



Bayfol® Dureflex® Makrofol®

Thermoplastic films for medical packaging

Improving protection and safety in medical applications



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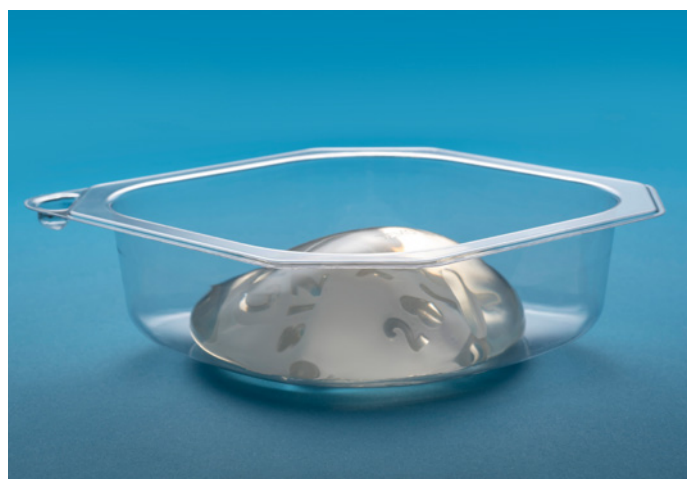
Exceptional standards require exceptional materials. That's why at Covestro, we have been able to maintain a long and successful history as a raw material supplier to the medical industry. Our range of **Makrofol® Dureflex® Bayfol®** polycarbonate, TPU and blended films meets the high-quality standards and performance criteria that the medical market requires.

Covestro films for the safety of medical packaging products

Medical packaging is a large market within healthcare where many different materials are at play. Packaging is an essential part of the final medical product. Depending on the value, the criticality of the device and the sterilization process opted for by the manufacturer, different materials will be selected. Covestro offers high performance materials for the most demanding of these applications.

Breast implant packaging – handling with greatest care

High-value breast implants have particularly stringent requirements. The packaging solution must be able to cope with high-temperature steam sterilization that removes all residues, yet also be essentially impact resistant.



Covestro high-performance **Makrofol®** MA507 and MA336 polycarbonate films are the perfect choice for breast implant packaging because they provide excellent transparency for a detailed visual check before unpacking, and are fully compatible with autoclave sterilization.

These medical-grade films deliver a high level of protection for high-value healthcare items including implants. Both films meet the American Society for Testing and Materials (ASTM) standard specifications for implantable breast prosthesis packaging F703-07 and F2051-00 and are manufactured in an ISO 9001 accredited facility.

Benefits:

- High temperature resistance
- Suited for steam sterilization and dry heat sterilization
- Excellent thermoforming processing
- Multiple gauges available for different draw depths
- Impact and puncture resistant
- Extremely durable
- High optical clarity
- High rigidity

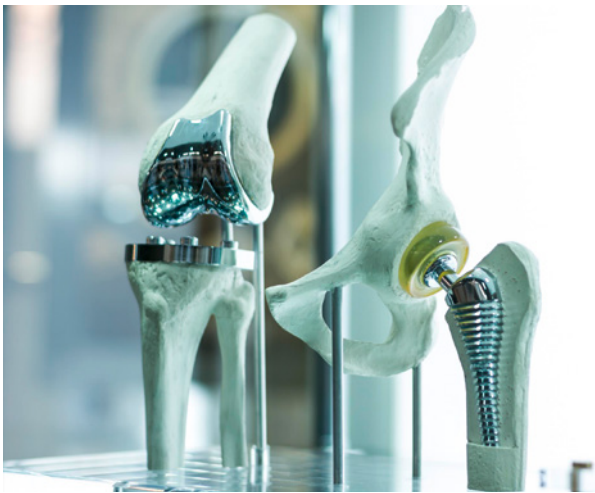
Steam autoclave sterilization typically operates at 121°C for most plastics. This technique enables zero residues to be reached with a less risky work environment than other techniques. Most polymer materials do not withstand these sterilization conditions, with the exception of polycarbonate.

Covestro **Makrofol®** MA507 and MA336 medical-grade films are made to withstand steam autoclave sterilization while featuring excellent clarity and transparency, allowing clinicians to visually inspect the device prior to the opening of the medical packaging. **Makrofol®** polycarbonate film can also be used for the production of medical blister packaging, medication bottles or drug containers that require steam sterilization.

Thermoplastic films for medical applications. Tailored to the medical industry, Covestro films offer custom solutions for overcoming processing and handling challenges, while enhancing safety.

Enhanced protection. Some devices or medicines will need enhanced protection or safety. This is the case with certain medicines, sharp surgical tools, or sensitive implants for examples. In these cases, the packaging will play a key role in safeguarding the integrity and safety of the device.

Orthopedic implants – double-sided protective solution



Orthopedic implants belong to the most expensive and most sensitive medical devices. They require packaging with a soft side in contact with the implant to ensure the rough surface (of the implant) can't abrade the packaging. Also a robust external shell is needed to protect implants from shocks during handling and transportation.

Bayfol® MA504 is a multi-layer film that meets these requirements. Excellent bonding between the layers ensures the packaging does not face any delamination during its lifetime while being very easy to thermoform.

Benefits:

- Two-layer film with one soft, one hard side
- Outstanding resistance to cracks, puncture and abrasion
- ISO 10993-5 and USP Class VI compliant
- Excellent processibility (thermoforming)
- Only one set of tools required to form
- Sterilizable (EtO, Gamma)
- High package rigidity
- Blue tint available
- One step thermoforming
- Reduces multiple material inventory

Surgical tools – puncture resistant flexible packaging

For applications that require high puncture resistance and don't require rigidity, like sharp edged surgical tools packaging, TPU will be the material of choice for delivering excellent hydrolysis and fungus resistance. Available in natural and blue, glossy or matt surface finish.

Dureflex® recommended grades are compliant with ISO 10993 and USP Class VI.

Benefits:

- Sterilizable (EtO, Gamma)
- Flexible
- Hydrolysis and fungus resistance
- Resists puncture from sharp tools





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[1] Please see the "Guidance on Use of Covestro Products in a Medical Application" document.]
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