

# MEDICAL GRADE SILICONE SHEETING



## PRODUCT INFORMATION

BioPlexus Medical Grade Silicone Sheeting is a flexible silicone elastomer material designed for general medical and laboratory applications. It is supplied non-sterile and sandwiched between clean room grade polyethylene sheets to facilitate handling and cleanliness. It is packaged in a resealable poly bag.

The Medical Grade Silicone Sheeting is available in several thicknesses of three product types, differing in their flexibility and strength.

**Non-Reinforced** – made from a medium durometer silicone elastomer and available in thicknesses of .002", .005", .010", .020", .040", .062", and .080".

**Reinforced** – made from a medium durometer silicone elastomer reinforced with polyester fabric and available in thicknesses of .007", .020", .030", and .040"

**Firm, Non-Reinforced** – made from a high durometer silicone elastomer and available in thicknesses of .020", .040", .080", and .120".

The advantages of Medical Grade Silicone Sheeting include:

- High degree of chemical inertness and bio compatibility.
- Easy to cut to size and shape.
- Reinforced sheeting minimizes stretching and allows suture attachment.
- Easy removal with minimal trauma.
- High permeability to gases.
- Autoclavable without significant changes in physical properties.

## APPLICATIONS

The purchaser should thoroughly test products made in part or otherwise incorporating Medical Grade Silicone Sheeting to determine the acceptability of the products in a specific application.

Medical Grade Silicone Sheeting has been utilized in a wide variety of scheduled and emergency surgical repairs.

## BIO COMPATIBILITY

Bio compatibility tests, which meet or exceed USP Class VI Plastics tests, have been performed on the elastomer from which Medical Grade Silicone Sheeting is produced. Every production lot of elastomer is tested for levels of trace metals and for absence of cytopathic effects using a tissue culture test. Results are based on comparison with defined USP negative controls:

- |                              |                       |
|------------------------------|-----------------------|
| 1. Hemolysis, percent:       | <1                    |
| 2. Pyrogenicity:             | Non-pyrogenic         |
| 3. Intracutaneous Injection: | Non-irritating        |
| 4. Systemic Injection:       | Non-toxic             |
| 5. Intramuscular Implant:    |                       |
| 3 days                       | Trauma free           |
| 10 days                      | Trauma free           |
| 90 days                      | Trauma free           |
| 6. Cell Tissue Culture:      | No Cytopathic Effects |

## CLEANING INSTRUCTIONS FOR USE

The Medical Grade Silicone Sheeting is sandwiched between two clean room grade polyethylene sheets. Remove the polyethylene sheets from the silicone. Scrub the entire surface of the silicone sheet thoroughly with a clean, soft sponge or soft bristled brush in a hot water and soap solution to remove skin contaminants. Use a non-oily cleaner or mild soap. Do not use synthetic detergents or oil based soaps, as these soaps may be absorbed and may subsequently leach out to cause tissue reaction. Rinse thoroughly in hot water and follow with a complete rinse in distilled water.

**STERILIZATION:** Must be sterilized before use.

### Steam

Wrap in non-linting material or place in a clean, open tray. Autoclave by one of the following methods:

- High-speed instrument (flash) sterilizer:  
10 minutes at 132° C. (270° F.) and 30 psi (2 kg/cm<sup>2</sup>).
- Standard gravity sterilizer:  
30 minutes at 121° C. (250° F.) and 15 psi (1 kg/cm<sup>2</sup>).

### Ethylene Oxide

Sterilization by ethylene oxide (ETO) is not recommended, unless sufficient data is available regarding the time required for complete out gassing of residual ethylene oxide and other ETO by-products from the specific system employed.