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

Department
biomedical engineering

BIOMATERIALS AND BIOCOMPATIBILITY

Working program of basic discipline (Syllabus)

Requisites for basic discipline	
Level of higher education	***First (bachelor's)***
Branch of knowledge	*16 Chemical and Bioengineering*
Specialty	*163 Biomedical Engineering*
Educational program	*Medical Engineering*
Discipline status	*Mandatory discipline*
Form of study	*full-time*
Year of preparation, semester	*2nd year, spring semester*
The scope of discipline	*5 ECTS credits*
Semester control / Control measures	*Test, Modular Control Work*
Lessons schedule	*According to the schedule on the site http://rozklad.kpi.ua/*
Language of instruction	*English*
Information about course leader / teachers	***Lecturer**: Yurii Yavorskyi* ***Practical**: Yurii Yavorskyi*
Course placement	*https://campus.kpi.ua*

Curriculum of the discipline

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

The Purpose of the Discipline.

„Biomaterials and Biocompatibility" is one of the important special subjects of the curriculum of the specialty 163 "Biomedical Engineering". The importance of this course is due to the need to train specialists with basic knowledge and competencies in the field of biomedical engineering, to formulate and substantiate medical and technical requirements for medical products, to analyze the dependence of the properties of medical material on various parameters, to make the choice of material in accordance with the technique in order appointment.

Given that the discipline is mandatory, it is necessary to be proficient in:

- ***skills:** basic knowledge of mathematics, physics, chemistry, biochemistry and material science;*
- ***competencies:** apply statistical methods of analysis of communication and dynamics of phenomena; collect, process and analyze source data; analyze and interpret data; solve mathematical, physical and materials science problems.*

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

- ***GC 1 -** Ability to apply knowledge in practical situations.*
- ***GC 2 -** Knowledge and understanding of the subject area and understanding of professional activity.*
- ***GC 3** - Ability to communicate in the state language both orally and in writing.*
- ***GC 4** - Skills in the use of information and communication technologies.*
- ***GC 5** - Ability to perform research at the appropriate level.*

- ***GC 6 -*** *Ability to search, process and analyze information from various sources.*
- ***GC 7 -*** *Ability to generate new ideas (creativity).*
- ***GC 8 -*** *Ability to make well-grounded decisions.*
- ***GC 9*** *- Ability to communicate with representatives of other professional groups of different levels (with experts from other fields of knowledge / types of economic activity).*
- ***GC 10*** *- Safe activities skills.*

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

- ***PC 5*** *- Ability to apply physical, chemical, biological and mathematical methods in the analysis, modeling of the functioning of living organisms and biotechnical systems.*
- ***PC 6*** *- Ability to effectively use tools and methods for analysis, design, calculation and testing in the development of biomedical products and services.*
- ***PC 8*** *- Ability to perfect research and observations on the interaction of biological, natural and artificial systems (prostheses, artificial organs, etc.).*
- ***PC 9*** *- Ability to identify, formulate and solve engineering problems related to the interaction between living and non-living systems.*
- ***PC 13*** *- Ability to provide and monitor compliance with safety and biomedical ethics when working with medical equipment .*

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

- ***PLO 1 -*** *Understanding of fundamental-applied, medical-physical and bioengineering bases of technologies and equipment for research of processes of a human body.*
- ***PLO 7 -*** *Understanding of scientific and technical principles that underlie the latest advances in biomedical engineering.*
- ***PLO 10 -*** *Knowledge of the basic physical and physicochemical patterns of biological objects functioning.*
- ***PLO 14 -*** *Possession of tools for experimental research (medical devices, biomaterials for medical purposes).*
- ***PLO 29 -*** *Professional communication with healthcare professionals in the state and foreign languages (English or one of the other official EU languages) and understanding of their requirements for biomedical products and services.*
- ***PLO 32 -*** *Understanding of theoretical and practical approaches to creation and application of artificial biological and biotechnical objects and materials of medical appointment.*
- ***PLO 37 -*** *Ability to analyze the level of compliance with modern world standards, as well as evaluate solutions and set tasks for the development of automated control systems, taking into account the capabilities of modern hardware and software for automation of medical equipment.*
- ***PLO 39 -*** *Recommendation and technical support of appropriate medical equipment and biomaterials for equipping medical institutions and support the main stages of the technological process of diagnosis, prevention and treatment.*

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

The discipline "Biomaterials and biocompatibility" is an interdisciplinary study that integrates according to its subject knowledge from other disciplines: physics, biochemistry, mathematics, material science etc. Following the structural and logical scheme of the training program, the discipline "Biomaterials and biocompatibility" is closely related to other disciplines of general and professional

training: "Material science and structural materials", "Radiation safety and dosimetry", "Devices for control of person's physiological parameters", etc. It is preceded by the discipline "Biochemistry".

The acquired practical skills and acquired theoretical knowledge during the study of the discipline "Biomaterials and biocompatibility" can be used in the disciplines:

- from the cycle of professional training (educational-professional program "Medical Engineering"): "Radiation safety and dosimetry", "Devices for control of person's physiological parameters;

- in elective disciplines (educational-professional program "Medical Engineering"): some disciplines;

- undergraduate practice and diploma design.

3. The content of the discipline

The main sections and topics considered in the course:

Section 1. Fundamental basics and applied aspects of biomaterials.

Subject 1.1. *Basic information about medical supplies.*

Subject 1.2. *Use of biomaterials in medicine.*

Section 2. Heat treatment of metals and alloys.

Subject 2.1. *Metals. Medical materials for biotissue reconstruction. Characteristics of materials.*

Subject 2.2. *Medical polymers for separation and diffusion of substances. Biomedical membranes.*

Subject 2.3. *Ceramics. Materials of biological origin. Suture materials.*

Subject 2.4. *Polymers of directional biological action.*

Subject 2.5. *Materials for cellular engineering.*

4. Training materials and resources

Basic literature:

1. *Biomedical Materials. Roger Narayan editor. – USA: Springer, 2009 – 569 c. ISBN 978-0-387-84871-6*
2. *Materials Science and Engineering. G. F. Carter, Giles F. Carter and Donald E. Paul, editors. – USA: ASM International, 1991 – 369.*
3. *Engineering of Biomaterials. Venina dos Santos, Rosmary Nichele Brandalise, Michele Savaris. - Springer International Publishing AG 2017 - 92. ISSN 2364-3307.*
4. *Biomaterials Science. B.D. Ratner et al., Elsevier, ISBN 0-12-582463-7*
5. *Biomaterials science : an introduction to materials in medicine / edited by Buddy D. Ratner ... [et al.].– 2nd ed. p. ; cm. Includes bibliographical references and index. ISBN 0-12-582463-7*

Additional literature:

1. *Titanium in Medicine, D.M. Brunette et al., ed Springer ISBN 3-540-66936-1, 2001.*
2. *"Bio-implant interface", J.E. Ellingsen, S.P. Lyngstadaas, ed.CRC press, ISBN 0-8493-1474-7, 2003.*
3. *Металознавство: Підручник. Бялік О.М. та ін. - К ІВЦ «Політехніка». 2001.-375 с. - ISBN 966-622-053-9.*
4. *Конспект лекцій Уклад 1 М. Курська, Г.О. Чернобай, С.Б. Єрьоменко. - Х.: УЦЗУ. 2008. - 136 с.*
5. *Технологія конструкційних матеріів і матеріалознавство. . Афтанділянц Є.Г., Зазимко О.В., Лопатько К.Г. – К.: Видавничий центр НАУ, 2007. –356 с*

Educational content

5. Methods of mastering the discipline (educational component)

Contents of lectures

Lecture 1. *History of the development of biomaterials. Definition of the concept of biomaterials. Subject and tasks of biomaterials. Basic directions of use of biomaterials in medicine.*

Lecture 2. *Classification of materials by their biological effect on a living organism., General*

medical and technical requirements for materials that come into contact with the biological environment. The concept of biocompatibility, bioinertia, bioactivity. Biocompatibility of medical materials.

Lecture 3. *Materials for medical equipment and instruments. The main characteristic of metals and their alloys. Physico-mechanical properties of metals and their alloys.*

Lecture 4. *Stainless steel and its purpose in medicine. Precious metals. Characteristics of alloys and their use in dental orthopedics. Corrosion of metals under the influence of biological environment.*

Lecture 5. *Bioceramics and its role in implantation. Bioinertiality and biocompatibility of ceramic materials with the human body and reducing their effect on the immune system. Classification of bioactive ceramic materials. Types of ceramics, the most common in medicine and their scope. Bioceramic materials for restoring the lost functions of individual organs.*

Lecture 6. *Materials for implantation in orthopedics and dentistry. Biological properties of implant materials. General properties of biological and synthetic implant materials.*

Lecture 7. *Classification and physico-mechanical properties of polymers. Characterization of basic synthetic polymeric materials and their use in medicine. Polymeric materials for cardiovascular surgery. General medical and technical requirements for materials that come into contact with the biological environment.*

Lecture 8. *Artificial membranes. Medical membranes. Membranes for blood dialysis. Membrane blood oxygenators. Basic requirements for dialysis membranes. Characteristics of cellulose dialysis membranes.*

Lecture 9. *The current state of the problem of creating perfect surgical suture material. Types of surgical suture threads and requirements for their use in medicine.*

Lecture 10. *Biomaterials used for the manufacture of heart valve prostheses. Development and use of biological heart valves.*

Lecture 11. *Polymeric systems for drug delivery. Polymers used for drug delivery are their features and properties.*

Lecture 12. *Tissue engineering as a basis for organ regeneration through directional and controlled stimulation of the required cells. Biomaterials for cellular matrixes.*

Lecture 13. *Basic requirements for collagen-based bioplastic materials. The use of bioplastic materials for the reconstruction of soft and bone defects.*

Lecture 14. *Biological reactions of the body to the implanted material. Creation of semi-synthetic tissues and organs in the laboratory.*

Contents of practical's

Practical 1. *Basic methods of research of biocompatible properties of biomaterials.*

Practical 2. *Microstructural analysis of metals and alloys.*

Practical 3. *Stereoscopic analysis.*

Practical 4. *Stereoscopic analysis of suture materials.*

Practical 5. *Electron-structural analysis.*

Practical 6. *Electron-structural analysis of microstructure of titanium alloys for medical purposes.*

Practical 7. *Analysis of transformations occurring in alloys during cooling and heating, determination of phase and structural state of alloys depending on their composition and temperature.*

Practical 8. *Determination of change of structural parameters of nanoscale materials using X-ray diffraction analysis.*

Practical 9. *CES Edupack software and Graphic representation of material properties.*

Practical 10. *Choice of material for engineering in the CES Edupack software.*

Practical 11. *Biological reactions of the body to implantable materials.*

Practical 12. *Biocompatibility of metals and their alloys.*

Practical 13. *Biodegradation and corrosion of biomaterials.*

Practical 14. *Interaction of bioceramics with bone tissue.*

Practical 15. *Assessment of biological safety of medical devices.*

Practical 16. *Biological properties of biocompatible biomaterials. Requirements for biomaterials for action on a living organism.*

Practical 17. *Polymeric materials of medical and technical importance.*

Practical 18. *Biomaterials for cardiac surgery. Materials for artificial heart valves.*

Practical 19. *Biodegradation of biomaterials used for implants.*

Practical 20. *Research of biocompatibility of components of medical devices (materials).*

Practical 21. *Adhesion and adhesion properties of materials.*

Practical 22. *Biological reaction of the organism to the medical material implanted in it.*

Practical 23. *Adsorption of proteins and biomolecules to the surface of the biomaterial.*

Practical 24. *Module control work.*

6. Independent student work

Independent work of students (total duration of 60 hours) on the discipline is:

- self-study of literary sources to expand the understanding of lecture topics - at the rate of 1 hours per lecture = 14 hours;

- preparation for practical work and formulation of conclusions - at the rate of 1 hour for 1 practical work = 23 hours;

- preparation of essay *- 8 hours;*

- preparation for module control work (MCW) - 5 hours;

- preparation for the final test - 10 hours.

Policy and control

7. Policy of academic discipline (educational component)

Attending classes

The system of requirements for students:

• Elaboration of material on all topics of lectures and practical classes is mandatory.

• Attendance at all classes is optional.

- The student must work off the missed lecture by writing a lecture synopsis of the missed topic.

- The student must complete the task of the missed practical lesson within the time agreed with the professor.

• It is forbidden to use mobile phones in audio mode during all classes. It is allowed to use a mobile phone only to perform the tasks set by the teacher in practical or lecture classes or to obtain additional information on the topic of the lesson.

• It is forbidden to use any gadgets when writing tests, tests and tests.

•The results of practical work are presented in the form of reports. The report consists of a theoretical part, a practical part and conclusions. The theoretical part of the report can be printed, the practical part and conclusions should be drawn up by hand. Direct defense takes the form of interviews, questions or answers.

• Incentive points can be awarded for special learning achievements - the application of a creative approach to practical work, including the use of data for work on their own research.

• Deadline policy stipulates the need for timely completion of tasks. The syllabus for the missed lecture must be provided to the teacher no later than 2 weeks from the time of the missed lecture. Reports on practical work are performed and submitted for inspection no later than 2 weeks after completion. All written documents must be defended before the end of the theoretical training in the semester.

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 "Biophysics" 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 is conducted by communication between teacher and students in a telegram group. Lectures are conducted with the help of Google Meet or ZOOM resources.

Practical classes with the help of Google Meet or YouTube resources. To perform a practical task, the student must draw up a protocol and send a scanned copy to the teacher. To get the final grade for a practical task, the student needs to take a test through the Google form or take an online interview with the teacher.

Modular control work is carried out in the form of an online interview between teacher and student.

Learning the discipline 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):

Table. 2. *Calculation of the final score*

№ s/n	*Control measure*	*Weight points*	*Number*	*Total*
1.	*Active participation in lectures*	*7*	*1*	*7*
2.	*Work on practical classes*	*3*	*23*	*69*
3.	*Essay*	*12*	*1*	*12*
4.	*Modular control work (MCW)*	*12*	*1*	*12*
	Total			*100*

- keeping notes and active participation in lectures (incentive points) - 5 points.

- work on practical classes (PC) 69 points - a maximum of 3 points for each work. Criteria for evaluating the results of work in practical classes (SO) table 2.

- essay is carried out once within a semester. The maximum score for essay is 12 points. Criteria for evaluating the results written by the essay are presented in tables 2.

- modular control work is conducted once a semester on the topics of lectures and practical classes. The maximum score for the MCW is 20 points. Criteria for evaluating the results written by the MCW are presented in tables 2.

***Table. 2.** Evaluation criteria and the number of points for work in PC, essay and MPW*

Criteria	***PC***	***Essay***	***MPW***
full answer (excellent)	*3*	*10-12*	*10-12*
incomplete answer (good)	*2*	*7-9*	*7-9*
incomplete answer (satisfactory)	*1*	*5-6*	*5-6*
unsatisfactory answer	*Less than 1*	*Less than 1*	*Less than 1*

***Calendar control (CC)** - is carried out twice a semester as monitoring of the current state of compliance with the requirements of the syllabus. To get a positive result in the first calendar control, you must have at least 20 points, the second - at least 50 points.*

Semester certification of students

The semester certification of students is test. Conditions of admission to semester control: semester rating not less than 60 points. If the student is satisfied with the number of points he received for the semester, he can get a test "automatically", but if the student wants to increase his rating, you need to have all the credited practical and calculation and graphic work and write a test. The rating for the semester is canceled, the test is 100 points, the total rating is evaluated on a university scale, the table of knowledge assessment of which is presented in table 3.

Optional conditions for admission to closure:

1. *Activity during practical classes.*
2. *Positive result of the first attestation and the second attestation.*
3. *Attending lectures.*

***Table 3.** Table of translation of rating points to grades on a university scale.*

Total rating points	***Grades according to the university scale***
100-95	*Excellent*
94-85	*Very good*
84-75	*Good*
74-65	*Satisfactory*
64-60	*Passed*
Below 60	*Unsatisfactory*
Violation of passing requirements	*Not passed*

9. Additional information on the discipline (educational component)

For a more in-depth study of the discipline, I recommend dealing with the following issues:

1. *The current state of the problem of creating perfect surgical suture material. Types of surgical suture threads and requirements for their use in medicine.*
2. *Polymeric systems for drug delivery. Polymers used for drug delivery are their features and properties.*
3. *Tissue engineering as a basis for organ regeneration through directional and controlled stimulation of the required cells. Biomaterials for cellular matrixes.*
4. *Basic requirements for collagen-based bioplastic materials. The use of bioplastic materials for the reconstruction of soft and bone defects.*
5. *Biological reactions of the body to the implanted material. Creation of semi-synthetic tissues and organs in the laboratory.*
6. *Artificial membranes. Medical membranes. Membranes for blood dialysis. Membrane blood oxygenators.*
7. *The biological response of the body to implanted material for medical purposes.*
8. *Composite materials. Types of Composite Materials. Use of Composite Biomaterials for Tissue Engineering. Creation of artificial composites.*
9. *Properties of polymeric materials used for artificial lungs. Gas permeability of membranes.*
10. *Obtaining antithrombogenic polymeric materials. Classification of antithrombogenic materials. Interaction of polymers with blood components.*
11. *Pharmacological polymers. Pharmacological auxiliary polymers .. Polymer coatings, methods for their preparation. Disintegration of polymeric material in the middle of a living organism. System of prolonged administration of drugs. Microencapsulation.*
12. *Standard films. The main mechanisms of controlled release of drugs. Microencapsular dosage form. Development of new drug delivery systems.*
13. *Osteintegration, calcification of biomaterials.*

Work program of the discipline (syllabus):

Compiled by

Approved by *the Department of Biomedical Engineering (protocol № ___ from 25 June 2021)*

Approved by *the Methodical Commission of the Faculty of Biomedical Engineering (protocol № __ from 27 August 2021)*