



Subject card

Subject name and code	Advanced Methods of Medical Device Design, PG_00072211						
Field of study	Mechanical and Medical Engineering						
Date of commencement of studies	October 2024	Academic year of realisation of subject			2026/2027		
Education level	first-cycle studies	Subject group					
Mode of study	Full-time studies	Mode of delivery			at the university		
Year of study	3	Language of instruction			Polish		
Semester of study	5	ECTS credits			2.0		
Learning profile	general academic profile	Assessment form			assessment		
Conducting unit	Division of Machine Design and Medical Engineering -> Institute of Mechanics and Machine Design -> Faculty of Mechanical Engineering and Ship Technology -> Faculties of Gdańsk University of Technology						
Name and surname of lecturer (lecturers)	Subject supervisor		dr inż. Sebastian Grelik-Urbanowski				
	Teachers		dr inż. Sebastian Grelik-Urbanowski				
Lesson types	Lesson type	Lecture	Tutorial	Laboratory	Project	Seminar	SUM
	Number of study hours	15.0	0.0	15.0	0.0	0.0	30
	E-learning hours included: 0.0						
Learning activity and number of study hours	Learning activity	Participation in didactic classes included in study plan		Participation in consultation hours		Self-study	SUM
	Number of study hours	30		1.0		19.0	50
Subject objectives	Development of advanced design skills, including: - understanding the complete medical device design process - gathering design inputs (e.g., load measurement, obtaining initial geometry from point clouds) - designing geometry using CAD software - verifying the design through numerical strength and stiffness analyses - conducting device risk analysis - preparing medical device documentation						

Learning outcomes	Course outcome	Subject outcome	Method of verification
	[K6_U06] can identify and formulate specifications for simple practical engineering tasks, and critically analyze existing technical solutions, evaluating their functionality, particularly in the context of designing mechanical and medical-mechanical devices	The student identifies phenomena occurring in machine components. They create the computational models necessary for machine design. They analyze and select appropriate computational models for detachable and permanent joints. They identify load and stress states at critical points of the analyzed machine components and assess their safety.	[SU1] Assessment of task fulfilment
	[K6_U03] is able to use information and communication skills or research techniques to solve typical engineering tasks related to design, production and manufacturing of materials or machine components	266 The student is able to design a medical device, covering the entire process from obtaining input data and formulating requirements to designing and verifying the device, as well as properly documenting it (technical and process documentation).	[SU4] Assessment of ability to use methods and tools [SU5] Assessment of ability to present the results of task [SU2] Assessment of ability to analyse information [SU3] Assessment of ability to use knowledge gained from the subject
	[K6_U04] is able to utilize empirical, analytical, simulation, and computer-based methods to formulate and solve engineering tasks in the field of medical and mechanical engineering	341 The student identifies phenomena occurring in machine components. They create the computational models necessary for machine design. They analyze and select appropriate computational models for detachable and permanent joints. They identify load and stress states at critical points of the analyzed machine components and assess their safety.	[SU4] Assessment of ability to use methods and tools
	[K6_W05] has knowledge in the areas of design, manufacturing, and operation of materials, machine parts, or technical devices, with a solid understanding of design principles and technical documentation preparation	The student identifies phenomena occurring in machine components. They create the computational models necessary for machine design. They analyze and select appropriate computational models for detachable and permanent joints. They identify load and stress states at critical points of the analyzed machine components and assess their safety. The student produces technical documentation using computer-aided design tools.	[SW3] Assessment of knowledge contained in written work and projects [SW1] Assessment of factual knowledge
Subject contents	Course content – lecture Developing skills in medical device creation, covering the entire design process: - understanding certification processes - defining the device - gathering input data - designing geometry - documenting the device - conducting risk analysis		
	Course content – laboratory Practical aspects of the topics covered in the lecture: - classification of sample devices in accordance with the MDR and FDA 510(k) requirements - device definition - data acquisition via pressure measurements on mats - generation of 3D geometry based on a point cloud - creation of technical documentation for the device - creation of design process documentation (Design History File – DHF) - conducting a medical device risk analysis		

Prerequisites and co-requisites	155 Biomechanics, engineering graphics, mechanics, strength of materials, fundamentals of machine design, and basic CAD software skills.		
Assessment methods and criteria	Subject passing criteria	Passing threshold	Percentage of the final grade
	Laboratory – reports and pre-lab quizzes	70.0%	30.0%
	Lecture – written assessment	70.0%	70.0%
Recommended reading	Basic literature	Help systems of the software used. ISO 14791	
	Supplementary literature	MDR Regulation FDA 510(k) requirements	
	eResources addresses		
Example issues/ example questions/ tasks being completed			
Practical activities within the subject	Not applicable		

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