National Technical University of Ukraine
"Igor Sikorsky Kyiv Polytechnic Institute"

Department of
biomedical engineering

ARTIFICIAL ORGANS

Working program of educational discipline (Silabus)

Requisites for educational discipline	
Level of higher education	***Second (master's)***
Branch of knowledge	*16 Chemical and Bioengineering*
Specialty	*163 Biomedical Engineering*
Educational program	*Medical Engineering*
Discipline status	*Electiv discipline*
Form of study	*full-time / day / mixed / remote*
Year of preparation, semester	*1 course (spring semester)*
The scope of discipline	*4 ECTS credits / 120 hours*
Semester control / Control measures	*Test Work, Modular Test Work*
Lessons schedule	*According to the schedule on the site http://rozklad.kpi.ua/*
Language of instruction	*English*
Information about course leader / teachers	***Lecturer:*** *cand.med.sc., associate professor Department of Biomedical engineering Kozyar Vasyl Vasylovych, e-mail – kozyarvasilij@gmail.com* ***Practical: :*** *cand.med.sc., associate professor Department of Biomedical engineering Kozyar Vasyl Vasylovych, e-mail – kozyarvasilij@gmail.com*
Course placement	*Platform «Sikorsky» - course «Artificial Organs»*

Distribution of hours

Semester	Lectures	Practical	Laboratory	Independent Work
spring semester	*28*	*44*	*-*	*48*

Curriculum of the discipline

1. Description of the discipline, its purpose, subject of study and learning outcomes

The main goal of the discipline "Artificial organs" is the formation of students' ability to design, construct improve and apply medical-technical and Bioengineering products that can effectively replace the lost functions of the body, assess biological and technical aspects and consequences of interaction of engineering-technical and Bioengineering objects with physiological systems, anticipate their mutual impact. The purpose of teaching the discipline is to provide students with theoretical knowledge and the formation of their practical skills and abilities regarding the history of the development of means of prosthetics of body functions and individual organs, the main requirements for artificial organs, the degree of approximation of their capabilities to physiological needs, existing and promising technologies of extracorporeal and intracorporeal prosthetics of organs and functions of the human body, the requirements for biocompatibility of raw materials used and energy supply of artificial organs. The discipline also covers issues of design solutions used in the creation of artificial organs and their control systems, problems of rejection of implanted devices, injuries and non-clotting of blood,

interface with the central nervous system and executive organs, organization of production and service.

The objectives of studying the academic discipline are:

- to identify modern needs and problems of creating artificial organs;

on assimilation of fundamental-applied, medico-physical and bioengineered foundations of technologies for prosthetics of human physiological processes;

- mastering the methods of calculation and selection of classical and Latest structures, biomaterials, elements, devices and systems for replacing body functions;

- mastering the methods of designing and constructing biocompatible autonomous artificial implantable organs;

- acquisition of knowledge of general principles and basic methods for assessing the functional state of human organs and systems, which involves the use of artificial organs;

- mastering methods for measuring the main indicators of the functioning of artificial organs and evaluating the results of their application.

Since the discipline is selective, it requires knowledge of the basics of developing operational documentation.

***Generalm competencies** (OPP was put into effect by the Rector's Order NON/ 89/2021 of 19.04.2021):*

***GC 1 -** Ability to abstract thinking, analysis and synthesis.*
***GC 2 -** Ability to search, process and analyze information from various sources.*
***GC 3 -** Ability to identify, formulate and solve problems.*
***GC 5 -** Ability to work in an international context.*

***Special (professional) competencies** (OPP was put into effect by the Rector's Order NON/ 89/2021 of 19.04.2021):*

***PC 4** -ability to create and improve biomedical engineering tools, methods and technologies for research and development of bioengineered facilities and systems for medical and technical purposes.*
***PC 6** -ability to study biological and technical aspects of the functioning and interaction of artificial biological and biotechnical systems.*
***PC 11** -ability to develop, plan and apply mathematical methods in the analysis and modeling of the functioning of living organisms, systems and processes in biology and medicine.*
***PC 12** -ability to conduct research and observations on the interaction of biological, natural and artificial systems (prostheses, artificial organs, etc.), plan biotechnical tests of artificial prostheses and systems.*

***The program learning outcomes after studying the discipline "Artificial organs" are** (OPP was put into effect by the Rector's Order NON/ 89/2021 of 19.04.2021):*

***PLO 4** -application of methods for calculating and selecting classic and latest designs of biomaterials, elements of medical devices and systems.*
***PLO 7** -knowledge of methods of research, design and construction of biomedical equipment objects, analysis and processing of experimental data.*
***PLO 9** -knowledge of the principles of development and modern problems of creating biocompatible materials in medical practice.*
***PLO 11** -understanding the latest advances in biomedical engineering.*
***PLO 16** -knowledge of methods of design, construction, improvement and application of medical-technical and bioengineered products, devices, apparatuses and systems in compliance with technical requirements, as well as support their operation.*

PLO 18 *-creation and improvement of biomedical engineering tools, methods and technologies for comprehensive research and development of bioengineered facilities and systems for medical and technical purposes.*

PLO 20 *-assessment of biological and technical aspects and consequences of interaction of engineering and Bioengineering objects with biological systems, foreseeing their mutual impact, legal, deontological and moral and ethical consequences of use.*

2. Prerequisites and postrequisites of the discipline (place in the structural and logical scheme of education according to the relevant educational program)

The academic discipline "artificial organs" is interdisciplinary in nature. It integrates, according to its subject, knowledge from other academic disciplines: biology, anatomy and Clinical Physiology, digital and analog circuitry, design and construction of electronic medical equipment, and so on. According to the structural and logical scheme of the master's degree program, the discipline is closely related to the discipline "artificial organs". The acquired practical skills and acquired theoretical knowledge during the study of the academic discipline "artificial organs" can be used in the future during the development of the academic discipline "scientific work on the topic of the master's thesis", the implementation of pre-graduate practice and is the basis for the preparation of Master's theses in the specialty and further practical work in the specialty.

3. The content of the discipline

The main sections and topics that will be considered in the process of studying the course:

Section 1. Ccategories of technical means used in medicine.

Subsect 1.1. Modern needs and problems of creating artificial organs.

Subsect 1.2. Requirements for medical devices that come into contact with the internal environment of the body and are intended for implantation.

Subsect 1.3. Promising methods of energy supply of implantable medical devices.

Section 2. Pprosthetics of the respiratory system.

Subsect 2.1. Physiology of the respiratory system.

Subsect 2.2. Pathophysiology of artificial ventilation.

Subsect 3.3. Requirements for equipment that prosthetics lung function.

Section 3. Equipment for replacing lung function.

Subsect 3.1. Types of mechanical ventilation devices;

Subsect 3.2. Methods and modes of artificial ventilation of the lungs.

Subsect 3.3. Conditioning of respiratory mixtures and monitoring of patients.

Section 4. Modern gas exchange systems.

Subsect 4.1. Intelctual artificial ventilation modes.

Subsect 4.2. Extracorporeal membrane oxygenation.

Subsect 4.3. Intravascular oxygenation.

Section 5. Devices for prosthetics and support of heart function.

Subsect 5.1. Anatomical and physiological bases of blood circulation.

Subsect 5.2. Contribution of domestic scientists to the introduction of artificial blood circulation in the practice of cardiac surgery.

Subsect 5.3. Medical and technical requirements for artificial blood circulation devices.

Section 6. Hardware and technical support of artificial blood circulation.

Subsect 6.1. Main functional nodes of the heart-lung machines.

Subsect 6.2. Design and characteristics of modern oxygenators.
Subsect 6.3. Complications of artificial blood circulation.
Section 7. Artificial heart.
Subsect 7.1. Requirements for heart function replacement devices.
Subsect 7.2. Varieties of artificial heart by degree of autonomy.
Subsect 7.3. Problems of management and energy supply of an artificial heart.
Section 8. Additional devices for maintaining blood circulation and gas exchange.
Subsect 8.1. External and implantable VADs.
Subsect 8.2. IABC.
Subsect 9.3. Prosthetic heart valves.
Section 9. Devices for replacing and maintaining pacemaker activity of the heart.
Subsect 9.1. Types of heart rhythm disorders.
Subsect 9.2. Devices for eliminating bradyarrhythmias.
Subsect 9.3. Implantable and external antitahiarrhythmic devices.
Section 10. Artificial Kidney.
Subsect 10.1. Anatomy and physiology of the kidneys, their structural units.
Subsect 10.2. Indicators of kidney function in normal and pathological conditions.
Subsect 10.3. Hhistory of creation and evolution of excretory function prostheses.
Section 11. Acute and chronic hemodialysis.
Subsect 11.1. Physical and chemical bases of dialysis, its types, indications for use.
Subsect 11.2.Hemodialysis modes, modern technical support of processes. performance monitoring.
Subsect 11.3. Peritoneal dialysis, biotechnological implanted models of "artificial kidney".
Section 12. Aartificial liver, devices for replacing the function of the pancreas.
Subsect 12.1. Basic liver functions, detoxification processes.
Subsect 12.2. Sorption detoxification technologies.
Subsect 12.3. Devices for maintaining blood glucose levels.
Section 13. Technical means of prosthetics of sensory functions.
Subsect 13.1. Prosthetic visual function.
Subsect 13.2. External and implantable hearing analyzer prostheses.
Subsect 13.3. Aartificial skin, restoration of nerve connections.
Section 14. Prosthetics of musculoskeletal function.
Subsect 14.1. Pprostheses of joints and individual components of the skeleton.
Subsect 14.2. Mechanical prosthetic limbs.
Subsect 14.3. Bionic and biomechanical prosthetic limbs.

4. Training materials and resources

Basic literature:

1. *Медицинские приборы: Разработка и применение / Авт. колл.: Д.В. Кларк мл., М.Р. Ньюман, В.Х. Олсон и др.; Ред. Дж. Г. Вебстер. – К.: Медторг, 2004. – 620 с. (бібліотека ФБМІ).*

2. *Горячев А.С., Савин И.А. Основы ИВЛ.- М.: Медиздат, 2009. – 256 с.*

3. *Белебезьев Г.И., Козяр В.В. Физиология и патофизиология искусственной вентиляции легких. - Киев: Ника-центр, 2003. – 312 с. (бібліотека ФБМІ).*

4. *Царенко С.В. Практический курс ИВЛ. - М.: Медицина, 2007.- 102 с.*

5. *Локшин Л.С., Лурье Г.О., Дементьева И.И. Искусственное и вспомогательное кровообращение в сердечно – сосудистой хирургии. М.: НЦХ РАМН,1998, 212 с.*

6. *Хенч Л., Джонс Д. Биоматериалы, искусственные органы и инжениринг тканей. М., Техносфера, 2007. – 304 с.*

Additional literature:

7. *Miller G.E. Artificial Organs. Sinthesis Lectures of Biomedical Engineering, lect. 4. N.Y., Morgan and Claypool, 2006. -72 p.*

8. *Національний стандарт України: Вироби медичні. Класифікація залежно від потенційного ризику застосування. Загальні вимоги. ДСТУ 4388:2005. – К.: Держспоживстандарт України, 2005. – 16 с.(НТБ «КПІ», кафедра БМІ).*

9. *Національний стандарт України: Вироби медичні. Розроблення і ставлення на виробництво. ДСТУ 3627:2005. – К.: Держспоживстандарт України, 2005. – 32 с. (НТБ «КПІ», кафедра БМІ).*

10. *Introduction to biomedical engineering / Eds: J. D. Enderle, S.M. Blanchard, J.D. Bronzino. - Academic press, 2000. – 1062 с. (кафедра БМІ).*

Educational content

5. Methods of mastering the discipline (educational component)

№ s/n	Subject	Program learning outcomes	The main tasks	
			Control measure	Deadline
1.	Categories of technical means used in medicine.	PLO 4 PLO 7	Practical work 1	1-st week
2.	Prosthetics of the respiratory system.	PLO 7 PLO 9	Practical works 2, 3	2-nd week
3.	Equipment for replacing lung function.	PLO 9 PLO 11	Practical works 4, 5	3-rd week
4.	Modern gas exchange systems.	PLO 4 PLO 9	Practical works 6, 7	4-th week
5.	Devices for prosthetics and maintaining heart function.	PLO 4 PLO 11	Practical works 8, 9	5-th week
6.	Hardware and technical support of artificial blood circulation.	PLO 7 PLO 11	Practical work 10	6-th week
7.	Artificial heart.	PLO 4 PLO 16	Practical works 11, 12	7-th week
8.	Additional devices for maintaining blood circulation and gas exchange.	PLO 7 PLO 16	Practical work 13	8-th week
9.	Devices for replacing and maintaining pacemaker activity of the heart.	PLO 9 PLO 18	Practical works 14, 15	9-th week
10.	Artificial kidney.	PLO 11 PLO 20	Practical works 16, 17	10-th week
11.	Acute and chronic hemodialysis..	PLO 7 PLO 18	Practical work 18	11-th week
12.	Artificial liver, devices for replacing the function of the pancreas. Modular Control work.	PLO 7 PLO 20	Modular control work	12-th week
13.	Technical means of prosthetics of sensory functions.	PLO 11 PLO 18	Practical work 20	13-th week
14.	Prosthetics of musculoskeletal function.	PLO 7 PLO 11	Practical work 21	14-th week
15.	Test.	PLO 4 PLO 7 PLO 9	Test	15-th week

№ s/n	Subject	Program learning outcomes	The main tasks	
			Control measure	Deadline
		PLO 11		

6. Independent student work

One of the main types of semester control during the mastering of the discipline is the implementation of home control work. In this silabus execution of home control work is not provided.

Policy and control

7. Policy of academic discipline (educational component)

Attending classes

Attendance at lectures is optional. Attending practical classes is desirable, as they are used to write express tests / tests, as well as to defend practical work.

The grading system is focused on obtaining points for student activity, as well as performing tasks that are able to develop practical skills and abilities.

Control measures missed

Missed control measures (defense of practical work) must be practiced in the next classes, provided that the task is scheduled for the current lesson, or in consultations.

Omissions of writing a module test are not fulfilled.

Violation of deadlines and incentive points

Encouragement points		Penalty points*	
Criterion	Weight points	Criterion	Weight points
Improving practical work	1 points (for each practical work)	Untimely implementation and test of practical work	From -0.5 points to -3 points (depending on the delivery date)
Passing distance courses on topics that are agreed with teachers	5 points	Untimely implementation and test of modular control work	From -2 points to -10 points (depending on the delivery date)
Registration of scientific work for participation in the competition of student scientific works	10 points		
Writing abstracts, articles, participation in international, national and / or other events or competitions on the subject of the discipline	5 points		

** if the control measure was missed for a good reason (illness, which is confirmed by a certificate of the established sample) - penalty points are not accrued.*

Academic integrity

The policy and principles of academic integrity are defined in Section 3 of the Code of Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute". Read more: https://kpi.ua/code.

Norms of ethical behavior

Normative principles of behavior of students and employees, defined in sections 2 of the Code of

Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute". Read more: https://kpi.ua/code.

Procedure for appealing the results of control measures

Students have the opportunity to raise any issue related to the control procedure and expect it to be addressed according to predefined procedures.

The student has the right to appeal the results of the control measure according to the approved provision on appeals in the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute" (approved by the order №NON/128/2021 from 20.05.2021)

- https://osvita.kpi.ua/index.php/node/182

Inclusive education

The discipline "Artificial organs" can be taught to most students with special educational needs, except for students with severe visual impairments who do not allow to perform tasks using personal computers, laptops and / or other technical means.

Distance learning

Distance learning takes place through the Sikorsky Distance learning Platform «Sikorsky».

Distance learning through additional online courses on certain topics is allowed subject to agreement with students. If a small number of students wish to take an online course on a specific topic, studying the material with such courses is allowed, but students must complete all the tasks provided in the discipline.

The list of courses is offered by the teacher after the students have expressed a desire (because the bank of available courses is updated almost every month).

The student provides a document confirming the completion of the distance course (in the case of a full course) or provides practical tasks from the distance course and subject to an oral interview with the teacher on the topics can receive grades for control measures provided for the studied topics (express control / test tasks, practical work).

Performance of practical works, and also performance of settlement and graphic work, is carried out during independent work of students in a remote mode (with a possibility of consultation with the teacher through e-mail, social networks).

Learning in a foreign language

Teaching in English is carried out only for foreign students.

At the request of students, it is allowed to study the material with the help of English-language online courses on topics that correspond to the topics of specific classes.

8. Monitor and evaluate the system of evaluation of learning outcomes (Rating System of Evaluation)

Evaluation system (current control):

№ s/n	Control measure	%	Weight points	Number	Total
1.	Test tasks	20	4	5	20
2.	Execution and test of practical works	60	3	20	60
3.	Modular control work (MCW)	20	20	1	20
4.	Test work[1]	100	100	1	100
				Total	100

[1] *The applicant receives a positive credit score for the results of the semester, if he has a final rating for the semester of at least 60 points and has met the conditions of admission to the semester control, which are determined by the RSE (Rating System of Evaluation).*
With applicants who have met all the conditions of admission to the test and have a rating of less than 60 points, as well as with those applicants who want to increase their rating, in the last scheduled lesson in the semester, the teacher conducts semester control in the form of test or interviews.
After performing the test, if the score for the test is higher than the rating, the applicant receives a score based on the results of the test.
If the grade for the test is lower than the rating, a "hard" RSE is used - the previous rating of the applicant (except for points for the semester individual task) is canceled and he receives a grade based on the results of the test. This option forms a responsible attitude of the applicant to the decision to perform the test, forces him to critically assess the level of his training and carefully prepare for the test.

Calendar control (CC) *- is performed twice a semester as monitoring of the current state of compliance with syllabus requirements.*
The purpose of calendar control is to improve the quality of student learning and monitor the implementation of the schedule of the educational process by students.

Criterion			The first CC	The second CC
Deadline of calendar controls			8th week	14th week
Conditions for obtaining a positive result from the calendar control	Current rating		≥ 12 points	≥ 24 points
	Execution of practical work	PW №№ 1-10	+	+
		PW №№ 11-21	-	+
	Express test tasks	At least 2 on any lectures	+	-
		At least 2 on any lectures	-	+
	Modular control work	Estimated MCW	-	+

In case of detection of academic poor quality during training - the control measure is not credited.

Semester certification of students

Mandatory condition for admission to the test		Criterion
1	Current rating	RD ≥ 60
2	Practical works are tested	Більше 30 балів
3	Obtaining a positive assessment for the performed modular control work	Більше 6 балів
4	Performang of tests	Більше 4 балів

The results are announced to each student separately in the presence or remotely (by e-mail). Also recorded in the system "Electronic Campus".

Optional conditions for admission to closure:
1. Activity in practical classes.
2. Positive result of the first attestation and the second attestation.
3. Attending of lectures.

Table of translation of rating points to grades on a university scale:

Number points	*Assessment on the university scale*
100-95	*Perfectly*
94-85	*Very good*
84-75	*Good*
74-65	*Satisfactorily*
64-60	*Enough*
Менше 60	*Unsatisfactorily*
Admission conditions are not met	*Not allowed*

9. Additional information on the discipline (educational component)

The list of questions for preparation for modular control work, and also for preparation for credit is given in appendix 1.

Distance learning through additional online courses on certain topics is allowed subject to agreement with students. If a small number of students wish to take an online course on a specific topic, studying the material with such courses is allowed, but students must complete all the tasks provided in the discipline.

The list of courses is offered by the teacher after the students have expressed a desire (because the bank of available courses is updated almost every month).

The student provides a document confirming the completion of the distance course (in the case of a full course) or provides practical tasks from the distance course and subject to an oral interview with the teacher on the topics can receive grades for control measures provided for the studied topics (express control / test tasks, practical work).

Work program of the discipline (syllabus):

Compiled by cand.мed.sc., associate professor Department of Biomedical engineering Kozyar Vasyl Vasylovych.

Approved by the Department of Biomedical Engineering (protocol № ___ to _____)

Approved by the Methodical Commission of the Faculty of Biomedical Engineering (protocol № __ to _____)

Appendix 1 to the syllabus of the discipline

"Artificial organs"

The list of questions for preparation for modular control work,

and also for preparation for test

1. Categories of technical means used in medicine.

2. Design characteristics of modern oxygenators.

3. Complications of artificial blood circulation.

4. Ccharacteristics of medical devices in accordance with Directive 93/42/EEC. Quality and safety standards.

5. Requirements for materials of the extracorporeal Circuit of the artificial circulation device.

6. Operating modes of artificial kidney devices.

7. Rrespiration and its stages, stages of gas transfer.

8. Methods of protecting the myocardium during heart surgery.

9. Structure and function of the liver as a basis for its modeling and prosthetics.

10. Structure and function of the respiratory system.

11. Prevention of material and gas embolism during artificial blood circulation.

12. Manifestations of liver failure, detoxification methods.

13. Physiological significance of the upper respiratory tract.

14. Modes of artificial blood circulation, requirements for the composition of perfusate.

15. Artificial liver, clinical application.

16. Respiratory muscles. Mechanics of spontaneous breathing.

17. Artificial Heart, its varieties.

18. Endocrine and excretory function of the pancreas.

19. Structure of the respiratory tract in connection with their function.

20. Biological and technological problems of creating heart prostheses.

21. Devices for automatic regulation of blood glucose levels.

22. Static pulmonary volumes, physiological significance of FZE.

23. Prosthetic heart valves, current state of development.

24. Equipment for the implementation of sorption technologies.

25. Respiratory volumes, "Dead Space", alveolar ventilation.

26. Auxiliary blood circulation support devices (ECMO, VADs, counterpulsators).

27. Prosthetics of musculoskeletal function, prostheses of joints and limbs.

28. Criteria for adequacy of gas exchange function of the lungs.

29. Vascular prosthetics and neoangiogenesis.

30. Artificial methods of providing alveolar ventilation.

31. Devices for replacing and maintaining pacemaker activity of the heart.

32. Differences between modern methods of artificial ventilation and spontaneous breathing.

33. Methods of electrocardiostimulation.

34. Classification of artificial respiration devices, their varieties.

35. One-, two - and three-chamber electrocardiostimulation.

36. Methods and modes of artificial ventilation of the lungs.

37. Classification and encoding of pacemakers.

38. Classification of ventilator modes by the level of spontaneous breathing replacement.

39. Implantable Cardioverters-defibrillators, indications for use.

40. Negative consequences of mechanical ventilation. The effect of hardware ventilation on other organs and systems.

41. Requirements for electrodes for electrocardiostimulation.

43. Eextracorporeal and intravascular oxygenation.

44. Complications of electrocardiostimulation.

45. Auxiliary devices for ensuring adequate gas exchange, control equipment.

46. Structure and function of the excretory system people. Structural unit of the kidney.

47. Circulatory system and functional anatomy of the heart. Blood supply to the heart.

48. Functioning of the kidneys under normal conditions.

49. Factors that affect heart performance.

50. Rrenal failure, laboratory criteria for the transition to extracorporeal blood purification.

51. Preload, Frank-Starling law.

52. Methods of replacement therapy of renal failure. An artificial kidney.

53. History of development and current state of hardware and technical support of artificial blood circulation.

54. History of creation of excretory function prostheses.

55. The main functional nodes of artificial blood circulation devices.

56. Physical and chemical bases of functioning and types of artificial kidneys.

57. The main functional nodes of artificial blood circulation devices.

58. Physical and chemical bases of functioning and types of artificial kidneys.

59. Pumping part of the artificial blood circulation device, types of pumps used.

60. Hhardware support of chronic hemodialysis.

Task 1: Calculate the electrical capacity (in mAa-hours) of a 3 V power supply to ensure the functioning of the pacemaker for 10 years. The frequency of stimulation is f imp./min., pulse duration t Ms, amplitude U V at load resistance R Ohms, the efficiency of the stimulator is 35%.

Task 2: Calculate the composition of the primary filling volume of the artificial circulatory apparatus for hypothermic perfusion at temperature t ° of a patient weighing m kg with an initial HCT (hematocrit).

Task3: calculate the minute alveolar ventilation of the lungs of a patient weighing m (kg) at a respiratory rate of f/min.

Task 4.Calculate the flow change when the vessel diameter changes and the pressure remains unchanged.