MEANING OF SYMBOLS ON THE LABEL

	Do not reuse
	Refer to the instructions for use or to the instructions for use in electronic form.
	Use before ...
	Lot number
	Radiation sterilization
	Storage temperature range
	Manufacture date
	Fragile. Handle with care
	Keep away from sunlight
	Protect from moisture
	Do not use if the packaging is damaged
	Do not resterilize
	Up

LIST OF APPLICABLE STANDARDS

GOST ISO 10993-1-2021	Medical devices. Biological evaluation of medical devices. Part 1. Assessment and research in the risk management process
GOST R 52770-2023	Medical devices. Biological action assessment system. General safety requirements
GOST ISO 11607-1-2018	Packaging for terminally sterilized medical devices. Part 1. Requirements for materials, sterile barrier systems and packaging systems
GOST R ISO 15223-1-2023	Medical devices. Symbols to be used with medical device labels, labelling, and information to be supplied. Part 1. General requirements
GOST R ISO 14630-2017	Non-active surgical implants. General requirements
TU 21.10.60-00456533116-2019	Intradermal collagen-based implant COLLOST micro

Last revision date: 11.03.2025

INSTRUCTIONS FOR THE USE OF A MEDICAL PRODUCT «Intradermal collagen-based implant COLLOST micro according to TU 21.10.60-004-56533116-2019»

Name of the medical product, design options: Intradermal collagen-based implant COLLOST micro according to TU 21.10.60-004-56533116-2019, design options:

I. Intradermal collagen-based implant COLLOST micro, 0.05 g, complete with:
1. Type I micronized collagen — 0.05 g,
2. Instructions for use — 1 pc.,
3. Sticker — 2 pcs.

II. Intradermal collagen-based implant COLLOST micro, 0.15 g, complete with:
1. Type I micronized collagen — 0.15 g,
2. Instructions for use — 1 pc.,
3. Sticker — 2 pcs.

III. Intradermal collagen-based implant COLLOST micro, 0.45 g, complete with:
1. Type I micronized collagen — 0.45 g,
2. Instructions for use — 1 pc.,
3. Sticker — 2 pcs.

Manufacturer/Organization accepting claims/Marketing authorization holder:
OOO "BIOFARMAKHOLDING", Russia, 123098,
Moscow, 18 Gamalei str., building 33.
tel.: +7 (495) 741-49-90, e-mail: safety@collost.ru

PURPOSE

intended for injection to correct manifestations of physiological and pathological atrophy of soft tissues, including the dermis and hypodermis of the skin, by replenishing the volume of the extracellular matrix of their connective tissue base.

The scope of medical application of the product:
cosmetology, dermatology, plastic surgery.

Indications for use:
age-related and aesthetic involutional changes in the soft tissues of the face, body, arms, legs of various etiologies, including thinning, flabbiness, decreased elasticity, hypotrophic and atrophic scar deformities, striae.

PRODUCT DESCRIPTION

the product is a sterile, finely dispersed biodegradable material consisting of micronized type I collagen with a particle size of no more than 250 microns obtained from the dermis of cattle skin. The material requires hydration immediately before use. Injection of the product is aimed at compensatory replenishment of the mechanical and volumetric functions of the extracellular matrix, which are lost during involutional (atrophic) soft tissue changes of various etiologies. The finely dispersed collagen material of the product is not a pharmaceutical substance. The effect of volumetric replenishment is realized through a special spatial microstructure of collagen particles. The composition of the implanted product material is dominated by particles of filamentous morphology (length significantly exceeds width), which is achieved by microstructuring technology during production. These particles intertwine to form a three-dimensional network with a large volume fraction of capillary spaces capable of holding liquid. Hydration of the material is necessary to give the product a flow property for the possibility of its injection implantation. After implantation into the tissue, a network formed by intertwining filamentous particles directly fills the lost volume of the extracellular matrix. The capillary spaces between the particles retain fluid in the tissue, increasing the turgor of the skin. Thus, the use of the product helps to replenish the mechanical function of both fibrous and amorphous components of the intercellular substance. After injection, the product undergoes gradual biodegradation. The duration of the product's stay in the tissues and the duration of action after a single injection is at least 30 days, depending on the individual physiological characteristics of the patient's body and does not exceed 90 days. The product comes in three different quantities of material packed in vials, the volume of which allows for hydration at an equivalent ratio of mass to volume of the added liquid. The product versions have identical technical characteristics and differ only in the volume of material prepared for subsequent injection, which is intended to facilitate its use by medical personnel when administering it into soft tissues of varying sizes:
1) ***0.05 g*** is the most convenient for procedures involving small areas of skin, such as the periorbital area;
2) ***0.15 g*** is the most versatile and suitable for most procedures, including correction of the face, neck, and hands;
3) ***0.45 g*** is intended for procedures requiring the insertion of an implant into soft tissue over a large area of the body, for example, for correction of the neckline, arms, abdomen, thighs, and buttocks.

Composition:
0.05, 0.15, or 0.45 g of micronized type I collagen. Product safety is ensured by the application of GOST R ISO 22442-1-2011, GOST R ISO 22442-2-2011, GOST R ISO 22442-3-2011 and GOST R 58164-2018/ISO/TR 22442-4:2010 standards.

CONTENTS OF DELIVERY:
1. Type I micronized collagen — 0.05, 0.15 or 0.45 g,
2. Instructions for use — 1 pc.,
3. Sticker — 2 pcs.

Type I micronized collagen is packaged in sterile glass vials sealed with rubber stoppers and Flip-Off combination caps equipped with a quick-release plastic lid. The product packaging process is validated according to GOST ISO 11607-2-2018.

Potential consumer of the product:
a medical professional.

Product specifications:
• Appearance, color: dry product of white or pale yellow color with a uniform consistency in the form of a finely divided powder containing single or agglomerated particles. One or more larger round lumps that crumble when lightly pressed are allowed. There are no extraneous inclusions visible to the naked eye.
• Weight, g: 0.05–0.06, 0.15–0.16, 0.45–0.47
• Moisture content, %, not more than: 10
• Collagen protein content, %, not less than: 90
• Bacterial endotoxins, EU/product, not more than: 20
• Sterility: must be sterile
• Primary packaging integrity: must be airtight
• Dynamic viscosity*, MPa·s: 10–30
• Osmolarity*: 239–376 mOsm/L
• pH*: 5.0–8.0

* for product after hydration

Sterility of the product:
The sterility of the product is ensured by radiation sterilization in the final package, validated according to GOST ISO 11137.
The product is not subject to repeated sterilization.

CONTRAINDICATIONS FOR USE

• The patient has a known hypersensitivity to the components of the product.
• The patient has a tendency to develop keloid and hypertrophic scars.
• The presence of severe chronic diseases in the acute stage.
• The presence of dermatoses in the acute stage.
• The presence of blood clotting disorders.
• Taking medications that increase blood clotting time.
• The patient has signs of inflammation and/ or an infectious process in the area of intended administration.
• The patient has autoimmune diseases.
• The patient has a positive reaction in the allergological skin test for the product.
• When performing hydration with autologous plasma (including platelet-enriched plasma) obtained in a sterile test tube: hypersensitivity to sodium citrate.
• When adding lidocaine hydrochloride to a hydrating solution: hypersensitivity to lidocaine.
• Being pregnant or breastfeeding.

SIDE EFFECTS

The patient should be warned of the possibility of adverse reactions due to the administration of the product, which may occur immediately or after a period of time. Possible side effects include:
• The development of inflammatory reactions in the administration area, manifested by redness, swelling, erythema, papules, and pressure soreness. The regression of the above phenomena can last up to 1 week.
• The occurrence of hematomas at the injection site.
• The development of allergic reactions to the components of the product.
• There is always a possibility of local infection when administering any injection products.

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

WARNINGS AND PRECAUTIONS

It is necessary to strictly comply with the requirements of these instructions in order to prevent possible adverse reactions in patients.

• The product is intended for single use!
• The product can only be used by qualified medical personnel in compliance with the rules of aseptics and antiseptics in medical institutions.
• Secondary medical personnel with additional professional education in the specialty "Nursing in cosmetology" can use the product as prescribed by a doctor.
• 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 the product, as well as in cases of any other adverse reactions. At the same time, the doctor must ensure that the patient receives the necessary treatment.
• The product requires preliminary hydration before use.
• Sterile 0.9% sodium chloride solution or autologous blood plasma (including platelet-enriched plasma) obtained in a sterile test tube may be used as a hydrating solution (sterile amino acids, trace elements, and other sterile components intended for intradermal and subcutaneous administration may be used in compliance with aseptic and antiseptic rules).
• Storage and reuse of a hydrated product is not permitted (its stability and sterility are not guaranteed).
• The product is intended for only one patient and one procedure.
• Before using the product, check the expiration date on the packaging. Do not use expired products.
• Do not administer the product into blood vessels.
• Do not exceed the maximum allowable dose of 0.75 g of administered implant per procedure.
• The product is intended only for injection into the connective tissue base of soft tissues.
• If the needle of the syringe is blocked when working with the product, do not increase the pressure on the plunger of the syringe, but remove the needle and replace it with another one.
• If there is a history of allergic anamnesis, in each specific case of use, the doctor must decide on the possibility of using the product, depending on the nature of the disease and the treatment being performed, as well as ensure strict monitoring of the patient. It is recommended to offer the patient a preliminary skin test for hypersensitivity, as well as to refrain from using the product in patients in the active stage of the disease.
• Patients receiving treatment with drugs that increase blood clotting time should be warned about the increased risk of petechiae, ecchymosis, and bruising during administration.
• There is no data on the safety of using the product in children and adolescents.

INTERACTION WITH MEDICINAL PRODUCTS

• It is not recommended to use the product 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.

EQUIPMENT AND MATERIALS

Materials required for the operation of the product, but not included in the delivery package:
• Disposable sterile syringes with a volume of 2, 3, or 5 mL, preferably with a Luer-Lock needle connector.
• Sterile injection needles of calibration size 34G-27G.
• Alcohol wipe, antiseptic for skin treatment.
• Sterile 0.9% sodium chloride solution for injection or autologous patient's blood plasma (including platelet-enriched plasma) obtained in a sterile tube containing sodium citrate as an anticoagulant (the use of sterile amino acids, trace elements and other sterile components intended for intradermal and subcutaneous administration is allowed, subject to the rules of aseptics and antiseptics).

INSTRUCTIONS FOR USE OF THE PRODUCT

• At the initial admission of the patient, his full medical history should be examined for contraindications to the use of the product.
• Before starting the injection, thoroughly disinfect the injection site with a skin antiseptic. Local application anesthesia of the injection area is recommended.
• The recommended minimum course of product application is 3-5 procedures with an interval between procedures of 2-3 weeks, up to 2 months.
• The duration of the cosmetic effect after administration of the product is individual and depends on many factors, including the soft tissues structure, age, and lifestyle of the patient.
• It is undesirable to carry out cosmetic and physiotherapy procedures, visit a sauna for 7 days after the procedure. Do not apply makeup for 12 hours after the procedure. Medical camouflage may be used immediately after the procedure.
• If necessary, at the discretion of the doctor, the implant can be removed by aspiration or surgery.
• The position of the implant in the tissues can be determined using methods used to visualize injectable dermal implants: sonography (US diagnostics), magnetic resonance imaging.
• The duration of the product's stay in the tissues is at least 30 days, depends on the individual physiological characteristics of the patient's body and does not exceed 90 days.
• The maximum allowable dose of administration for one patient per procedure is 25 mL of hydrated product.
• Extensive scientific literature indicates that lidocaine has no effect on the structure and properties of collagen. In this regard, to reduce discomfort during the implantation procedure, at the discretion of the physician, it is permissible to add a sterile solution of lidocaine hydrochloride 2% to the product at a rate of 0.04-0.10 mL per mL of hydrated product.

PREPARATION FOR PRODUCT OPERATION

1. Remove the sterile syringe and the sterile needle from the package. Connect the needle to the syringe.
2. Fill the syringe with sterile sodium chloride solution or autologous blood plasma (including platelet-enriched plasma) obtained in a sterile test tube at a ratio of 1 mL per 0.03 g of material:
• when using 0.05 g – 1.7 mL;
• when using 0.15 g – 5.0 mL;
• when using 0.45 g – 15.0 mL
The amount of hydrating solution used may be adjusted at the discretion of the physician depending on the severity of the patient's aesthetic concerns.
3. Remove the plastic lid of the vial by pulling it up by the edge.
4. Wipe the vial stopper with an alcohol cloth.
5. Using a syringe needle, pierce the section of the rubber stopper of the vial located under the removed lid.
6. By pressing on the plunger of the syringe, transfer the saline solution completely through the needle into the inner space of the vial. Remove the syringe needle from the vial lid. Shake the vial vigorously for 3–5 minutes.
7. Soak the vial for 5-10 minutes to hydrate the collagen material, periodically shaking it intensively.
8. Insert the syringe needle into the vial lid. Turn the vial upside down. Carefully remove the contents of the vial back into the syringe. Remove the needle from the vial lid.
9. Replace the syringe needle. Press down on the plunger and fill the needle with hydrated material.
10. Proceed with injection.
11. When working with autologous blood plasma (including platelet-enriched plasma), to prevent excessive clumping of the material during hydration, it is recommended to add sterile saline solution to the vial using a separate syringe and needle in an amount equal to 30% of the total volume of the hydrating solution (for 0.05 g – 0.5 mL, 0.15 g – 1.5 mL, 0.45 g – 4.5 mL), and then add 70% of the blood plasma volume.

PRODUCT APPLICATION PROCEDURE

The product should be injected into soft tissue, intradermally or subdermally. Product insertion techniques: linear, short-line, papular, microbolus, point injections.

OPERATING CONDITIONS

The injection implantation of the product should be carried out at a temperature from +18°C to +25°C. The temperature range of the product in body tissues after implantation ranges from +32°C to +42°C.

Storage conditions:
Store in a place protected from light at a temperature from +5 ° C to +25 ° C and humidity not exceeding 65%. Do not freeze or expose to high temperatures. Do not use if the sealing of the primary packaging is damaged.

Transportation conditions:
Transport at temperatures from +5 ° C to +25 ° C and humidity not exceeding 65%, do not freeze or expose to high temperatures.

Disposal:
In accordance with the classification of SanPiN 2.1.3684-21, the following types of waste are generated when using the product:
• Products remaining unused in unopened packaging after the expiration date, and packaging containers (class A);
• Products that remain unused after opening the packaging and material that has come into contact with patients' biological fluids (class B). Class A waste is disposed of in accordance with the requirements of the current Sanitary Rules for the handling of solid municipal waste.
Class B waste is subject to mandatory disinfection/neutralization.
Disposal is carried out under contract with specialised organisations licensed to dispose of medical waste in accordance with Federal legislation.
An expired product and its after-use residues are accounted for and monitored internally by the distributor organization engaged in medical and/or pharmaceutical activities.

Shelf life:
The shelf life of the product is 5 years from the date of manufacture. It is not allowed to use the product after the expiration date.

Warranty obligations:
The manufacturer guarantees the quality and safety of the product during the entire shelf life (5 years from the date of manufacture), provided that the storage conditions specified in these instructions are met.