CHEMISTRY THAT MATTERS™

SABIC Specialties

MAKE IT POSSIBLE
MAKE IT ULTEM™ RESIN

DURABLE MATERIAL SOLUTIONS WELL SUITED FOR MEDICAL DEVICES COMPATIBLE WITH MULTIPLE STERILIZATION PROCESSES AND CYCLES

LEVERAGE OUR EXPERTISE TO GET YOUR JOB DONE

We can offer more than materials.

SABIC Specialties business can offer more than just materials. We stay ahead of the game by developing new products to keep up with the latest regulatory, scientific, and consumer trends. And we're always looking for new ways to add value to your experience.

We invite you to work with us in a personal and collaborative approach. Our team is well-equipped to support your product development teams with our knowledge of materials, design, application development and testing.

Contact us today to learn more.
Email us at Specialties@sabic-hpp.com
or scan the code.

make it COLORABLE | make it ULTEM™ resin

Is lasting colorability for customization and identification important for your medical devices? ULTEM resins are available in custom colors – both opaque and transparent.

Whether your product color is used to differentiate your product, build your brand, or just look great in the final application, we can help. Our Worldwide Innovation Centers excel in new color development for specialty thermoplastics.

SABIC's ColorXpress™ Services offer maximum flexibility and speed:

- **Access a full library of over 50,000 colors**
- **Easily find and order color chips online**
- **Get support with color management services**

make it POSSIBLE | make it ULTEM™ resin

Good news! Your medical devices and accessories have the potential to reach new levels of design and performance. And ULTEM resin can help to make it possible.

LET'S REVIEW THE ULTEM RESIN FACTS:

You don't have to sacrifice the stiffness and precision control you've come to expect from **metal**.

ULTEM resin offers outstanding compression strength and is one of **the most dimensionally stable** thermoplastics available, helping medical devices deliver predictable and reliable performance.

Its **outstanding chemical resistance** against harsh healthcare disinfectants can help to prevent part failure due to environmental stress cracking.

Through repeated use and thanks to its compatibility with **multiple sterilization processes**, ULTEM resin maintains its excellent strength, dimensional stability, and aesthetics.

All these performance benefits can contribute to an **extended useful life** for medical devices, helping to avoid costly premature replacements.

Not only can you appreciate the durability of ULTEM resin, but you can enjoy the **design freedom** to create complex thin-wall parts that are lighter weight and easier and faster to produce versus metal.

Dimensionally stable, durable material that delivers consistent performance long-term

Material solutions that stand up to multiple sterilization processes

High precision, strong, lightweight material that may replace metal

Considering metal or a different thermoplastic instead of ULTEM resin? Don't miss the comparative performance included in this brochure.

make it STERILE | make it ULTEM™ resin

ULTEM resin is a material solution for medical devices that can stand up to multiple sterilization processes and repeated cycles

Sterilization methods have the potential to degrade your medical devices over time, diminishing their mechanical integrity, interfering with performance, or altering their aesthetics. Medical device OEMs must carefully consider material selection early in their product development process to ensure it can withstand these harsh environments.

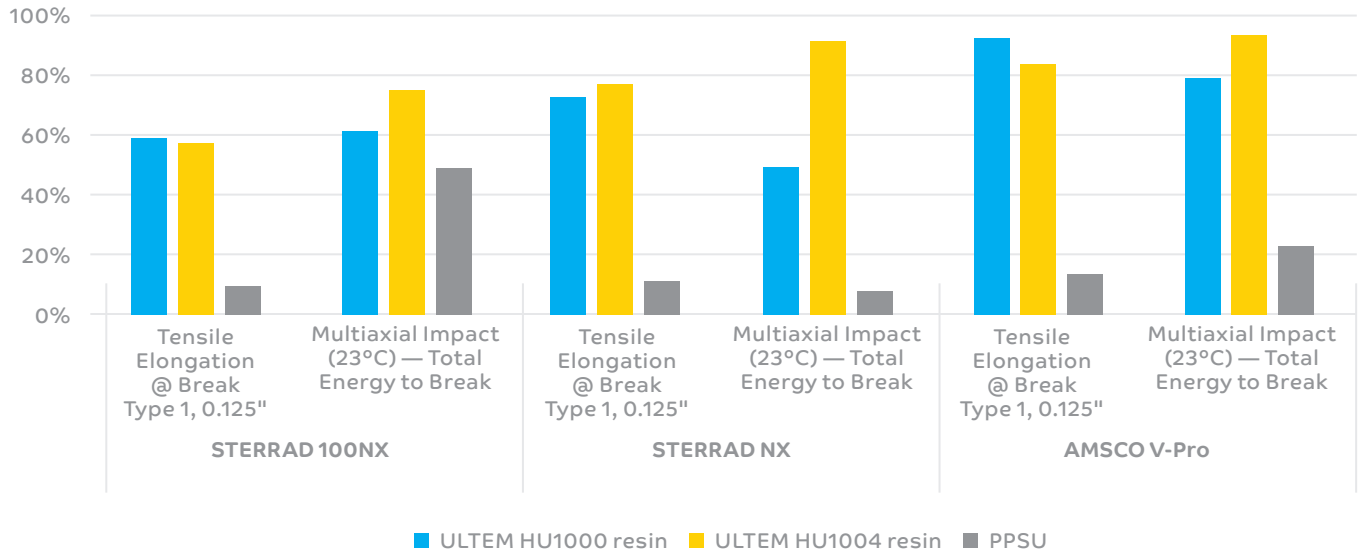
NO MORE WORRY.

Which sterilization methods do your customers require? ULTEM HU1000 and HU1004 resins are compatible with many mainstream methods:

- Vaporized Hydrogen Peroxide gas plasma (VHP)
- Steam autoclave at 134°C
- Gamma radiation, electron beam, and X-ray
- Ethylene Oxide (EtO)
- Ultraviolet C (UV-C)

ULTEM resins maintain tensile strength and ductility in VHP sterilization systems.

PROPERTY RETENTION AFTER 300 VHP STERILIZATION CYCLES

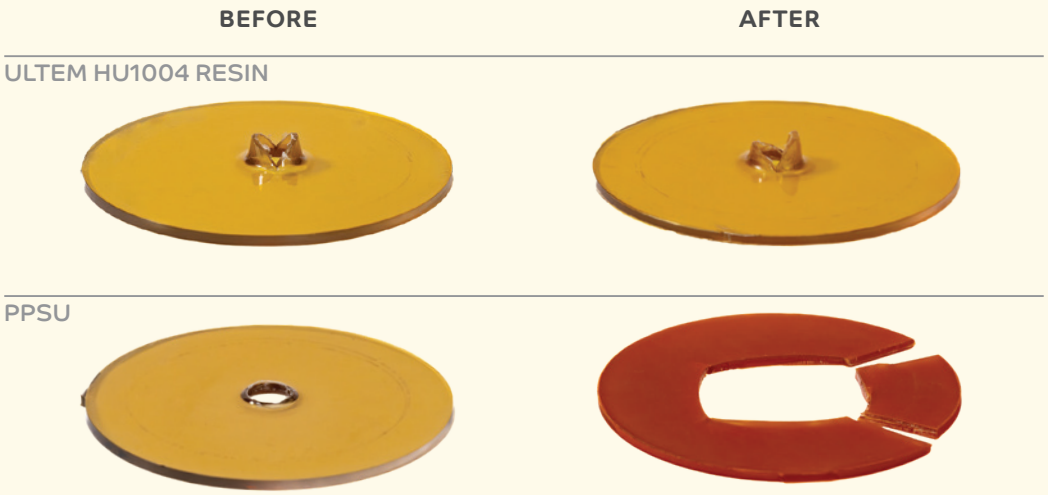


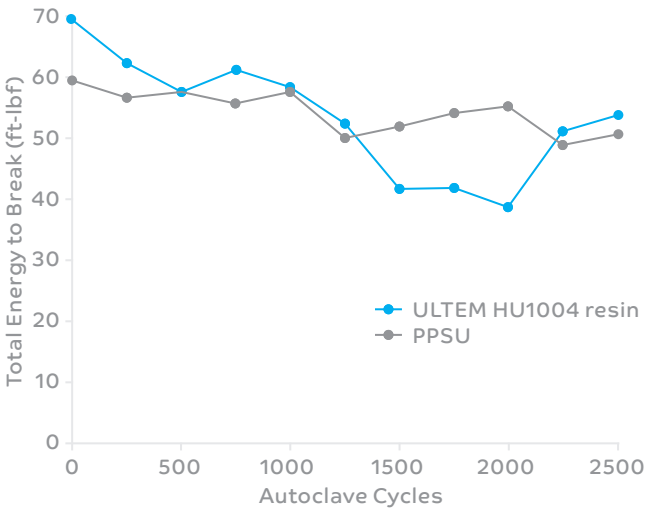
ULTEM HU1004 resin maintains 91% of its multiaxial impact vs PPSU of only 7%, breaking easily upon impact. PPSU material becomes embrittled as it goes through VHP sterilization

One of the mainstream sterilization methods for medical devices is Ethylene Oxide. The EPA ruling on the monitoring of EtO sterilization emissions is on the horizon. Give your customers peace of mind with a material solution that is stable across a multitude of sterilization methods and repeated cycles.

Versus polyphenylsulfones (PPSU), ULTEM HU resins perform better with retention of strength and color, even after 300 VHP sterilization cycles.

MULTIAXIAL IMPACT AFTER 300 STERRAD NX CYCLES





AUTOCLAVE PERFORMANCE

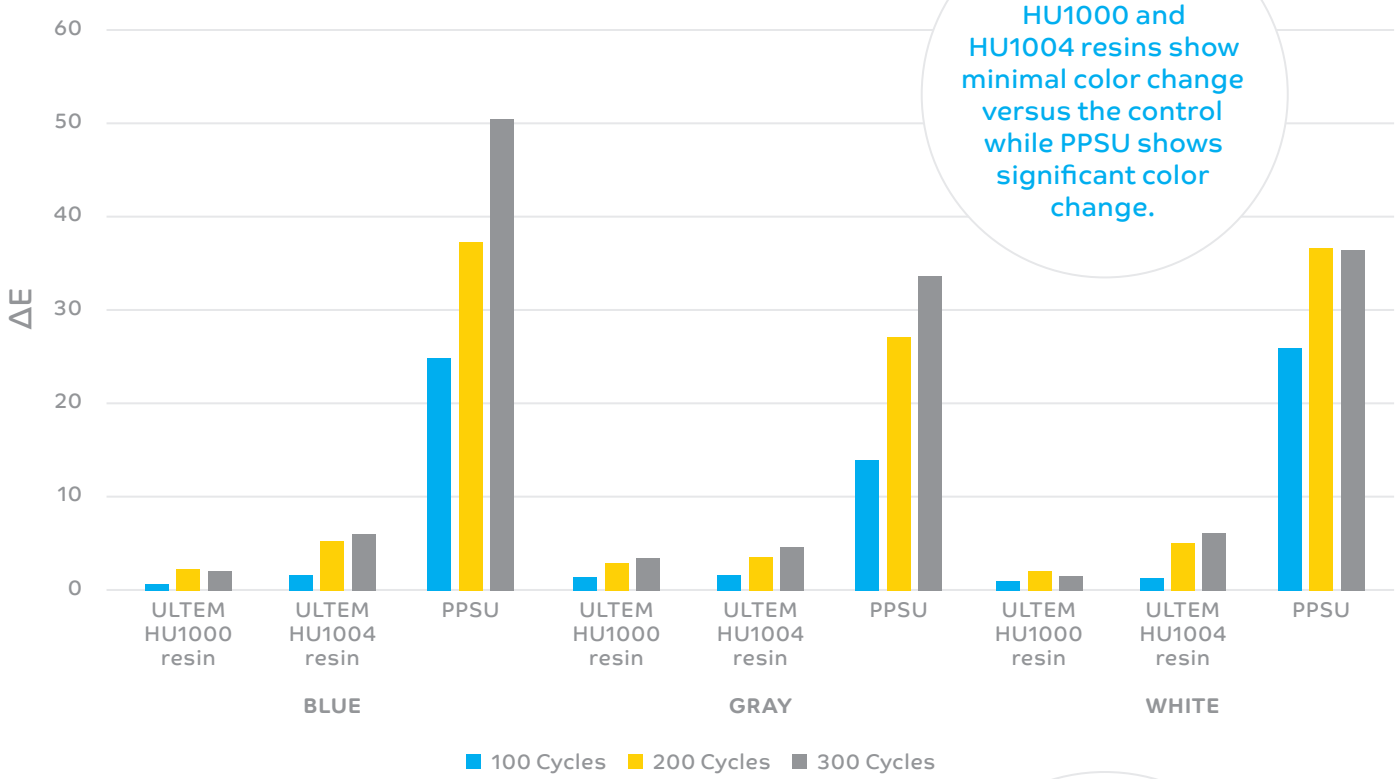
For extended autoclave cycles, ULTEM HU1004 resin would be the preferred choice. ULTEM HU1004 resin shows comparable performance in total energy to break.

For fewer cycles, ULTEM HU1000 resin would be well suited (up to 250 cycles).

ULTEM HU1004 resin and PPSU show equivalent performance with steam sterilization (within experimental error).

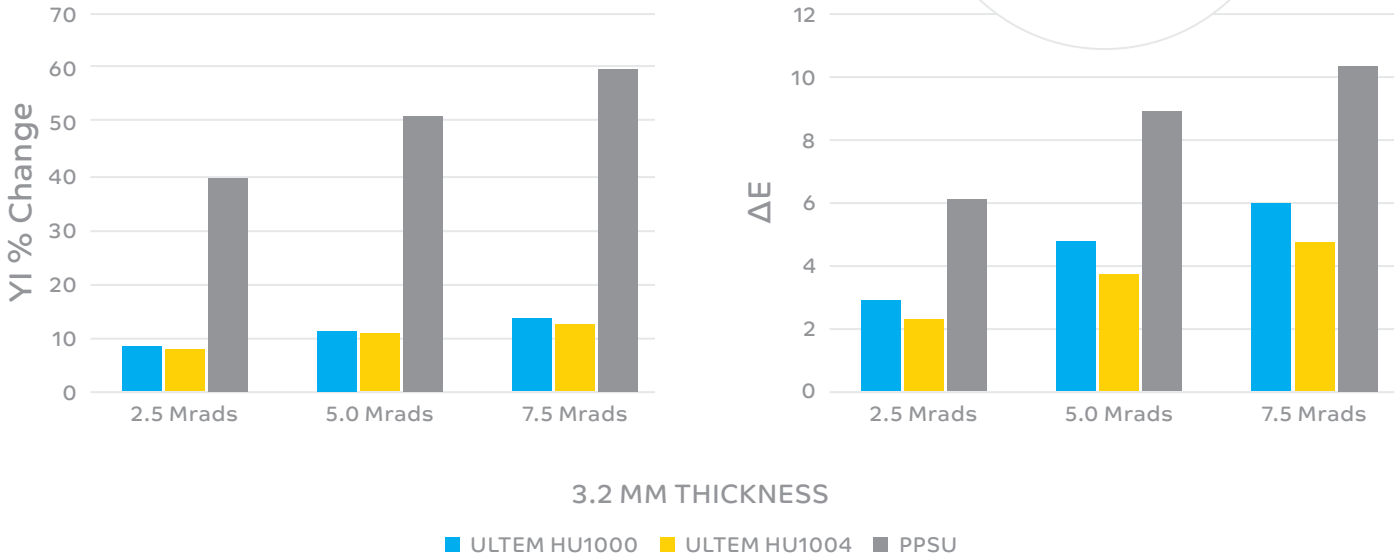
DELTA E COLOR CHANGE AFTER STERRAD NX STERILIZATION CYCLES
ULTEM HU RESINS AND PPSU

ULTEM HU1000 and HU1004 resins show minimal color change versus the control while PPSU shows significant color change.



YELLOWNESS INDEX AND DELTA E COLOR CHANGE AFTER GAMMA IRRADIATION STERILIZATION
ULTEM HU RESINS AND PPSU

ULTEM resins exhibit less visual difference versus PPSU at three different gamma radiation levels



RETAIN AESTHETICS AND COLOR EVEN AFTER STERILIZATION

ULTEM HU resins have a superior ability to retain color and aesthetics. SABIC's study tested the performance of ULTEM HU1000 resin, ULTEM HU1004 resin and PPSU in at least 300 sterilization cycles in STERRAD NX, STERRAD 100NX plasma and AMSCO V-PRO vapor systems.

COLOR CHANGE AFTER 300 STERRAD NX CYCLES
ULTEM HU RESINS AND PPSU

ULTEM HU1000 and HU1004 resins show minimal color change versus the control while PPSU shows significant color change with blue turning green, white turning yellow, and gray turning brown after 300 STERRAD NX cycles.

WHICH OF YOUR MEDICAL DEVICES MIGHT BENEFIT FROM ULTEM RESIN?

◀ ROBOTIC SURGERY EQUIPMENT

Strong and stiff ULTEM resin provides design freedom to replace metal (ie robotic arms) and can be laser welded. It helps to eliminate secondary operations for potential cost savings.

▲ SKIN STAPLER

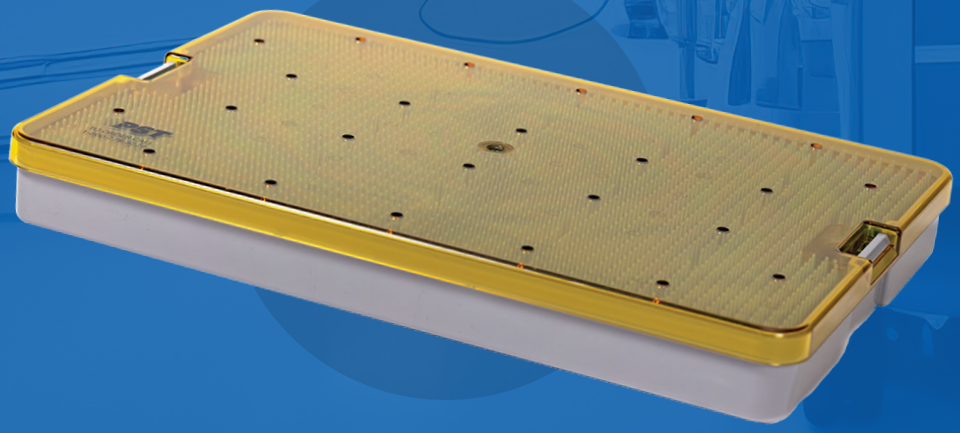
ULTEM resin was chosen for the INSORB|20 subcuticular skin stapler. High mechanical strength was required in its nose, arm, and yoke components due to the force of compression during use. Broad sterilization capability and ability to maintain strength and color after sterilization were also important.

▲ SPEEDRELEASE™ GUIDED RELEASE INSTRUMENT

Treace Medical Concepts, Inc. chose ULTEM resin for its sterile-packed, single-use guided release surgical instrument. ULTEM resin offered a high level of compatibility with gamma sterilization required and helped to enable a seamless conversion from machining to molding. The resin also provided consistent manufacturing performance translatable to multiple applications.

▶ STERLIZATION TRAYS

Plastic Sterilization Trays, Inc. (PST) chose ULTEM resin for its multi-sterilization capability, durability, impact resistance for a tray application, and color ability and stability.

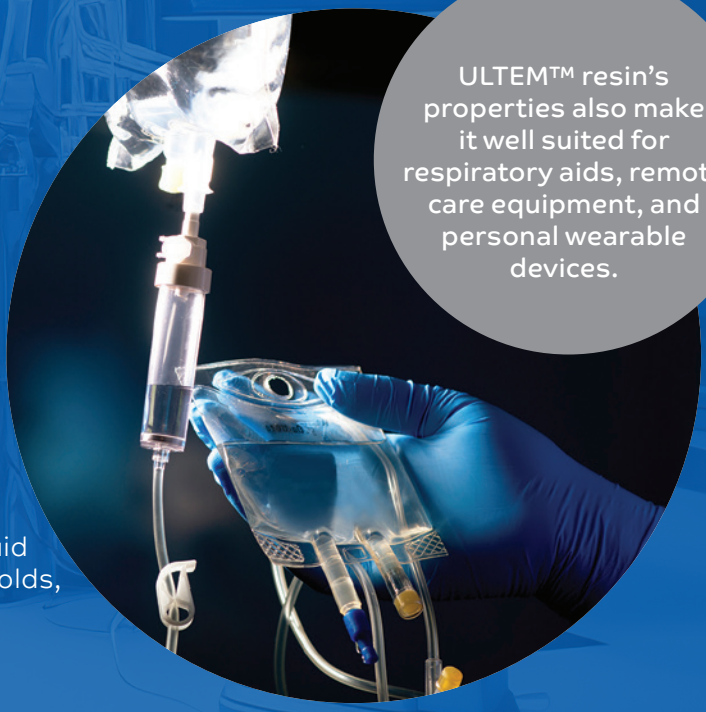


▶ EXAMINATION LAMPS

ULTEM resin can be used for reflective components in lighting. It provides tight tolerances, direct metallization capability, and the high temperature resistance required.

◀ PATIENT TESTING

ULTEM resin maintains its aesthetics and strength after multiple sterilization cycles contributing to longer life of medical equipment such as electronic medical devices, diagnostic and imaging equipment



ULTEM™ resin's properties also make it well suited for respiratory aids, remote care equipment, and personal wearable devices.

▶ DRUG DELIVERY

The outstanding strength of ULTEM resin provides dimensional stability even at thin walls and offers repeatability of precise dimensions of drug delivery devices such as hybrid fluid connectors, valves, seats, plugs, manifolds, dosing.

Make ULTEM resin your FIRST CHOICE for applications that must meet stringent physical, harsh environment and demanding regulatory requirements.

MORE REASONS TO MAKE IT ULTEM RESIN

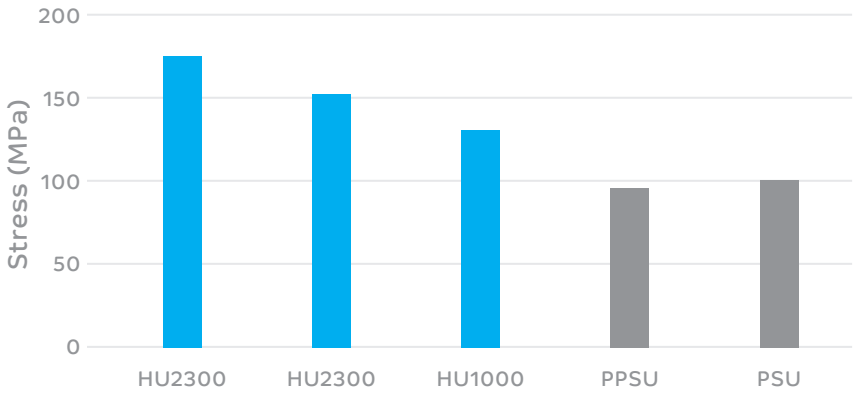
Currently using a plastic solution and not satisfied with some of its properties? ULTEM resin provides superior stiffness (up to 55% higher) and better dimensional stability (up to 30% higher) versus PPSU. With ULTEM resin, you can use less material in thinner part designs while getting the stiff, strong and stable parts you need.

MAKE IT STRONG

ULTEM resin is among the most dimensionally stable plastics available and exhibits excellent compression strength too. If you're using metal today, designing with ULTEM resin can help you to achieve comparable stiffness and precision control. So, you can rest easy and rely on its performance.

Unfilled ULTEM HU1000 resin shows 26% higher compression strength vs PPSU. When even higher strength is required, glass fiber reinforced grades HU2200 or HU2300 resin are well-suited options.

COMPRESSION STRENGTH AT YIELD, 23°C

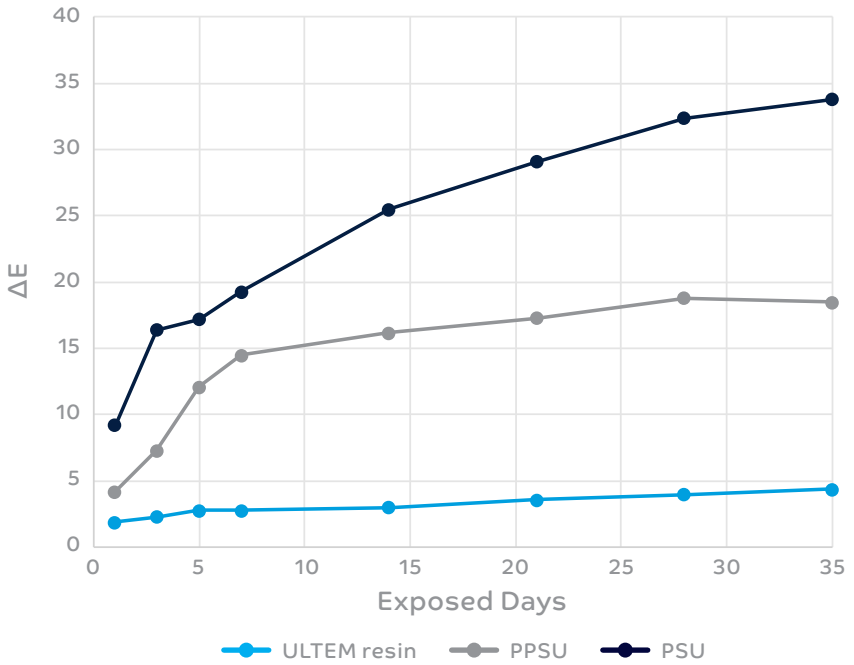


MAKE IT DURABLE

ULTEM HU resin series can handle many of your medical device challenges, helping you create durable devices that last longer. It offers outstanding chemical resistance against harsh healthcare disinfectants and is compatible with multiple sterilization processes.

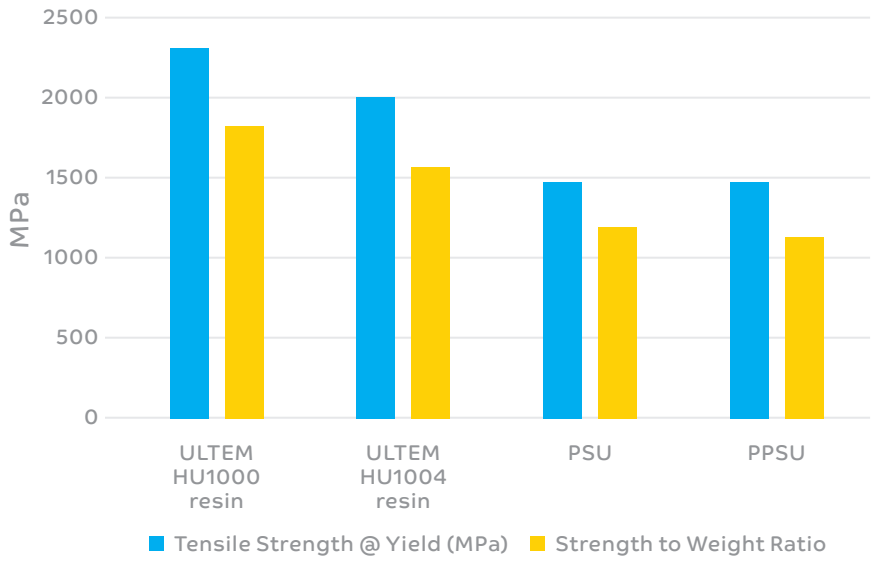
As shown in this UV exposure chart, ULTEM resins hold their color much better than polysulfones. Such long-term stability translates to consistent product performance in terms of optical properties and color.

DELTA E COLOR CHANGE AFTER UV EXPOSURE



MAKE IT LIGHTWEIGHT

ULTEM resin is an unreinforced polymer that provides very high strength and stiffness. ULTEM resin's superior strength to weight ratio makes it an ideal candidates for designing lightweight thin-wall components for potential metal replacement. Its higher tensile strength helps to ensure durability and functionality contributing to a longer useful life for devices.



MAKE IT CHEMICAL RESISTANT

The good chemical resistance of ULTEM resin to blood, lipids and disinfectants helps to prevent chemical attack, hydrolysis, and staining in harsh environments so your parts can last longer. ULTEM resin displays excellent property retention and resistance to environmental stress cracking after exposure to alkaline cleaners, disinfectants including Sani-Cloth AF3, and rinse aids.

	ULTEM resin	PSU	PPSU
Aromatic Hydrocarbons	3	1	4
Aliphatic Hydrocarbons	10	7	10
Chlorinated Hydrocarbons	3	1	5
Alcohols	10	7	10
Inorganic Base	1	10	10
Acetates / Ketones	4	1	4
Acids	7	7	7

Chemical Resistance (1 =poor; 10=excellent)

THE ULTEM HU RESIN FAMILY DESIGNED TO BE WELL SUITED FOR MEDICAL DEVICES

The ULTEM HU resin series is well suited to meet your performance requirements for a strong, durable, and colorable material that is compatible with multiple sterilization methods.

ULTEM HU resins have agency approval of the FDA, biocompatibility (ISO 10993 or USP Class VI) and UL yellow card.

ULTEM HU1000 RESIN

An unreinforced amorphous polyetherimide (PEI) resin – ULTEM HU1000 resin is a strong, durable, lightweight material that can withstand multiple sterilization methods.

ULTEM HU1004 RESIN

A PEI resin blend with all the performance benefits of ULTEM HU1000 plus enhanced hydrolytic stability in steam autoclave sterilization – boasting ductility retention >1000 autoclave cycles.

ULTEM HU2000 RESIN SERIES

Reinforced PEI compounds with 10 to 30% glass-fiber can help your medical devices and accessories be even stronger and still provide all the performance benefits of ULTEM HU1000 resin.

A new portfolio of ISCC+ certified bio-circular ULTEM resins that deliver a lower carbon footprint while offering the same high performance and processability as incumbent ULTEM materials is now available.

Dimensionally stable, durable material that delivers consistent performance long-term

Material solutions that stand up to multiple sterilization processes

High precision, strong, lightweight material that may replace metal

PROPERTY	UNIT	ULTEM HU1000 RESIN	ULTEM HU1004 RESIN	ULTEM HU2300 RESIN
MECHANICAL				
Flexural modulus, 1.3 mm/min, 50 mm span (ASTM D790)	MPa (KPSI)	3200 (464)	3000 (435)	9700 (14100)
Tensile Modulus, 5 mm/min (ASTM D638)	MPa (KPSI)	3350 (486)	2900 (421)	10400 (1510)
Tensile Strength at yield Type I, 5 mm/min (ASTM D638)	MPa (KPSI)	110 (160)	95 (141)	175 (254)
Tensile Strain, brk, Type I,5 mm/min (ASTM D638)	%	60%	85%	2.50%
IMPACT				
Izod Impact, Reverse Notched, 3.2 mm (ASTM D256)	J/m(ft-lb/in)	1335 (25)	3300 (62)	470 (8.8)
THERMAL				
HDT, 0.45 MPa, 6.4 mm, Unannealed (ASTM D648)	°C (°F)	210 (410)	214 (417)	212 (414)
HDT, 1.82 MPa, 6.4 mm, Unannealed (ASTM D648)	°C (°F)	201 (394)	204 (399)	210 (410)
CTE, -20°C to 150°C, flow (ASTM E831)	E-05 1/°CE-05(in/in/ °F)	5.2 (2.9)	5.6 (3.1)	1.8(1.0)
CTE, -20°C to 150°C, xflow(ASTM E831)	E-05 1/°CE-05 (in/in/ °F)	5.2 (2.9)	5.5 (3.1)	4.8(2.7)
PHYSICAL				
Specific Gravity (ASTM D792)	—	1.27	1.28	1.51
Melt Flow Rate, 337°C/ 6.6 kgf(ASTM D1238)	g/10 min	9	10	5

PROCESSING

ULTEM resin can be used in multiple part manufacturing processes including injection molding, thermoforming, and machining. Specific ULTEM resins are also well suited for select additive manufacturing processes. ULTEM resin is compatible with laser welding. It is also laser marking capable.

The product passed the following tests:

- ISO 10993 part 5 tests for in vitro cytotoxicity (L929 neutral red uptake)
- ISO 10993 part 6 tests for local effects after implantation (2-wk intramuscular implantation)
- ISO 10993 part 10 tests for irritation and skin sensitization (kligman maximization and intracutaneous injection)
- ISO 10993 part 11 tests for systemic toxicity (systemic injection and rabbit pyrogen)
- ASTM F756-08 standard practice for assessment of hemolytic properties of materials (hemolysis - rabbit blood)
- United States Pharmacopeia 35 monograph <661> containers, physicochemical tests (non-volatile residue)
- United States Pharmacopeia 35 monograph <662> containers, physicochemical tests

SABIC does not recommend and will not support the use of any SABIC products in medical devices intended to remain continuously in the human body for long term use (>29 days). The customer is in the best position to know the details of the intended conditions of use of their product. It is incumbent on them to carry out the appropriate biocompatibility tests of their product to assure safety, efficacy, and regulatory compliance. SABIC considers the determination of suitability of ULTEM HU resin in a medical device to be the responsibility of the device manufacturer and the drug packager.

To assist in the review of the use of ULTEM HU resin in medical devices and drug packages with the appropriate FDA regulatory personnel, we maintain a drug master file (DMF-1562) and a device master file (MAF-91) with the FDA. The DMF / MAF contain detailed formulation information and test data on certain grades of ULTEM resins.

SABIC considers this information proprietary and does not divulge it without a properly executed secrecy agreement. The FDA holds this information in confidence, but with our specific authorization will review it on behalf of a specific company's application or submittal for the purpose of rendering an opinion about the safety and suitability of the proposed usage.

MEDICAL DEVICE PRODUCERS CAN RELY ON SABIC'S SPECIALTY MATERIALS

We're here to help make your medical device design and development easier. Subject to user testing, medical device manufacturers rely on SABIC's specialty resins and compounds to deliver benefits ranging from design freedom to strength and durability. These materials can help you meet regulatory mandates and reach your sustainability goals.

SABIC is a preferred global supplier to the industry, offering 100+ medical-grade materials for potential use in surgical and drug delivery, patient testing and general healthcare applications. They are backed by SABIC's Healthcare Product Policy, which verifies that these materials meet global safety standards, are covered by an FDA Drug or Device Master File, and are subject to formula lock and a stringent change management process

Save time and expense when developing a new product. Reach out to us today. We're happy to help.

Email us at Specialties@sabic-hpp.com or scan the code.

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MEDICAL DEVICES