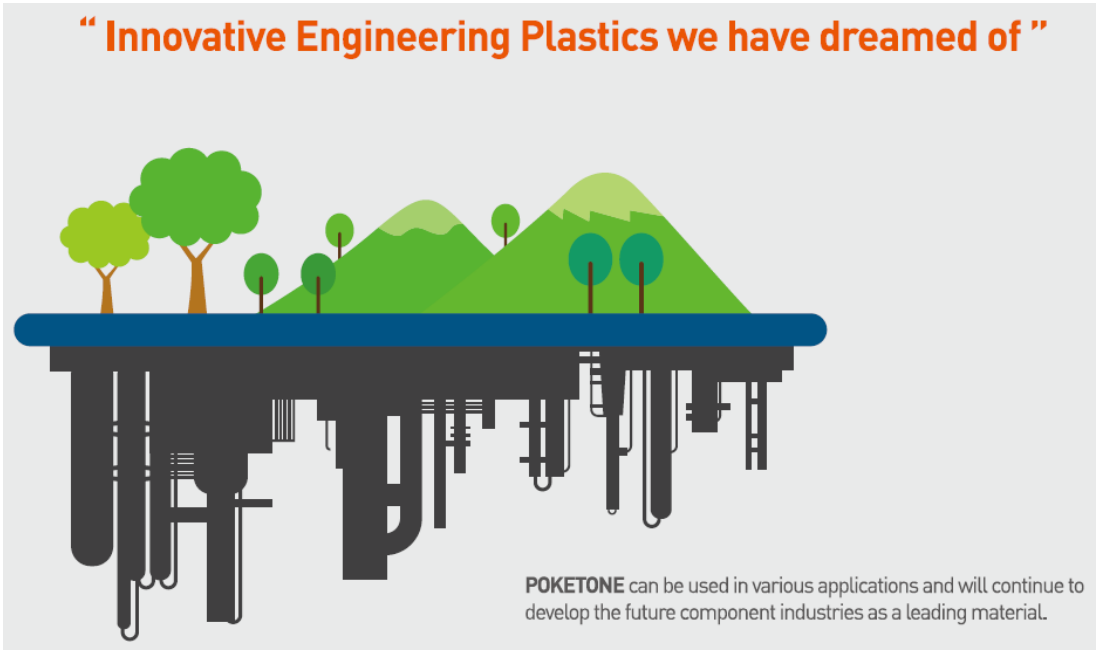
POKETONE™
HYOSUNG POLYKETONE

Sterilization of POKETONE for medical



POK Biz. Division

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1. Introduction of POKETONE for medical app.

POKETONE is a polyketone resin produced by Hyosung Chemical Co., Ltd. polyketone is a crystalline polymer, an engineering plastic with excellent strength, elastic modulus, and impact strength. It is an eco-friendly material that is harmless to the human body. POKETONE F Series, a medical material, is applied to various medical device industries. In general, since medical device products are used semi-permanently, several sterilization and disinfection processes are required. Therefore, materials used in medical devices should not change in physical properties during the sterilization process.

(1) POKETONE F Series' sterilization suitability

Sterilization method / Product	Steam sterilization	EtO gas	Gamma ray	E-Beam
POKETONE F Series	++	+++	+	+

※ Example:

+++	Excellent
++	Excellent, but certain conditions must be met.
+	Excellent, but some conditions must be met.
x	Not recommended

(2) Application range of POKETONE F Series

Medical devices can generally be divided into three categories.

1) Products without skin contact

2) Products with limited contact with normal skin

3) Products with direct contact with the wound

For your safety and product warranty, please select a material according to the categories mentioned above. In general, the POKETONE F Series is classified in Category 1, and other uses should be used after consulting with POK biz. Division TS team.

2. Sterilization

In general, sterilization methods used in the medical industry are as follows.

(1) Steam sterilization

(2) Ethylene oxide (EtO) gas

(3) Radiation (gamma, E beam)

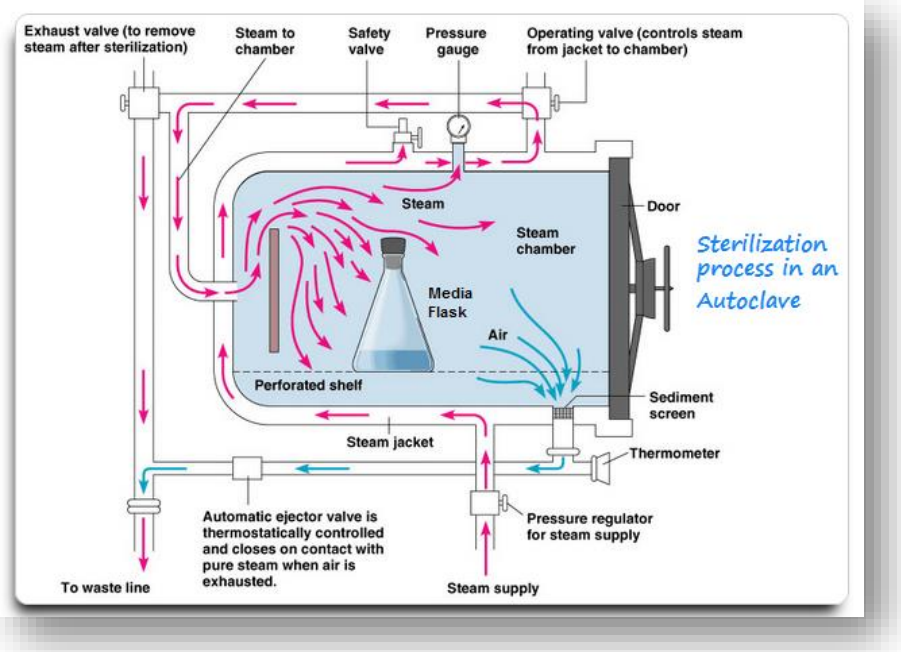
(4) Dry heat

(5) Plasma

2.1 Steam sterilization

(1) Sterilization method

Steam sterilization is the most widely used and old sterilization method due to the following advantages.



<Image source: https://www.pharmaguideline.com/2011/10/steam-sterilisation-heating-in.html#gsc.tab=0 >

- Economical compared to other sterilization methods.
- Easy to use equipment.
- Eco-friendly and safe using steam gas.

In general, sterilization of steam sterilization in the medical device field uses 1 cycle of 121℃, 15 minutes or 134℃, 3 minutes. However, many engineering plastics have poor thermal stability when used repeatedly at high temperatures, so care must be taken when selecting sterilization conditions.

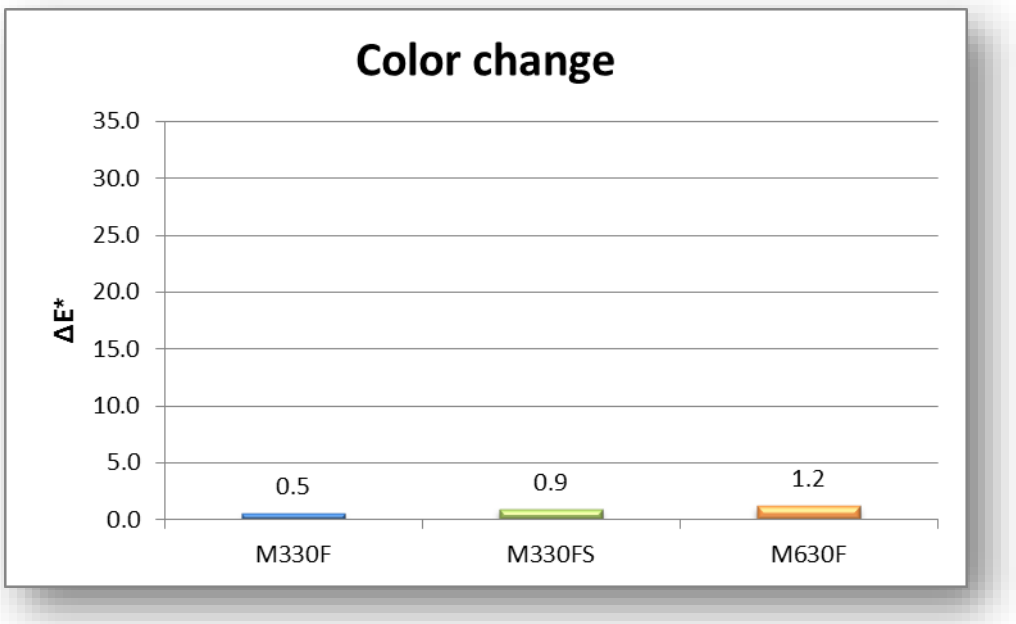
The most used steam sterilization sterilizer is gravity displacement type. This method sterilizes steam gas by pushing it into the chamber and releasing the air inside at that pressure. Steam sterilization The sterilization process involves heating the steam to high temperatures to remove bacteria. However, this steam alone is not enough to remove bacteria, so high pressure is applied to create a favorable environment for sterilization.

(2) POKETONE F Series (121℃, 15min)

1) Color

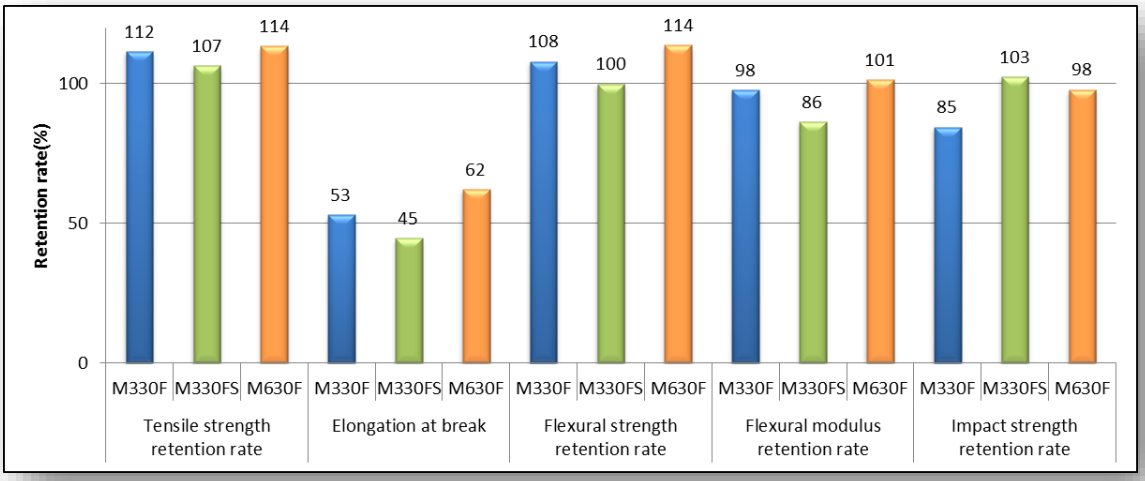
<Before>

<After>



POKETONE F Series does not change color before and after steam sterilization.

2) Mechanical property



POKETONE F Series has no mechanical property changes except elongation at break before and after steam sterilization.

(3)Application

Steam sterilization is widely used in surgical instruments. However, many other medical devices are vulnerable to high temperature, high humidity, and high pressure environments. For this reason, the need for sterilization methods other than steam sterilization has emerged.

2.2 Ethylene Oxide (EtO) Gas

(1) Sterilization method

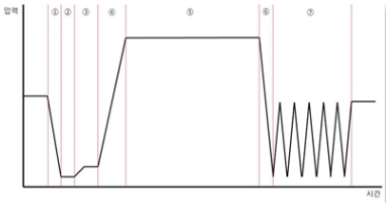
EtO gas sterilization was first introduced in the 1950s and is a chemical sterilization method that proceeds at low temperatures. This sterilization method takes 16 to 18 hours, so recently it may be sterilized for 6 hours.) It takes quite a long time compared to the steam sterilization method. However, EtO gas sterilization is suitable for products that can be damaged under high temperature and high humidity because it uses a low temperature (50℃ ~ 60℃). The sterilization process follows the following process.

Advantages and disadvantages of EtO gas sterilization

Advantages	Disadvantages
➢ Materials that are sensitive to heat and denature to radiation are possible ➢ Excellent sterilization effect ➢ No need for high temperature, high humidity and high pressure ➢ Low cost compared to radiation	➢ Aeration ➢ Many parameters of sterilization process (Temperature, humidity, sterilizer, time, pressure, degassing, etc.) ➢ After sterilization process, residual amount inspection is required ➢ Special packaging (gas permeability) required

EtO Sterilization Process

- Preconditioning (전 조절)
- Sterilization cycle (멸균 사이클)
  1. Evacuation (공기제거)
  2. Vacuum hold (leak test) 진공유지(누기시험)
  3. Conditioning (조절)
  4. Sterilant injection (멸균제 투입)
  5. Exposure (노출)
  6. Sterilant removal (멸균제 제거)
  7. Flushing (세척)



- Aeration (통기)

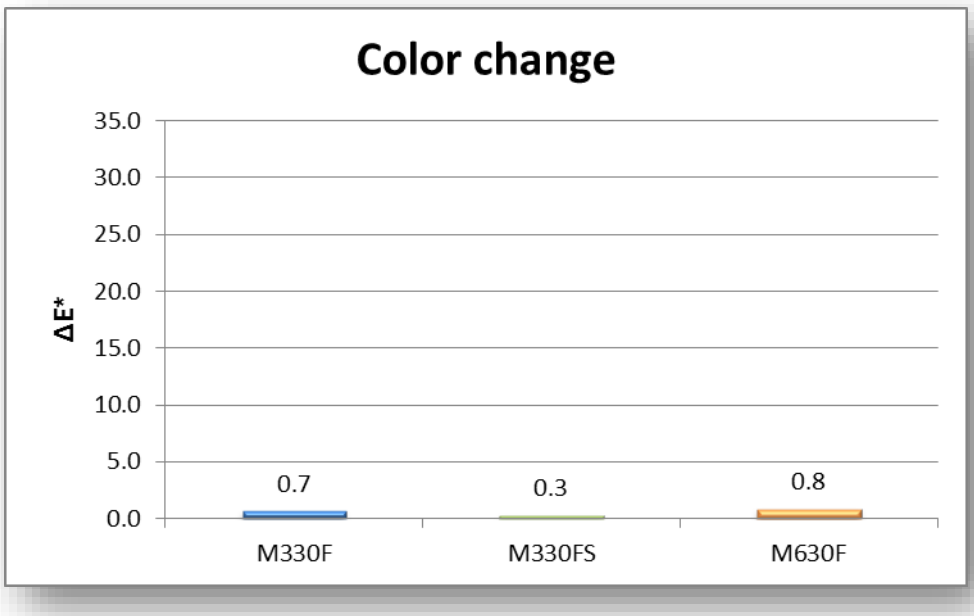
<Image source: https://www.greenpiatech.com/kr/business/eto.php>

(2) POKETONE F Series

1) Color

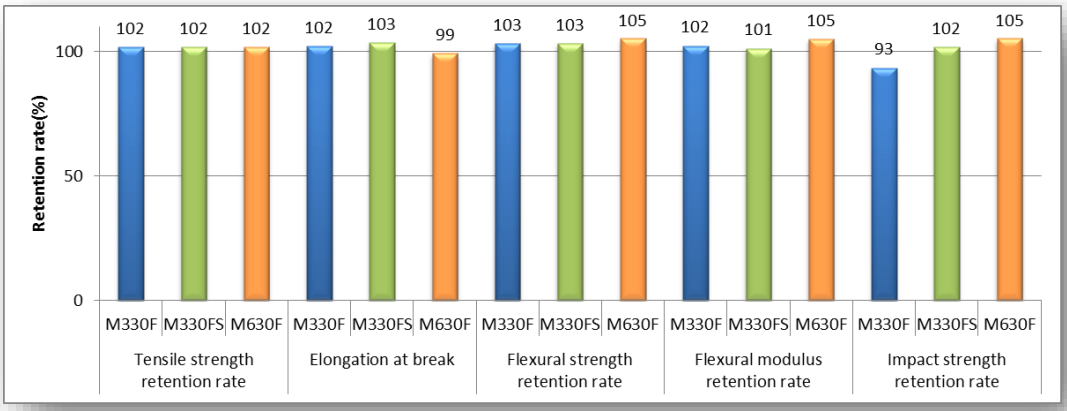
<Before>

<After>



POKETONE F Series does not change color before and after sterilization of EtO gas.

2) Mechanical property



POKETONE F Series does not change mechanical properties before and after sterilization of EtO gas.

3) Application

EtO gas sterilization method is used for sensitive electronic products under high temperature and high humidity environment. Of course, EtO gas is toxic and there is a big disadvantage that it can remain in the product, so be careful when sterilizing medical devices.

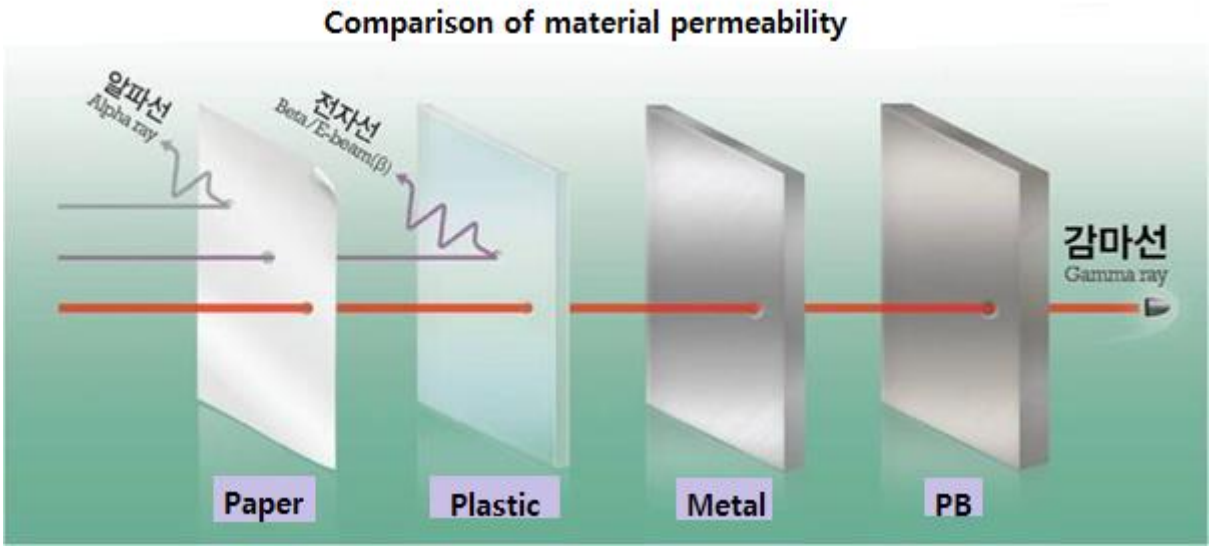
2.3 Radiation

Radiation is divided into 2 types, and it is performed by cooling method, not by conventional heating method. For this reason, it is also called cold sterilization.

(1) Gamma ray sterilization

1) Sterilization method

Gamma ray sterilization is a commercially easy sterilization method. This is because gamma-ray sterilization can be performed on the packaged product before shipment. Gamma ray sterilization takes about 10 to 20 hours and proceeds to a low temperature of (30℃ to 40℃). The main energy source for gamma-ray sterilization is cobalt 60 (Co 60), one of the radioactive isotopes. Cobalt 60 decomposes as soon as it forms and releases energy in a gamma-ray fashion. The released energy destroys the DNA, removing bacteria and preventing microbial invasion.



<Image source: http://m.kfdn.co.kr/a.html?uid=13343>

Using this process, the gamma ray sterilizer stores activated cobalt 60 pellets in a stainless steel source rack. At the start of sterilization, the power supply shelf in water is lifted, and the product receives gamma ray along the conveyor belt, and sterilization proceeds. The gamma ray generated here is not strong, so no radioactive contamination occurs.

As such, gamma-ray sterilization is a very complex and sophisticated method since it requires extensive knowledge. However, uniform energy can be irradiated strongly, and there is an advantage that no residual

component remains. The unit uses kGy, a measure of how much gamma rays are absorbed, and is usually investigated at 30 kGy. (1 Gy = 1 J/kg = 100 rads, 1 rad: absorbs 100 erg of radiation energy per gram of substance) This amount is affected by product density, size, gamma irradiation dose, exposure time, and product design.

The reason why gamma-ray sterilization technology is in the spotlight worldwide is that, firstly, the high-permeability gamma-ray effectively sterilizes the product that is completely sealed, thereby reducing packaging costs. There is no need to install and operate. Therefore, it is possible to reduce production costs such as sterilizer installation cost, management cost required for operation, labor cost, and material cost. The third is that it is safe for patients or medical staff because there is no release of toxic substances or environmental pollutants remaining after sterilization of gamma rays.

The main drawback is that gamma rays can potentially affect the product. This effect causes polymer degradation and discoloration. In addition, gamma-ray sterilizers also have the disadvantage that they must be equipped with a thick, sturdy safety system to prevent leakage of radioactive isotopes.

Gamma sterilization investigation standard

Standard	Dose	Conditions
VD Max 15	Korea (15~30kGy)	When there are few early bacteria
VD Max 25	Korea (25~40kGy) U.S.A. (25~50kGy)	When there are many early bacteria

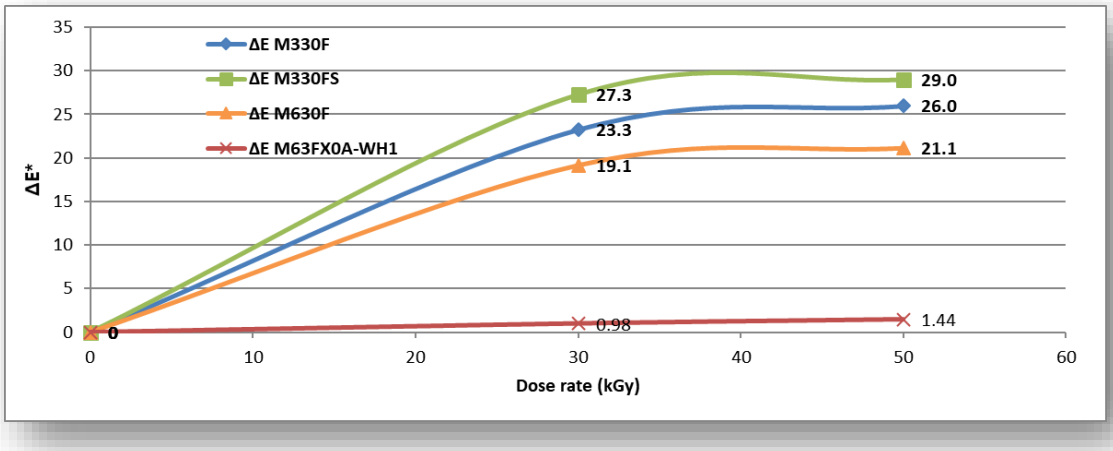
2) POKETONE F Series

① Color

<Before>

<After Gamma ray(30kGy)>

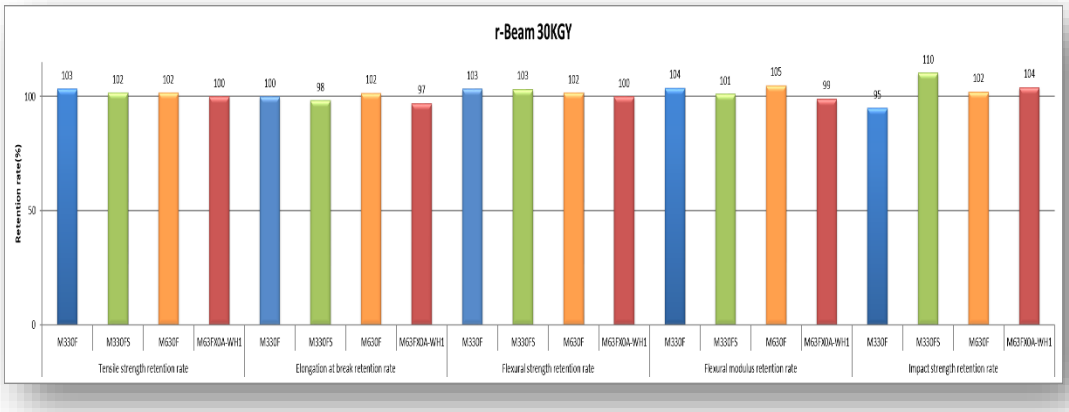
< M63FX0A-WH1>

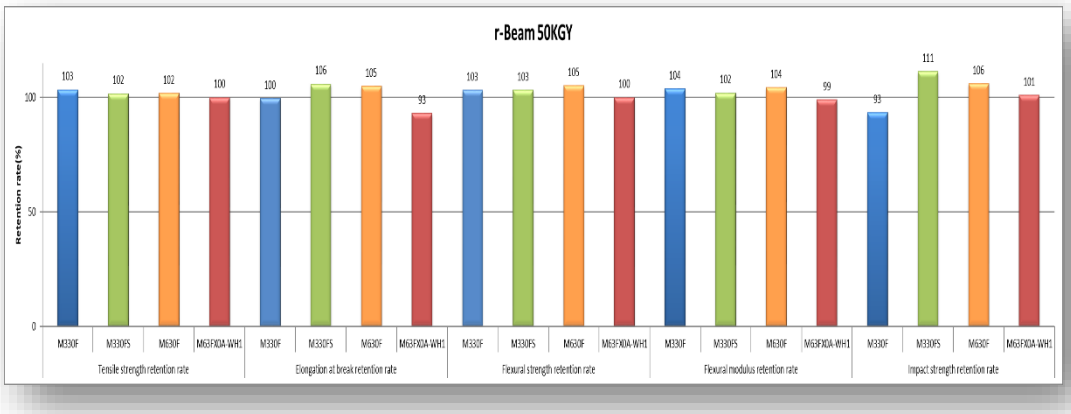


POKETONE F Series has a distinct color change after gamma ray sterilization.

If you color POKETONE F Series with white, there is no color change.

② Mechanical property





POKETONE F Series does not change mechanical properties after gamma-ray sterilization.

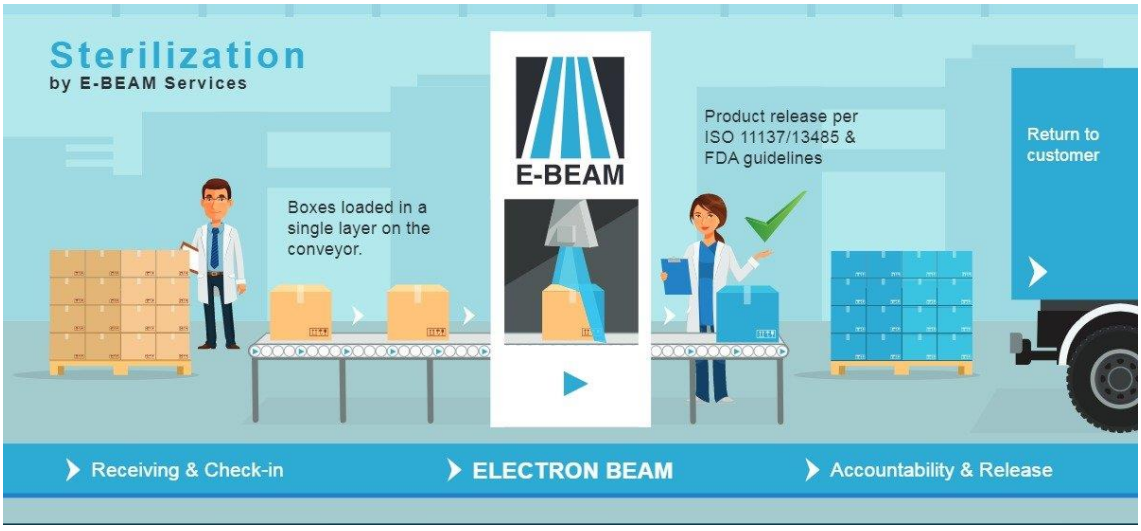
3) Application

The gamma-ray sterilization method is convenient for commercial use. However, it may change the physical properties and structure of the product and should be avoided, especially for medical devices that contain adhesives.

(2) E-Beam Sterilization

1) Sterilization method

E-Beam sterilization is called E-Beam by using emitting electrons in a heated tungsten gun. These emitted electrons enter the vacuum tube and sterilize the product back and forth through an oscillating magnetic field.



<Image source: https://ebeamservices.com/e-beam-sterilization/>

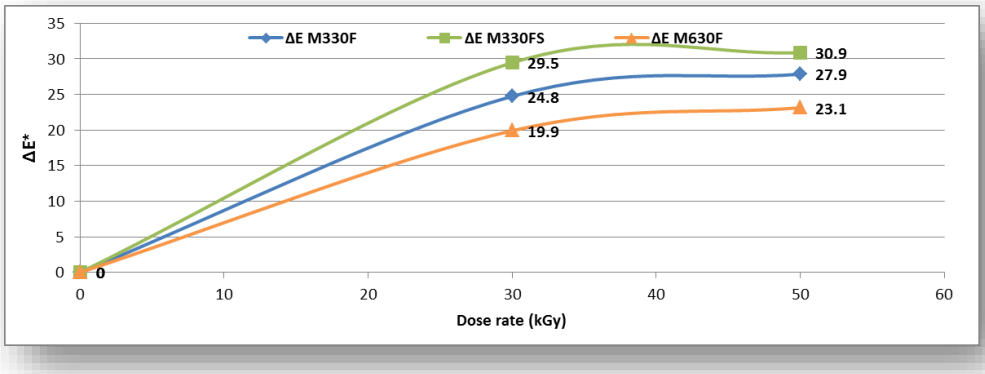
E-Beam sterilization eliminates bacteria using ionized radiation in the same way as gamma-ray sterilization. In addition, there are many requirements, such as the cost of equipment and obtaining validation of sterilization methods. However, E-Beam sterilization can be turned off and on freely, and has the advantage of being able to sterilize many products at once.

2) POKETONE F Series

① Color

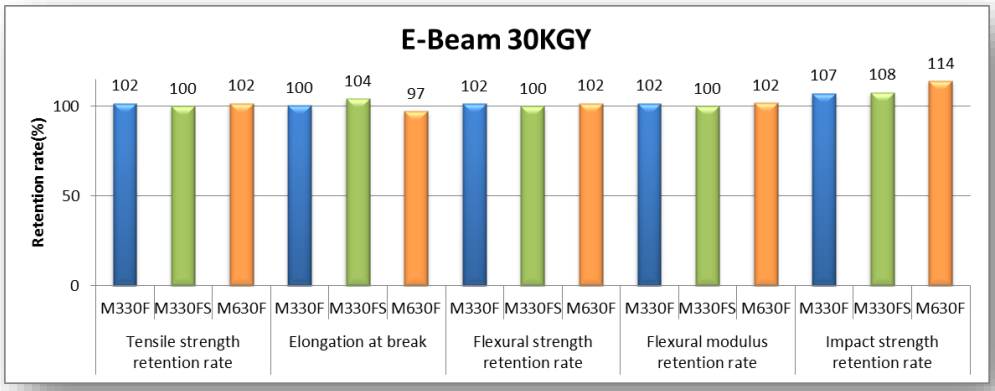
<Before>

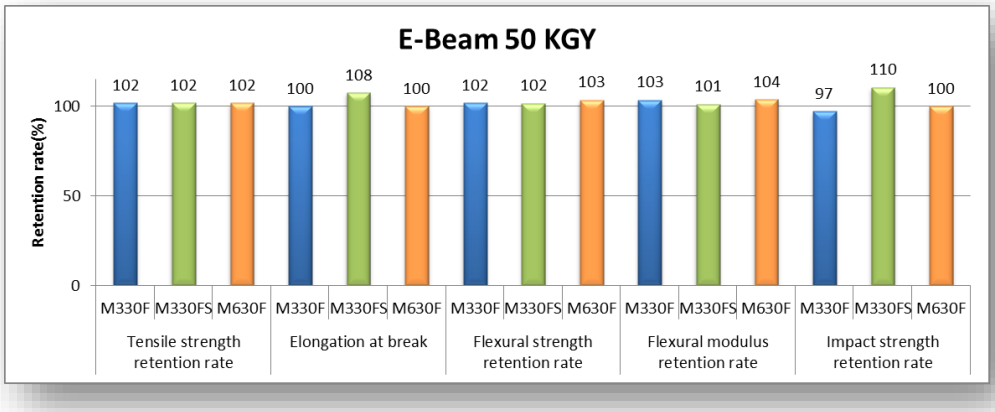
< After E-Beam(30kGy)>



POKETONE F Series has a distinct color change after sterilization of E-Beam.

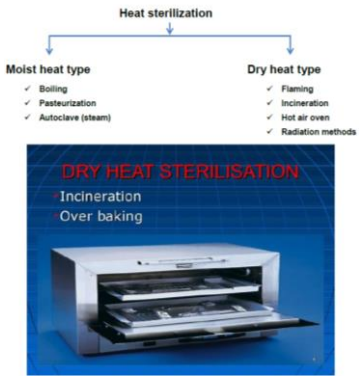
② Mechanical property





POKETONE F Series does not change mechanical properties after E-Beam sterilization.

2.4 Dry heat



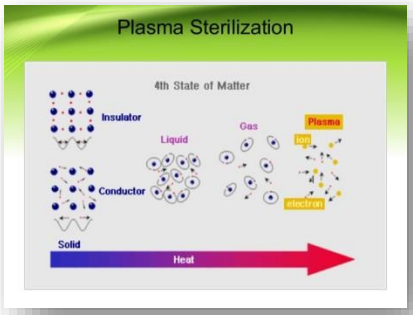
< Image source: http://image.slidesharecdn.com/sterilizationanddisinfection-131201225846-phpapp01/95/sterilization-and-disinfection-4-638.jpg?cb=1385938773>

Dry heat sterilization usually takes place at 2 hours, (160℃ ~ 170℃). The degree of exposure varies depending on the bioburden concentration in the product and the heat resistance of the product. Considering these points, it is important to set

proper sterilization conditions. The most important thing about this sterilization method is that it is highly dependent on the heat resistance of the product.

2.5 Plasma

Plasma is a gas state separated by negatively charged electrons and positively charged ions. Overall, it is considered to be the fourth material state that is neutral with the same number of positive and negative charges. Hydrogen peroxide is popular. The types of plasma sterilization are divided into atmospheric plasma reforming and vacuum plasma reforming depending on the pressure. The general principle is that plasma is formed by discharge in a gas, and this plasma reacts violently with the surface molecules of the object to change the surface molecular structure. As such, the sterilization process is simple and safe, and it is emerging as an alternative method of EtO sterilization. However, due to price issues, it is being used in limited ways.



3. General considerations for polymer sterilization

In general, medical devices undergo a sterilization process. Therefore, medical device developers need to choose not only the expertise of medical devices, but also materials that can withstand the sterilization process. If you lack this material expertise, you may be in a situation where you have to re-select materials during development. This can lead to wasted resources and a lot of time, and it can lead to the failure of product development itself. Therefore, it is necessary to know the sterilization stability of medical device materials in advance and to avoid the problems that may occur during development.