

FLEXSHIELD[®]

BY UFP TECHNOLOGIES

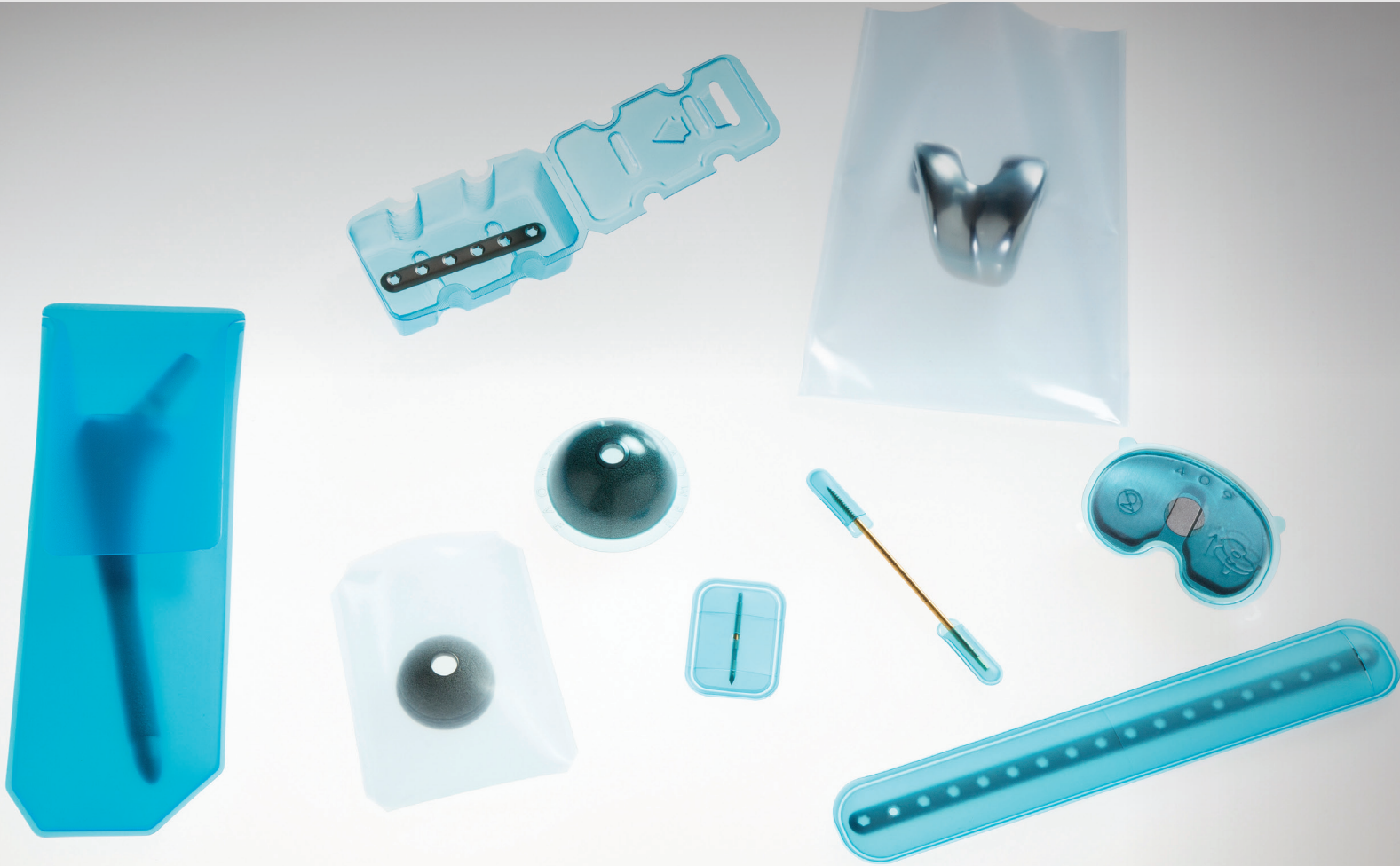


STERILE BARRIER INTEGRITY PROTECTION

PUNCTURE AND ABRASION RESISTANCE

USP CLASS VI, FDA APPROVED, BIOCOMPATIBLE MATERIAL

INDUSTRY PROVEN PROTECTION



Sterile Barrier Integrity Puncture & Abrasion Resistance

FlexShield is a flexible thermoplastic polyurethane film used for medical packaging, component, and product applications. Its durability and sterility lend itself to providing excellent protection for devices and patients.

Cleanroom Fabrication

All FlexShield products are manufactured and packaged within ISO Class 8 (Class 100,000) cleanrooms in ISO 13485 certified facilities.

Utilizing FlexShield®, UFP Technologies designs and manufactures a variety of solutions for the medical industry including: surgical instrument and orthopedic implant packaging, protection for medical equipment, or any application requiring sterile barrier integrity protection.

PROPERTIES AND TEST DATA¹

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

3 and 20 mil meets the requirements of the following:

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

Specific Gravity (ASTM D792-08)	Average (sp gr)	3 mil	Control	EtO	15 kGy Gamma	50 kGy Gamma
		40 mil	1.16	1.16	1.16	1.16
Tensile Test (ASTM D882-12)	Max Force (lbf)	3 mil	Control	EtO	15 kGy Gamma	50 kGy Gamma
		40 mil	160	166	166	160
Shore Hardness (ASTM D2240-05)	Average (Shore A)	3 mil	Control	EtO	15 kGy Gamma	50 kGy Gamma
		40 mil	87.3	86.4	88.2	87.9
Tear Resistance (ASTM D1004-13)	Average (lbf/in)	3 mil	Control	EtO	15 kGy Gamma	50 kGy Gamma
		40 mil	476	508	472	481

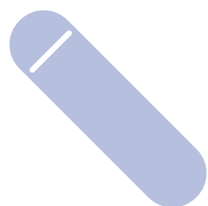
Mechanical Properties Testing Post 5-Year Accelerated Aging

Specific Gravity (ASTM D792-08)			Control	EtO	15 kGy Gamma	50 kGy Gamma
	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)			Control	EtO	15 kGy Gamma	50 kGy Gamma
	Max Force (lbf)	3 mil	26	20	22	23
		40 mil	168	157	147	157
Shore Hardness (ASTM D2240-05)			Control	EtO	15 kGy Gamma	50 kGy Gamma
	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)			Control	EtO	15 kGy Gamma	50 kGy Gamma
	Average (lbf/in)	3 mil	457	530	463	483
		40 mil	496	496	495	497

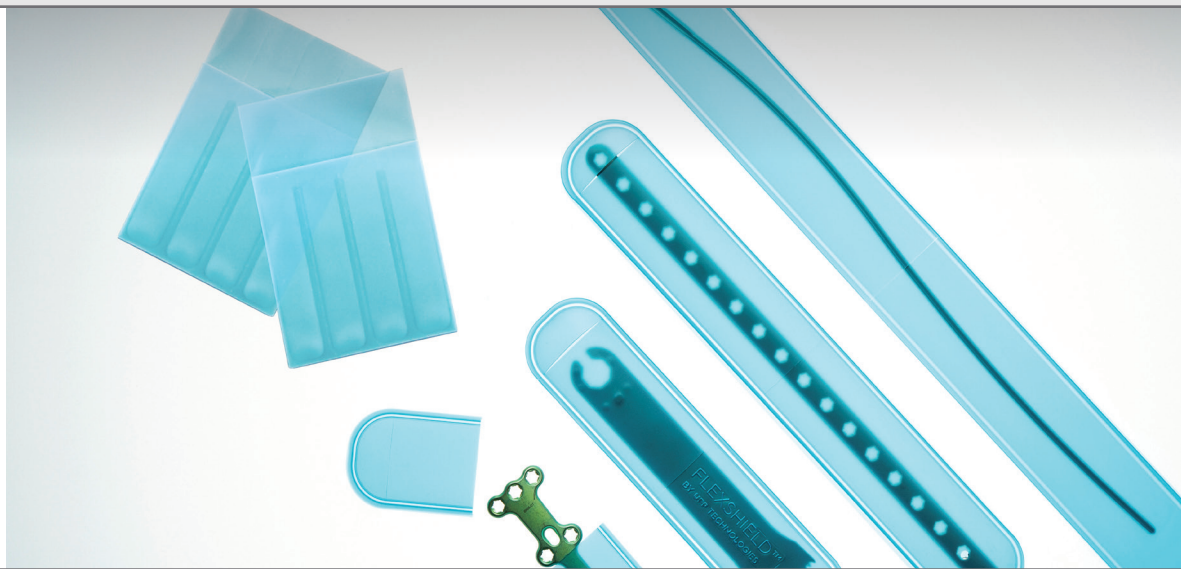
Detailed reports available on request.

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.

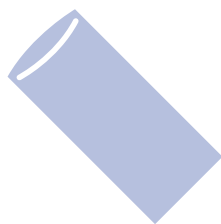
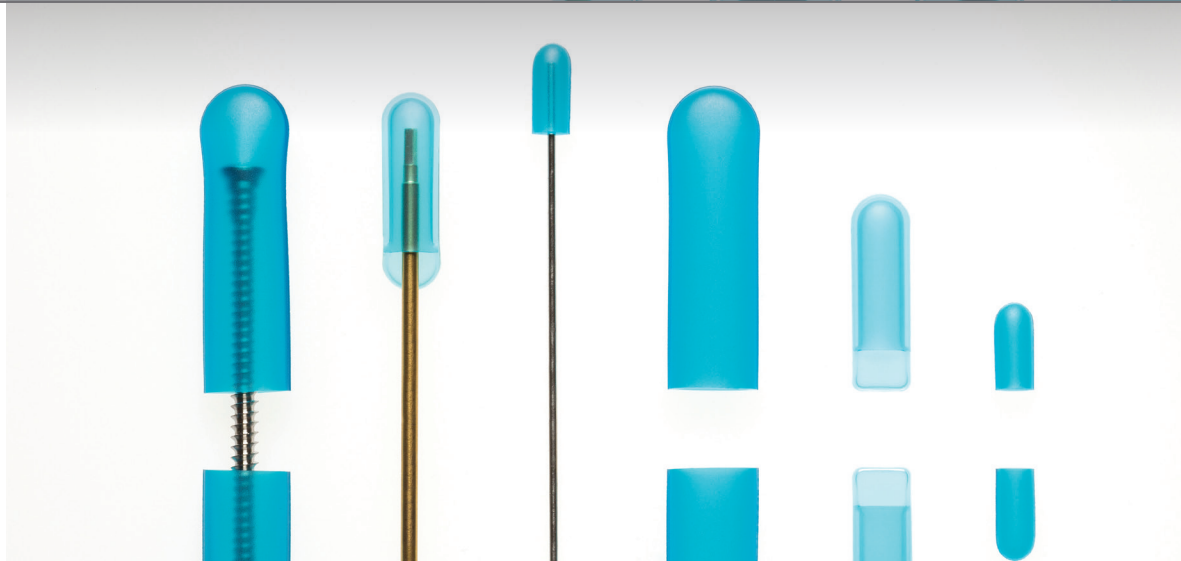
STANDARD SOLUTIONS



Packaging Pouches



Tip Protectors



Bags



To create the industry’s most innovative solutions, we use the world’s most advanced materials




FlexShield provides puncture and abrasion resistance in order to safely ship medical instruments without incurring damage to external packaging.

Utilizing FlexShield within your packaging systems will ensure the integrity of the sterile barrier between your instruments and outside contaminants.

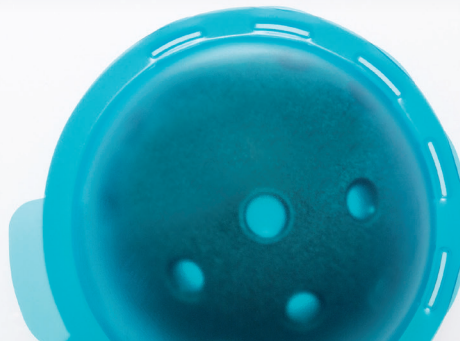
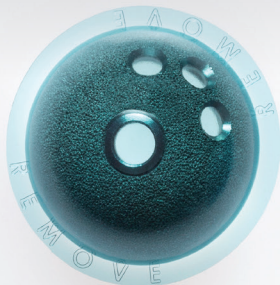
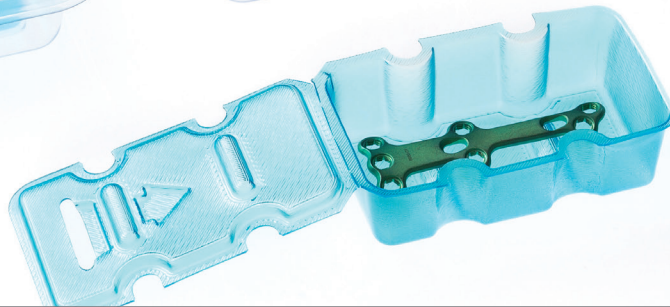
We offer the following standard FlexShield packaging products:

- Packaging pouches
- Tip protectors
- Bags

These products require no engineering or tooling investment.

Product	Available Sizes in Inches					Suggested Applications
<div>Pouches</div> <div></div>	1 x 9 1 x 14	1.43 x 2 1.43 x 4 1.43 x 6 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, & screws
<div>Tip Protectors</div> <div></div>	0.39 x 1.33	0.58 x 2 0.58 x 3	1.5 x 3	1.63 x 2.6		Catheters Surgical saw blades Surgical needles, pins, & screws Trocars
<div>Bags</div> <div></div>	4 x 6	5 x 7	6 x 9			Aceabular cups Fixation plates Hip stems Knee implants Surgical needles, pins, & screws

CUSTOM SOLUTIONS





Diverse solutions with one thing in common: superior engineering

FlexShield can be formed into unique shapes to ensure the integrity of the sterile barrier for your device. The material is approved for skin contact and has been used to protect patients from infection during surgery and to safeguard sensitive medical equipment.

Our team of engineers can create designs to meet your specific requirements.

Industry proven uses:

- Within sterile barrier packaging systems
- Sterile barrier integrity protection for medical equipment
- Surgical aids for infection prevention
- Robotics components
- Negative pressure wound therapy (NPWT) device components

ALL OF OUR SOLUTIONS ARE SHAPED BY A LEVEL OF DESIGN, MATERIALS, AND PROCESS EXPERTISE THAT IS UNIQUE TO UFP TECHNOLOGIES.

THE MATERIAL WE'RE MADE OF

When we design a solution, we're not just thinking about cell structures, densities, and other technical matters. We're thinking about the people who depend on us every day. The safety of the soldier in the field. The health of the patient in the operating room. The comfort of the driver on the highway. And everyone else who needs our solutions to perform at the highest level.

For us, it's not just about making great products better, or getting them to market safely. ***It's about protecting and improving lives, in every way we can.***

CAPABILITIES

Design & Engineering
Fabrication
Cleanroom Manufacturing
Contract Manufacturing
Thermoforming
Tooling

CERTIFICATIONS

FDA Registered
ISO 13485
ISO 9001
IATF 16949
AS9100

LOCATIONS



UFP
TECHNOLOGIES

FlexShield® is a registered trademark of UFP Technologies, Inc.

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Shaping Innovation

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