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Assessment of Prospect of Textile Technologies for Medical Devices

Abstract
This article includes the assessment of fibrous medical devices as well as borderline products from the point of view of expenditures necessary for the realisation of research and implementation in industrial and clinical practices, the range of practice implementation benefits as well as potential barriers restricting studies and implementation. The scale of investment necessary for the realisation of research and implementation in industrial practices in relation to the benefits of implementing them in practice as well as the limitations that restrict the research and implementation of selected fibrous technologies for medical devices are discussed in detail.

Key words: *medical devices, textile technologies, foresight, dressing, implants.*

Assessment of technologies of fibrous medical devices

Assessment of technologies of fibrous medical devices from the point of view of expenditures necessary for the realisation of research and implementation, the range of practice implementation benefits as well as potential barriers restricting research and implementation

This article includes an assessment of textile medical devices from the point of view of expenditures necessary for the realisation of research and implementation, the range of practice implementation benefits as well as potential barriers restricting studies and implementation.

This study was conducted within the framework of project No. UDA-01.01.01-00-005/09 „Modern Technologies for Textile Industry. A Chance for Poland". The following technology groups incorporating particular technologies were selected and defined in ***Table 1*** [1]:

During the analysis of the textile medical devices, the following barriers, restricting studies and implementations on the market were identified:
- structural and formal-legal barriers;
- economic barriers;
- social/ethical barriers;
- informational barriers.

A detailed description of the factors mentioned above, such as expenditures necessary for the realisation of research and implementation in industrial and clinical practices, the range of practice implementation benefits and potential barriers which restrict research and implementation are listed in ***Table 1***.

The critical barriers restricting research on fibrous medical devices are as follows: absence of expertise of researchers regarding CE-certification of the medical devices and borderline products (knowledge of the laws and pharmaceutical requirements), and the absence of an infrastructure for designing advanced medical devices (implants, drug carriers, scaffolds and artificial organs) such as clean-zones, sterilisation plants etc. Additionally the necessity to have indispensable knowledge of technologies in the field of manufacturing medical devices, borderline products and the requirements for initial materials is the main barrier to providing technology for textile medical devices showing the possibility of implementation in industrial and clinical practices. SME's, the global leader of innovations, should have a global partner with a highly-developed distribution network, due to the relatively high cost of the implementation of new technology compared to the rate of return of investment if there is no global marketing network. Continuously changing legal requirements of medical devices and borderline products is another of the main limitations prolonging the implementation of new technologies and fibrous medical devices in clinical practices. In the case of societal barriers, the most important limitation in the development of innovative fibrous medical devices is the absence or low acceptance of medical devices con-

Table 1. *Technologies and groups of technologies; [1)] According to [2], borderline products are defined as medical devices incorporating medicinal substances. Additionally the medical device and the substance are physically or chemically combined during applications to the patient. The medicinal substance incorporated in the medical device should meet the following conditions: if used separately, may be considered to be a medicinal product, is liable to act upon the human body and its action is ancillary to that of the medical device [2].*

Groups of technologies	Particular technologies
1. Wound dressings	1.1. Auxiliary materials for wound dressings – secondary wound dressings
	1.2. Primary wound dressings (non-occlusive)
	1.3. Primary wound dressings (occlusive)
	1.3.1. Resorbable wound dressings
	1.3.2. Advanced wound dressings incl. wound dressing designed from genetically modified raw-sources containing bioactive substances and/or designed using biotechnologies, etc.
2. Auxiliary textile medical devices	
3. Fibrous implants	3.1. Implants for hernia treatments
	3.2. Implants for vaginal reconstructionsor urinary incontinence treatments
	3.3. Implants for the reconstruction of skull and facial bones
	3.4. Implants for vascular reconstructions
	3.4.1. Components of endo vascular prostheses for less-invasive surgical procedures
4. Sutures	4.1. Resorbable
	4.2. Non-resorbable
5. Fibrous scaffolds for the tissue reconstructions	
6. Advanced fibrous carriers for medicines	
7. Artificial organs or fibrous components for artificial organ design	
5, 6, 7 - Fibrous borderline products[1)] (medical devices containing bioactive substancesor incorporating, as an integral part, ancillary medicinal substances,ancillary human blood derivative, drug-delivery scaffolds or carriers).	

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***Table 2**. Assessment of defined technology groups and particular technologies of fibrous medical devices concerning expenditures necessary for the realization of research and implementation in industrial and clinical practices, the range of practice implementation benefits as well as potential barriers which restrict research and implementations [1-11]; A - range of expenditures necessary for realization of research; B - range of expenditures necessary for implementations; C - range of benefits from practice implementation; low: 1 – 2; medium: 3 – 4; high: 5 – 6.*

Technology groups	Particular technologies	A	B	C	Identified barriers restricting research	Identified barriers restricting the implementation in industrial practice
1. Fibrous wound dressings	1.1. Auxiliary materials for wound dressings – secondary wound dressings (such as woven or knitted bandages, dressing net or bends, etc.)	1	1	1	1) Low innovativeness; 2) Low profitability.	1) Entrepreneurs have the necessary knowledge to modernise current technologies; 2) Due to low profitability, entrepreneurs do not invest in the development of technologies; 3) Relatively high cost of implementation, compared to the rate of return of investment; 4) High risk of quick saturation of market(s) with new products/technologies;
	1.2. Primary wound dressings (non-occlusive, such as non-impregnated gauze dressings in form of pads, ropes, ribbons, strips, rolls and impregnated with anti-adhesion substances, activated charcoal cloth)	1	1	2		
	1.3. Primary wound dressings (occlusive) – 1.3.1. Resorbable wound dressings (such as sodium/calcium alginate dressings in form of non-woven pads or woven nets, carboxymethylcellulose non-woven pads, etc.)	3	2	4	1) Lack of expertise among research personnel in the requirements regarding CE-certification of medical devices; 2) Relatively high cost of research compared to results expected. 3) Continuously altering legal requirements for medical devices; 4) Necessity to own a research and laboratory infrastructure adequate to the range of the design works.	1) High saturation of the market for similar medical devices; 2) Necessity to own an adequate research, technological and manufacturing infrastructure; 3) Necessity to have adequate expertise in implementing new technologies, realising clinical tests and CE-certifying equivalent medical devices; 4) In the case of SME – the necessity to have a partner with a global-range distribution network; 5) The risk of unknown clinical complications occurrence; 6) High risk of quick saturation of market(s) with new products/technologies; 7) Continuously altering legal requirements for medical devices; 8) No acceptance of part of society and lack of clear legal requirements for medical device applications in the case of applying genetically modified raw materials and animal derived substances.
	1.3. Primary wound dressings (occlusive) – 1.3.2. Advanced wound dressings incl. wound dressing designed from genetically modified raw-sources (presently not used clinically, during investigation – genetically modified flax wound dressings)	5	4	4	1) Lack of research personnel expertise in the requirements for medical devices CE-certification; 2) Relatively high cost of research compared to results expected; 3) Continuously altering legal requirements for medical devices; 4) In the case of applications of medicinal products or biotechnologies – knowledge of laws and pharmaceutical requirements; 5) Necessity to own a research and laboratory infrastructure adequate to the scope of design works.	
2. Auxiliary textile medical devices (such as surgical loops, etc.)		3	2	1	1) Low innovativeness; 2) Low profitability; 3) Lack of research personnel expertise in the requirements for medical devices in CE-certification; 4) Continuously altering legal requirements for medical devices; 5) Necessity to own a research and laboratory infrastructure adequate to the scope of design works.	1) Because of low profitability, entrepreneurs do not invest in the development of technologies; 2) Relatively high cost of implementation compared to the rate of return of investment; 3) High risk of quick saturation of the market(s) with new products/technologies; 4) Necessity to own an adequate infrastructure, both research and technological ,and to manufacture.
3. Fibrous implants	3.1. Implants for hernia treatments (such as non-resorbable knitted meshes, semi-resorbable knitted meshes, composite hernia meshes made from knitted mesh and resorbable or non-resorbable films, etc.)	4 - 5	3	3	1) Lack of research personnel expertise in the requirements for implants in CE-certification, especially of the highest class (the IIIth class); 2) The interdisciplinary scope of research and development works conducted; 3) Continuously altering legal requirements for medical devices; 4) The necessity to have indispensable knowledge of technologies in the field of manufacturing medical devices and requirements for raw-materials; 5) Necessity to own research and laboratory infrastructures adequate to the scope of design works.	1) High saturation of the market for similar goods, 2) Necessity to own an adequate infrastructure, both research and technological, as well as to manufacture 3) Necessity to have adequate expertise in implementing the new technologies, executing clinical tests and CE certification; 4) In the case of SME – the necessity to have a partner with a global-range distribution network; 5) Continuously altering legal requirements for medical devices; 6) Saturation of the market(s) with new products/technologies.
	3.2. Implants for vaginal reconstructions or urinary incontinence treatments (such as non-resorbable or resorbable knitted tapes, non-resorbable knitted meshes, etc.)	4 - 5	4	4		1) High saturation of the market for similar medical devices; 2) Necessity to own an adequate infrastructure, both research and technological; 3) Necessity to have adequate expertise in implementing new technologies, executing clinical tests and CE-certification; 4) Necessity to have a partner with a global-range distribution network in the case of SME's; 5) Continuously altering legal requirements for medical devices; 6) Saturation of the market(s) with new products/technologies; 7) Necessity to own an indispensable manufacture infrastructure (clean-zone with high environmental purity).

***Table 2**. continued*

Technology groups	Particular technologies	A	B	C	Identified barriers restricting the research	Identified barriers restricting the implementation to the industrial practices
3. Fibrous implants	3.3. Implants for reconstruction of the skull and facial bones (such as composited multilayered polypropylene –polyester prosthesis of scull bones, non-resorbable meshes for reconstruction of facial defects, etc.)	4 - 5	4	4	1) Lack of research personnel expertise in the requirements for implant CE-certification; 2) The interdisciplinary scope of the research conducted and development works; 3) Continuously altering legal requirements for medical devices; 4) The necessity to have indispensable knowledge of technologies in the field of manufacturing medical devices and requirements for materials; 5) Necessity to own a research and laboratory infrastructure adequate to the scope of design works.	1) High saturation of the market for similar goods, 2) Necessity to own an adequate infrastructure, both research and technological, as well as to manufacture 3) Necessity to have adequate expertise in implementing the new technologies, executing clinical tests and CE certification; 4) In the case of SME – the necessity to have a partner with a global-range distribution network; 5) Continuously altering legal requirements for medical devices; 6) Saturation of the market(s) with new products/technologies.
	3.4. Implants for vascular reconstruction (such asnon-resorbable or semi-resorbable, knitted or woven vascular prostheses, bifurcated or straight, knitted or woven vascular patches, vascular prostheses made by non-conventional techniques, i.e. electrospinning, etc.)	6	5	2	1) Lack of research personnel expertise in the requirements for implant CE-certification; 2) The interdisciplinary scope of the research conducted and development works; 3) Continuously altering legal requirements for medical devices; 4) The necessity to have indispensable knowledge of technologies in the field of manufacturing medical devices and requirements for materials; 5) In the case of applications of medical devices or biotechnologies – knowledge of the laws and pharmaceutical requirements; 5) Necessity to own a research and laboratory infrastructure adequate to the scope of design works.	1) Necessity to own an adequate infrastructure, both research and technological; 2) Necessity to have adequate expertise in implementing new technologies, executing clinical tests and CE-certification; 3) In the case of SME – the necessity to have a partner with a global-range distribution network; 4) Continuously altering legal requirements for medical devices; 5) Saturation of the market(s) with new similar products/technologies; 6) Necessity to own an indispensable manufacturing infrastructure (clean zone with high environmental purity); 7) Absence or low acceptance of part of society and lack of clear legal requirements for medical device applications in the case of applying genetically modified material, animal or human derived substances;
	3.4.1. Components of endovascular prostheses (such as non-resorbable woven coating of endovascular prostheses – stent-grafts)	6	4	5	1) Lack of research personnel expertise in the requirements for implants CE-certification; 2) The interdisciplinary scope of the research and development works conducted; 3) Continuously altering legal requirements for medical devices; 4) The necessity to have indispensable knowledge of technologies in the field of manufacturing medical devices and the requirements for materials; 5) In the case of applications of medicinal products or biotechnologies – knowledge of the laws and pharmaceutical requirements; 6) Lack of experience in realising similar (thematically) projects regarding implementation; 7) Necessity to own a research and laboratory infrastructure adequate to the scope of design works.	1) Necessity to own an adequate infrastructure, both research and technological; 2) Necessity to have adequate expertise in implementing new technologies, executing clinical tests and CE-certification; 3) In the case of SME – the necessity to have a partner with a global-range distribution network; 4) Continuously altering legal requirements for medical devices; 5) Saturation of the market(s) with new products/technologies; 6) Necessity to own an indispensable manufacture infrastructure (clean zone); 7) Absence or low acceptance of part of the society and lack of clear legal requirements for medical device applications in case of applying genetically modified material, animal or human derived substances.
4. Sutures	4.1. Resorbable (such as multifilament or monofilament a. made of synthetic resorbable polymers with controlled time of degradation; raw-source: catgut, polyglactin 910, glycomer 631, polyglecaprone, polyglycolid acid, lactomer 9-1, polydoxanone; b. made of natural sources: silk)	4 - 5	4	4	1) Lack of research personnelexpertise in the requirements for medical CE-certification; 2) The interdisciplinary scope of research and development works conducted; 3) Continuously altering legal requirements t for medical devices; 4) The necessity to have indispensable knowledge of technologies in the field of manufacturing medical devices and the requirements for materials; 5) Necessity to own a research and laboratory infrastructure adequate to the scope of design works.	1) High saturation of the market for similar products; 2) Necessity to own an adequate infrastructure, both research and technological; 3) Necessity to have adequate expertise in implementing new technologies, executing clinical studies and CE-certification; 4) In the case of SME – the necessity to have a partner with a global-range distribution network; 5) Continuously altering legal requirements for medical devices; 6) Saturation of the market(s) with new products/technologies; 7) Necessity to own an indispensable manufacture infrastructure (clean zone).
	4.2. Non-resorbable (such as mostly polypropylene, polyamide, polyester; monofilament or multifilament)	4 - 5	3	3	1) Absence of research personnel expertise in the requirements for implant CE-certification; 2) The interdisciplinary scope of research and development works conducted; 3) Continuously altering legal requirements for medical devices;	1) High saturation of the market with similar products; 2) Necessity to own an adequate infrastructure, both research and technological; 3) Necessity to have adequate expertise in the commercialisation of new technologies, executing clinical studies and CE-certification;

***Table 2**. continued.*

Technology groups	Particular technologies	A	B	C	Identified barriers restricting the research	Identified barriers restricting the implementation to the industrial practices
4. Sutures	4.2. Non-resorbable (such as mostly polypropylene, polyamide, polyester; monofilament or multifilament)	4 - 5	3	3	4) The necessity to have indispensable knowledge of technologies in the field of manufacturing medical devices and the requirements for materials; 5) Necessity to own a research and laboratory infrastructure adequate to the scope of design works.	4) In the case of SME – the necessity to have a partner with a global-range distribution network; 5) Continuously altering legal requirements for medical devices; 6) Saturation of the market(s) with new products/technologies; 7) Necessity to own an indispensable manufacture infrastructure (clean zone).
5. Fibrous scaffolds for tissue reconstructions (such as resorbable, semi-resorbable or non-resorbable fiborous flat or three dimensional pads made by electrospinning techniques, fibrous composites containing bioactive substances, etc.)		6	4	6	1) Absence of research personnel expertise in the requirements for borderline products; 2) The interdisciplinary scope of research and development works conducted; 3) Continuously altering legal requirements for medical devices and borderline products; 4) The necessity to have indispensable knowledge of technologies in the fieldof manufacturing medical devices, borderline products and the requirements for initial materials; 5) In the case of applications of medicinal products or biotechnologies – knowledge of the laws and pharmaceutical requirements; 6) Absence of experience in realising similar (thematically) projects, regarding implementation and commercialization; 7) Necessity to own a research and laboratory infrastructure adequate to the scope of design works.	1) Necessity to own an adequate infrastructure, both research and technological, as well as biotechnological; 2) Necessity to have adequate expertise in implementing new technologies, executing clinical studies and CE-certification; 3) In the case of SME – the necessity to have a partner with a global-range distribution network; 4) Continuously altering legal requirements for medical devices; 5) saturation of the market(s) with new products/technologies; 6) Necessity to own an indispensable manufacture infrastructure (clean zone); 7) No acceptance of part of society and lack of clear legal requirements for medical device applications in the case of applying genetically modified material, animal or human derived substances and stem cells; 8) Considerable risk of unknown complications (such as: tumors).
6. Advanced fibrous carriers for medicines (resorbable, semi-resorbable or non-resorbable 3-D fibrous systems, composites containing drugs or other bioactive substances, etc.)		5	6	5	1) Absence of research personnel expertise in the requirements for CE-certification and registration of borderline products; 2) The interdisciplinary scope of research and development works conducted; 3) Continuously altering legal requirements for medical devices; 4) The necessity to have indispensable knowledge of technologies in the field of manufacturing medical devices and the requirements for raw-materials; 5) In the case of applications of medicinal products or biotechnologies – knowledge of the laws and pharmaceutical requirements; 6) Absence of experience in realising similar (thematically) projects, regarding implementation and commercialisation; 7) Necessity to own a research and laboratory infrastructure adequate to the scope of design works.	1) Necessity to own an adequate infrastructure, both research and technological as well as biotechnological; 2) Necessity to have adequate expertise in implementing new technologies, executing clinical studies and CE certification; 3) In the case of SME – the necessity to have a partner with a global-range distribution network; 4) Continuously altering legal requirements for medical devices and borderline products; 5) Saturation of the market(s) with new products/technologies with similar application ranges; 6) Necessity to own an indispensable manufacture infrastructure (clean zone); 7) No acceptance of part of society and lack of clear legal requirements for medical good applications in the case of applying genetically modified material, animal or human derived substances; 8) Considerable risk of unknown complications (e.g, tumors).
7. Artificial organs or fibrous components for artificial organ design (such as a non-resorbable or resorbable heart valve or parts thereof , components of an artificial heart, nerve prostheses , components of an artificial kidney, etc.)		5	6	5	1) Lack of research personnel expertise in the requirements for the certification of implants and borderline products; 2) The interdisciplinary scope of research and development works conducted; 3) Continuously altering legal requirements for medical devices; 4) The necessity to have indispensable knowledge of technologies in the field of manufacturing medical devices and the requirements for materials; 5) Necessity to own a research and laboratory infrastructure adequate to the scope of design works.	1) Necessity to own an adequate infrastructure, both research and technological; 2) Necessity to have adequate expertise in implementing new technologies, executing clinical studies and CE-certification 3) In the case of SME – the necessity to have a partner with a global-range distribution network; 4) Continuously altering legal requirements for medical devices 5) Saturation of the market(s) with new products/technologies 6) Necessity to own an indispensable manufacture infrastructure (clean zone)
5, 6, 7 - Fibrous borderline products (medical devices containing bioactive substances or incorporating, as an integral part, ancillary medicinal substances, ancillary human blood derivative, drug-delivery scaffolds or carriers):						

Table 3. *Current state of advancement of research in the field of fibrous medical devices in Poland and abroad, and the degree of readiness for implementation in practice [1]; The degree of progress: 0 – no research works on given scope ; + - low; ++ - medium; +++ - high.*

Groups of technologies	Particular technologies	The stage of research in Poland	The stage of research abroad
1. Wound dressings	1.1. Auxiliary materials for wound dressings – secondary wound dressings	++	++
	1.2. Primary wound dressings (non-occlusive)	++	++
	1.3. Primary wound dressings (occlusive)		
	1.3.1. Resorbable wound dressings	++	+++
	1.3.2. Advanced wound dressings	++	+++
2. Auxiliary textile medical devices		0	0
3. Fibrous implants	3.1. Implants for hernia treatments	+++	++
	3.2. Implants for vaginal reconstructions or urinary incontinence treatments	+++	++
	3.3. Implants for reconstruction of skull and facial bones	+++	+++
	3.4. Implants for vascular reconstructions	+	+
	3.4.1. Components of endovascular prostheses	+	+++
4. Sutures	4.1. Resorbable	+	+++
	4.2. Non-resorbable	0	+
5. Fibrous scaffolds for tissue reconstructions		+	+++
6. Advanced fibrous carriers for medicines		+	+++
7. Artificial organs or fibrous components for artificial organ design		+	+++
5, 6, 7 - Fibrous borderline products (medical devices containing bioactive substances or incorporating, as an integral part, ancillary medicinal substances, ancillary human blood derivative, drug-delivery scaffolds or carriers)			

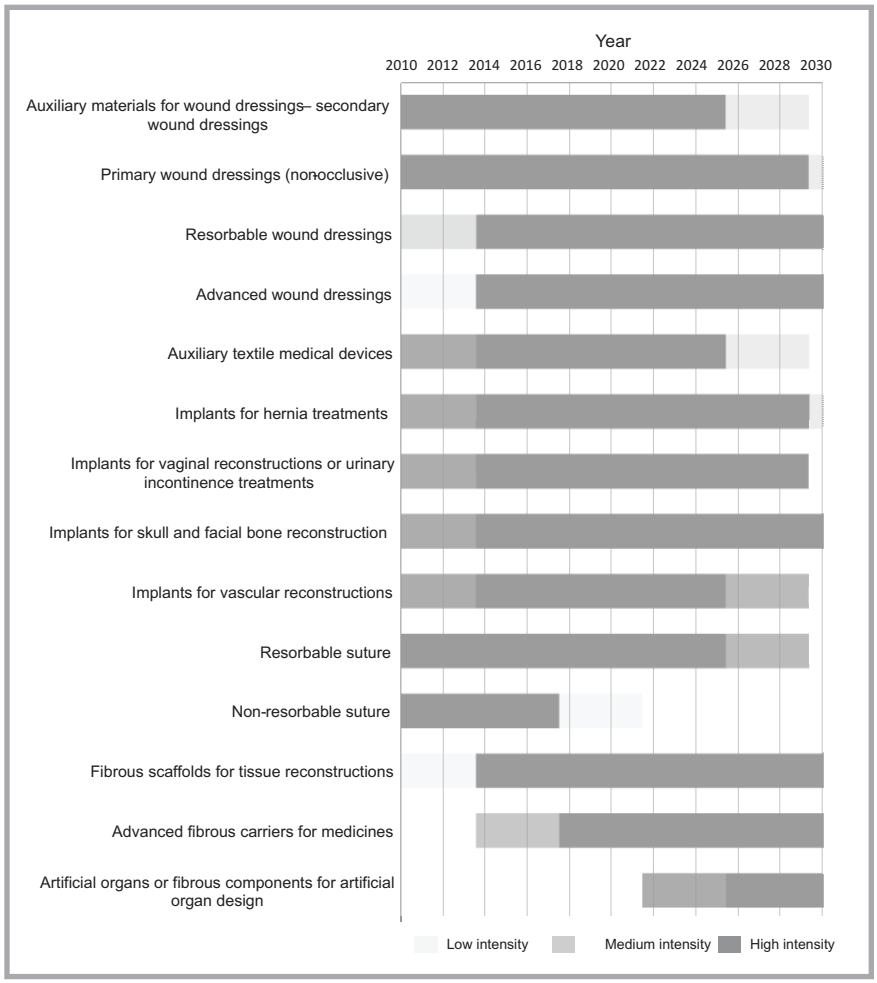

Figure 1. *Anticipated trends in the development of fibrous medical devices in 2010 - 2030.*

taining genetically modified raw materials, animal or human derived substances, steam cells, etc.

The more the degree of innovation of the fibrous medical device, the higher the costs associated with its implementation in industrial practice and the more prolonged the time required for the development of a technology, but with a higher chance of getting a faster return on capital invested.

The main limitations connected with advanced medical devices are unclear essential requirements for those containing medicinal products or human blood-derived substances (borderline products), as well as restricted requirements for animal tissue derived compounds of fibrous medical devices.

The degree of readiness for practical (industrial and clinical) implementations and current state of advancement of research in the field of fibrous medical devices in Poland

Table 2 includes an assessment of the state of research advancement in the technology groups and particular technologies in Poland and abroad as well as the degree of readiness for practical implementation.

It should be noted that standard textile fibrous implants for hernia treatments by the open or laparoscopic (less-invasive) method, where the knitted implant is secured by direct contact with internal organs using a peritoneum or resorbable implant, as well as prostheses for bone reconstruction and knitted vascular prostheses are being manufactured in Poland [12, 13].

TRICOMED S.A, as a manufacturer, applies non-resorbable polyester (poly[ethylene terephthalate]) or polypropylene for the design of knitted hernia meshes [14], while BALTON has worked for some years on a Polish stent-graft based on own stainless steel stent technology.

The main research work in the world has focused on three groups of fibrous medical devices: fibrous scaffolds for tissue reconstructions, advanced fibrous carriers for medicines and artificial organs, and fibrous components for artificial or-

Table 4. *Likely trends in future research on technologies in the field of fibrous medical devices [1, 10, 17, 18, 21 - 23, 25 - 33].*

Groups of technologies	Particular technologies		Likely directions of future research on technologies
1. Wound dressings	1.1. Auxiliary materials for dressings		1) Research on auxiliary dressing materials made of renewable raw materials; 2) Research on developing auxiliary wound dressing materials of significantly high flexibility and low weight.
	1.2. Regular dressings (non-occlusive)		1) Research on the development of non-occlusive wound dressings made of resorbable materials 2) Research on the fractionalisation of non-occlusive wound dressings; 3) Implementing modern textile processes for a significant reduction in technology and increase in the performance of non-occlusive wound dressings.
	1.3. Specialised dressings (occlusive)	1.3.1. Resorbable dressings	1) Developing new materials aimed at: a. increasing accessibility; b. gaining repeatability; c. improving the performance of resorbable wound dressings. 2) Implementing modern, non-conventional textile processes for a significant reduction in the manufacture process (-es) and increase in the performance of non-occlusive wound dressings; 3) Optimizing the composition of resorbable wound dressings for: a. multifunctionality; b. increased bioactivity; c. obtaining new properties which optimise the wound healing process. 4) Implementation of modern biotechnologiesfor both the modification of textile materials and the synthesis of new fibrous materials and finished products; 5)Wound dressings developed by genetic modification of raw-materials.
		1.3.2. Advanced wound dressings	1) Research on the optimisation of advanced bioactive wound dressings; 2) Research on developing or screening new substances accelerating wound healing; 3) Individualisation of the production technology of advanced wound dressings; 4) Development of new technologies for the incorporation of bioactive substances into the fibrous structure of wound dressings; 5) Optimising the composition of advanced wound dressings for: a. multifunctionality; b. increased bioactivity; c. obtaining new properties which optimise the wound healing process; d. obtaining the correct regeneration of damaged skin tissue structures (healing without scarring). 6) Implementing modern biotechnologies for both the modification of textile materials and the synthesis of new fibrous materials and finished products containing substances which accelerate tissue regeneration; 7) Implementing modern solutions in the field of nanotechnology.
2. Auxiliary textile medical devices			1) Development of modern nanotechnology for manufacture of nano-filters for filtering the body fluids.
3. Fibrous implants	3.1. Implants for hernia treatments		1) Development of modern textile technology for: a. significant reduction in the weight of the product and to provide anatomical properties; b. significant reduction in technological processes; c. proper restoration / regeneration of tissue structures at the implantation location. 2) Research on applying biotechnology in the development of biomimetic implants; 3) Individualising implants for an individual patient; 4) Implementing nanotechnology for supporting the reconstruction process of muscle fascia; 5) Development of optimal resorbable materials regarding the dynamics of implant over-healing and resorption of synthetic material; 6) Development of new materials featuring properties (chemical, biological, physical) of the tissue at the implantation (biomimetic of implant); 7) Optimisation of the implant design in terms of a lower degree of invasiveness of surgical procedures.
	3.2. Implants for vaginal reconstructions or urinary incontinence treatments		1) Development of modern textile technology for: a. significant reduction in the weight of the product and to provide anatomical strength; b. significant reduction in technological processes; c. proper restoration / regeneration of tissue structures at the implantation location; 2) Research on applying biotechnology in the development of biomimetic implants; 3) Individualising implants for an individual patient; 4) Development of optimal resorbable materials regarding the dynamics of prosthesis over-healing and resorption of artificial material; 5) Development of new materials featuring the properties (chemical, biological, physical) of the tissue at the implantation (biomimetic of implant); 6) Optimisation of implant design in terms of a lower degree of invasiveness of surgical procedures.
	3.3. Implants for reconstruction of the skull and facial bones; reconstructions of bone loss		1) Individualisation of technology for the manufacture of textile prostheses for the reconstruction of bone defects; 2) Development of new materials featuring the properties (chemical, biological, physical) of the tissue at the implantation (biomimetic of implant); 3) Implementation of nanotechnology to support the reconstruction process; 4) Development of modern textile technology for a significant reduction in technological processes; 5) Development of optimal resorbable materials regarding the dynamics of prosthesis over-healing and resorption of synthetic material; 6) Development of optimal resorbable materials regarding the dynamics of natural bone tissue reconstruction; 7) Optimisation of implant design in terms of a lower degree of invasiveness of surgical procedures.
	3.4. Implants for vascular reconstructions		1) Individualisation of textile technologies for vascular prostheses; 2) Development of new materials featuring the properties (chemical, biological, physical) of the tissue at the implantation (implant biomimetic); 3) Implementation of nanotechnology and biotechnology to support the reconstruction process; 4) Development of modern textile technology for significant reduction in technological processes; 5) Development of optimal resorbable materials regarding the dynamics of prosthesis over-healing and resorption of synthetic material and the effect of degradation products on haemostasis; 6) Development of optimal resorbable materials regarding the dynamics of the reproduction of natural structures of blood vessels; 7) Research on new materials and their optimisation for low thrombogenicity; 8) Research on the biomimetic of vascular prostheses.

Table 4. *continued.*

Groups of technologie	Particular technologies	Likely directions of future research on the technologies
3. Fibrous implants	3.4. Implants for vascular reconstructions	1) Individualisation of textile technologies for vascular prostheses; 2) Development of new materials featuring the properties (chemical, biological, physical) of the tissue at the implantation (implant biomimetic); 3) Implementation of nanotechnology and biotechnology to support the reconstruction process; 4) Development of modern textile technology for significant reduction in technological processes; 5) Development of optimal resorbable materials regarding the dynamics of prosthesis over-healing and resorption of synthetic material and the effect of degradation products on haemostasis; 6) Development of optimal resorbable materials regarding the dynamics of the reproduction of natural structures of blood vessels; 7) Research on new materials and their optimisation for low thrombogenicity; 8) Research on the biomimetic of vascular prostheses.
	3.4.1. Components of endovascular prostheses	1) Optimisation of individualisation technologies for endovascular prostheses; 2) Development of new materials featuring properties (chemical, biological, physical) of the tissue at the implantation (implant biomimetic); 3) Implementation of nanotechnology and biotechnology to support the procedure of implant introduction into the body and the reconstruction processes; 4) Development of modern textile technology for a significant reduction in technological processes; 5) Development of optimal resorbable materials regarding the dynamics of resorption of synthetic material and effect of degradation products on haemostatic; 6) Reducing the invasiveness degree of procedures of the introduction of endovascular implants; 7) Research on new materials and their optimisation for low thrombogenicity; 8) Research on the biomimetic of endovascular prostheses; 9) Unification of the design of endovascular prostheses.
4. Sutures	4.1. Resorbable	1) Developing new materials aimed at gaining: a. increase in accessibility; b. repeatability; c. improved performance of suturing materials; d. controlled resorption and maintaining an adequate strength of the place of suturing. 2) Implementing modern textile processes for a significant reduction in technology and increase in performance; 3) Optimisation of suturing material composition and design regarding: a. multifunctionality; b. gaining new properties which accelerate tissue regeneration at the place of suturing. 4) Implementation of modern biotechnologies for both the modification of textile materials and the synthesis of new fibrous materials and finished products.
	4.2. Non-resorbable	1) Development of modern textile technology for: a. significant reduction in the weight of the product and to provide anatomical strength to maintain proper tissue anastomosis; b. significant reduction in technological processes; c. proper restoration / regeneration of tissue structures at the implantation location.
5. Fibrous scaffolds for tissue reconstructions		1) Developing new materials aimed at gaining: a. increase in accessibility; b. repeatability; c. improved functionality; d. unification of excipients for tissue reconstruction. 2) Implementation of modern textile processes in order to significantly reduce technology and improve performance; 3) Optimisation of composition to gain: a. multifunctionality; b. bioactivity improvement; c. new properties improving the regeneration process. 4) Implementation of modern biotechnologies for both the modification of textile materials and the synthesis of new fibrous materials and finished products; 5) Product developed by genetic modification of organisms; 6) Research on the optimisation of material design and composition regarding the biomimetic.
6. Advanced fibrous carriers for medicines		1) Development of technology for targeted drug therapy using nano-fibres; 2) Studies on the properties of nano-fibres with a view to applying them as drug carriers.
7. Artificial organs or fibrous components for artificial organ design		1) Developing artificial organs (kidneys, liver, spleen, heart, blood vessels) using advanced textile nanotechnologies and biotechnologies.
5, 6, 7 - Fibrous borderline products (medical devices containing bioactive substances or incorporating, as an integral part, ancillary medicinal substances, ancillary human blood derivative, drug-delivery scaffolds or carriers).		

gan design. The conventional technique of fibrous medical device manufacture is used for the elaboration of knitted or woven externally communicating products, whereas the non-conventional one is for producing more innovative medical devices, mostly implants, drug carriers or fibrous scaffolds [15 - 17].

The dominant groups of studies in Poland are related to the design of advanced wound dressings containing bioactive compounds such as antibacterial substances, and growth factors or some derivatives accelerating wound healing [16, 18]. The second groups of advanced wound dressings are medical devices designed by biotechnologies, i.e. wound dressings made of bacterial cellulose [19, 20].

The main research works were carried out on technologies of resorbable or semi-resorbable implantable medical devices [21 - 24] or a reduction in the amount of man-made fibres to produce biomimetic implants [25].

Based on trends in researches, estimation of the initialisation dates of the research activities, maximum periods related to the practical applications of the research results and the final period associated with lack of interest in the results of

the projects (quench of researches) have been elaborated (***Figure 1***).

Factors stimulating the development of research and innovation implementations in the field of fibrous medical devices

The following factors stimulate the development of the research and implementation of fibrous medical device innovations in industrial and clinical practices above all:

- changes in the society profile of highly industrialised countries, where the 50+ population is growing, which predisposes the development of medical technologies related to diseases of the skeletal system (orthopedics, traumatology) and the vascular and cardiovascular system as well as complications resulting from diabetes and obesity;
- the sector of medical devices has shown steady, high growth over the years, regardless of the regional or global economy conditions;
- necessity to provide a high level of social security regarding applications and implementations in clinical practice as well as more and more effective medical technologies improving the patient's life-span;
- political pressure to reduce healthcare costs by introducing more cost-effective technologies resulting in a decrease in the cost of surgical procedures, a reduction in the hospitality period and post-surgery care, a significant reduction in the percentages of post-surgery complications, etc.;
- numerous initiatives to support research processes in modern medical technologies, both regional and European;
- the need to maintain and invest in technologies increasing the level of social security;
- stable supply markets - the main recipients of the products are state-owned hospitals, stably funded from National Funds (National Healthcare Fund - NFZ/Poland) or private insurance sources;
- several new solutions applied in the field of medical devices or borderline products have the status of an innovation and wider prospect for development in terms of optimisation, searching for new ranges of applications and markets and realising new development processes;
- European Union strategy and national strategies promote researches on medical devices as one of the innovative branches of science improving people's lives;

Implementation in clinical practices of new surgical procedures (such as less-invasive laparoscopy) is supported by the development and expansion of new medical devices [1, 6].

Possible trends for further research on technologies in the field of fibrous medical devices

Research trends for further research on technologies in the field of fibrous medical devices, as shown in ***Table 3***, may be divided into four groups:

a. improving the process(-es) of the manufacture of fibrous medical devices resulting in an increase in repeatability (mostly quality);
b. implementation of new technologies to obtain features or improve the process(-es) of manufacture, such as biotechnologies and nanotechnologies;
c. implementation of new raw-materials yielding new features in the final medical device, such as resorption, bioactivity, multifunctionality, etc.;
d. elaboration of new designs of fibrous medical devices using non-conventional fibrous techniques to obtain new features such as biomimetic and individualisation.

Summary

The article represents a thorough discussion of fibrous medical devices currently present on the market and future technologies thereof from the point of view:

- the scale of investment necessary for the realisation of research and implementation in industrial practices,
- scale of the benefits of implementing the selected textile technologies of fibrous medical devices in practice,
- potential barriers that restrict the research and implementation of selected fibrous technologies for medical devices.

In addition, the current state of advancement of research on textile medical devices in Poland and abroad is presented along with an attempt to estimate the rate of readiness for industrial and clinical implementations.

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