for a better future

KEP

The suitability of common sterilization techniques on KEPITAL medical grades

R&D Center

KOREA ENGINEERING PLASTICS CO.,LTD.

1. Introduction of KEPITAL medical grades

KOREA ENGINEERING PLASTICS CO.,LTD offers Polyacetal resin (POM), type of co-polymer. POM resin is crystalline polymer featuring excellent strength and superior modulus.
KEPITAL MX Series (Medical grades) have excelled in various aspects of the medical industry.

Surgical equipment of sterilization is essential to aseptic technique. Some disposable materials such as sutures or scalpel blades are available pre-sterilized. Reusable materials such as surgical instruments must be sterilized prior to use. As such it is essential to ensure that the sterilization process retains not only the material properties but also succeeds in destroying microbes. An overview is given below :

(1) The suitability of common sterilization techniques on the mechanical properties of KEPITAL medical grades

Product	Sterilization process			
	Autoclave	EtO	Gamma	E-beam
KEPITAL® MX series(POM)	+	++	x	x (assumption)

***Legend :**

++	Excellent performance
+	Good performance (Some considerations)
x	Not recommended

(2) The categories for KEPITAL MX Series

Medical devices can be classified into the 3 following categories :

1) A non-critical device which doesn`t have surface contact with skin.
2) A semi-critical device which has limited surface contact with healthy skin.
3) A critical device which experiences direct contact with tissue or damaged skin.

Depending on the aforementioned category, appropriate sterilization of these medical devices

will be an essential step in the manufacture of healthcare products to ensure both their shelf-life and reliability when in use. KEPITAL MX Series is commonly used in the first category, non-critical devices and other uses need to be discussed with our quality assurance team (QA team)

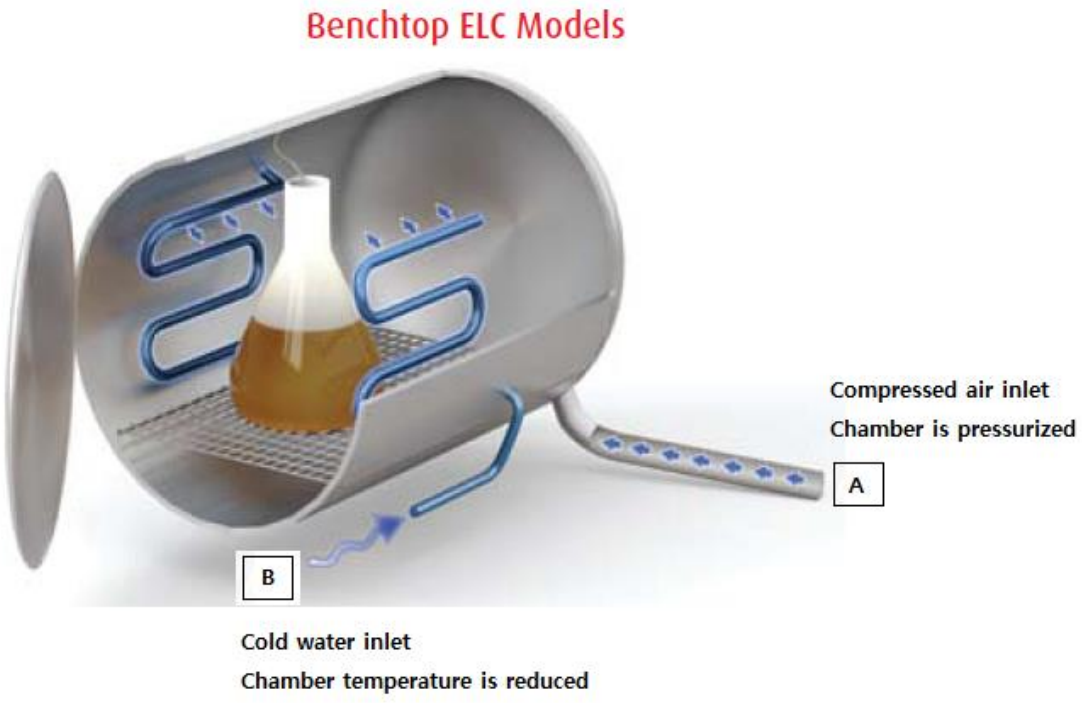
2. Sterilization techniques

Typical sterilization techniques are :

(1) Autoclave (steam)
(2) Ethylene-oxide (EtO) gas
(3) Radiation (gamma, E-beam)
(4) Dry heat
(5) Plasma

2.1 Autoclave (steam sterilization)

(1) Sterilization method
Autoclave or steam sterilization is a widely used method.



<Image source : http://www.tuttnauer.com/sites/www.tuttnauer.com/files/FastLiquidCoolingHorizontal.png>

- ✓ can be performed with relatively low-cost equipment.
- ✓ Easy to use.
- ✓ Safe and environment-friendly equipment that uses saturated steam.

Typical process conditions in the medical industry are 121 °C for 15 minutes or 134 °C for 3 minutes. The limiting factor for many engineering polymers is their heat resistance. particularly so for single-use devices, and hydrolytic resistance in the case of multiply sterilization cycles.

The common types of autoclave sterilization cycles are gravity-displacement, which removes air from the chamber via steam-entering chamber which exerts pressure on air and the pre-vacuum cycle, which removes air by a vacuum pump while steam is simultaneously injected into the chamber.

In the steam autoclave process, microorganisms are killed by heat, and this is accelerated by the addition of moisture. Steam by itself is not sufficient for sterilization, and pressure that is greater than atmospheric pressure is needed to increase the temperature of steam for thermal destruction of microbial life.

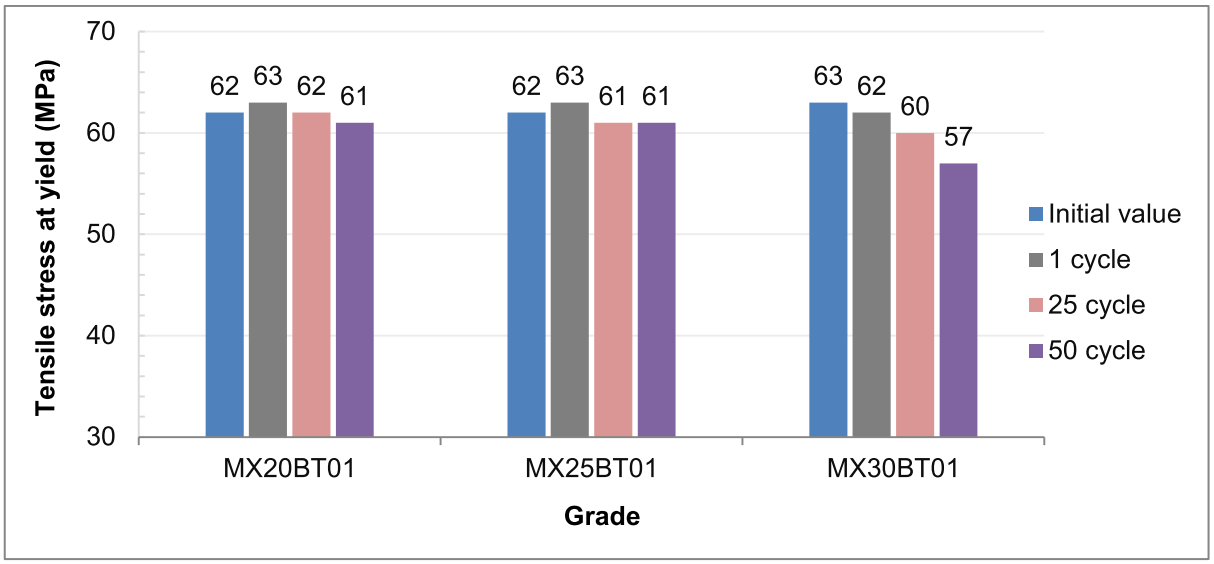
(2) KEPITAL MX series (POM)

1) Test condition

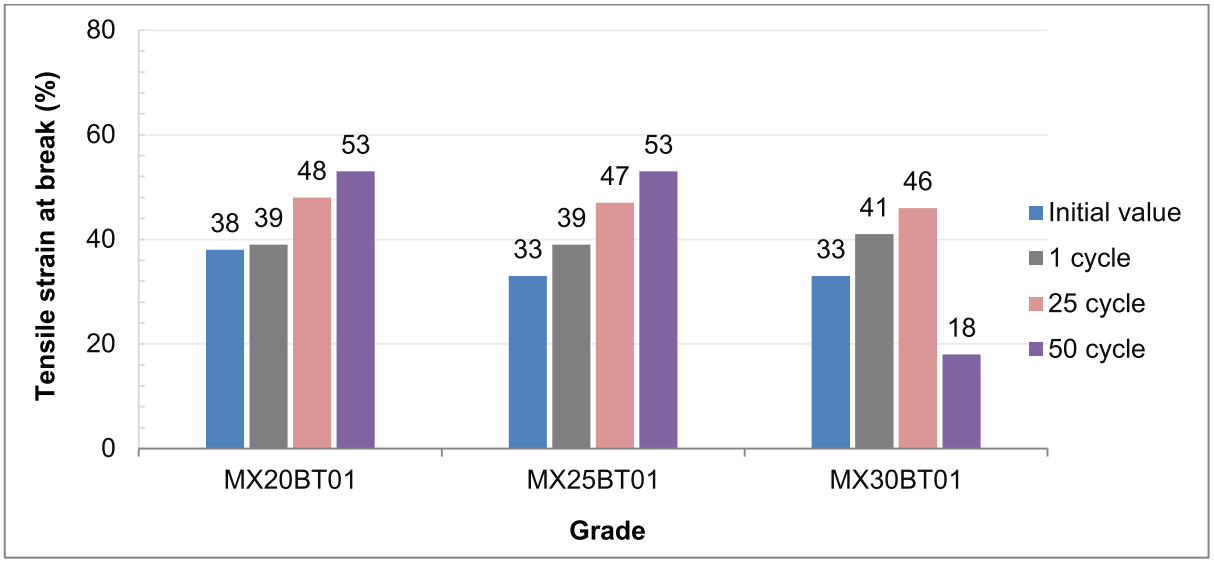
- Equipment : Tuttnauer 3850EL-D with multiple cycle program
- Cycle : Multiple cycle up to 50
- Temperature : 134 °C
- Pressure : 29.4 psig
- Sterilization time : 3 min
- Waiting time : 30 min
- Total time (1 cycle) : 57 min

2) Test results

a) Tensile strength



b) Tensile strain at break



MX series shows good autoclave sterilization behavior until 25 cycles.

(3) Application

Autoclave sterilization is used mostly for surgical instruments. This method is not well-suited for heat sensitive materials and instruments.

Many surgical instruments are not designed to withstand the prolonged heat and moisture of the steam sterilization process.

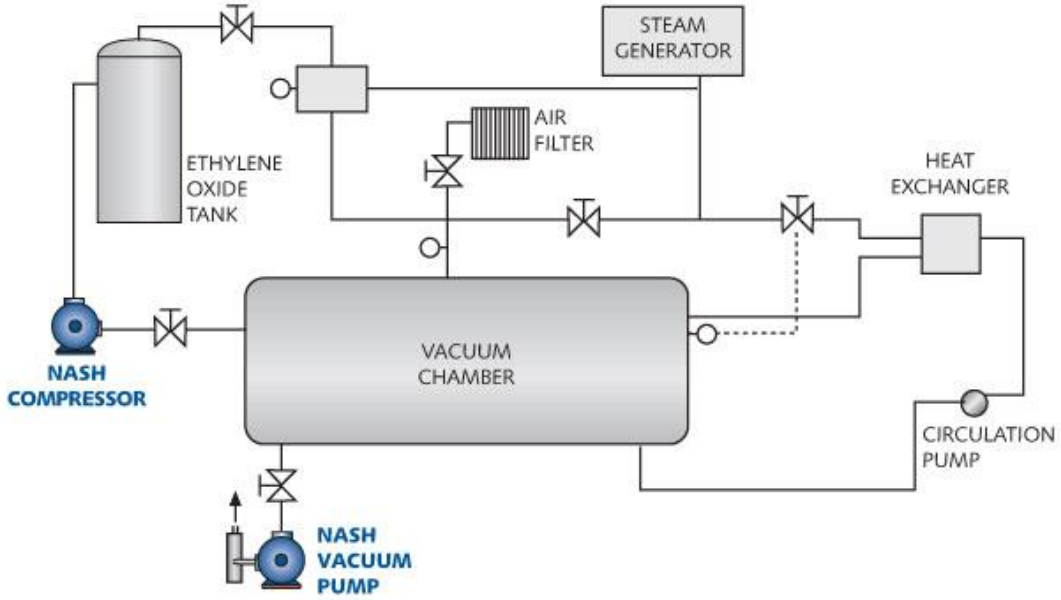
This leads to the necessity for alternative sterilization techniques : chemical sterilization and radiation sterilization, which allow heat and moisture-sensitive materials to be sterilized.

2.2 Ethylene-oxide (EtO) Gas

(1) Sterilization method

Ethylene-oxide gas was introduced in the 1950`s, and it is an effective, low temperature chemical sterilization method. It also takes longer than steam sterilization, typically, 16 ~ 18 hours for a complete cycle. (Recent advances have cut the time to 6 hours) Due to the nature of the process it is particularly suitable for medical devices containing electronic components. The process is detailed below :

***Temperature & pressure = 50 °C, Vacuum**



<Image source : http://www.gdnash.com/uploadedimages/library/e-newsletters/en_may_12/eto-diagram-1c.jpg?n=576>

Ethylene-oxide (EtO) is a chemical agent that kills microorganisms, including spores. EtO gas must have direct contact with microorganisms to be effective. Due to EtO being highly flammable and explosive in air, it must be used in an explosion-proof sterilizing chamber in a controlled environment.

Items sterilized by this process must be packaged with wraps and aerated. The aeration time may be long and is needed to make sterilized items safe for handling and patient use.

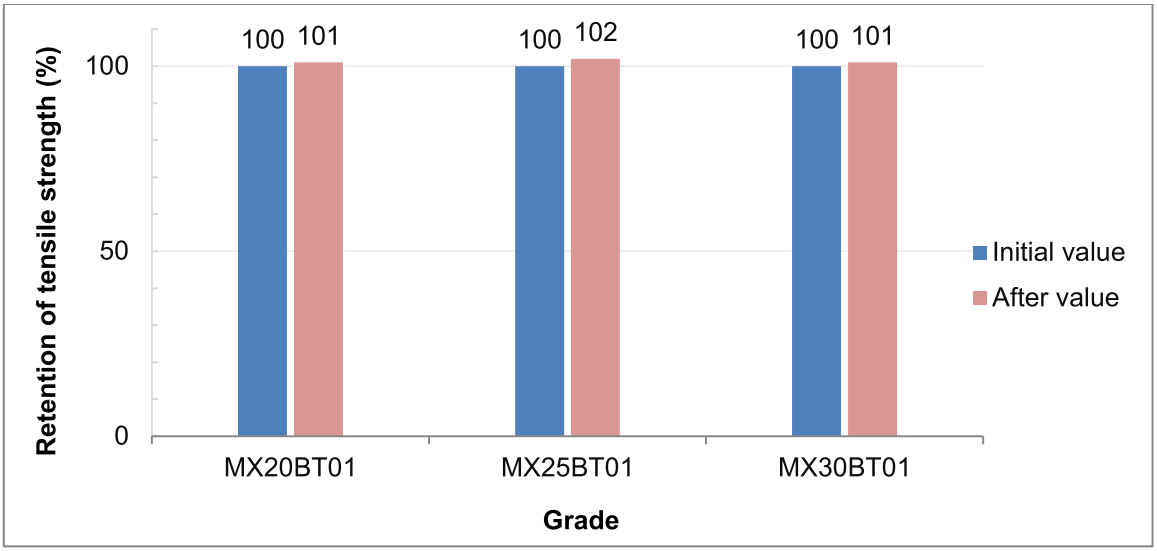
(2) KEPITAL MX series (POM)

1) Test condition

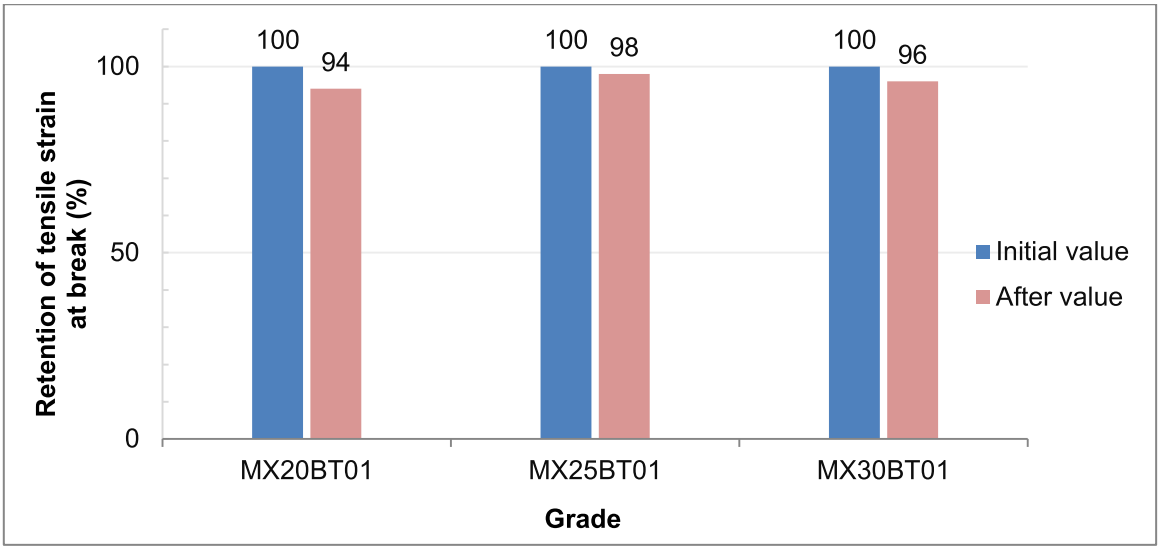
- Regulation : ISO 11135-1
- Gas : 30 % ethylene oxide + 70 % CO2
- Temperature : 52 ~ 58 °C
- Humidity : 90 ± 10 % R.H.
- Exposure time : 6 h

2) Test results

a) Tensile strength



b) Tensile strain at break



c) Color difference

<Before sterilization>

<After sterilization>

The properties of MX series are retained after EtO sterilization.

(3) Application

EtO is used to sterilize items that are heat or moisture-sensitive. The disadvantages of EtO gas include toxic residue on sterilized items and several physical and health hazards to personnel and patients that merit special attention.

2.3 Radiation

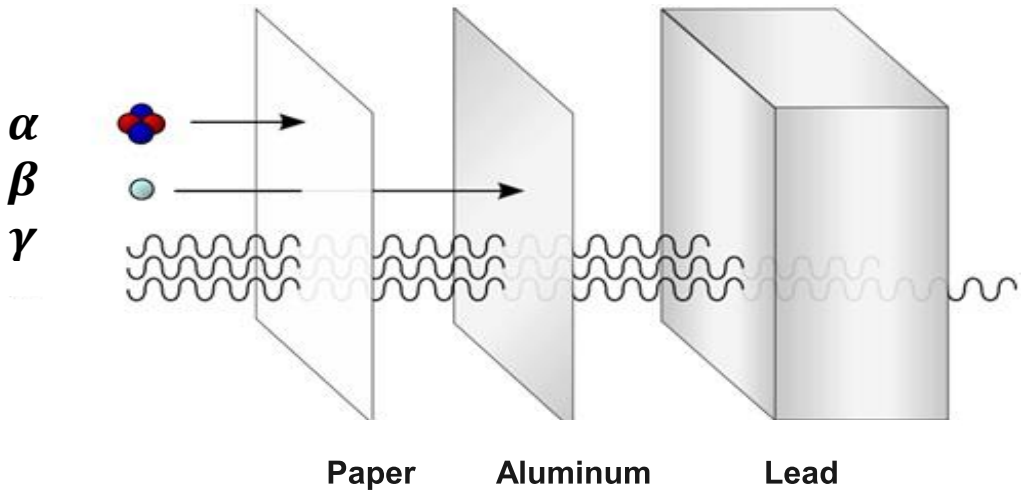
Radiation is a type of cold sterilization, and there are two forms :

2.3.1 Gamma ray sterilization

(1) Sterilization method

Gamma rays are suitable for commercial uses as they can sterilize final product on a conveyor belt before shipment. The product to be sterilized is exposed to radiation for 10 ~ 20 hours, depending on the strength of the source. The highest temperatures reached in gamma sterilization are usually (30 ~ 40) °C

Gamma sterilization uses the radioisotope Cobalt 60 as its energy source. Once formed, Cobalt 60 instantly begins to decay, releasing energy in the form of gamma rays. This released energy, kills microorganisms by disruption of the DNA molecules, therefore preventing cellular division and propagation of biological life.



<Image source : http://images.tutorvista.com/cms/images/95/gamma-rays.jpg>

The artificially activated Cobalt 60 pellets are encapsulated in stainless steel "pencils" held in a source rack. To deliver the sterilization dose the source rack is raised from a deep pool of water and the product is passed around this radiation source on a conveyor system. The energy emitted is insufficient to induce radioactivity in any material, irrespective of the length of exposure to the source.

Sterilizing products by gamma radiation is a sophisticated process requiring extensive knowledge of the kinetics of microbial inactivation, polymer selection and process controls. Gamma Irradiation possesses excellent penetrative capability. The unit of absorption is the Gray, expressed in kGy.
(1 Gy = 1 J/kg = 100 rads, 1 rad : absorbed 100 erg of radiation per substance 1 g)
This absorbed dose is impacted by product density, pack size, dose rate, exposure time and to some degree by part design.

The main disadvantage associated with gamma irradiation concerns the potentially damaging effects of gamma rays on the product, particularly those products that contain polymeric components. Another drawback with this technique is the bulky shielding required to store the radioisotope.

(2) Suitability of various polymers for gamma ray sterilization

Radiation Stability	Material
Excellent	Polyimide, Polyphenylene Sulfide, SAN, PC, PC/ABS, Polysulfone PET, LCP, Phenolics, Epoxies, Polyester, Urethane, Styrenic TPE's
Good/Excellent	Polyethylene, Polyvinyl Fluoride (PVF), Polyvinylene Fluoride (PVDF), Polyamides, Polyurethane, Natural Rubber, Nitrile
Good	Silicone, Acrylics (PMMA), PVC, Neoprene
Poor	Polypropylene (non-stabilized), PTFE ,FEP, Acetal, Butyl Rubber

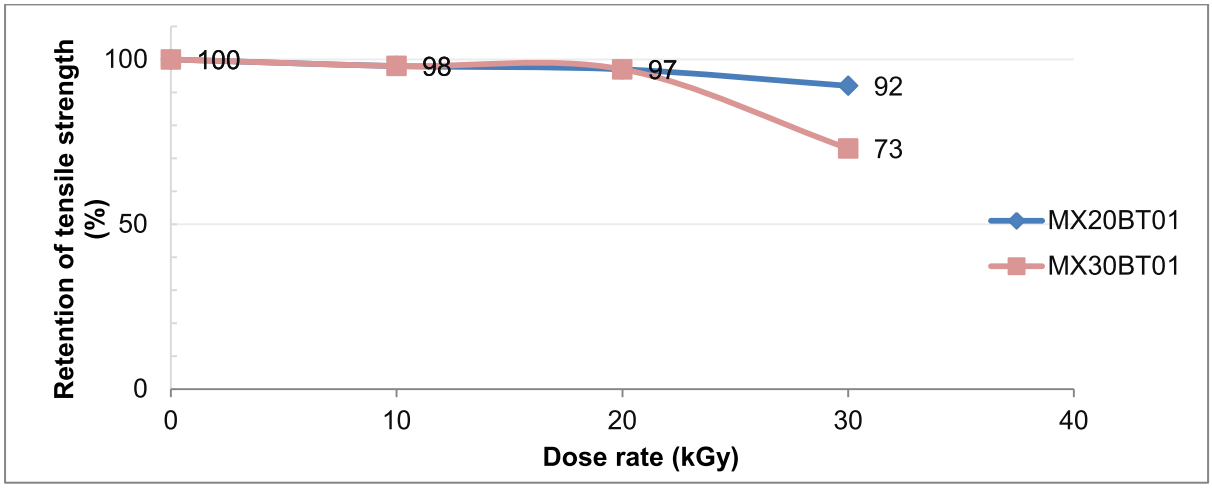
(3) KEPITAL MX series (POM)

1) Test conditions

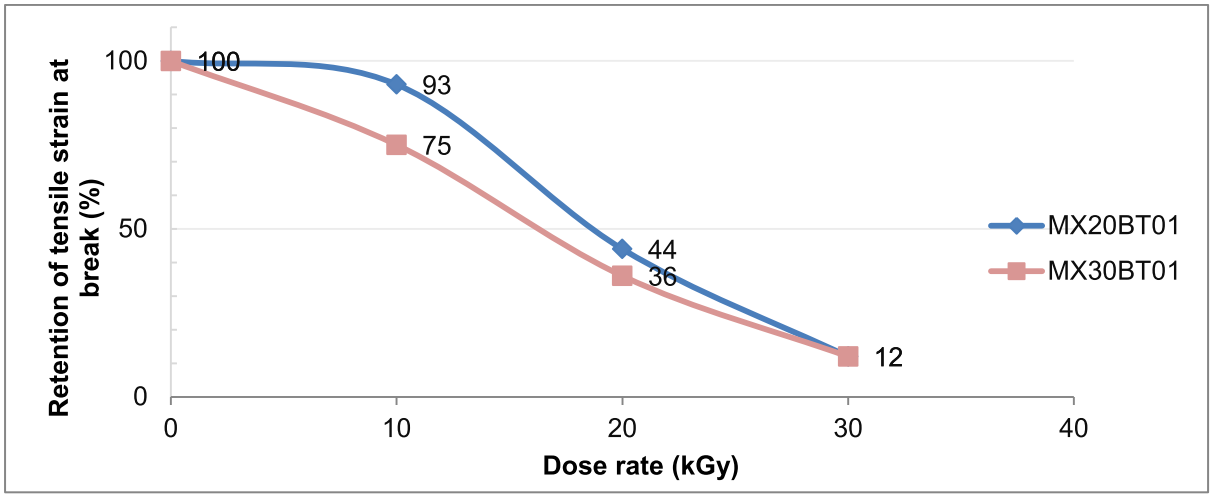
- Regulation : ISO 11137; Sterilization of health care product pakage
- Dose rate : 10 kGy, 20 kGy, 30 kGy

2) Test results

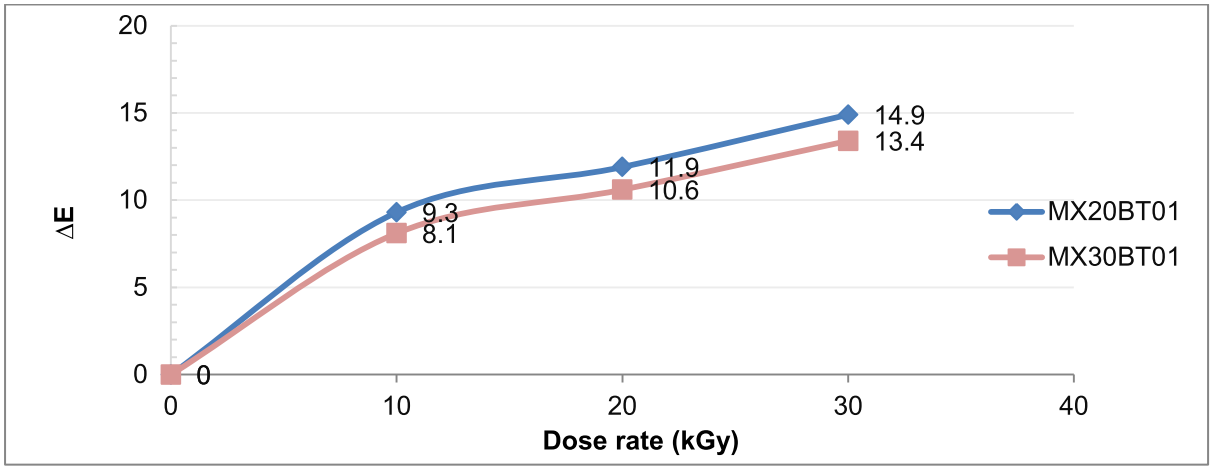
a) Tensile strength



b) Tensile strain at break



c) Color difference



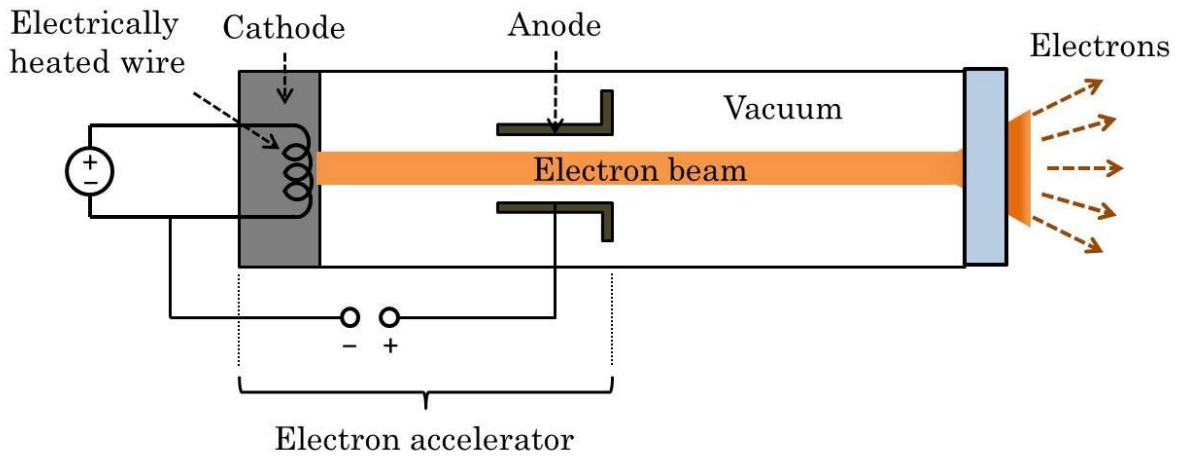
The properties of MX series are NOT retained after gamma ray sterilization

(4) Application

Gamma sterilization is very convenient, so it has been used for commercial uses. However the radiation can change the properties of some materials like plastics and have adverse effects on glues or adhesives.

2.3.2 E-beam sterilization

Sterilization using an Electron beam involves emitting electrons from a heated tungsten filament gun and accelerating them down an evacuated tube. This beam then passes through an oscillating magnetic field which "scans" it back and forth across the sample ensuring a uniform dose of radiation.



<Image source : http://www.intechopen.com/source/html/38340/media/image2.jpeg>

The E-beam process achieves lethality using ionising radiation which acts on cellular constituents in a similar manner to Gamma radiation.

E-beam sterilization has a number of advantages over gamma irradiation including its ability to be switched on and off at will, greater product compatibility and potentially very high throughput. Disadvantages include higher machine complexity and poor material penetration. In addition, validation and control of this technology is more demanding.

2.4 Dry heat

Heat sterilization

Moist heat type

- ✓ Boiling
- ✓ Pasteurization
- ✓ Autoclave (steam)

Dry heat type

- ✓ Flaming
- ✓ Incineration
- ✓ Hot air oven
- ✓ Radiation methods

<Image sorce : http://image.slidesharecdn.com/sterilizationanddisinfection-131201225846-phpapp01/95/sterilization-and-disinfection-4-638.jpg?cb=1385938773>

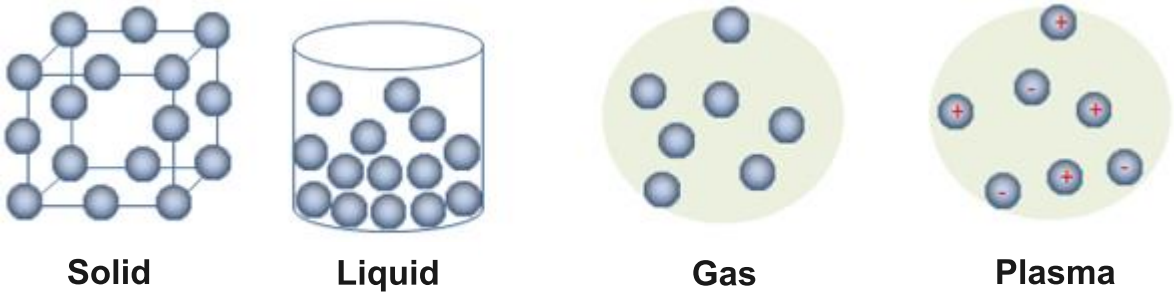
Dry Heat Sterilization is generally conducted at (160 ~ 170) °C for a minimum of two hours. Specific exposures are dictated by bioburden concentrations and temperature tolerances of the products. It is important to set up conditions keeping these in mind. The required equipment is Forced-air type ovens with temperature monitoring capabilities. This type of sterilization is highly dependent on the temperature resistance of the polymer.

2.5 Plasma

A plasma is a hot ionized gas consisting of approximately equal numbers of positively-charged ions and negatively-charged electrons. The characteristics of plasmas are significantly different from those of ordinary neutral gases so that plasmas are considered a distinct "fourth state of matter."

The Sterrad system is a Hydrogen Peroxide Gas Plasma Sterilization system with an operating temperature range of (45 ~ 50) ℃. Operating cycle times range from 45-70 minutes, depending on the size of the system.

Low-temperature plasma sterilization was introduced to fill the gap between autoclave and EtO gas sterilization, which leaves toxic residue.
It is typically used when devices cannot handle high sterilization temperatures.



3. General Considerations of Polymers for Sterilization

Designers of medical devices require multiple skills to ensure safe and reliable components for healthcare applications. In addition to their medical engineering capabilities they need to be experts in function integration to enable component cost to be minimized and they also require advanced material knowledge for the appropriate polymer selection.
In most projects the sterilization method is already known at an early stage. Therefore, it is necessary to check the polymer material candidates' resistance to the selected sterilization method upfront, which will help avoid any surprises during the later stages of device development.

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