Abstract

The barriers for entering the medical textiles market are rather strong as it is highly technically specialised and dominated by long established players. Existing intellectual properties and competencies require careful consideration before venturing into this business to avoid infringement disputes. An approach for entering this market could be to consider the newly evolving 3D-weaving and uniaxial noobing processes as they produce entirely new 3D fabric structures compared with traditional 2D structures. They thus present completely fresh research and business opportunities for developing and marketing innovative 3D fabric based healthcare products. The relative newness of both these processes can be suitably utilised for producing certain niche 3D fabric based medical products. Scaffolds for tissue engineering and organ regeneration, reinforcements for lightweight composite materials for replacing relatively heavy and unfavourable metal implants and certain prosthesis items, and profiled items for artificial ligaments and tendons are some applications for which 3D fabrics could be considered.

The business of medical textile products requires constant strategic innovation and its protection, safety assurance and committed entrepreneurs capable of sustaining consistent quality deliveries for commercial success. Patents are indispensable for both research and entrepreneurship. Utmost care must be exercised to avoid infringement of intellectual property rights. To be globally competitive in this market, their certification and clean-room manufacturing practices are obligatory requirements. This paper outlines a roadmap for enterprising textile technologists who want to be researchers in the field of medical textiles and subsequently become entrepreneurs to provide value through innovation. The principles of 3D-weaving and noobing processes, relevant intellectual property and dedicated entrepreneurship aspects relating to 3D fabric based healthcare products, by way of example, are presented from the perspective of a researcher-entrepreneur.

Key words: 3D Textiles, 3D Fabrics, 3D-Weaving, Noobing, Textile healthcare products

1: Introduction

Fabrics designed for healthcare and hygiene applications come under the medical textiles group of the technical textiles market. Medical textiles is a highly specialised field and its chief reference sources are Adanur (1995), Horrocks and Anand (2000) and Rajendran (2009). It is an area of rapid growth because it is driven by innovations in both textile technology and modern medical procedures. From research and business points of view it is necessary to make intellectual property rights the basis for knowledge entrepreneurship and leverage it as a core competence. Unlike clothing and furnishing fabrics, each technical textile product holds certain unique potential for commercial exploitation requiring protection of the uniqueness. Their specific textile architecture influences performance and together with their high-value and low-volume nature, they become important and advantageous for research and business. It is for these reasons that the medical textiles industry identifies itself with innovative and value-added patented products and thereby succeeds in its business. Just being a source for bulk manufacture and supplier of ordered medical textiles goods is commercially unattractive in this highly innovative and competing field.
Fabric-based healthcare products are broadly classified on the basis of their applications. These include preventive (e.g. nonwoven face masks), hygiene (e.g. braided dental floss), external mitigation (e.g. knitted pressure garment), external healing (e.g. knitted wound dressing), internal mitigation (e.g. woven veins) and internal healing (e.g. sutures). Some of the new developments in medical textiles relate to their functionality. For example, active healing components, use of bio-active textiles, tissue engineering as an alternative to human donor organs, and inclusion of antimicrobial agents in hospital linen for remedying the increasing number of hospital-acquired infections.

The medical textile products exemplified above are perceived to have a direct application and considered relatively more valuable than certain other products that are indirectly healthcare related. For example, mosquito nets, ballistic protection vests, butcher’s gloves, fire suits and chemical resistant suits, although usually not seen as direct medical application fabric products, anyhow have a major influence on a person’s well being. Such dual-use products are not considered medical products because they are non-sterile and non-implantable. However, if such dual-use type product is marketed as a medical device then it has to comply with necessary legal requirements and if sold as personal protection equipment, then comply with corresponding legal requirements. Hygiene products such as bedding materials, napkins and surgical gowns are marketed as disposable personal protection items - not as medical devices. They are regarded commodity products and hence valued relatively lower.

The direct and indirect categories of healthcare products are perceived highly differently in both medical practice and market. From practice point of view the former category of products possesses the value of being sterilised as they are manufactured in clean room conditions and officially approved for safe use. From market point of view the products of the former category are more interesting because they are specialised items and therefore of relatively high value and low volume. While these factors are important to a large extent for a product’s success, it is the specifics of the patent that forms the basis of the product and also its business, and significantly impacts the product’s commercial value. Needless to emphasise, the credibility of the product’s manufacturer seals the long term commercial success.

Given that the traditional fabric-forming technologies have been employed for so long and innovative products thereof are constantly patented, the barriers for entry are high for the lucrative medical textiles market. One cannot compete in this field with established and dominating players and products on just lowered costs. Penalties for infringing patents can be too harsh for a business. The product’s safety certification cannot be ignored. Medical textiles business has a bearing on a number of other factors as well:

- Population growth rates
- Changes in demographics, including ageing of population
- Changes in living standards
- Increased awareness of risks to health
- Continuing dominance of the leading suppliers and brands
- Ongoing enhancement in product performance
- Growing dominance of purchasing which demands increasing value for money

It will be apparent from the foregoing that it is almost impossible to gain entry in the medical textiles market with products based on traditional textile methods. To seek new opportunities, the emergent 3D-weaving and
noobing technologies could provide a way as they are relatively new and offer innovative possibilities for developing and manufacturing novel niche 3D fabric based healthcare products. Accordingly, the principles of 3D-weaving and noobing processes, relevant intellectual property and dedicated entrepreneurship aspects relating to 3D fabric based healthcare products, by way of example, are presented from the perspective of a, and for a would-be, researcher-entrepreneur. The contents of this presentation should not be assumed in any way to be free from intellectual property rights.

2: 3D Fabric-forming Processes
The relatively recent emergence of 3D fabric manufacturing processes opens new opportunities for research and entrepreneurship. One area, other than the composite materials, that is considered potentially favourable for 3D fabric research and business is the medical application. This is because 3D fabric structures are new and they can be manipulated in countless ways to perform differently for different applications. They provide limitless possibilities to engineer new and different fabric properties and structures. Each interesting solution provides an opportunity for commercial exploitation. To understand this attractive and emerging field, it is pertinent to present here the definition of 3D fabric and the main aspects of 3D-weaving and noobing processes, which were first defined and explained by Khokar (1996, 2001, 2002).

2.1: Definition of 3D Fabric
A 3D fabric is a single fabric system (i.e. layer-less), the constituent yarns of which are supposed to be disposed in a three mutually perpendicular planes relationship. A 3D fabric need not necessarily comprise three orthogonal sets of yarns; it can be produced using one set, and even five sets of yarns.

2.2: Relevant Aspects of Conventional Weaving
To explain the processes of 3D-weaving and noobing, it is essential to recapitulate certain relevant aspects of the traditional 2D-weaving process that has been in practice for at least 27000 years as reported by BBC News (2000). Its principal operations, shedding and weft inserting, are too well established to require any detailing. It is technically referred to as the 2D-weaving process because its inherent working design enables interlacing of only two mutually perpendicular sets of yarns, the warps and the wefts, notwithstanding whether the warp yarns are supplied in a single layer or multiple layer. While processing a single warp layer results in a sheet-like 2D fabric, processing of multiple layer warps results in a 3D fabric. Such a production of 3D fabric is not the 3D-weaving process because the functioning of the 2D-weaving process remains identical whether producing 2D or 3D fabrics and both these woven fabric types comprise only two sets of yarns. In both these cases, the shedding operation displaces the warp yarns in only the fabric-thickness direction to create a shed in the fabric-width direction into which the weft is inserted. Because the devised shedding operation can displace warp yarns in only one direction (viz. fabric-thickness), it is referred to as the mono-directional shedding system.

2.3: 3D-Weaving
The 3D-weaving process was invented by Khokar and described by him (2001). It differs fundamentally in two important technical aspects from the conventional 2D-weaving process. The first concerns the incorporation of dual-directional shedding operation, which enables displacement of a grid-like arranged warp yarns not only in the fabric-thickness direction, but also in the fabric-width direction. As a consequence, multiple sheds are created in two mutually perpendicular directions. The second aspect unique to the 3D-weaving process is the possibility of inserting correspondingly multiple wefts in the multiple sheds of the
fabric-width and also fabric-thickness directions. By doing so, the warp is interlaced by two mutually perpendicular sets of wefts - the horizontal and the vertical sets of wefts. The woven material produced by the 3D-weaving process thus comprises three sets of yarns - the warps, the horizontal wefts and the vertical wefts. The schematic of 3D-weaving process is illustrated in Fig. 1.

![Diagram of 3D-weaving process](image)

**Fig. 1** The 3D-weaving process is enabled by the dual-directional shedding operation.

The 3D-weaving process offers new possibilities in directly engineering solid, shell, tubular and their combination structures. Further, these structures can be produced in a countless cross-sectional profiles. Some of the profiled materials, developed for composite material applications, are exemplified in Fig. 2.

![Profiled materials](image)

**Fig. 2** The flexibility of 3D-weaving process enables direct production of profiled cross-section materials in shell, solid and tubular types.

### 2.4: Noobing

Non-interlacing, Orientating Orthogonally and Binding are the fundamental features of this process, the acronym of which forms its name. This process evolved in the second half of the 20th century and it originated in the aerospace industry primarily for overcoming the problem of delamination (i.e. separation of sheets/layers) of composite materials. It was erroneously assumed to be 3D-weaving until Khokar (1996, 2001, 2002) brought it to light and explained its unique principle and technicalities.

This process is of two types - uniaxial and multiaxial. In the former type, a set of axial yarns is bound by two mutually perpendicular sets of yarns in fabric-width and -thickness directions. In the latter type, four sets of yarns, which are mutually orientated in as many different directions (length, width and +/- bias), are bound by the fifth set of yarns in the fabric-thickness direction; such fabrics are commercially called multiaxials or NCF (non crimp fabrics). An important characteristic feature of the noobed fabric is that all the incorporated sets of yarns occur linearly as they neither interlace, nor inter-loop nor intertwine in any way, disregarding the manner in which they are bound / connected on the fabric’s surfaces. The structures of both these noobed fabrics are illustrated in Fig. 3, without the binding constructions on the surfaces.
The Noobing process is of uniaxial and multiaxial types, each producing a characteristically different structure but comprises linear yarns. While multiaxial noobing enables production of sheet-like multiaxial materials, the uniaxial type is highly versatile as it can directly produce countless types of shaped or formed objects such as cones, cylinders, graters and flanged items.

3: 3D Fabric Products
From the point of healthcare and hygiene products, the described structures producible by the 3D-weaving and uniaxial noobing are attractive for research and business. Their unique structures can be used for developing high-performance and functional medical textile items through research. Such value-added products can be taken up for manufacturing and marketing by dedicated entrepreneurs. By way of example, the following three products could be developed using 3D fabrics.

3.1: Scaffold Textile scaffolds function as reinforcement substrates to help regeneration of tissues and organs. They are preferred because they can be uniquely engineered to be porous while providing shape, dimensions and directions for the biological mass to spread and grow. Additionally, textile scaffolds can be made relatively light, strong and biodegradable. Fig. 4 shows an inorganic sponge, found on sea floor, that has a unique structure to bear enormous loads. 3D-weaving process provides a possibility to produce similar structures which can be useful in scaffold application.

3.2: Composite material implant Textile materials constitute the reinforcement component of a composite material, the other being a suitable matrix, such as a polymeric material, epoxy resin etc. for the proposed end-use application. Together they form a relatively lightweight and strong material, making it highly suitable for a variety of medical applications - from implants for mending broken bones (internal) to artificial limbs.
3D Fabrics, by virtue of being a single fabric system and having yarns in its thickness direction as well, are most suitable because they prevent delamination and thereby increase material reliability. In comparison to metal components, composite materials are also advantageous in that the tissue/flesh can be made to attach on its bio-active surface obtained through selection of suitable matrix formulation and/or surface treatment. Other advantages of composite materials for medical use include fatigue tolerance, corrosion resistance, high mechanical strength, electrical and thermal insulation, good damping and resonance, and radiolucency (transparent to electromagnetic radiation). As a consequence, they are a high-performance, functional and reliable material for medical applications. In Fig. 5 are exemplified two composite material products for internal (bone joining plate) and external (limb) medical applications.

![Composite material products](image)

**Fig. 5** Textile reinforced composite materials provide high strength to weight ratio and also radiolucency.

### 3.3: Profiled materials

3D Fabrics, on account of being producible in a variety of cross-sectional shapes, are highly suited for being used as artificial ligaments and tendons which are cord-like. The structure of such 3D fabrics can be engineered in a variety of ways to obtain required flexibility/stiffness. A 3D fabric, for example when required for replacing a torn or damaged anterior cruciate ligament for knee, should exhibit resistance to creep from repeated loading. To realise such a 3D fabric, it can be directly composed using different fibre types at the surface and in the interior and thereby obtain a product with specific performance and function. Both 3D-weaving and uniaxial noobing processes offer possibilities for producing artificial ligaments and tendons in suitable cross-sectional profiles as well as in tape forms.

### 4: Research and Patent

Textiles for medical application can be developed only with the active involvement of relevant textile and medical experts. As development of such products require multidisciplinary knowledge and efforts, a research plan should specify at the very outset the different knowledge that shall be required and identify their possible sources.

Healthcare medical textiles are highly specialised and valued products. High premium is attached to certain products, such as implants, depending on their application. The premium is charged not only for the benefit it brings to the patient, but also for the ease with which it can be handled by the surgeon during a surgery. The innovation must offer, certain differentiator/s - either one for benefiting the patient or for ease of handling by the surgeon or both. Such an enlarged scope for innovation increases the invention possibilities as well.

The purpose of research is not only creating new knowledge. Such new knowledge, particularly if it is technology related, should be practicable because it is created at certain cost and it also involves considerable time and effort. It must bring some returns and rewards. While the academic research often
overlooks the commercial aspect of its results, the same research if carried out in industry seeks commercial potential of the results in terms of one or more of the following practicable things:

a) Creation of either a new production method or improvement of existing one in certain unique way
b) Improvement in either quality of the process or the product thereof
c) Creation of either new or improved material properties
d) Enhancement of either material performance or process in certain unique way
e) Creation of either new product or by-product
f) Reduction of costs - not necessarily in financial terms, but also in time and effort

A research normally does bring forward at least one of these indicated innovative things. Hence, it is not only important to become aware of the new technological knowledge being created early in the research project, but also securing and protecting that new knowledge.

Formulation of a patent application requires particular skills. This might not be available directly within the group. It is important that the application is prepared by a professional so that its circumvention is not easily possible. A strong patent is more commercially interesting and more valuable. Patents originating from an institution, either academic or industrial, render such organisations intellectually and economically powerful. Patents are also a measure of knowledge based economy and enable innovation based companies. In this context it is interesting to consider briefly the latest statistical data provided by WIPO (2010) shown in the Table below. It relates to patents filed by certain countries during 2009 (a year of recession).

Table: Statistics relating to patents (2009)

<table>
<thead>
<tr>
<th>Country</th>
<th>Number Filed</th>
<th>Per Cent</th>
<th>Ranking</th>
<th>Persons/Patent</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>45790</td>
<td>29.4</td>
<td>1</td>
<td>6 709</td>
</tr>
<tr>
<td>Japan</td>
<td>29827</td>
<td>19.1</td>
<td>2</td>
<td>4 260</td>
</tr>
<tr>
<td>Germany</td>
<td>16736</td>
<td>10.7</td>
<td>3</td>
<td>4 919</td>
</tr>
<tr>
<td>South Korea</td>
<td>8066</td>
<td>5.2</td>
<td>4</td>
<td>6 014</td>
</tr>
<tr>
<td>China</td>
<td>7946</td>
<td>5.1</td>
<td>5</td>
<td>168 463</td>
</tr>
<tr>
<td>France</td>
<td>7166</td>
<td>4.6</td>
<td>6</td>
<td>8 939</td>
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<tr>
<td>UK</td>
<td>5320</td>
<td>3.4</td>
<td>7</td>
<td>11 487</td>
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<tr>
<td>Netherlands</td>
<td>4471</td>
<td>2.9</td>
<td>8</td>
<td>3 738</td>
</tr>
<tr>
<td>Switzerland</td>
<td>3688</td>
<td>2.4</td>
<td>9</td>
<td>2 062</td>
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<tr>
<td>Sweden</td>
<td>3667</td>
<td>2.4</td>
<td>10</td>
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<tr>
<td>India</td>
<td>761</td>
<td>0.48</td>
<td>-</td>
<td>1 520 233</td>
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<tr>
<td>Singapore</td>
<td>594</td>
<td>0.38</td>
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<td>7 840</td>
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<tr>
<td>Brazil</td>
<td>480</td>
<td>0.3</td>
<td>-</td>
<td>414 040</td>
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<tr>
<td>South Africa</td>
<td>389</td>
<td>0.25</td>
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<td>126 099</td>
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</table>

From a total of 155900 patents that were filed, 132677 (85%) patents belonged to the top 10 ranking countries. Two important points emerge from these statistics:
(1) Innovation leads to their commercialisation which in turn generates funds to sustain further innovation, and

(2) Patents provide the necessary barriers for sustaining the innovation cycle indicated in the point above.

The trueness of these observations become clearer when considering the top three entities that filed the patents during the year 2009:

1 - Panasonic Corp., Japan - 1891
2 - Huawei Technologies Co. Ltd., China - 1847
3 - Robert Bosch GmbH, Germany - 1586

That these companies could individually file over 1500 patents in a given year is a clear indication of innovation-funding-innovation. Perhaps the most innovative way to sustain a business! Clearly, for a business to flourish, innovation is indispensible to sustain it. Perhaps herein lies the key for the countries with relatively high persons/patent to strengthening their innovativeness through research and commercialisation of research. After all, innovation feeds innovation.

Among the universities, the one with most patents was University of California with 321 patents; ranking at number 40 in the list of top 100 companies. These many innovations from a single university uniquely enhances its reputation while enabling spin-off companies. These start-ups will bring not only economic returns to their respective mother institutions but also generate new knowledge that will as much advance them as the institutions. This is a win-win situation for all.

From textiles point of view, there were 2997 patents filed out of a total of 155900, that is 1.9%. Thus, every 52nd patent was a textile related patent. Given that the basic fabric-forming processes continue to dominate and new processes are not easy to come by, it can be a safe guess that at least half of the indicated patents relate to new fabric products produced by the existing methods. Obviously 3D-weaving and uniaxial noobing processes, being relatively new, hold immense potential for creating innovative 3D fabric products notwithstanding that employing these processes requires one to consider infringement issues.

5: Research and Entrepreneurship

The goal of research should go beyond just creating new knowledge. Its practical applicability should always be made a purpose. This is because it can be highly motivating and satisfying for researchers to see their work being employed commercially or industrially. Participating in such a venture can be highly rewarding as well. To realise such a situation requires that the enterprising researchers seek protection for their innovation as soon as its commercial potential becomes apparent. Spread of newly created information should be controlled by considering the following:

- Analysis of its practical impact
- Determination of its commercial impact
- Publication of relevant results with due care
- Determination of practicability and scaling up possibilities
- Careful discussion within core group for securing idea
- Searching and formulating patent to form a safe basis for publishing a technical/scientific paper
- Filing patent application
Alongside the above activities, and at the appropriate stages of research work, it is important to ensure that the idea works practically. Development of a simple working model can directly help in verifying the idea. The patent search can yield valuable information on the obtaining state-of-art. Visits to important and relevant industrial exhibitions can bring fresh inputs and establish valuable contacts. Careful publication of certain results in trade magazines can generate commercial interest and provide leads to commercial viability of the idea. No matter how good the idea appears to be, the most important thing is to quantify the benefits it will bring. If there is little to gain from the idea, there will be no commercial interest in it.

The steps indicated above are necessary to follow as they help in identifying the inventions/ideas that have practical and commercial potential. It must be borne in mind that patents cost a lot and therefore all inventions and ideas cannot be considered for patenting.

Generation of research based patents bring certain prestige to the researcher and also to the institution where the research is carried out. Unlike a technical/scientific paper, a patent can bear the name/s of only the true inventor/s. Usually, an idea generates in only one person’s mind. It is possible that more than one idea can be combined to achieve an objective. In such a situation the true inventors are jointly indicated.

It is important to have only the true inventors indicated in an application because it will have to be properly defended during its examination and prosecution. Otherwise, the invested time, effort and money will come to nothing. Also, indication of true inventor/s helps enormously to avoid later problems relating to commercial implementation of the patent. For example, last minute backing out of potential investors and licensees from a proposed deal, should there be any indication of disagreement between the ownership of the invention.

The research institution stands to gain substantial goodwill from a fairly administered patent. Foremost is the high credibility and trust in the institution. Industrial funding for research becomes possible. New skill sets evolve in the institution that make it academically and industrially more preferred to researchers as well as external collaborators. Specialists/experts working with new technological developments increase the institution’s reputation. Satisfied research students benefit the institution in many supporting ways. There is thus a lot to be gained by all stake holders in acknowledging the true inventor/s.

6: Obligatory Requirements
To be able to offer medical textile products commercially, it is not just a question of producing them cost-efficiently. A number of other factors have to be considered, particularly the obligatory requirements relating to product certification and clean-room aspects. Both these require careful and strict adherence as they are very wide in scope with legal aspects. Only a rudimentary introductory points are presented here to make entrepreneurs new to this field aware about these issues.

6.1: Product Certification
Products such as new drugs and medical devices must be proven to be safe and effective before the companies can launch them on the market. All medical product evaluation decisions are based on whether the new product's benefits to users will outweigh its risks. Even such a controlled product can never be totally risk-free. Yet these carefully considered decisions are important. Notified institutions are empowered to review the results of clinical tests conducted by companies to determine if the product is safe and effective, and complies with the specifics of the relevant directives and standards. This is a requirement to
enable the manufacturer declare that the product is approved for market, usually through a marking, such as CE in Europe. Such markings are a prerequisite for exporting medical textiles.

Apart from safety certification, mandatory notification is also required to indicate conformity with certain parameters such as the product’s composition in respect of:

- Product composition: fibre type, coating type etc.
- Presence of certain harmful substances: toxic (such as pesticides, heavy metals) softeners, fire retardant products
- Maintenance and care of the product
- Process validation
- Users instructions

Another requirement is the Certificate of Compliance which refers to the following features:

- Inflammability
- Antistatic properties
- Utility properties
- Hygiene properties
- Protection against UV radiation

Each produced item is also required to bear a tracking label to enable quick investigation into its production history, should problems relating to its performance, effectiveness, defectiveness and function occur. These problems have to be remedied immediately in a transparent manner failing which the penalties can hurt the business, not only financially but also through loss of confidence or credibility. Another reason that could hurt the business is product recall. This should be avoided by taking the following precautions:

- Knowing and complying with legal requirements and standards
- Controlling the supply chain
- Testing
- Monitoring product use
- Evaluating complaints, inquiries and injuries
- Acting on customer feedback
- Responding to retailer/importer notifications
- Reporting safety issues

In certain situations, a problem relating to a product could be resolved through independent, third party testing and certification services provided for global companies. However, resolving problems by this approach can be expensive and time consuming.

Notwithstanding the above presented obligatory requirements relating to products, there is also the need to comply with the manner in which the medical textiles are produced. This aspect mainly concerns the clean-room practice which is briefly presented next.
6.2: Clean-room Practice

Clean-room ensures an environment with highly reduced levels of particulate, microbes, and contamination of all kinds. Generally this is achieved by continuously flushing a work area by forcing highly filtered air through High Efficiency Particulate Air (HEPA) filters which can prevent over 99.97% of particles measuring greater than 0.3 microns from entering the work area.

Horizontal Laminar Air Flow and Vertical Laminar Air Flow are two types of clean-rooms. In the former type, HEPA filters are mounted on a wall and force clean air from one side of the room to the other. In the later type, HEPA filters are fixed on the roof and force clean air down to the floor. In both cases, air is forced through the filters at a rate of about 30 m/minute.

The level of contamination control required by an industry is designated by Classes 100,000, 10,000, 1,000, 100, 10 and 1 which refer to the maximum number of particles bigger than one half of a micron that can be allowed in 0.028 m$^3$ of clean-room air. Thus, a Class 10 clean-room, would not contain more than 10 particles bigger than half a micron in the given volume. Clean-room certification is a must and it can be performed when either empty or with people for simulating true working conditions.

As people are the main source of contamination in a clean-room, special overall garments made of very tightly woven fabrics are required. Apart from such garments, personal belongings and the equipment and materials too have to be regulated. These aspects are briefly listed below.

- **Clean-room Garments:** Only approved types can be worn following a dressing procedure in which the hood is tucked into the coveralls which in turn is tucked into the boots. Gloves are worn over the coverall arms. Hair should always remain tucked under the hood. Opening of the garment is prohibited. Worn garments should be deposited in dedicated containers outside the clean-room.
- **Personal Clothing:** Clothing made from synthetic materials are preferred as they shed less particles and fibres.
- **Jewellery/Watches:** These are not allowed as they retain dead skin flakes.
- **Cosmetics:** All items such as eye-liners, nail polish, hair and body sprays, powders, perfumes, are prohibited.
- **Gloves:** Gloves prevent medical textile products from getting contaminated by skin and dirt particles. They should be removed and discarded outside the clean-room after each use.
- **Eyeglasses/Goggles:** Glasses and goggles should be cleaned of any visible contamination before entering the clean-room.
- **Food/Medicines:** No edibles and medicines are allowed in the clean-room.
- **Smoking:** Smoking is forbidden in or near the clean-room. A person who has smoked can be allowed in the clean-room after one hour, and after drinking at least one glass of water.

The equipment and materials in the clean-room have to be chosen with care:

- **Buckets** should made of stainless steel.
- **Trolleys** should have a stainless steel or smooth painted surface with wheels made of polyurethane.
- **Furniture** should have laminated exteriors or made of steel or polypropylene with scratch resistant surfaces.
- **Glove box** may be used for storing documents and be made of transparent plastic for ease of viewing.
- Packaging material should be certified for use in clean-room.
- Paint should be scratch and chip resistant and of low out-gassing type.
- Paper products such as regular and card-boards should never be allowed in the clean-room.
- Pens/Pencils of only one-piece type should be used as click-type pens generate metal and plastic particles. Pencils should never be used as they generate graphite particles.
- Rubber products can disintegrate either physically or chemically and should be contained in clean-room packaging material.
- Racks and cabinets should be made with open grate stainless steel to minimise air turbulence and kept away from critical process areas.
- Chemicals should be kept in only approved containers.
- Adhesive tapes should not leave adhesive residues behind when pulled out.
- Tools should be clean-room dedicated to eliminate repeated cleaning. Abrasive tools should be employed with vacuum assistance to catch generated particles.
- Vacuum cleaners should use filtered exhausts to prevent contamination of air during cleaning.
- Vented cooling systems employed for cooling electronic parts should either be vented to the outside or filtered within the clean-room.

7: Conclusions
Medical textiles industry, which produces healthcare and hygiene products, is innovation based and requires specialist textile and medical knowledge. Established and leading players dominate the market with strong barriers through patents. Entry into this market is difficult, if not impossible. Infringement of intellectual property invites penalties. Products manufactured employing traditional 2D fabric-forming processes are difficult to market because of obtaining patents. An opening could be available through the newly emerging 3D fabric-forming processes 3D-weaving and noobing as they enable completely new structures. They present new opportunities in creating innovative products such as scaffolds, bone joining plates made of textile reinforced composite materials and ligaments and tendons. 3D Fabrics thus offer fresh research and entrepreneurship possibilities for medical textiles.

Researchers and entrepreneurs wanting to develop 3D fabrics for medical applications must protect their innovations through patents. Both academics and industrialists from textiles and medical fields can complement each other to flourish. Infringement of intellectual property in any way and form could damage the prospects of a researcher as well as the entrepreneur. Another requirement with medical textiles concerns their safety in use for which obtaining appropriate certifications are obligatory. New start-ups must consider this aspect because any failure to comply with the statutory requirements invites penalties that can lead to collapse of business. Production of medical textiles requires clean-room practice. Entrepreneurship in this field is interesting because medical textile products are highly specialised items having relatively high economic value and low production volumes. Patents are indispensable for commercial success as they provide a barrier and also a basis for innovation to fund innovation and thereby help sustain the business.

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References