bioPmed

PIEMONTE INNOVATION CLUSTER

Health care: trends, priorities and relations with textiles

Fabrizio Conicella – Audrey Dayon

Contents

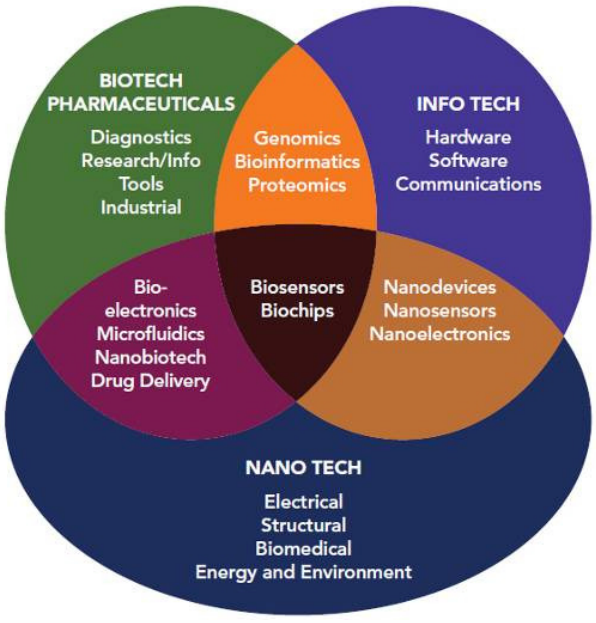
- Health care trends
- Textile and biomedical fields
- Opportunities for the future

Health: key trends for the future

- Cost pressure
- Ageing and chronic diseases
- Infection Control
- Safety of the patient and healthcare staff
- Social inclusions
- Economic growth rate and Structural changes in our economic systems
- Brain drain
- Bioeconomy and Environmental Stewardship
- **Converging technologies**

Converging technologies

And innovative textiles solutions??



Gràfic: Biotech 2009: Life Sciences, Navigating the Sea Change, Burrill & Company, 2009.
Font original: Technology Convergence Consortium TC2

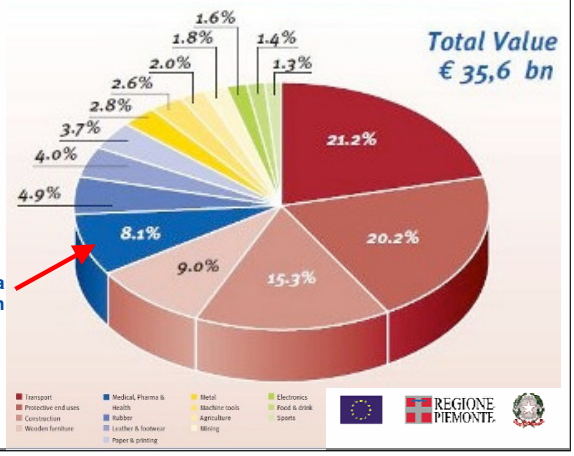
Trends

Textile market

- In Europe, growth of Technical textiles market from 65 to **85 billion €** from 1995 to 2005.
- 8.5 million tonnes, half of global technical textile production, is consumed in Asia, followed by US (5.8 million tonnes) and Europe (4.8 million tonnes).
- In Europe four countries consume about half of the technical textiles in terms of value: Germany, France, the UK and Italy.
- The technical textiles industry in Germany represents 45% of the European textile industry, followed by France (30%), UK (30%) and Italy (12%).
- Smart textiles to see rapid growth to 2012
- Health care → market opportunity

http://www.tikp.co.uk/knowledge/market-sectors/medical-and-hygiene/market-information/

Technical fibre use across the Technical Textile Sectors



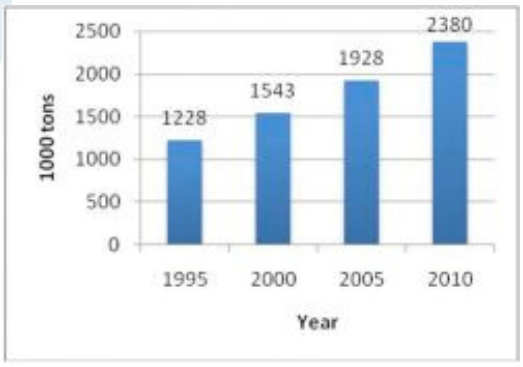
Medical, Pharma & Health

Trends

Medical textile market

- Medical Textiles are one of the faster growing sectors of the global Technical Textile industry.
- The global market for medical textiles was about **$8 billion** in 2007
- Every year this niche market becomes more relevant and its importance will increase even more in the future

World consumption of medical textiles (1995-2010)



Source: Development of Medical Textile Market, Robert Czajka , 2005

Trends

Medical textile market

- Advancements in textile technologies A driver of innovation for medical device industry
- New materials (Advanced polymers) More choice and flexibility in design
- Search of less invasive products
- Orthopaedic soft tissue repair market: from US$920 million (2009) to US$1.6 billion (2016)

Soft Power: How Biomedical Textiles Are Driving Innovation in Orthopaedics

Creating Value with Biomedical Textiles Leads to Innovative Quality Practices

By Carola Hansen, Business Manager for Dyneema Purity® fiber of DSM, and Kevin Johnson, Director of Quality Assurance and Regulatory Affairs, Biomedical Structures LLC

Over the last few years, much of the innovation in the medical device industry has been fueled by advancements in fiber and other textile technologies specifically designed for use inside the human body. These medical textile breakthroughs have supported a broad array of implantable devices ranging from vascular grafts and surgical mesh to heart valve components and orthopaedic sutures to fabric scaffolds designed to aid in tissue engineering. The fabrics these applications are built upon help deliver more life-like products with the potential to perform better, last longer, and increase comfort in the body—all of which can potentially significantly improve outcomes for patients.

Source:Quality Matters: Creating Value with Biomedical Textiles Leads to Innovative Quality Practices, Biomedical Structures LLC, 2012

Converging technologies

MEDICAL TEXTILE:

→ Antibacterial textiles

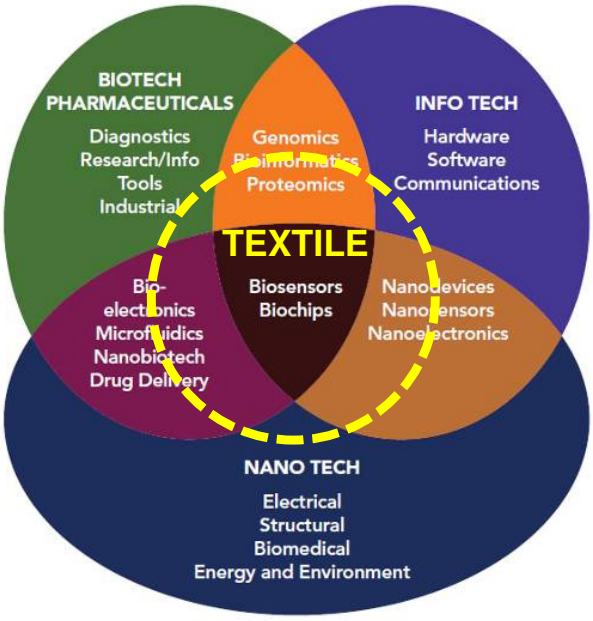
→ Antimicrobial wound dressings

→Anti-adhesive wound dressings

→**Implants**

→**Nanotech and Materials**

→**Medical Smart Textiles:** integration with electronic devices, including sensing, monitoring and information processing tools, able to react to the conditions and stimuli, like the mechanical, thermal, chemical, electrical, transmitted by the wearer. Es. → **Telemedecine**



http://www.newclothmarketonline.com/nanotechnology-textiles-medical-textiles-sportoutdoor-textiles/

Gràfic: Biotech 2009: Life Sciences, Navigating the Sea Change, Burrill & Company, 2009.
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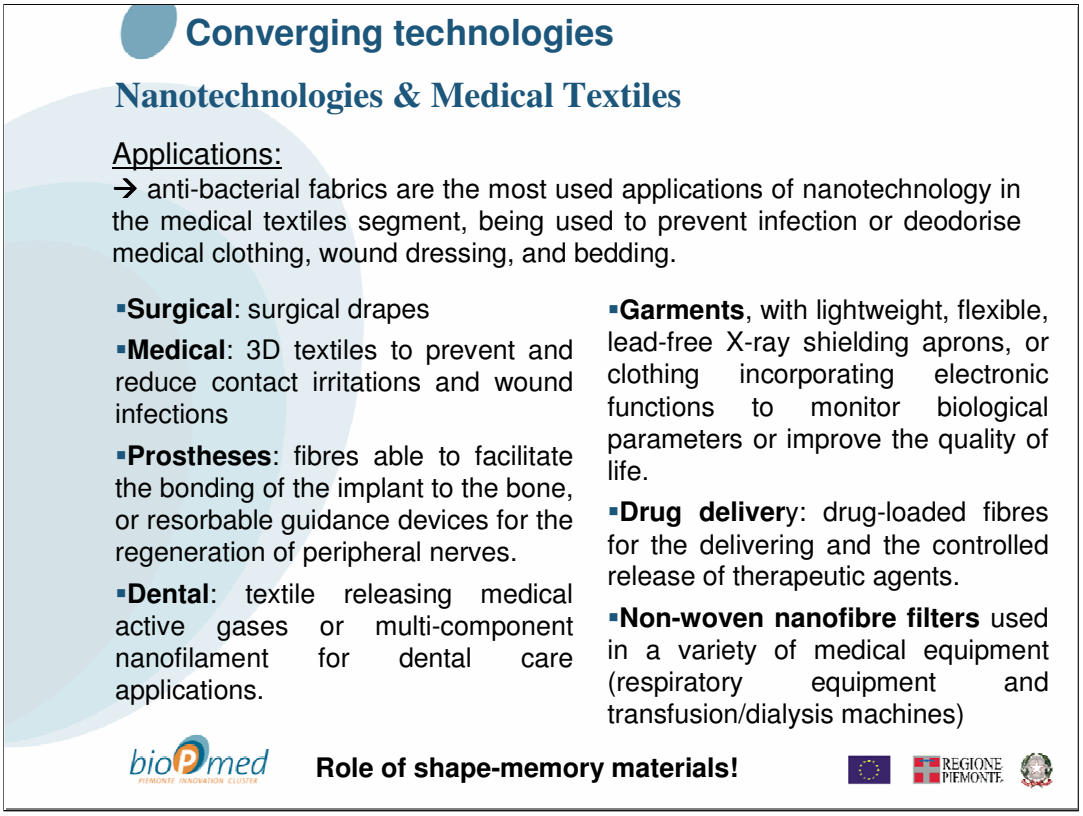


Woven intrecciato/tessuto

Shape memory materials specifically polymers recover their original shapes upon exposure to an external stimulus such as heat, moisture, light or a magnetic field.

ES: Woven fabric with shape memory element strands
US 8177834 B2

Abstract

The disclosure relates to a woven fabric for use in an implantable medical device. The woven fabric comprises shape memory element strands woven with textile strands. At least one of the shape memory element strands has at least one float of at least five textile strands between binding points.

Converging technologies

Nanotechnologies & Textile

Drivers and barriers

Medical textiles must fulfil **specific characteristics**: non-toxicity, noncarcinogenic, non-allergic and sterilisation capability, without suffering chemical or physical damage.

→main driver to use **nanotechnology** as a promising way of obtaining the desired performance requirements while retaining the key textile features/properties.

→The **environmental factor** is a key aspect to take into account. Nanotechnologies can have beneficial effects on the environment, but their use can also raise concerns for the potential harmful impact on it.

→The need to assure the **safety** for the wearer of these types of garments is fundamental for the acceptance/success of these products on the open market.

Biomedical textile

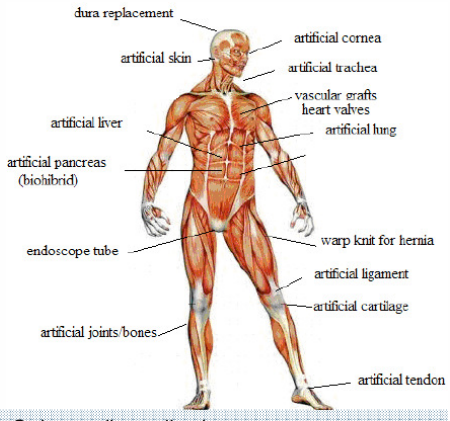
- Combination of Textile Technology and Medical Sciences
- Textile products and constructions, for medical and biological applications

Non-implantable: bandage, wound dressing, plaster...

Implantable: sutures, ligaments, hernia repair-related tissue, **dental implant**, **orthopaedic implant**, vascular grafts, surgical mesh, heart valves, artificial skin, cartilage, stents...

Extracorporeal: devices used to support the function of vital organs (kidney, liver, lung...)

Textiles for healthcare and hygiene-related usage



Orthopaedic applications:

- Internal stabilisation of a long bone fracture
- Annular repair
- Dynamic stabilisation of the spine
- Musculoskeletal repair

Source: Implantable Medical textiles: characterization and applications, Scarlet et al., 2010

Biomedical textile

Why textile implants?

- Biocompatible materials
- Material combinations
- 2D- and 3D-structures
- Mechanical characteristic adapted to the environment
- Adjustable macroscopic structure
- Specific surface design
- Controllable degradation

Biomedical textile

Main factors for biomedical textile:

•**Function:** the textile needs to fulfil the purpose for which it was designed, for example swabs require an absorbent textile, sutures may require a biodegradable textile, while hospital bedding should be comfortable and durable.

•**Biocompatibility**: this refers to the reaction of the textile with blood and tissue in the body. An implantable device has more potential for reaction than an external device and is, therefore, subject to tighter regulations. For example an artificial ligament is permanent and is able to react with blood cells and the surrounding tissue, compared to an external bandage that is temporary and only contacts the outer skin tissue.

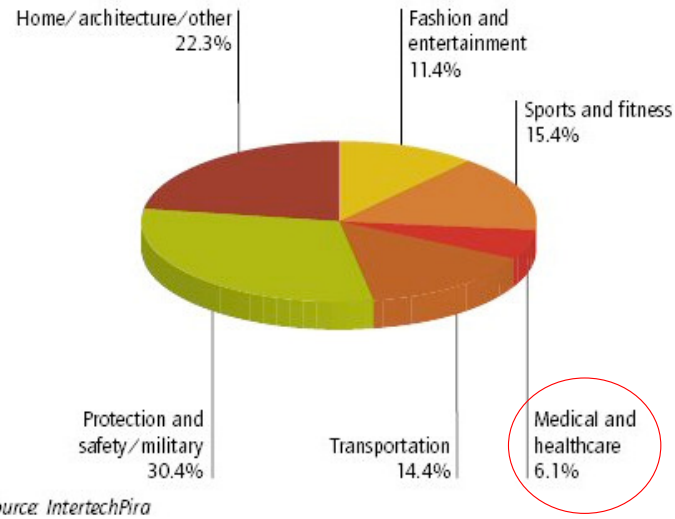
•**Cost**: this will depend on the raw materials, manufacturing process and product end-use

•**Product approval**: each country has its own regulations and standards for medical textiles. European Union has introduced Community Legislation to govern medical devices. The three directives are: Active Implantable Medical Devices, Medical Devices Directive and In-Vitro Diagnostic Medical Devices.

Trends

Smart Textile market

Smart fabrics: end-use markets, 2011 (% share by value, €188.15 million)



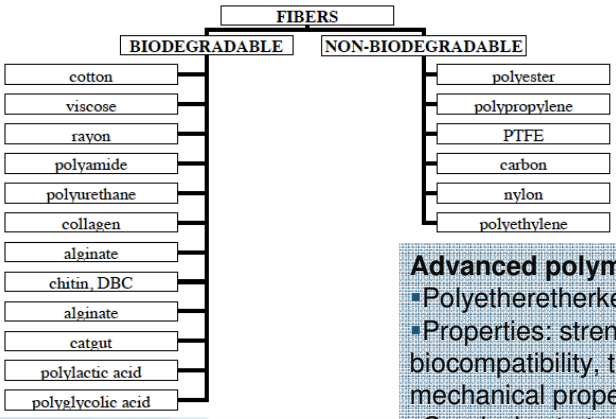
Source: IntertechPira

https://www.smithersapex.com/smart-textiles-to-see-rapid-growth-to-2021.aspx

Biomedical textile

Potential source of Innovation → FIBERS

Biodegradable, non-biodegradable, plastics
Monofilament, Multifilament Yarn, Staple fiber...



Advanced polymers in fiber form → PEEK textiles

- Polyetheretherketone (thermoplastic)
- Properties: strength, stiffness, fatigue resistance, biocompatibility, thermal stability, radiolucency, mechanical properties
- Conducive to textile-forming processes
- Potential to yield the **maximum amount of design freedom** for custom orthopedic devices

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Source: European medical device technology, 2012
Implantable Medical textiles: characterization and applications, Scarlet et al., 2010

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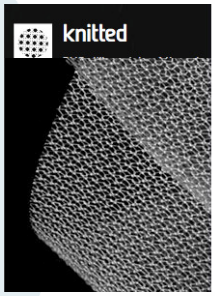
Tesutti termoplastici

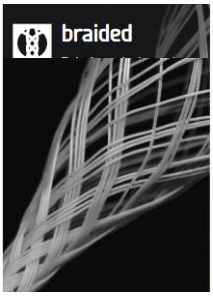
Stiffness denso-rigido

Biomedical textile

Potential source of Innovation → TISSUE/MATERIAL STRUCTURE/DESIGN

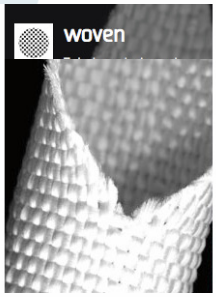
- Surgical mesh
- Hernia repair
- Urogynecologic slings and prolapse devices
- Reconstructive and cosmetic surgery mesh
- Other containment devices

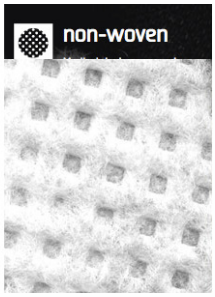




- Device assembly and carriers
- Sutures and sewing threads
- Tethers and component attachment
- Retrieval / deployment systems
- Tubes and tubing reinforcement
- Ports
- Sheaths
- Reinforcement devices
- Catheters
- Tendon / ligament fixation

- Cardiovascular grafts
- Heart valves
- Annuloplasty rings
- Orthopedic spacers
- Tethers
- Containments
- Ligament repair
- Tendon reinforcement
- Fixation devices





- Scaffolds for tissue engineering
- Scaffolds for stem cell applications
- Dental and cosmetic applications
- Absorbable additives for cements and hydrogels
- High surface area material for trauma applications
- Markers, Pledgets, Washers, Spacers, Cuffs

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Source: http://www.bmsri.com/

Braided intecciato

Knitted lavorato a maglia

Woven intecciato

Biomedical textile

Potential source of Innovation → TEXTILE SCAFFOLDS

- To promote cell growth and build cell structures
- Regenerative medicine
- Applications:
  - Tissue Engineering → bone, cartilage,
  - Regenerative Medicine → to guide nerve reconnection and regeneration,
  - Research applictions (e.g. cell growth)

Tissue Application	Cell Lines
Urethra, Bladder	Epithelial, Smooth muscle cells
Pancreas, Liver	Pancreatic islets, Hepatocytes
Dental gum	Epithelial, Smooth muscle cells
Vascular	Endothelial, Smooth muscle cells
Lung, Esophagus	Airway epithelial cells

Figure 2: Examples of needs for engineered tissues

Double wall
Resorbable textile scaffold

Source: 3D Textile Architecture for tissue engineering scaffolds, National Textile Center Annual Report, 2010
Biomaterials unlock potential of regenerative medicine, Secantmedical, 2012

Biomedical textile

Potential source of Innovation → TEXTILE SCAFFOLDS

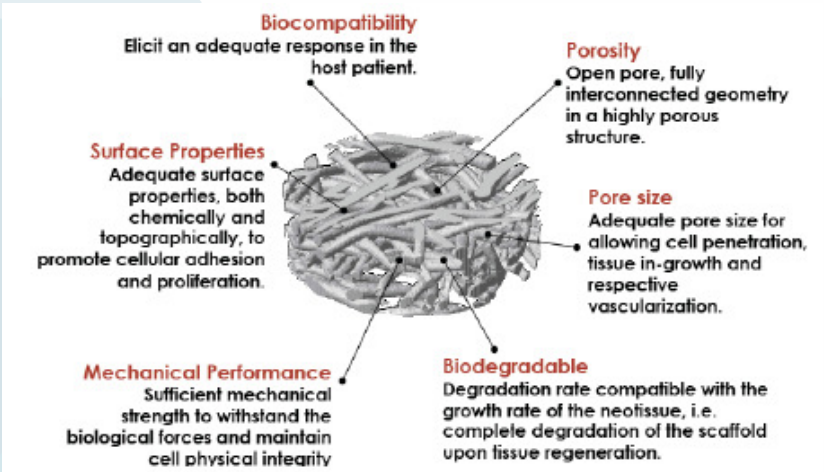


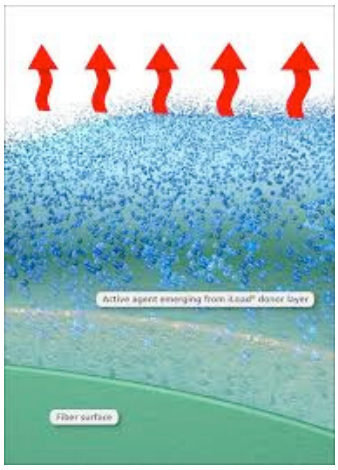
Figure 3: Required parameters for a tissue engineered scaffolds

Source: 3D Textile Architecture for tissue engineering scaffolds, National Textile Center Annual Report, 2010

Biomedical textile

Potential source of Innovation → DRUG DELIVERY

- Drug loaded fibers. Delivery of controlled amounts of drugs and biologically based entities (e.g. Analgesic, hormons, proteins, growth factors, enzymes, small molecules...)
- Biodegradable / non biodegradable fibers
- Nanofibers
- Applications:
  - Drug delivery (advanced dressings for wound healing...)
  - Regenerative Medicine (Growth factors..)
  - Implantable medical devices → delivery at the site of patient's surgical procedure : sutures, stents, meshes...

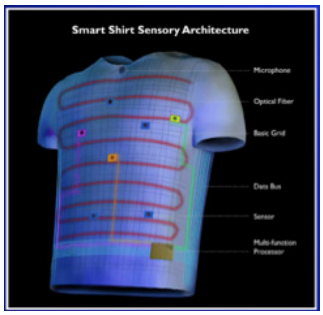


www.innovationintextiles.com

Biomedical textile

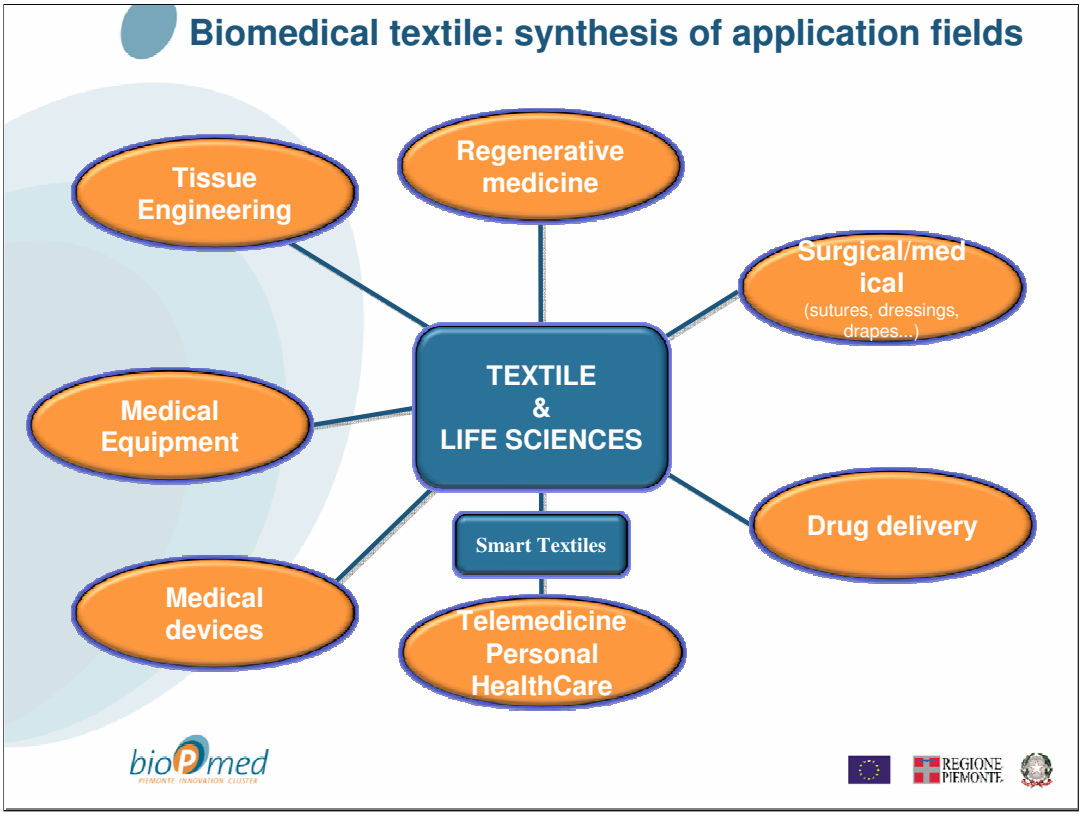
Potential source of Innovation → Enanched smart textiles

- Interface of electronics and patient care
- Textiles engineered with electronic sensors (embedded and not embedded, programmable and not programmable)
- Applications:
  - Monitor patient vital signs
  - Moisture Management
  - Provide pressure sensing
  - Protection from unwanted Interference (radio waves, X-rays, UV)
  - Telemedicine
  - Environmental monitoring/alert
  - Multi parametric monitoring



www.itu.dk

www.wearable.ethz.ch


Biomedical textile: synthesis of application fields
Tissue Engineering
Regenerative medicine
Surgical/medical
(sutures, dressings, drapes...)
Medical Equipment
TEXTILE & LIFE SCIENCES
Drug delivery
Smart Textiles
Medical devices
Telemedicine Personal HealthCare
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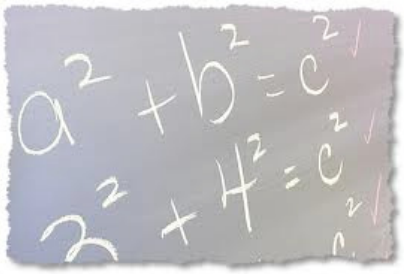
Biomedical textile: key variables to be considered

- R&D costs and product life cycle
- Production processes
- Raw materials (Synthetic vs natural fibers)
- Environmental impact
- Intellectual Property
- Business models
- Marketing strategy/market access
- Competition



BIOINDUSTRY PARK
SILVANO FUMERO

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…It is the team that wins, not the single player…..

bioPmed @ Bioindustry Park Silvano Fumero S.p.A.

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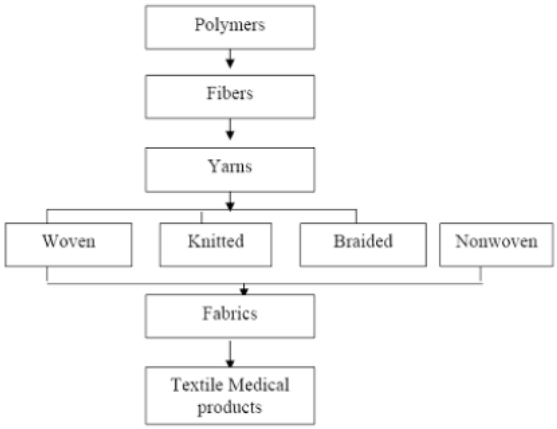
Back-up slides

Constituent element of Medical Textile products:-



Biomedical textiles are manufactured from a wide range of processes. Extruded polymers can be further processed or used as filaments or tapes in dental floss and toothbrushes. Braided textiles are used for sutures and to replace damaged tendons and ligaments. Woven and knitted materials are used extensively in bandages, vascular grafts and hernia meshes. A specialised area of medical textiles is the extrusion of hollow fibre membranes used in extracorporeal devices. Non-wovens are primarily made from synthetic fibres and uses include wound dressings, hygiene products and protective clothing.

Various synthetic and natural fibres, each with unique properties, are used to construct biomedical textiles. Fibres are used in a variety of applications depending on the characteristic required; for example carbon fibre known for its absorption properties is used in wound dressings and absorption columns. However it is used for its strength in artificial ligaments and for its lubricity in orthopaedic cushioning. Synthetic polymers, used extensively, can be divided into permanent e.g. polyamide, polyester, polyethylene, polypropylene, PTFE and polyurethane and biodegradable which are mainly used in sutures and tissue engineering structures e.g. polycaprolactone, polyglycolic acid and polylactic acid. Natural biological fibres include: chitin (from the cells of crustacea) a polysaccharide renowned for its wound healing properties and incorporated into wound dressings; collagen (a fibrous protein found in connective tissue, tendons, etc.) used in cell engineering structures, for example artificial skin; and alginate fibres which can interact with the wound to form an absorbent gel, that acts as a protective barrier and still allows the wound to breathe.

Players dealing in innovative/advance Medical Textile products

Bandages & Wound Care: Kimberly Clark, Beiersdorf, Battelle Memorial Institute, Perlei Medical, Quick- Med Technologies, Comvita, NewZeland, Conva Tec,, Imedex Biomateriaux, Nycomed Pharma, 3M, Smith & Nephew, Area Labs, J & J, Ethicon

Sutures: Johnson & Johnson,Ethicon, Honeywell International, Poly-Med, Tyco Healthcare, Biotronik

Vascular prostheses (grafts): W.L.Gore, Edward Life Science, Boston Scientific

Casts / **Plasters:** BSN Medical, Ossur, Alcare,

Stents: J & J, Ethicon, Scimed Life Systems, Vascutek

Cell growth technology: Tufts University

Cartilage and bone regeneration: Bioretec

Nerve reconnection and regeneration: Asrtra Tec, Oxford Biomaterials

Anti microbial fabrics: CC Technology Investment, Foss Manufacturing Company, Rhodianyl

Ortho joints: J & J, Inor

Medical/healthcare textiles

InEurope
UK (JR Nanotech)
Ireland (Alltracel Pharmaceuticals)
Czech Republic (Elmarco/Nanopeutics)
Japan (Takeda Chemical Industries, Osaka)
USA (Nanotech Institute, University of Texas, Dallas),
Canada (Nucryst Pharmceuticals)
South Korea (Chonbang Co.)
China (Fountain Set, Hong Kong).