

SUPPORTING OPTIMAL PATIENT
WELL-BEING WITH HIGH-PERFORMANCE

OSTOMY GARMENTS

Best practice and important
aspects to consider

IMPORTANT ASPECTS TO CONSIDER

WHEN DESIGNING OSTOMY GARMENTS

With several decades of experience in developing medical textiles for ostomy purposes we, at Tytex know just how challenging it can be to supply high-performance ostomy garments to end users and clinicians. In this guide, we have highlighted some of our best practices and advice to inspire the development of your branded garment and successfully bringing it to market. Advice covers subjects such as clinical factors, technical factors, patient-specific factors and external factors.

UNDERSTANDING CLINICAL INDICATIONS

Knowing the implications of the clinical procedure preceding the ostomy care is crucial when creating a secure and effective ostomy garment solution. A colostomy poses different challenges than a urostomy, when it comes to applying support or compression both directly following the surgery and in the years to come. This in turn will affect the choice of design, level of compression, texture and fit.

At Tytex, we work closely with clinicians and other industry authorities to determine clinical indications and define intended use. In everything we do, we also apply cross-clinical insights and knowhow from many of our other clinical areas — such as wound care and post op compression after reconstructive surgery.

This does not only secure compliance with a diversity of global regulatory systems, it also enable us to work strategically with clinical evaluation and post-market surveillance to create the best possible garments with the best possible patient outcomes. We offer these insights as an integrated part of our collaboration with you.

DETERMINING INTENDED USE

Support and compression garments such as belts, tubes and underwear may have multiple purposes in ostomy care.

Understanding the intended use and clinical indications is essential when deciding technology as well as composition, design, level of compression and other key properties of a specific garment.

At Tytex we have more than five decades of experience in regards to developing and manufacturing support and compression garments. Our extensive insight into all key properties regarding garments for the healthcare industry is what truly defines our DNA and when working with us you will be developing your brand and product portfolio together with our experts and thereby be accessing all our knowledge and insight.



A GARMENT MAY HAVE SEVERAL INTENDED USES

- Parastomal hernia management
- Enhance patient sense of security and well-being
- Generate fixation and support for the bag
- Keep the protruding tissue in place and relieve discomfort
- Aid the patient in creating sense of normality

TECHNOLOGY IS KEY WHEN DESIGNING FOR

HERNIA MANAGEMENT AND PATIENT WELL-BEING

There are myriads of textile solutions in the marketplace. You can choose to have your garments woven, knitted or made by neoprene just to name a few of the options available. All technologies have various advantages and disadvantages. Some solutions have superior moisture absorbing properties while other technologies offer water resistant qualities. Some are easier and cheaper to manufacture or have better qualities in regards to providing body-fit. Some technologies offer superior stretch capabilities which ensure that the garment will always adapt to the specific body contour of the patient.

All of the above-mentioned solutions can be beneficial in providing compression and support, but you need to consider the various pros and cons when you start designing your ostomy garment line. Above all, choosing a technology which ensures flexibility is crucial to support the stoma or hernia without obstructing stoma flow.

THE COMFORT OF THE PATIENT AT THE CORE OF YOUR PROMISE

When making garments for the healthcare industry it is of the utmost importance to develop a solution based on the comfort of the user. In the experience of the experts at Tytex, it is crucial that medical garments applied to the body exert the least amount of additional stress to the patient and the operated area. Moreover, the garment needs to minimise the risk of infection as well as provide the necessary compression and correction to the critical area.

Another important aspect in regards to comfort is that each patient is different. Variations in needs are especially pronounced in regards to support level. As the need for support and compression varies from person to person any garment which caters to the needs of people suffering from ostomy or hernia needs to address as many patientspecific factors as possible.

WEFT-KNITTED TUBES

Although, all textile technologies come with benefits and drawbacks we, at Tytex, have chosen to focus on weft-knitted tubes, as the primary technology for our compression and support garments*.

The weft-knitting technology offers a variety of opportunities in regards to the stretch and firmness of the knitted fabric and makes it possible to produce at scale. This allows us to produce high quality body-fitted garments with targeted and controlled support and compression at competitive prices. And this is really what we want to achieve.

Circular knitting also allows us to make 100% seamless knitting for critical areas of the body. The absence of hard seams reduces the risk of irritation to both the patient's skin in general and specifically in the stoma or hernia area.

In regards to supporting the patient's well-being, we are able to provide targeted compression at exactly the right place and nowhere else on the

patient's body by optimizing the patterns of the weft-knitted fabrics. In other words, with this technology, we can provide necessary compression and support exactly where needed and otherwise not strain the patient.

Lastly, a crucial aspect in regards to ostomy care is addressing the stretch qualities of the garments. When a garment is able to stretch, the user feels comfortable and the body is both able to move freely as well as remain immobile during prolonged wear.

When you choose medical garments from Tytex for your brand, you are guaranteed that the needs of the patients are deeply integrated in your garments and are at the center of your brand promise.

* We do also have other technologies at our disposal. However, weft-knitted tubes is the technology we mainly apply when making compression and support garments.

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LATEX
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Making postsurgical products latex free, Oeko-Tex certified and making sure the products adhere to all existing medical legislation ensures patients find comfort throughout their entire postoperative experience and have support of their surgical site. All factors are contributing to enhancing the quality of life post-op.



PATIENT-SPECIFIC FACTORS TO CONSIDER

A stoma will be placed somewhere on the patient's abdomen. The stoma site is always selected by the health care professionals in collaboration with the patient.

Considerations regarding stoma site selection include: length, size and shape of abdomen, exposed abdomen in various positions, occupation of patient, clothing worn by patient, use of devices, physical issues, mobility, eye sight, dexterity, self-care ability as well as surgeon and patient preferences to name just a few. All these factors also impact the choice of garment applied to the stoma site both directly after surgery and in the years to follow.

FIXATION AND COMPRESSION GARMENTS USED FOR STOMAS AND HERNIAS NEED TO ADDRESS ALL FACTORS AND MORE

As all the above-mentioned considerations are factored in before selecting the stoma site, all these considerations with the addition of several other considerations – e.g. allergies, skin conditions as well as aesthetic and psychological

factors – also affect the requirements of the garments being applied to the stoma area.

The garments need to be made of material which reduces the risk of allergic reaction to the end user and also be made with a technology which does not adversely affect the aesthetic appearance or the sense of well-being felt by the user.

Moreover, some of the biggest concerns amongst ostomates are skin irritation, the leakage risk, skin pancaking and the sound escaping the intestine. When designing garments for ostomates it is therefore very important to use technologies and textiles which optimally address these considerations.

At Tytex we have developed ostomy and hernia garments which address all the above-mentioned concerns to make the end user feel safe and confident at any time for more than 50 years. Also, our garments are made of strong and durable fabrics which optimally address the needs of the users as well as adhere to the strictest legal requirements.



REGULATORY COMPLIANCE

THE COMPETITIVE EDGE IN THE MARKETPLACE OF TOMORROW

As of May 26, 2021 all of us in the medical industry have been facing new challenges. As the European Union has begun enforcing the Medical Device Reporting (MDR) regulations, many distributors and medical brands have been challenged in more ways than one.

Medical products can be prevented from being sold or become recalled for a number of reasons. But if your product does not comply with one of the many rules of market access, it may prevent you from selling your product entirely resulting in lost revenues, lost accounts and loss of critical market shares. Your products can also risk being recalled resulting in large expenditures in shipping and handling as well as a large amount of time spent on diplomacy with external parties.

EU MDR

The reasoning behind the introduction of MDR was the overall protection of the end user and the felt need to ensure that products marketed within the European Union do not do any harm to humans or the environment. Even despite the fact that medical brands have been complying with

REACH and RoHS for a great deal of time, many have never had their products certified under the new MDR regulations.

The MDR regulations were adopted in 2017 and succeeded the EU Medical Devices Directive (MDD), and many companies are now beginning to struggle in order to comply with the intricate legislation.

At Tytex we have been preparing and have worked relentlessly to be ready for when MDR came into effect. Our specialists are well-versed in all the intricacies of the regulations and we are experienced in helping as well as ready and eager to assist all our partners should they need any assistance in navigating the regulatory system and gain the competitive edge in the medical devices industry.

Please do not hesitate to reach out should you need any advice from us regarding MDR as well as other regulatory systems – e.g. FDA and the Russian regulatory system or the new rules and regulations in relation to Brexit.

ABILITY TO INNOVATE AND HAVING A STABLE SUPPLY CHAIN

ARE CRUCIALLY IMPORTANT FACTORS TODAY

Global demographics are changing, lifestyle patterns are switching and the high prevalence of bladder cancer and colorectal cancer do not seem to be decreasing. Therefore, the market for ostomy care and accessories is growing rapidly.

More and more possibilities exist and new market innovations in regards to surgical methods as well as technological possibilities are continuously appearing. We operate in a market where clinics and hospitals develop rapid surgical advancements and offer a steady stream of innovations like silicone-based ostomy seals and where the patients place continuously increasing demands on the health care sector and shifting towards home care services and displaying ever-increasing preferences for products with IOT-features and technology integrated.

Suppliers of postsurgical ostomy products and accessories need to intelligently cover a wide range of needs, use cases, diagnosis and patient-specific conditions in order to stay competitive. Innovation as well as constant market development is paramount in order to stay competitive in a very regulated, highly competitive and demanding business sector. At Tytex we have more than 50 years experience in working with medical devices. These experiences have left us with effective market surveillance processes — covering FDA, MDD and now MDR compliance — enabling our partners and us to adhere to regulations as well as stay ahead of the market demands and requirements.

SECURING SUPPLY CHAIN AND QUALITY CONSISTENCY

One last aspect we encourage you to consider is your supply chain security and quality consistency.

It is of crucial importance never to let your customers down and here your supply chain is a key factor.

At Tytex, we develop and produce all our medical textile garments according to EU standards, in EU currencies and with short delivery times. Thanks to our Europe based and highly automated production facilities, our customers benefit not only from a highly skilled work force, but also our ability to keep production costs low. This means a reliable and stable supply chain delivering quality products at the best possible prices.

For more than five decades we have developed and refined our product and consultancy offerings. Today, we offer an advanced technological platform supported by a tried and tested process for developing products for ostomy and hernia. We possess extensive knowhow regarding both the manufacturing of textiles but also with satisfying the complex needs of the medical sector and the patients who use our products. No other medical textiles manufacturer operates this professionally with the four unique parameters that we offer: 4-way stretch, real seamless, targeted compression and fixation as well as fact-based sizing.

Like no other company Tytex is able to make your medical garments the right way — providing excellent value for money, European production facilities and a possibility of ordering high quality products at low MOQs. We are very interested in engaging in a further dialogue with you regarding your brand and your business needs. Please contact us should you want us to help you with developing and making products for the ostomy and hernia area.



CONTACT US

Hope you got inspired by this catalogue. Do not hesitate to contact us should you have any questions in relations to your ostomy garment brand.

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