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KRAKOWSKA INTERDYSCYPLINARNA SZKOŁA DOKTORSKA

# Interdisciplinary Aspects of Materials Engineeing
# Biomaterials

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# Interdisciplinary Aspects of Materials Engineeing
# Biomaterials

» **Introduction**
» Historical overview
» Three generations of biomaterials
» Latest generation biomaterials – in XXI century

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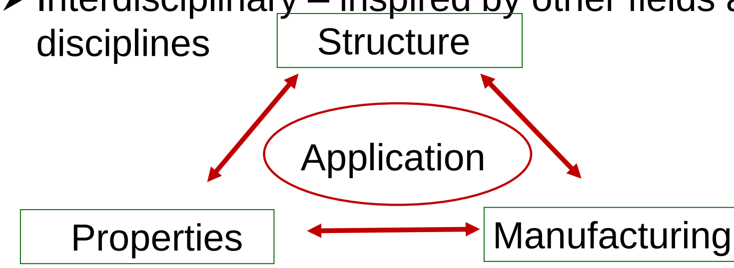
# Materials Engineering

- Scientific discipline in the field of engineering and technical sciences (Regulation of the Ministry of Science and Higher Education of September 20, 2018)
- Objective: development and production (technology) of materials with defined properties intended for a specific application
- Interdisciplinary – inspired by other fields and disciplines

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# Material structure

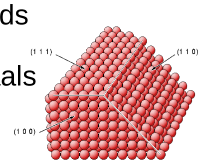
» **Nano-scale → structure (spatial arrangement of atoms and type of bonds)**

» Micro-scale → microstructure (phases, grain size, porosity)

» Macro-scale → macrostructure (fibers, granules, layers)

- **Interatomic forces** - chemical bonds
- primary: ionic, covalent, metallic;
- secondary: hydrogen, van der Waals

  **Arrangement of atoms** - crystal structure, structure

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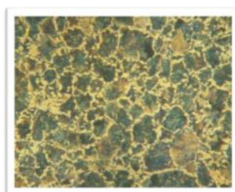
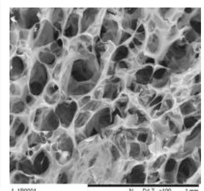
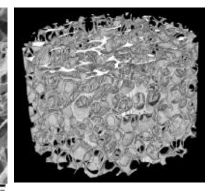



# Material structure

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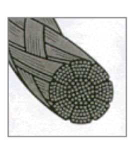
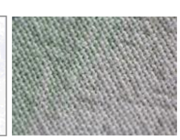
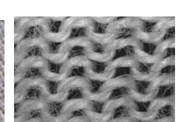
- » **Macro-scale → macrostructure (fibers, granules, layers)**

Fibers:
threads, fabrics,
knitted materials

→ in the context of the application

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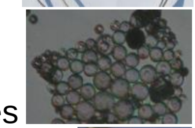
# Material properties

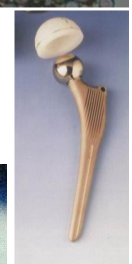
» **Electrical** - e.g. ability to receive and send electrical signals, electrodes in pacemakers)

» **Chemical** - e.g. material solubility / degradation in drug release systems; intelligent systems



» **Mechanical** - e.g. tribology of joint prostheses

» **Thermal** - e.g. thermal conductivity and heat capacity in large joint prostheses



» **Optical** - e.g. appropriate optical characteristics for an artificial lens

→ in the context of the application



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# Biomaterials engineering

Biomaterials engineering - an interdisciplinary field of knowledge drawing from medicine, biology, materials science and material technology, the aim of which is:

- design and production of biomaterials intended for specific applications
- testing the suitability of materials for medicine
- searching for correlation between the properties of the material and the response of a living organism
- solving practical problems (packaging, sterilization)
- procedures related to introducing medical devices on the market

# Biomateriały

*A biomaterial – is a nonviable material intended to interface with biological systems* in order to evaluate, treat, augment, or replace any tissue, organ or function of the body.*

* Definition stresses that biomaterial must be in a direct contact with cells/tissues/biological systems. e.g. elements of electronic device such as pacemaker (battery, electronics packed inside the pacemaker envelope) are not considered to be biomaterials;

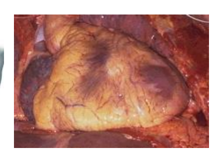

Williams DF, Black J, Doherty PJ. Second Consensus Conference on Definitions in Biomaterials of the European Society for Biomaterials Chester, England, 1987,



# Transplants and Implants

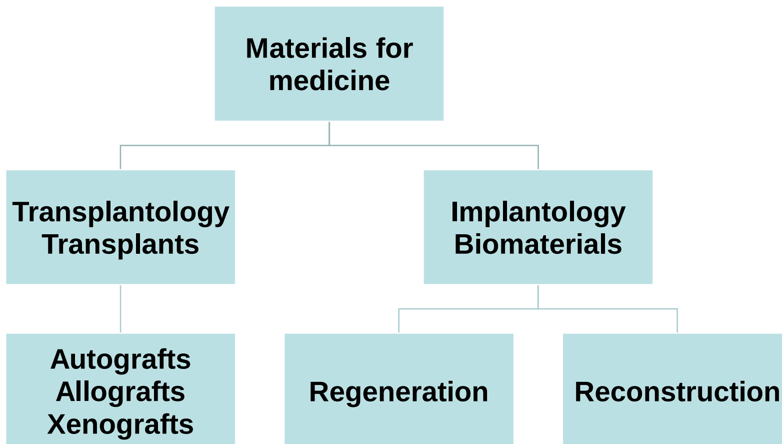
**Transplant** – material made of natural tissue in which blood circulation is restored after introduction into a living organism

→ autografts
→ allografts
→ xenografts



**Implant** – medical device produced from one of more biomaterials intentionally introduced into the body, located wholly or partially underneath the epithelium.

# Biomaterials

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# Medical devices

» ‘Medical device’ means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, **intended by the manufacturer to be used**, alone or in combination, for human beings**, for** one or more of the **specific medical purpose(s)** of:

» diagnosis, prevention, monitoring, treatment or alleviation of disease,

» diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

» investigation, replacement, modification, or support of the anatomy or of a physiological process,

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# Medical devices…continued

» supporting or sustaining life,
» control of conception,
» disinfection of medical devices
» providing information by means of in vitro examination of specimens derived from the human body;

**and does not achieve its primary intended action by pharmacological, immunological or metabolic means**, in or on the human body, but which may be assisted in its intended function by such means.



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# Medical devices

Medical device - is, for example, an implant, instrument, apparatus, in vitro reagent or related material used for the diagnosis, prevention or treatment of diseases or other pathological conditions; it is not a drug

- Implants
- Prostheses
- Artificial organs
- Drug and gene carriers
- Biosensors - materials for diagnostics, facilitating diagnostics and used in diagnostic tests

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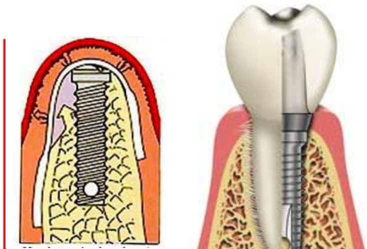
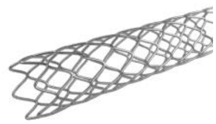
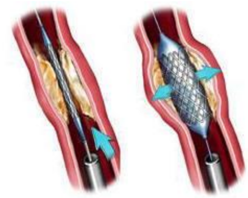
# Medical devices → different clinical situations

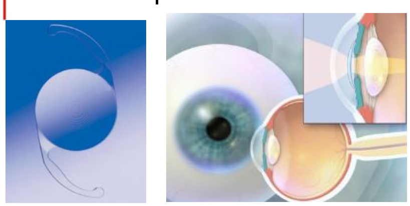


Dental implants

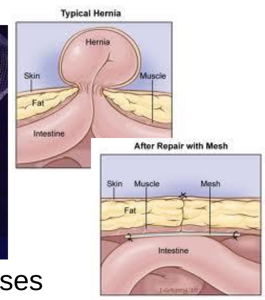




Cardiovascular stents



Intraocular lenses




Hernia prostheses



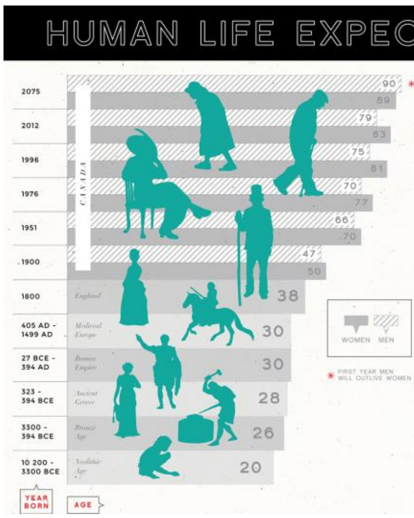
# Demand for biomaterials and medical devices

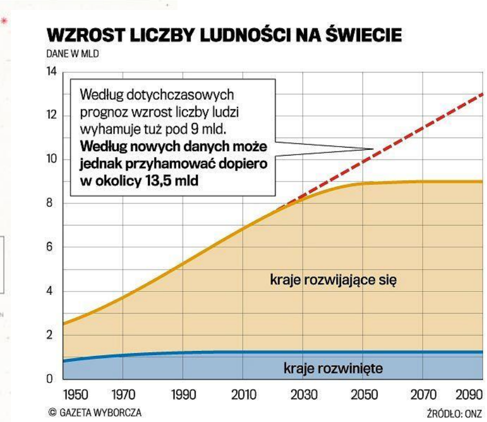
## Numbers of Medical Devices/yr. Worldwide

| | |
|---|---|
| intraocular lens | 7,000,000 |
| contact lens | 75,000,000 |
| vascular graft | 400,000 |
| hip and knee prostheses | 1,000,000 |
| catheter | 300,000,000 |
| heart valve | 200,000 |
| stent (cardiovascular) | >2,000,000 |
| breast implant | 300,000 |
| dental implant | 500,000 |
| pacemaker | 200,000 |
| renal dialyzer | 25,000,000 |
| left ventricular assist devices | 100,000 |

*Millions of lives saved. The quality of life improved for millions more.*

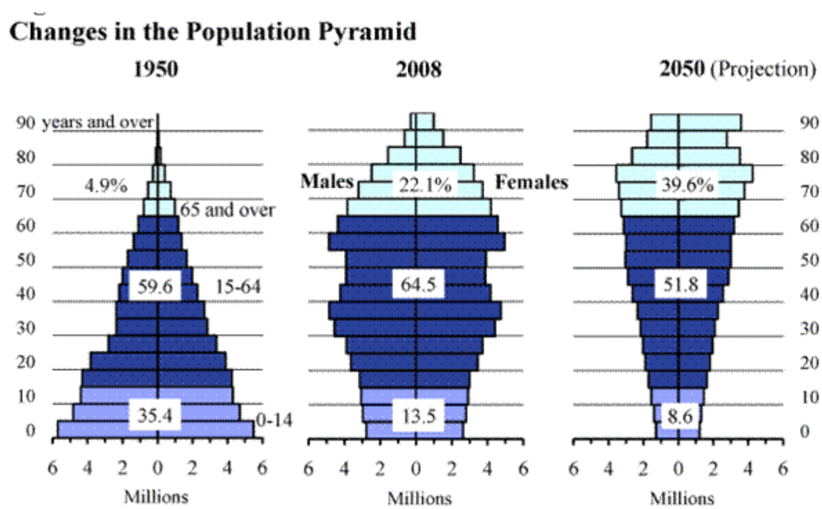
# Demand for biomaterials and medical devices






# Demand for biomaterials and medical devices




Source: Statistics Bureau, MIC; Ministry of Health, Labour and Welfare.

# Demand for biomaterials and medical devices

**Life-style diseases and injuries**

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# Biomaterials classification

» Type of tissues (bone, cartilage, nerves, mussles)

» Interation between biomaterial and tissues (biostable, degradable, resorbable)

» Medical field

(biomaterials for ophthalmology, laryngology, dentistry, orthopedic surgery, cardiac surgery, etc)

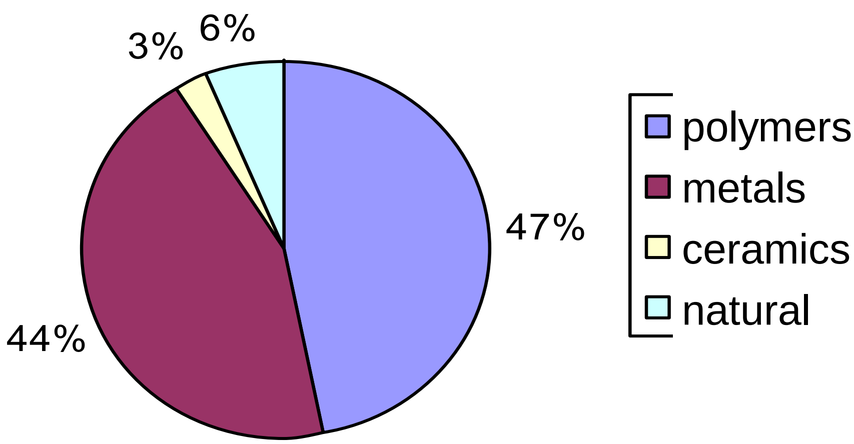
» Contact time with tissues

(temporary, permanent)

» Type of material

(metallic, polymer, ceramic, composite, natural origin)

# Biomaterials market

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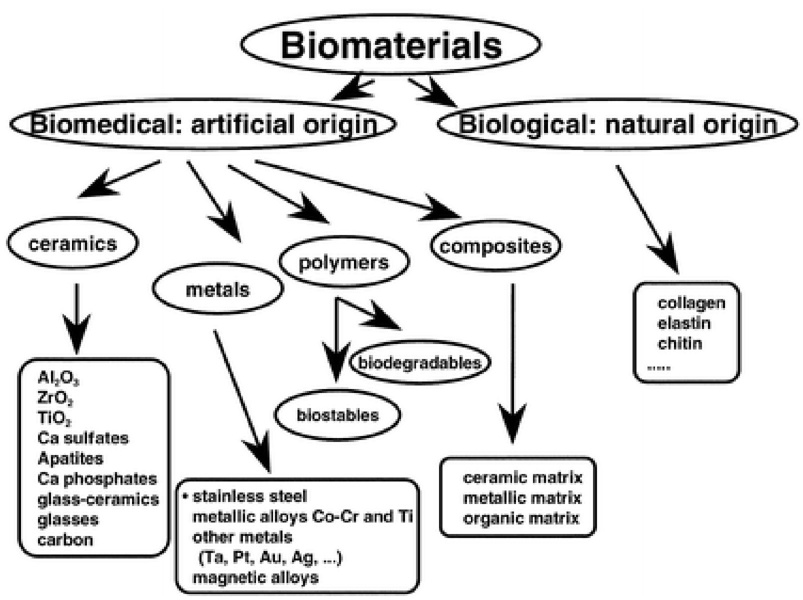
# Biomaterials classification



# Biomaterials

| Material | Pros | Cons | Examples |
|---|---|---|---|
| **Polymers** | Elasticity, easyprocessing | May undrego deformation, may degrade | Surgical sutures, prostheses of arteries, soft tissue filling materials, scaffolds for tissue engineering, drug delivery systems, components of artificial organs |
| **Metals and alloys** | Durability | Possible corrosion difficult in processing | Elements of artificial joints, dental implants, plates and screws for osteosynthesis |
| **Ceramics** | Biomompatible with bone | Fragile, low elongation and fracture toughness | Dental implants, bone tissue defects fillers |
| **Composites** | Possibility to tune different properties | Advanced manufacturing techniques needed | Elements of artificial joints, plates and screws for osteosynthesis |



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# Biocompatibility

*Consensus definition, 1987*

*Biocompatibility is the ability of a material to perform with an appropriate host response in a specific application.*

» Prerequisites of materials biocompatibility:

→ non-cytotoxic

→ non-cancerogenic

→ non-mutagenic

→ non-allegrgenic

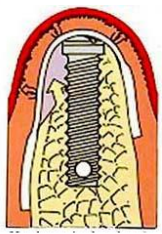


Williams DF, Black J, Doherty PJ. Second Consensus Conference on Definitions in Biomaterials of the European Society for Biomaterials Chester, England, 1987,
In: Doherty PJ, Williams RF, Williams DF, Lee AJC, editors. Biomaterial–tissue interfaces. Advances in Biomaterials,vol. 10. Amsterdam: Elsevier; 1992.

# Biocompatibility

*Biocompatibility is the ability of a material to perform with an appropriate host response* ***in a specific application.***

Dental implant



Osteointegration
Promotion of bone tissue growth

**Biocompatible in contact with bone**

Cardiovascular stent

Promotion of endothelialization

**Biocompatible in contact with arteries**

Hernia prosthesis

Overgrowth of connective tissue

**Biocompatible with soft tissue**

Intraocular lenses

Protein repulsive

**Biocompatible with eye**

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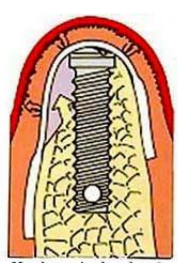
# Biocompatibility

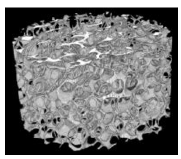
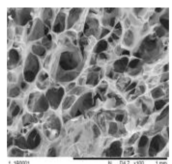
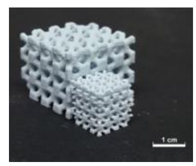
» *The biocompatibility of a long term implantable medical device refers to the ability of the device to perform its intended function, with the desired degree of incorporation in the host, without eliciting any undesirable local or systemic effects in that host*



On the mechanisms of biocompatibility
David F. Williams Biomaterials 29 (2008) 2941–2953

# Biocompatibility

» *The <u>biocompatibility of a scaffold or matrix for a tissue engineering product</u> refers to the ability to perform as a substrate that will support the appropriate cellular activity, including the facilitation of molecular and mechanical signalling systems, in order to optimise tissue regeneration, without eliciting any undesirable local or systemic responses in the eventual host.*



On the mechanisms of biocompatibility
David F. Williams Biomaterials 29 (2008) 2941–2953



# Biocompatibility

*the current definition, 2014*

» *<u>Biocompatibility</u> refers to the ability of a biomaterial to perform its desired function with respect to a medical therapy, without eliciting any undesirable local or systemic effects in the recipient or beneficiary of that therapy, but generating the most appropriate beneficial cellular or tissue response in that specific situation, and optimising the clinically relevant performance of that therapy.*



David Williams Essential Biomaterials Science, Cambridge University Press, 2014

# Factors influencing biocompatibility

Chemical structure, micro- and nanostructure, morphology
Crystallinity
Mechnaical properties, elastic constant
Electrical properties
Water content
Size: bulky, microparticulate, molecular

Hydrophilic/hydrophobic properties
Surface free energy
Surface chemistry
Topography

Corrosion and degradation processes
Degradation products, leachable substances

Materials Engineering

Biomaterials Engineering



# Interdisciplinary Aspects of Materials Engineeing
## Biomaterials

» Introduction
» **Historical overview**
» Three generations of biomaterials
» Latest generation biomaterials – in XXI century

# Biomaterials – 7000 years of history

Toe prosthesis made of wood and leather, Ancient Egypt 1550-700 BC

An eyeball prosthesis made of bitumen was covered with a layer of gold, ancient Iran 2900 BC

H..F. Hildebrand, BioNanoMat 2013,14(3-4), 119-133

# Biomaterials – 7000 years of history

Dental prostheses * attached with gold wires, Phoenician civilization

Dental prostheses * attached with gold bands, Etruscan civilization

* teeth were obtained from sheep or dogs

H..F. Hildebrand, BioNanoMat 2013,14(3-4), 119-133

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# Biomaterials – 7000 years of history

Tooth prosthesis - an implant made of iron; Gallo-Roman necropolis, Chatambre, France, 1st-2nd century AD

Cranioplasty with golden plate Peru, ca 4th century AD.

H..F. Hildebrand, BioNanoMat 2013,14(3-4), 119-133



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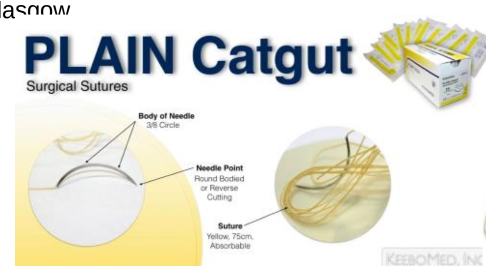
# Biomaterials – 7000 years of history… and present times


Galen of Pergamon, (130-200 AD), reported that silk or catgut (threads made of twisted bovine tendons) were used to sew severed gladiatorial tendons.

Catgut sutures prepared by Sir Joseph Lister, XIX century. Glasgow

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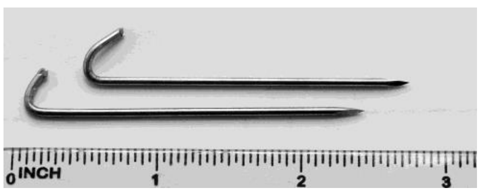
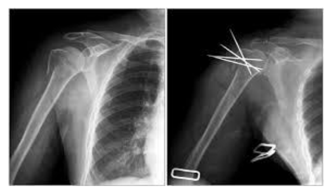
# Biomaterials – history and present times

Beginning of the 20th century - steel screws, wires, plates for connecting bones, Kirschner wires (1909)

Martin Kirschner (1879-1942)

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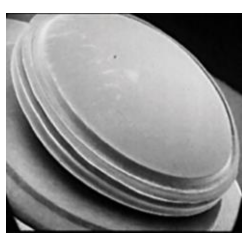
# Biomaterials – history and present times

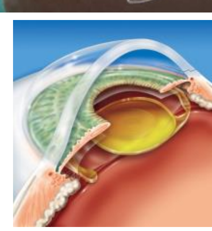
1949 Acrylate polymers (PMMA) intraocular lenses for the treatment of cataracts

Sir Harold Ridley
1906 –2001



Ridley's lens

**Nowadays Poly (2-hydroxyethyl methacrylate) polyHEMA**



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# Biomaterials – history and present times

1958 - the first vascular prostheses from polyester fabrics dacron (PET)

Michael E. DeBakey, M.D.
1908 –2008

Currently used knitted dacron (PET) blood vessel prostheses

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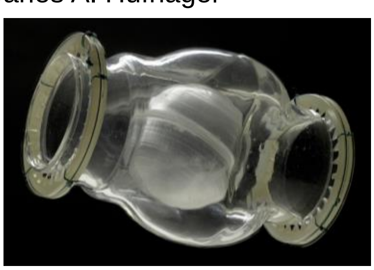
http://www.houston.va.gov/debakey.asp



# Biomaterials – history and present times

1952 – first heart valve
Carles A. Hufnagel



**Currently used heart valves**

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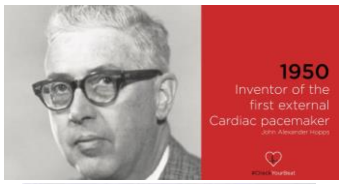
# Biomaterials – history and present times

1949 – the first implantable cardiac pacemaker
– John Hopps





**Currently used cardiac pacemaker**





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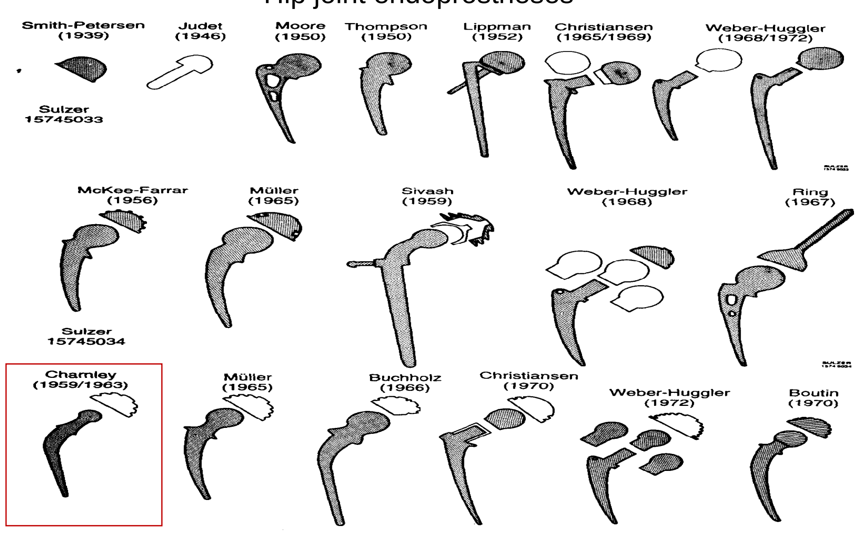
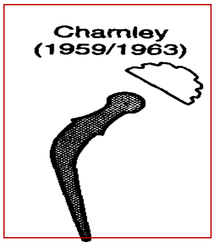
# Biomaterials – history and present times

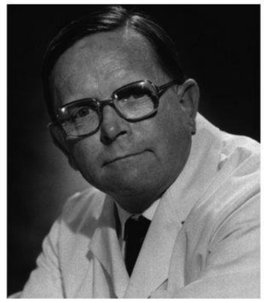
Hip joint endoprostheses



# Biomaterials – history and present times

Hip joint endoprostheses



Sir John Charnley - a pioneer of total cement arthroplasty



# Biomaterials – history and present times

**Endoprotezy stawu biodrowego**

<u>Head:</u>
316L medical steel
Co-Cr-Mo alloys
alumina or zirconium ceramics
<u>Cup:</u>
polyethylene (UHMWPE)
<u>Stem:</u>
316L medical steel
Co-Cr-Mo alloys
titanium and titanium
alloys composite materials

# Biomaterials – history and present times

» 1970s - creation of a new field of science - **biomaterials engineering**

» Introduction to the medical market in addition to metals and alloys, polymeric, ceramic and carbon materials and their composites for the construction of medical devices



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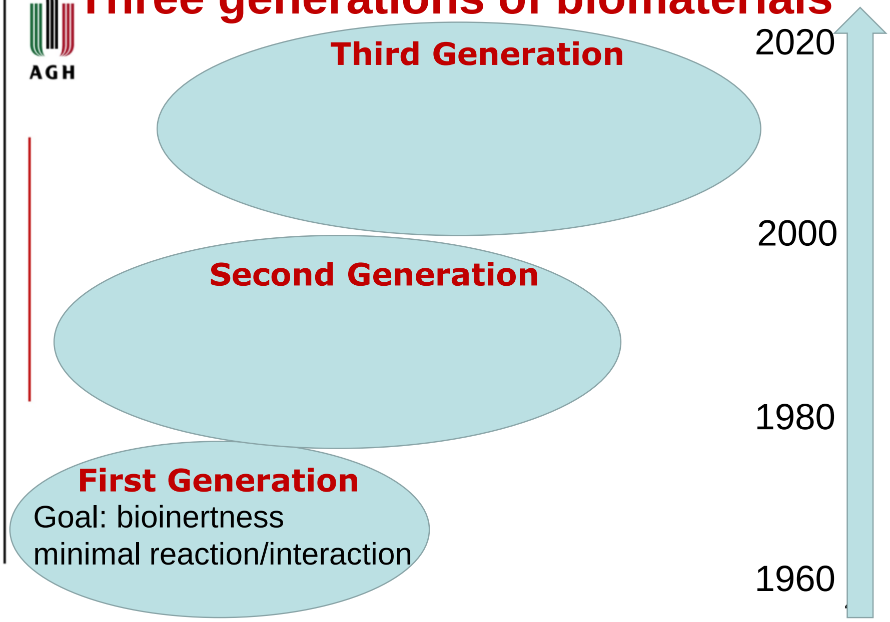
## Three generations of biomaterials





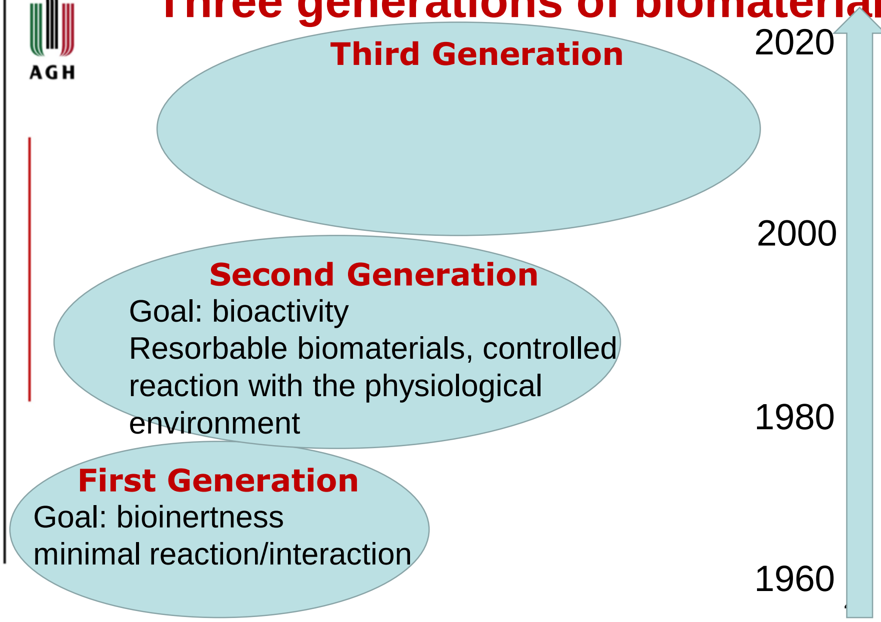

## Biomaterials – the first generation 1960’- 1980’

» Goal – achieve a suitable combination of functional properties to adequately match those of the replaced tissue without deterious response of the host.

» **Goal → bioinertness (minimal response from the tissue)**

» Examples: silicone rubber, pyrolytic carbon, stainless steel, titanim alloys

## Three generations of biomaterials






## Biomaterials – the second generation 1980’- 2000’

» Goal – elicit a controlled reaction with the tissues into which they were implanted in order to induce a desired therapeutic effect.

» **Goal → bioactivity and degradation**

» Resorbable biomaterials, controlled reaction with the physiological environment (bioactive glass), e.g bone bonding, drug release

» Examples: bioactive glasses,

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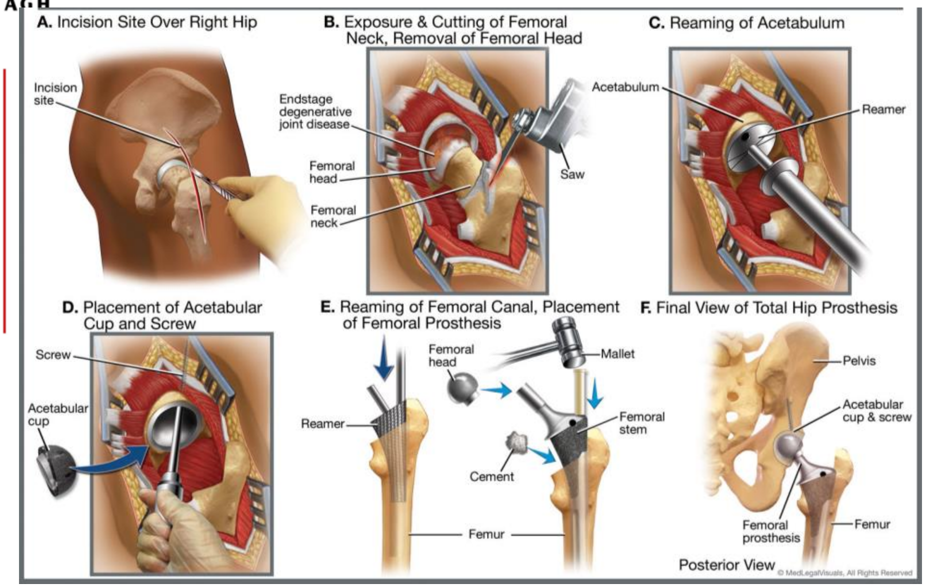
# Hip endoprosthesis – implantation



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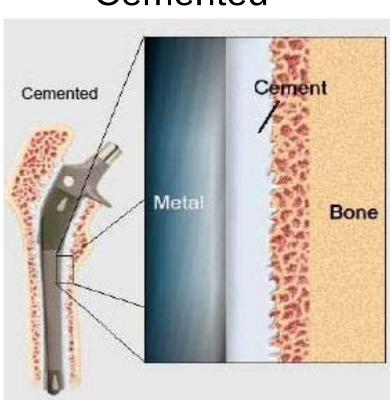
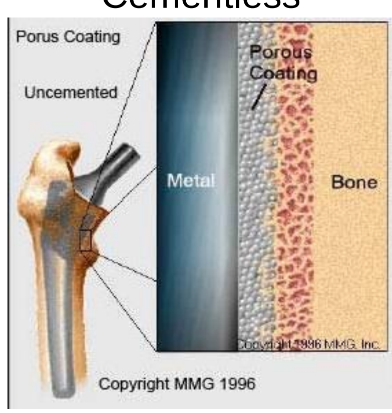
# Hip endoprostheses

## Cemented




Fixing the stem with a cement that penetrates into the pores of the bone tissue

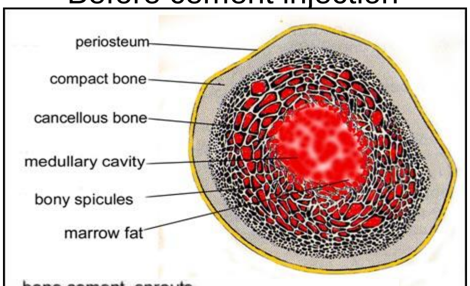
## Cementless



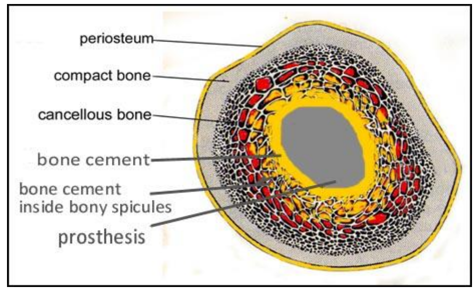

Osseointegration, i.e. the creation of a direct chemical bond between the implant and bone tissue

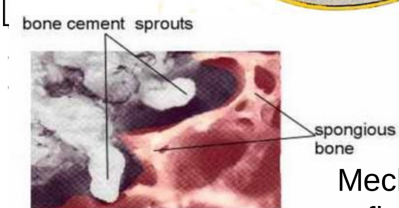
# Hip endoprosthesis - cemented

Before cement injection




After cement injection



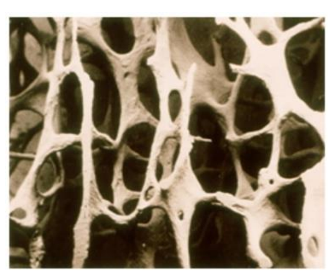

Mechanical fixation

The cement penetrates into the pores of the spongy bone tissue and stabilizes the stem in the bone canal

# Hip endoprosthesis - cemented

- Smooth stem (if it were rough, micromovements would damage the cement)

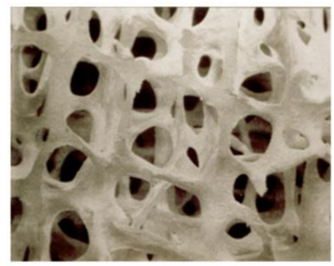
- Hole to be easily removed if revision becomes necessary (revision operation)
- Purpose - for osteoporotic bone; the patient can load the limb immediately after the procedure



Osteoporotic bone

## Hip endoprosthesis - cementless

- Rough, porous stem, modified with hydroxyapatite to facilitate the adhesion of osteoblasts and their formation of a direct implant / bone connection
- Application - to healthy bone; the patient cannot load he limb immediately after the procedure, longer rehabilitation is necessary



Healthy bone



## Three generations of biomaterials

2020

**Third Generation**
Goal: regenerate functional tissue
Biointeractive, integrative, resorbable, stimulate specific cell response at the molecular level

2000

**Second Generation**
Goal: bioactivity
Resorbable biomaterials, controlled reaction with the physiological environment

1980

**First Generation**
Goal: bioinertness
minimal reaction/interaction

1960

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## Biomaterials – the third generation since 2000’

» **Goal – regenerate functional tissue**

» Biointeractive, integrative, resorbable, stimulate specific cell response at the molecular level (i.e. proliferation, differentiation, ECM productiona nd organization

» Examples: materials for tissue regeneration, e.g. artificial skin - Integra, guided tissue regeneration membranes (dentistry, oral surgery, cartilage regeneration)



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## Biomaterials – the third generation *guided tissue regeneration*

Materials bioengineering, materials designed to elicit a specific cellular response, surface bioengineering, biomimetic microstructure

Examples: Integra - artificial skin
GTR technique in dentistry

**Purpose - regeneration of functional tissue**

# *Integra** - artificial skin

**Inner Layer**:

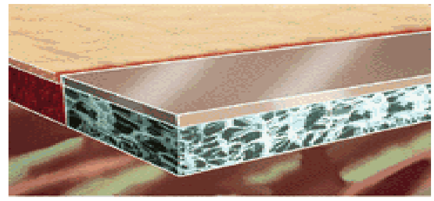
Type I collagen and glycosaminoglycans

*It is a scaffold for newly formed blood vessels and skin cells*

**Outer Layer**:

Silicone membrane

*It protects against infection, closes the wound, and prevents heat loss*



http://www.integra-ls.compdf



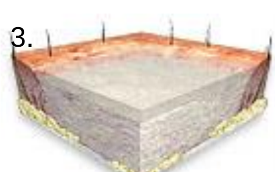
# *Integra®* - application

1.

Burned skin

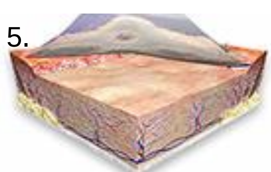
2.

Excision

3.

Integra placement

4.

Cell infiltration (7-14 days)

5.

Removal siliconmembrane (ca. 21 days)

6.

Epidermis transplant (ok. 21 dni)

7.

Completion of the healing process(25-56 days)

http://www.integra-ls.compdf

# *Integra®* - application

CASE 1

*Left:* Two-year-old neck scar contracture before INTEGRA template treatment

*Right:* Neck 1.5 years after contracture release and treatment with INTEGRA template

CASE 3

*Left:* Hand scar contracture before INTEGRA template treatment

*Right:* 5 weeks after release and treatment with INTEGRA template patient regained functional use of hand



http://www.integra-ls.compdf

# *Integra®* - product

**Ordering Information**

| Catalog Number | Description | Unit of Measure |
|---|---|---|
| IAS4051 | INTEGRA Dermal Regeneration Template, 4" x 5" | 1 Sheet |
| IAS405 | INTEGRA Dermal Regeneration Template, 4" x 5" | 5 Sheets/Case |
| IAS4101 | INTEGRA Dermal Regeneration Template, 4" x 10" | 1 Sheet |
| IAS410 | INTEGRA Dermal Regeneration Template, 4" x 10" | 5 Sheets/Case |
| IAS8101 | INTEGRA Dermal Regeneration Template, 8" x 10" | 1 Sheet |
| IAS810 | INTEGRA Dermal Regeneration Template, 8" x 10" | 5 Sheets/Case |

The sale of INTEGRA template is restricted to physicians who have completed the INTEGRA Physicians Training Module.

To place an order for INTEGRA template products, please call the Integra LifeSciences Call Center at 877-444-1122 or 609-275-9004, Monday–Friday, 8:30 AM to 5:30 PM (EST).

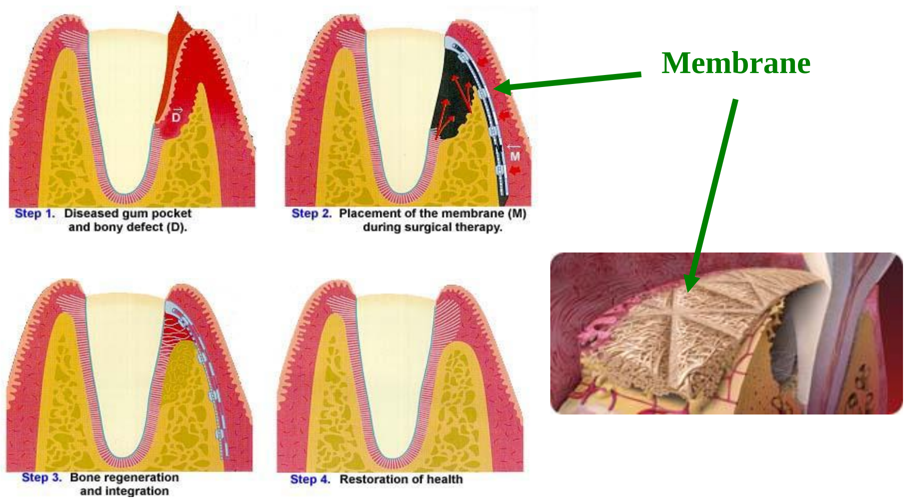


£1400 (8 cm × 10 cm)



http://www.integra-ls.compdf

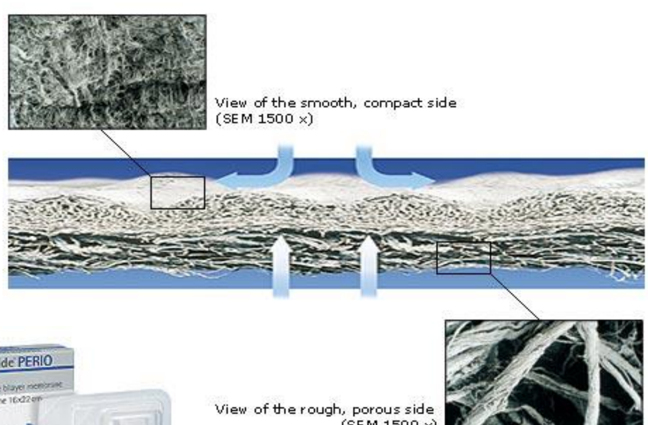
# Guided tissue regeneration (GTR) in periodontology




http://www.periodont.com/perio.htm



# Guided tissue regeneration (GTR) in periodontology





**Bio-Gide® – collagen membrane**

http://www.geistlich.com/biomaterials/en/dental/index.html

## Guided bone regeneration (GBR) in periodontology

**Bio-Oss® collagen** – collagen – hydroxyapatite sponge

Shape formation respective to the size of the defect

http://www.geistlich.com/biomaterials/en/dental/index.html



## Interdisciplinary Aspects of Materials Engineeing
## Biomaterials

- » Introduction
- » Historical overview
- » Three generations of biomaterials
- » **Latest generation biomaterials – in XXI century**

# Biomaterials - the latest generation

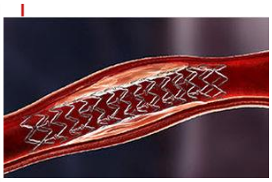
## Local drug delivery - implants

Implants

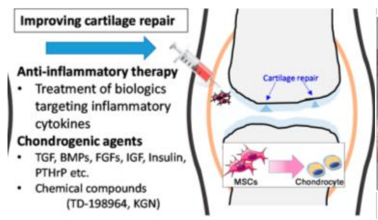
PMMA beads loaded with gentamycin

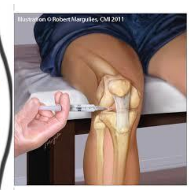
Dental implants coated with ldrugs improving osteointegration

Hydrigel injections

Stents coated with drugs preventing restenosis



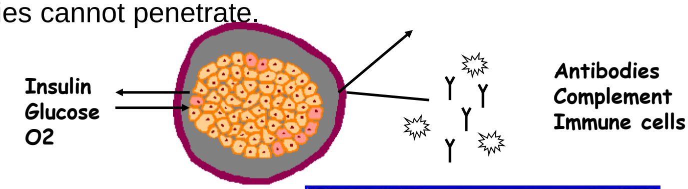



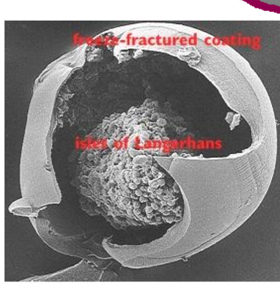


# Biomaterials - the latest generation

## Hybrid organs – cell immunoizolation

Pancreatic cell encapsulation (pancreatic islets of Langerhans) - creating a layer that is permeable to glucose, oxygen and insulin, through which cells of the immune system and the patient's antibodies cannot penetrate.

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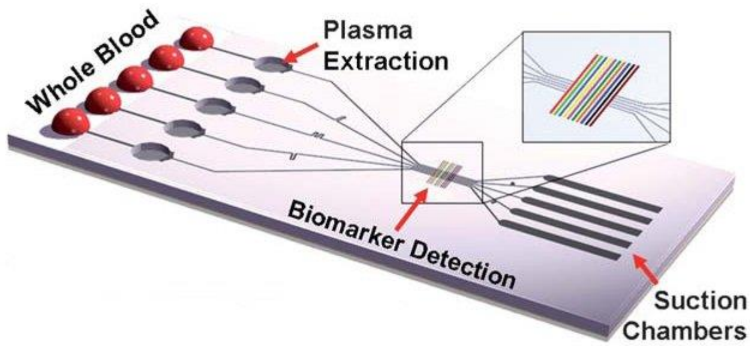
## Biomaterials - the latest generation

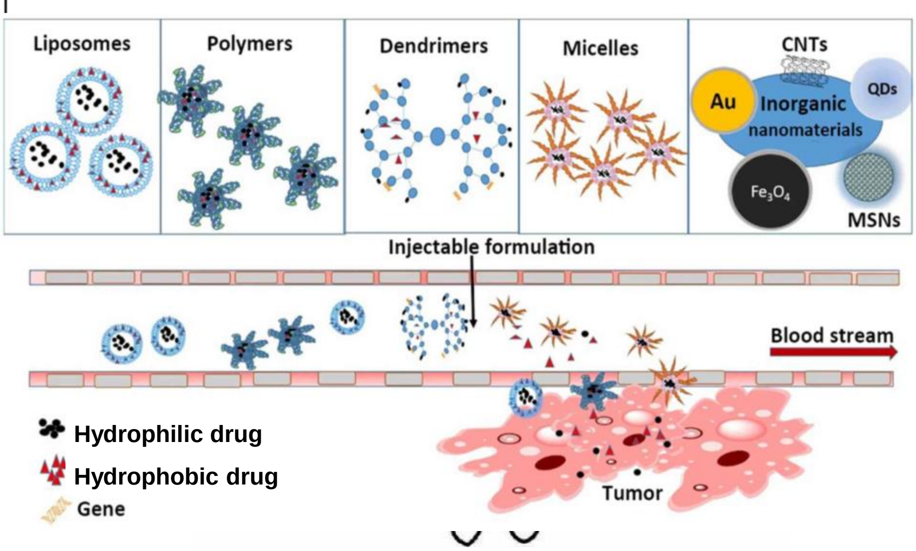
**Laboratory on a chip**, LOC (lab-on-a-chip) - a miniature analytical device, usually flat, ranging in size from a few millimeters to several square centimeters; it has flow channels into which a liquid sample is introduced, often also electromechanical microelements that allow you to control the flow or read the result.





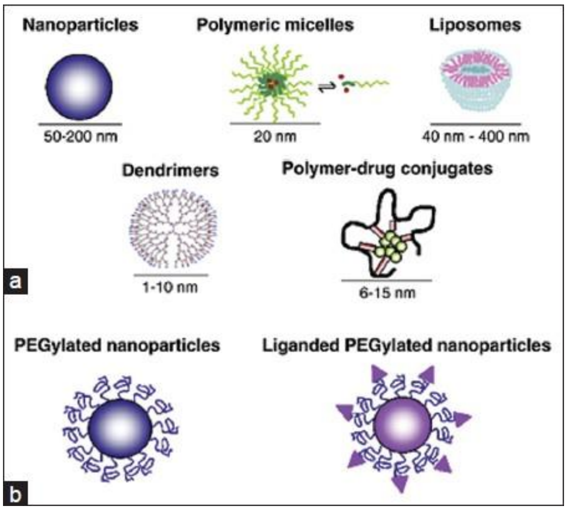

## Biomaterials - the latest generation

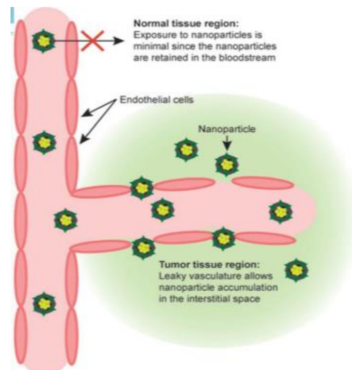
### Drug nanocarriers in cancer therapies



# Biomaterials - the latest generation

## Drug nanocarriers in cancer therapies






# Regenerative Medicine

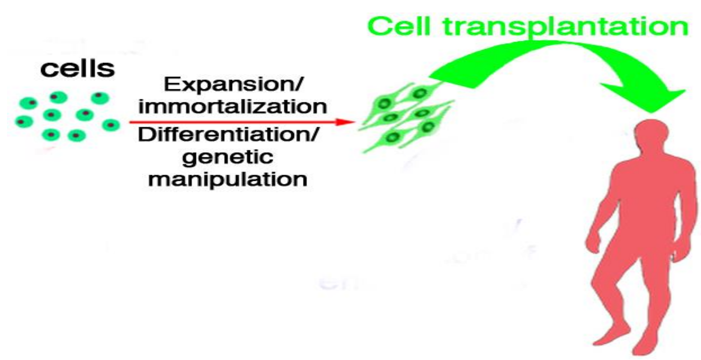
Regenerative medicine is a new field of clinical medicine that focuses on new approaches to autologous repair and / or replacement of cells, tissues and organs.

- Cell therapy
- Gene therapy
- Stimulation of endogenous repair processes using biomolecules (e.g. growth factors)
- Tissue engineering

# Regenerative Medicine

- **Cell therapy**

→ The use of stem cells without differentiation or differentiated in the right direction with biologically active factors



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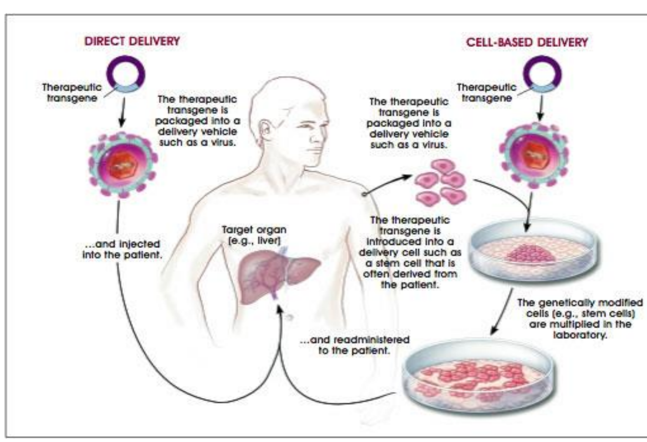
# Regenerative Medicine

- **Gene therapy**

→ Treatment of patients by introducing foreign genes into cells



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# Regenerative Medicine

- Stimulation of endogenous repair processes using biomolecules (e.g. growth factors)


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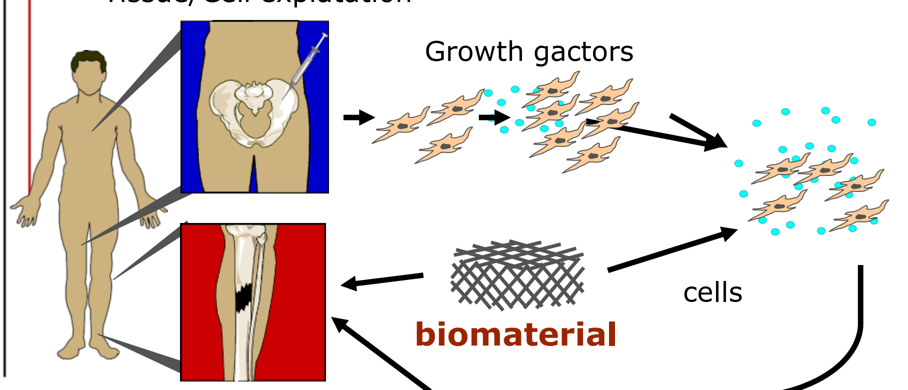
# Regenerative Medicine

- **Tissue engineering**

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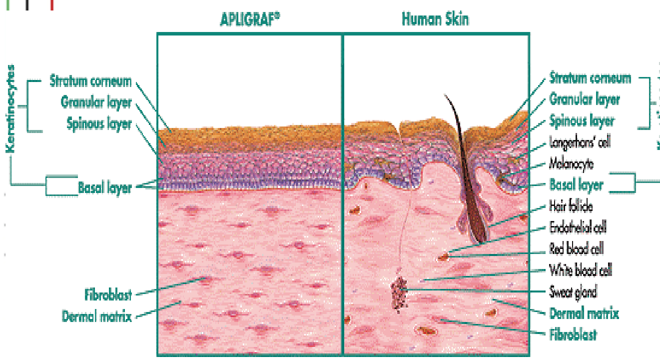
www.owlnet.rice.edu/~bioe531

# Tissue engineering products – Artificial skin

## Apligraf®

Two-layer skin substitute
Inner layer (dermis) - fibroblasts suspended in a collagen matrix
Outer layer (epidermis) - keratinocytes




http://www.organogenesis.com

# Tissue engineering products – Artificial skin

## Apligraf®

➢ treatment of leg ulcers

www.agh.edu.pl

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www.agh.edu.pl

# Tissue engineering products – Artificial skin

## Apligraf®

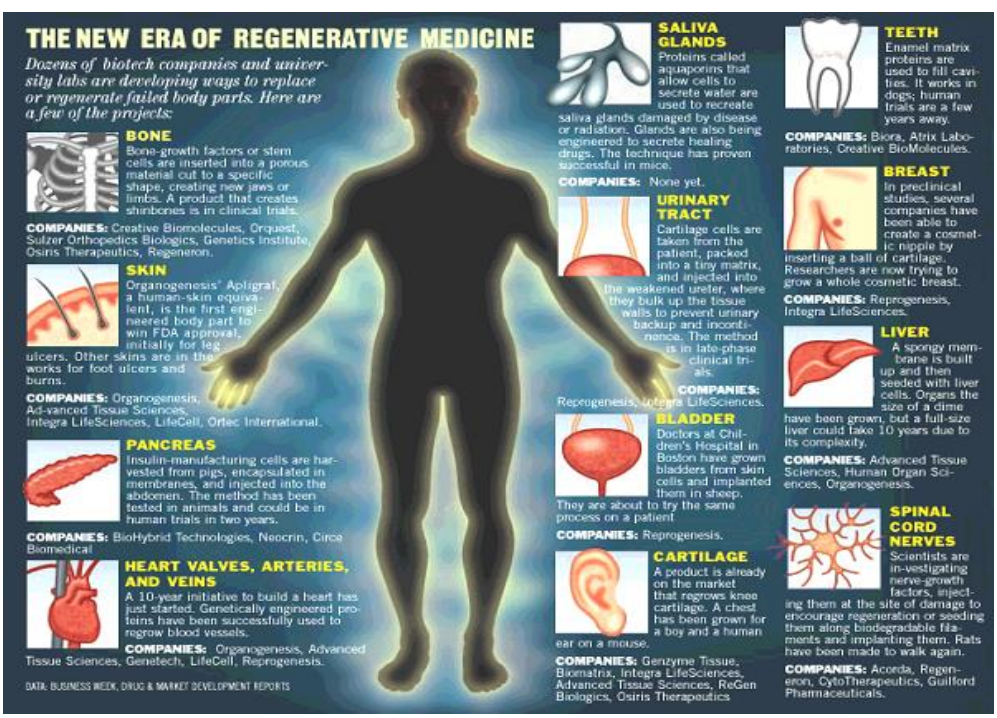
- Diabetic foot ulcers


5 weeks

16 weeks

| | |
|---|---|
| **Patient:** | **H.A.***<br>Diabetic foot ulcer |
| **Age**: | 51 years old |
| **Sex:** | Male |
| **Duration of the condition**: | 2 years |

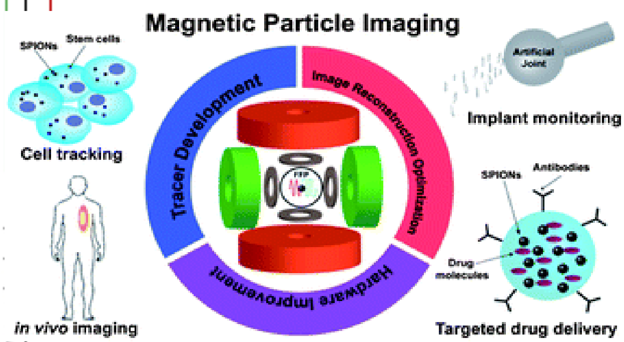
http://www.organogenesis.com/content/casestud_dfu_aipstein.htm

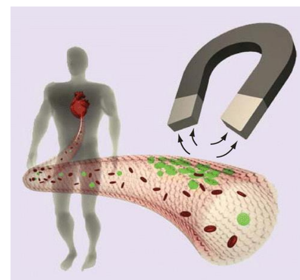


## Biomaterials - the latest generation

### Nanotechnology in medicine - Nanomedicine

» New methods of diagnosis and treatment (e.g. visualization, hyperthermia)



Magnetic nanoparticles, gold nanoparticles, silver nanoparticles, carbon nanoforms, quantum dots

## Biomaterials

**Biomaterials can be:**

» Macroscopic or nanoparticulate

» Solid ort liquid

» Manufactured or self-assambled *in situ*

***There are no chemical or structural limitations to what may constitute a biomaterial***

David Williams Essential Biomaterials Science, Cambridge University Press, 2014

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# Biomaterial

*the current definition, 2014*

*Biomaterial - a substance that has been engineeried to take a form which, alone or as a part of a complex system, is used to direct, by control of interations with components of living systems, the course of any therapeutic or diagnostic procedure*.*

*Procedures involve the replacement, repair or regeneration of tissues and organs, the control of the delivery of active molecules to patients, ot the technologies of diagnosis and imaging



David Williams Essential Biomaterials Science, Cambridge University Press, 2014

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# Interdisciplinary Aspects of Materials Engineeing Biomaterials

» Introduction
» Historical overview
» Three generations of biomaterials
» Latest generation biomaterials – in XXI century



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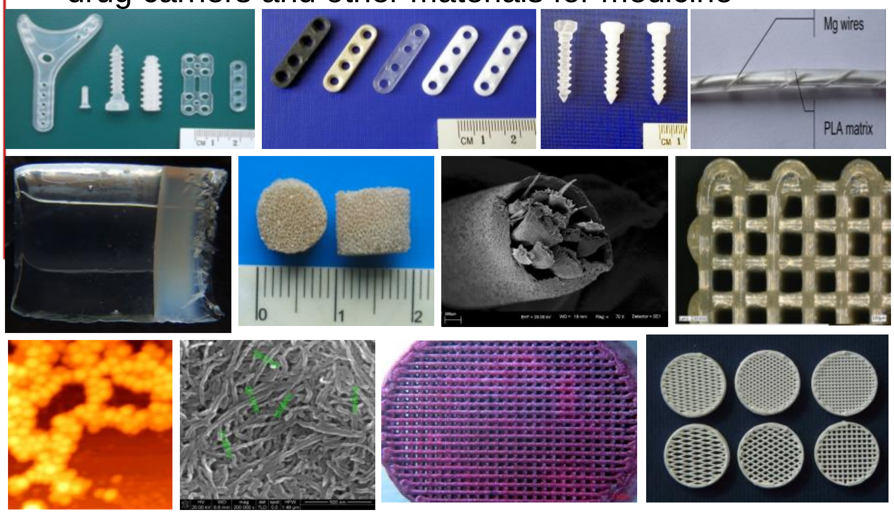
## What we are doing at the Department of Biomaterials and Composites?

» Design, manufacturing and testing of implant materials, drug carriers and other materials for medicine



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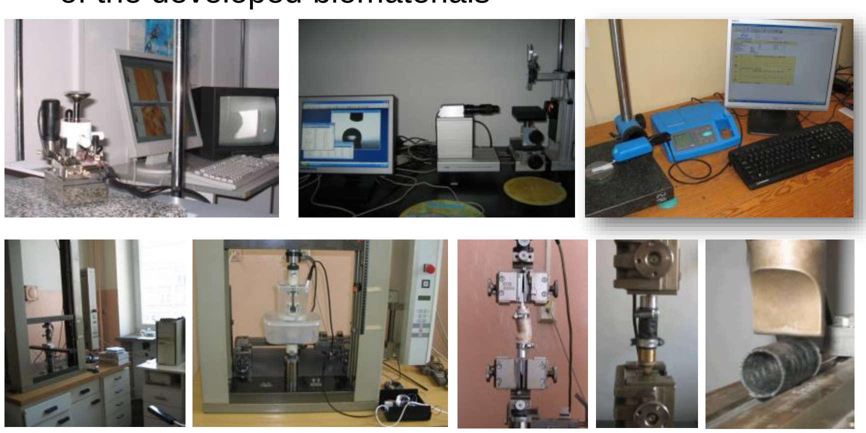
## What we are doing at the Department of Biomaterials and Composites?

» Study of the structure and physicochemical properties of the developed biomaterials



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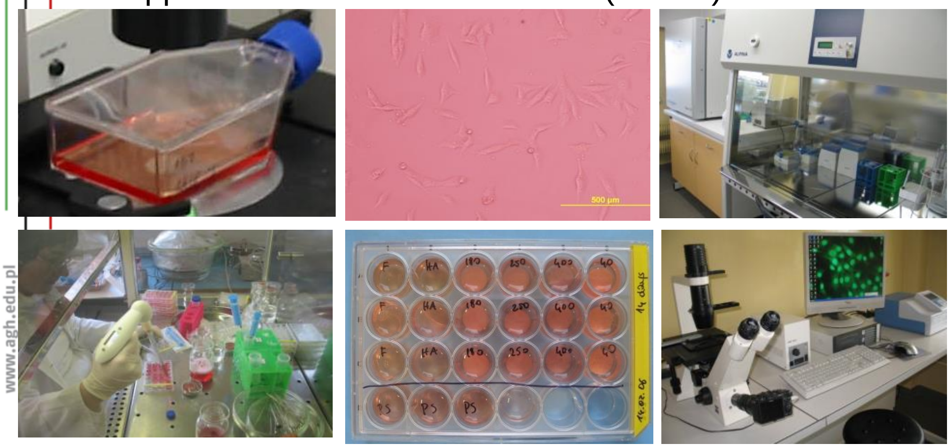
## What we are doing at the Department of Biomaterials and Composites?

» Biocompatibility tests of materials for medical applications in contact with cells (in vitro)



www.agh.edu.pl

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*Thank you for your attention*

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