GUJARAT TECHNOLOGICAL UNIVERSITY

Program Name: Diploma Engineering

Level: Diploma

Branch: Plastics Engineering

Subject Code: DI04023081

Subject Name: Plastics in Medical

w. e. f. Academic Year:	2025-26
Semester:	4th
Category of the Course:	Professional Elective - II

Prerequisite:	None
Rationale:	The subject "Plastics in Medical" focuses on the role of polymeric materials (commonly referred to as plastics) in healthcare applications, including medical devices, equipment, packaging, and emerging biomedical innovations. A dedicated curriculum on Plastics in Medical equips learners with the scientific understanding, technical skills, and ethical awareness required to design, evaluate, and manage polymer-based solutions in healthcare. Hospitals and manufacturers face rising pressure to reduce waste, adopt greener materials, and comply with stringent environmental and safety regulations. By integrating this subject, educational institutions can prepare students for a market where medical plastics are projected to grow due to aging populations, technological advancements, and global health demands, while promoting eco-friendly practices like recycling and bio-based polymers.

Course Outcome:

After Completion of the Course, Student will able to:

No	Course Outcomes	RBT Level
01	Explain the classification of medical devices	R,U
02	Analyze various material requirements for medical devices.	R,U,A
03	Select proper material for medical device	R,U,A
04	Classify various additives for polymers in medical devices	R,U,A
05	Identify various applications of polymers in Medical field	R,U,A

**Revised Bloom's Taxonomy (RBT)*

Teaching and Examination Scheme:

Teaching Scheme (in Hours)			Total Credits L+T+(PR/2)	Assessment Pattern and Marks				Total Marks
				Theory		Tutorial / Practical		
L	T	PR	C	ESE(E)	PA(M)	PA(I)	ESE(V)	
3	0	2	4	70	30	20	30	150

Course Content:

Unit No.	Content	No. of Hours	% of Weightage
UNIT – I Introduction To Medical Devices	**Introduction to Medical Devices and its regulations** • Introduction to medical plastic market • Medical Device-Definition and risk based classification (Class I to III) • History and Evolution of Medical Devices- Transition from mechanical to digital/smart devices • Types of medical devices – Disposable and non disposable • Introduction of materials used in medical devices • Medical devices- Material Selection Process • Introduction to key Regulatory Frameworks for Plastics in Medical Devices (India)- Medical Device Regulations (CDSCO / Drugs & Cosmetics Act), Quality Management & Risk Standards, Plastic Waste / Environmental Regulations, Material-Specific Regulations / Standards, Regulatory Notifications / Licensing	5	10
UNIT – II Material Requirements for Medical Devices and Testing of Material	**Material requirements for Medical Devices and Testing of material** • Introduction to material requirements and testing methods for medical devices • Material requirements and related testing methods for : ➢ Material characterization – Composition, Mechanical and Thermal properties ➢ Sterilization-Steam sterilization and dry heat ➢ Irradiation-Gamma and Electron-beam radiation ➢ Chemical resistance- Extractable/Leachable ➢ Biocompatibility ➢ USP Class VI ➢ ISO 10993 ➢ Shelf life and aging • Joining and welding – Mechanical techniques, Heat and Friction techniques	13	30
UNIT – III Materials in Medical Devices	**Materials Use in Medical Devices** • Classification of various materials for Medical Devices • Types of Materials ➢ Metals	09	20

	➢ Ceramics and Glass ➢ Plastics ▪ Introduction of plastic material as medical device ▪ Advantages of Plastics as a material for medical device ▪ Disadvanges Plastics as a material for medical device ▪ Composites • Commodity Plastics - Polyethylene (LDPE, HDPE, UHMWPE), Polypropylene (PP), Polyvinyl Chloride (PVC) • Engineering Thermoplastics- Polycarbonate (PC), Acrylic (PMMA), ABS, Polyethylene Terephthalate (PET, PETG) • High-Performance Thermoplastics- Polyether Ether Ketone (PEEK), Polysulfone (PSU), Polyethersulfone (PES),Polyimide (PI) • Thermosets • Elastomers • Polymer Alloys and Blends		
UNIT – IV Polymer Additives for Plastics use in Medical Devices	**Polymer Additives for Plastics use in Medical Devices** • Introduction • Things to Consider when using Additives • Types of Additives ➢ Plasticizers ➢ UV Stabilizers ➢ Antioxidants ➢ Wear-Resistant and Lubricious Additives ➢ Colorants / Pigments ➢ Radiopaque Additives ➢ Antimicrobials ➢ Conductive Fillers ➢ Nano additives	09	20

UNIT – V Application of Plastics in Medical Devices and Future Trends	**Application of Plastics in Medical Devices and Future Trends** • Disposable Medical Devices- Syringes and hypodermic needles, Intravenous (IV) sets, blood bags, Catheters, Surgical gloves, Face masks and PPE • Medical Packaging and Containers - Blister packs and trays, Pharmaceutical bottles and vials • Implantable and Long-Term Devices-Orthopedic implants (joint replacements, screws, plates), Cardiovascular devices: heart valves, stents, pacemaker components, Dental implants and prosthetics, Ophthalmic implants: intraocular lenses • Prosthetics and External Medical Devices-Prosthetic limbs and sockets, Hearing aid shells • Respiratory and Anesthesia Devices-Oxygen masks, nebulizers and ventilator tubing • Sustainability and Future Trends in Medical Plastics ➢ Emerging and Advanced Applications-3D-printed custom implants and surgical guides, Wearable medical devices, Smart polymers and nanotechnology for targeted therapies ➢ Recycling challenges for medical waste and biodegradable alternatives	09	20
	Total	**45**	**100**

Suggested Specification Table with Marks (Theory):

Distribution of Theory Marks (in %)					
R Level	**U Level**	**A Level**	**N Level**	**E Level**	**C Level**
25	**50**	**25**	---------	————————	————————

Where R: Remember; U: Understanding; A: Application, N: Analyze and E: Evaluate C: Create (as per Revised Bloom's Taxonomy)

References/Suggested Learning Resources:

(a) Books:

S.No.	Title of Book	Author	Publication with place, year and ISBN
1	Plastics in Medical Devices: Properties, Requirements, and Applications	Vinny R. Sastri	Elsevier, Amsterdam, Netherlands, 2022, 978-0323851268
2	Applications of Polymers and Plastics in Medical Devices: Design, Manufacture, and Performance	Syed Ali Ashter	William Andrew (Elsevier), Norwich, NY, USA, 2022, 978-0128209806
3	Medical Plastics: Degradation Resistance & Failure Analysis	Robert C. Portnoy	William Andrew (Elsevier), Norwich, NY, USA, 2008, 978-1884207600
4	Emerging Trends in Medical Plastic Engineering and Manufacturing	Markus Schönberger, Marc Hoffstetter	William Andrew (Elsevier), Norwich, NY, USA, 2016, 978-0323370233
5	Handbook of Polymer Applications in Medicine and Medical Devices	Sina Ebnesajjad	William Andrew (Elsevier), Norwich, 2013, 978-0323228053

(b) Open-source software and website:

1. https://polymer-additives.specialchem.com/selection-guide/biocompatible-polymers-for-medical
2. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products
3. https://doi.org/10.1007/978-3-319-16559-6_2-1
4. https://doi.org/10.1016/B978-0-323-22805-3.00003-7
5. https://www.acplasticsinc.com/informationcenter/r/medical-uses-for-plastic-materials
6. https://bmpmedical.com/resource/what-plastics-are-used-in-medical-devices/
7. https://modernplastics.com/industries/plastics-for-medical-devices/
8. https://topas.com/medical-grade-plastic-topas/
9. https://swayam.gov.in/
10. National Digital Library of India

Suggested Practical List:

Sr. No.	Practical/Exercise (Course Outcomes in Psychomotor Domain according to NBA Terminology)	Approx. Hrs Required
1	Identification and Classification of Common Medical Devices	02
2	Study of various regulations for Medical devices and applications.	02
3	Study various sterilization methods for materials and devices.	04
4	Study test method for chemical resistance of medical devices.	04
5	Study various joining and welding techniques for medical devices.	04
6	Study various commodity and engineering plastics use for medical devices.	02
7	Study various high performance plastics, alloys and blends use for medical devices.	02
8	Identification of Common Additives in Medical-Grade Plastics	02
9	Study various applications of Plastics in Medical.	04
10	Analyze Sustainability and Future Trends in Medical Plastics	02
TOTAL		**30**

Suggested Activities for Students:

1. Assignments
2. Technical Quiz/MCQ Test
3. Preparation of non-working models of various heat exchange equipments and its importance.
4. Preparation of power-point slides, which include videos, animations of various heat exchange equipments

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