IGGESUND
HOLMEN GROUP

MEDTECH PACKAGING GUIDE

How to minimize risk and bring your brand value to healthcare professionals using high-performance paperboard.

THE PACKAGING DIFFERENCE

You invest heavily in developing next-generation medtech products that must clear regulatory hurdles, save or improve lives and deliver superior value to medical professionals. Now what about the packaging? How could it help strengthen your brand, improve your CSR profile and keep your product safe until the point of usage?

Enhance your brand value
As the competition heats up, smart manufacturers of medical technology are increasingly using packaging to stand out. In many cases, the packaging may be their only point of contact with surgeons, nurses and other key support personnel. So if you've got a high-quality product, shouldn't your packaging reflect that? Quality packaging can help minimize risks and convey a premium feeling that lives up to your brand values. But whether you're an experienced packaging engineer or a product manager at a startup, you're likely to have some questions.

Paperboard expertise for packaging success
Would you like to enhance the value of your products? Boost your sustainability profile? Reduce risk? This guide will show you how.

On these pages you can read about ways to lower total cost of ownership, including transport, storage and sterilization, as well as tips for meeting regulatory requirements and reducing waste.

Here for you
Our team of experts is on hand to share knowledge and answer your questions. Please don't hesitate to contact us if there's anything more you would like to know.

The Iggesund Medtech Team

CONTENTS

1
GET IT RIGHT FROM THE START

What should you consider to optimize your packaging design from the start and avoid risks down the road?

Few would disagree that packaging design is a vital part of the entire medical device development process. Yet all too often it is not given enough consideration until the very end of the product development process. This can lead to complications down the road in terms of added life cycle costs, compliance issues and even the risk of delayed product introductions.

Whether you've got an orthopedic implant, cardiological device or reusable injector, it has its own unique packaging requirements. If you are like most medical device manufacturers, you want the packaging to match the quality of your brand. This requires balancing sometimes conflicting variables: quality versus cost profile; production efficiency versus safety needs; material properties versus sterilization requirements. Should you use plastic bags, overwraps or pouches? Foil or paperboard? And if you decide to go with a paperboard carton, will it be stiff enough to protect the device during transport, storage and handling?

Designing for manufacturability

Packaging system validation is a costly and lengthy process. To optimize product development and speed to market, packaging must be considered as early as possible. It's one thing to produce prototypes or small batches and quite another to handle higher volumes. So ask yourself: are you following a Designed for the Manufacturability (DFM) process? Have you taken into account Design Failure Mode Effects Analysis (DFMEA)? It doesn't matter how fantastic a product is – if it suffers damage by sterilization or package failure during transportation or storage, it is worthless. Many device manufacturers are now incorporating DFM and DFMEA thinking into the process early on to ensure their packaging will be mistake-proof.

Avoiding new compliance processes

One final factor. Once you've certified a certain packaging material, received FDA or EN/ISO 11607 approval and gotten everyone onboard, it can be costly and time consuming to later change to a different type of material. So think twice first; set clear goals and take a holistic view from the start.

STANDARD PACKAGING REVALIDATION PROCESS

$100,000

6-month lead time

+ Big headaches

A good reason for making wise initial decisions when specifying packaging materials

2
GO CLEAN & SPOT FREE

What does it take to secure a clean, spot-free surface in your device packaging?

Purity is of the essence when it comes to medical technology packaging. So it's understandable that keeping printing surfaces free from printing defects and surface dust is a major concern today. Unfortunately, it's not uncommon for packagers to face problems due to loose fibers, clumps and coating particles. These have no place in any premium product and reflect badly on your brand.

Avoiding stoppages and waste
When an inferior board is used, there is always a risk that loose particles – in the form of solid or fibrous material on the paperboard edges or surfaces – will be transferred to the printing blanks, plate or cylinder during the printing operation. This can result in print design defects, unnecessary stoppages, lower press efficiency and material rejection. So how can you make sure this doesn't happen?

Pure virgin fiber helps avoid dust formation
For starters, make sure your packaging partner is using a solid bleached board grade made of virgin fiber. Such grades contain 100% pure intact fibers from chemical pulp. Mechanical pulp, on the other hand, contains fibers that are shorter and more fragmented. This might sound like a detail, but it's critical. Why? Because when the paperboard sheet is cut in the finishing process, the chemically processed fibers will sheer much more cleanly, with very few particles. By contrast, board produced with shorter-fiber mechanical pulp tends to create more dust. The same applies when your box blanks are die-cut prior to folding and filling.

Securing high-quality production
Finally, ask your paperboard supplier about the types of quality assurance controls they have in place. Premium board producers continuously measure hundreds of quality parameters during production and after each batch to ensure that all properties are within the technical specification.

3
DEMAND CONSISTENT QUALITY

Can your supplier specify and guarantee up to 32 properties on their paperboard – with tight tolerances?

Quality matters. So make sure the board properties you specify are the ones you actually get – from batch to batch, sheet to sheet. This is important because even small variations in agreed tolerance levels can impact packaging line efficiency or jeopardize the safety and integrity of your package. Serious board manufacturers specify up to 32 properties, with tight tolerance ranges in their product sheets.

We're talking about properties relating to stiffness, strength, shade, grammage, and dimensional stability. Even small variations in these properties and the carton's relevant structural design features can cause disturbances in the optimum settings necessary to achieve efficient performance in the packaging operation. Dimensional variations may cause misregister between the printed image, as well as cuts or creases. So demand consistent tolerance levels.

Ask for a full list of product specifications

Many suppliers talk about quality and the consistency of their product. They may specify and guarantee four or five key properties and even excel in some areas. But what about tear resistance, L*a*b* values, moisture content and other key properties? The fact is that quality board makers have complete spec sheets and can guarantee tolerances of +/-4% on grammage (ISO 536), thickness (ISO 534) and more. Be sure to request a complete product sheet.

EXAMPLE OF 32 SPECIFIED PROPERTIES ON A MEDICAL-GRADE VIRGIN FIBER BOARD

1. Opacity (%)

Printing side properties

Color

2. L* (%)
3. a*
4. b*
5. Whiteness (%)
6. ISO Brightness (%)
7. Surface roughness (µm)
8. Board gloss 75° (%)
9. Surface pH
10. Ink absorption (%)

Surface strength IGT (m/s)

11. Blister
12. Pick

Reverse side properties

Color

13. L* (%)
14. a*
15. b*
16. Whiteness (%)
17. ISO Brightness (%)

Board properties

18. Ply Bond (J/m^2)
19. Wick-Test (kg/m^2)

Cobb (g/m^2 min)

20. Printing side
21. Reverse side
22. Moisture content (%)

Bending stiffness[2] L&W 5° (mNm)

23. MD
24. CD

Bending resistance L&W 15° (mN)

25. MD
26. CD

Bending moment Taber 15° (mNm)

27. MD
28. CD

Tensile strength (kN/m)

29. MD
30. CD

Tearing resistance (mN)

31. MD
32. CD

** See general technical information on printing and color reproduction in Iggesund Reference Manual*

4
SECURE STERILITY

What to consider when selecting a paperboard to meet your sterilization requirements.

As a medical device manufacturer, you need to secure, document and validate purity and sterility for patient-doctor safety. Your packaging must be of the highest quality – including package integrity, shelf life and sterility assurance levels. Choosing a high-quality paperboard for the secondary packaging or insert will be essential in terms of permeability, cleanliness and quality. It must be robust and stand up to tough conditions.

Whether you are sterilizing in your own clean room facilities or outsourcing, your method will depend on the type of material used in your medical device, the type of microorganisms involved, the classification of the item, to mention just a few factors.

So when selecting your packaging material, make sure to check that it is compatible with your sterilization method. Ask your material suppliers for the relevant material data and insist on samples for testing, to ensure it can endure the stresses and strains of sterilization.

Three common methods
The three most widely used methods are: ethylene oxide gas, ionizing radiation (gamma or electron beam) and steam sterilization. What all of these methods have in common is that packages are subjected to considerable stress and strain during the process. So it's vital that your board is strong and durable, with enough porosity to allow the sterilizing medium into and out of the pack.

Ethylene oxide gas
Ethylene oxide (EtO) is often used for sterilizing medical products that cannot withstand high temperatures or get discolored with irradiation. The packaged medical devices are loaded into a vessel that is then sealed. Air is evacuated and humidity is introduced before the injection of EtO gas. This type of sterilization is slower than steam and radiation; it may take a few hours or even days since the final step also includes removing the EtO from the packaging and product before they can be considered safe. Much like steam sterilization, EtO requires packaging material that is porous to the sterilant, while also providing a barrier to microorganisms. For paperboard requirements, ask your supplier about permeability, OBA content, moisture absorption and surface properties, including roughness.

Radiation sterilization
Gamma-ray and electron beam are both radiation techniques. Radioactive gamma-ray sterilization is generally performed inside a structure built of thick concrete walls using cobalt 60 isotope. The irradiation process is carried out on packaging disposables, such as syringes and dressings, and must meet rigorous safety requirements. Faster than steam and gas, the penetrating effects of gamma rays do not require that the packaging material is porous as with EtO. The package needs to be designed and constructed for radiation stability.

Electron-beam radiation uses a charged stream of accelerated electrons to sterilize the product and packaging. Electron beam has a faster dose rate and lower penetration than gamma and can be used for packed products on a conveyor belt. However, since the process produces radioactive waste, some device manufacturers shy away from it. Ask your board supplier about fiber types, density, stiffness and tearing resistance.

Steam sterilization
Also known as autoclaving, steam sterilization is a well-proven and popular method in hospitals since there are no harmful gases or radiation involved. For the most part, this is done on medical instruments after the primary packaging has been removed. Paperboard is not always recommended due to the wet steam at temperatures up to 134°C with a cycle time of around 15 minutes. The packaging should have enough porosity to allow the entrance and exit of steam, yet afterward be an effective barrier against recontamination.

Not all startups or OEMs are familiar with the complexities of sterilization and may often partner with a contractor. In this respect, it’s important to be aware of the quality of the paperboard being used and consult your packaging partner as part of this process.

5
STAND OUT

How to build your brand on the surgeon's supply shelf.

First and foremost, the packaging for your medical technology product needs to be clearly labeled and marked for safety purposes. When busy hospital personnel are reaching for your product, there can be no risk of confusion. And while such packaging may play a lesser role in delivering brand value than it would for consumer products, the feeling of quality and ease of use should not be underestimated.

The quality perception of packaging can be a way to set your product apart and stand out on the supply shelf or in the emergency room, especially in categories where there is strong competition. This makes sense, too, considering that you many have invested substantially in engineering a product that may cost a significant amount of money. When the packaging is attractive, of high quality and easy to open and close, it sends quality signals to doctors, nurses and support staff.

Communicate your full brand value

In some cases, medical device purchasing decisions, especially for implantable products such as cardiac stents, are being made by physicians – despite the power of purchasing departments. When a medical professional comes into contact with your packaging, you want to make sure it communicates your full brand and product value.

Patient-centric packaging

Today, many device manufacturers are using design techniques to move beyond the regulatory mandatories of safety and efficacy to create and enhance brand value and user-friendliness. In some cases, this involves creating more patient-centric packaging that incorporates aspect of usage and instructions into the carton design.

6
SHAPE IT YOUR WAY

Does the packaging material you are using allow you to create technically challenging designs?

Do your sales and marketing departments want your medtech packaging to stand out more? Are they looking for integrated solutions to increase user-friendliness and functionality – special closure tabs, integrated compartments, insert trays to hold an implant securely? With the right paperboard, the only limits are your imagination.

Strong, resilient and pliable

A strong and robust multilayer board made out of virgin fibers enables you to create more advanced shapes than any other regular board material. Due to the strength and elasticity of the fiber mix in the different layers, the carton can be designed to incorporate complex geometries involving deep and narrow creases. The board can also be made into an insert to hold the medical device in place, safeguarding it from transport damages or scratches during transport.

Creating handy compartments

For the secondary packaging, you can create compartments that facilitate easy dispensing for healthcare professionals and efficient packing, enabling the product to slip into the right place without manual handling. With a high-quality virgin fiber board, the possibilities for creating unusual multilayer geometric shapes with board are endless – so don't hesitate to ask your supplier, or a contact at Iggesund, for new ideas.

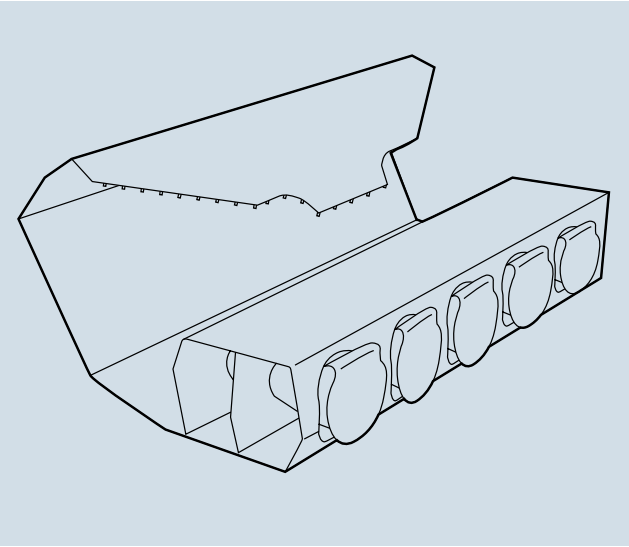
Avoid rips and tearing

With this in mind, it's important to use a forgiving material with strength in all directions; a material that resists cracking along creased folds, cuts and openings. Otherwise, there is a risk that the premium feel of the box will quickly be destroyed. Rips and tears in the packaging reflect badly on the manufacturer – no matter how reputable the product.

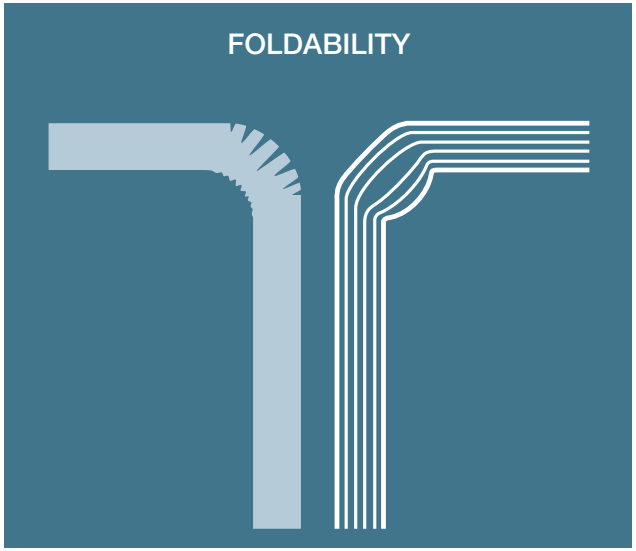
Thousands of folds, no cracks
Remember, a typical monolayer paper – that is, a pulp created from chemical pulp rather than mechanical pulp – will crack almost immediately and break after 20 or even fewer folds due to its construction. So be sure to ask for a multilayer virgin fiber board that can be bent, creased and folded several thousand times without breaking.

The right tools and converting conditions
Using a multilayer board gives the consumer a great experience and enables your box to withstand the toughest printing and converting processes. It provides the durability and dimensional stability to avoid print misregister as well as potential dust build up when die cutting blanks.

Ask for technical support
Ultimately, achieving just the right converting conditions demands the right tools, machine settings and converting conditions. To guide you through this process, the best paperboard partners have skilled technical support teams. So don't hesitate to ask for help.



PERFORATED SEAL, TABS AND FOLDS
Example of a technically challenging device packaging using 100% virgin fiber paperboard to handle perforated seal, tab closure and protective casing, while minimizing the risk of ripping tearing. The one-piece solution protects the product and holds it securely.



AVOIDING CRACKS WITH MULTI-LAYER BOARD
Foldability comparison between single layer and multi-layer paperboard.

7
ENSURE BROAD & ACCURATE COLOR REPRODUCTION

Do you have the right shade of whiteness and surface properties for consistent, accurate color reproduction over a broad spectrum?

Clean, smooth, bright white packaging has a modern, hygienic feel that is essential for medical packaging. It also provides a good base for sharp print reproduction of branded graphics and favorable contrast for reading vital instructions. In other words, it boosts safety while enhancing your brand towards medical professionals.

When choosing paperboard, it's very difficult to know how well the white shade you are viewing will reproduce a broad color spectrum. Nearly all paperboard producers apply a white coating to the surface of their board for enhanced printability in the conversion process. Since some print jobs may involve a full coverage, four-color process, you should ask to review a printed sample.

Trust your eyes
This is especially important if you print a special pink or other light tone. The fact is, many paperboards include high amounts of dyes that create a bluish white that can adversely affect the printing result. So trust your eyes and don't simply accept a specified whiteness value under the right lighting conditions.

Numbers can be deceptive
Remember that the whiteness value alone does not tell the full story of the shade characteristics under the right lighting conditions. The important things are the perceived whiteness and printing results you get.

8
GUARD AGAINST THE FADE FACTOR

Are you getting a balanced, lasting whiteness in your stock that helps resist yellowing and fading-shade changes?

Exposure to light can cause your packaging to fade.
You might have noticed several boxes from one print run sitting next to a newly produced batch that looks quite different on the shelf – basically different shades of white.
Naturally, this can have an adverse impact on the premium image of your brand.

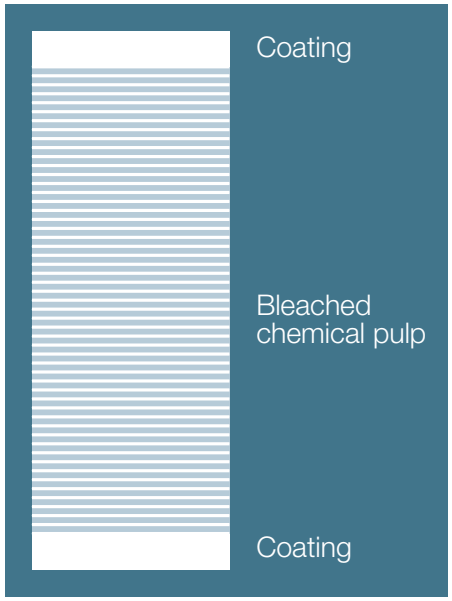
Less lignin, more whiteness
So why does this occur and how can you avoid it? One common reason for yellowing is the presence of lignin, a substance in wood that binds the fiber together. Lignin, which is found in mechanically processed pulps such as folding box board, tends to turn yellow over time. This is due in part to oxidation and to the reaction of ultraviolet light with chemicals used in dyes, as well as excessive amounts of optical brightening agents (OBAs). However, this risk is avoided or lessened by using virgin fiber pulp that has been bleached to remove the lignin and is thus more stable when exposed to light. So be sure you are using a solid bleached board.

Avoid excessive optical brighteners
Even if you are using a bleached board, you may run into trouble if you've specified a more "bluish white" to create a superficially fresher look. The problem here is that this shade is often achieved by adding dyes, which deteriorate over time. The more OBAs and dyes used, the faster the degradation. So be sure to ask your paperboard supplier if their board will slow down the chemical degradation of dyes and OBAs. Ask whether they can guarantee a consistent level of whiteness over time and if they have proof to back it up.

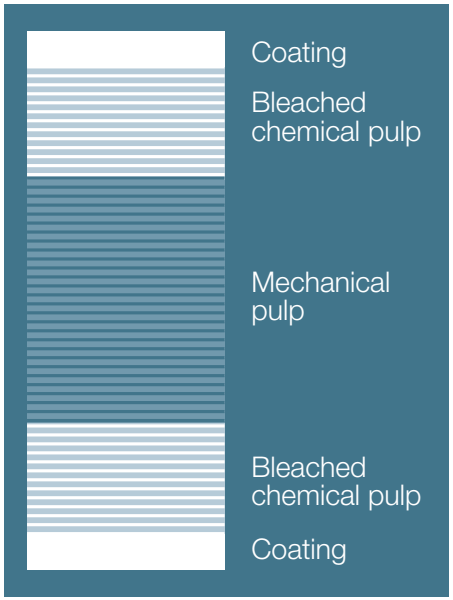
9
KNOW YOUR PAPERBOARD BASICS

What exactly is virgin fiber paperboard and why is it so well suited to the packaging of medical technology products?

If you're not so familiar with packaging, you might be wondering: "What exactly is paperboard?" In simple terms, it's a thick, paper-based material with multiple layers. Because it's strong, bendable and easy to cut, shape and print on, it makes a superb packaging material. Although there are several types, just a few are ideal for the packaging of medical products.



Solid bleached board (SBB)



Folding box board (FBB)

Solid bleached board (SBB)
Pure and hygienic, this board is made from virgin fibers that are chemically processed to give it superior whiteness, hygienic and converting properties. Due to its long and flexible fibers, SBB offers the highest strength properties of all bleached paperboards. It also provides excellent bonding and good network forming ability, meaning it can easily absorb and distribute forces upon impact in transport and avoid ripping or tearing.

SBB can be made in either a single-ply construction or, more commonly, in several plies (multi-ply).

The advantage of the multi-ply construction lies in the ability to optimize fiber characteristics in different layers to reach certain functionalities e.g. surface properties in the outer layer and stiffness and strength in the middle layers. Important properties for cutting and creasing can also be optimized.

A singly-ply (monolayer) construction is more limited since the entire board consists of one fiber composition in which certain key properties are compromised. A singly-ply board is usually more dense and often has a lower stiffness than a multilayer one. The difficulty often shows up as a compromise between stiffness and surface structure. The monolayer structure will not perform as well in creasing and folding as a multilayer board.

Folding box board (FBB)
FBB has a layer of virgin fibers that are processed mechanically and sandwiched between layers of chemically processed virgin fiber. The fibers are shorter and more fragmented than in a pure virgin fiber SBB. The fiber network is also voluminous, reducing its strength slightly. FBB is not as strong as SBB but offers higher stiffness. This can be advantageous when lighter weight is desired, but is a disadvantage for more technically challenging packaging designs.

Ask for board selection advice
Ask your converter or paperboard partner to help select a grade and type that's suited to your product's material, weight and form – whether it is a disposable or reusable. And make sure it will be compatible with the type of sterilization involved.

To sum up, SBB is the optimal material for demanding medtech packaging that needs to look pristine, maintain integrity during transport and be opened and closed multiple times.

10
REDUCE PLASTIC

Plastic is fantastic, but how much do you really need in your product packaging?

Disposable plastic syringes. Dental implants. New heart valves. While there's little doubt that plastic is a vital material for many types of medical devices and their packaging systems, there is growing concern today about the adverse impact on the environment. Many companies today are replacing petroleum-based plastic with renewable organic materials such as paperboard or laminates, in applications where the plastic does not provide critical functionality.

There are no easy solutions for medtech packaging. Each case needs to be evaluated on its own merits and a complete life-cycle analysis should be done to get a full picture. There is little question that plastic materials have certain competitive performance advantages, including being transparent, moisture resistant and, in some cases, cost-effective.

Moving to renewable materials

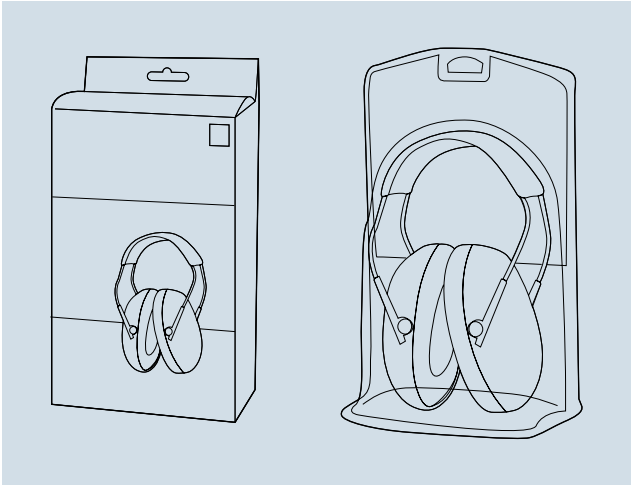
Having said that, replacing plastic with non-fossil materials is a trend that is impacting all industries, including the packaging of medical devices. The reasons are simple: switching from non-renewable plastic to alternative materials such as paperboard reduces companies' climate impact. It also helps them to reach and communicate their sustainability goals. Apple, for example, switched out two stacked plastic trays in its iPhone 7 to achieve an 84% plastic reduction. It did this by creating a single insert with various cuts and folds that elegantly secured the product.

Rethinking packaging design

Admittedly, changing an established infrastructure takes time, especially if it means that the packaging must be redesigned, the packing equipment and machines modified or replaced – not to mention validation and regulatory approval. So if you are just starting a new project, it can be good to think about this from the start.

Tackling the waste issue

It is estimated for that eight million tons of plastic enters our oceans every year. Over the past 50 years, we've moved from reusable solutions to disposable single-use items as plastics production has increased 20-fold. This also impacts landfills, where large amounts of non-biodegradable plastic material can be found. Many manufacturers of medical devices are looking for ways to minimize or even eliminate the use of plastics.



PLASTIC VS PAPERBOARD

In an independent study of two comparable boxes – one in plastic and the other in paperboard – it was shown that the plastic packaging had a 50 times higher CO_2 emissions profile than the paperboard box.

Source: IVL Swedish Environmental Research Institute

11
MINIMIZE ENVIRONMENTAL IMPACT

When asked about the environmental credentials of your packaging material, do you have good answers?

Procurement departments everywhere are growing increasingly concerned about the sustainability of production methods and materials used by their suppliers. This includes the materials used in packaging. Paperboard is a renewable and recyclable material. But what do we mean by that?

Well, wood fiber derives from the forest and, if well-managed, provides a continuously growing raw material source that is also part of the ecological cycle of nature. But here's the catch: you need to check that your paperboard provider is using sustainable methods to reduce environmental impact through the entire supply chain – from raw material sourcing through production all the way to final delivery of the products.

Renewable and recyclable

One key environmental advantage to using virgin fiber paperboard is that it can be recycled six to eight times prior to being incinerated for energy in its final stage. In fact, the recycled paper and board industries depend on getting a steady stream of fresh fiber into the system. Otherwise they would run out of material for their products.

Sustainably managed forests

Responsible forestry groups make a positive contribution to the forests by planting more trees than they cut down. This is vital since trees capture and store CO_2 while emitting oxygen. However, only 9% of the world's forests are independently certified as sustainably managed. So make sure you choose a supplier with sustainable practices from start to finish.

12
GET THE RIGHT CERTIFICATES

Can your paperboard supplier provide you with all the quality and environmental certificates you need?

Regulatory compliance with key medical standard and certificates (FDA, ISO, etc.) is vital. In particular, many medical technology companies are focused on meeting the new and updated ISO 1348:2016 standard. It's important to know that your paperboard materials supplier is also maintaining a high quality level and supporting you.

In addition to meeting compliance needs, certificates and standards are a positive way to set common benchmarks. In some cases, they can also be helpful in marketing your products. While these can vary widely, a few key international standards to ask your supplier about are:

– Forest Stewardship Council® (FSC®), FSC-C110018
– Program for the Endorsement of Forest Certification schemes (PEFC™)
– ISO certificates (ISO 9001, ISO 14001 and ISO 50001) quality management, environmental management and energy management
– OHSAS 18001, the international standard for management of occupational health and safety

In addition to the above, check how your supplier is rated on some of the global indexes that take a more holistic look at sustainability across the company:

– UN Global Reporting Initiative and Carbon Disclosure Project
– UN Global Compact 100 list
– Corporate Knights Global 100

PAPERBOARD IN ACTION
THREE CASES

On the following pages you will find three cases of how best-in-class medical technology companies are overcoming packaging challenges with pure virgin fiber paperboard. These have been kept anonymous for confidentiality.

CASE STORY 1

Securing safe and consistent packaging for ETO-sterilized surgical sutures

For more than 40 years, cardiovascular surgeons have used this company's leading brand of sutures to close wounds in more than 100 million patients worldwide. However, the thread material can be sensitive to water vapor transmission. As a result, the company needed packaging material that would retain (but not impact) the antimicrobial agent inside while absorbing small amounts of moisture. Iggesund Paperboard has been proud to support their efforts with Invercote board for more than 20 years.

"We provided a coated solid bleached board – without extra optical brightening agents and free from chemicals that might interact with the medical agent, while still being able to absorb small amounts of potential moisture build-up in the EtO gas sterilization process."

ULRICH PFAU, TECHNICAL SERVICE MANAGER, IGGESUND PAPERBOARD

Although surgical sutures have been used for thousands of years, recent development of new shapes, sizes and thread materials have transformed the business. Today, surgeons can choose between numerous materials, many of which are treated with medical agents to support wound healing and kill bacteria. They must be strong enough to hold tissue securely but flexible enough to be knotted.

Nothing but pure paperboard

Regardless of the type of suture being used, purity and sterility are of paramount importance – and the same goes for the selection of primary and secondary packaging. In this case, the customer wanted a coated solid bleached board (SBB) – without any extra optical brightening agents (OBAs) – and made of pure virgin fiber. Their packaging and conversion team was also attracted to the superior strength and durability of a multi-layer board, compared to grades containing mechanical or recycled fibers or monolayer SBB board.

Low amounts of paper dust

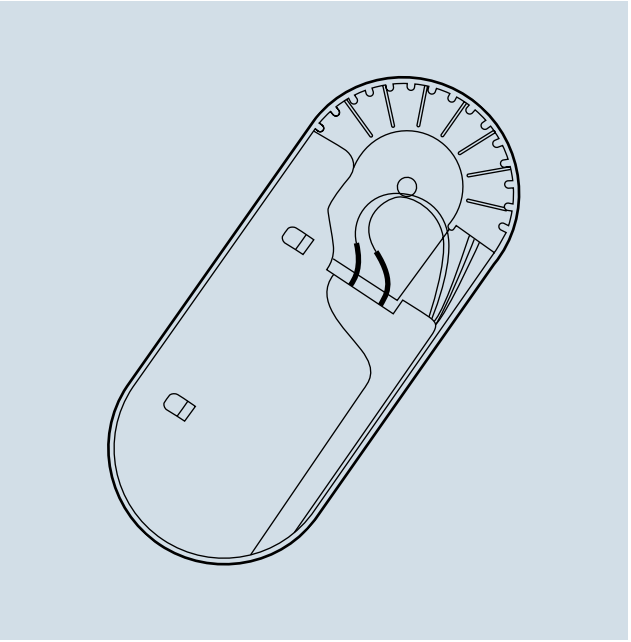
"As with many of our medtech customers, this situation highlights some key challenges facing healthcare professionals," says *Ulrich Pfau*, Technical Service Manager at Iggesund Paperboard. "First, they wanted a strong, pure board with the dimensional stability and durability to withstand some rather advanced die-cutting, creasing and perforation – without creating a lot of paper dust. The minimization of paper-dust particles, which can arise during the sheeting and perforation process, was vital since the customer adheres to strict hygienic criteria for its own clean rooms."

Free from moisture and OBAs

But according to Mr. Pfau this was just the start. The customer also needed a board that was free from any chemicals that might interact with the medical agent, while still being able to absorb small amounts of potential moisture build-up in the ethylene oxide (EtO) gas sterilization process. This meant using a board that was free from traces of OBAs – used to enhance surface brightness. "Although OBAs are harmless, in this case their toxicologists were concerned that they might potentially interact with the medical agent on the sutures. It was also important that the paperboard should not absorb the medicine!"

Validated and used for 200 applications

The validation process was extensive. It included bio-compatibility studies, permeability tests, transport analysis, mechanical tests and more.



"This is a multinational player with sourcing in one country, testing in another and production spread out across the world. The surgical sutures they produce can be found in the operating theaters in countries with tropical climates, so guarding against moisture is key."

GINNY SAMUEL, MANAGER BRAND OWNERS AND RETAIL, IGGESUND PAPERBOARD

In the end, the customer selected our FDA-compliant Invercote T grade for use as the printed, card-like carrier in the inner packaging, which is covered in foil.

Slightly smaller in size than a mobile phone, it holds the sutures in place and helps to contain the medical agent used to promote healing and reduce microbial buildup. To ensure the absence of humidity, the board is first dried and then the "cards + thread" are wrapped in aluminum foil and packed in plastic bags before being sterilized.

Zero customer complaints

Today, the approved Invercote T grade is used for some 200 different suture packaging applications or sub-products. Tight tolerances, consistent quality, reliable stock availability and service are all of essential importance. "In my eight years of working with this customer, I haven't received a single complaint regarding the board quality itself," says Ulrich Pfau, who adds that Iggesund Paperboard is always very careful when making any upgrades that could influence the packaging. "The last thing in the world customers want is a lot of unexpected changes," he says.

Promoting longer shelf life

Shelf life and longevity were also very important, according to ***Ginny Samuel***, Manager Brand Owners and Retail at Iggesund Paperboard. "This is a multi-national player with sourcing in one country, testing in another and production spread out across the world. The surgical sutures they produce can be found in the operating theaters in countries with tropical climates, so guarding against moisture is key. Since they also offer a 5.5-year guarantee to customers, it means surgeons, nurses and other healthcare professionals must feel secure that they've always got a premium product on the shelf."

A business built on trust

"When you boil it down, this whole business is based on trust," says Ms. Samuel. "It takes many years to build customer confidence. After working with us for a while, our customers come to understand that we are a very stable and reliable company. We've been around for more than 400 years and will continue to be at their side."

Advancing surgical outcomes

"In this case, our customer is committed to shaping the future of surgery with meaningful solutions that enhance outcomes. Our role is to make sure their vision can always be achieved with premium packaging material that is safe, reliable and offers no surprises," concludes Ms. Samuel.

ULRICH PFAU
Technical Service Manager
Iggesund Paperboard
ulrich.pfau@iggesund.com

GINNY SAMUEL
Manager Brand Owners
and Retail
ginny.samuel@iggesund.com

CASE STORY 2

How one medtech company stands out on the shelves of cardiovascular catheter labs

At eye level on the shelf of a European hospital is a box containing a next-generation-drug coated balloon catheter. Set against a dark cover, the 3D rendering depicts the device navigating through veins like a spaceship, emitting a sparkling chemical agent. The product name, claims and imagery are bold – backed by years of clinical evidence and huge investments. Clearly the company behind it wants to convey the full benefits of its product in a competitive market. The packaging material must also reflect the high quality of the product – with consistent performance and no surprises.

"Product consistency from batch to batch is absolutely critical – no changes at all – and that applies to the entire product life cycle as well as an uninterrupted and guaranteed supply chain to multiple European production sites over many years. This is really a top priority for our customers."

IAN HUSKINSON, TECHNICAL SERVICE MANAGER, IGGESUND PAPERBOARD

Change. It's the one word that manufacturers of medical devices have a love-hate relationship with. On the one hand, their future depends on new therapeutic technologies that are safer, less invasive, improve patient outcome and drive down costs. And yet even small modifications to an existing device or packaging system may necessitate a whole new validation process requiring a minimum of a year to complete and costing hundreds of thousands of euros. This challenge was made clear to Iggesund Paperboard for a drug-coated balloon packaging in which a board upgrade was under consideration.

Clean and premium box

"The customer basically told us 'please don't change anything right now,'" says ***Ian Huskinson***, a technical service manager at Iggesund Paperboard who is based in the UK. He adds that Invercote G had been recommended by a well-respected converter due to its ability to create a smooth, clean, premium-feeling box with good printability. The box in question, which is roughly A4 sized and 15-20 mm deep with a tuck-in flap, contains an insert tray where the catheter is placed, covered in a sealed plastic pouch. To accommodate their needs, Iggesund developed a contingency solution with a bespoke product.

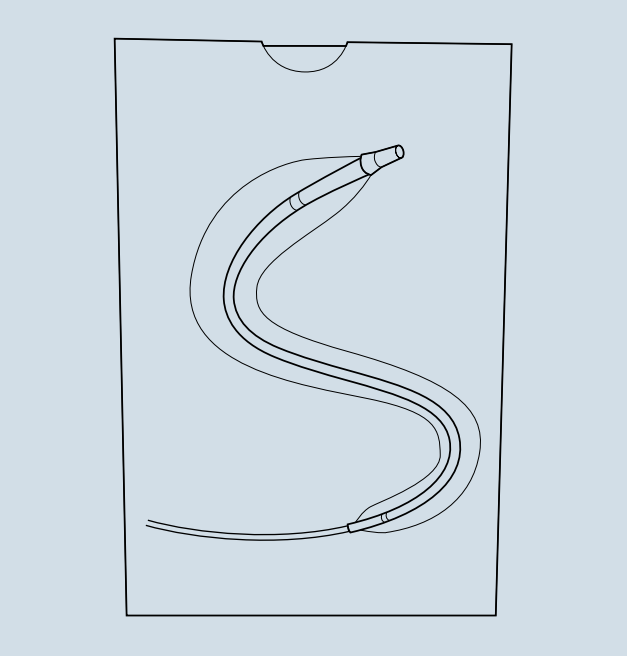
"This situation really underscored to us how important product longevity and consistency, in terms of packaging materials, are to our customers," says Huskinson. "Product consistency from batch to batch is absolutely critical – no changes at all – and that applies to the entire product life cycle as well as an uninterrupted and guaranteed supply chain over many years. This is really a top priority for us."

Easy to use and fully compliant

"In this case, the actual technical requirements of the carton, in terms of the shape, were not extremely challenging, but the customer also had an extensive list of quality assurance requirements for risk reduction," he says. "Their QA parameters include everything from packaging sterilization, permeability and transport to ease-of-use demands in the catheter labs of hospitals. Invercote G is fully compliant with all FDA requirements and has been successfully validated by the customer for ethylene oxide (EtO) sterilization, gamma irradiation and more."

Drug-coated balloons

The drug-coated balloon (DCB) is a new type of minimally invasive intravascular catheter used by cardiovascular surgeons to reduce or eliminate blockage in blood vessels and arteries. It emits a chemical agent that helps to reduce deposits on the wall of the artery and shortens the need for additional procedures for a period of up to four years. It has been shown to deliver safe and consistent results, particularly in the onset of peripheral artery disease as well as other indications.



A competitive market

The need for such novel devices is growing in parallel with the rise of aging populations, the prevalence of diabetes and high intake of fatty foods in general – all of which contribute to the blockage or narrowing of blood vessels and arteries (atherosclerosis). But according to a series of studies by iData MedTrack, the DCB catheter space, while growing, is fiercely competitive, meaning that leading device manufacturers are under pressure to prove efficacy in patient outcome, pharma-economic benefits and also promote their brand difference to healthcare professionals.

Standing out on hospital shelves

"Clearly, the packaging of a device sitting on a hospital storage shelf does not have the same need for design effects that a branded product closer to consumer use might have, but it still needs to look professional and promote ease of use. Customers want to convey a sense of quality that matches the premium quality of their own products," says Ian Huskinson. "There are a lot of different catheters on the market, so there is a need to differentiate your brand even in the operating theater – something that nurses and surgeons can be sensitive to as well."

High sterilization requirements

According to Huskinson, the proven ability of Invercote to work smoothly and consistently in the sterilization process was also a key factor. In the customer's cleanroom, the boxes are double and triple-checked for packaging integrity, cleanliness and purity. The packaging is preconditioned at a temperature of 54°C with humidity levels ranging between 30 and 90% for a period of approximately 12–17 hours. The filled boxes are then flushed with ethylene oxide gas to kill any bacterial culture that may appear, in accordance with the ISO 11135 standard.

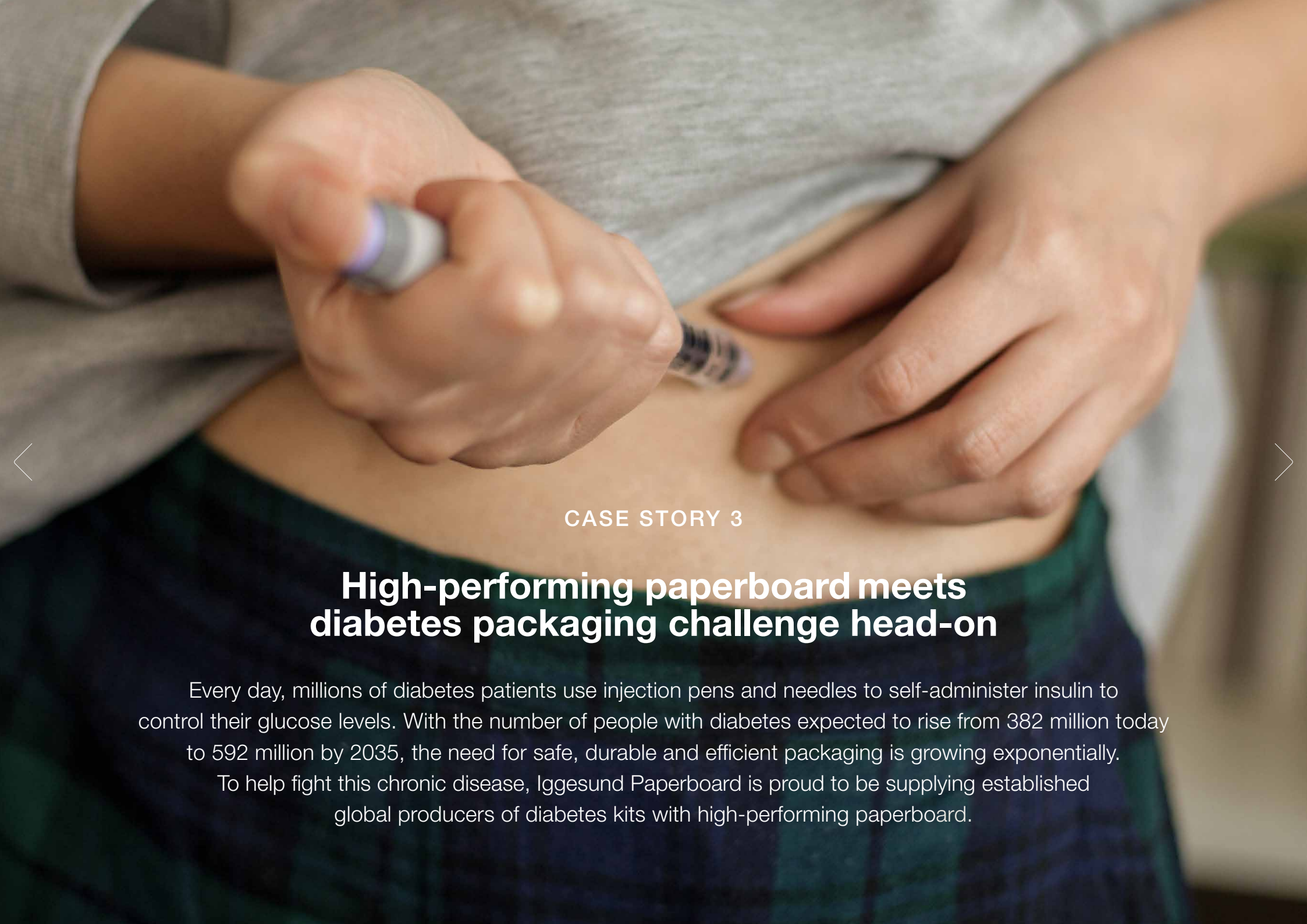
Safe, durable and consistent

"When you are selling a novel device that stands for safety, durability and consistency, you need to be sure that the packaging material lives up to this as well," says Huskinson. He notes that Iggesund meets all of the relevant ISO certifications and can secure data from its entire supply chain.

Risk minimization in every step

"Their team of toxicologists was very happy that we could provide detailed information regarding the chemical composition of our board to safeguard any theoretical impurity issues. It was a transparent exchange of information and constructive discussion from both sides to meet mutually beneficial goals. At the end of the day, we all want to minimize risk by securing the integrity of the product – every step of the way," he concludes.

IAN HUSKINSON
Technical Service Manager
Iggesund Paperboard
ian.huskinson@iggesund.com



CASE STORY 3

High-performing paperboard meets diabetes packaging challenge head-on

Every day, millions of diabetes patients use injection pens and needles to self-administer insulin to control their glucose levels. With the number of people with diabetes expected to rise from 382 million today to 592 million by 2035, the need for safe, durable and efficient packaging is growing exponentially. To help fight this chronic disease, Iggesund Paperboard is proud to be supplying established global producers of diabetes kits with high-performing paperboard.

"From batch to batch, Invercote delivers the same thickness, grammage, stiffness and more to within the tightest of tolerances. This means that printers can keep running their lines at high speeds to meet the demands on volume without worrying about stoppages and unscheduled downtime."

MASSIMO FALCINELLI, ACCOUNT MANAGER, IGGESUND PAPERBOARD

Not too long ago, if you had diabetes you went to the hospital to receive your regular insulin injection. But a lot has changed since the first insulin pump was introduced in the 1970s and the first insulin pens in 1985. New device improvements have allowed patients to administer the insulin themselves, improving quality of life and driving down healthcare costs. Here the packaging plays a prominent role in maintaining product performance, conveying vital information, and keeping the product safe and secure until the point of usage.

When cheap becomes expensive

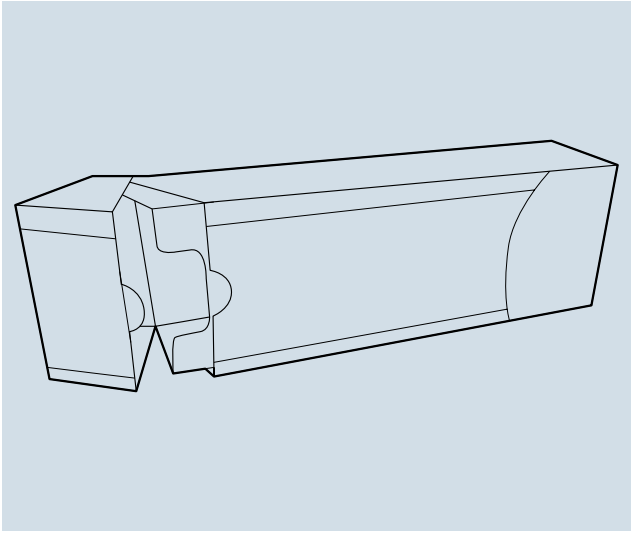
"Today, the market for prefilled pens, needles, pumps and related devices is exploding all over the world, especially in emerging markets with a growing middle class," says ***Bengt Johansson***, Key Account Manager at Iggesund Paperboard. "As production volumes and cost pressures increase, there is a parallel need to gain greater production efficiencies, while still maintaining product safety. But in their quest to drive down costs, manufacturers must be cautious when chasing savings in packaging materials, since production stops and slower speeds on the packaging line may end up being more expensive in the long run, when considering total cost of ownership."

Safe and smart functionality

It's a delicate balancing act that medtech manufacturers know all too well. They must weigh the needs for smart functionality, safety and ease of use in innovative new packaging concepts against the desire to optimize production-line efficiency. There is simply no room for line stoppages or safety issues. Iggesund Paperboard has supplied high-performing Invercote for more than 20 years to insulin producers in Europe and Asia, helping them to secure hassle-free packaging and risk minimization.

Innovative and cost-effective

One key customer challenge is to find a pure, white paperboard with good printability and the structural stability needed for numerous small folds and creases in the compartments enclosing the insulin needles and pens. Clear, accurate print reproduction is also essential since the packaging often includes both branding elements and vital instructions for users on the outer and inner surfaces of the box. At the same time, the packaging solutions need to be cost-effective, convenient and user-friendly.



“Safety is of utmost importance. These kits, pens and pumps are often kept in a refrigerator or near the patient where they are used many times a week. The packaging must have superior functionality to be opened and reclosed with no tearing or ripping.”

MASSIMO FALICINELLI, ACCOUNT MANAGER, IGGESUND PAPERBOARD

No tearing and ripping

“Safety is of utmost importance,” emphasizes *Massimo Falicinelli*, Account Manager at Iggesund Paperboard. “These kits, pens and pumps are often kept in a refrigerator or near the patient where they are used many times a week. In other words, they need to have superior functionality to be opened and reclosed with no tearing – or be able to handle potential condensation buildup without deteriorating strength properties.”

The choice was Invercote®

In evaluating different board materials, including folding box board (FBB) and recycled board, Iggesund's insulin customers have selected Invercote®, a solid bleached board (SBB) made from pure virgin fiber sourced from sustainably managed forests. For years, Invercote has been recognized as one of the world’s best-performing paperboards by independent sources, due to its quality consistency, design versatility, purity and longevity. Thanks to its multi-layer construction, with its long and strong bleached fibers, it is not only pure and white, but can also be bent and creased many times in all directions – without breaking.

Consistently high-performing board

According to Mr Falcinelli, while pliability and purity were key factors in initially selecting Invercote, another advantage that has emerged is its consistent high performance, with tight tolerances on all parameters. “From batch to batch, Invercote delivers the same thickness, grammage, stiffness and more to within the tightest of tolerances. This means that printers can keep running their lines at high speeds to meet the demands on volume without worrying about stoppages and unscheduled downtime. And since the product offers consistent dimensional stability, they do not need to constantly recalibrate their presses for new sheet stock.”

The number of people with diabetes is expected to rise from 382 million today to 592 million by 2013.

SOURCE: INTERNATIONAL DIABETES FEDERATION

BENGT JOHANSSON
Key Account Manager
Iggesund Paperboard
bengt.gi.johansson@iggesund.com

ABOUT OUR EDITORIAL TEAM

This Medtech Packaging Guide was compiled by paperboard technical experts at Iggesund Paperboard in collaboration with outside consultants, including printers and converters.

Ulrich Pfau,
Technical Service Manager

Based in the Karlsruhe Area of Germany, Ulrich is a technical service manager, printing and packaging expert who oversees contacts with printers and packagers as well as handling trials and customer training. He holds degrees in printing technology from Fachschule für Drucktechnik in Munich. *ulrich.pfau@iggesund.com*

Ginny Samuel,
Manager Brand Owners and Retail

Based in Chester, UK, Ginny is responsible for supporting and managing Iggesund's brand owners and retailers. This includes educating and specifying paperboard products for the medtech and other industries. She holds a degree in chemistry with business studies from De Montfort University in Leicester, UK. *ginny.samuel@iggesund.com*

Elin Li,
Business Development Manager

Based in Stockholm, Sweden, Elin is working in business development and leading the medtech focus area at Iggesund Paperboard. Elin holds a degree in engineering, design and product realization from KTH Royal Institute of Technology, Sweden. *elin.li@iggesund.com*

Ian Huskinson,
Technical Service Manager

Located in Nottingham, UK, Ian is a technical packaging expert with extensive experience in the field of medical technology packaging, among other areas. He collaborates closely with medical device makers as well as printing and converting houses. Ian holds a degree from Loughborough University in the UK. *ian.huskinson@iggesund.com*

Christiane Klaas,
Manager Brand Owners and Retail

Working out of Lake Constance, Germany, Christiane is responsible for supporting and managing Iggesund's brand owners and retailers. This includes educating and specifying paperboard products for the medtech and other industries. She holds a degree in industrial engineering from HdM Stuttgart, Germany. *christane.klaas@iggesund.com*

OTHER REFERENCES

Do you need more in-depth material? Over the years, we've built up an extensive knowledge bank of information on packaging and paperboard that can be provided digitally or physically upon request. Key publications, which are part of Iggesund Anchor Material, are:

– Paperboard Product Catalog
– Paperboard Reference Manual
– Paperboard – the Iggesund Way
– Graphics Handbook
– iggesund.com

Please don't hesitate to get in touch with our Medtech Team directly via their email addresses on the preceding page if you require further guidance or information.

Iggesund Paperboard
SE-82580, Iggesund, Sweden
+ 46 650 28000
Website: iggesund.com

ABOUT IGGESUND PAPERBOARD

Iggesund Paperboard strives to inspire next-generation packaging with sustainable paperboard products, services and advice that enhance the value of world-class brands. Our market-leading Invercote® brand is used by some of the world's most demanding medical technology brand owners. Outstanding characteristics include superior durability, excellent color reproduction, whiteness that does not fade, taint and odor neutrality and design versatility. Established in 1685 and part of the Holmen forest industry group, the company relies on its own sustainably managed forests to ensure renewable materials for centuries to come.

IGGESUND
HOLMEN GROUP

LEGAL DISCLAIMER

The information contained in this Medtech Packaging Guide is intended solely for educational purposes, to provide helpful information and overall guidance on the topic of using paperboard for medical technology packaging. It is not intended as definitive medical packaging advice for specific situations or requirements. Every attempt has been made to verify the accuracy, completeness, legality and reliability of the content. However, we cannot and will not take responsibility for any inadvertent errors in the content or in the application or usage of this advice in different packaging situation, by brand owners, converters, printers or other third parties. We strongly recommend that packagers of medical technology products and their suppliers follow all relevant local and international regulations in close collaboration with certified medical experts, to safeguard the protection of their products as well as healthcare professionals and patients.

Iggesund Paperboard
SE-82580, Iggesund, Sweden
+ 46 650 28000
iggesund.com