INSTRUCTIONS FOR USE

This device is indicated for specialized procedures, which must be performed by qualified implantology professionals. For best results, use the product with appropriate techniques. Always apply the product under appropriate conditions, in a surgical setting.

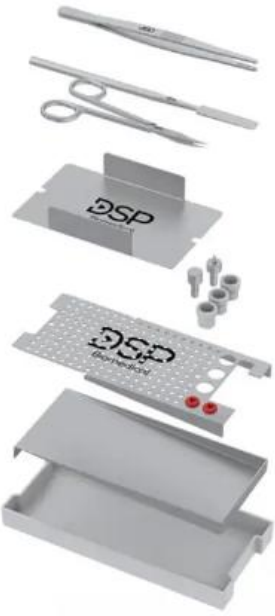
INDICATIONS FOR USE

The L-PRF DSP Kit Instruments are intended for use in the technique of using and manipulating autologous platelet-rich fibrin (L-PRF) membranes from a small blood sample at the patient's point of care. L-PRF (Fibrin-Rich Plasma) therapy is a method of concentrating platelets, growth factors, leukocytes, and proteins in a flexible biological matrix for use in grafting procedures in Implantology, Oral and Maxillofacial Surgery, and Periodontics, aiding in tissue regeneration or revitalization of the dental pulp.

COMPOSITION

The PRF Kit instruments are made of stainless steel. The housing cylinder is made of Teflon.

1 PRF seating pin
1 PFR capture pin
3 PRF seating pin housings
1 compression plate
1 drip tray
1 perforated tray
1 straight tweezers
1 spatula for PRF
1 curved scissors
1 case.



APPLICATION

L-PRF has been indicated in treatments of periodontal plastic surgery, osteonecrosis of the jaws, bucco-sinusal communication, regeneration of infra-bone defects , alveolar preservation, maxillary sinus lifting, furcation lesions , gingival recession, implant surgeries and is an excellent adjuvant in the tissue regeneration process.

CONTRAINDICATION

This product has no contraindications, as long as it is used correctly for the purposes indicated.

HOW TO USE

Protocol 1

Step 1:

Collect the patient's own blood by venipuncture in 10ml vacuum tubes[1] (at least 2 tubes).

Immediately transfer the tubes to a centrifuge at high speed, 2700 RPM, for 12 minutes. After centrifugation, the blood components separate into three layers.

1 - Top layer: platelet-poor plasma (PPP).

2 – Middle layer: platelets and leukocytes (fibrin clot that we call L-PRF)

3 – Bottom layer: Red blood cells accumulate at the bottom of the tube.

Observations:

[1] Tubes must be made of glass. Do not use a syringe to collect blood.

[2]Centrifugation must begin within a maximum of 2 minutes after the start of blood collection.

Step 2:

After centrifugation, the platelet-poor plasma should be discarded. The middle layer (platelets and leukocytes) should be removed with sterile forceps. Using gauze, scissors, a spatula, and the forceps, remove the portion of red blood cells adhered to the clot.

Step 3:

To form the membrane, the fibrin clot is placed on the perforated tray in the PRF box and compressed for 5 minutes by the metal plate. No pressure or force is needed on the metal plate; the action is performed by gravity. The gravitational force of the heavy lid gently compresses the clot and expels the serum from the PRF clot without damaging the fibrin network.

Fibrin membranes should be used as soon as possible. They can remain in the box for 2 to 3 hours, as long as they are hydrated with exudate.

The exudate released by the clot due to its compression will be stored in the lower compartment of the box. The exudate generated by this process can be used as a source of biomaterial irrigation.

Step 4:

After compression, the membranes are ready for use. They can be used to cover grafts , donor sites, and recipient sites.

Protocol 2: L-PRF Plug

Step 1: To obtain a plug, it is necessary to centrifuge the blood in the glass tube for 12 minutes, as per step 1 of protocol 1.

Step 2: After centrifugation, the platelet-poor plasma should be discarded. The middle layer (platelets and leukocytes) should be removed with sterile forceps and placed into the storage cylinder available in the L-PRF kit.

Step 3: Use the seating pin to slowly press the fibrin clot into the plug's housing cylinder. Continue pressing until the top edge of the pin is flush with the top edge of the housing cylinder. This technique will form a thick, round fibrin plug for the extraction cavity. Use your preferred biomaterial.

Protocol 3: Sticky Cap

Step 1: The patient's blood should be collected in 6 glass-lined tubes and 2 plastic-lined tubes. The plastic-lined tubes do not trigger the coagulation cascade, leaving the fibrinogen in a liquid state. These tubes should be removed after 3 minutes of centrifugation; the others should be kept until the cycle is complete. The fibrinogen (yellow liquid inside the plastic-lined tube) should be removed from the portion closest to the red blood cells that settle at the bottom of the tube using a plastic pipette, but without aspirating them. The liquid should be kept inside the syringe. At the end of the centrifugation of the remaining tubes, the L-PRF clots are removed and gently compressed, as previously mentioned, forming the L-PRF membranes. In a glass or metal container, two membranes should be cut into small fragments with scissors and mixed with 0.5g of bone substitute until a uniform mixture is obtained. 1cc of liquid fibrinogen (i-PRF) should be added, mixing gently for approximately 5 seconds, shaping the L-PRF block.

MANUAL CLEANING AND DISINFECTION

HYGIENE

This product must be properly sanitized after each use.

Proceed as follows:

1. Disassemble the instruments (when applicable).
2. Immerse the instruments for at least 1 minute in the enzymatic detergent (CIDEZYME®, 1.6% v/v) so that the instruments are sufficiently covered. Be careful not to allow contact between the instruments.
3. Carefully use a soft brush to aid the cleaning process. Shake the instruments several times during cleaning.
4. Immerse the instruments for 15 minutes in the cleaning solution (CIDEZYME®, 1.6% v/v) under ultrasonic treatment, ensuring that the instruments are sufficiently coated. Be careful not to allow contact between the instruments.
5. Remove the instruments from the cleaning solution and rinse them thoroughly at least 3 times (for at least 1 minute) under running water.

DISINFECTION

1. Immerse the instruments (disassembled, if applicable) for 10 minutes in the disinfectant solution (CIDEX® OPA - OPA Solution - undiluted) so that the instruments are sufficiently covered.
2. Remove the instruments from the disinfectant solution and wash them according to the instructions below:

INSTRUCTIONS WASHING

1. After removing the instruments from the CIDEX® OPA solution, rinse the medical device thoroughly by immersing it completely in a large volume of water. Use sterile water.
2. Keep the device fully immersed for at least 1 minute.
3. Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. 5. Repeat the procedure 2 more times, for a total of 3 rinses, with large volumes of clean water to remove any residue of CIDEX® OPA solution (OPA residue can cause serious side effects).
6. Inspect and pack instruments immediately after removal.

AUTOMATIC CLEANING AND DISINFECTION

Neodisher ® MediZym detergent .
2. Disassemble the instruments, if necessary;
3. Transfer the instruments to the Disinfectant Washer (be careful that the instruments do not come into contact);
4. Start the program;
5. Remove the instruments from the Washer Disinfectant after the program ends;
6. Check and pack instruments immediately after removal.

STERILIZATION

This product is reusable and supplied non-sterile and packaged individually. This product must be properly sanitized and sterilized before use. Sterilize it the day before or on the day of the procedure. CAUTION: These products should not be autoclaved in their original packaging. For sterilization, use only the steam sterilization method according to the parameters below:

	Fractional Vacuum/Dynamic Air Removal [1]	**Gravitational[2]**
Sterilization time	4 minutes	15 minutes
Sterilization temperature [3]	134ºC / 273ºF	134ºC / 273ºF

Drying time	At least 20 minutes [4]	At least 20 minutes [4]

1. At least three vacuum passes.
2. The less effective gravitational sterilization procedure should not be used if the fractional vacuum procedure is available.
3. Maximum sterilization temperature 134°C (273°F). The required drying time efficiency depends directly on the parameters under the user's responsibility (configuration and load density, sterilization conditions, and these must be determined by the user. However, the applied drying time must not be less than 20 minutes).

NOTES:

1. After sterilization, pack the instruments in a dry, dust-free environment.
2. The immediate use/flash sterilization procedure should not be used.
3. Do not use thermal dry sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

PRECAUTIONS

The L-PRF Surgical Instrument Kit is supplied in non-sterile packaging. It is the team's responsibility to sterilize the product before use, following standard autoclaving and biosafety protocols.

ADVERSE EFFECTS

No adverse effects are expected, provided the product is used according to the instructions for use.

ADDITIONAL INFORMATION FOR THE PROFESSIONAL

Instruct the patient on the need for professional medical monitoring after surgery and follow guidelines on precautions, hygiene, and medication prescriptions. These guidelines are the responsibility of the responsible professional.

STORAGE CONDITIONS

This product must be stored in its original packaging in a clean, dry place, at a maximum temperature of 45°C and protected from direct sunlight.

DISPOSAL OF MATERIAL

Any product or consumable used during dental implant surgery can jeopardize the health of those who handle them after use. Before disposing of them in the environment, it is recommended to observe and adhere to current legislation.

VALIDITY

8 years

EXPIRATION DATE

See the label.

SYMBOLISM

SYMBOLISM	DESCRIPTION	SYMBOLISM	DESCRIPTION
LOT	Batch number		Consult the instructions for use
	Date of manufacture		Attention
	Manufacturing		Keep dry
NON STERILE	Non-sterile		Keep away from sunlight
REF	Product Code		Expiration date
45°C	Temperature limit	UDI	Unique device identifier
	Humidity limit		Do not use if packaging is damaged and consult instructions for use.
EC REP	European Representative	CC	Manufacturer's country
#	Model number	MD	Medical device
	Fragile, handle with care		Importer
CE	CE Mark	CE 1304	CE marking with notified body number: SIQ, number 1304
	Do not reuse	Rx only	FDA Mandatory Prescription Notification for the United States Market

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