Chemical Services: Biocompatibility

Biocompatibility evaluation is performed to determine the biological response as a result of human bodily exposure to a medical device for a specified period of time. ARDL is here to help test and investigate your product, process and material problems to supply you with economical solutions so you can move forward with Premarket Approval (PMA) and the 510(k) process. Various systematic testing procedures available at ARDL can ensure that your medical device or protective equipment is fit for its purpose.

ARDL specializes in ISO 10993-14 (Material Characterization). You will be provided with the guidance needed to select the appropriate evaluation methods for your medical device based upon its chemical characteristics, intended application and the extent and type of contact to be made with the body.

Chemical Services: Biocompatibility (cont.)

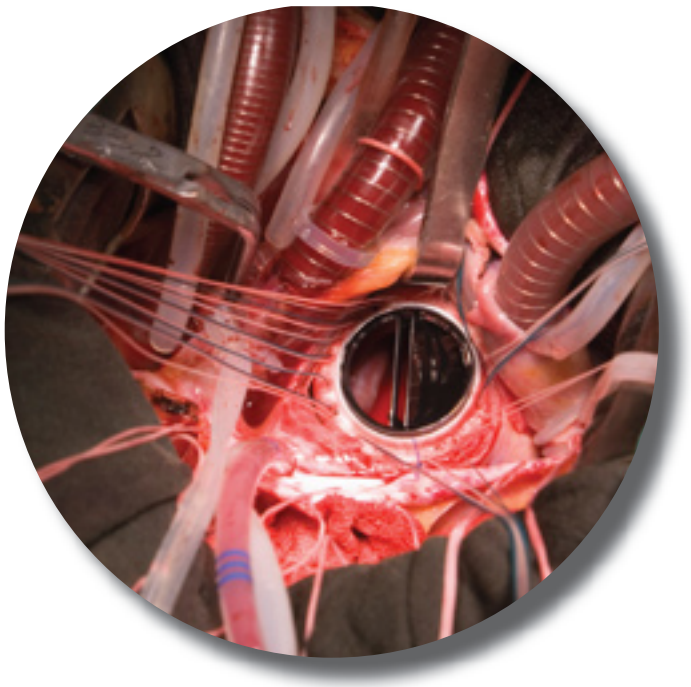
Various resources can be utilized to obtain the data needed about the formulation of your material, along with data about impurities and extractables that could cause potential problems. Please see the list below for a variety of procedures available at ARDL to help you produce the safest, most effective product possible.

Chemical Analysis

- Attenuated Total Reflectance (ATR) & Fourier Transform Infrared Spectroscopy (FTIR)
- Contaminant Identification
- Dynamic Mechanical Analysis (DMA) & Dynamic Thermal Mechanical Analysis (DTMA)
- Differential Scanning Calorimetry (DSC)
- Element Analysis (Carbon, Hydrogen, Nitrogen, Oxygen, Sulfur)
- Extractables Content
- Gas Chromatography/Mass Spectrometry (GC/MS)
- High Performance Liquid Chromatography (HPLC)
- Inductively Coupled Plasma/Optical Emission Spectroscopy (ICP/OES)
- Leachables Studies
- Liquid Chromatography/Mass Spectrometry (LC/MS^n)
- Moisture Content by Karl Fischer Titration
- Polymer Identification
- Pyrolysis (GC/MS)
- Thermal Gravimetric Analysis (TGA)
- Thin Layer Chromatography (TLC)
- Ultraviolet Spectroscopy (UV)

Microscopy

- Energy Dispersive X Ray (EDX)
- Light Optical Microscopy (LOM)
- Optical Comparator (OC)
- Scanning Electron Microscopy (SEM)
- Transmission Electron Microscopy (TEM)



AKRON RUBBER DEVELOPMENT LABORATORY, INC.
www.ardl.com
2887 Gilchrist Rd. | Akron, Ohio 44305 | answers@ardl.com
Toll Free (866) 778-ARDL | Worldwide (330) 794-6600 | Fax (330) 794-6610