TUFFAK® FD
FDA COMPLIANT

MEDICAL GRADE POLYCARBONATE FOR DIRECT SKIN CONTACT APPLICATION

TUFFAK FD is a transparent polycarbonate product produced from resin which is biocompatible to many ISO 10993-1 and United States Pharmacopeia (USP) Class VI test requirements. TUFFAK FD also complies with FDA regulation 21 CFR 177.1580 requirements for food contact.

Approved under ISO Standard 10993-1:

"Biological Evaluation of Medical Devices" for the categories including:

- Skin contact
- Up to 24 hours contact with circulating blood, tissue, bone, and dentin
- Up to 30 days contact with mucosal membranes, compromised surfaces, and blood path, indirect
- Medical uses such as single autoclave use, hospital trays, medical bulk storage bins, bassinets, incubators, and sneeze guards, medical device storage containers

» Approved for medical use: Approved under ISO 10993-1 and USP VI

» High clarity

» Outstanding impact strength

» Temperature resistant

» Easy to clean and disinfect (see page 2)

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TUFFAK® FD polycarbonate can be cleaned, disinfected and sterilized by almost any of the well-known methods employed in routine practice. The smooth surface of the parts is seen to be advantageous in these applications.

CLEANING

Standard Cleaning Instructions:

Thoroughly pre-rinse with warm water to loosen and wash away surface material, grit and grime. Using a soft microfiber cloth or moist non-abrasive sponge, gently wash with a mild diluted soap (Dawn or Baby Shampoo). Rinse thoroughly with lukewarm clean water.

Dishwashers - avoid the use of strong alkaline cleaning products

DISINFECTION

Disinfectants containing Hydrogen Peroxide or Isopropyl Alcohol (aka isopropanol or 2-Propanol) are compatible with polycarbonate sheet. Avoid using products containing aldehydes, phenols, hydroxides or amines as the active ingredient. Avoid disinfectants containing bleach or ammoniated chloride.

STERILIZATION

Sterilization by Steam (saturated steam)

To prevent deformation of molded parts, the sterilization temperature should not exceed 250°F. Avoid boiler feed water containing alkaline corrosion inhibitors. TUFFAK FD can be sterilized by steam many times before gradual chemical decomposition reduces its mechanical strength. Typically, after 100 cycles of 30 minutes each at 250°F, the parts still retains comparatively good impact strength although hairline cracks may develop along with whitening of the plastic's surface. In view of these gradually occurring changes, TUFFAK FD parts are intended only for a single use autoclave cleaning.

Sterilization with Ethylene Oxide (ETO)

Sterilization by ethylene oxide, either undiluted or mixed with carbon dioxide or inert gases in a ratio of 10 to 20% ethylene oxide / 90 to 80% remainder mixture. The temperature during sterilization should not exceed 150°F. The impact strength of test specimens treated with pure ethylene oxide at 30°F for 50 cycles of 6 hours each is unchanged in comparison with the starting level despite slight crack formation.

Sterilization with High-energy Radiation (γ-radiation)

TUFFAK FD polycarbonate has a high resistance to the effects of high-energy radiation. Its resistance depends on the ambient conditions and the radiation dosage applied. Assuming that 28 kGy (2.8 Mrad) of energy is required to sterilize TUFFAK FD, it can be sterilized 10 to 20 times before any appreciable reduction in mechanical strength occurs. Polycarbonate does, however, become progressively more yellow with each sterilization.

Sterilization with Peracetic Acid

TUFFAK FD can be sterilized with a 2% concentration peracetic acid without suffering damage. Appropriate safety precautions must be observed when handling peracetic acid.

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