

Bormed - Medical Grade Plastics for sterilization

Amel Murgic - Application Development Engineer Healthcare

December 14th 2023





Who we are

What makes us us

120

Countries. Head Office in Vienna. Austria

6900

employees worldwide



Production and distribution

of polyolefins solutions, base chemicals and fertilizers

Ownership structure:

75%

OMV, Austria

25%

ADNOC, United Arab Emirates

Our JV's: Bayport Polymers (Baystar ™) – brings Borstar® technology to American polyethylene markets



Our JV's: Borouge – one of the world's largest integrated polyolefin complexes (Ruwais, UAE)

#2

Among polyolefin producers in Europe

#8

Among polyolefin producers worldwide

1.4 bnEUR

net profit, total sales 12.3 bnEUR (2021) >100

Priority patents filed in 2021, #1 in Austria

5

Polyolefin recycling operations in Europe

Our transformation framework

WHAT IS OUR VISION

A clear vision for our transformation journey

A global leader in advanced and sustainable chemicals and material solutions

HOW WE WANT TO TRANSFORM

Key pillars of our strategy 2030 for the challenges ahead



WHAT WE WANT TO ACHIEVE

Commitments 2030 we set ourselves and what to be judged by:



1.8 million tonnes of circular products and solutions

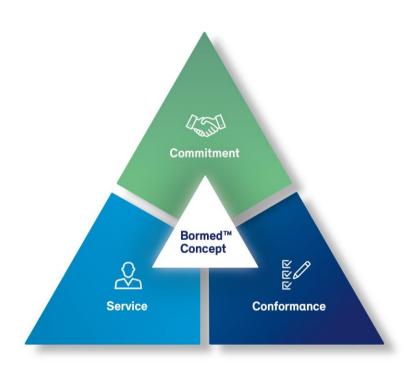


100% of electricity used of renewable origin



< 2 million tons of Scope 1 & 2 emissions*

> * Scope 1 and Scope 2, compared to base year 2019



The Bormed™ Concept

The Healthcare dimension in Polymers

Often, the materials used in Healthcare applications are relatively standard.
Only a few have specific Healthcare related properties i.e. for gamma irradiation.

What makes the difference for polymer producers supplying the Healthcare grade is their level of understanding of the industry they supply, added services and support.



The diversity of Healthcare applications (1/2)

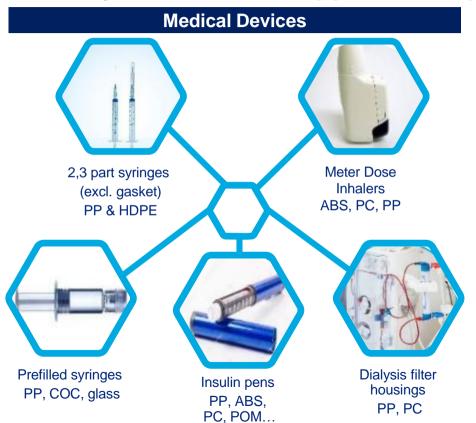
Pharma Packaging Pouch systems **Blister** PVC, PP, PE PP, PVDC, PVC Caps & Closures LD, HD, PP IV Bottle Glass, LDPE, PP Ampoules Glass, LDPE, PP, COC

Tubing

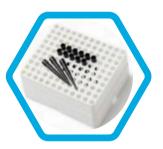


PVC, PP, PE, compounds

The diversity of Healthcare applications (2/2)



Diagnostics



PP, PS

Bormed™ Concept: Dedicated service for the Healthcare Industry

Commitment

- Dedicated portfolio of branded PE & PP
- Continuity of supply regulated by Technical Delivery Specification
- Product made available up to 5 years (2 years pre-notification and a last call volume combined with 3-year shelf life)
- Consistency of the product recipe via rigorous change control procedure
- The Bormed[™] Directive: operating instructions for the development, production, storage and delivery to the end customer of Bormed™ products

Conformance

Pharmacopeia compliance

External Ph. Eur., USP (incl. 661.1) and ISO 10993 testing: analysis reports can be shared on request; DMF listing; following VDI guidelines on MGP

Service

- Extractable profiles that can be shared on request
- Globally available dedicated team of experienced technical and regulatory specialists
- Innovation in products and services relevant for Healthcare industry
- **Enabling data driven product development**





Device development...where it all starts

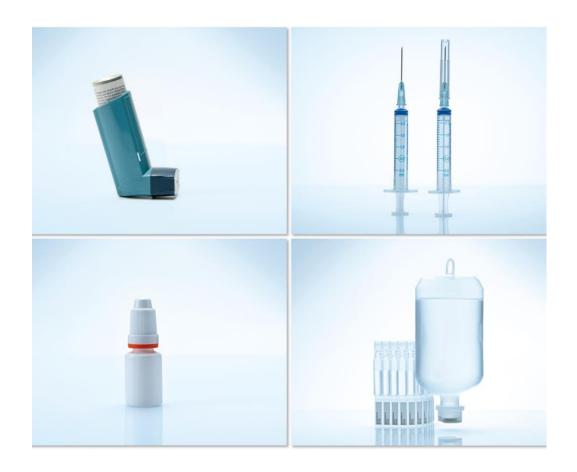
How Borealis can support

Beside of the usual technical data Borealis provides for its medical grade plastic (MGP) Polyolefins (Bormed™) additional data, like

This data can bring important guidance on the choice of material to optimise development time, as e.g. the suitability of a material for a certain sterilisation process is already proven

AVAILABLE DATA	ALL BORMED GRADES	REPRESENTATIVE BORMED GRADES
Tensile Data @ 23°C	~	
Tensile Data @ 40°C, 60°C		~
Flexural Data @ 23°C	~	
Creep Data @ 23°C, 40°C, 60°C		~
Charpy Impact	~	
Vicat Softening Temperature	~	
Heat Deflection Temperature	~	
Coefficient of linear Thermal Expansion (CLTE)		~
Multi Shrinkage Data	~	
Moldflow Data	~	
Rheological Data	~	
Touch & Feel Samples	~	
Hardness, ShoreD 15s		~
Optical Data (Haze, Transmittance, Clarity)	~	
Gamma, Beta, X-Ray Sterilization Data		~
Extractable Data	~	

Suitability of different PO types for sterilization



Common sterilization methods

- -Ethylene Oxide
- Steam sterilization preferably at 121°C
- -Irradiation sterilization
 - -Gamma
 - -E-Beam (Beta)
 - -X-Ray
- -Others: UV, Plasma



Deep Dive Library Events Press Releases

COVID-19

Recalls Diagnostics Cybersecurity

Diabetes

Manage risk, eliminate variance,

May 9, 2023

and facilitate compliance

DIVE BRIEF

FDA mulls pilot program on alternative sterilization for medical devices The Trusted Source for Drug and Device Insights

Published June 8, 2022

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Responses to sterilisation capacity challenges

Conversations in the healthcare community increasingly refer to challenges in accessing sufficient sterilisation capacity.

In recent years organisations, including the IAEA, have referred to alternative technologies suggesting that the market is looking to switch from gamma to alternatives including EB and X-ray. In reality the healthcare community, which accounts for by far the largest part of the demand for gamma irradiation, requires access to all irradiation technologies as demand is challenging and/or exceeding existing available capacity.



Sterigenics to Pay \$408 Million to Settle Ethylene Oxide

Emissions Cases The Learning Portal will be under maintenance on 15

January 17, 2023

DEVICES

REGULATORY AFFAIRS

EPA proposes rules on EtO with implications for medical device sterilization

Regulatory News | 11 April 2023 | Ferdous Al-Faruque

The US Environmental Protection Agency (EPA) has proposed two muchanticipated rules that would restrict how much ethylene oxide (also referred to as EO or EtO) medical device sterilizers are allowed to use and release into the environment, and how much of it workers can be exposed to. The agency said its aim is to reduce cancer risk for workers and communities adjacent to EtO



X-Rays for Single-Use Sterilization

The ISO 10993 standard provides the requirements for sterilizing medical devices with X-rays, but many regulators are unfamili

Single-use systems for bioprocessing rely on components that must be sterilized. Currently, gamma irradiation is used, but X-rays could be a better choice.

Recently, Adam Grzelak, PhD, senior scientist of Pall Europe, and his colleagues described the sterilization challenges. When asked more about the situation, Grzelak says, "There is a lot of concern whether gamma capacity will be sufficient to meet the increasing demand for single-use and contract irradiation." Much of the concern arises from supply-chain challenges with cobalt-60, which is used in sterilization with gamma radiation. "It takes

Sterilization overview

Ethylene Oxide

Advantages

Disadvantages

- No adverse effect on PO properties

- Widely used for sterilization of various healthcare products
- Simple to operate and monitor
- Suitable for less clean production places

Dangerous to environment, production people, patients

- Residues control needs special attention
- Requires time to remove EtO residues (longer cycle time)
- Complex part geometries are difficult to sterilize (corners)

Sterilization overview

Ethylene Oxide

Steam

Advantages

Disadvantages

- No adverse effect on PO properties
- Widely used for sterilization of various healthcare products
- Simple to operate and monitor
- Suitable for less clean production places

- Non-toxic sterilisation method
- Better penetration power vs. dry heat
- Inexpensive method
- Cycle easy to control and monitor

- Dangerous to environment, production people, patients
- Residues control needs special attention
- Requires time to remove EtO residues (longer cycle time)
- Complex part geometries are difficult to sterilize (corners)

- Potential impact on PO properties
- Potential burns
- Not suitable for devices with electronics
- Water drops could impact device performance

Sterilization overview

	Ethylene Oxide	Steam	Gamma
Advantages	 No adverse effect on PO properties Widely used for sterilization of various healthcare products Simple to operate and monitor Suitable for less clean production places 	 Non-toxic sterilization method Better penetration power vs. dry heat Inexpensive method Cycle easy to control and monitor 	 Well established in the market No residues in end product Shorter cycle time (no aeration needed) High penetration
Disadvantages	 Dangerous to environment, production people, patients Residues control needs special attention Requires time to remove EtO residues (longer cycle time) Complex part geometries are difficult to sterilize (corners) 	 Potential impact on PO properties Potential burns Not suitable for devices with electronics Water drops could impact device performance 	 Adverse effect on PO properties One reliable supplier of Cobalt in the EU Not possible to switch off and on easily High overexposure Radioactive source

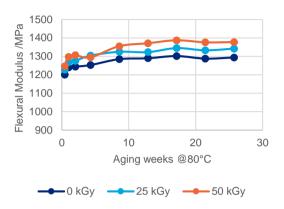
	Ethylene Oxide	Steam	Gamma	E-Beam
Advantages	 No adverse effect on PO properties Widely used for sterilization of various healthcare products Simple to operate and monitor Suitable for less clean production places 	 Non-toxic sterilization method Better penetration power vs. dry heat Inexpensive method Cycle easy to control and monitor 	 Well established in the market No residues in end product Shorter cycle time (no aeration needed) High penetration 	 Easy switch on and off Better availability Shorter cycle time (no aeration needed) Less harmful to PO properties Low overexposure
Disadvantages	 Dangerous to environment, production people, patients Residues control needs special attention Requires time to remove EtO residues (longer cycle time) Complex part geometries are difficult to sterilize (corners) 	 Potential impact on PO properties Potential burns Not suitable for devices with electronics Water drops could impact device performance 	 Adverse effect on PO properties One reliable supplier of Cobalt in the EU Not possible to switch off and on easily High overexposure Radioactive source 	 Low penetration Not possible to sterilize pallets, only single boxes High electricity consumption

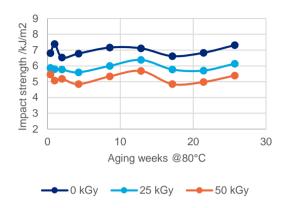
	Ethylene Oxide	Steam	Gamma	E-Beam	X-Ray
Advantages	 No adverse effect on PO properties Widely used for sterilization of various healthcare products Simple to operate and monitor Suitable for less clean production places 	 Non-toxic sterilization method Better penetration power vs. dry heat Inexpensive method Cycle easy to control and monitor 	 Well established in the market No residues in end product Shorter cycle time (no aeration needed) High penetration 	 Easy switch on and off Better availability Shorter cycle time (no aeration needed) Less harmful to PO properties Low overexposure 	 Easy switch on and off Highest penetration Efficient & targeted delivery of dose Lower overexposure vs. gamma possible Can sterilize pallets No radioactive source Less harmful to PO properties compared to gamma
Disadvantages	 Dangerous to environment, production people, patients Residues control needs special attention Requires time to remove EtO residues (longer cycle time) Complex part geometries are difficult to sterilize (corners) 	 Potential impact on PO properties Potential burns Not suitable for devices with electronics Water drops could impact device performance 	 Adverse effect on PO properties One reliable supplier of Cobalt in the EU / low capacity Not possible to switch off and on easily High overexposure 	 Low penetration Not possible to sterilise pallets, only single boxes High electricity consumption 	 Limited adoption of technology, backup possibility might not be available Switch from Gamma require revalidation High electricity consumption
19 ©	Borealis Borouge December 2023		 Radioactive source 		Sensitivity: Externa

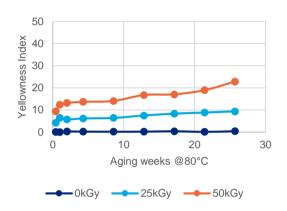
...because not all Polyolefins can be sterilized the same way.

	Polypropylene	Polyethylene
Ethylene Oxide	– Resistant	– Resistant
Steam Sterilization	Resistant up to 121°CMost types can also withstand 132°C	 HDPE depending on the type might be used up to 121°C LDPE due to the lower melting point is not resistant. Lower temperatures and longer times need to be considered
Gamma Irradiation	Not resistantYellowing occurs, mechanical properties decreaseSpecial additive package needed	 Resistant Yellowing and crosslinking occur, mechanical properties increase
E-Beam Irradiation	Partly resistantDepending on the PP type	- Resistant
X-Ray	Partly resistantYellowing occurs, special additive package needed	– To be explored

Bormed™HD810MO



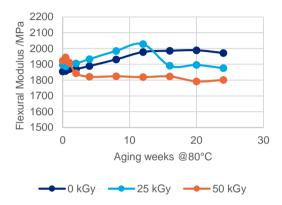




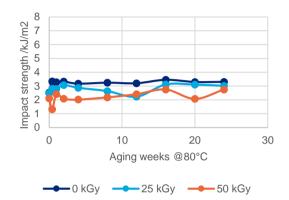
Property	Typical value
Polypropylene type	Homopolymer
Gamma stabilisation	Yes
Melt flow rate (230°C/2.16 kg)	10 g/10min
Typical application	Plunger for syringes

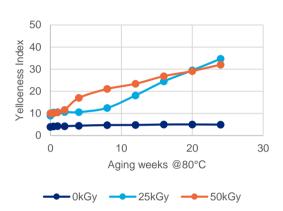
- After gamma sterilization flexural modulus of HD810MO increases and impact strength decreases
- Excellent mechanical properties retention thanks to the gamma irradiation package
- Increase in yellowness is high for 50 kGy and moderate for 25 kGy. Not critical for coloured articles

Bormed™HG820MO



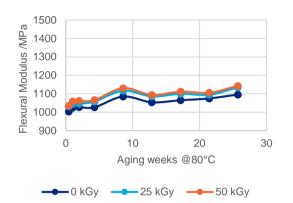
Property	Typical value
Polypropylene type	Homopolymer
Gamma stabilisation	No
Melt flow rate (230°C/2.16 kg)	28 g/10min
Typical application	Diagnostic devices

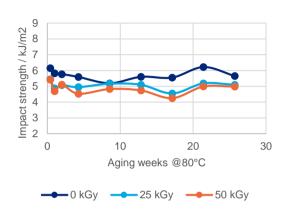


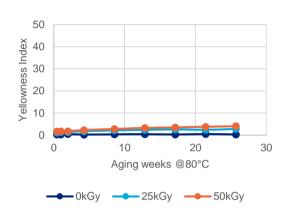


- Non gamma stabilized PP show decrease in stiffness after gamma sterilization and decrease in impact performance
- Much faster increase in colour observed compared to stabilized resin

Bormed™RF830MO



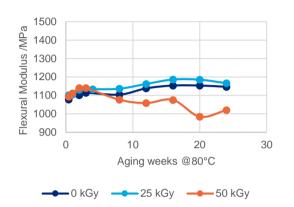




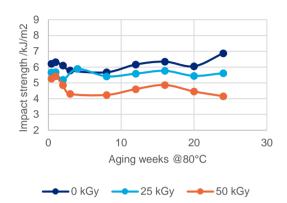
Property	Typical value
Polypropylene type	Random Copolymer
Gamma stabilisation	Yes
Melt flow rate (230°C/2.16 kg)	20 g/10min
Typical application	Diagnostic consumables

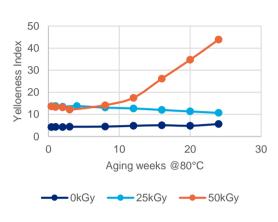
- Excellent mechanical properties retention thanks to gamma irradiation package
- Yellowness index change much less compared to homopolymer -> can be used for non-coloured articles
- Overall better properties retention when comparing with homopolymer

Bormed™RF825MO



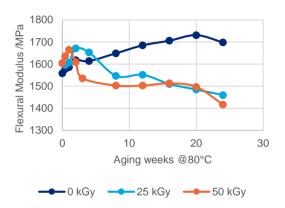
Property	Typical value
Polypropylene type	Random Copolymer
Gamma stabilisation	No
Melt flow rate (230°C/2.16 kg)	20 g/10min
Typical application	Diagnostic consumables



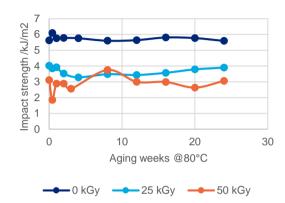


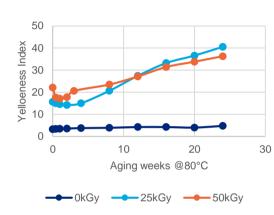
- Comparing with gamma resistant random PP, mechanical properties remain still on high level, stiffness decreases
- We can see significantly worse colour retention in nongamma resistant resin

Bormed™BJ868MO



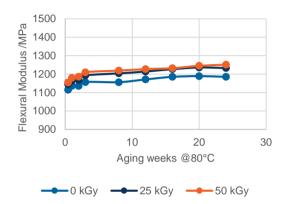
Property	Typical value
Polypropylene type	Impact Copolymer
Gamma stabilisation	No
Melt flow rate (230°C/2.16 kg)	70 g/10min
Typical application	Pipette tips



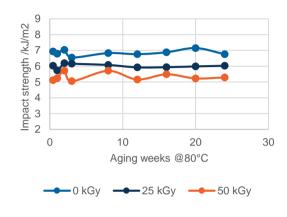


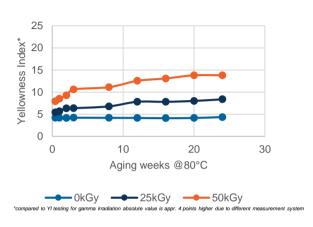
- Impact block copolymer has the worst retention of properties among the polypropylene types
- All properties change significantly

Bormed™HD810MO



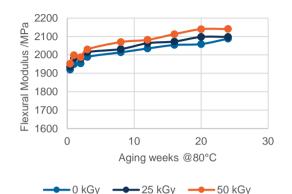
Property	Typical value
Polypropylene type	Homopolymer
Gamma stabilisation	Yes
Melt flow rate (230°C/2.16 kg)	10 g/10min
Typical application	Plunger for syringe

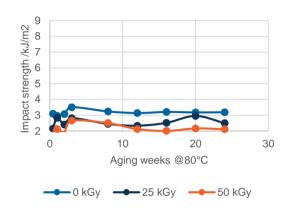


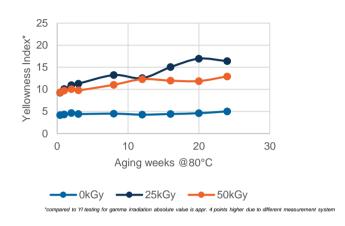


- After E-Beam sterilization flexural modulus of PP increases and impact strength decreases
- Mechanical properties remain on a high level despite the sterilization
- Increase in yellowness index significantly lower compared to gamma sterilization

Bormed™HG820MO



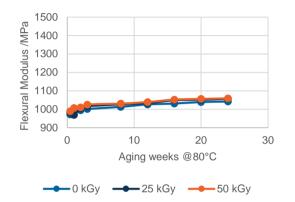


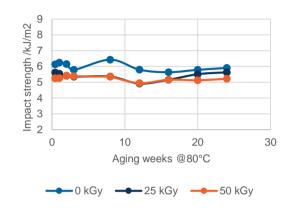


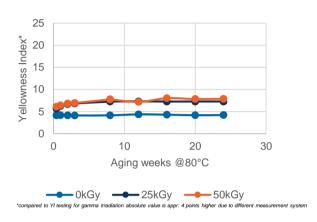
Property	Typical value
Polypropylene type	Homopolymer
Gamma stabilisation	No
Melt flow rate (230°C/2.16 kg)	28 g/10min
Typical application	Pipette tips

 Homopolymers with and without gamma stable additivation show same level of adverse effects on properties after E-Beam sterilization

Bormed™RF830MO



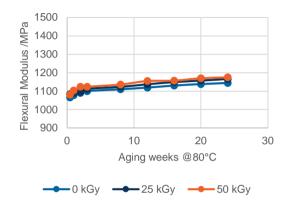




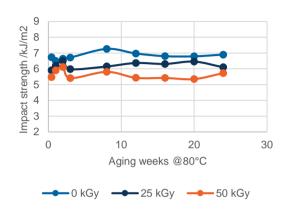
Property	Typical value
Polypropylene type	Random Copolymer
Gamma stabilisation	Yes
Melt flow rate (230 °C/2.16 kg)	20 g/10min
Typical application	Diagnostic consumables

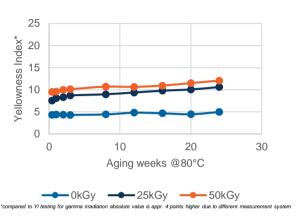
- Flexural modulus remains on the same level after E-Beam sterilization
- Drop in impact strength is low and similar to the gamma sterilization
- Very low increase in yellowness index -> material of choice for not coloured articles
- Overall lower adverse effects on properties vs. homopolymers

Bormed™RF825MO



Property	Typical value
Polypropylene type	Random Copolymer
Gamma stabilisation	No
Melt flow rate (230 °C/2.16 kg)	20 g/10min
Typical application	Barrel for 3-part syringe

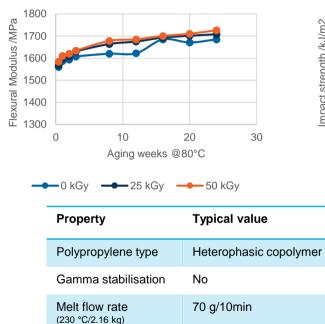




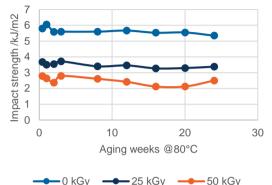
- Higher increase in yellowness index compared to the additivated random copolymer
- Random copolymers with and without gamma stable additivation show the same level of adverse effects on mechanical properties after the E-Beam sterilization
- Material of choice for coloured articles due to the lower level of additive loading
- Compared to gamma sterilization, lower impact on the material overall

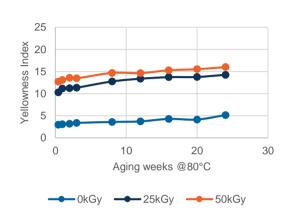
Bormed™BJ868MO

Typical application



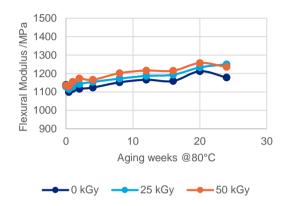
Inhaler



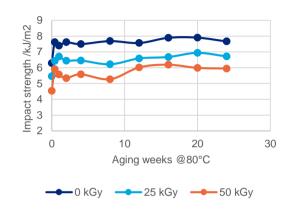


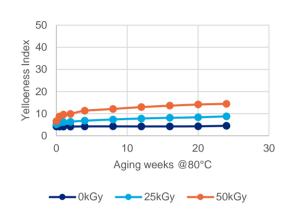
- Comparable increase in flexural modulus to the homopolymers and random copolymers
- Drop in Impact strength after E-Beam sterilization is significant and higher compared to the other PP families
- Compared to gamma sterilization, significantly lower increase in colour and change in the stiffness

Bormed™HD810MO



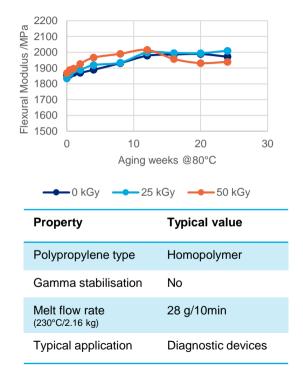
Property	Typical value
Polypropylene type	Homopolymer
Gamma stabilisation	Yes
Melt flow rate (230°C/2.16 kg)	10 g/10min
Typical application	Plunger for syringes

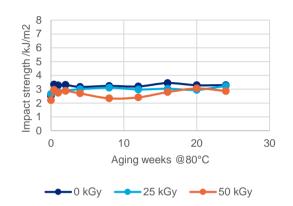


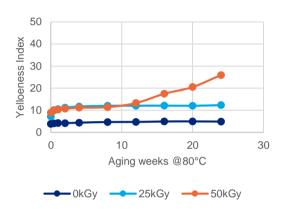


- X-Ray sterilization increases the stiffness of the resin, reduces its impact performance and increases the yellowness index
- Material with gamma additive package, shows good retention of properties after X-Ray sterilisation
- Compared to gamma sterilization, we see similar retention of mechanical properties and significantly lower increase in the yellowness index

Bormed™HG820MO

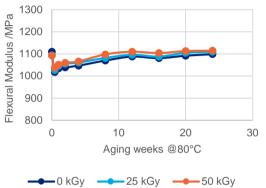




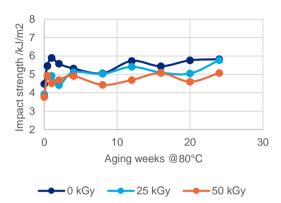


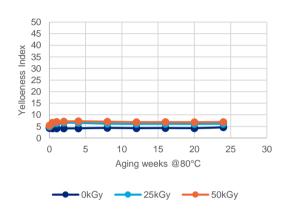
- Non gamma stabilized PP homopolymer shows good stability of mechanical properties after the X-Ray sterilization
- As in case of HD810MO, the yellowness increase is significantly lower in X-Ray compared to gamma sterilization

Bormed™RF830MO



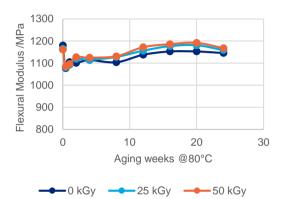
Property	Typical value
Polypropylene type	Random Copolymer
Gamma stabilisation	Yes
Melt flow rate (230°C/2.16 kg)	20 g/10min
Typical application	Diagnostic consumables



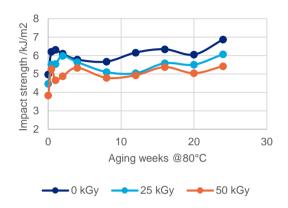


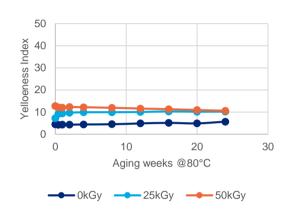
 Gamma stable random copolymer PP shows excellent retention of properties after X-Ray sterilization

Bormed™RF825MO



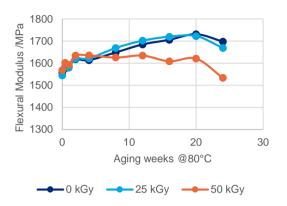
Property	Typical value
Polypropylene type	Random Copolymer
Gamma stabilisation	No
Melt flow rate (230°C/2.16 kg)	20 g/10min
Typical application	Diagnostic consumables



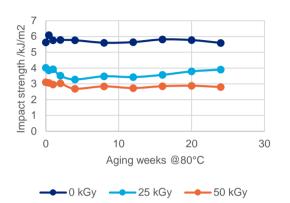


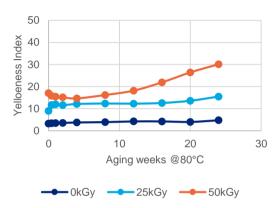
- Resin without gamma resistance shows worse mechanical properties retention compared to RF830MO, nevertheless overall properties retention looks acceptable
- Same as in other cases we see lower yellowing effect compared to gamma sterilisation

Bormed™BJ868MO



Property	Typical value
Polypropylene type	Impact Copolymer
Gamma stabilisation	No
Melt flow rate (230°C/2.16 kg)	70 g/10min
Typical application	Pipette tips



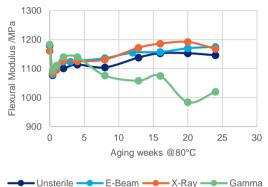


 Impact copolymer PP as well as in other sterilization methods shows worse performance and significant impact on properties after X-Ray sterilization

Sterilization Method Comparison – impact on the material

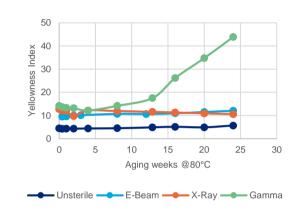
Comparison of all sterilization methods

Bormed™RF825MO



	1 mbact			
)	2	10	20	30
		Aging weeks	@80°C	
a	Unste	rile —— E-Beam ——	X-Ray	Gamma
_	_	Gamma im	pact stif	fness
	_	Gamma ca followed by		
	_	Gamma ca	uses the	e biad

strength /kj/m2



Property	Typical value
Polypropylene type	Random Copolymer
Gamma stabilisation	No
Melt flow rate (230°C/2.16 kg)	20 g/10min
Typical application	Diagnostic consumables

amma impact stiffness of the RF825MO the most

- amma causes biggest drop in impact performance, llowed by X-Ray and E-Beam
- Gamma causes the biggest increase in yellowness index, followed by X-Ray and E-Beam
- Conclusion: Gamma has highest impact on PP followed by X-Ray and E-Beam

Summary

Results summary

- -Sterilization study show that gamma resistant resins retain properties better after sterilisation with any method
- -Among polypropylene families, random copolymers retain properties the best followed by homopolymers. Impact copolymer performs the worst in all sterilization methods and in all properties retention
- -All materials shows similar performance in both gamma and X-Ray with significant difference in yellowing effect where X-Ray shows less impact on material
- -We have confirmed that additivation designed for gamma sterilisation works in X-Ray too
- -The sterilization method with least impact is E-Beam followed by X-Ray and ending with Gamma as method with the most impact on polypropylene. Those results confirm that dose rate in sterilization is crucial. Low dose rate (Gamma) causes higher material deformation compared to high dose rate (E-beam)



Sterilization for the Healthcare Market with Borealis

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Thank you!

Let's collaborate!

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