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in cooperation with
Palladin Institute of Biochemistry of the
National Academy of Sciences of Ukraine
(NASU) within the USF
program of dual purpose projects grant
support*

**Development of the
effective hemostatic agent
capable of biodegradation**

Brief description of innovative product

The unique collagen matrix is suitable for use both in everyday life and in surgery, modified by specific activator of blood coagulation. This innovative hemostatic agent, efficiently stopping the bleeding, retains the collagen's biological compatibility, does not provoke the wound healing process complication, does not need to be removed from the wound surgically, promotes healing of the wound and restoring of surrounding tissues, and is effective in case of hemophilia of both types.

Collagen



Specific blood coagulation activator



Unique hemostatic agent capable of biodegradation



Unique hemostatic agent capable of biodegradation

- collagen's biological compatibility;
- no need of removing from the wound;
- promotes healing of the wound and recovering of surrounding tissues;

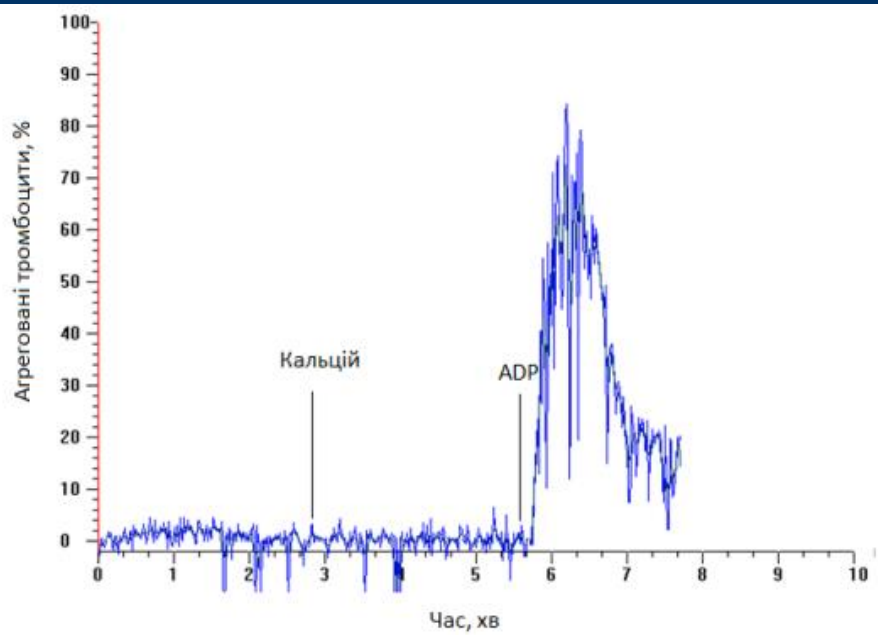
- blood coagulation activator, possessing the proven safe and effective hemostatic action even in case of hemophilia



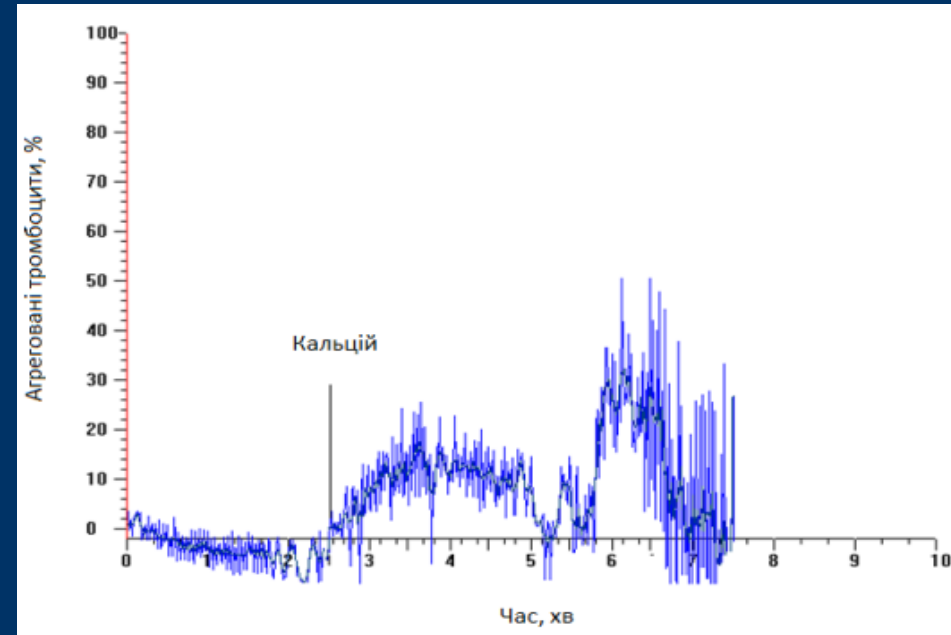
Unique hemostatic agent with powerful adhesive and reparative properties

Efficiency

Aggregation of thrombocytes



The aggregation of human platelets in platelets-rich blood plasma under the presence of collagen matrix fragment, produced in laboratory conditions of industrially-obtained raw. 2.5 min - CaCl_2 ($2 \cdot 10^{-3}$ M) input, 5 min - ADP input ($2.5 \mu\text{M}$)



The aggregation of human platelets in platelets-rich blood plasma under the presence of collagen matrix fragment, produced in laboratory conditions of industrially-obtained raw and improved with the blood coagulation activator. 2.5 min - CaCl_2 ($2 \cdot 10^{-3}$ M) input

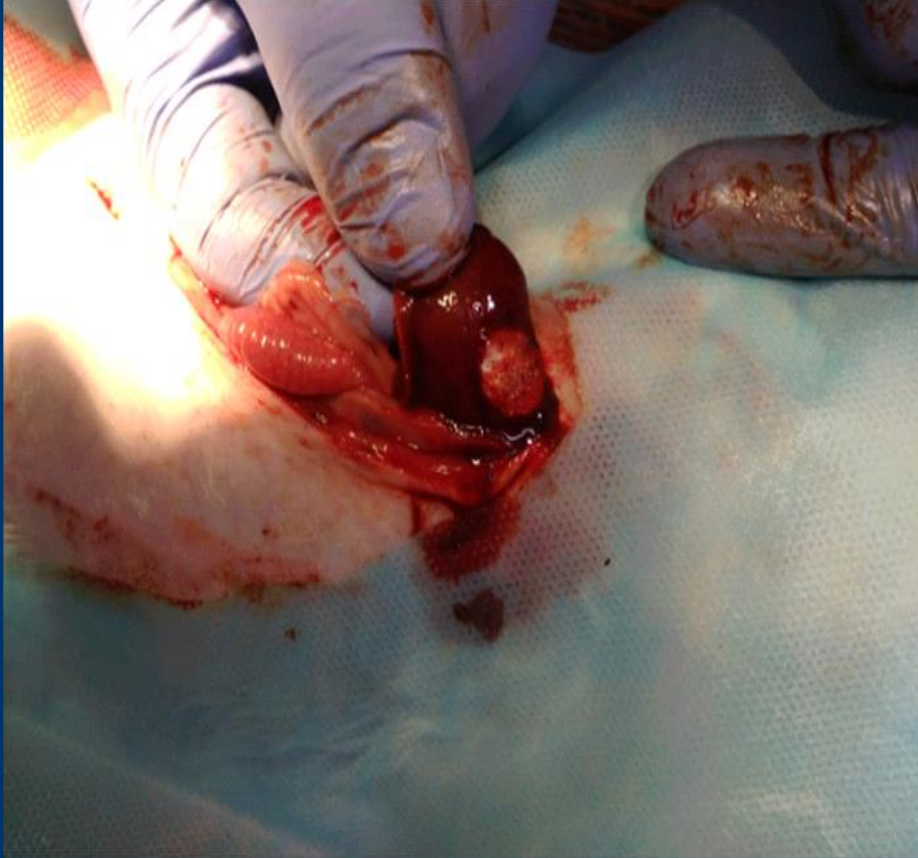
Efficiency

Aggregation of platelets

Collagen matrix modified by blood coagulation activator, causing the accelerated coagulation of blood plasma, and the aggregation of platelets *in vitro*

Efficiency

Hemostatic action



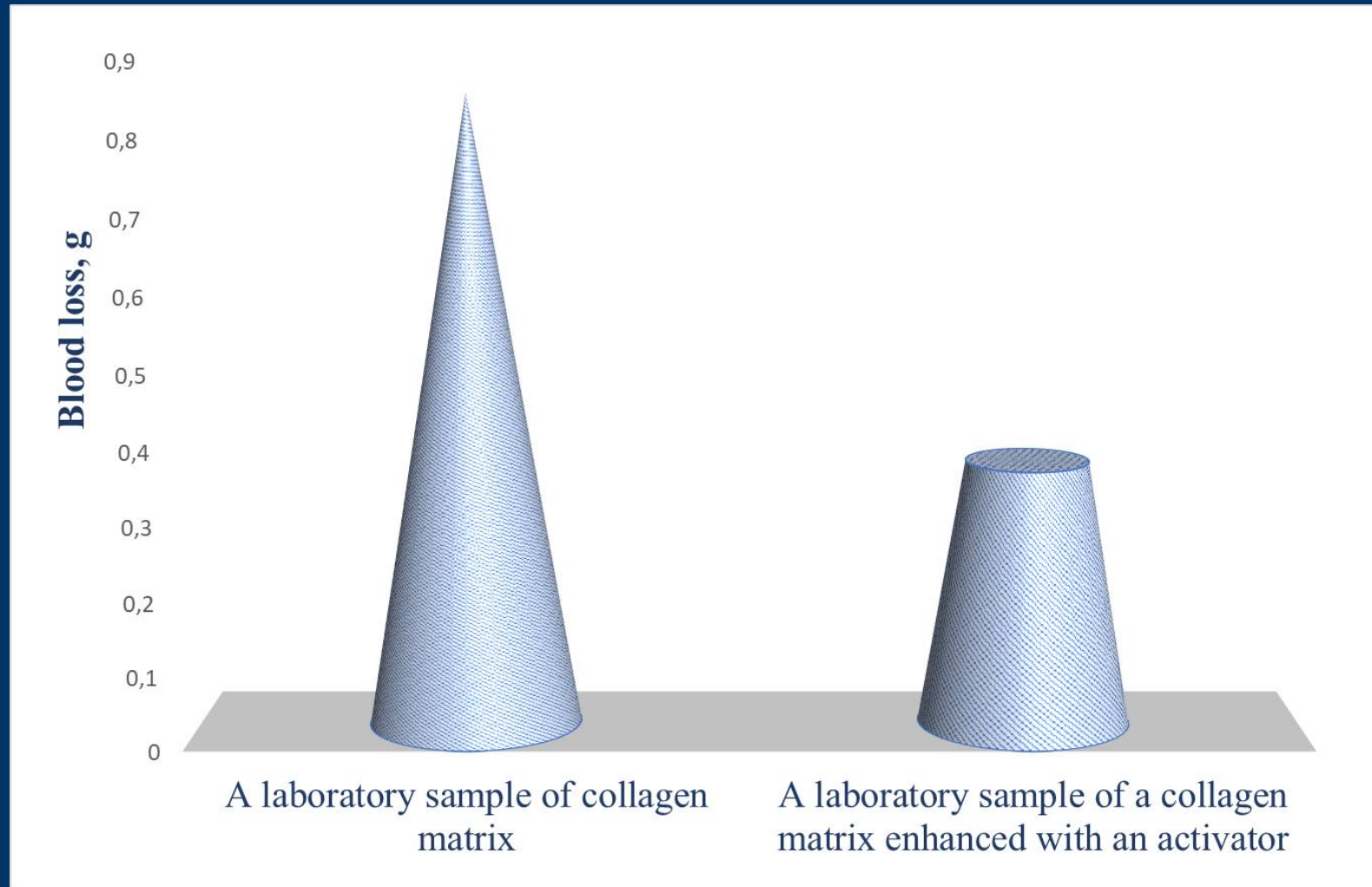
The laboratory sample of collagen matrix soaked with blood during the operation. The high sorption capacity, and effective blood absorption were noted.



The laboratory sample of collagen matrix, improved by the blood coagulation activator, soaked with blood during the operation. The quick stop of bleeding, and the absence of notable absorption were noted.

Efficiency

Hemostatic action



Blood loss in rabbits in the simulation of parenchymal bleeding, using a collagen matrix laboratory sample and an activator-enhanced laboratory matrix

Efficiency

Hemostatic action

There was observed a quick effective stop of bleeding at the moment of applying the collagen matrix improved by blood coagulation activator.

Efficiency

Wound healing action



Laparoscopic picture of rabbit liver in 14 days after operation with usage of collagen matrix improved with blood coagulation activator. The process of adhesions formation was noted. Inflammation and edema were absent.



Laparoscopic picture of rabbit liver in 14 days after operation with usage of collagen matrix improved with blood coagulation activator. The process of adhesions formation was noted. Inflammation and edema were absent.

Efficiency

Wound healing action



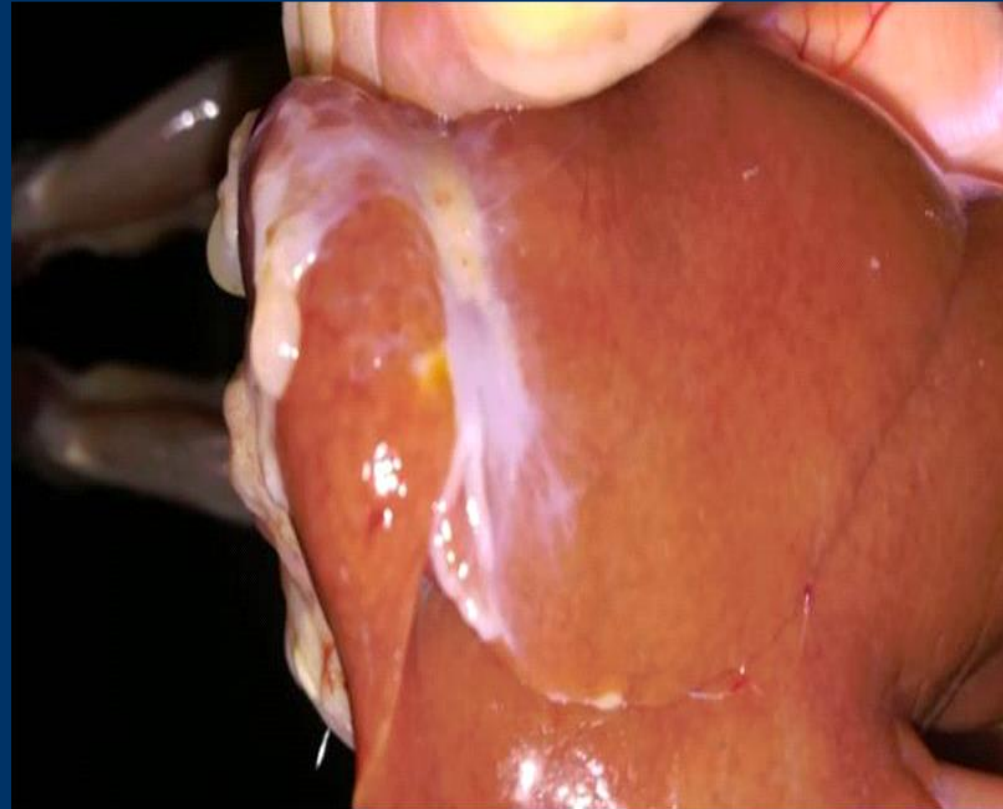
Laparoscopic picture of rabbit liver in 14 days after operation with usage of collagen matrix sample created by us. The process of adhesions formation was not noted. Inflammation and edema were absent.

Efficiency

Wound healing action



Laparoscopic picture of rabbit liver in 14 days after operation with usage of commercially available sample of collagen matrix. The process of adhesions formation was not noted. Inflammation and edema were absent.



Laparoscopic picture of rabbit liver in 14 days after operation with usage of commercially available sample of collagen matrix. The process of adhesions formation was notable. Inflammation and edema were absent.

Efficiency

Wound healing action

Evaluation of adhesions formation by V.V. Plechev

Group	№ of animal	Adhesions formation characteristics		
		expression level	type of adhesions	% among the group
Collagen	1	0	0	0
	2	0	0	
	3	0	0	
Collagen + activator	1	2+	Tensile type (visceral-visceral)	33,3
	2	0	0	
	3	0	0	

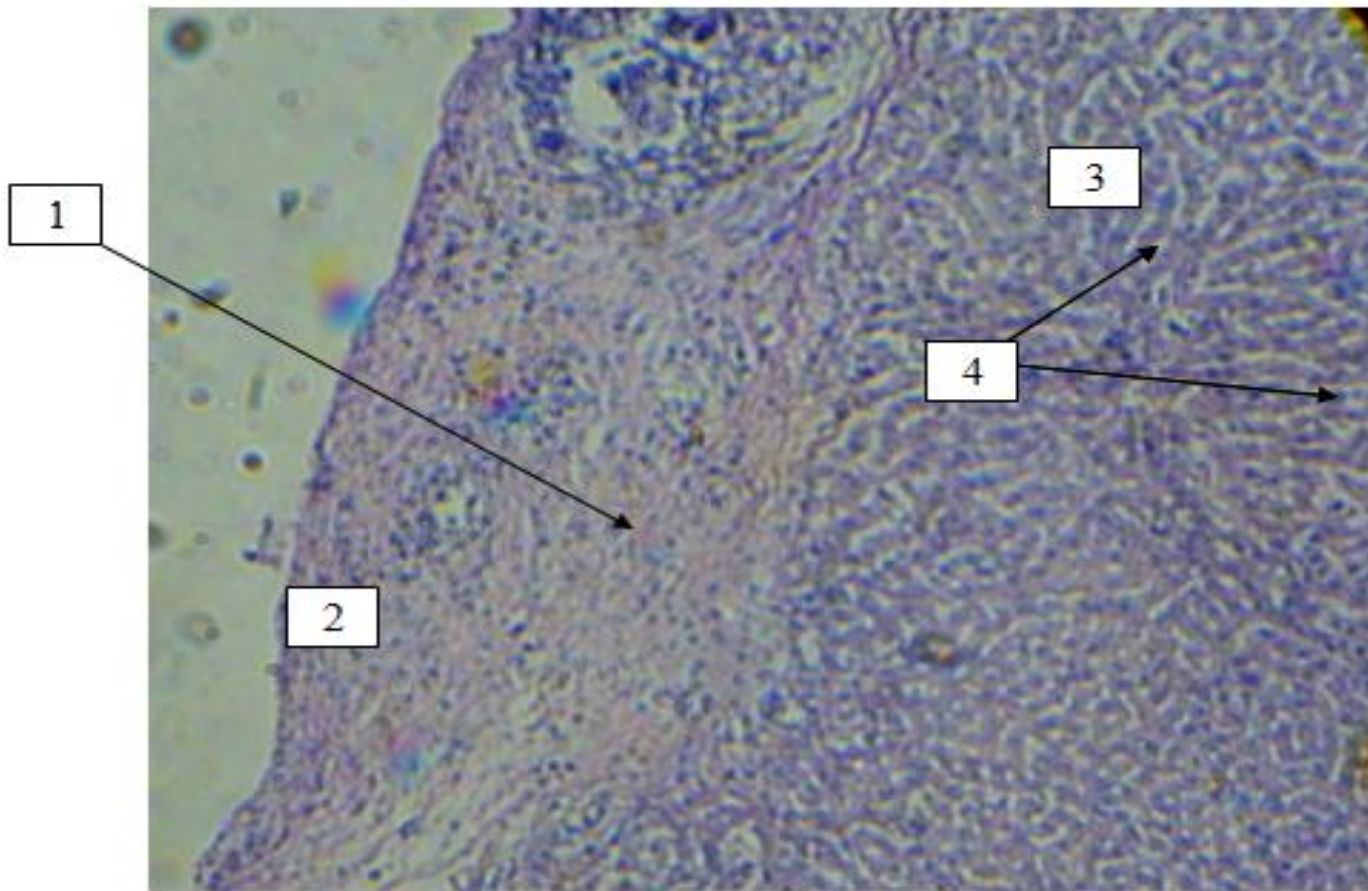
Efficiency

Wound healing action

In the 14 days after the use of laboratory sample of collagen matrix modified by blood coagulation activator, effective wound healing was observed along with absence of edema or inflammation. The clearly outlined healed wound surface was noted.

Efficiency

Reparation



1 – border between liver tissue and regenerate;

2 – tissue, forming at the place of collagen matrix;

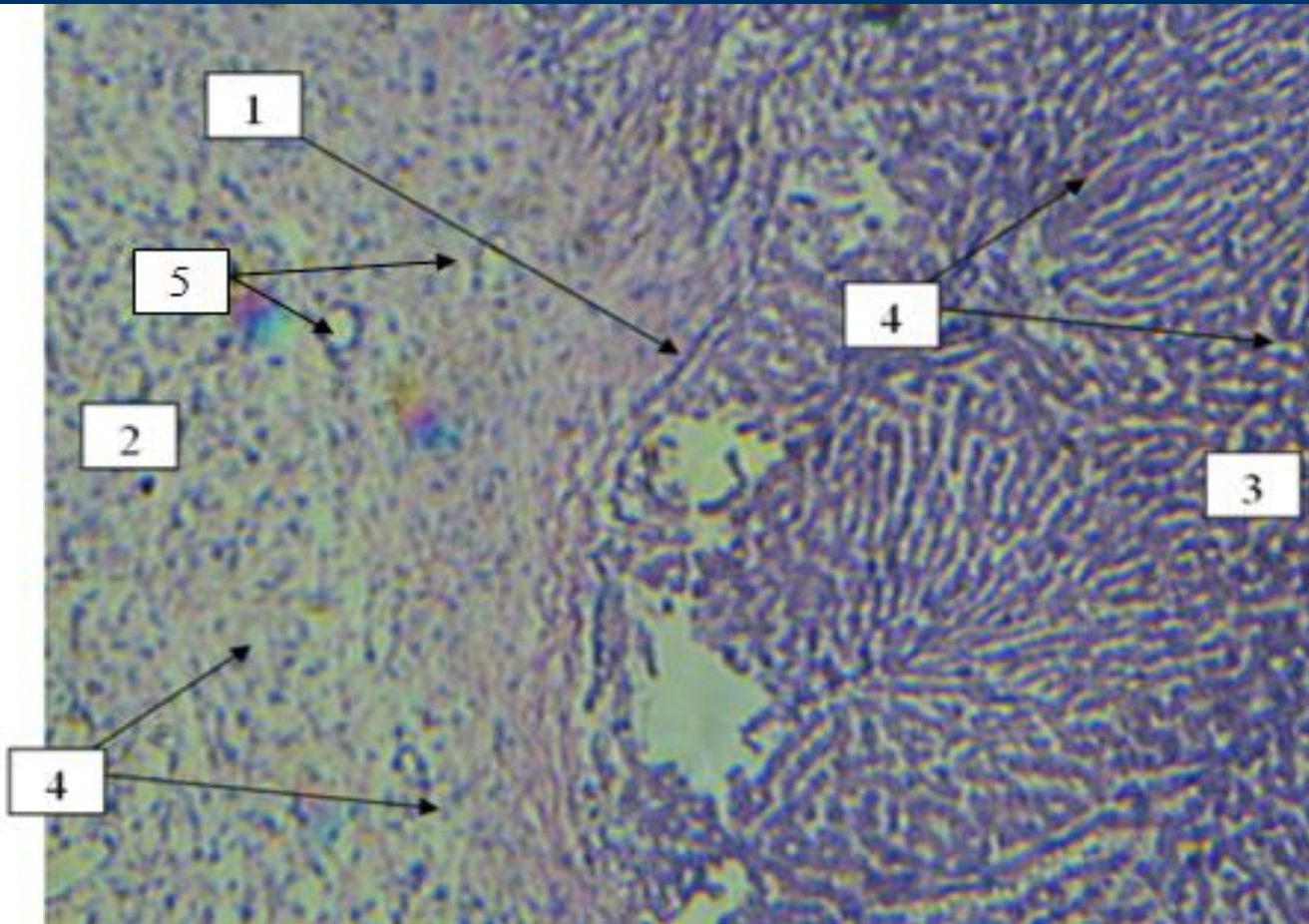
3 – liver tissue;

4 – liver sinusoids.

The reparation of liver at the 14 day after the use of collagen matrix modified by blood coagulation activator. Stained with hematoxylin-eosin. Magnification 1:150.

Efficiency

Reparation

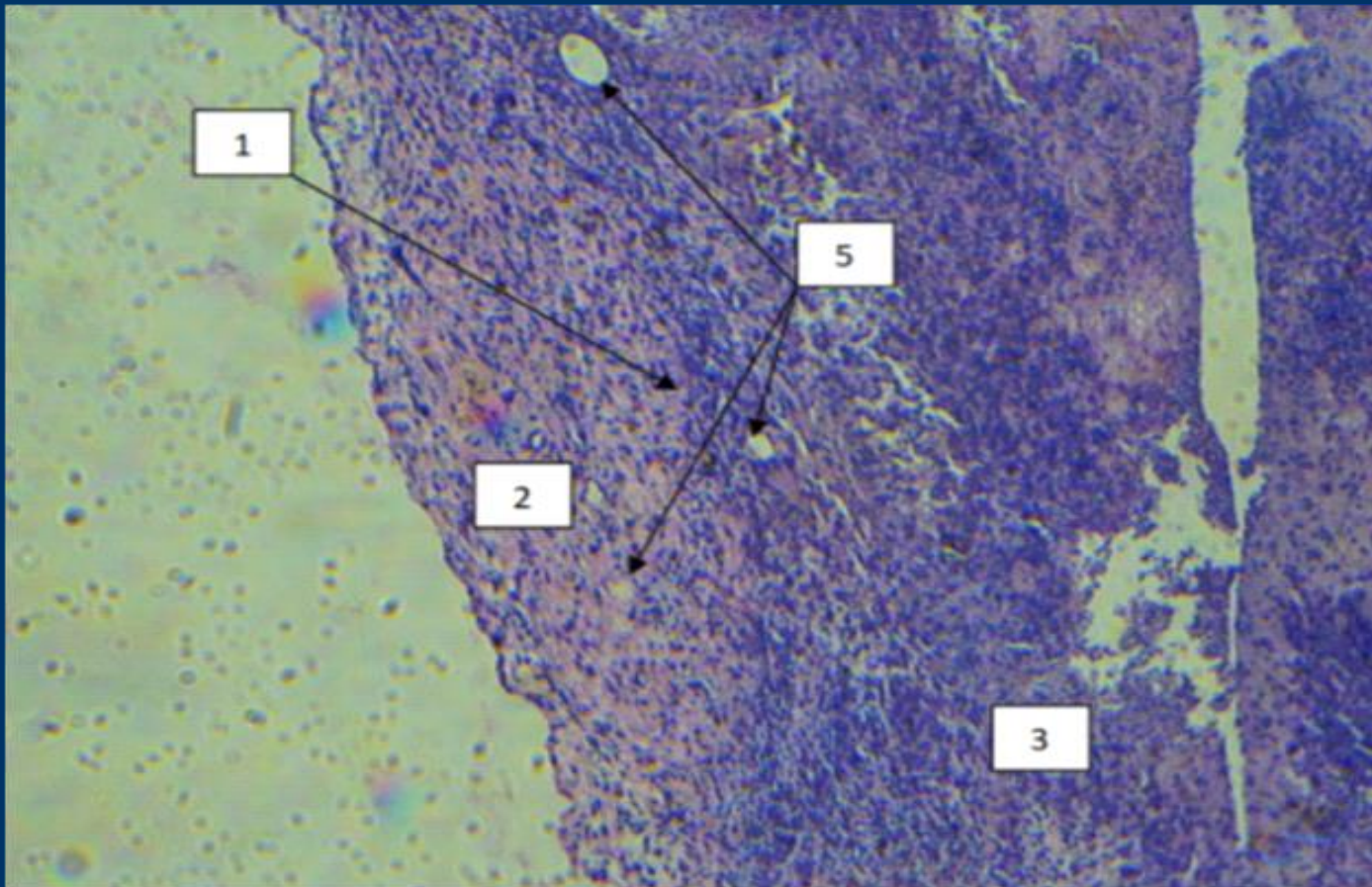


- 1 – border between liver tissue and regenerate;
- 2 – tissue, forming at the place of collagen matrix;
- 3 – liver tissue;
- 4 – liver sinusoids;
- 5 – blood vessels.

The reparation of liver at the 14 day after the use of collagen matrix modified by blood coagulation activator. Stained with hematoxylin-eosin. Magnification 1:300.

Efficiency

Reparation

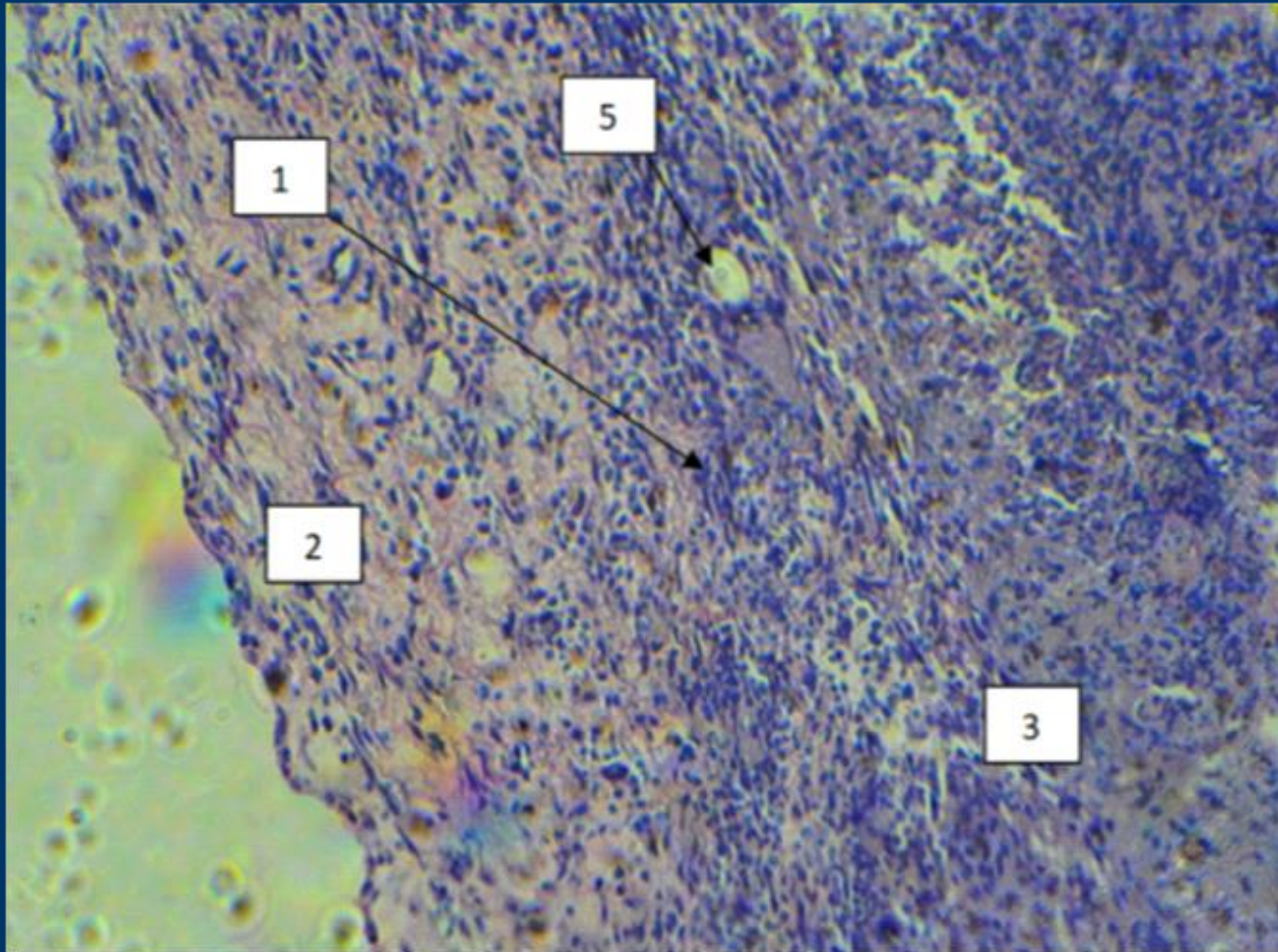


- 1 – border between liver tissue and regenerate;
- 2 – tissue, forming at the place of collagen matrix;
- 3 – liver tissue;
- 4 – liver sinusoids;
- 5 – blood vessels.

The reparation of liver at the 14 day after the use of collagen matrix. Stained with hematoxylin-eosin. Magnification 1:150.

Efficiency

Reparation

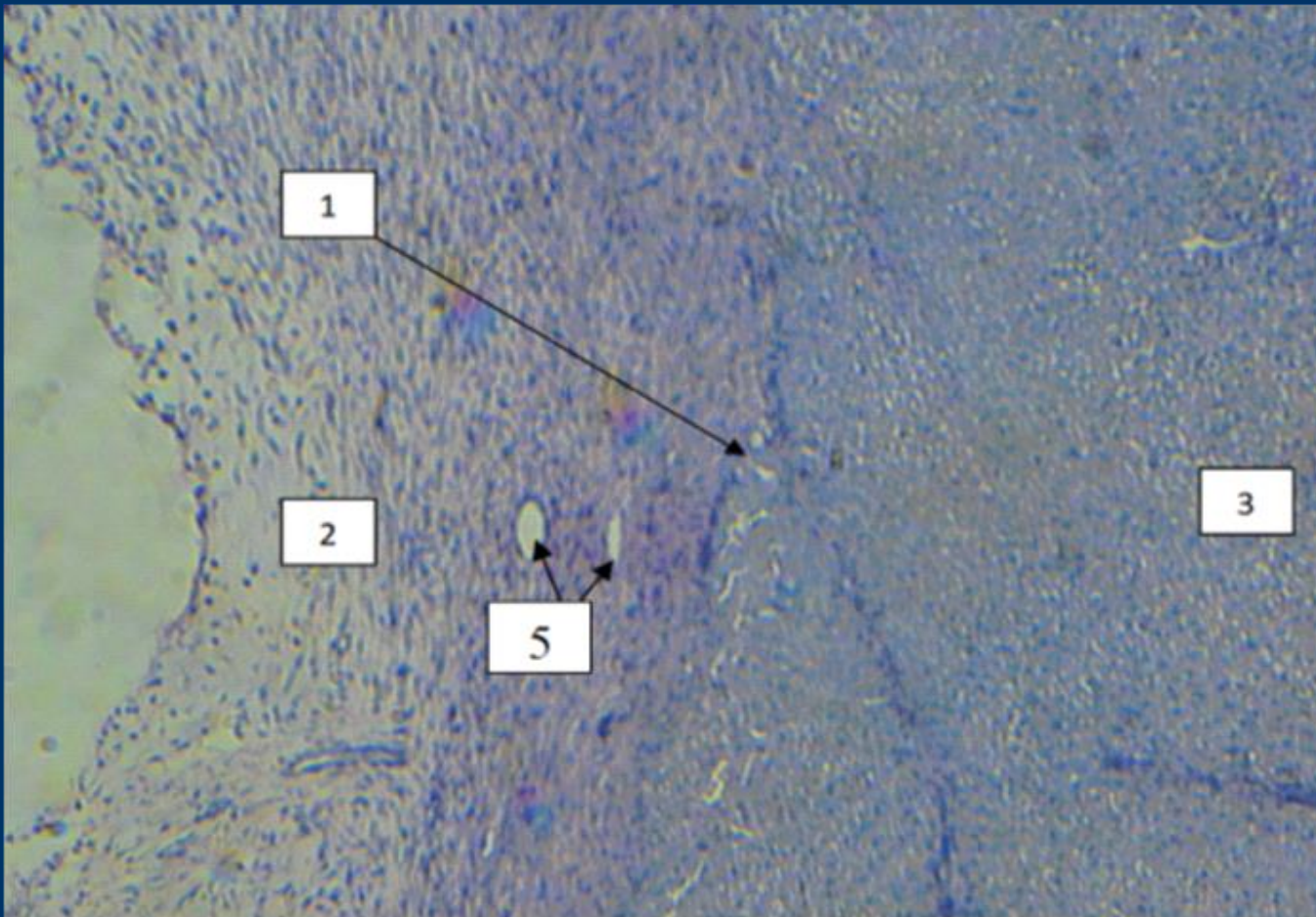


- 1 – border between liver tissue and regenerate;
- 2 – tissue, forming at the place of collagen matrix;
- 3 – liver tissue;
- 4 – liver sinusoids;
- 5 – blood vessels.

The reparation of liver at the 14 day after the use of collagen matrix.
Stained with hematoxylin-eosin. Magnification 1:300.

Efficiency

Reparation

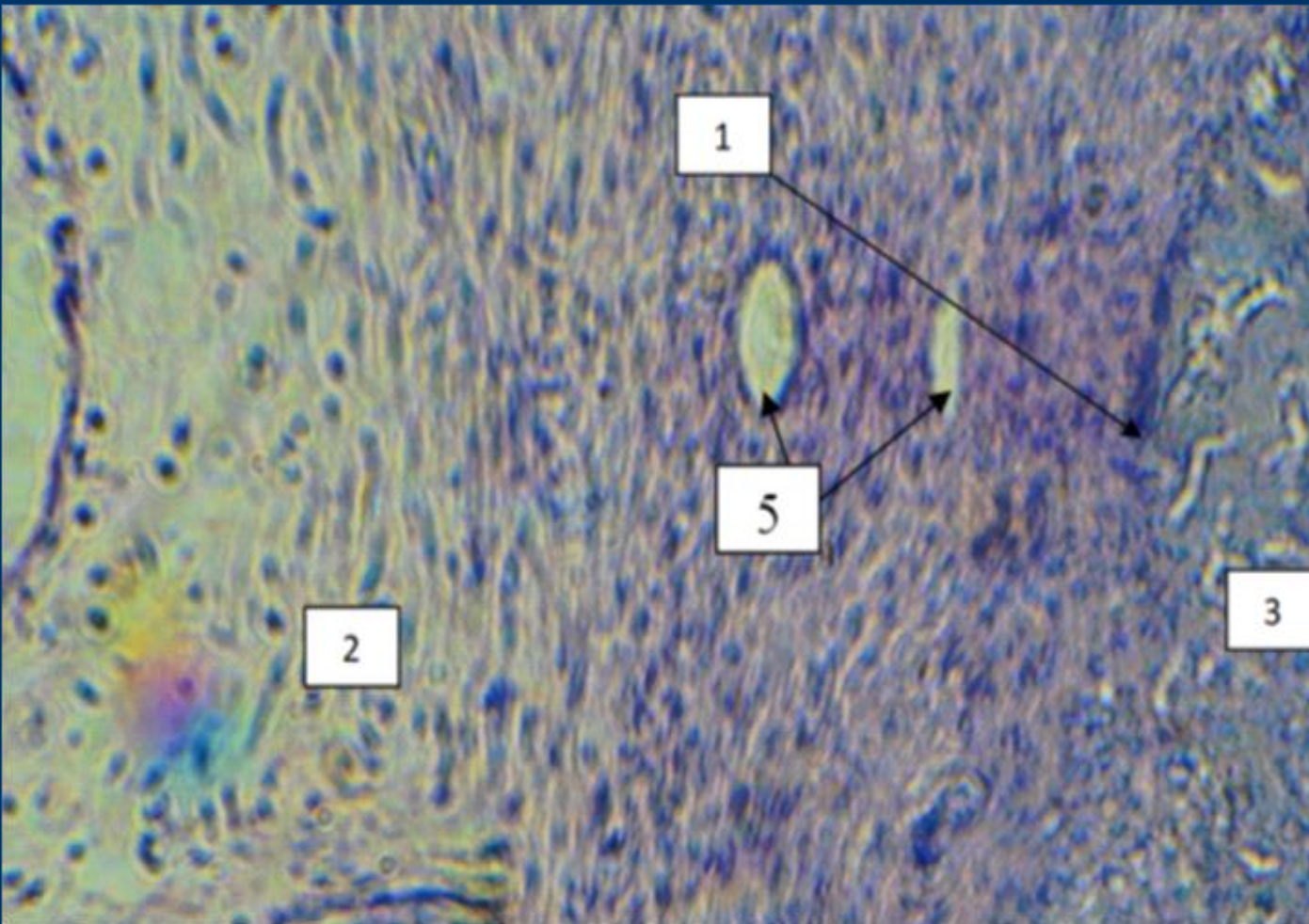


- 1 – border between liver tissue and regenerate;
- 2 – tissue, forming at the place of collagen matrix;
- 3 – liver tissue;
- 4 – liver sinusoids;
- 5 – blood vessels.

The reparation of liver at the 14 day after the use of commercially available collagen product. Stained with hematoxylin-eosin. Magnification 1:150.

Efficiency

Reparation



- 1 – border between liver tissue and regenerate;
- 2 – tissue, forming at the place of collagen matrix;
- 3 – liver tissue;
- 4 – liver sinusoids;
- 5 – blood vessels.

The reparation of liver at the 14 day after the use of commercially available collagen product. Stained with hematoxylin-eosin. Magnification 1:300.

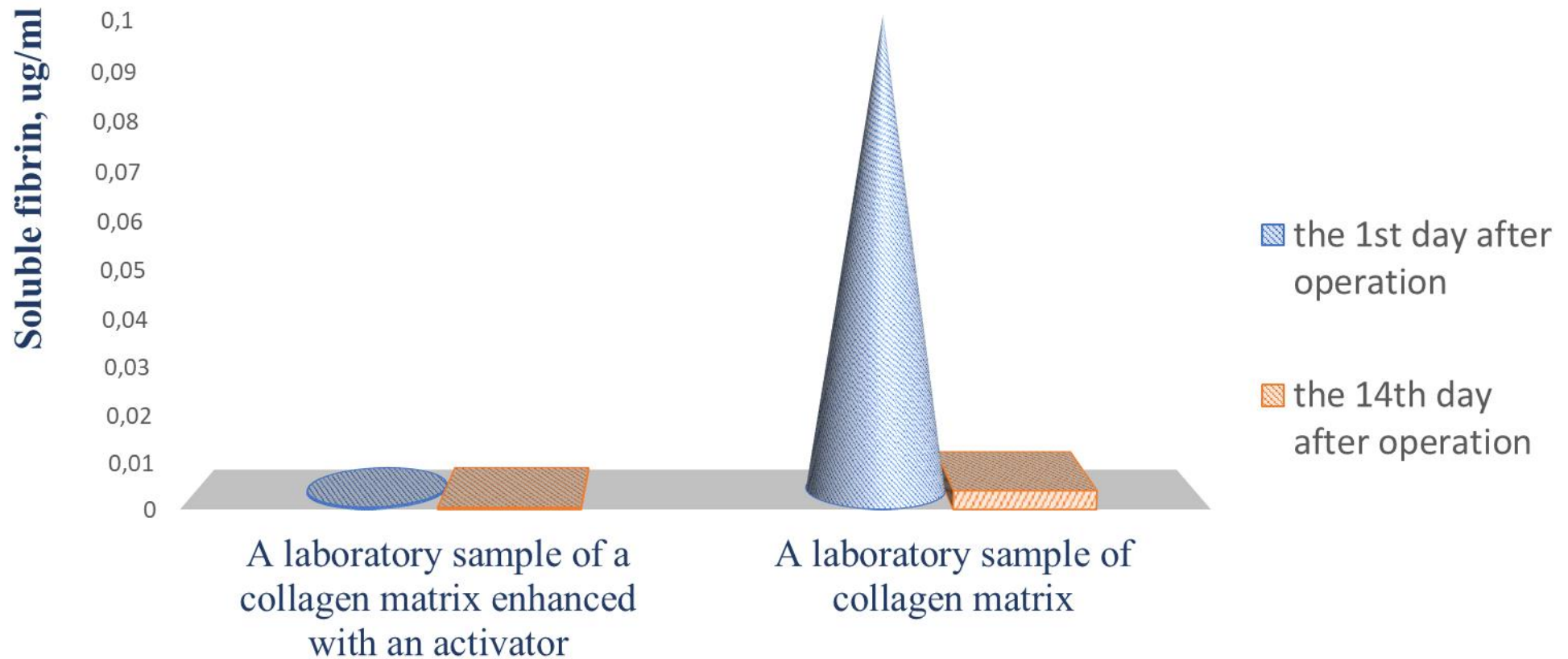
Efficiency

Reparation

The collagen matrix modified by blood coagulation activator is identified as the separate histological unit at the 14 day after the operation. There is clearly notable border between liver tissue and the regenerate. The formation of liver sinusoid is observed. The process of vascularization is ongoing.

Efficiency

The risk of thrombosis



The content of soluble fibrin in rabbit blood plasma at the 1 and 14 days after the operation

*- results, significant with $p \leq 0.05$

Efficiency

The risk of thrombosis

In case of using the collagen matrix with blood coagulation activator added, there is no activation of blood coagulation system in rabbits

Competitors' analysis									
Parameters	Hemostatic agent capable of biodegradation (innovative product)	Hemostatic sponge LLC “Biopharma PLASMA”, Ukraine	Tachcomb, Austria, Austria	Takeda GmbH, Austria	Celox, Proctos Electra House, UK	MedTrade Z-Medica, USA	QuickClot, Z-Medica, USA	REVUL bandage, LLC “YURiA-PHARM”, Ukraine	Krovospas, LLC “Vyrobnnyche Obiednannia Teteriv”, Ukraine
Action compound	Collagen modified by prothrombin activator	Blood plasma	Thrombin+fibrinogen	Chitosan	Kaolin	Chitosan	Kaolin		
Hemostatic action	+++	+	+	++	++	++	++		
Biodegradation	+++	++	+	++	-	++	-		
Formation of antibodies to the blood plasma proteins	-	++	++	-	-	-	-		
Hypersensitivity reaction	+	+++	+++	+	+	+	+		
Hemocontact mechanism of infection transmission	-	+++	++	-	-	-	-		
Features of use	No obligatory need of qualified specialist	Basic medical education or training	Qualified specialists are needed	No need of qualified specialist	No need of qualified specialist	No need of qualified specialist	No need of qualified specialist		
Efficiency in case of hemophilia	+++	+	+	+	-	+	-		
Wound healing effect	++	+	++	-	-	-	-		

SWOT -ANALYSIS

Strengths

Clearly formulated idea

Hemostatic action, exceeding that in analogs

Reparation properties are no less than that of analogs

Almost no analogs presented on the domestic market

Method was worked out in the laboratory

Efficiency in case of hemophilia

Increasing number of surgical procedures globally to fuel demand

Professional motivated team

Demand of the product (ongoing military actions)

SWOT -ANALYSIS

Weaknesses

Absence of business plan

Absence of promotion plan

Lack of funding, absence of investments

Clinical trials were not conducted

Absence of production facilities

Method was not scaled

SWOT -ANALYSIS

Opportunities

Contact with the pharmaceutical companies

Leading role on the domestic market

Presentation of the product at the target exhibitions and conferences

Country's defence capacity increasing (ongoing military actions)

Entering the global market

SWOT -ANALYSIS

Threats

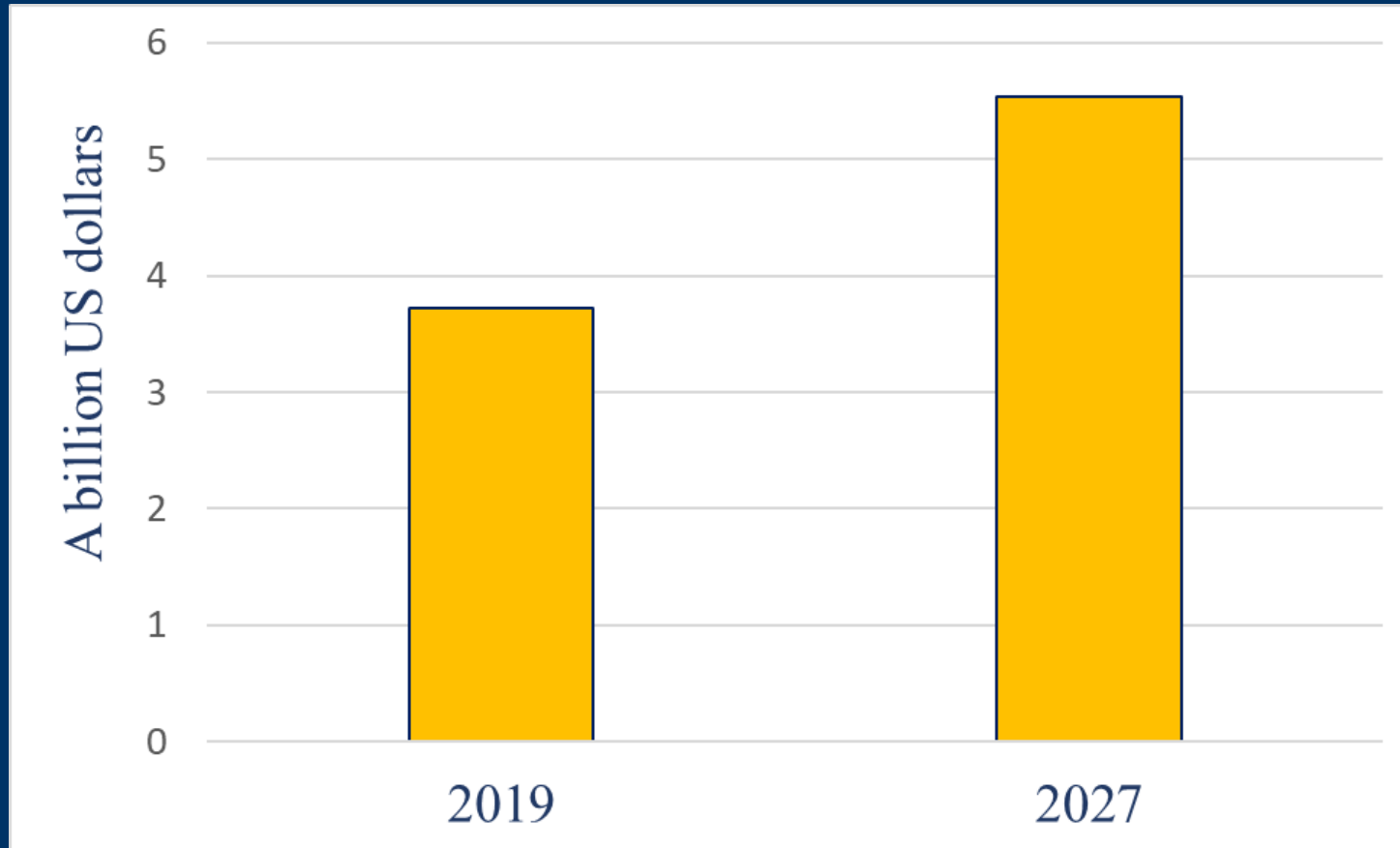
Absence of international patent

Trademark is not registered

Clinical restrictions

**Increasing number of advanced technological
innovations in this field**

MARKET ANALYSIS



According to the Fortune Business Insights, the hemostatic global market consisted of US\$ 3.72 billion in 2019, and may reach US\$ 5.54 billion till 2027, according to the prognoses

STATE MARKET ANALYSIS

According to the Ministry of Health data on the medicine and medical products state (state budget) purchase , particularly for the areas of adult hemophilia and hemophilia in children



Hemophilia in children



Adult hemophilia

***ACTUAL RESULTS, WHICH CAN BE ACHIEVED
BY GRANT MONEY USING***

The consignment of experimental product samples will be obtained

The report on the pre-clinical trials from the Ministry of Health-certified center will be obtained

The laboratory regulations on product manufacturing will be developed

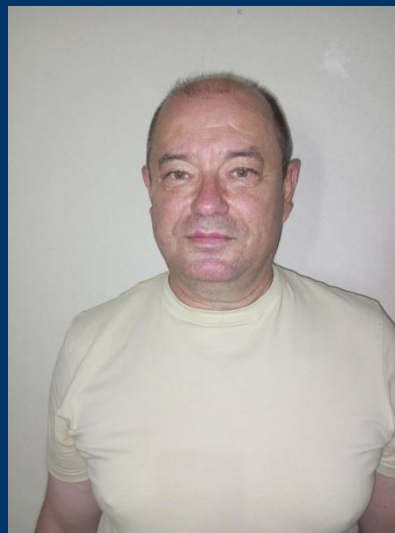
ACTION PLAN FOR ACHIEVING RESULTS

1. The study on the efficiency of activator mobilized on the collagen matrix *in vitro* will be performed.
 2. Activator production.
 3. Obtaining the consignment of experimental product samples.
 4. Clinical trials conducting.
 5. Animal testing aimed at the examination and proving of hemostatic and wound healing action.
 6. Development and approval of laboratory regulations of product manufacturing
-
-



Investigator –
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TEAM



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CONCLUSIONS

There was developed, characterized and approved *in vitro* and *in vivo* the collagen matrix with enhanced hemostatic action, which is not inferior to existing analogs in its wound healing action efficiency, and vastly exceeds them in its capacity to stop the parenchymatous organs' bleeding.

Considering the increasing global hemostatics market, the demand of innovative advanced combined products, and the presence of qualified team to perform the project's tasks - the present product has extremely high potential to reach the top positions on the market!

THANK YOU FOR YOUR ATTENTION!

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