

FLEXSHIELD®

Thermoplastic Polyurethane (TPU) Film



Preserve the sterile barrier with puncture and abrasion resistant FlexShield®.

Utilizing FlexShield, we design and manufacture a variety of solutions for the medtech industry, including packaging for orthopedic implants and surgical instruments, protection for medical equipment, and other applications that require sterile barrier protection.

FlexShield offers unmatched puncture and abrasion resistance, ensuring the safe shipment of medical devices, implants, and instruments without damage to its external packaging. We create standard and custom sterile barrier solutions for a wide range of medical products including:

- Orthopedic implants
- Surgical instruments and tools
- Catheters
- Surgical robot drapes, wearables, and more



Features



Puncture and Abrasion Resistant

Superior durability with puncture and abrasion resistance to protect medical devices.



Biocompatible

FDA approved and meets USP Class VI standards, ensuring safe use in medical applications and in contact with the human body.

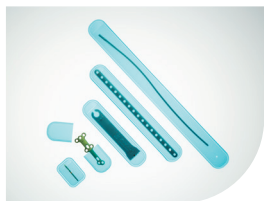


Sterilizable

Compatible with EtO and Gamma sterilization methods.

Standard Packaging Solutions

Increase speed to market and eliminate tooling costs with our standard FlexShield packaging solutions. Our standard offerings are designed to accommodate a broad range of products and are available in the following configurations.



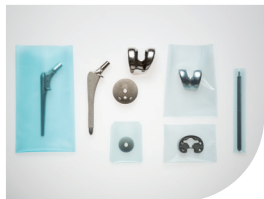
Pouches

Designed with surgeons and nurses in mind, pouches break apart to provide effortless aseptic presentation.



Tip Protectors

Used to protect the ends of sharp, delicate medical instruments such as surgical screws, pins, and trocars.



Bags

Provides versatility as a packaging medium and can be used across multiple medical products of varying sizes.



Tubs

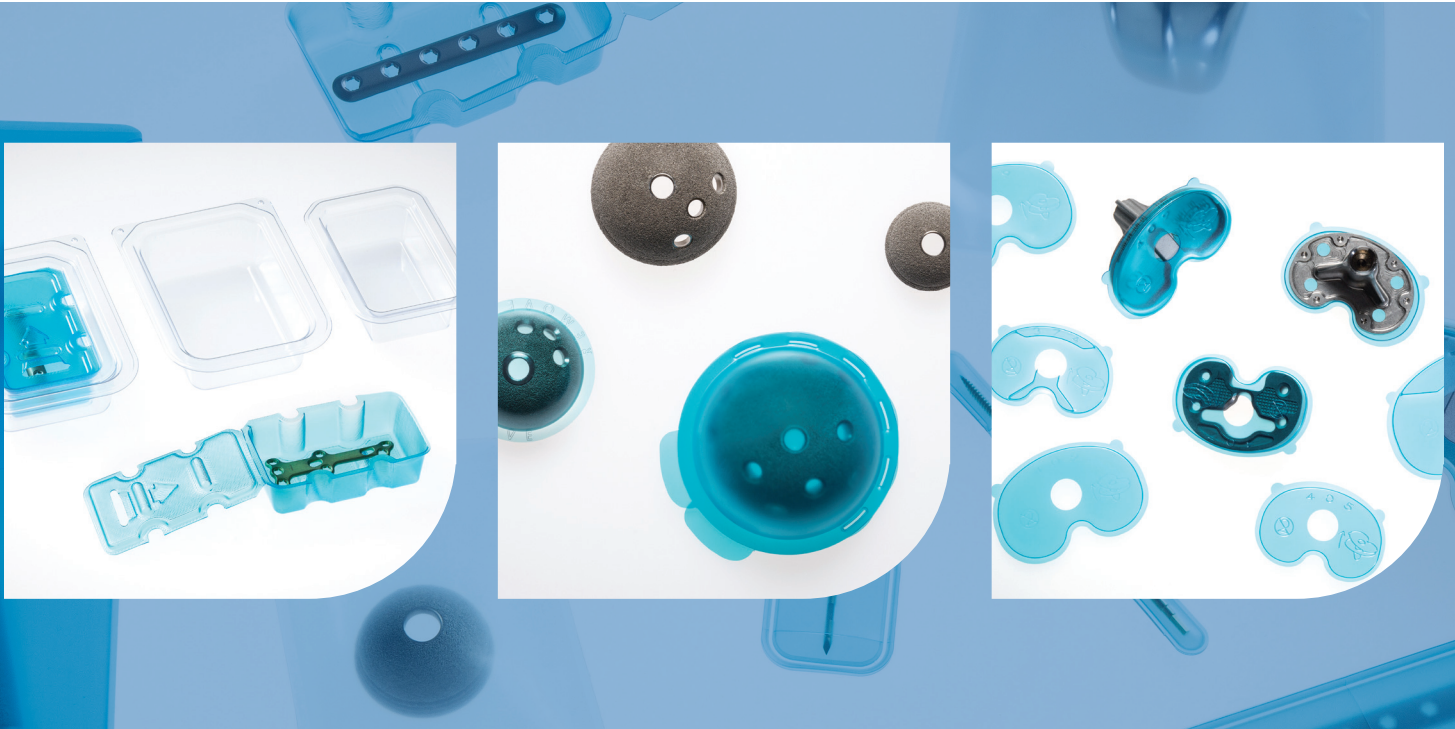
Designed to nest inside of a rigid plastic tray and hold a variety of part sizes, which allows for SKU consolidation.

Standard Packaging Sizes

FlexShield Product	Available Sizes (in inches)	Suggested Applications
Pouches	1 x 9 1 x 14 1.43 x 2 1.43 x 4 1.43 x 6 1.43 x 7 1.43 x 9 1.43 x 14 1.5 x 11 2.29 x 3.5 (4 Chambers) 2.5 x 2 2.5 x 4 2.5 x 6 2.5 x 9 2.5 x 11	Fixation plates IM rods Surgical saw blades Surgical needles, pins and screws
Tip Protectors	0.39 x 1.33 0.66 x 2.01 0.66 x 3.01 1.5 x 3 1.63 x 2.6	Catheters Surgical saw blades Surgical needles, pins and screws Trocars
Bags	2 x 2.5 3 x 5 4 x 6 5 x 7 6 x 9	Acetabular cups Fixation plates Hip stems Knee implants Surgical needles, pins and screws
Tubs	3.35 x 1.70 x 1	Fixation plates Surgical needles, pins and screws Surgical saw blades

Custom Packaging Solutions

For specialized applications, our team will collaborate with you to design and develop custom FlexShield packaging solutions that are tailored to your exact requirements while providing the same unmatched sterile barrier protection as our standard products.



Medical Devices and Sterile Drapes

FlexShield can also be formed into unique shapes for a variety of medical device applications. The material is approved for skin contact and has been used to protect patients from infection during surgery and to safeguard sensitive medical equipment.

- Fluid and air management
- Negative pressure wound therapy (NPWT) devices
- Medical wearable enclosures
- Surgical robot drapes and equipment covers

Our Expertise

At UFP MedTech, we are uniquely positioned to meet your most stringent demands by offering:



Risk Mitigation

Redundant cleanroom manufacturing capabilities and multiple global suppliers for medical TPU allow us to provide continual, reliable service to our customers.



Speed to Market

A catalog of standard available sizes helps us provide quicker turnaround times and eliminates the need for added design and tooling costs.

Material Specifications

FlexShield is made from a medical-grade thermoplastic polyurethane (TPU) film.

Material Properties	
Certifications	USP Class VI Resin, FDA Approved, Biocompatible
Sterilization Compatibility	EtO, Gamma
Thicknesses	0.003" - 0.055"
Colors	Blue, Natural
Finishes	Matte, Gloss

Not all options available in all configurations

Material Biocompatibility Results ¹
<i>3 and 20 mil meet the requirements of the following:</i>
ISO 10993-5 ME Elution Cytotoxicity
ISO 10993-10 Irritation-Intracutaneous Reactivity Testing
ISO 10993-11 Acute Systemic Toxicity Testing
ISO 10993-11 Pyrogenicity Testing

Mechanical Properties Testing Post Sterilization ¹						
			Control	EtO	15 kGy Gamma	50 kGy Gamma
Specific Gravity (ASTM D792-08)	Average (sp gr)	3 mil	1.12	1.12	1.12	1.12
		40 mil	1.16	1.16	1.16	1.16
Tensile Test (ASTM D882-12)	Max Force (lbf)	3 mil	28	26	28	26
		40 mil	160	166	166	160
Shore Hardness (ASTM D2240-05)	Average (Shore A)	3 mil	89.6	88.5	88.8	89.5
		40 mil	87.3	86.4	88.2	87.9
Tear Resistance (ASTM D1004-13)	Average (lbf/in)	3 mil	404	474	428	435
		40 mil	476	508	472	481

Mechanical Properties Testing Post 5-Year Accelerated Aging ¹						
			Control	EtO	15 kGy Gamma	50 kGy Gamma
Specific Gravity (ASTM D792-08)	Average (sp gr)	3 mil	1.12	1.15	1.16	1.15
		40 mil	1.13	1.12	1.11	1.12
Tensile Test (ASTM D882-12)	Max Force (lbf)	3 mil	26	20	22	23
		40 mil	168	157	147	157
Shore Hardness (ASTM D2240-05)	Average (Shore A)	3 mil	85.2	84.4	85.4	84.6
		40 mil	85.2	84.9	85.6	86.0
Tear Resistance (ASTM D1004-13)	Average (lbf/in)	3 mil	457	530	463	483
		40 mil	496	496	495	497

Detailed reports available on request.

¹ Data for informational purposes only. Data are representative for a typical TPU material and does not represent a guarantee of performance. No warranty is implied.

