

# Plastics Solutions for Home Care Medical Devices

February 27, 2019





## Irving Paz – Healthcare Market Manager

- More than 17 years in the industry, serving in various roles for Fortune 500 companies, on the manufacturing/supplier side and in several consulting, technical and development positions.
- MSc degree from the University of Warwick, along with degrees in strategic leadership and strategic marketing planning from Babson College and London Business School.
- Primary function in current role is driving strategic growth in the Healthcare market



## Ed Flaherty – Application Development Engineer

- Ed has over 40 years of experience in managing facilities molding Healthcare, Military, Commercial and Electronic products throughout the United States and Asia.
- Previous experience includes overseeing R&D, molding, tooling and design for new product design and manufacturing. Prior to joining Nexeo Solutions, Ed has worked for Texas Instruments, Schick, Bic, US Surgical, Borg Warner, Data General, Spectrum Plastics, Barnes Group, GE Plastics, PTA Plastics and Quantum Leap
- Holds patents in LED manufacturing
- Proud SPE Member since 1976 and past President of the Connecticut Section.
- A graduate of Lowell Technological Institute (LTI) with a BS Plastics Engineering
- Primary function in current role is support/drive application development initiatives in various markets including Healthcare

# Who Is Nexeo?

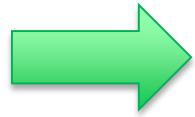
Nexeo Solutions is a leading global chemicals and plastics distributor, representing products from world-class producers to a diverse global customer base. From product specification to sustainable solutions, we go beyond traditional logistics to provide value-added services across many industries, including chemicals manufacturing, oil and gas, coatings, personal care, healthcare, automotive, 3D printing, wire & cable and more.



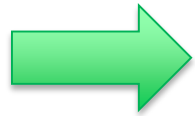
*As of March 1, 2019, the plastics division will be known as Nexeo Solutions Plastics, LLC.*

# Overview

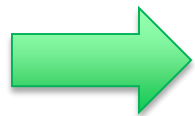
For the purpose of this presentation, topics covered will be:



Trends and segmentation of home care medical device industry



Considerations in evaluating the ideal thermoplastic material for your application



Performance requirements and attributes of home care medical devices

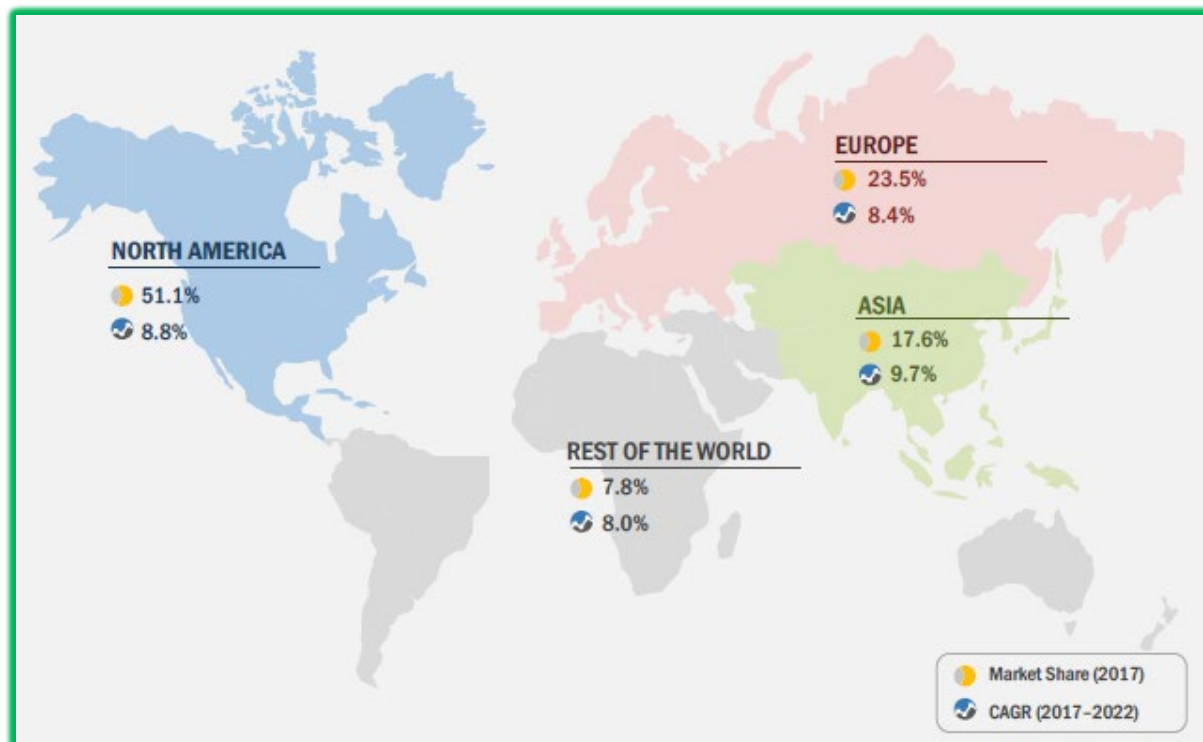


# What is the Home Healthcare Industry?

The home healthcare industry is an aggregate of home healthcare medical **devices, services, software, and telehealth technology.**

- Global market projected to reach **USD 364.69 billion** by 2022 @ CAGR 8.8%

## Global Market Share and CAGR



# Key Growth Drivers of Home Healthcare Industry

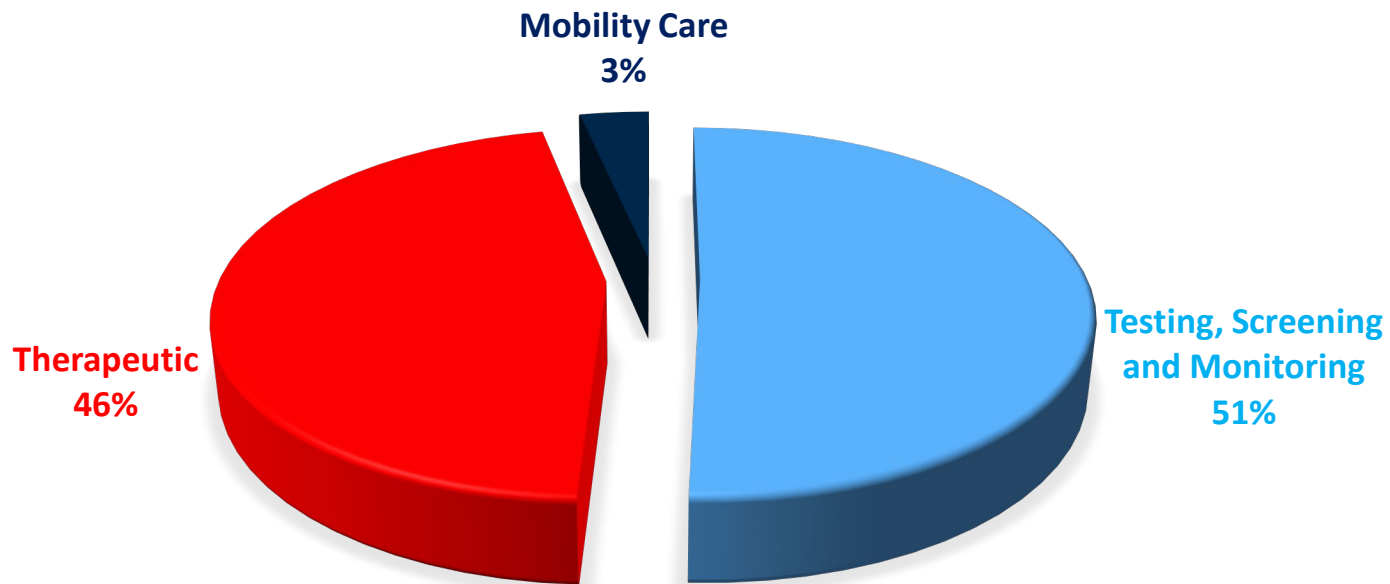
- **Aging Population**
  - Global population over 65 years expected to reach 604 million by 2020
- **Chronic Diseases**
  - Cardiovascular, cancer and respiratory diseases
- **Healthcare Costs**
  - Increased demand for affordable healthcare delivery systems
- **Technological Advancements**
  - Wireless Communication, Telemedicine, Smart Devices (phones, sensors, mobile monitoring devices)
- **Government Initiatives**
  - Decreased government spending, tightening regulations and pricing pressure



In 2017, the Home Care Medical Devices (HCMD) market had a share of 30% of the total Home Healthcare Industry with an expected CAGR of 9.7% until 2022

*The Home Care Medical Devices Market (HCMD) is segmented into 3 markets*

## GLOBAL HOME CARE MEDICAL DEVICES MARKET SEGMENTATION

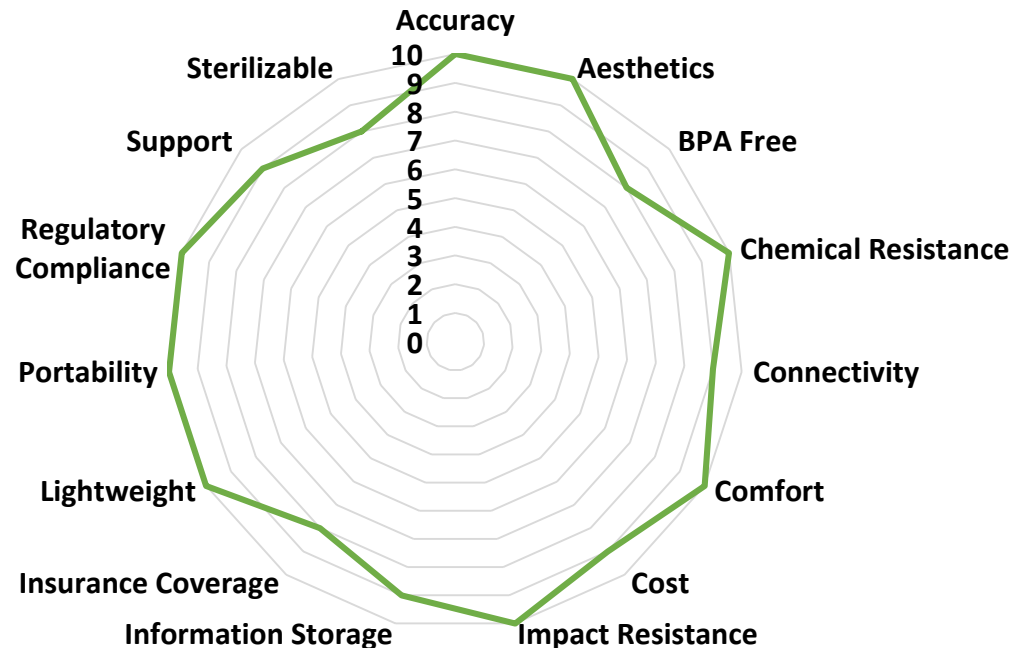


# Requirements of TSM Devices

Nexeo Solutions identified 15 requirements of Home Care Medical Devices and assessed relevance for Testing, Screening and Monitoring (TSM) Devices.

## Devices Analyzed

- Blood Glucose Monitors
- ECG/EKG Monitors
- Sleep Apnea Monitors
- Blood Pressure Monitors
- Cholesterol Monitors
- Hearth Rate Monitors
- Holter Monitors
- Pulse Oximeters



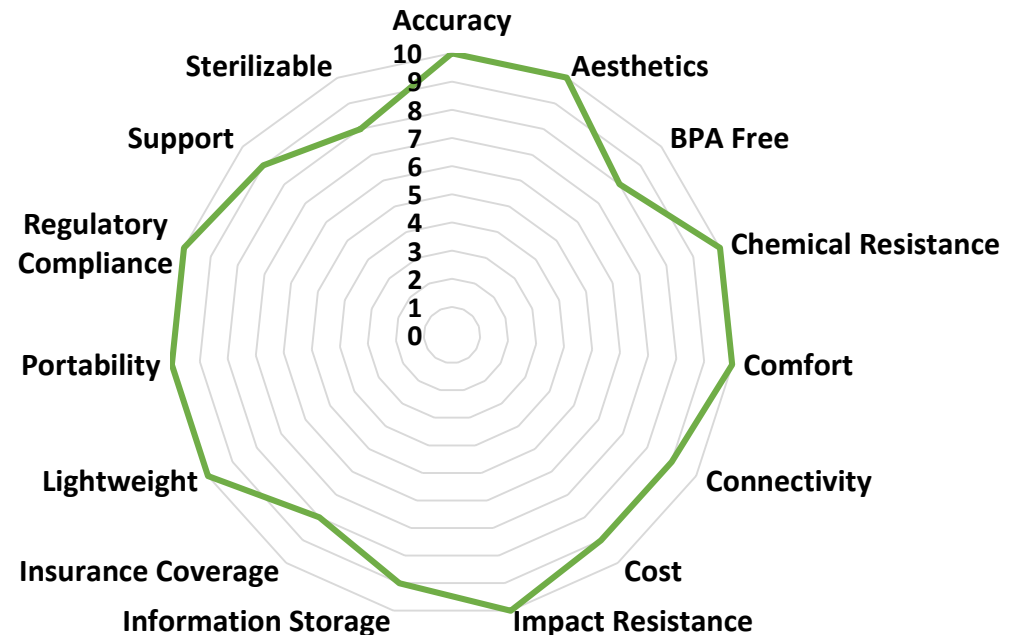


# Requirements of Therapeutic Devices

Nexeo Solutions identified 15 requirements of Home Care Medical Devices and assessed relevance for Therapeutic Devices.

## Devices Analyzed

- Insulin Delivery Devices
- Sleep Apnea Therapy
- Dialysis Equipment
- IV Equipment
- Oxygen Delivery
- Ventilators
- Nebulizers
- Wound Care Devices

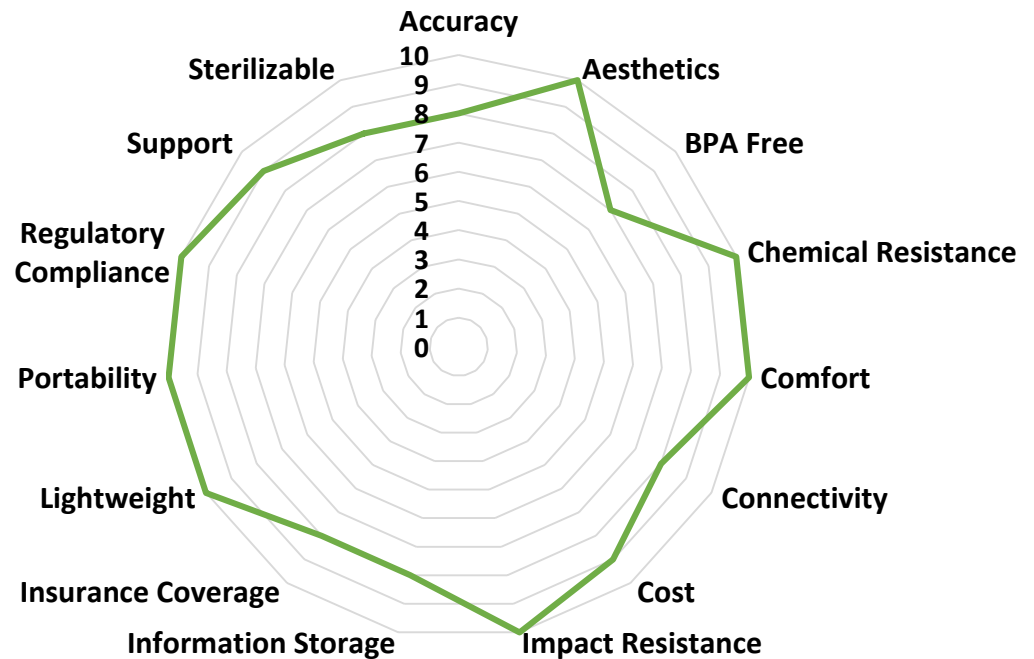


# Requirements of Mobility Care

Nexeo Solutions identified 15 requirements of Home Care Medical Devices and assessed relevance for Mobility Care.

## Devices Analyzed

- Wheelchairs
- Walkers
- Rollators
- Mobility Scooters
- Canes
- Crutches

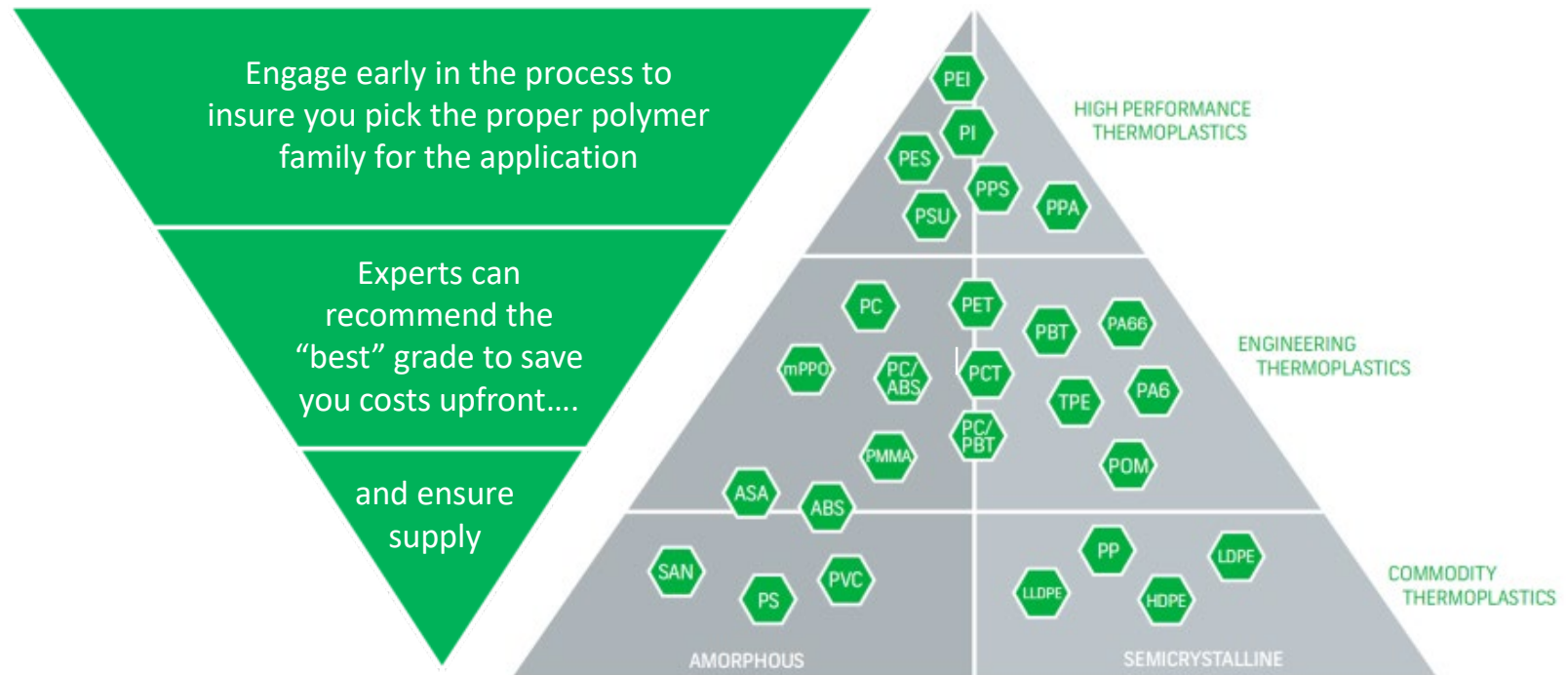


## Evaluating Thermoplastic Material for your Medical Device Application

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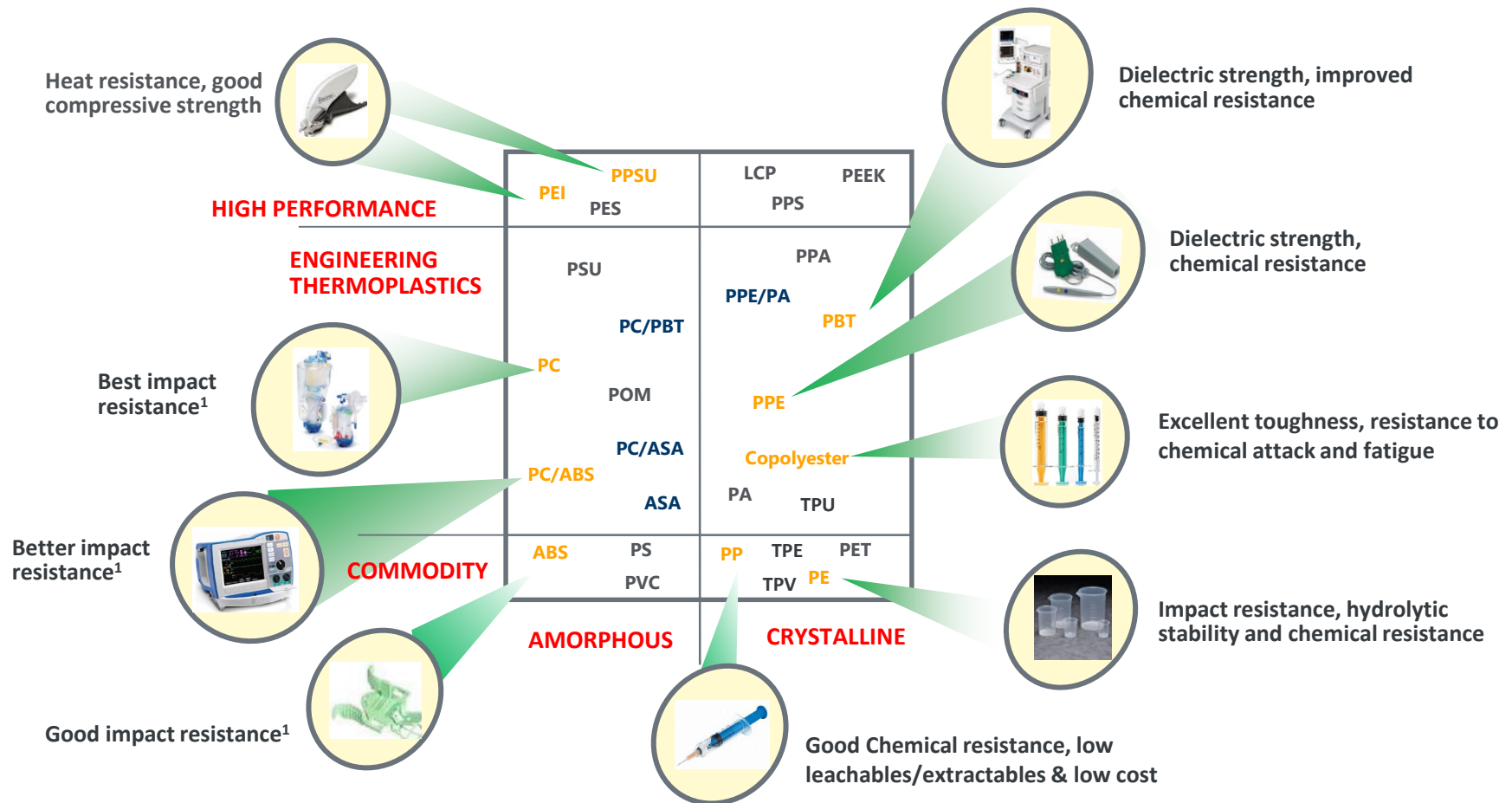
# Available Thermoplastic Materials

There are about **70** types of plastics, and over **80,000 grades**. A grade of plastic is created by adding different additives to a single type of plastic, or to a mix of two or more types of plastic, to create specific material properties.



# Thermoplastics for Home Care Medical Devices

Each material has a unique balance of properties and each product has special requirements. Matching the material properties to the product requirements is primary goal of understanding application development.



1: relative performance of ABS, PC/ABS, PC resins

# Defining Part Requirements for End Use

Questions to ask in order to define requirements for end use property decisions, include:

- **Mechanical Properties**
  - Must meet or exceed the application requirements
- **Biocompatibility**
  - Consider skin contact, airflow pathways, fluid storage and dispensing
- **Clarity or Colorability**
  - Pigments will also need to be biocompatible with base resin
- **Sterilization**
  - **Which technique is best fit for property requirements?**
- **Impact and chemical resistance**
- **Flame retardancy and EMI/RFI shielding for equipment housings**
- **Noise reduction for equipment**
- **Plastic resins subject to formulation lock and change management process**
  - Must be clearly defined to understand product life expectancy and material availability
- **Pre-assessment of resin biocompatibility according to:**
  - ISO 10993 or USP Class VI standards
  - U.S. Food & Drug Administration (FDA)

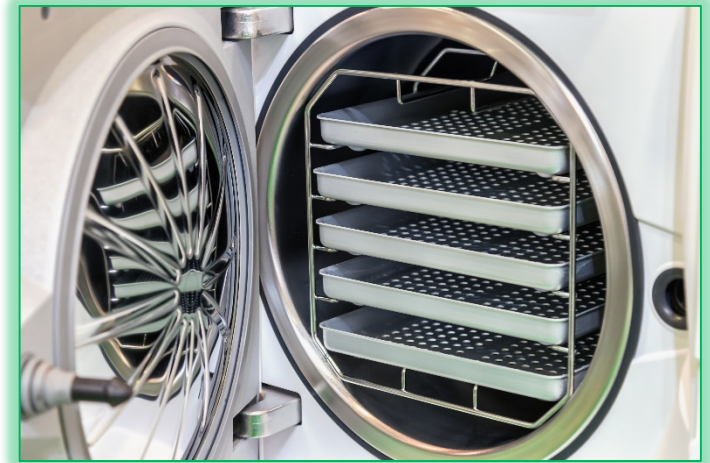


# Decision to Consider: Sterilization Technique

*Sterilization is a process that eliminates pathogens present on a medical device surface.*

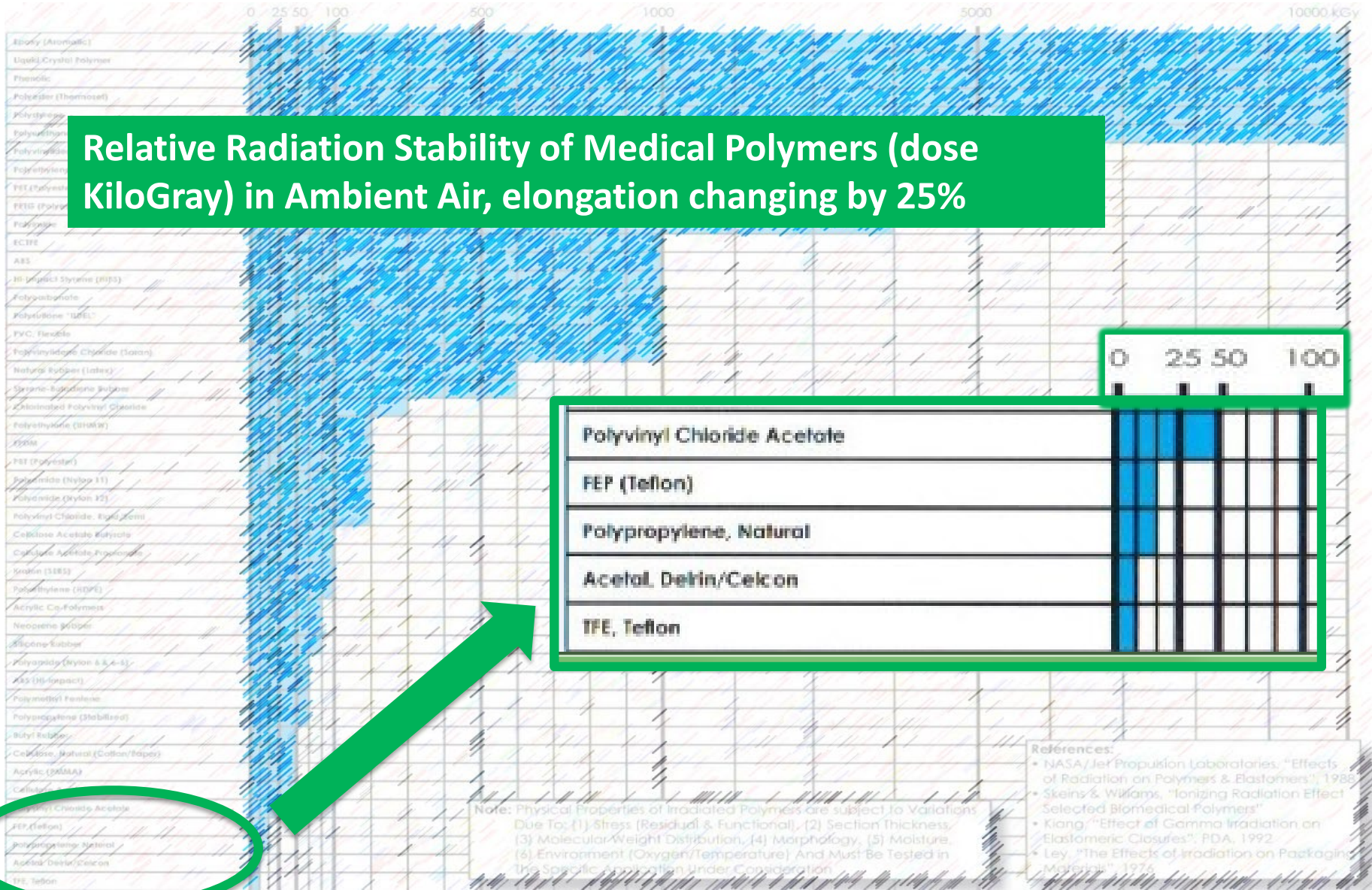
*The four major sterilization techniques are:*

- **Autoclave**
  - *Most used for reusable products*
  - *Critical to define number of cycles and process used to determine grade of plastic to be used*
- **Ethylene Oxide (EtO)**
  - *Most widely used process for sterilization of disposables*
  - *Highly compatible with most plastics, complex procedure with lengthy cycle times*
- **Gamma Irradiation**
  - *Fastest growing technique, widely used for disposables*
  - *Can cause chain fissures on more susceptible plastics*
- **E-Beam**
  - *Similar to Gamma but lower cost and rapid turn around time*
  - *Product size limitations*



# Sterilization Technique: E-Beam

**Relative Radiation Stability of Medical Polymers (dose KiloGray) in Ambient Air, elongation changing by 25%**



Note: Physical Properties of irradiated Polymers are subject to Variations Due To: (1) Stress (Residual & Functional), (2) Section Thickness, (3) Molecular Weight Distribution, (4) Morphology, (5) Moisture, (6) Environment (Oxygen/Temperature) And Must Be Tested in The Specific Application Under Consideration

- References:
- NASA/Jet Propulsion Laboratories, "Effects of Radiation on Polymers & Biomaterials", 1988
  - Skeins & Williams, "Ionizing Radiation Effect Selected Biomedical Polymers"
  - Kiang, "Effect of Gamma Irradiation on Elastomeric Closures", PDA, 1992
  - Ley, "The Effects of Irradiation on Packaging Materials", 1976



# Targeting a Material – Begin by Asking the Right Questions!

Successful material selection begins with an early and accurate assessment of application requirements.

Assess product requirements with regard to the following topics:

- **Environment**
  - *Consider shipping exposure, stress and time part will be exposed, chemical resistance, UV stability*
- **Product Use Considerations**
  - *Clear or opaque? How large is part, does device contact body? Is it sterilized?*
- **Functional and Mechanical Considerations**
  - *Is product weight important? How rigid does part need to be? What's the targeted cost?*



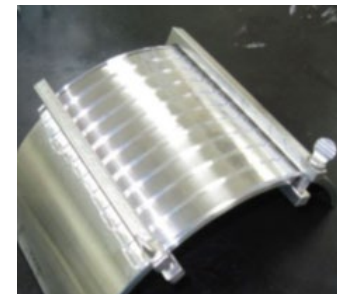
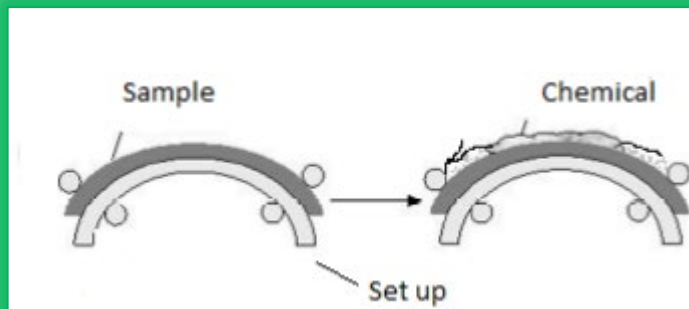
# Environment: Chemical Resistance

*There are many testing procedures used to determine if a specific chemical will reduce the mechanical properties of the plastic you are considering.*

- A simple test is to mount an ASTM test bar on a fixture which will put the bar under a prescribed strain (usually 0.5, 1.0 or 1.5% strain).
  - The chemical is applied to the top of the strained bar (the fixture may be placed in a bag).
  - The test bar is then observed after a specified time and visually inspected or mechanically tested for property retention.
- Normally done at room temperature.
- Results are for reference and the actual part must be tested under normal operating conditions and environment.



Example of stress cracking fracture on plastic boss



**Examples: Selecting the right materials  
and processes to meet requirements  
and reduce product costs.**

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# Requirements Define Choice of Thermoplastic

## Case Study: Humon – Wi-Fi Monitoring Device

**Product Description:** The Humon Hex is the first clinically validated muscle oxygen tracker that wearer uses to optimize workout intensities, minimize injury, and monitor progress.

**Requirements:** When discussing attributes with the customer, we took into consideration outdoor UV exposure, chemical resistance to DEET and Sun Screen, in use temperature extremes, clarity, ultrasonic welding capability, and elastomer switch cover ductility.



PEBA  
Switch  
Over Mold



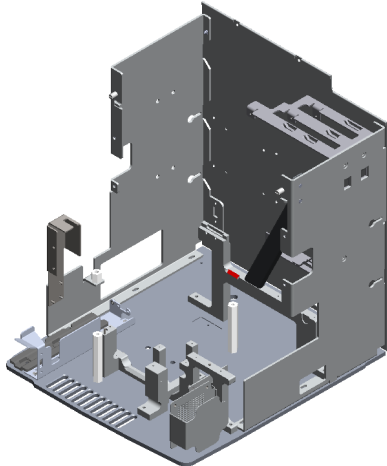
Clear MX73



**Result:** Opaque, Clear and Ductile Nylon 12 were chosen for all parts.

# Material Consideration: Metal to Plastic Conversion

## Sheet Metal Assembly



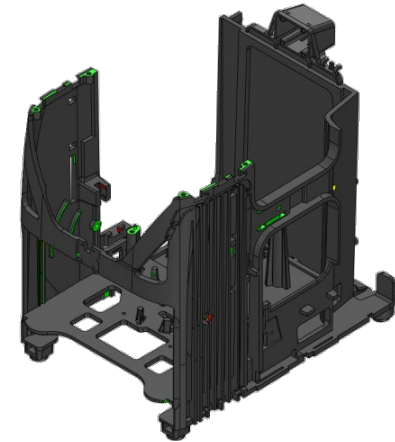
13 Parts @ \$250.00 per assembly



### Engineering Resin Suggestions

- PPSU
- PES
- PEI
- PPE
- PC
- ABS
- PC/ABS
- Copolyester

## Molded Part



1 Part @ \$57.00 per part

### Structural Components – Metal Replacement

- Fiber filled resin – Glass or Carbon Fiber
- Structural foam molding
- Gas counter pressure



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