INSTRUCTIONS
for the use of a medical product
Resorbable collagen material COLLOST®
for filling bone defects, soft tissue contouring, and covering non-infected wound surfaces
according to TU 9393-001-56533116-2015
in the following modification: gel 7% - 0.1 cm^3 / 0.5 cm^3 / 1.0 cm^3 / 1.5 cm^3, gel 15% - 0.1 cm^3 / 1.0 cm^3 / 1.5 cm^3."

1. PURPOSE

The medical prodcut "Resorbable collagen material COLLOST®" provides essential biological resources to improve the condition of collagen fibers in the dermis, hypodermis, and scar tissue of any location; to enhance skin tone and tension, increasing its elasticity; and to improve the condition of scar tissue.

2. MAIN TECHNICAL SPECIFICATIONS

2.1. Product description
COLLOST® gel is a medical product containing native non-engineered type I collagen from the dermis of cattle. A colorless or slightly yellowish opaque gel with a collagen content of 7% or 15% in a glucose solution of 10.0% for infusion.

2.2. Mechanism of action
Mechanism of action: collagen, being the main fibrillar protein of connective tissue, provides its structural basis. Collagen molecules act as a physiological matrix that ensures normal repair processes.

The effect of "COLLOST®" in soft tissues: COLLOST® provides the area of correction with the basic biological resources required for wound healing. The collagen implant binds to the wound, fibroblasts migrate to it from the surrounding tissues and invade the implant. A transitional matrix is created that stimulates the body's immune system and the activation of granulocytes, macrophages and fibroblasts, improves the transfer of growth factors released from cells, enhances fibroblast migration and epithelial cell proliferation. With the administration of COLLOST®, new collagen fibers are produced that fill the cavity in the implantation area, and the implant itself, gradually dissolving, is replaced by an auto-tissue.

2.3. Device configuration

- 1 Gel 7 % 0.1 cm^3 / 0.5 cm^3 / 1.0 cm^3 / 1.5 cm^3 in a syringe with a plug or Gel 15 % 0.1 cm^3 / 1.0 cm^3 / 1.5 cm^3 in a syringe with a plug – 1 pc.;
- 2 Instructions for use – 1 pc.
- 3 Sticker – 4 pcs.

Note: All listed individual COLLOST® release forms may be supplied at the customer's request in various configurations with other release forms.

2.4. Sterilization
The method of radiation sterilization is used for sterilization of COLLOST®. The sterilizing dose for the gel should be 11 kGy. The maximum dose for the gel should not exceed 25 kGy.

3. SCOPE OF APPLICATION

Cosmetology, dermatology, plastic surgery.

4. POTENTIAL CONSUMER

a medical professional.

5. INDICATIONS FOR USE

- Weakening of the tension (elasticity) of the skin during involutional skin changes;
- Hypotrophic and atrophic scars after acne, chickenpox, striae;
- Post-traumatic and postoperative skin depression.

6. CONTRAINDICATIONS TO USE

6.1. Contraindications to use
- Severe chronic diseases in the acute stage;
- Positive test sample;
- Autoimmune diseases;
- Hypersensitivity to the components of a medical product;
- Tendency to form hypertrophic and keloid scars;
- Blood clotting disorders;
- Dermatoses in the acute stage;

COLLOST® should not be injected into skin areas with signs of inflammation and/or infection (acne, herpes, etc.).

6.2. Adverse reactions and complications
The patient should be warned of the possibility of adverse reactions due to the administration of COLLOST® gel, which may occur immediately or after a period of time. Side effects include (but are not limited to):
- Inflammatory reactions (redness, swelling, papules, erythema, etc.), accompanied by itching, as well as pain when pressed, may occur after injection. Such an inflammatory reaction may persist for up to one week.
- Hematomas.
- The patient should notify the doctor as soon as possible of all cases of persistent local inflammatory reaction for more than one week after the administration of COLLOST® gel or in cases of any other adverse reactions. At the same time, the doctor must ensure that the patient receives appropriate treatment.

All cases of other undesirable side effects associated with the injection of COLLOST® gel should be notified to the manufacturer.

6.3. Use during pregnancy and lactation
The use of COLLOST® during pregnancy and lactation has not been studied.

7. INTERACTION WITH MEDICINAL PRODUCTS

- 2 It is not recommended to use COLLOST® gel simultaneously with taking anticoagulants, antiplatelet agents, isotretinoin, non-specific anti-inflammatory drugs for topical use, and enzyme preparations. The interaction with these drugs has not been studied.
- 1 It is allowed to use COLLOST® with antibacterial and antiseptic drugs.

8. SAFETY PRECAUTIONS

It is necessary to strictly comply with the requirements of these instructions in order to prevent possible adverse reactions in patients.
- Potential consumer of COLLOST®: a medical professional.
- The use of COLLOST® is possible only by qualified medical personnel in compliance with the rules of aseptics and antiseptics.
- Secondary medical personnel with additional professional education in the specialty "Nursing in cosmetology" can use COLLOST® gel as prescribed by a cosmetologist.
- Do not reuse COLLOST®. Repeated use of a gel syringe does not guarantee that it remains sterile.
- In case of routine use, especially in the case of a burdened allergic history, the doctor is recommended to perform a skin test for hypersensitivity to a medical device (allergic test) 14 days before the start of implantation of the COL LOST gel. To do this, 0.1 cm^3 of COLLOST® gel should be intradermally injected into several points in the forearm area (do not inject the entire volume into one papule) using a 4 mm long needle, the calibration size ranges from 27G to 33G. If an allergic reaction is detected, the test sample is considered positive, and in this case, COLLOST® should not be used.
- There are no available clinical data regarding the efficacy and safety of COLOST® when injected in patients with indications of autoimmune diseases or disorders in the past or in the presence of a clinically manifested autoimmune disease or disorder at the moment, or in patients undergoing immunosuppressive therapy. In each specific case of use, the doctor must decide on the possibility of using COLLOST® gel, depending on the nature of the disease and the treatment being performed, as well as ensure strict monitoring of such patient. In particular, it is recommended to offer such patients a preliminary skin test for hypersensitivity, as well as to abandon the use of COLLOST® gel in people in the active stage of the disease.
- It is not recommended to use COLLOST® gel during periods of exacerbation of allergic conditions.

- There is no available clinical data on the tolerability of COLLOST® gel when injected in patients with a history of severe allergic reactions and/or polyallergic reactions. At the same time, in each specific case, the doctor must decide on the possibility of using the gel, depending on the nature of the existing allergy, as well as ensure special monitoring of such patients from this risk group. In particular, it may be suggested to perform a hypersensitivity test or appropriate preventive treatment before each gel injection. It is not recommended to administer the drug to patients with a history of anaphylactic shock.
- Patients receiving treatment with anticoagulants or using substances that may increase the duration of bleeding should be warned about the increased risk of petechiae, ecchymosis, and bruising during administration.

9. EQUIPMENT AND MATERIALS

When using COLLOST® gel 7%, it is recommended to use injection needles of calibration size 27-33G with a length of 4-13 mm.

When using COLLOST® gel 15%, it is recommended to use injection needles of calibration size 26-30G with a length of 4-13 mm or cannulas of calibration size 23-25G.

10. PREPARATION FOR PRODUCT OPERATION

Before use, it is necessary to keep a blister pack with a syringe filled with COLLOST® gel, as well as a blister pack with an injection needle planned for use, in a thermostat at 38°C for at least 15-20 minutes before the gel becomes liquid, in order to ensure the subsequent free passage of the gel through the needle. It is allowed to repeatedly heat the syringe with gel during one procedure for one patient. Before each subsequent heating, the needle must be replaced.

11. PRODUCT OPERATION PROCEDURE

The method of application and the combination of different forms of the COLLOST® medical device are determined individually for each patient in accordance with the clinical pattern, nature, size and form of the defect.

11.1. Methods of administration of COLLOST® gel
A. Point injection technique.
The gel is injected into the dermis, the needle section is facing downwards, placing the injection along the line of the corrected wrinkle / fold, while avoiding the gap between individual portions of the injected material or with a distance of 2-5 mm for diffuse treatment of the selected area.

B. Short-linear technique.
A 4-6 mm needle at an angle of 30 for the entire length is inserted into the skin parallel to the wrinkle / crease line with a distance of 2-5 mm for diffuse treatment of the selected area, except for the paraorbital area. The gel should be injected into the middle / lower part of the dermis on the back of the needle with uniform pressure on the plunger of the syringe.

C. Linear technique.
A 12-13 mm needle at an angle of 30 for the entire length is inserted into the skin parallel to the wrinkle / crease line with a distance of 5 mm between lines for diffuse treatment of the selected area, except for the paraorbital area. The gel should be injected into the dermis or hypodermis in the back of the needle with a steady pressure on the plunger of the syringe.

11.2. The duration of the cosmetic effect after the introduction of gels is individual and depends on many factors: the skin structure, age, lifestyle of the patient, as well as on the injection technique and the volume of the drug administered per unit area of the skin. The recommended minimum course is 3-5 procedures with an interval between procedures of 2 weeks and up to 2 months. Usually, a repeat course of procedures is required after 3-6 months. With repeated administration of the gel, the effect lasts longer.

11.3. Recommendations for patients after intervention
After administration, patients with COLLOST® are advised to avoid excessive sunlight, visits to the sauna, sauna immediately after the intervention. Do not apply makeup for 12 hours after the procedure. Cosmetic or physiotherapy procedures in the area of intervention may accelerate the metabolism of the product or provoke the development of an inflammatory reaction.

12. STORAGE AND TRANSPORTATION CONDITIONS

12.1. Storage conditions
Keep in a dry place protected from light at a temperature of 5 to 25°C. Do not freeze or expose to high temperatures. Do not use if the sealing of the primary packaging of COLLOST® is damaged.

12.2. Transportation conditions
Transport by all means of transport at temperatures from 5 to 25°C. Do not freeze or expose to high temperatures.

13. EXPIRATION DATE

3 years from the date of release. Do not use after the expiration date indicated on the package. Expired COLLOST® and its residues after use are placed in a container for non-toxic waste and sent for disposal.

14. PRESCRIPTION CONDITIONS

It is available without a doctor's prescription.

15. DISINFECTION, DISPOSAL

COLLOST® belongs to class B – epidemiologically hazardous waste. Class B waste is subject to mandatory disinfection/neutralization in accordance with the requirements of SanPiN 2.1.7.2790-10. The expired COLLOST® and its after-use residues are accounted for and monitored internally by the distributor organization engaged in medical and/or pharmaceutical activities. Disinfection/neutralization and disposal is carried out under a service agreement in accordance with Federal law.

16. COMPLAINTS ABOUT THE QUALITY OF A MEDICAL PRODUCT SHOULD BE SENT TO THE MANUFACTURER

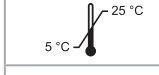
«BioPHARMAHOLDING», LLC, Russia, 123098, Moscow, 18 Gamalei str., building 33
tel.: +7 (495) 741-49-90, fax: +7 (495) 601-94-05, www.collost.ru, e-mail: safety@collost.ru.

17. PLACE OF PRODUCTION

«BioPHARMAHOLDING», LLC, Russia, 123098, Moscow, 18 Gamalei str., building 33.

«BioPHARMAHOLDING», LLC, Russia, 249930, Kaluga oblast, Mosalsk, 71 Revolutsii str.

"YUTIPADO", LLC, Russia, 121471, Moscow, 43 Riabinovaia str., building 1, floor 2, premises I, room 39-45.

Symbols on the product packaging	
STERILE R	Radiation sterilization
	Caution! Refer to the accompanying documentation
	Do not reuse
	Storage temperature range (storage conditions from 5 to 25 0 C)
LOT	Lot code
	Manufacture date
	Expiration date

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