Biocompatibility of KYDEX® Thermoplastic Sheet

INTRODUCTION

What is Biocompatibility?

A materials ability to act and perform without impairing basic immunological functions of the body. Biocompatible plastics enhance healing functions without causing injurious, negative physiological, allergic or toxic reactions.

COMPLIANCE

When do products have to be biocompatible?

When in direct contact with human tissue, the material must have the ability to be in contact with a living system without producing an adverse effect. The ISO 10993 series of standards identify three categories of contact (Surface Device, External Communicating Device, Implant Device) and three levels of contact duration (Limited, Prolonged, Permanent).

What is the ISO Standard 10993?

The ISO 10993 set entails a series of standards for evaluating the biocompatibility of medical devices to manage biological risk. The standards are as follows:

- ISO 10993-1 - Evaluation and testing within a risk management process
- ISO 10993-2 - Animal welfare requirements
- ISO 10993-3 - Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4 - Selection of tests for interactions with blood
- ISO 10993-5 - Tests for in vitro cytotoxicity
- ISO 10993-6 - Tests for local effects after implantation
- ISO 10993-7 - Ethylene oxide sterilization residuals
- ISO 10993-8 - Selection of reference materials
- ISO 10993-9 - Framework for identification and quantification of potential degradation products
- ISO 10993-10 - Tests for irritation and skin sensitization
- ISO 10993-11 - Tests for systemic toxicity
- ISO 10993-12 - Sample preparation and reference materials
- ISO 10993-13 - Identification and quantification of degradation products from polymeric medical devices
- ISO 10993-14 - Identification and quantification of degradation products from ceramics
- ISO 10993-15 - Identification and quantification of degradation products from metals and alloys
- ISO 10993-16 - Toxicokinetic study design for degradation products and leachables
- ISO 10993-17 - Establishment of allowable limits for leachable substances
- ISO 10993-18 - Chemical characterization of medical device materials within a risk management process
- ISO 10993-19 - Physico-chemical, morphological and topographical characterization of materials
- ISO 10993-20 - Principles and methods for immunotoxicology testing of medical devices

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COMPATIBILITY

KYDEX® Thermoplastic products are utilized in Skin Contact applications with Limited to Prolonged Exposure levels. Biocompatible KYDEX® Thermoplastic products have exhibited passing results to both ISO 10993-5: In Vitro Cytotoxicity and ISO 10993-10: Irritation and Skin Senisitization testing. Biocompatible KYDEX® Thermoplastic products are typically utilized in equipment housing, hospital bed, examination table, orthopedic splints and prosthetics, and various other applications.

EXPLANATION OF TESTING

ISO 10993-5: Testing for In Vitro Cytotoxicity – Cytotoxicity testing is a means to determine whether a material contains significant quantities of biologically harmful extractables. Extracts from the test material are exposed to developing cell cultures. The cells are observed for signs of toxicity that include change in size, appearance or the decrease in living cells. The test system is considered suitable if the following conditions are met:

- The viability % for the negative control article should be ≥70%.
- The vialbility % for the positive control article should be <70%.
- The mean of each column of the untreated control must be within ±15% of the untreated control mean.

The lower the viability % value, the higher the cyotoxic potential of the test article is. If viability is reduced to <70% of the blank, the test article is considered to have a cyotoxic potential. When tested, most KYDEX® Thermoplastic products resulted in a viability of 95-99%.

ISO 10993-10: Tests for Irritation and Skin Sensitization – ISO 10993-10 is a means to minimize the potential exposure of human patients to irritating materials used in medical devices. Extracts from the test material are applied to the test subject via topical and intradermal application. The injection sites on each test subject are observed for signs of erythema and oedema immediately following injection and at 24 ± 2 hours, 48 ± 2 hours, and 72 ± 2 hours after injection of the test article. Observations of erythema and oedema reactions are scored on a scale of 0-4, then totaled.The primary or cumulative irritation index is characterized by number and description.

0 to 0.4 = Negligible
0.5 to 1.9 = Slight
2.0 to 4.9 = Moderate
5 to 8 = Severe

When tested, KYDEX® Thermoplastic products have exhibited negligible effects.

BIOCOMPATIBLE PRODUCTS

When tested to ISO 10993-5&10, the following products have shown to adverse effects and meet the criteria of being biocompatible materials:

- **KYDEX® 100**
- **KYDEX® 110**
- **KYDEX® 430**
- **KYDEX® T**
- **KYDEX® XD**
- **KYDEX® XD03**

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