

GUJARAT TECHNOLOGICAL UNIVERSITY (GTU)**Competency-focused Outcome-based Green Curriculum-2021 (COGC-2021)**

Semester-VI

Course Title: Biomaterials & Implants**(Course Code: 4360302)**

Diploma programmer in which this course is offered	Semester in which offered
Biomedical Engineering	sixth

1. RATIONALE

Biomaterials in the form of implants like sutures, bone plates, joint replacements and medical devices i.e. pacemakers, artificial cardiac valves, blood tubes are widely used to replace and restore the function of traumatized or degenerated tissues or organs, and thus improve the quality of life of the patients. The biocompatibility profiles of materials employed for the replacement or augmentation of biologic tissues has always been a critical concern within the health care disciplines. This course curriculum is important for a diploma biomedical engineer to develop an understanding of the concepts underlying the design and selection of materials for use in prostheses and implants and develop relevant skills to work effectively in health care industries.

2. COMPETENCY

The course content should be taught and curriculum should be implemented with the aim to develop required skills in the students so that they are able to acquire following competency:

- **Select appropriate bio-materials and implants as per requirement.**

3. COURSE OUTCOMES (COs)

The theory should be taught and practical should be carried out in such a manner that students are able to acquire required learning outcomes in cognitive, psychomotor and affective domain to demonstrate following course outcomes:

- Explain the concept and need of bio-materials, implants and bio compatibilities.
- Recognize the types of various metals, alloys and ceramics used for implantation according to their formation and applications
- Describe the use of various polymers used for designing implants.
- Identify different biomaterial uses for vascular and optical implants.
- Select appropriate biomaterial for Dental and Orthopedic Implant and also Select effective method to discard implants.

4. TEACHING AND EXAMINATION SCHEME

Teaching Scheme (In Hours)			Total Credits (L+T+P/2)	Examination Scheme			
				Theory Marks		Practical Marks	
L	T	P	C	CA	ESE	CA	ESE

3	0	2	5	70	30	25	25	150
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(*): Out of 30 marks under the theory CA, 10 marks are for assessment of the micro-project to facilitate integration of COs and the remaining 20 marks is the average of 2 tests to be taken during the semester for the assessing the attainment of the cognitive domain UOs required for the attainment of the COs.

Legends: L-Lecture; T – Tutorial/Teacher Guided Theory Practice; P -Practical; C – Credit, CA - Continuous Assessment; ESE -End Semester Examination.

5. SUGGESTED PRACTICAL EXERCISES:

The following practical outcomes (PrOs) that are the subcomponents of the Co. *Some of the PrOs marked '*' are compulsory, as they are crucial for that particular CO at the 'Precision Level' of Dave's Taxonomy related to 'Psychomotor Domain'.*

S. No.	Practical Outcomes (PrOs)	Unit No.	Approx. Hrs. Required
1	Identify various implants used in the biomedical field.	I	02*
2	To Study about characteristics of tissue response to implants.	I	02*
3	To Study about characteristics of biocompatibility.	I	02
4	Identify various metals and alloys used in the biomedical field.	II	02
5	Identify various stainless used in the biomedical field.	II	02*
6	Identify various ceramics used in the biomedical field.	II	02
7	Identify various polymers used in the biomedical field.	III	02*
8	To Study about Sterilization process for various polymers used in the biomedical field.	III	02*
9	To Study about cardiac valve implant shape with its material specifications.	IV	02
10	To Study about cardiac pacemaker implantations process with safety aspect	IV	02
11	To Study about models of intraocular lens implantations process with safety aspect.	IV	02*
12	To Study about models of cochlear implantations process with safety aspect	IV	02*
13	To Study about models of knee joints and implant shape with its material specifications.	V	02
14	To Study about models of hip replacements implant shape with its material specifications.	V	02*

15	To Study about models of different dental implantations and implant shape with its material specifications	V	02
16	To Study about materials for implants can have significant environmental implications.	V	02*
Minimum 14 Practical Exercises			32Hrs.

Note

- i. More Practical Exercises can be designed and offered by the respective course teacher to develop the industry-relevant skills/outcomes to match the COs. The above table is only a suggestive list.
- ii. The following are some sample 'Process' and 'Product' related skills (more may be added/deleted depending on the course) that occur in the above listed Practical Exercises of this course required which are embedded in the COs and ultimately the competency.

6. MAJOR EQUIPMENT/ INSTRUMENTS REQUIRED

Sr.No.	Equipment Name with Broad Specifications	PrO. No.
1	Pacemaker Simulator is capable of producing diseased as well as corrected possible waveforms after the Pacemaker action, depends on connectivity of Pacemaker Lead Electrode to the heart electrical conduction system (SA - node, AV - node). Provides amplified Normal Sinus Rhythm output with P, Q, R, S, T waves - Provides information about abnormal (Diseased) waves which indicates particular abnormality in heart - Provides information about corrected wave which indicates possible wave shapes after Pacemaker action - Provides information about pacemaker modes (Single/Dual) of operation - Provides information about single as well as dual chamber pacing/sensing of heart - Every Systolic action of heart is indicated by LED (visible) and audible (Buzzer) sound controls.	10
2	Dental implants Dental Implant and Crown Bridge Demonstration Model Expose the roots and implant fixture. All three tooth crowns are removable.	15
3	Artificial knee joint Life Size Knee Model, 2nd Stage Osteoarthritic Knee Model and Knee Model with Implant. Anatomically accurate, made of high quality unbreakable PVC Plastic	13
4	Hip joints Ball and socket joint Demonstrates anteversion, retroversion,	14

	abduction & internal/external rotation. Includes flexible, artificial ligaments. Ball and socket joint Demonstrates anteversion, retroversion, abduction & internal/external rotation.	
5	Intra Ocular Lens Implant - Should be UV Absorbance - Lens Material-Hydrophilic Acrylic - Power, D(Diopter)-20 - Design Type-Foldable - Item Type-Single Piece - Haptic Design-Modified C-Loop - Optic Type-Bi-Convex Optic Diameter-6 millimeter	11

7. AFFECTIVE DOMAIN OUTCOMES

The following **sample** Affective Domain Outcomes (ADOs) are embedded in many of the above mentioned COs and PrOs More could be added to fulfill the development of this course competency.

- Work as a leader/a team member.
- Follow ethical practices.
- Practice environmentally friendly methods and processes.

The ADOs are best developed through the laboratory/field based exercises. Moreover, the level of achievement of the ADOs according to Krathwohl's 'Affective Domain Taxonomy' should gradually increase as planned below:

- 'Valuing Level' in 1st year
- 'Organization Level' in 2nd year.
- 'Characterization Level' in 3rd year.

8. UNDERPINNING THEORY: The major underpinning theory is given below based on the higher level UOs of *Revised Bloom's taxonomy* that are formulated for development of the COs and competency. If required, more such UOs could be included by the course teacher to focus on attainment of COs and competency.

Unit	Unit Outcomes (UOs) (4 to 6 UOs at different levels)	Topics and Sub-topics
Unit-I Introduction of Biomaterials and Implants	1a. Define Biomaterial, Implant 1b. Classify different Biomaterial 1c. Enlist the need of biomaterial 1d. Explain in detail the need of biomaterial for the society	1.1. Introduction To Biomaterial 1.2. Need Of Biomaterial 1.3. Classification Of Biomaterial

	1e. Describe tissue response to implants. Or foreign body response towards any bio material or implant. 1f. Explain bio compatibility 1g. Give Classification for different implant 1h. Explain acute and chronic inflammation. 1i. Enlist the infections that happen due to implants. 1j. Explain the concept of biocompatibility of implants with the human body	1.4 Introduction to Implant 1.4.a Classification of Implant 1.5. Tissue Response To Implants 1.5.a. Biocompatibility 1.5.b. Inflammation and Infection
Unit – II Metals and Ceramics	2a. Explain the types of stainless steel along with the formation. 2b. Enlist properties of stainless steel 2c. Describe the types of co-ch along with the formation 2d. Describe the types of Ti based alloys and describe formation 2e. Describe the types of nitinol and describe formation. 2f. Describe the types of carbons and their formation along with applications. 2g. Describe the types of Al and their formation 2h. Describe the types of surface reactive ceramics and their formation 2i. Mention the application of Stainless steel, Cobalt-chromium, Titanium based alloys, Nitinol, Carbons and Alumina for biomedical field. 2j. Mention the application of Ceramics for biomedical field	2.1 Stainless steel 2.2 Cobalt-chromium alloys: Cast alloys, Wrought alloys, Forged alloys 2.3 Titanium based alloys: Cast alloys, Wrought alloys, Forged alloys 2.4 Nitinol and other metals 2.5 Carbons 2.6 Alumina 2.7 Ceramics-Surface reactive ceramics: Bioglass, Ceravital

	2k. Distinguish between metal and ceramics	
Unit– III Polymers	3a. Enlist the types of polymer chain. 3b. Enlist the types of Polymers in biomedical use 3c. Explain the polymerization process and their classification. 3d. Describe the Polyamides and Poly Methyl Methacrylate (PMMA) used in the biomedical field. 3e. Explain sterilization process of polymer. 3f. List out the application of PMMA and acrylic polymer. 3g. Distinguish between metal, ceramics and polymer.	3.1 Polymerization: Types of polymer chain, Polymers in biomedical use 3.2 Polyethylene and polypropylene 3.3 Per fluorinated polymers 3.4 Acrylic polymers 3.5 Polyamides and Poly Methyl Methacrylate (PMMA) 3.6 Sterilization of polymer
Unit– IV Vascular implants and Optical implants	4a. Comprehending the vascular implant. 4b. Outline the material used in Implantable pacemaker, stent 4c. Describe the material used in endocardial electrodes of cardiac pacemakers. 4d. Interpret Cardiac assisting device. 4e. Infer Contact lenses. 4f. Distinguish the soft and hard lenses 4g. Describe the material use for disposable lenses 4h. Explain intra ocular lens. 4i. Define Auditory Implants, Vascular grafts 4j. Describe in brief Cochlear Implant.	4.1 Vascular grafts, Heart valves, Cardiac assisting devices, Stent, Implantable pacemaker 4.2 Optical implants 4.2.1 Contact lenses-Soft and hard lenses 4.2.2 Disposable lenses 4.2.3 Intraocular lenses (IOLS), 4.3 Auditory implant - cochlear implant

Unit- V Dental implants ,Orthopedic implant and implant waste management	5a. Define Dental Implant and Orthopedic implant.	5.1 Dental implants: Impression materials, Fillings and restoration materials
	5b. Describe impression materials, fillings and restoration materials.	5.2 Orthopedic implant:
	5c Give a classification of Orthopedic Implant.	5.2.1 Temporary fixation devices
	5d. Describe total hip replacement in detail.	5.2.2 Joint replacements:
	5e. Describe Total knee replacement in detail.	5.2.2.1 Total Hip replacement
	5f. Explain the choice of materials for implants can have significant environmental implications.	5.2.2.2 Total knee replacements
	5g. Explain the manufacturing processes involved in producing implants can contribute to environmental effects.	5.3 The choice of materials for implants can have significant environmental implications.
		5.4 The manufacturing processes involved in producing implants can contribute to environmental effects.

9. SUGGESTED SPECIFICATION TABLE FOR QUESTIONPAPER DESIGN:

Unit No.	Unit Title	Teaching Hours	Distribution of Theory Marks			
			R Level	U Level	A	Total Marks
I	Introduction of Bio Materials and Implants	8	5	7	2	14
II	Metals and Ceramics	12	7	7	4	18
III	Polymers	6	3	7	0	10
IV	Vascular implants and Optical implants	8	4	3	7	14
V	Dental implants, Orthopedic implant and implant waste management	8	2	7	5	14
Total		42	21	31	18	70

Legends: R=Remember, U=Understand, A=Apply and above (Revised Bloom's taxonomy)

Note: This specification table provides general guidelines to assist student for their learning and to teachers to teach and question paper designers/setters to formulate test items/questions to assess the attainment of the UOs. The actual distribution of marks at different taxonomy levels (of R, U and A) in the question paper may slightly vary from above table.

10. SUGGESTED STUDENT ACTIVITIES

Other than the classroom and laboratory learning, following are the suggested student-related *co-curricular* activities which can be undertaken to accelerate the attainment of the various outcomes in this course: Students should conduct following activities in group and prepare reports of about 5 pages for each activity, also collect/record physical evidences for their (student's) portfolio which will be useful for their placement interviews:

- a) Prepare charts of different biomaterials of the body implant.
- b) Undertake micro-projects in teams for making working models of different implants.
- c) Seminar/Presentation on any relevant topic.
- d) Categorized various disorders commonly found in various organs and selected implants accordingly.

11. SUGGESTED SPECIAL INSTRUCTIONAL STRATEGIES (if any)

These are sample strategies, which the teacher can use to accelerate the attainment of the various outcomes in this course:

- a) Massive open online courses (MOOCs) may be used to teach various topics/sub topics.
- b) Guide student(s) in undertaking micro-projects.
- c) 'L' in section No. 4 means different types of teaching methods that are to be employed by teachers to develop the outcomes.
- d) About 20% of the topics/sub-topics which are relatively simpler or descriptive in nature is to be given to the students for *self-learning*, but to be assessed using different assessment methods.
- e) With respect to section No.10, teachers need to ensure to create opportunities and provisions for *co-curricular activities*.
- f) Guide students on how to address issues on environment and sustainability.
- g) Guide students for using instructional manuals.

12. SUGGESTED PROJECT LIST

Only one micro-project is planned to be undertaken by a student that needs to be assigned to him/her in the beginning of the semester. In the first four semesters, the micro-project are group-based (group of 3 to 5). However, in the fifth and sixth semesters, the number of students in the group should *not exceed three*. The micro-project could be industry application based, internet-based, workshop-based, laboratory-based or field-based. Each micro-project should encompass two or more COs which are in fact, an integration of PrOs, UOs and ADOs. Each student will have to maintain a dated work diary consisting of individual contributions in the project work and give a seminar presentation of it before submission. The duration of the microproject should be about 14-16 (*fourteen to sixteen*) student engagement hours during the course. The students ought to submit micro-project by the end of the semester to develop the industry-oriented COs.

A suggestive list of micro-projects is given here. This has to match the competency and the COs. Similar micro-projects could be added by the concerned course teacher:

- a. Prepare a chart to describe various Biomaterials.
- b. Prepare a chart or describe various types of Implants.
- c. Prepare a chart or model to describe inflammation process and concept of biocompatibility
- d. Design various implant by using open source designing software.
- e. Make a 3d model of dental implants
- f. Make a 3d model of Vascular implants
- g. Make a 3d model of Optical implants
- h. Make a 3d model of Orthopedic implants
- i. Prepare a chart for implant waste management
- j. Make a working model of cochlear implants

13. SUGGESTED LEARNING RESOURCES

S. No.	Title of Book	Author	Publication with place, year and ISBN
1	Biomaterials	Sujata V. Bhatt,	Second Edition, Narosa Publishing House, 2005
2	Biomaterials - Principles and Applications	Joon B. Park Joseph D. Bronzino	CRC Press, 2003
3	Biomaterials Medical Devices and Tissue Engineering	Fredrick H. Silver Chapman and Hall	London J.V. Park, Biomaterials Science and Engineering, Plenum Press, New York

4	Biomaterials Science- An introduction to materials in medicine	Buddy D. Ratner, Allan S. Hoffman, Frederick j. Schoen, Jack E. Lemons	Edition: Third Edition Publisher: Academic Press Publication Year: 2013 Place of Publication: Burlington, MA, USA ISBN-13: 978-0123746269 ISBN-10: 0123746264
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14. SOFTWARE/LEARNING WEBSITES

<https://nptel.ac.in/courses/102106057>

<https://nptel.ac.in/courses/113108071>

15. PO-COMPETENCY-CO MAPPING:

Semester I	Human Biology (Course Code: 4310301)						
	POs						
Competency & Course Outcomes	PO 1 Basic & Discipline specific knowledge	PO 2 Problem Analysis	PO 3 Design/development of solutions	PO 4 Engineering Tools, Experimentation & Testing	PO 5 Engineering practices for society, sustainability & environment	PO 6 Project Management	PO 7 Life-long learning
<u>Competency</u>	Select appropriate bio-materials and implants as per requirement.						
I. Explain the concept and need of bio-materials, implants and bio compatibilities.	3	1	1	1	-	-	2

ii. Recognize the types of various metals, alloys and ceramics used for implantation according to their formation and applications	3	1	2	2	-	-	2
iii. Describe the use of various polymers used for implantation.	3	1	2	2	1	-	2
iv. identify different biomaterial uses for vascular and optical implants.	3	2	2	1	1	-	2
v. Select appropriate biomaterial for Dental and Orthopedic Implant and also Select effective method to discard implants.	3	2	2	1	3	-	3

Legend: '3' for high, '2' for medium, '1' for low and '-' for no correlation of each CO with PO.

16. COURSE CURRICULUM DEVELOPMENT COMMITTEE

GTU Resource Persons

Sr. No.	Name and Designation	Institute	Contact No.	Email
1.	Ms. Aarti R Dalwadi	GGP Ahmedabad	9099314217	ankitadalwadi98@gmail.com
2.	Ms. Poonam.G.Lakhani	GP Gandhinagar	9898645087	poonamlakhani.bm@polytechnicgnr.gujarat.gov.in