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Advancing Possible

Advancing Quality Healthcare

Healthcare Customer Event, NH Collection Media Park, 15 June 2022

Dr. Ugur Akgün, Head of Application Development & Technical Service, Polyethylene, LyondellBasell

Content

- LyondellBasell, a Polyolefins Technology Leader
- LyondellBasell’s Commitment to the Healthcare Industry
- Industry Standards for Medical Grade

Polyolefins Development History

Polypropylene

- 1954 – Giulio Natta invented Polypropylene
- 1957 – 1st PP slurry plant
- 1975 – High Yield Catalysts for PP
- 1982 – *Spheripol* PP Process
- 1990 – *Catalloy* PP Process
- 2002 – *Spherizone* PP Process
- 2003 – Polybutene Solution process
- 2003 – Introduction of *Purell* PP grade range
- 2012 – PP phthalate catalyst replacement

Polyethylene

- 1938 – First LDPE synthesis in BASF
- 1952 – Discovery of titanium based catalysts for the low-pressure, polymerization of ethylene by Karl Ziegler
- 1954 – First production of HDPE in Hoechst
- 1955 – First LDPE plant in Wesseling
- 1963 – Nobel price for Ziegler and Natta
- 1964 – First K0 *Hostalen* plant in Frankfurt
- 1991 – First HDPE gasphase plant in Wesseling
- 1997 – First *Hostalen* ACP plant in Frankfurt
- 2004 – Introduction of *Purell* PE grade range
- 2020 – Start up of first *Hyperzone* plant in La Porte

LyondellBasell Committing since Decades to Advance Polyolefins Technologies and Applications

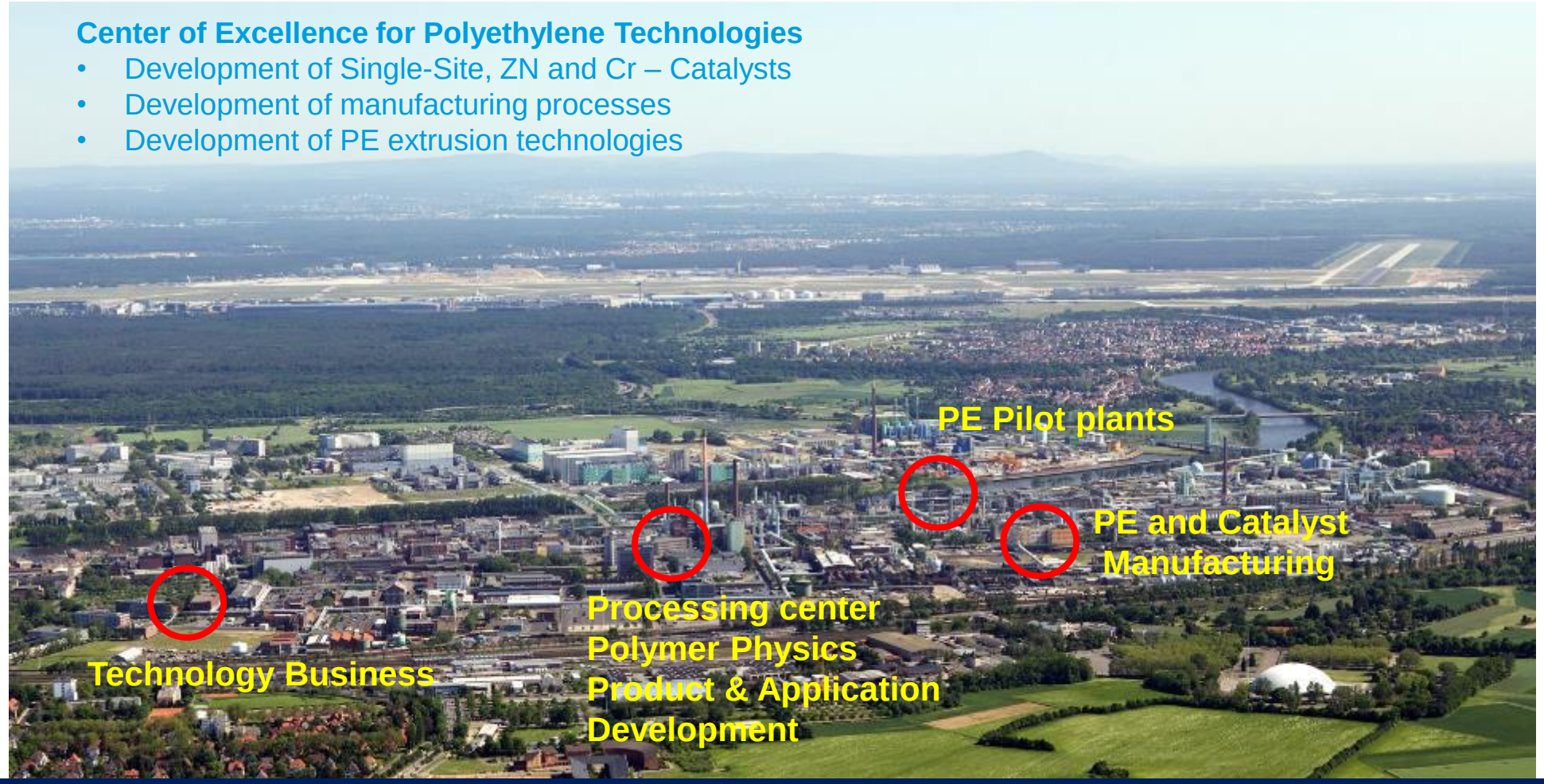
Manufacturing and R&D site Ferrara, Italy

Center of Excellence for Polypropylene and Polybutene-1 Technologies

- Development of Single-Site and ZN – Catalysts
- Development of manufacturing processes
- Development of PP extrusion technologies

Ferrara, Italy, Polypropylene Birthplace and Global Innovation Leader

Manufacturing and R&D site Industrial Park Hoechst, Frankfurt



Frankfurt, Germany, Polyethylene Birthplace and Global Innovation Leader

Healthcare End-User needs

High demanding needs in order to provide the highest level of safety for the patient

- Medication protection
- No defects or flaws
- Inert; No or low interaction with drug and/or patient
- Compliant with healthcare requirements
- Supply chain predictability and security

Why to Choose *Purell* grades!

Conventional Grades

- Pharmaceutical industry has more stringent requirements than food industry
- Procedures on production, storage and handling not in line with expectation of pharmaceutical or medical industry
- Food contact compliant grade formulations can change without notification

What do *Purell* grades portfolio offer?

- Product regulatory support
- High standards of quality
- Consistency of product formulation
- Management of change (MOC)

Purell Service Protocol and Portfolio

Portfolio & Services

- Comprehensive polyolefins portfolio under the *Purell* brand
- Innovative resins based on manufacturing experience and technology know-how
- Dedicated and experienced Sales and Technical team
- Leachable & extractable data available for dedicated *Purell* grades mainly in Pharmaceutical packaging applications

Quality & Consistency

- Dedicated manufacturing plants
- Dedicated quality assurance programs
  - Production
  - Supply chain specific operating procedures
- ISO 15378 certified for manufacturing of Purell in Wesseling (LDPE and PP) and in Frankfurt (HDPE)

Change Management & Regulation

- Management of change: minimum two years notification to support a sustainable transition
- Meeting European Pharmacopeia requirements and USP, possible compliance with country specific regulatory requirements
- Drug Master File (DMF) listing
- Long-term sample retention and documentation

Since the 1980s, LyondellBasell has been serving the specialized needs of the Healthcare Industry

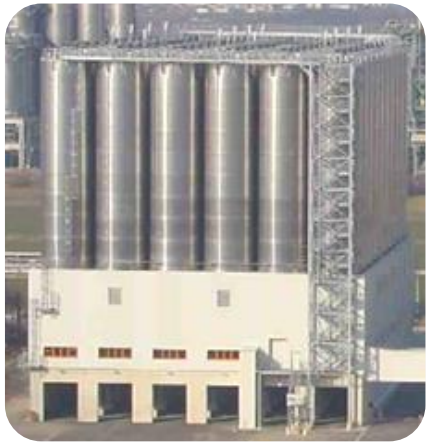
Purell Operating Procedures: Quality Control

- **Laboratory testing protocols**
  - MFR and density both online and offline measurement
  - Online OCS on pellets for contamination control
  - Online Film note measurement
  - Spectrometric measurement of density and additive concentration on a continuously extruded blown film
- **Laboratory testing for organoleptic quality**
- **Processing laboratory for product validation**

Dedicated Quality Control for *Purell* Grades

Purell Operating Procedures: Logistics & Transportation

- Storage in silos (closed system)
- Most modern FFS (“Form-Fill-Seal”) bagging lines in use
- Indoor warehousing & storage for all *Purell* grades
- Pest control
- Highest transportation standards with defined cleaning procedures (ECD) and sealing
- 4-Eyes principle / checklists at various stages of the process
- Regular training program for own staff in all functions including haulers and drivers



Dedicated Logistics & Storage Solutions

VDI Workgroup Plastics in Medical & Akzept Network

- **Focus:**
  - Definition of requirements for Medical Grade Plastics
- **Applicable for:**
  - Medical Devices
  - Pharmaceutical Packaging
  - In-Vitro-Diagnostics
  - Active Implantable Medical Devices
- **Participants:**
  - Chair: Prof. T. Seul, Prof. S. Roth (University of Applied Sciences Schmalkalden)
  - Medical device manufacturers (market placer), (B.Braun Melsungen, Fresenius, Roche)
  - Parts‘ manufacturers (RKT, Ypsomed)
  - Raw material producers (Albis, LyondellBasell, Styrolution, Borealis, Kraiburg)
  - Notified body (DQS med)
- **Timeline**
  - April 2018: release “Greenprint”
  - March 2019: final version “Whiteprint”
  - April 2020: first review meeting
  - March 2020 – April 2021 : VDI workshops
  - 2021- 2022: first revision of MGP guideline

Ref.: VDI Wissensforum

Guideline for material customers and suppliers

VDI 2017 – Characteristics of Medical Grade Plastics (MGP)

- **Change Management** with respect to raw material specifications/-ingredients, manufacturing site/-technology or regulatory status
- **Quality Management Requirements** with respect to development, manufacturing und handling of MGPs
- **Assurance of Security of Supply** and availability as well as **requirements for logistics** of MGPs and
- **Support of medical device provider** (market placer) to achieve the respective **Regulatory Requirements**, such as check of biocompatibility

1. **Scope of the directive**
2. **Terms: general, materials, parties involved**
3. **Abbreviations**
4. **Definition Medical Grade Plastics (MGP)**
5. **Regulatory requirements for MGPs**
6. **Consistency of formulation**
   - Scope and definition of formulation of a MGP
   - Requirements for consistency of formulation
   - Assessment of consistency of formulation
   - Information and Documentation
7. **Security of Supply**
8. **Change Management**
9. **Packaging, storage und logistics**
10. **Customer-Supplier relationship**

- **Appendix**
  - Example for Quality Agreement (QA)
  - Example for risk assessment
  - Example for declaration of conformity for MGPs
  - Risk factors in processing of material

***Purell* Concept already addresses the requirement of VDI MGP**

Implementation of VDI MGP into the LyondellBasell *Purell* Concept

So how to certify compliance to VDI MGP?

- **Indirect way: ISO 15378:2017 “manufacturing of pharmaceutical packaging materials”**
  - ISO 15378 specifies requirements for a quality management system for primary packaging materials for medicinal products.
  - This mandatory for pharmaceutical companies but can be applied to raw material suppliers
  - ISO 15378 covers all aspects that VDI MGP is requesting
- **Logic consequence:**
  - ISO 15378 certification for *Purell* LDPE *and* PP Wesseling established in 2016, annual re-audits passed successfully
  - ISO 15378 certification for *Purell* HDPE Frankfurt achieved end 2020
- **Outlook:**
  - Preparation for internal certification audit according to VDI MGP until end 2022
  - Mid term aim of ISO 15378 certification for Muenchsmuenster for end 2022
  - Long term aim of ISO 15378 certification for all European sites that produce *Purell* PE, PP and PB-1

Advancing Polyolefins in Healthcare Applications

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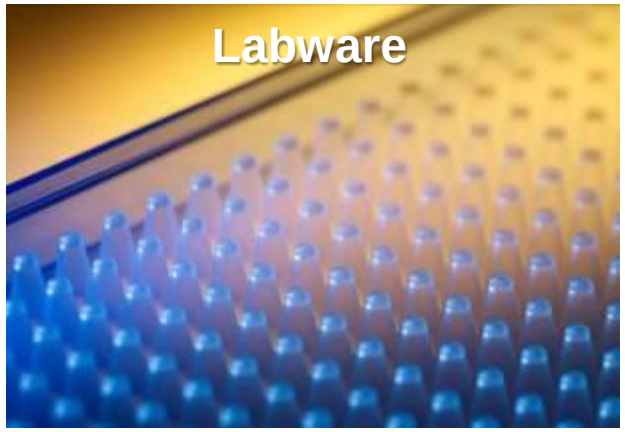
Dr. Ugur Akgün, Head of Application Development & Technical Service, Polyethylene

Emanuele Burgin, Head of Application Development & Technical Service, Polypropylene

Typical *Purell* PE Customers' Applications

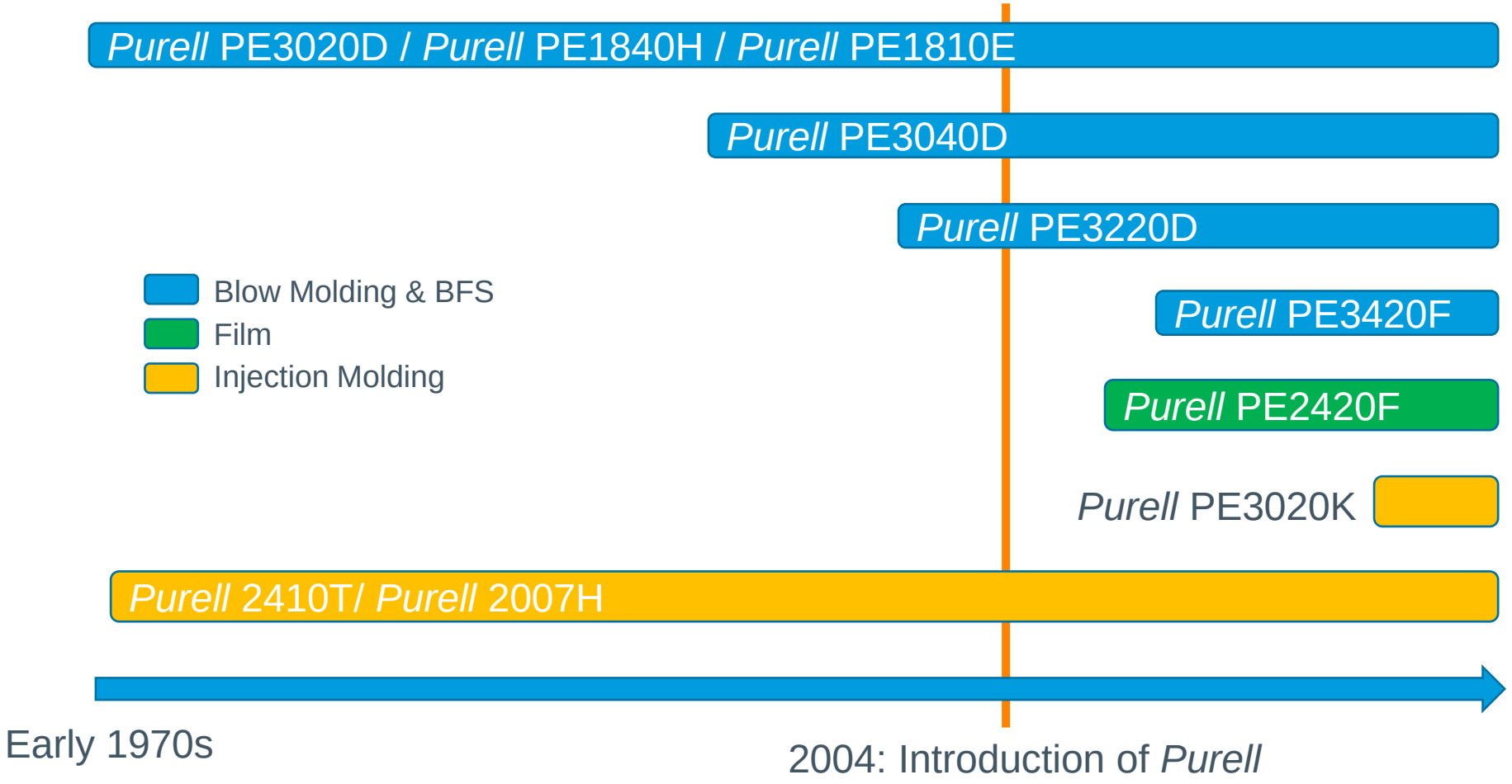
Blow-Fill-Seal

2-part, 3-part



EBM/IBM

LDPE *Purell* Portfolio



Most Comprehensive Healthcare LDPE Portfolio

Purell LDPE for BFS – the new benchmark *Purell* PE3420F

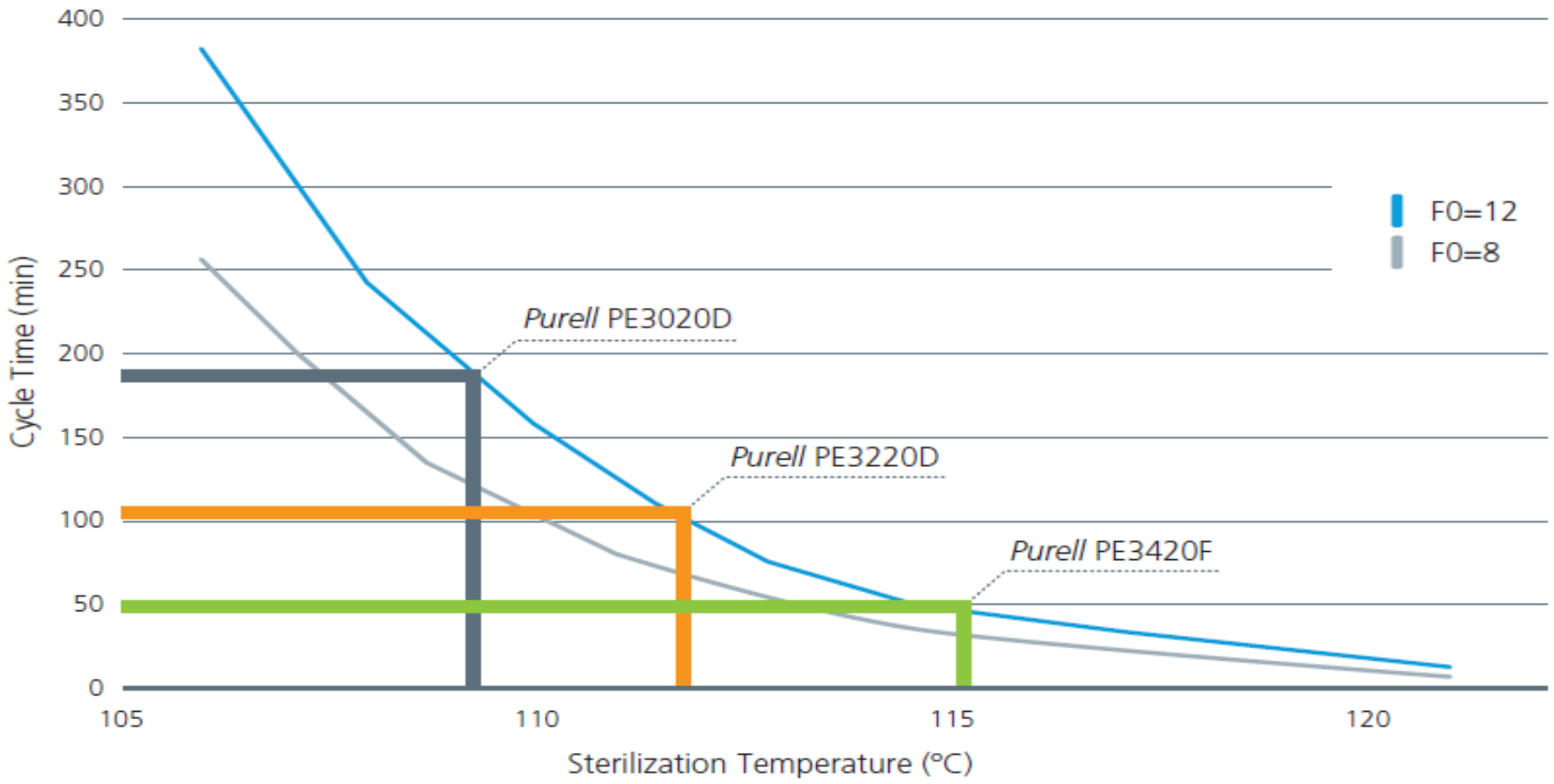
- **Industry benchmark resins for blow fill seal applications offering good optical, thermal and organoleptic properties**
- **Typical customer applications: IV bags and bottles and ampules for pharmaceutical packaging**
- ***Purell* PE3420F offers potential for further weight reduction and increased sterilization temperature**

Properties	*Purell* PE 3020D	*Purell* PE 3040D	*Purell PE 3220D*	*Purell PE 3420F*
	LDPE	LDPE	LDPE	**LDPE**
Density (g/cm³)	0.927	0.928	0.930	**0.933**
PE: MFR (190°C/2.16kg) (g/10 min)	0.3	0.25	0.40	**0.9**
Tensile modulus (MPa)	300	300	430	**520**
Melting point (°C)	114	115	117	**119**
Vicat softening point A/50 (°C)	102	102	110	**111**

Typical properties; not to be construed as specifications

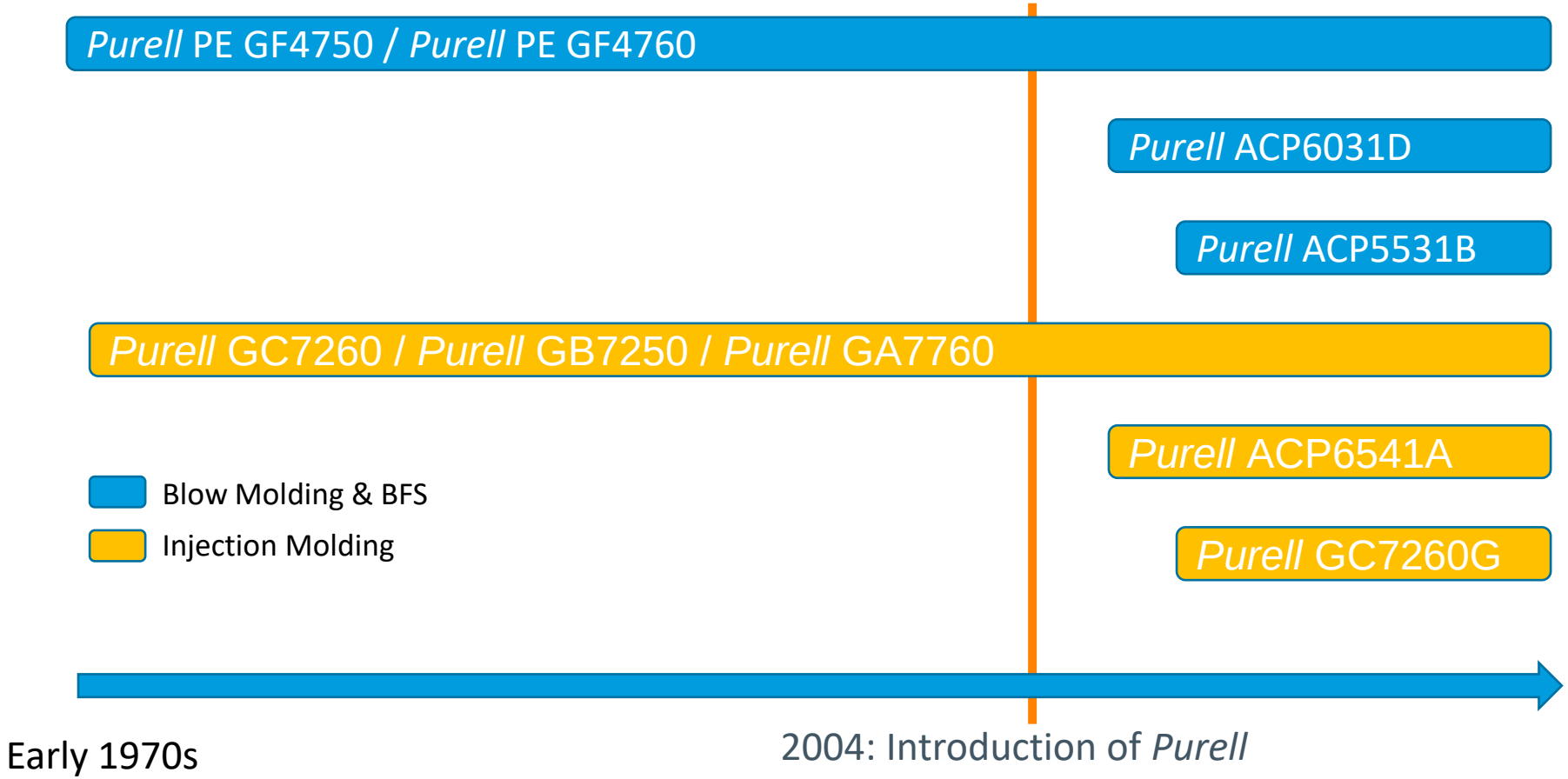
Expanding the Boundaries of LDPE BFS (Blow Fill Seal) Grades

Time and Cost Savings with *Purell* Grade PE3420F in Autoclaving



As Density of LDPE ↑ Sterilization temperature can be increased
Under F0=8 conditions, Purell PE3420F allows reduction of 97 mins versus Purell PE3020D
Under F0=12 conditions, Purell PE3420F allows reduction of 146 mins versus Purell PE3020D

HDPE *Purell* Portfolio



Most Comprehensive HDPE Healthcare Portfolio

Purell PP portfolio made by LyondellBasell, a wide range of applications

- **Film**
  - Flexible packaging
  - I.V. Bags
- **Injection Molding**
  - Syringes
  - Medical devices components
  - Labware
  - Caps & Closures
  - Containers, rigid packaging
- **Blow molding**
  - I.V. Bottles
  - BFS bottles and ampoules
- **Textile**
  - Meltblown
  - Spunbond

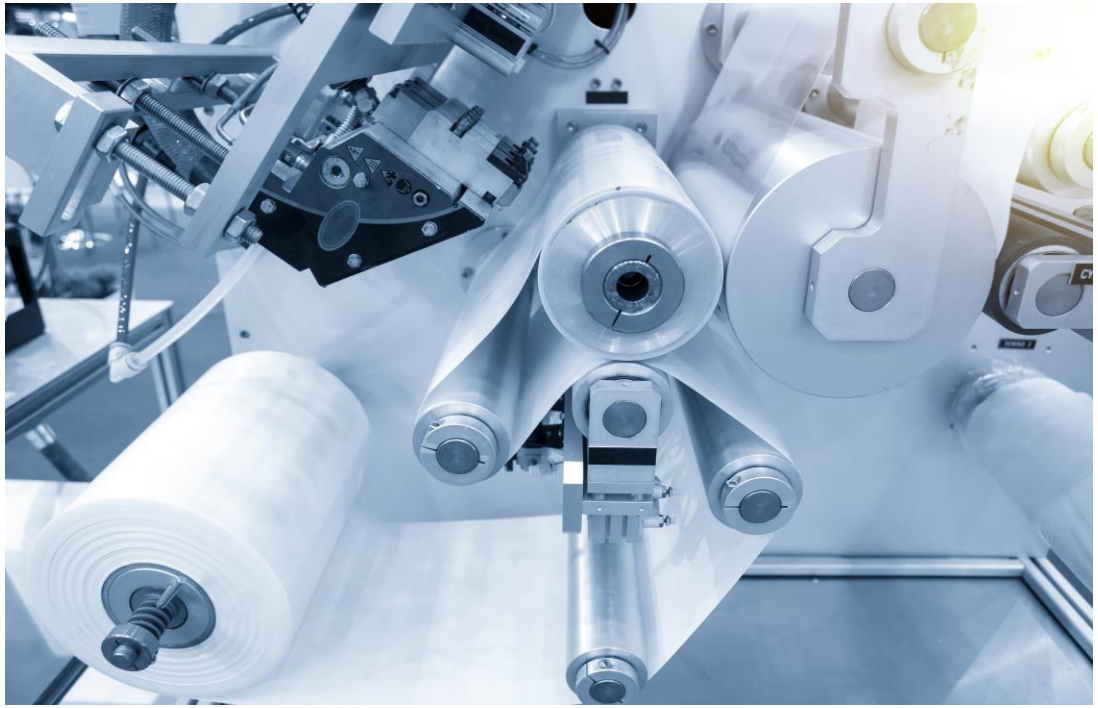





Healthcare Film Packaging : requirements

Typical Applications

- Flexible Primary Packaging for Pharmaceuticals
- Packaging of Medical Devices



Key Properties

- Suitability for different conversion technologies: Cast Film, Air Blown Film, Water Quenched Blown Film (WQBF)
- Transparency
- Tensile strength
- Puncture resistance
- Sealability
- Printability
- Autoclavability

Healthcare Film Packaging : *Purell* PP offer

- Portfolio of grades meeting both Cast and Blown film processing requirements
- PP homopolymer : the material of choice for good thermal stability
- PP random copolymers : good opticals, softness and seal ability
- Specific additivation for Slip & Antiblocking behavior
- Autoclave sterilizability

Properties	*Purell* RP270G	*Purell* HP570M	*Purell* RP315M	*Purell* RP370M
	RACO	HOMO	RACO	RACO
MFR (230°C/2.16kg) (g/10 min)	1.8	7.5	8.0	8.0
Tensile modulus (MPa)	1000	1400	1100	850
Melting point (°C)	147	161	147	143
Vicat softening point A/50 (°C)	136	154	135	135
Additive package	-	-	Slip & AB	-

***Purell* Film Portfolio Combines Thermostability, Optical and Mechanical Properties**

Healthcare IV Bags : requirements

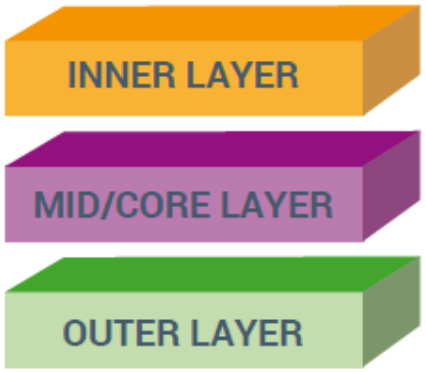
Typical Applications

- IV Bags (saline, buffer solutions)
- Peritoneal Bags

Key Properties

- Suitability for different conversion technologies (Cast, Blown, WQBF)
- Transparency
- Flexibility
- Tensile strength
- Puncture resistance
- Impact resistance
- Sealability
- Printability
- Autoclavability

Healthcare IV Bags : *Purell* PP and PB-1 offer

Main Requirements		Polymeric Approach	Purell solution
Good Sealing, stickiness, no slip & antistatic		PP RACO + plastomer	*Purell* RP370M + *Purell* KTMR07
Transparency mechanicals, flexibility melt strength		PP RACO + plastomer	*Purell* RP370M and/or *Purell* RP270G + *Purell* KTMR07
Thermal stability, scratch resistance, printability		PP HOMO	*Purell* HP570M

Properties	*Purell* HP570M	*Purell* RP370M	*Purell* RP270G	*Purell* KTMR07
	HOMO	RACO	RACO	PB-1 Plastomer
MFR (230°C/2.16kg) (g/10 min)	7.5	8.0	1.8	1.3 *
Tensile modulus (MPa)	1400	850	1000	< 10 **
Melting point (°C)	161	143	147	-

*MFR (190°C/2.16kg) (g/10min) - ** Flexural Modulus (MPa)

Healthcare Injection Molding Labware: requirements

Typical Applications

- Pipette / Cuvette
- Petri Dishes
- PCR plates
- Trays

Key Properties

- Transparency
- Rigidity / Toughness balance
- Processability / Flowability
- Dimensional stability
- Resistance to sterilization (autoclave, irradiation)
- Chemical resistance

Healthcare Thin Wall Injection Molding Labware : *Purell* PP offer

- Good transparency given by addition of clarifying agents
- Controlled rheology, to prevent post-molding warpage
- On top of autoclavability, some grades are specifically designed to offer enhanced gamma-ray resistance

Properties	*Purell* HP570U	*Purell* HP373P	*Purell* HP671T	*Purell* RP375R	*Purell* RP378T
	HOMO	HOMO	HOMO	RACO	RACO
MFR 230°C/2.16kg (g/10min)	75	18	55	25	48
Tensile modulus (MPa)	1350	1250	1900	1100	1100
Haze 1mm (%)	---	12	18	9	9
Additive package		Clarified Gamma-ray resistant	Clarified Gamma-ray resistant	Clarified Gamma-ray resistant	Clarified, Antistatic

Purell PP Offers Versatile Properties for Labware Requirement

Injection Molding: Focus on *Purell* EA678P, the new PP High Stiffness Copolymer for Healthcare

- **An heterophasic copolymer designed for Injection Molding**
  - Higher rigidity compared to conventional PP heterophasic copolymers, for potential intermaterial replacement
  - Nucleated grade, for faster cooling and reduced cycle times
  - Excellent balance of mechanical properties for a wide variety of healthcare applications
- **Typical applications: autoinjectors and insulin pens, oral care devices, transport trays, hospital devices, other medical device components, closures.**

Properties	*Purell* EA678P
MFR 230°C/2.16kg (g/10min)	18
Tensile modulus (MPa)	1750
Charpy Notch. 23°C (KJ/m2)	6,5
Charpy Notch -20°C (KJ/m2)	2,5
Gloss 60° (%)	70

Potential Inter-Material Replacement of Engineering Materials with Better Recyclability

Healthcare Injection Molding Syringes : requirements

Typical Applications

- Disposable empty syringes (2 or 3 parts)

Key Properties

- Transparency (syringe barrels)
- Mechanicals (toughness on syringe barrels, stiffness on plungers)
- High fluidity, allowing short cycle times on highly complex multicavity tools
- Dimensional stability, for proper functionality
- Regular glide force

Healthcare Injection Molding Syringes : *Purell* PP offer

- Medium/High fluidity grades, to meet demanding injection molding requirements (thin wall, complex design, multicavity molds)
- PP random copolymers in syringe barrels syringes offer optimal transparency
- PP homopolymers enhance stiffness, as needed in plungers
- Specific additive packages (e.g. slip agent) , for different types of syringes (2 or 3 parts)
- Controlled rheology grades, for better dimensional stability

Properties	*Purell* RP373R	*Purell* RP374R	*Purell* HP570R	*Purell* *HP548N*
	RACO	RACO	HOMO	HOMO
MFR 230°C/2.16kg (g/10min)	25	25	23	11
Tensile modulus (MPa)	1000	1000	1400	1800
Haze 1mm (%)	9	9	-	-
Additivation	Clarified Slip Agent	Clarified	-	Nucleated Antistatic
Application	2P syringe barrels	3P syringe barrels	plungers, hubs	plungers, hubs

***Purell* PP is the Material of Choice for Syringes Applications**

Healthcare Blow Molding and BFS : requirements

Typical Applications

- Bottles for pharma packaging
- Ampoules
- IV Bottles

Key Properties

- Rigid
  - Good stiffness/toughness balance
  - Good transparency
  - Chemical resistance
- Soft (BFS IV bottles)
  - Collapsibility
  - Transparency
  - Autoclave sterilization 121°C

Healthcare Blow Molding and Blown-Fill-Seal (BFS): PP and PB-1 *Purell* offer

- Rigid
  - Purell RP270G offers a good balance of properties (processability, opticals, mechanicals) for a broad variety of applications
  - Purell RP270G has an additive package designed to minimize interactions with IV solutions
- Soft
  - In combination with Purell KTMR07, it is possible to have high temperature sterilization (121°C) and meet the key-requirements of BFS IV bottles: softness, transparency and processability, without need of plasticizers
  - Soft PP (as monosolution) is under development

Properties	*Purell* RP270G	*Purell* KTMR07
	RACO	PB-1 Plastomer
MFR (230°C/2.16kg) (g/10 min)	1.8	1.3*
Tensile modulus (MPa)	1000	< 10**
Melting point (°C)	147	-

*MFR (190°C/2.16kg) (g/10min) - **Flexural modulus (MPa)

We are Committed to Advance PP Softness to Address a Variety of High Temperature Sterilizable Applications

Healthcare Textile : requirements

Typical Applications

- Face masks
- Surgical drapes & gowns
- Adult incontinence pants
- Ostomy bags
- Hygiene, sanitary products

Key Properties

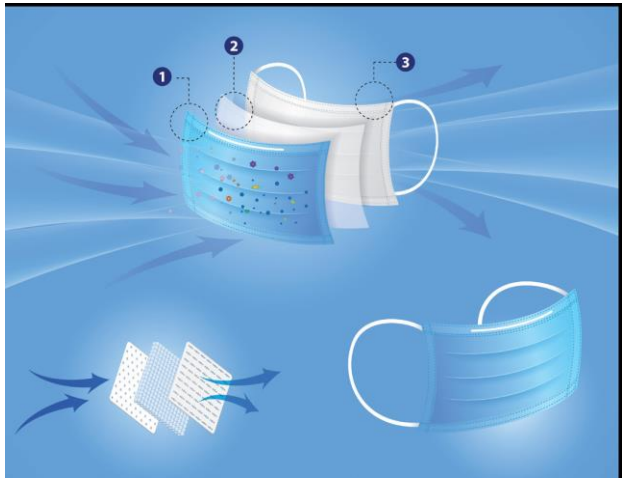
- **Excellent homogeneity**
- **High purity**
- **Meltblown:**
  - very high flowability, to produce finer filaments, resulting in nonwoven fabrics with outstanding barrier and filtration properties
- **Spunbond nonwovens**:
  - Exceptional tenacity, for nonwoven light-weight fabrics
  - Formulated with an anti-gas fading package

Healthcare Textile : *Purell* PP offer

- ***Purell* HP570Y and HP570Z** are PP homopolymers for meltblown extrusion
  - Excellent homogeneity and high purity
  - Very high flowability to produce fine filaments, resulting in nonwoven fabrics with outstanding barrier and filtration properties

- ***Purell* HP571R** is a PP homopolymer for spunbond nonwovens
  - Very narrow molecular weight distribution
  - Formulated with an anti-gas fading additive package
  - Exceptional tenacity, typically used for nonwoven light-weight fabrics

1	Outer Layer	Spunbond	***Purell* HP571R**
2	Middle Layer	Meltblown	***Purell* HP570Y or *Purell* HP570Z**
3	Inner Layer	Spunbond	***Purell* HP571R**



Properties	*Purell* HP571R	*Purell* HP570Y	*Purell* HP570Z
MFR (230°C/2.16kg) (g/10 min)	25	1200	1500

Enabling *Purell* for New Healthcare Requirements in Textile

Conclusions

- In the Healthcare applications, *Purell* portfolio has confirmed its versatility and polymer property very broad profile
- We have been working to enlarge our *Purell* portfolio offer to meet the increasing and evolving market demand and to support industry to face the current exceptional and critical times
- More innovations for the *Purell* portfolio are under development to meet future market demand and to enable advancing our customers new solution offerings
- In an improved sustainability perspective, most *Purell* grades can now also be offered as *Circulen* solutions via mass balance certification, fully complying with all the Pharma regulations

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(iii) life-sustaining medical applications.

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