CGF K1 GSP**.
10 - Place the fibrin clot in the fibrin Dappen dish CGF K1 DFD adding a vial of saline solution CGF K1 FSL and a 600 mg vial of Lincocin (not supplied). Under this condition, fibrin can be used within one hour; however the earlier, the better.
11 - Take a portion of the red clot from the grid CGF K1 GSP and place it on the platelet Dappen dish CGF K1 DPC closing the cap to prevent oxidation.
12 - The fibrin clot contained in the fibrin Dappen dish CGF K1 DFD is ready for use.

2.4.1 MAKE A MEMBRANE

1 - Use the Membrane shaping pliers **CGF K1 FMP** to prepare the membranes whose thickness is regulated by pressing the two plates on the fibrin block:
   - Take a fibrin clot
   - Place it on the plate with the raised edge of the clamp
   - Press until obtaining a membrane with the desired thickness.
2 - Use the membrane positioning spatula **CGF K1 PMS** to place the membrane on the implant site without any contamination risk.
3 - To accelerate the healing you can wet the wound with serum contained in the fibrin separator **CGF K1 SPF** using a brush.

The membrane can be sutured and remain exposed.

2.4.2 USE OF FIBRIN INJECTOR

A different use of the fibrin clot is the placement of particulates in the implant site by means Injector Syringe **CGF K1 INF**:

1 - Break into small pieces the fibrin clot into Dappen for particulate **CGF K1 DPC** with the scissors **CGF K1 FPS**.

2 - Draw up the fibrin particulate from the Dappen for particulate **CGF K1 DPC** with the syringe of Fig. 2.

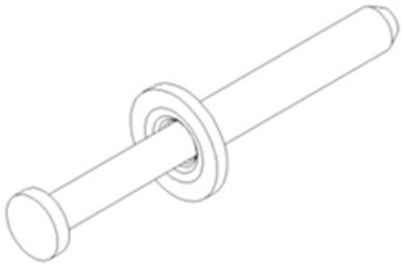


Fig. 2 syringe

3 - Fit the injector (Fig. 3 fibrin injectorFig. 3) with the syringe (Fig. 2) as shown in Fig. 4.

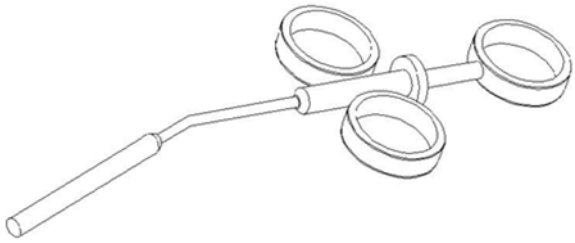


Fig. 3 fibrin injector

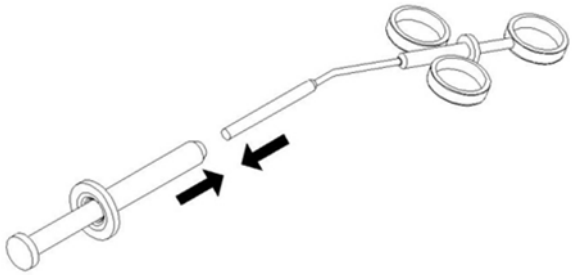


Fig. 4 Coupling syringe - injector

4 - With the syringe push the fibrin particulate into injector

5 - Divide the syringe from injector

6 - With injector push the fibrin particulate into site of operation.

Another way to use the GCF is mixed with autologous bone, or with synthetic bone:

7 - Break into small pieces the fibrin clot into Dappen for particulate **CGF K1 DPC** with the scissors **CGF K1 FPS**.

8 - Mix the fibrin particulate with fragments of autologous or synthetic bone using the straight spatula **CGF K1 SPD** the final product can be used as fill.

2.5 USE WITH ROUND UP HOMOGENIZER

To get good results in the repair/regeneration of bone you can use ROUND UP, the homogenizer that allows obtaining a homogeneous mixture without dimensional changes or structural:

1 - Break into small pieces the fibrin clot into Dappen for particulate **CGF K1 DPC** with the scissors **CGF K1 FPS.** Dry it with the Garza topper **CGF K1 GAR**.

2 - Add the bone (of any nature) as described above in the same amount as the fibrin

3 - Add a small part of material left aside in the fibrin Dappen dish **CGF K1 DFD**.

4 - Put everything in the inner container of the Steel ROUND UP and close the cover securely.

5 - Insert the stainless steel container in the outer one, close it securely and place it in ROUND UP following the instructions of the machine.

6 - Set 7 seconds and start the machine..

7 - The final result is a homogeneous gel without structural changes or dimensional usable for filling.

2.6 CLEANING AND MAINTENANCE

All components of the kit have their own maintenance procedures; however, it is important to put emphasis on the importance of sterility of the materials used in the process of preparing and using the CGF. Immediately after use on the patient, reusable instruments must be disinfected by placing them in solutions with recognized effectiveness even on HIV, to reduce the risk of infection on personnel. It is therefore important to avoid "dry out" the residues of the intervention on instruments to avoid compromising the effectiveness of disinfection and sterilization and to prevent corrosion on the instruments. Many of the products used have corrosive effects on the patient, it would be appropriate to remove them as soon as possible by the tools.

Residues of disinfectants on surfaces can be removed with neutral cleaners.

For the protection of personnel, all procedures for decontamination and cleaning of instruments must be performed using appropriate personal protective equipment.

The instruments that can be disassembled, or otherwise articulated, must be opened so that the disinfectant can go in contact with all their parts.
The products for pre-disinfection must be a combination of disinfectant and cleanser, in no case, the liquid must be for example saline solution because the contact, even relatively long, with the tools leads to corrosion or rust formation. After decontamination, instruments must be rinsed with running water and resistant residues can be removed brushing the instrument using brushes with bristles of nylon or nylon-based sponges. The abrasive cleaners and excessive manual pressure must be avoided and is also necessary pay close attention not to bump or drop tools. It is advisable to use non-corrosive detergents, preferably enzymatic nature. It is advisable to use non-corrosive detergents, preferably enzymatic nature.

Never use metal brushes or sponges as these will damage the instruments.

Reusable instruments used for cleaning must be cleaned, disinfected and sterilized after use.

Cleaning with ultrasounds is particularly effective in removing stubborn dirt, however, requires special attention because the tools placed close to one another and containers too loaded can cause scratches on the instruments.
After being dried the instruments must be immersed in a disinfectant solution different from that used immediately after patient use, after that time necessary for disinfection is passed, should be rinsed with demineralized water, decontaminated, and dried immediately to avoid stain.
The next phase is the packaging that has the purpose to maintain the sterility of the instruments until their use. The packaging material most widely used are bags or rolls made with film of paper and plastic materials for autoclave, it is therefore appropriate to recommend that there are no too many inserted instruments, so as to leave enough space between them, to allow a smooth passage of the steam.
The sterilization system recommended is with the saturated steam autoclave. The recommended sterilization cycles with saturated steam autoclaves with fractionated vacuum are:
- 134°C, exposure time of 7 minutes and pressure 2.1 bars or
- 121°C, exposure time of 15 minutes and pressure 1.1 bars.

Exposure times refer to the machine in the regime of temperature and pressure with values already achieved.
It is to emphasize the importance of the drying cycle for wrapped instruments, because if it is not done properly could compromise the integrity of the instrument triggering corrosion, and altering the maintenance of sterility same because any remaining water, could give rise to the formation of bacteria, which would put the doctor in condition of transmit any infections to the patient without his knowledge.

3 ATTACHEMENTS TO THIS MANUAL

La strumentazione chirurgica, quando necessario, contiene le istruzioni per l'uso.

I singoli dispositivi, come i lacci emostatici monouso, contengono avvertenze per l'uso.

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