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Abstract

The aim of this paper is to present the harmonisation of the global medical textile market and the categories of medical textiles based on their applications. The paper also contains an analysis of some trends in the foreign trade of medical textiles on the world economy.

Key words: textiles, Global Harmonisation Task Force, categories, medical textiles, healthcare sector.

important and growing part of the textile industry.

In 2004, the number of people aged over 60 amounts to 40% of the entire population. In 1980, only 22% of the Europeans belonged to this group age. Textiles represent an absolutely ideal interface between man and medical treatment facilities, and it would be a loss not to make use of the possibilities they offer [1].

Harmonisation Global Market of Medical Devices Including Medical Textiles

The world medical devices market is represented by the Global Harmonisation Task Force (GHTF). The GHTF is comprised of representatives from five founding members (the European Union, the United States, Canada, Australia, Japan). They are grouped into three geographical areas: Europe, Asia-Pacific and North America, each of which actively regulates medical devices using their own individual regulatory framework [2]. The GHTF views harmonisation as a way of defining common regulatory approaches for medical devices at a international level. The GHTF has identified as a priority the need to harmonise the documentation of evidence of conformity to regulatory requirements. Differences in documentation requirements necessitate additional work for the same device in different jurisdictions. As a result, the costs increase and barriers in international access to medical devices between countries arise. These barriers also have an economic impact [3].

According to the Global Harmonisation Task Force, a medical device is defined as “any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, 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 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,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.”

Risk is based on classification of medical devices including medical textiles. According to the GHTF, medical devices may be classified into 4 classes as follows:

- Class I (generally regarded as low risk).
- Class IIa (generally regarded as medium risk).
- Class IIb (generally regarded as medium risk).
- Class III (generally regarded as high risk).

Generally, class III devices affect the functioning of vital organs and/or life-support systems, whereas class I devices are non-invasive and do not come into contact or interact with the human body [4].

Characteristics of the Medical Textiles Market

According to ‘Technical Textiles and Industrial Nonwovens: World Market Forecast to 2010’ published by David Rigby Associates¹⁾ (DRA), it is forecast that the world market for technical textiles and industrial nonwovens will increase by 3.5% per annum between 1995 and 2005, and 3.8% per annum from 2005 to 2010

Introduction

Technical textiles are one of the faster growing sectors of the global textile industry. The world textile industry is moving rapidly toward the manufacture of high-added value textile structures and products such as medical textiles, protective textiles and smart textiles. Textile materials used in the medical and applied healthcare and hygiene sectors are an

in volume terms, to reach 23.8mn tonnes with a value of \$126bn by 2010. The division of technical textiles (according to DRA) into the different application areas is presented in Figure 1.

On the basis of DRA's research, over 1.5mn tons of textile materials, with a value of US\$5.4bn, were consumed worldwide in the manufacture of medical and hygiene products in 2000. This is predicted to increase in volume terms by 4.5% per annum to 2010 to reach 2.4mn tons with a value of US\$8.2bn. This sector probably offers the greatest scope for the development of the most sophisticated and highest value textiles for niche applications [7].

Technical textiles will find many different kinds of application with medical and hygiene products in the healthcare sector. The diversity of applications encountered in medical and healthcare products is quite remarkable, e.g. simple bandages, biocompatible implants and tissues, antibacterial wound treatment material, prosthetics, and intelligent textiles.

Each of these categories covers a broad range of applications, and the many end-uses with their disparate requirements create opportunities for all kinds of textile such as fibres, mono- and multi-filament yarns, woven, knitted, nonwoven, braiding and composite fabrics [5,6].

Medical textiles embrace all those textile materials used in health and hygiene applications in both the consumer and medical markets. As such, it comprises a group of products with considerable variations in terms of product performance and unit value. Because of the nature of their application, many medical products are disposable items. Nonwovens ac-

Table 1. Non-implantable materials (from Rajendran et al. [10]).

Fibre Type	Fabric Structure	Applications
Cotton, viscose, lyocell	Nonwoven	Absorbent pad
Alginate fibre, chitosan, silk, viscose, lyocell, cotton	Woven, nonwoven, knitted	Wound- contact layer
Viscose, lyocell, plastics film	Woven, nonwoven	Base material
Cotton, viscose, lyocell, polyamide fibre, elastomeric-fibre yarns	Woven, nonwoven, knitted	Simple non-elastic and elastic bandages
Cotton, viscose, lyocell, elastomeric-fibre yarns,	Woven, nonwoven, knitted	High-support bandages
Cotton, viscose, lyocell, elastomeric-fibre yarns,	Woven, knitted	Compression bandages
Cotton, viscose, lyocell, polyester fibre, polypropylene fibre, polyurethane foam	Woven, nonwoven	Orthopaedic bandages
Cotton, viscose, plastics film, polyester fibre, glass fibre, polypropylene fibre,	Woven, nonwoven, knitted	Plasters
Cotton, viscose, lyocell, alginate fibre, chitosan	Woven, nonwoven, knitted	Gauze dressing
Cotton	Woven	Lint
Viscose, cotton linters, wood pulp,	Nonwoven	Wadding
Poly lactide fibre, polyglycolide fibre, carbon	Spunlaid, needle-punched nonwoven	Scaffold

count for a high part of the sector overall in terms of tons of fibre used [7]. Also, another feature of the medical textile market will be the growing proportion of composite materials used in wound management products. This will mean the combination of textiles with such materials as films, foam and adhesives to form structures for the treatment of wound and healthcare products [8]. The increased use of textiles in composite applications will provide major growth fibre consumption in terms of volume. The hitherto increase and forecast in world consumption of medical textiles is presented in Figure 2.

European producers are world leaders in the market for technical/industrial textiles and nonwovens, for example industrial filters, hygiene products or in the medical sector. Although the textile sector

is marked by small- and medium-sized enterprises and local developments, it is important that research efforts take place in a more integrated way so as to achieve a critical mass and be competitive on the global market. The European technical textile sector should continue to develop highly specialised products. This is the case, for example, in medical textiles based on biomaterials, interactive and intelligent textiles provided for textile sensors and improving test methods [9].

Categories of medical textiles include:

- non-implantable materials,
- implantable materials,
- extracorporeal devices,
- healthcare and hygiene products.

The application of different fibres for manufacturing various medical products is illustrated in Tables 1-4 [10].

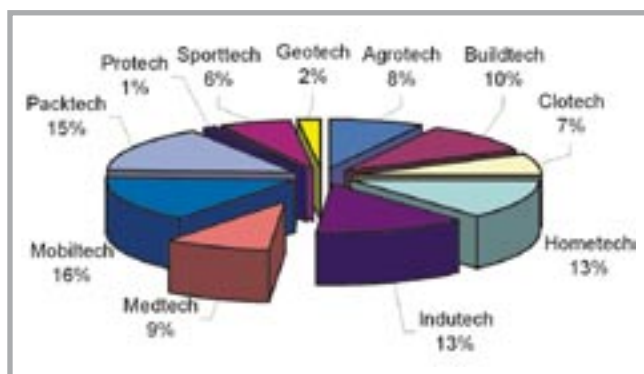


Figure 1. World end-use consumption of technical textiles in 2000 by application areas (volume terms). Source: DRA, <http://www.davidrigbyassociates.com/DRA%20WEBSITE%2003/assets/TTandN.pdf>

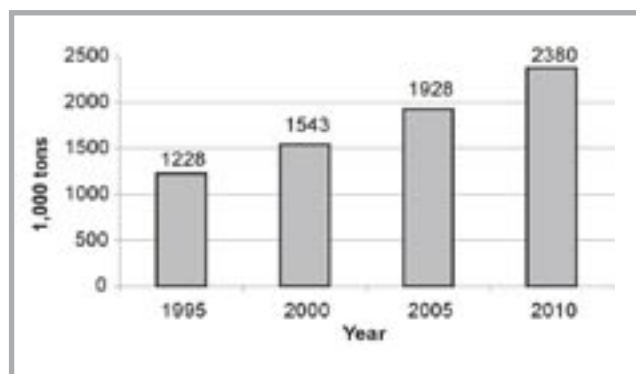


Figure 2. Forecast world consumption of medical textiles, 1995-2010, Volume (1,000 tons). Source: DRA, <http://www.davidrigbyassociates.com/DRA%20WEBSITE%2003/assets/TTandN.pdf>

Trends in World Trade of Medical Textiles

The market for medical textiles is being driven by a number of factors [11]:

- population growth rates, particularly in newly developing global regions,
- changes in demographics, including the ageing of the population in the Western European market,
- changes in living standards,
- attitude to health risks; increased awareness of the risks to health workers from health threats from blood-borne diseases and airborne pathogens,
- the continuing dominance of the leading suppliers and brands (especially in the consumer market),
- ongoing enhancement in product performance,
- the growing dominance of purchasing which demands increasing value for money,
- the increasing share of nonwovens on the medical world market in relation to traditional textile materials.

These trends will be further fed by the

increasing development of the medical textile market and industry.

Conclusions

Medical textiles are one of the most dynamically expanding sectors in the technical textile market. Growth rates are above average as a result of increases in consumption in developing countries in Asia and growth rates in the Western market. The prospects for medical textiles are rather better, especially for non-woven materials and disposable medical textiles used in surgical rooms.

Table 2. Implantable materials (from Rajendran et al. [10]).

Fibre Type	Fabric Structure	Application
Collagen, catgut, polyglycolide fibre, polylactide fibre	Monofilament, braided	Biodegradable sutures
Polyester fibre, polyamide fibre, PTFE fibre, polypropylene fibre, polyethylene fibre	Monofilament, braided	Non-biodegradable sutures
PTFE fibre, polyester fibre, silk, collagen, polyethylene fibre, polyamide fibre	Woven, braided	Artificial tendon
Polyester fibre, carbon fibre, collagen	Braided	Artificial ligament
Low-density polyethylene fibre		Artificial cartilage
Chitin	Nonwoven	Artificial skin
Poly (methyl methacrylate) fibre, silicon fibre, collagen,		Eye-contact lenses and artificial cornea
Silicone, polyacetyl fibre, polyethylene fibre		Artificial joints/bones
PTFE fibre, polyester fibre	Woven, knitted	Vascular grafts
Polyester fibre	Woven, knitted	Heart valves

Table 3. Extracorporeal devices (from Rajendran et al. [10]).

Type Fibre	Application	Function
Hollow polyester fibre, hollow viscose	Artificial kidney	Remove waste products from patients' blood
Hollow viscose	Artificial liver	Separate and dispose of patients' plasma and supply fresh plasma
Hollow polypropylene fibre, hollow silicone membrane	Mechanical lung	Remove carbon dioxide from patients' blood and supply fresh oxygen

Table 4. Healthcare/hygiene products (from Rajendran et al. [10]).

Fibre Type	Fabric Structure	Application
Cotton, polyester fibre, polypropylene fibre,	Woven, nonwoven	Surgical gowns
Viscose	Nonwoven	Surgical caps
Viscose, polyester fibre, glass fibre	Nonwoven	Surgical masks
Polyester fibre, polyethylene fibre,	Woven, nonwoven	Surgical drapes, cloths
Cotton, polyester fibre, polyamide fibre, elastomeric-fibre yarns	Knitted	Surgical hosiery
Cotton, polyester fibre	Woven, knitted	Blankets
Cotton	Woven	Sheets, pillowcases
Cotton, polyester fibre	Woven	Uniforms
Polyester fibre, polypropylene fibre	Nonwoven	Protective clothing, incontinence, diaper/sheet, coverstock
Superabsorbent fibres, wood uff,	Nonwoven	Absorbent layer
Polyethylene fibre,	Nonwoven	Outer layer
Viscose, lycocell	Nonwoven	Cloths/wipes

Editorial note

1) David Rigby Associates is a consultancy specialising in the fibre, textiles and clothing industry, based in Manchester, UK.

References

1. D. Höfer, M. Swerev, 'The Future of Medical Textiles: High-tech For the Well-being of the Patient', *Journal of Textiles and Apparel, Technology and Management*, 2003.
2. 'Global Harmonisations Task Force (GHTF)', *AHWP Technical Committee Meeting and Workshop, Malaysia*, 2001.
3. 'GHTF Summary Technical Documentation', *Asia Harmonization Working Party Technical Committee, Bangkok*, 2002.
4. 'Risk-based Classification of Medical Devices in the European Union (GHTF): Point of View from a Notified Body', *3rd AHWP Technical Committee Meeting, Taipei, Chinese Taipei (Taiwan)*, 2004.
5. S. Anand, 'Medical Textiles', *Woodhead Publishing Ltd, Abington*, 2001.
6. 'Opportunities for healthcare and medical textiles growth', *Technical Textiles International*, 2003.
7. 'Technical Textiles and Industrial Nonwovens: World Market Forecast to 2001', article taken from *DRA Service* <http://www.davidrigbyassociates.com>
8. A. Fischer, G. Fischer, 'Composite materials in healthcare and wound management' *Technical Textiles International*, Vol. 12, 2003.
9. 'The future of the textiles and clothing sector in the enlarged European Union', *Commission of the European Communities, Brussels*, 2003.
10. S. Rajendran and S.C. Anand, 'Development in Medical Textiles', *Textile Progress*, 2002, pp.10-13.
11. 'NWDA Northwest Textile Cluster, Mapping Project', *DRA*, 2001.

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