Materials for Bioengineering

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Learning objectives for this lecture unit

Ansys software mentioned	• Ansys Granta EduPack™, a teaching software for materials education

Intended Learning Outcomes	
Knowledge and Understanding	Broad knowledge of the different areas of Bioengineering
Skills and Abilities	Ability to select materials for Bioengineering applications
Values and Attitudes	Awareness of how biomaterials compare with engineering ones

Resources

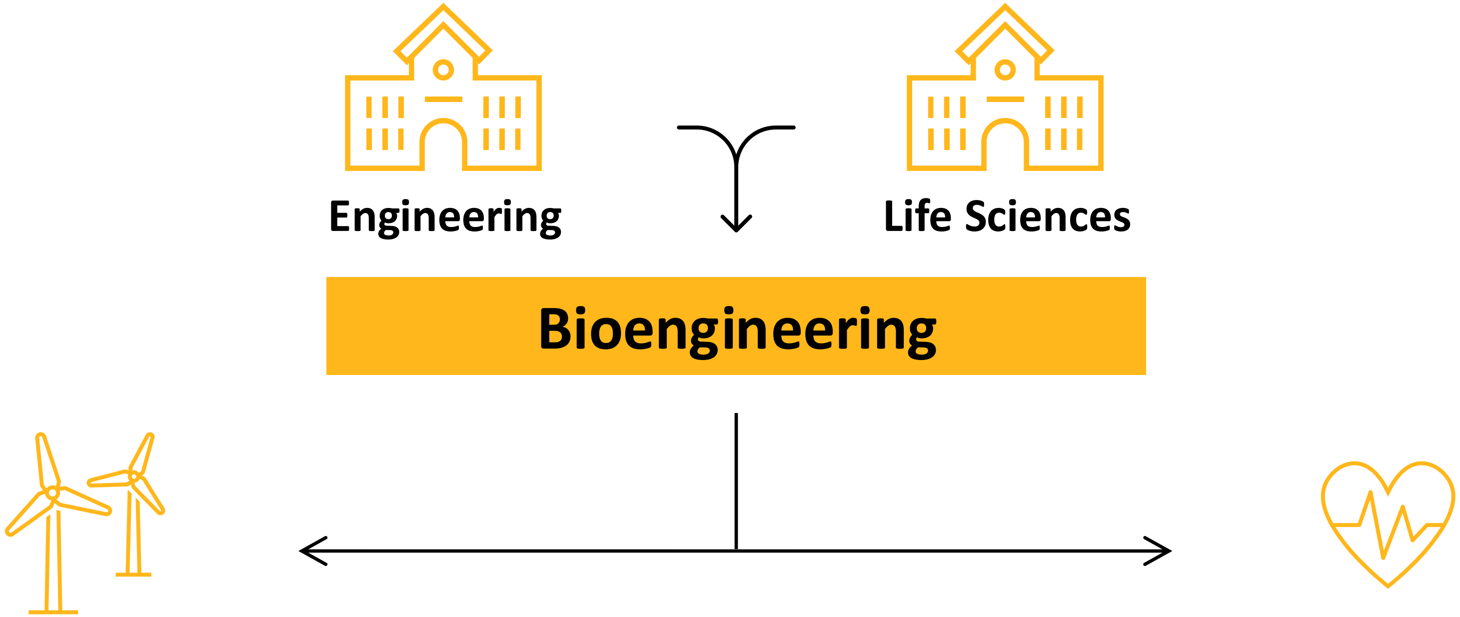
- White Paper: **“Bioengineering Database > Part 1: Introduction to Biological and Bio-medical materials”**
- White Paper: **“Bioengineering Database > Part 2: Bio-derived materials and example applications”**
- White Paper: **“Medical Devices- biomedical applications of materials”**
- Text: “***Materials Selection in Mechanical Design***”, 5th edition, by M.F. Ashby, Butterworth Heinemann, Oxford, 2016.

Outline

- What is bioengineering?
- Ansys Granta EduPack software databases
  - Level 2 Bioengineering
  - Level 3 Bioengineering
- Materials selection for biomedical applications
  - Biomaterials Selection for a Joint Replacement
  - Biomedical Waste: Health vs Environment

What is bioengineering?

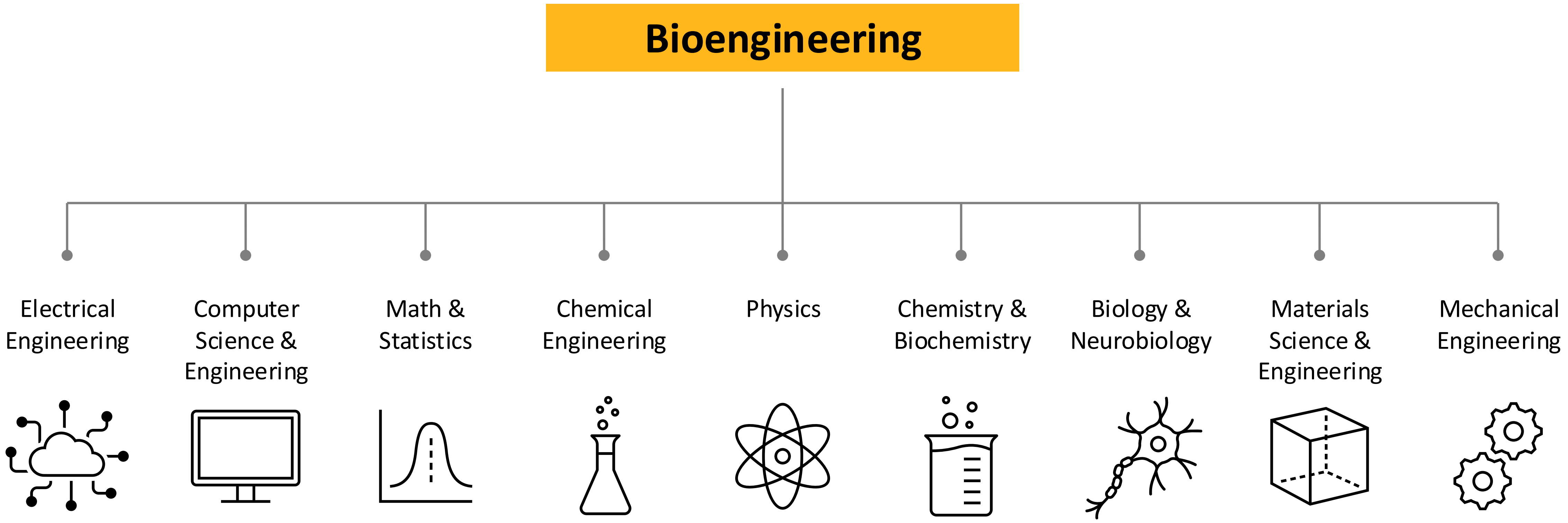
“A discipline that advances knowledge in engineering, biology and medicine, and improves human health through cross-disciplinary activities that integrate the engineering sciences with the biomedical sciences and clinical practice.” - Whitaker Foundation



Application of “biological systems knowledge” to engineering issues *e.g.,* bio-inspired wind turbine blades

Application of “engineering principles” to challenges in biology and medicine *e.g.,* pacemakers

Specialist areas



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Materials in Bioengineering

What is a biomaterial?
Any matter, surface, or construct that interacts with biological systems. Biomaterials can be derived from nature or synthesized in the laboratory using metallic components, polymers, ceramics, or composite materials.
National Institute of Biomedical Imaging and Bioengineering

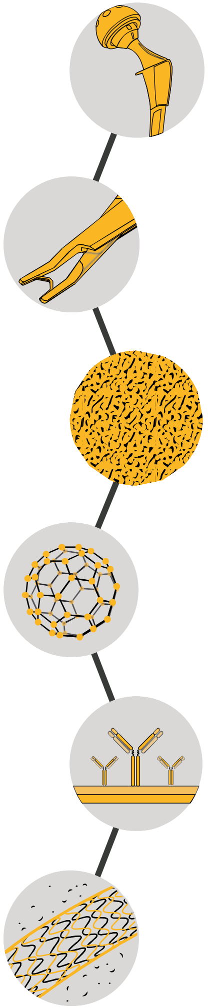
1 **METALS**
Hard, ductile and conduct heat and electricity *e.g.* stainless steel 316L

2 **POLYMERS**
Widely variable, relatively soft and flexible *e.g.* polypropylene

3 **CERAMICS**
Hard, brittle, resistant to corrosion, electrically non-conductive *e.g.* alumina

4 **COMPOSITES**
Materials with distinct phases larger than the atomic scale *e.g.* CFRP

Where are biomaterials currently used in medical practice?



Medical implants *e.g.* heart valves, stents, and grafts; artificial joints, ligaments, and tendons; hearing loss devices; dental implants; and devices that stimulate nerves.

Promote human tissue healing *e.g.* wound closure using sutures, clips, and staples; dissolvable dressings.

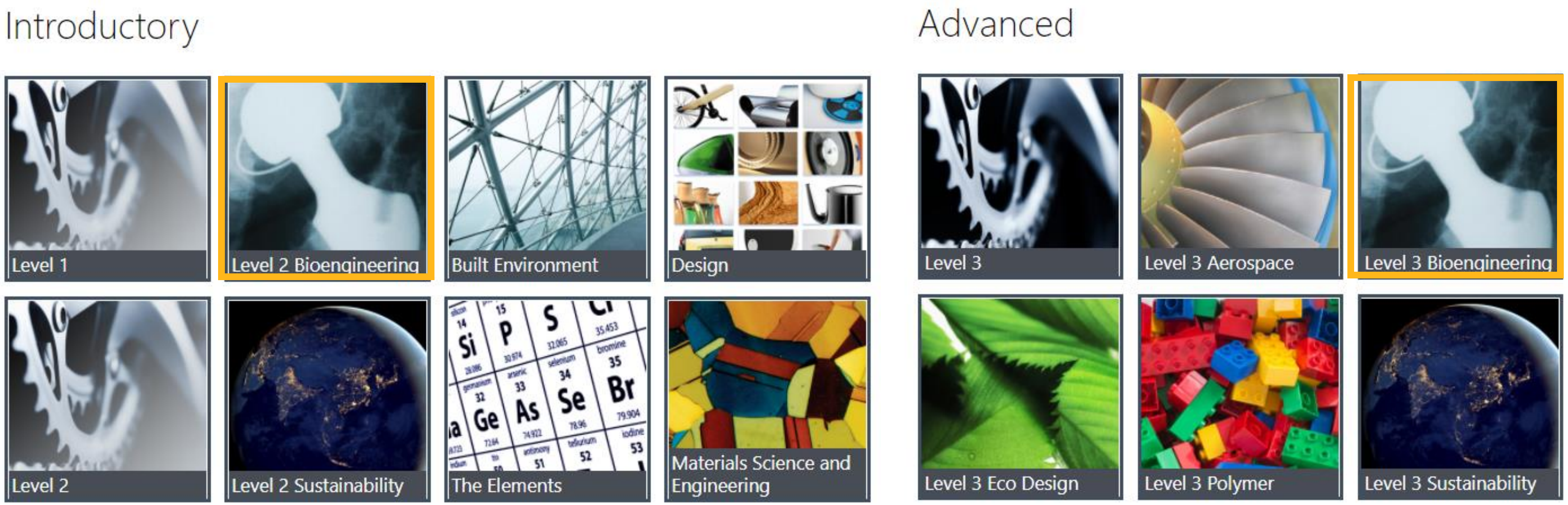
Human tissue regeneration scaffolds, cells, and bioactive molecules can all be used to support host tissue growth.

Molecular probes and nanoparticles that break through biological barriers and support cancer imaging and therapy at the molecular level.

Biosensors use biological material, such as DNA, enzymes and antibodies, to detect specific biological, chemical, or physical and then transmits or reports this data.

Drug-delivery systems that carry and/or apply drugs to a disease target *e.g.,* drug-coated vascular stents, implantable chemotherapy wafers for cancer patients.

Biomaterials Data in the Ansys Granta EduPack Software



Ansys Granta EduPack software: Level 2 Bioengineering

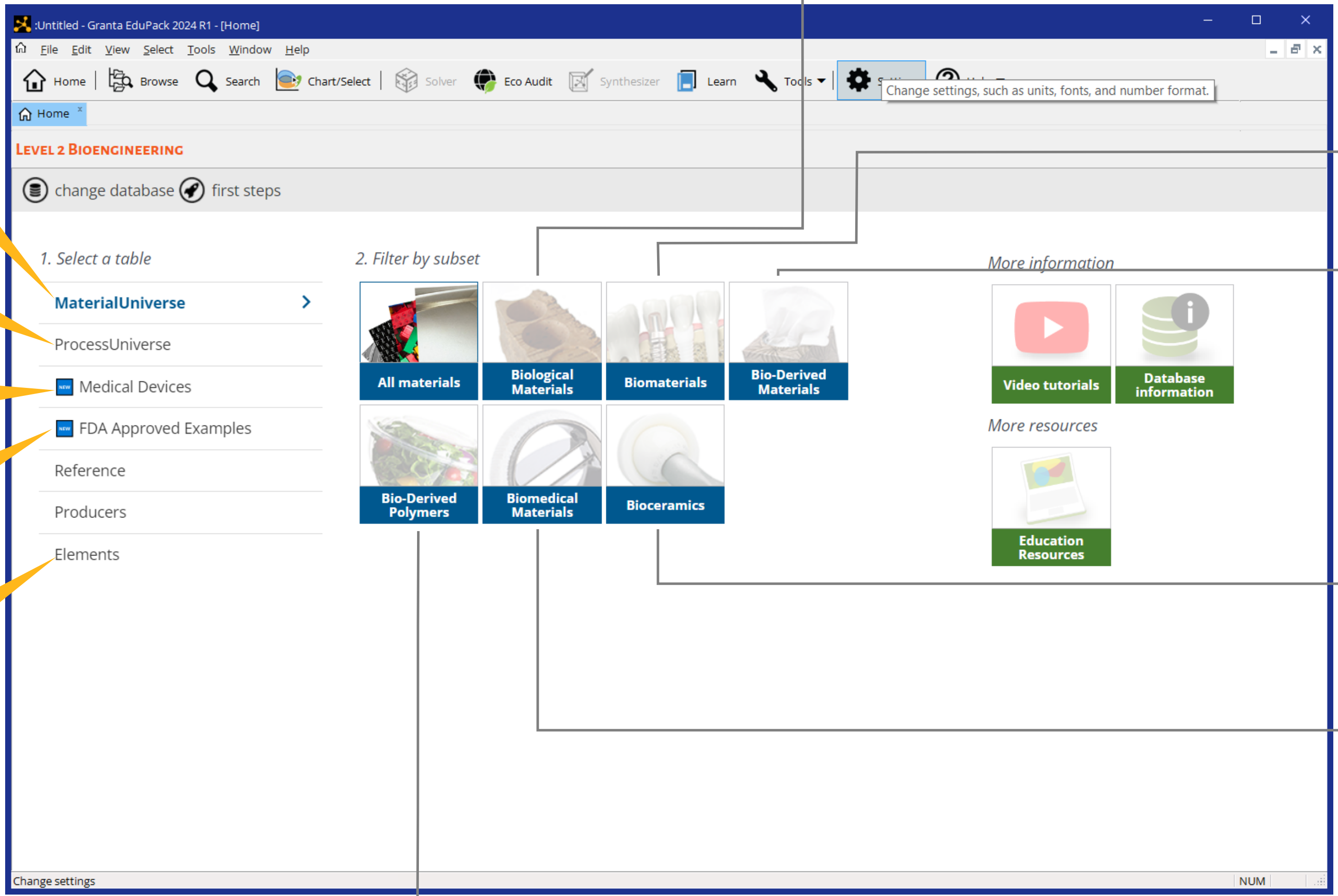
321 materials

116 processes

62 medical devices

117 FDA examples

Elements



Produced by a biological system *i.e.,* plant and animal

Blanket term for biological, natural, bio-derived, bio-inspired and biomedical materials

Uses natural/ biological source as raw material

Specific subset useful for biomedical materials

Biocompatible materials used in medical applications

Polymers which use natural/biological source as raw material

Tools

Eco Audit

Ansys Granta EduPack software: Level 3 Bioengineering

4261 materials

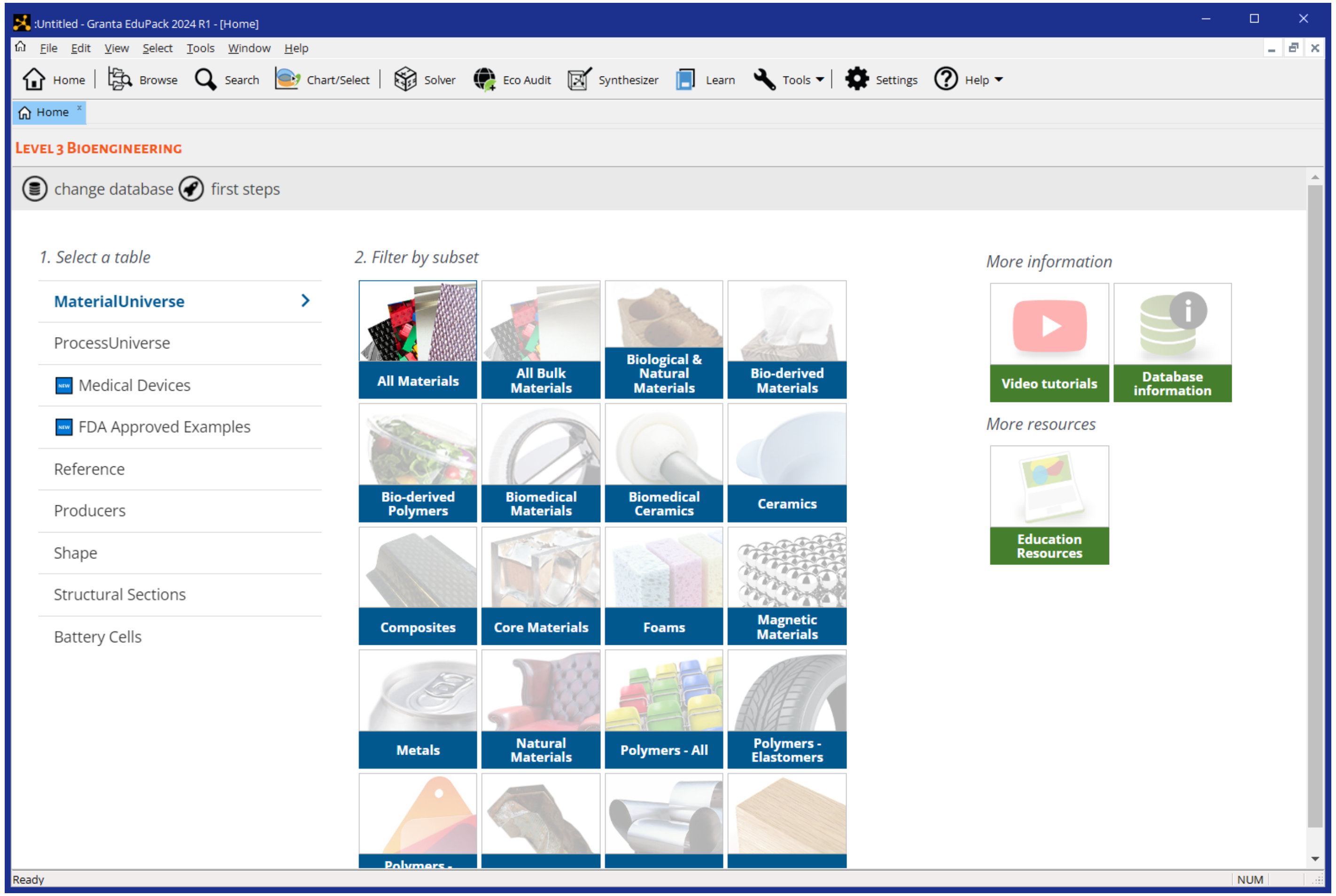
250 processes

62 medical devices

117 FDA examples

Shape

Structural Sections



20 subsets *e.g.*, Natural Materials, Biomedical Materials, Composites, Polymers-Elastomers

Tools

Engineering Solver

Enhanced Eco Audit

Synthesizer

Record of a Tendon, Level 2 Bioengineering

Description

The material

Tendons and ligaments are the cordage of the animal kingdom. Tendons link muscle to bone. Ligaments link bone to bone. Both are largely made up of collagen fibers, aligned to carry tension when pulled by muscle or motion.
Tendon and ligament are both designed to transmit tensile forces. Both are made up of roughly parallel collagen fibers aligned to form rope-like structures, but there are important differences. Tendon contains 60 - 86% dry weight of collagen and less than 5% dry weight of elastin which allows it to transmit tensile forces with minimal energy loss and little stretching - strains seldom exceed 10%. Ligament, with a lower (50-70% dry weight) collagen content, has a lower stiffness. At the same time its higher elastin content (10-20% dry weight) allows it to almost double its length before it fails; strains of up to 80% are typical. The structure, too, is important. Tendon has an ordered fiber alignment while that of ligament is less regular, sometimes curved and often laid at an oblique angle to the length of the tendon to cope with off-axis loads.
This record is for tendon.

Composition (summary) ⓘ

Tendon contains 60 - 86% dry weight of collagen and less than 5% dry weight of elastin.

General properties

Density	ⓘ	*	1.3e3	-	1.35e3	kg/m^3
Biomaterial	ⓘ		✓			
Biological material	ⓘ		✓			
Guidance for MRI Safety	ⓘ		No Interaction - MR Safe			

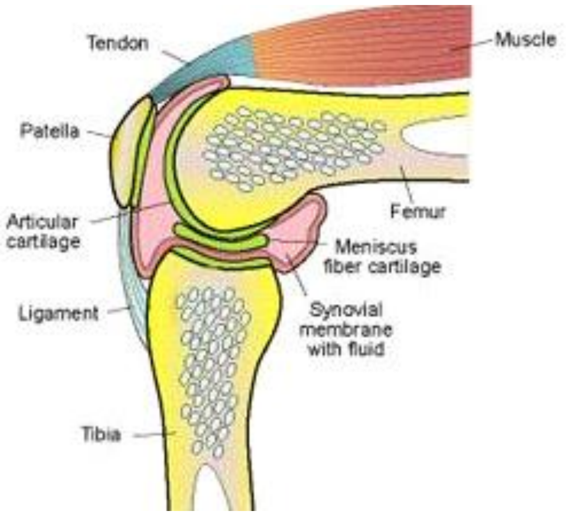
Mechanical properties

Young's modulus	ⓘ	0.8	-	2	GPa
Tensile strength	ⓘ	50	-	72	MPa
Elongation	ⓘ	8	-	10	% strain

Notes on mechanical properties

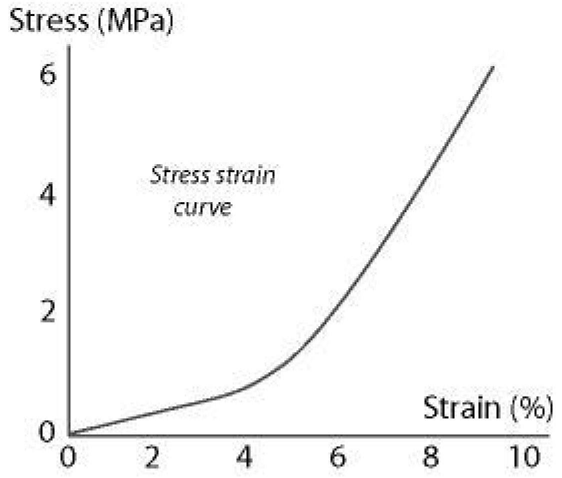
Wainwright, S.A., Biggs, W.D., Currey, J.D. and Gosline, J.M. (1976) "Mechanical design in organisms", Edward Arnold Ltd. London, UK. ISBN 0-7131-2502-0.

Yamada, J. (1970) "Strength of biological tissue", edited by Evans, F.G., Williams and Wilkinson, Baltimore, USA. Library of Congress Number 75-110279.



Caption

Tendon links bone to muscle.



Graph caption

Stress strain curve of calcaneal tendinous tissue

Thermal properties

Thermal conductor or insulator?	ⓘ		Poor insulator			
Thermal conductivity	ⓘ	*	0.46	-	0.51	W/m.°C
Specific heat capacity	ⓘ	*	2.8e3	-	3e3	J/kg.°C
Thermal expansion coefficient	ⓘ	*	200	-	227	µstrain/°C

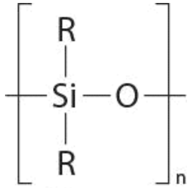
Notes on thermal properties

The thermal conductivity and expansion coefficient are estimated from those for muscle.

Critical Materials Risk

High critical material risk?	ⓘ	No

Record of silicone, Level 2 Bioengineering



Silicone

Description

The material

Silicone and fluoro-silicone elastomers have long chains of linked O-Si-O-Si- groups (replacing the -C-C-C-C- chains in carbon-based elastomers), with methyl (CH3) or fluorine (F) side chains. They have poor strength, but can be used over an exceptional range of temperature (-100 C to + 300 C), have great chemical stability, and an unusual combination of properties. Certain silicones have been developed for medical use and carry FDA approval, though concern is expressed by the FDA about the long-term effects of silicone transplants.

Composition (summary)

(O-Si(CH3)2)n

Price	*	8.65	-	10.3	GBP/kg
Biomaterial		✓			
Biomedical material		✓			
Guidance for MRI Safety		No Interaction - MR Safe			

Mechanical properties

Young's modulus		0.008	-	0.03	GPa
Shear modulus	*	0.003	-	0.01	GPa
Bulk modulus	*	2	-	2.2	GPa
Poisson's ratio	*	0.498	-	0.5	
Yield strength (elastic limit)	*	5.4	-	7	MPa

Thermal properties

Glass temperature		-123	-	-73.2	°C
Maximum service temperature		250	-	270	°C
Thermal conductor or insulator?		Good insulator			
Thermal conductivity		0.2	-	0.3	W/m.°C
Specific heat capacity		1.05e3	-	1.1e3	J/kg.°C
Thermal expansion coefficient	*	250	-	300	µstrain/°C

Electrical properties

Electrical conductor or insulator?		Good insulator			
Electrical resistivity		3.2e19	-	3.2e20	µohm.cm
Dielectric constant (relative permittivity)		2.9	-	4	
Dissipation factor (dielectric loss tangent)		0.002	-	0.008	
Dielectric strength (dielectric breakdown)		16	-	28	MV/m

Optical properties

Transparency		Transparent			
Refractive index		1.4	-	1.44	

Critical Materials Risk

High critical material risk?	Yes

Primary material production: energy, climate change and water

Climate change (CO2-eq), primary production (virgin grade)	*	6.19	-	6.89	kg/kg
Embodied energy, primary production (virgin grade)	*	118	-	130	MJ/kg

Supporting information

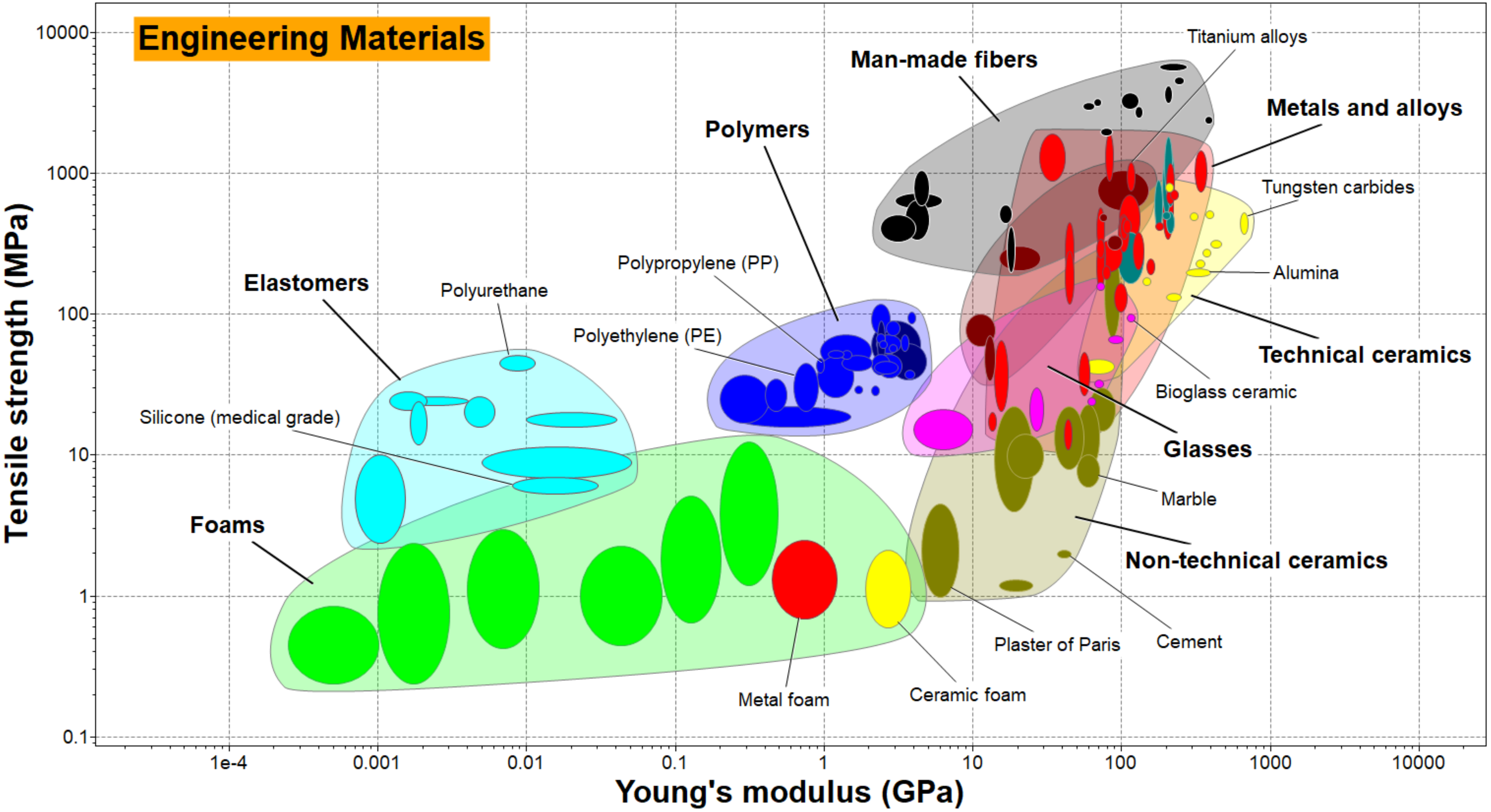
Medical applications

Baby bottle tips, burn dressings, ear implants, arterial grafts, breast implants, surgical and food processing equipment.

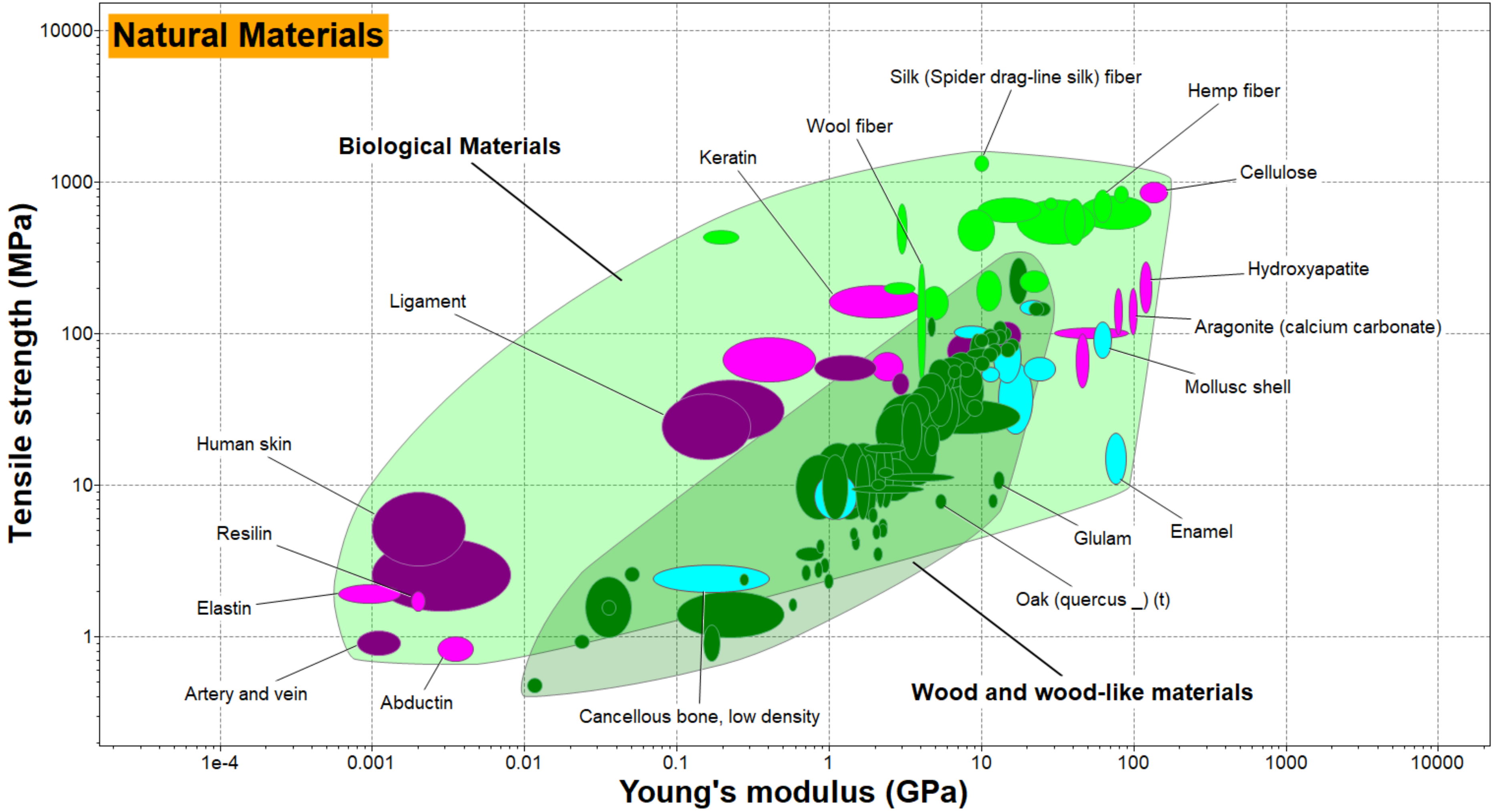
Bio-data

Biocompatible	✓
Medical grades	✓

Material property chart, Level 2 Bioengineering



Material property chart, Level 2 Bioengineering



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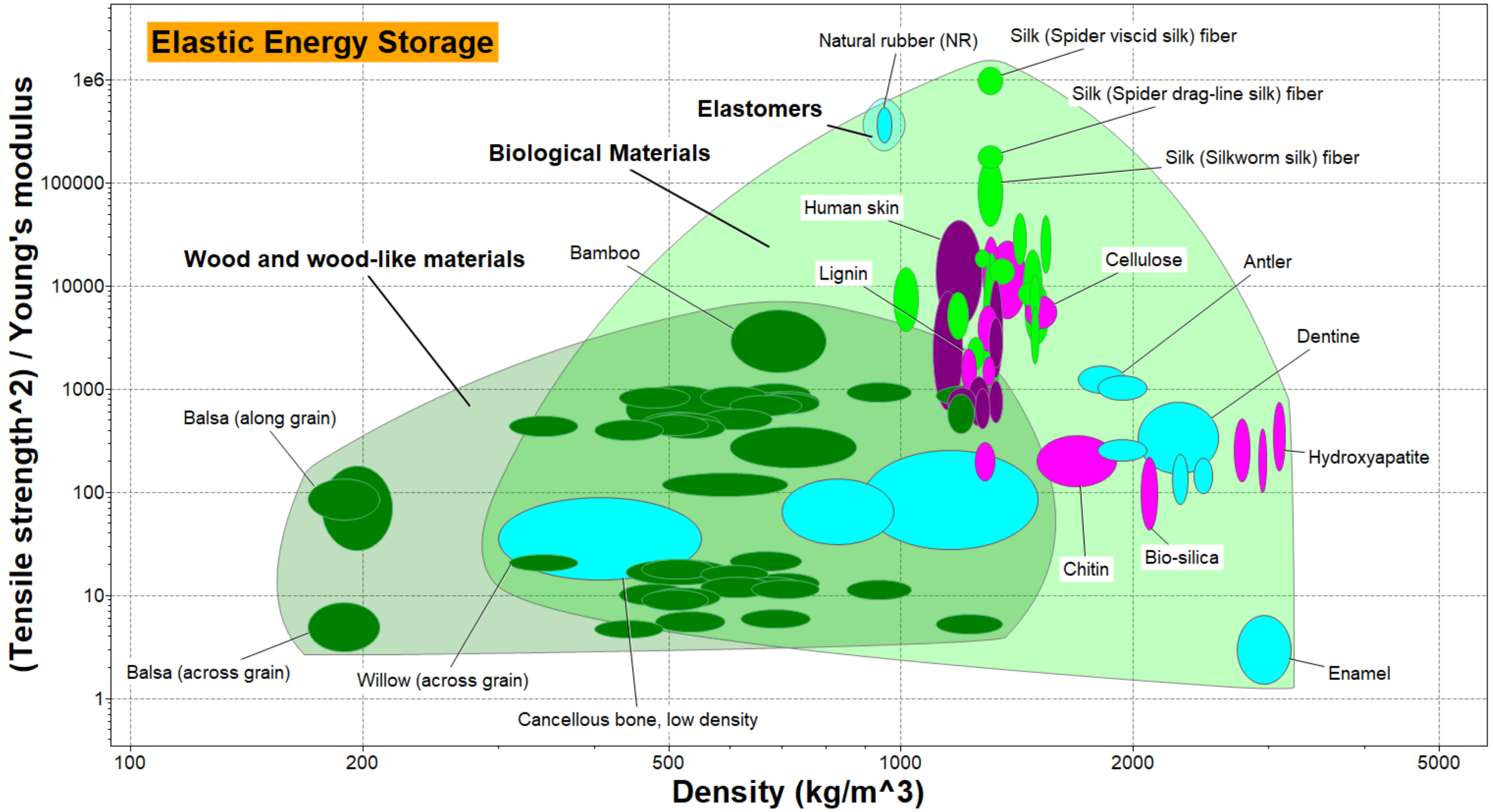
Material property chart, Level 2 Bioengineering



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Record of silicone, Level 3 Bioengineering

More data at Level 3

General information

Designation

Silicone (VMQ, heat cured, 10-30% fumed silica), Silicone elastomer / Polydimethylsiloxane / Vinyl methyl silicone (VMQ / SI), heat cured

Tradenames

Baysilone; Elastosil-R; Ge Lim; Rhodorsil Hcr; Shincor; Shincor Lim; Silastic; Silopren; Tufel

Typical uses

Automotive: seals, hose, spark-plug boots, gaskets, mounts, cable sheathing electric scooters, electric cars, hybrid cars. Electrical/electronic: computer keypads, insulators, surge arresters, smart watches, fitness trackers, VR headsets, gaming consoles, electric toothbrushes, robotics. Food contact: Gaskets for Pressure Cookers, Heat resistant kitchen mats. Medical: seals, syringe plungers, breast nipple protectors, catheters, sterilization mats, O-Rings for dialyzers, baby bottle parts. Sports: swimming goggles and caps. Other: molds.

Biomaterials - All	✓
Biomedical materials	✓
Included in Materials Data for Simulation	✓
Materials Data for Simulation name	Rubber, silicone (VMQ)

Composition overview

Compositional summary

Polymer of dimethyl silicone, formula -(OSi(CH3)2)-, with some methyl groups substituted by vinyl groups as cure sites (crosslinking sites), formula -(OSiCH3CH=CH2)-. Typically compounded with 10-30% fumed silica (SiO2) with 100-325 m2/g surface area. Contains organic peroxide or platinum (addition) heat cure system for LIM (liquid injection molding) or HTV (high temperature vulcanization).

Material family	Elastomer (thermoset, rubber)			
Base material	SI-VMQ(hc) (Silicone rubber, vinyl methyl type, heat cured)			
% filler (by weight)	10	-	30	%
Filler/reinforcement	Mineral			
Filler/reinforcement form	Particulate			
Polymer code	SI-VMQ-MD20			

Composition detail (polymers and natural materials)

Polymer	70	-	90	%
Silica (fumed)	10	-	30	%

Price

Price	* 3.24	-	3.65	GBP/kg
Price per unit volume	* 3.3e3	-	4.45e3	GBP/m^3

Physical properties

Density	1.02e3	-	1.22e3	kg/m^3

Mechanical properties

Young's modulus	0.005	-	0.05	GPa
Specific stiffness	0.00448	-	0.0449	MN.m/kg
Yield strength (elastic limit)	7	-	11.5	MPa
Tensile strength	7	-	11.5	MPa
Tensile stress at 100% strain	1.2	-	3.6	MPa
Specific strength	6.2	-	10.4	kN.m/kg
Elongation	270	-	600	% strain
Elongation at yield	270	-	600	% strain
Compressive modulus	* 0.005	-	0.05	GPa
Compressive strength	* 8.4	-	13.8	MPa
Flexural modulus	0.005	-	0.05	GPa
Flexural strength (modulus of rupture)	* 16	-	22.7	MPa
Shear modulus	* 3e-4	-	0.02	GPa

Impact & fracture properties

Fracture toughness	0.133	-	0.927	MPa.m^0.5
Toughness (G)	1.58	-	38.4	kJ/m^2
Impact strength, notched 23 °C	590	-	600	kJ/m^2
Impact strength, notched -30 °C	590	-	600	kJ/m^2
Impact strength, unnotched 23 °C	590	-	600	kJ/m^2
Impact strength, unnotched -30 °C	590	-	600	kJ/m^2

Thermal properties

Glass temperature	-70	-	-60	°C
Maximum service temperature	200	-	250	°C
Minimum service temperature	-60	-	-50	°C
Thermal conductivity	0.2	-	0.3	W/m.°C
Specific heat capacity	1.05e3	-	1.1e3	J/kg.°C
Thermal expansion coefficient	* 250	-	300	µstrain/°C
Thermal shock resistance	* 651	-	6.59e3	°C
Thermal distortion resistance	* 7.19e-4	-	0.00111	MW/m

Electrical properties

Electrical resistivity	3e19	-	5e20	µohm.cm
Electrical conductivity	3.45e-19	-	5.75e-18	%IACS
Dielectric constant (relative permittivity)	2.3	-	3.1	
Dissipation factor (dielectric loss tangent)	0.003	-	0.024	
Dielectric strength (dielectric breakdown)	16	-	20	MV/m
Comparative tracking index	400	-	600	V

Magnetic properties

Magnetic type	Non-magnetic

Optical, aesthetic and acoustic properties

Refractive index	1.4	-	1.44	
Transparency	Translucent			
Acoustic velocity	57.2	-	248	m/s
Mechanical loss coefficient (tan delta)	0.06	-	0.15	

Healthcare & food

Food contact	Yes
Medical grades? (USP Class VI, ISO 10993)	✓

Medical tradenames

Shincor LIM, GE LIM, Baysilone, Tufel

Healthcare applications	Bone fixation and repair, Catheters and cannulas, Electrodes, Embolization and occlusion devices, Endoscopes, Grafts, Haemodialysis devices, Heart valves, Implantable pacemakers and defibrillators, Joint replacement, Nerve stimulators, Ossicular replacement, Patches, Peritoneal dialysis devices, Shunts, Spinal devices, Surgical instruments, Surgical mesh, Wound and tissue closure
Sterilizability (ethylene oxide)	Excellent
Sterilizability (radiation)	Marginal
Sterilizability (steam autoclave)	Good
Guidance for MRI Safety	No Interaction - MR Safe
ASM Medical Materials datasheet (subscription required)	Silicone, Rubber

External Link

Restricted substances risk indicators

RoHS 2 (EU) compliant grades?	✓
SIN List indicator (0-1, 1 = high risk)	0.01

Notes

May contain restricted (wt%): Stabilizer / Pigment up to 0.7%

Critical materials risk

Contains >5wt% critical elements?	No

Absorption & permeability

Water absorption @ 24 hrs	0.1	-	0.15	%
Water vapor transmission	1.53	-	3.51	g.mm/m^2.day
Permeability (O2)	1.29e4	-	3.01e4	cm^3.mm/m^2.day.atm
Permeability (CO2)	6.88e4	-	2.03e5	cm^3.mm/m^2.day.atm
Permeability (N2)	1.09e4	-	2.74e4	cm^3.mm/m^2.day.atm

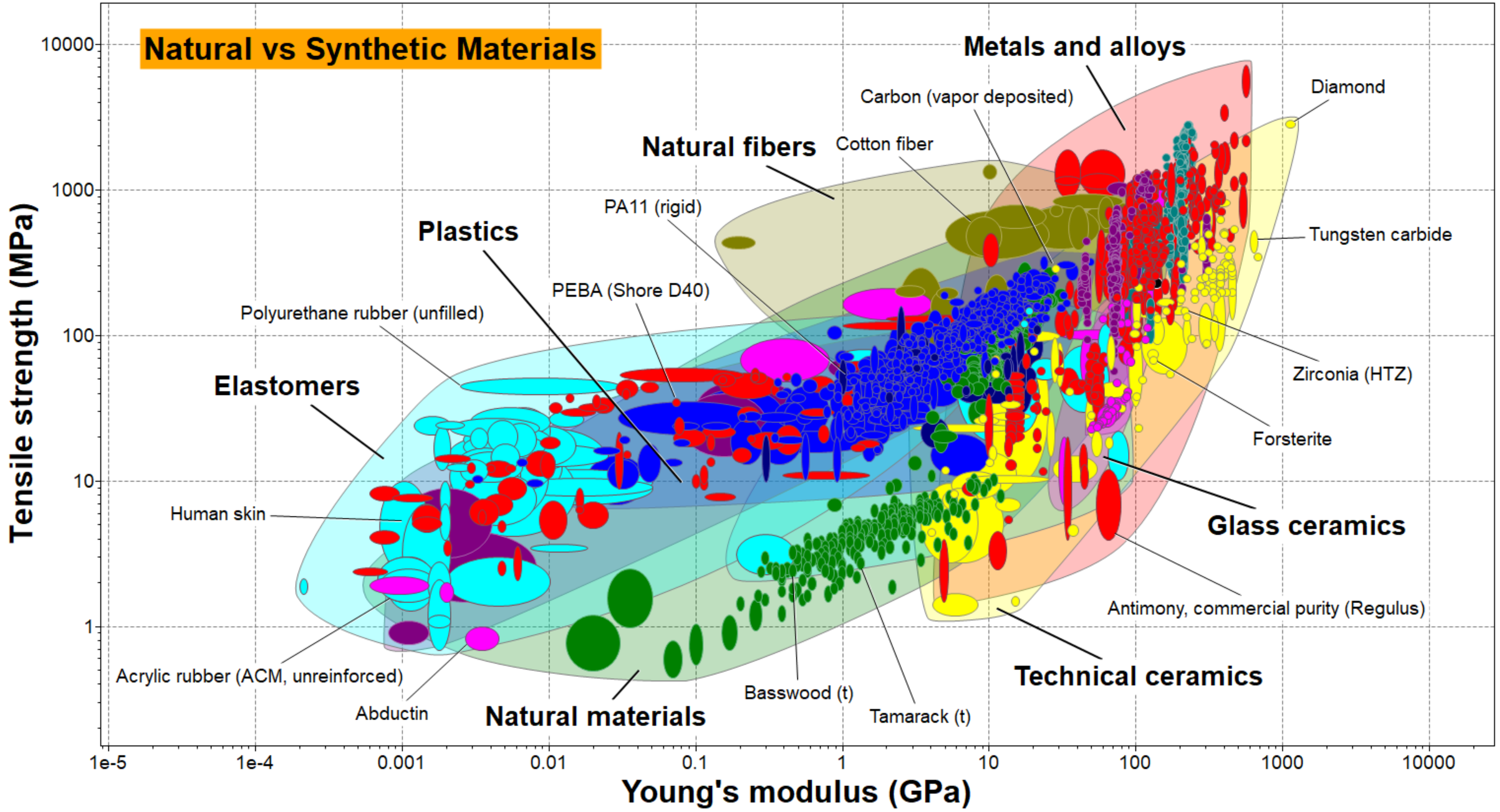
Processing properties

Polymer injection molding	Acceptable			
Polymer extrusion	Acceptable			
Polymer thermoforming	Unsuitable			
Linear mold shrinkage	2.4	-	4	%
Mold temperature	180	-	200	°C

Durability

Water (fresh)	Excellent
Water (salt)	Excellent
Weak acids	Excellent
Strong acids	Excellent

Material property chart, Level 3 Bioengineering

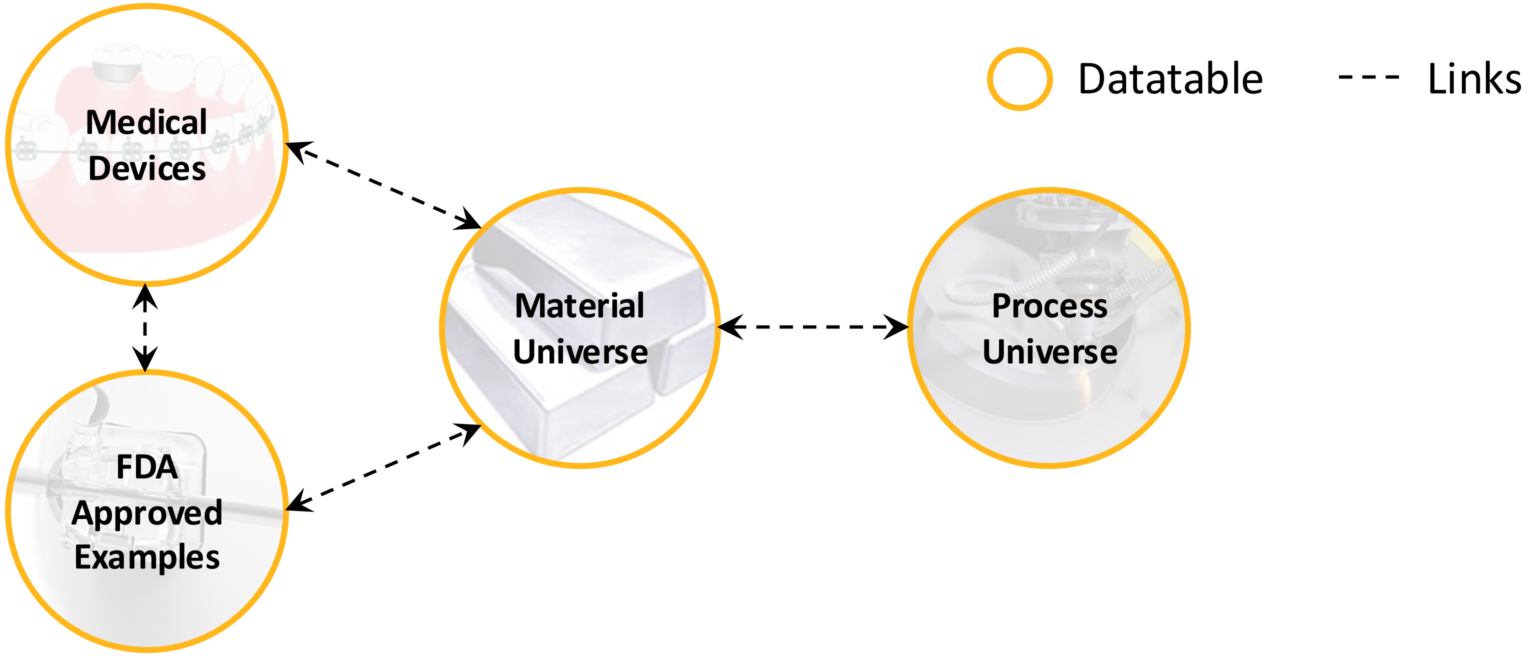


Ansys / GRANTA EDUPACK

Database contents and structure

The Ansys Granta EduPack software is therefore an excellent source of material and medical device information.

But the structure of its datatables also allows students to explore specific links between medical devices and the materials that have been used to make them.



The next two slides show an example from the medical devices and FDA approved examples, as well as the links which connect them.

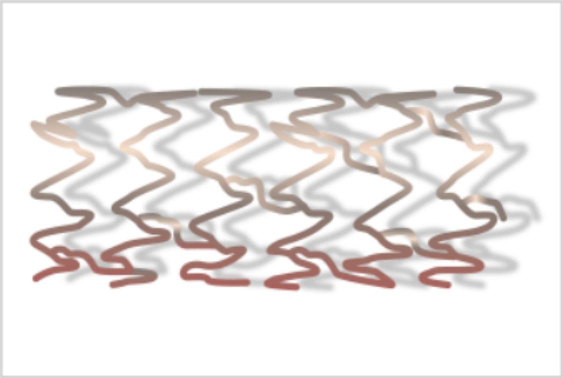
Medical Device record

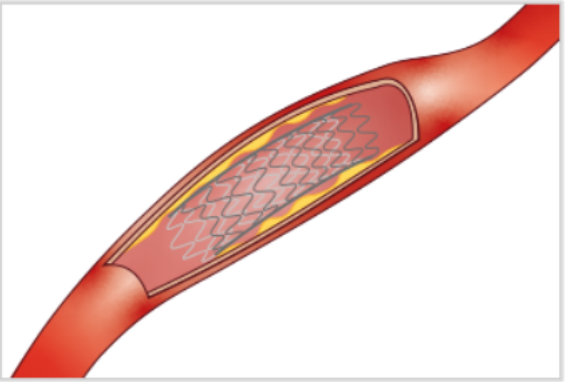
Medical Devices

Cardiovascular > Stents >

General information

Image





Caption

1) Metal stent; 2) Metal stent used to enlarge the lumen of a blood vessel with a build up of plaque

Keywords	Cardiovascular; stent
Typical materials	Cobalt-chromium alloys, Elgiloy, Nitinol, Polytetrafluoroethylene, Stainless steel

Overview

Application

Stents are most often used to treat conditions that result when arteries narrow or become blocked.

Description

A stent is a small, lattice-shaped metal tube that is inserted permanently into an artery. The stent helps hold open an artery so that blood can flow through it.

Duration of use	Permanent (> 30 days)

Classification

FDA	Class III
CE mark	Class III

Design

Design requirements

The stent should generate sufficient radial expansive force to maintain patency, and it should be sufficiently pliable to conform to the wall of the artery.

Deployment method

A stent is inserted through a main artery in the groin (femoral artery) or arm (brachial artery) and threaded up to the narrowed section of the artery with a tiny catheter (balloon catheter.) Once in the right location, the balloon is slightly inflated to push the plaque out of the way and expand the artery (balloon angioplasty). Some stents are stretched open (expanded) by the balloon at the same time as the artery. Other stents are inserted into the artery immediately after the angioplasty procedure. When in place, the stent helps to hold the artery open, allowing blood to flow to the heart muscle.

Guidance documents	FDA Guidance Document

Links

- FDA Approved Medical Devices
- MaterialUniverse
- References

Easy **links** from this generic metal stent to real-life FDA Approved Examples; typical materials used for application and references.

FDA Approved Example

FDA Approved Examples

General introduction to the 16 medical specialties, referred to by the FDA as panels.

3 letter combinations which associate a device's type with the product's classification *e.g.* NIP (Stent, Superficial Femoral Artery)

Specific details about the device including physical characteristics, date it was approved by the FDA and it's 510(k) or PMA number.

FDA Cardiovascular > Stents >

General information

Medical industry	Cardiovascular
Medical device type	Stents
Product	Superficial Femoral Artery Stent
Duration of use	Permanent (> 30 days)

US FDA Classification

Product code	NIP
FDA Classification	Class III

US FDA Summary

FDA Decision date	04/10/2018

Description

The BioMimics 3D Vascular Stent System comprises an implantable, self-expanding, nickel-titanium alloy (Nitinol) stent and a delivery system for endovascular placement and release of the stent at the treatment site.

The BioMimics 3D Stent is laser cut from a straight Nitinol tube and helical curvature is stored in the Nitinol shape memory. Three tantalum radiopaque markers are located at each end of the stent. The BioMimics 3D Stent is provided in a matrix of stent lengths and diameters to accommodate the morphology of the treatment site within the superficial femoral and proximal popliteal arteries.

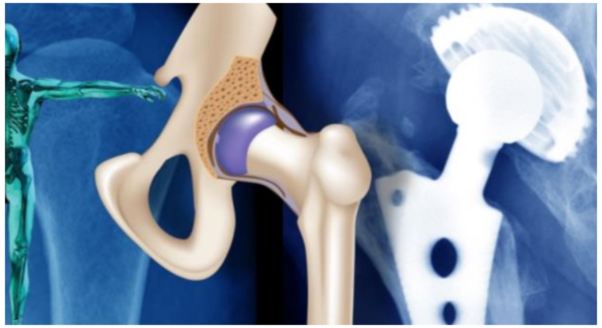
510(k) number or PMA number	P180003

Links

- MaterialUniverse
- Generic device type
- References

Ashby’s materials selection methodology

1. Biomaterials Selection for a Joint Replacement



All Materials

↓

Breakdown design requirements into:
Function – *What does the component do?*
Constraints – *What essential conditions must be met?*
Objectives – *What is to be maximized or minimized?*

↓

Screen on constraints – *‘Go/ no-go’ criteria (usually many)*
Rank on objectives – *Ordering of materials that ‘go’*

↓

Top Candidate Materials

↓

Supporting information – *Specialist databases, contact suppliers*
Local conditions – *Preferred suppliers, process capability, location*

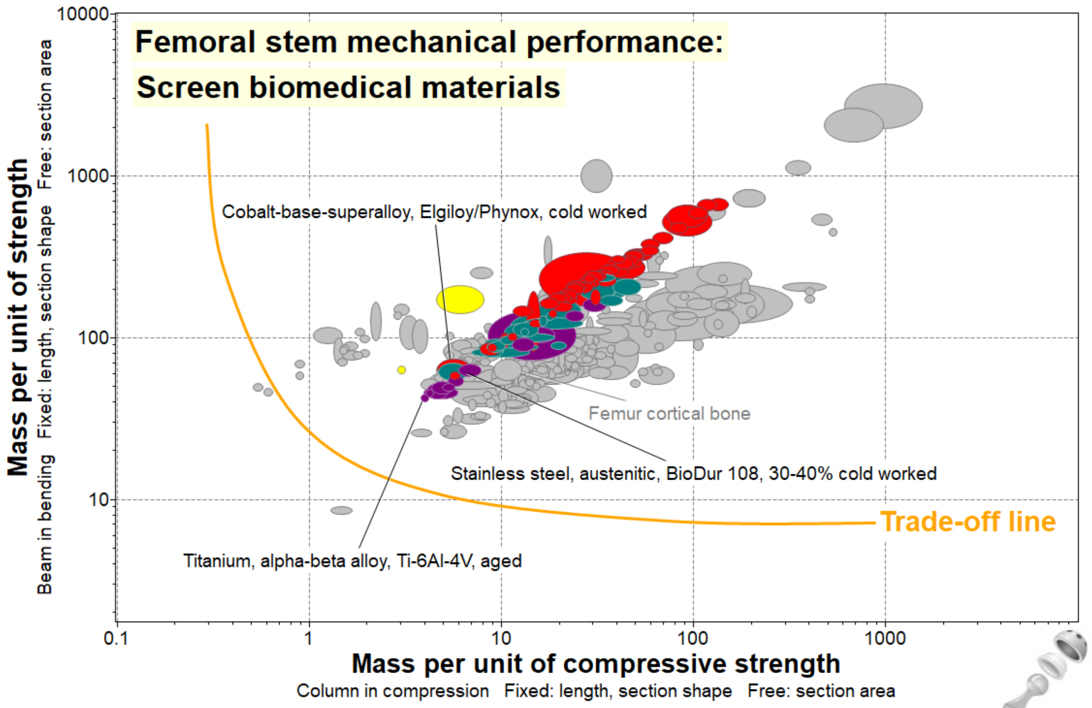
↓

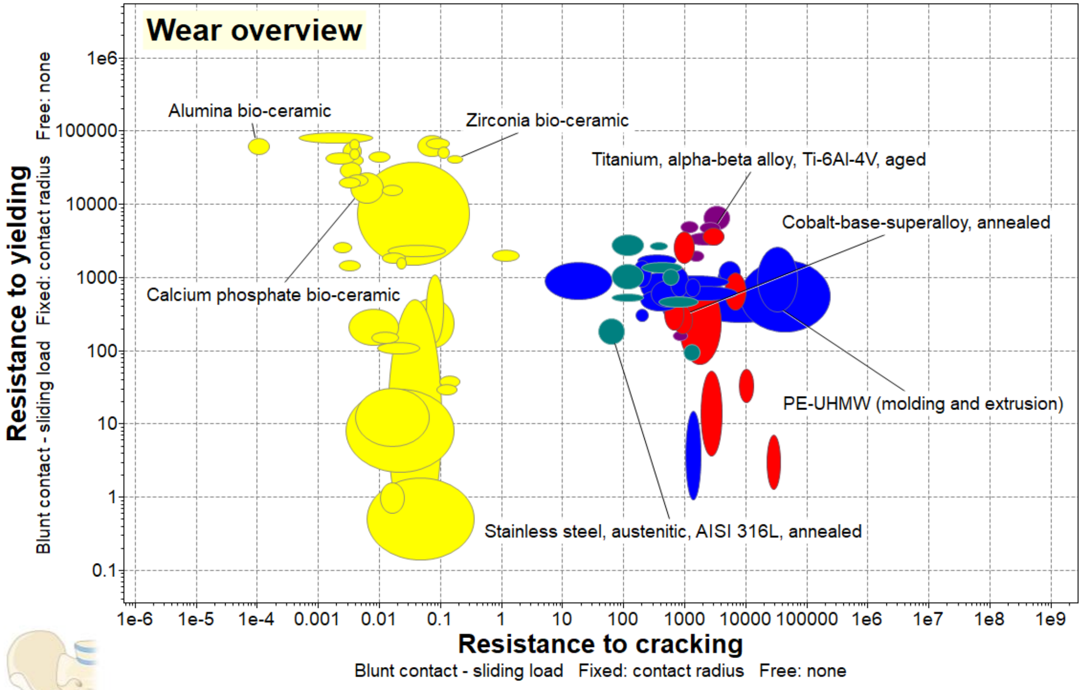
Final Selection

2. Biomedical Waste: Health vs Environment

1. Biomaterials selection for a joint replacement

Objective: 1) Femoral stem, maximize specific strength and minimize cost; 2) Femoral head, maximize compressive strength and minimize wear (blunt abrasion)





*Ansys Granta EduPack software 2022R2 release used for Case Study.

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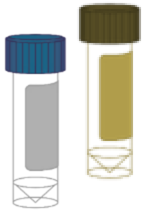
2. Biomedical waste: health vs environment

Objective: investigate suitable materials for a biomedical sample vial and primarily assess options to minimize carbon footprint and then cost.



Material, manufacture and end of life

Qty.	Component name	Material	Recycled content	Mass (kg)	Primary process	End of life
100	Cap	Polypropylene (PP)	Virgin (0%)	0.003	Polymer molding	Combust
100	Vial	Polystyrene (PS)	Virgin (0%)	0.01	Polymer molding	Combust

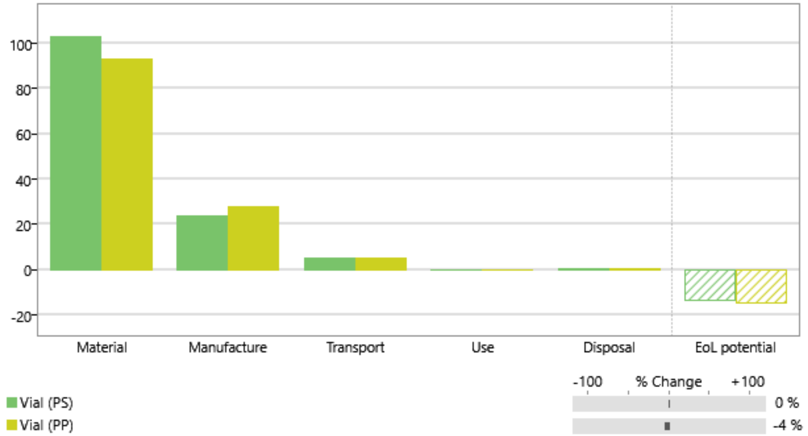
Transport

Name	Transport type	Distance (km)
Ship Shanghai-UK	Ocean freight	2.2e+04
Lorry UK	14 tonne (2 axle) truck	100

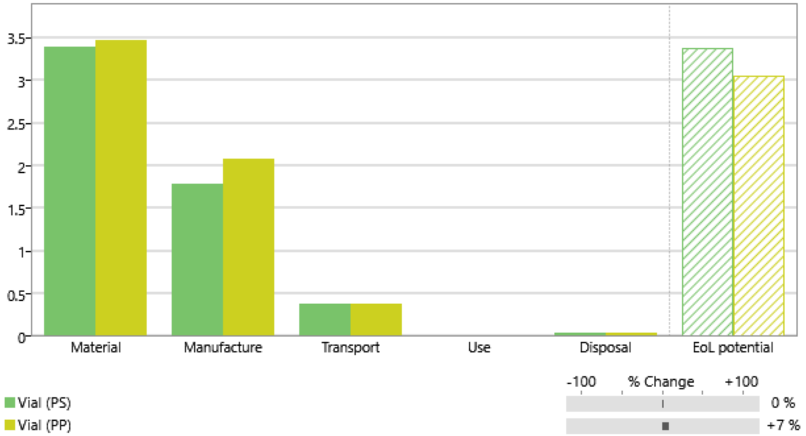
Changing this section allows comparison between the two material combinations:

1) Polystyrene vial with a polypropylene cap
2) Polypropylene vial with a polyethylene cap

Energy (MJ)



CO2 Footprint (kg)



*Ansys Granta EduPack software 2022R2 release used for Case Study.

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Summary

- The Ansys Granta EduPack software Bioengineering databases presents natural and biomaterials in a well-organized and comprehensive format
- Ashby charts help to visual the remarkable properties of natural materials
- Enables comparison with man-made materials and systematic selection
- Stimulates thinking about replacement and mimicry
- Introduced in 2023R1, Medical Devices and FDA Examples are included in both Level 2 and Level 3 databases, with links between materials, devices, and FDA examples
- Links to the Advanced Case Studies can be found here: www.ansys.com/education-resources

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Document Information

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