IOM3 Webinar
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Elastomer solutions for pharmaceutical packaging and medical devices

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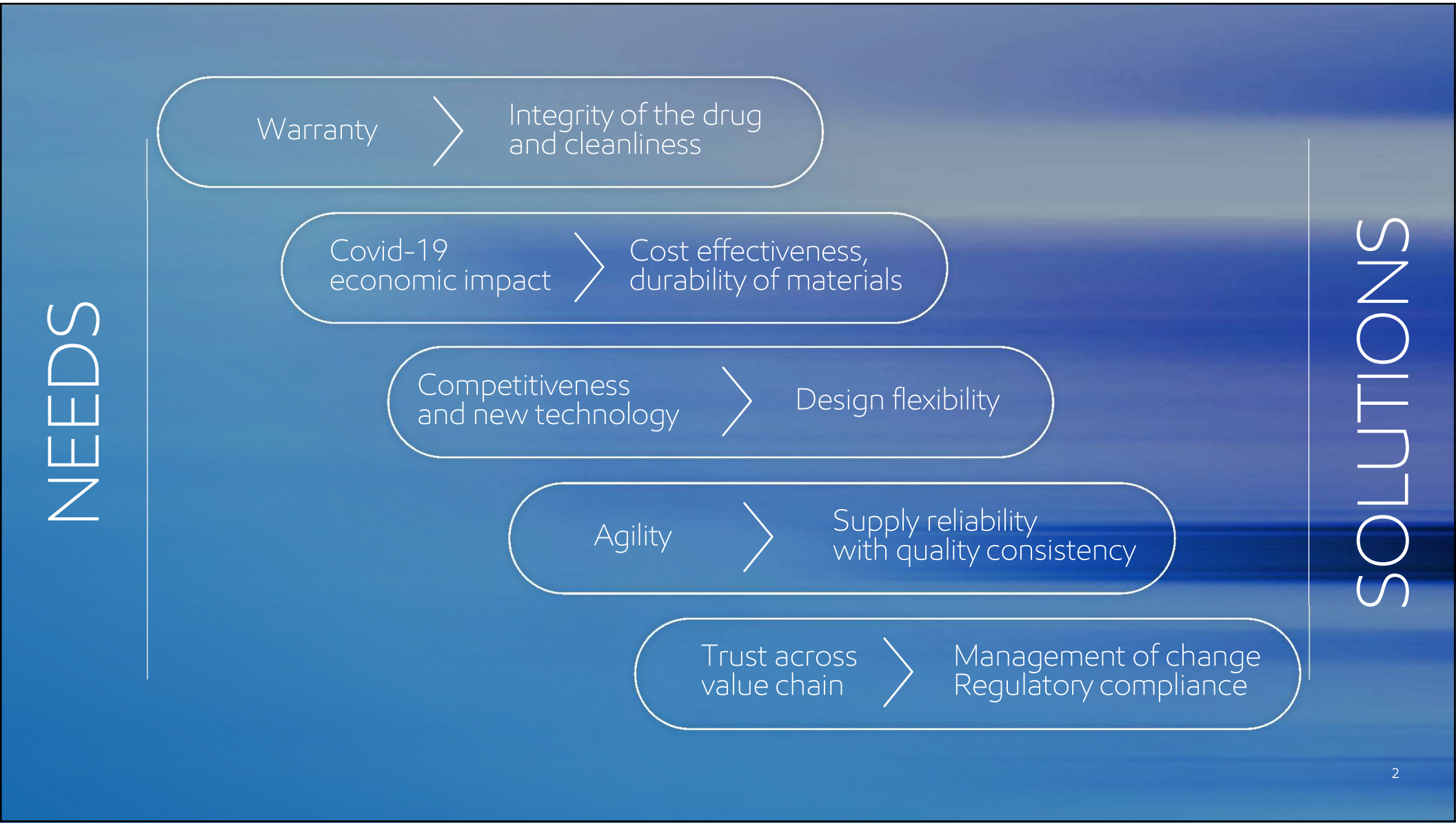
Energy lives here*

ExxonMobil


NEEDS
SOLUTIONS
Warranty
Integrity of the drug and cleanliness
Covid-19 economic impact
Cost effectiveness, durability of materials
Competitiveness and new technology
Design flexibility
Agility
Supply reliability with quality consistency
Trust across value chain
Management of change
Regulatory compliance

Agenda

01

Butyl rubber

02

Exxpro™ specialty elastomer
The super clean choice

03

Santoprene™ thermoplastic vulcanizates (TPVs) in **medical devices**

What does it take to achieve cleanliness through pharma stopper value chain?

Requirement from drug manufacturers

- Cleanliness
- Regulatory compliance

Requirement for stopper

- Clean – low extractable/leachable
- Protection – sealing/ re-sealing
- Sterilization resistance
- Product consistency process, zero defects

Requirement for raw material

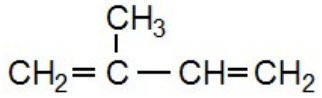
- Low additives/oligomer
- Impermeability
- Elasticity
- Aging performance
- Consistent high quality

Why use butyl rubber?

- NR contains protein, could cause allergenic reaction
- Highly impermeable to moisture and gases
- Highly saturated backbone
- Chemically inert / non-polar
- Versatile and efficient vulcanization using clean curatives
- Adequate self-sealing & fragmentation behavior

Butyl rubber is the #1 choice worldwide for Pharmaceutical Stopper Application

Butyl polymer family



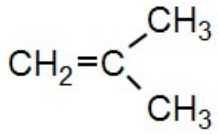
Isoprene → Butyl rubber (IIR)

Butyl rubber (IIR) + Cl_2 → Chlorobutyl (CIIR) → Star-branched chlorobutyl

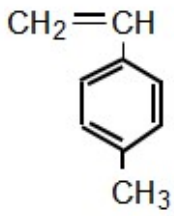
Butyl rubber (IIR) + Br_2 → Bromobutyl (BIIR) → Star-branched bromobutyl

Branching agent

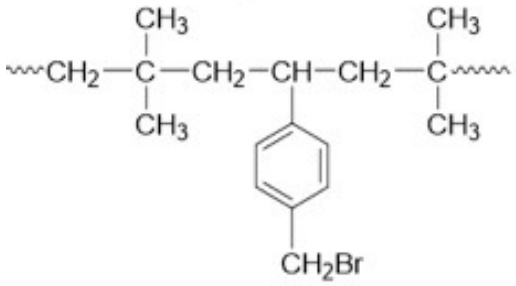
Isobutylene



PMS



Br_2

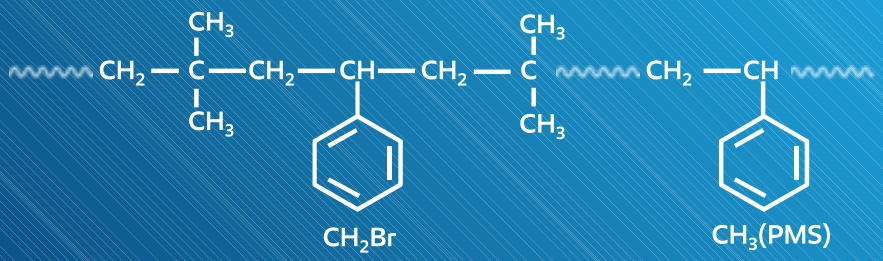


Specialty polymers:
Exxpro™ specialty elastomers (BIMSM)

Source: ExxonMobil Chemical Data

Exxpro™ specialty elastomers
the super clean choice

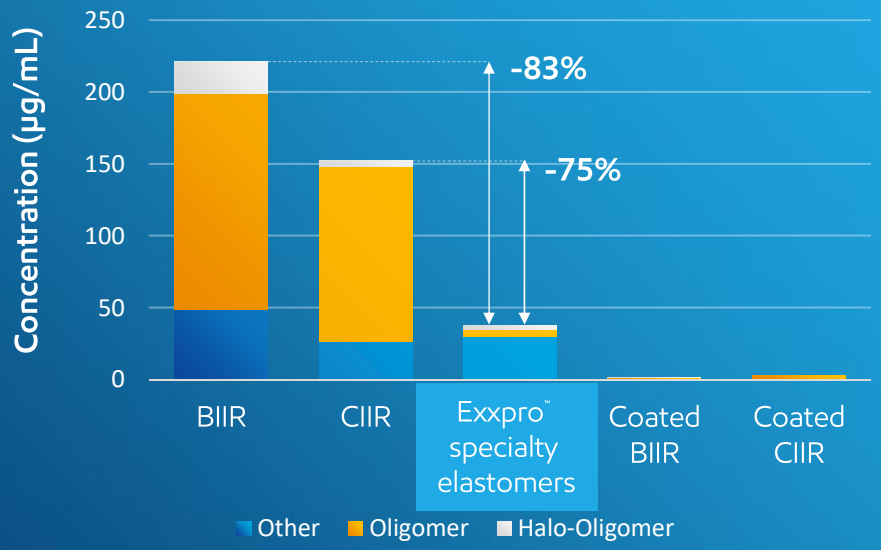
Exxpro™ specialty elastomers
are brominated copolymers of
Isobutylene and para-methylstyrene



Brominated para-methylstyrene (PMS)

Attribute	Performances
Isobutylene backbone	Maintains all Butyl elastomer properties, impermeability, dampening
Pendant pMS ring	Lower permeability Gamma Sterilization stability
Fully saturated backbone (no double bond)	Better resistance to ozone, heat, chemicals, and weathering Excellent ageing resistance without antioxidant
Highly reactive benzylic bromine	Versatile cure chemistry

Cleanliness through low extractables



* All stoppers are resin cured

Note: some extractable content is specific to compounding materials (additivies and curatives) and is not introduced by the polymer (BIIR, CIIR, Exxpro™ specialty elastomers)

Chart data source: ExxonMobil Chemical

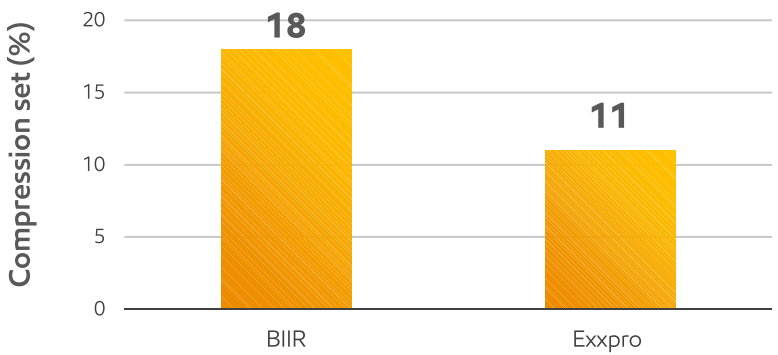
Cleanliness through sealing and low permeability

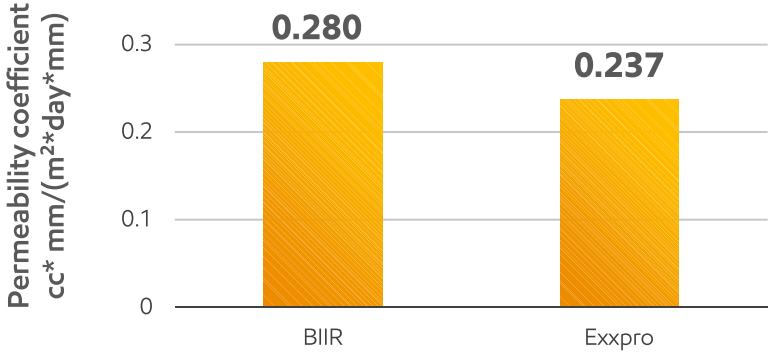
35%

Improved
compression set

15%

Reduced
permeability



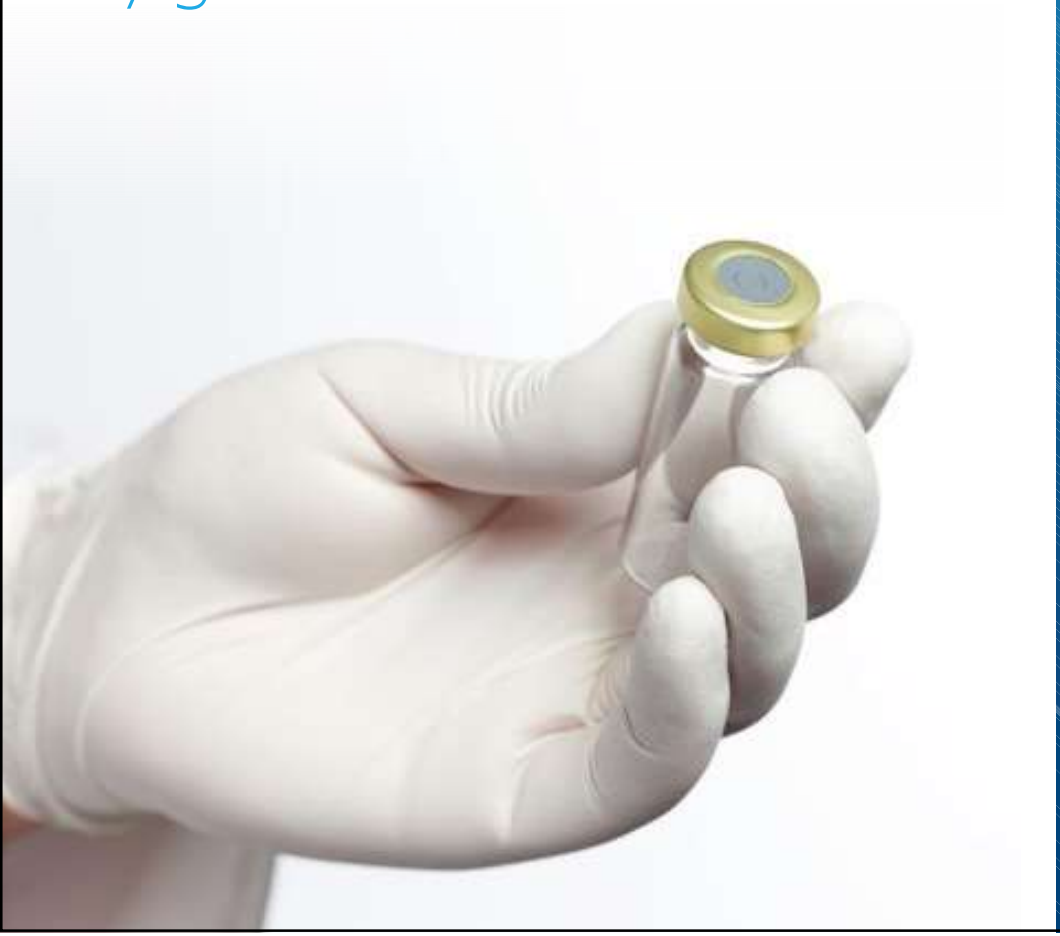


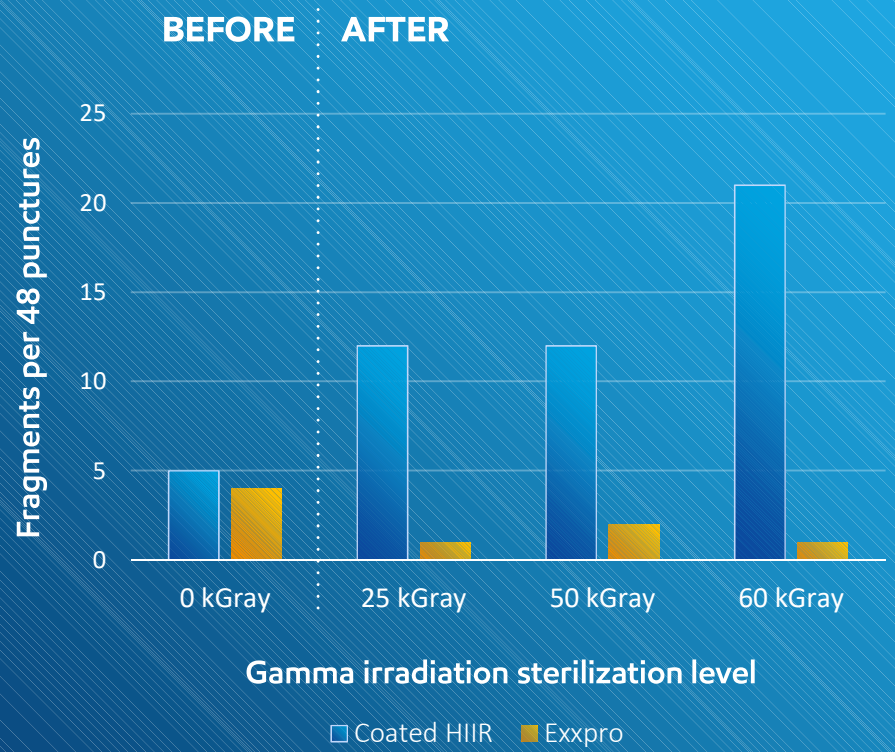
* 25% deflection for 22 hrs @ 70°C

Chart data source: ExxonMobil Chemical

Chart data source: ExxonMobil Chemical

Cleanliness challenged by gamma irradiation

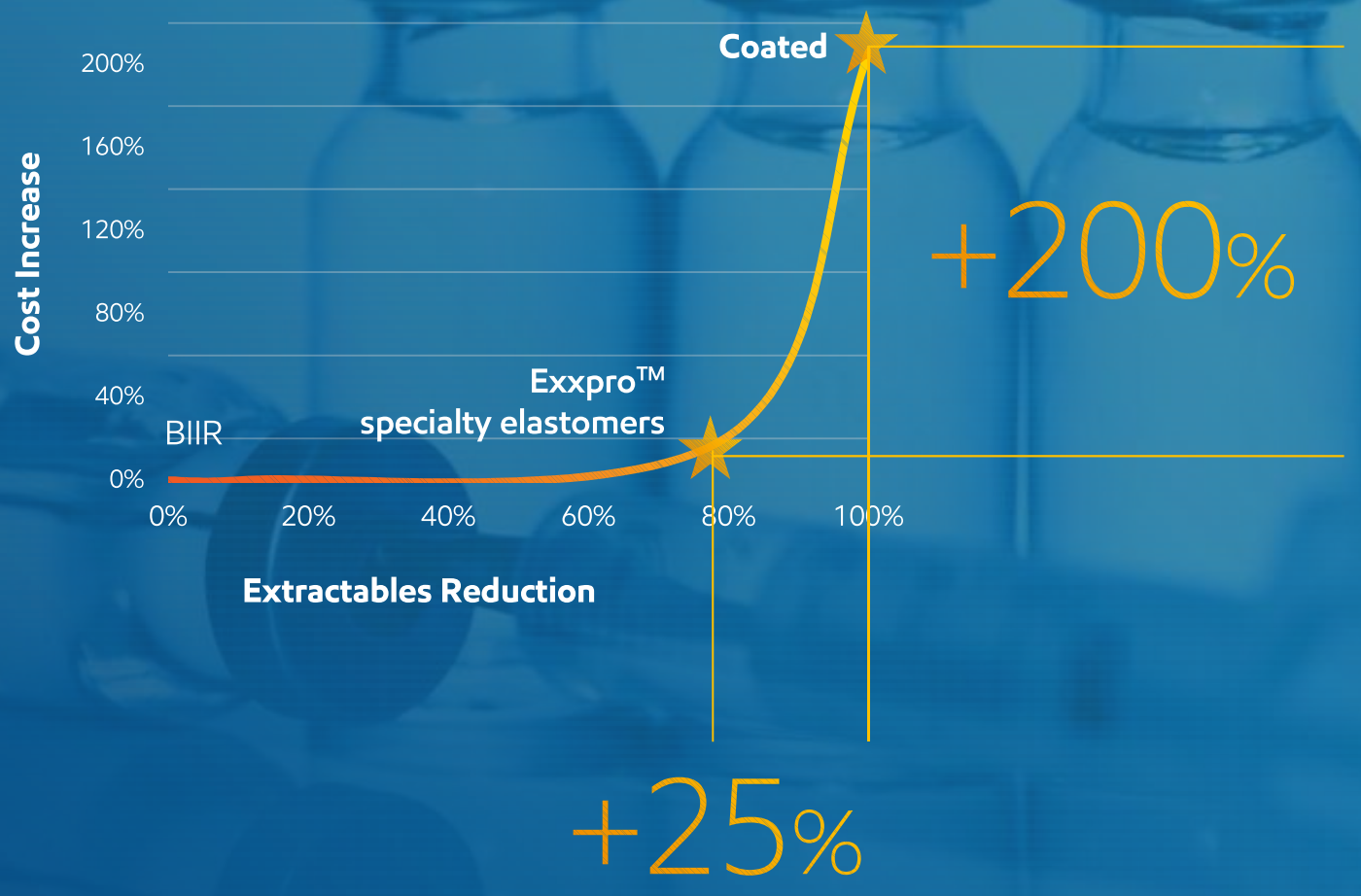




Testing based on USP 381 Elastomeric Closures for Injections wherein visible particles are counted after puncturing a stopper, 4 punctures per stopper, across 12 stoppers

Chart data source: ExxonMobil Chemical

Exxpro economics for **premium** stoppers



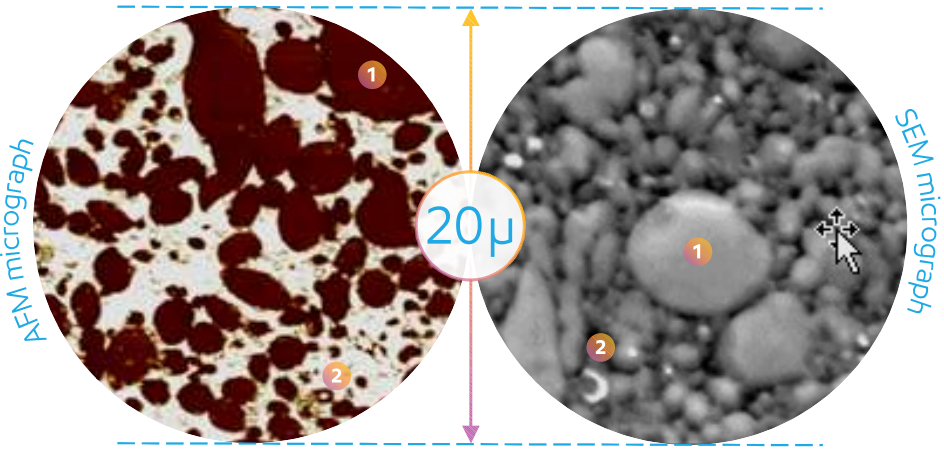
ExxonMobil estimates

Elastomers for medical devices: **Santoprene™ TPV**

What is Santoprene™ TPV?

Behaves like a rubber
Processes like a plastic

- Chemically crosslinked (vulcanized) rubber encapsulated in thermoplastic matrix
- Homogeneous dispersion
- Locked-in morphology



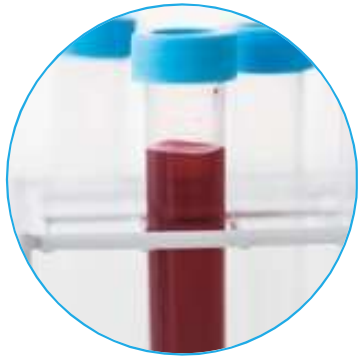
1 Cured rubber

2 Thermoplastic

Santoprene™ TPV in medical and healthcare applications

Peristaltic pump tubing

Syringe plunger tips



Blood tube gaskets, caps, and closures

Strain relief handheld device

And more ...

Innovative elastomers for cost effective medical solutions

Santoprene™ TPV: What it brings to your product?

Sustainability enabler

In process recycling
Lower weight versus EPDM

Reliable Sealing Performance

Superior Aesthetics

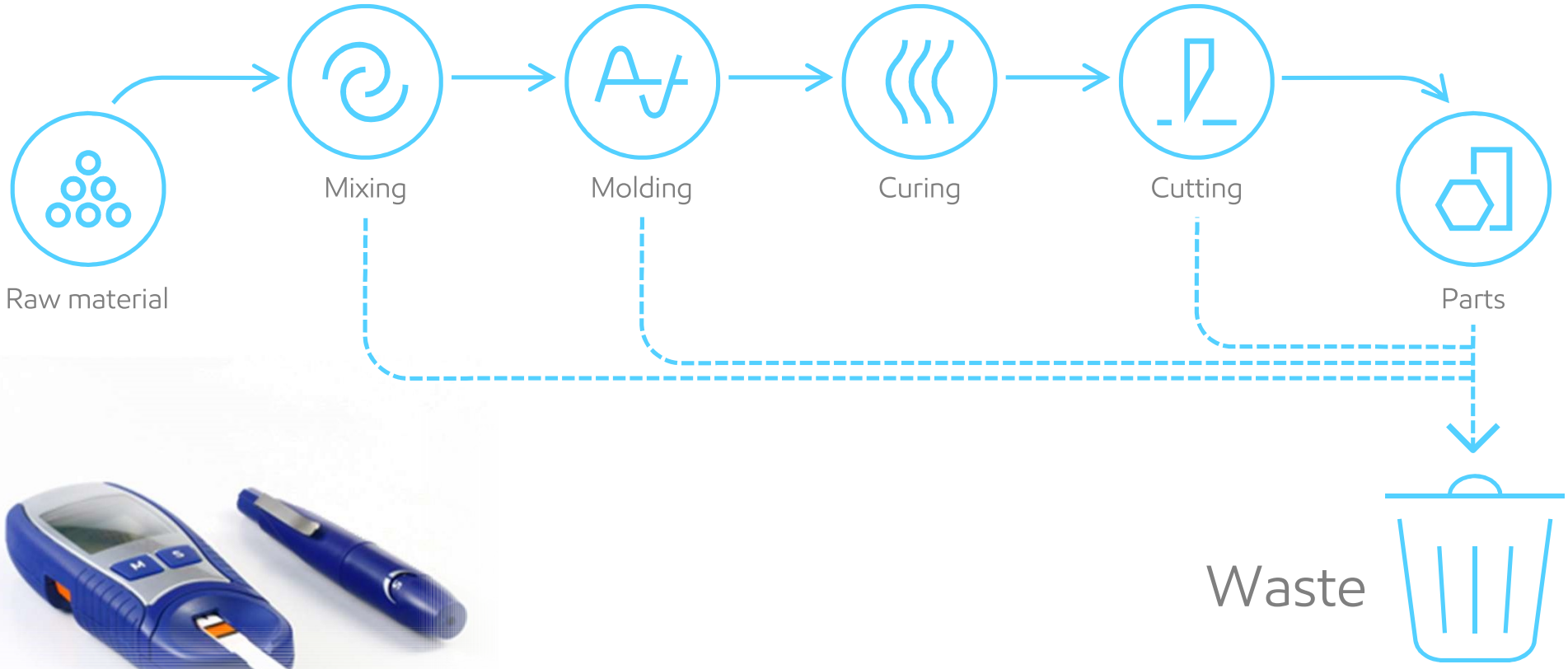
Design Flexibility

Injection molding, extrusion, 3D print...

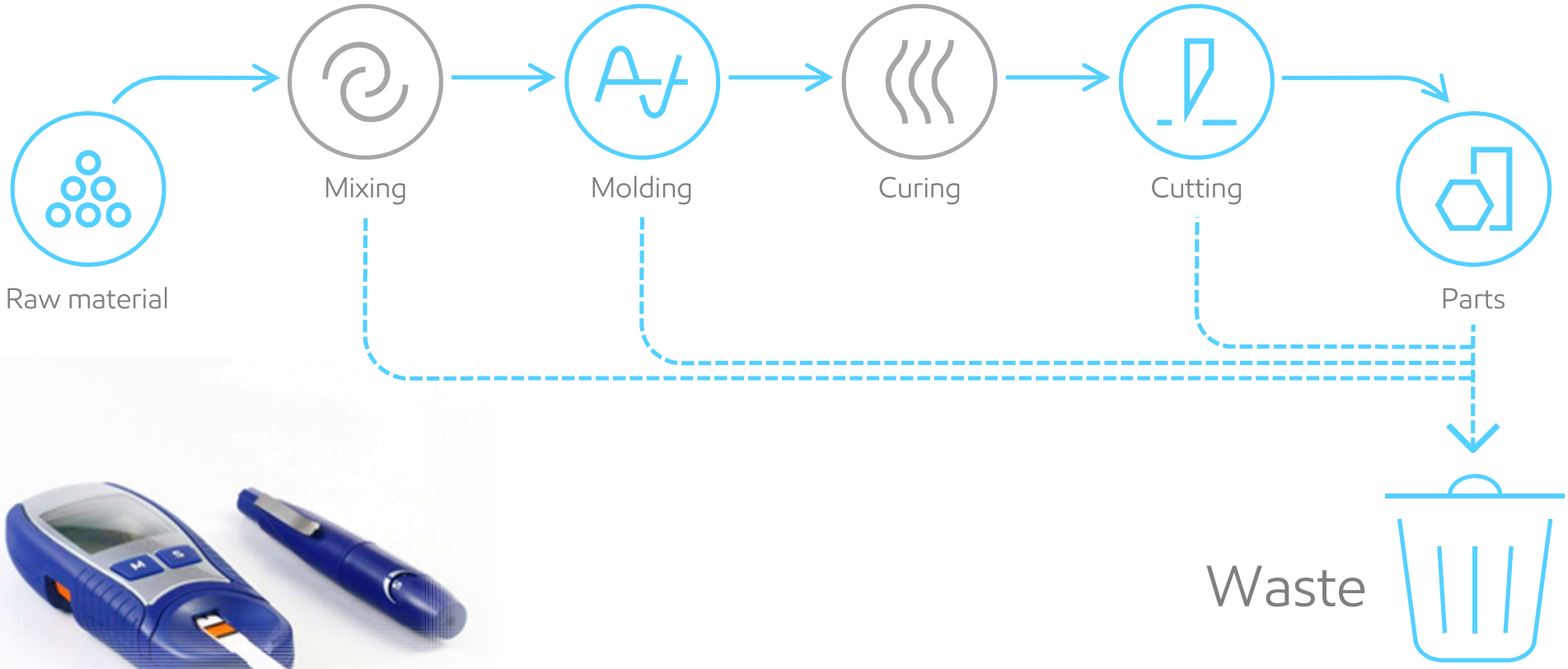
Certificate Compliance

USP Class VI
ISO 10993-1 Biocompatibility
GMP compliances
Drug master file maintained with FDA

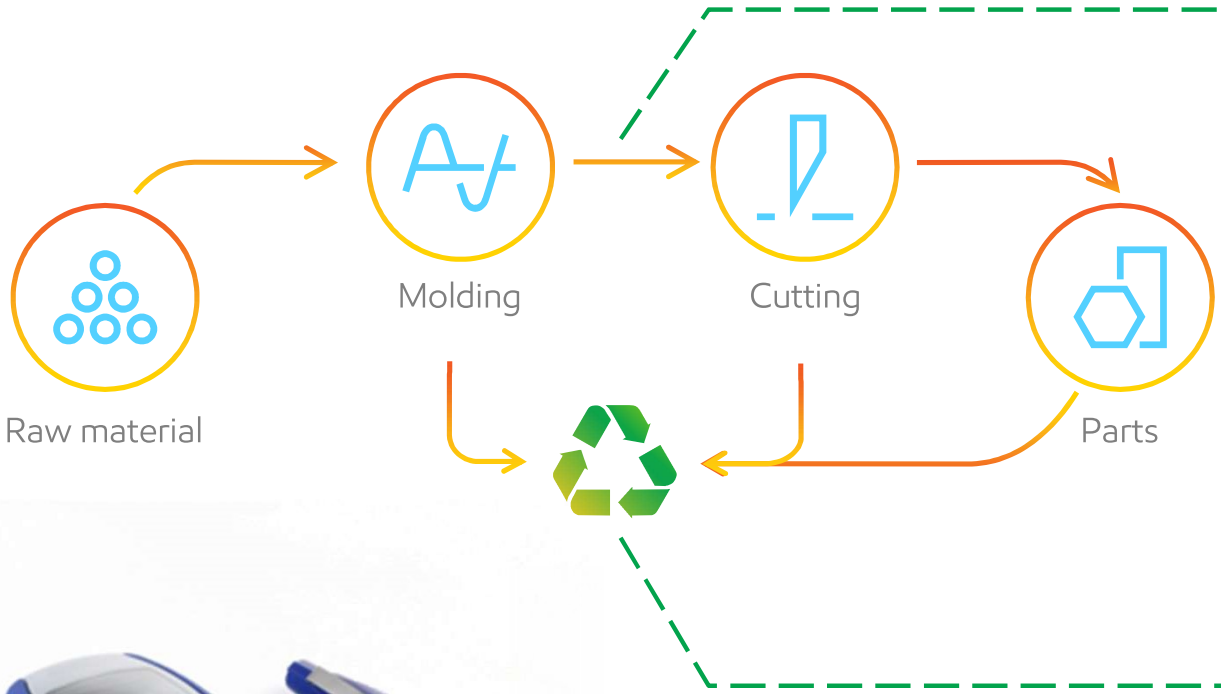
Reduced Waste | Thermoset rubber production



Reduced Waste | Thermoset rubber production



Reduced Waste | Santoprene™ TPV



up to 50%
less energy usage

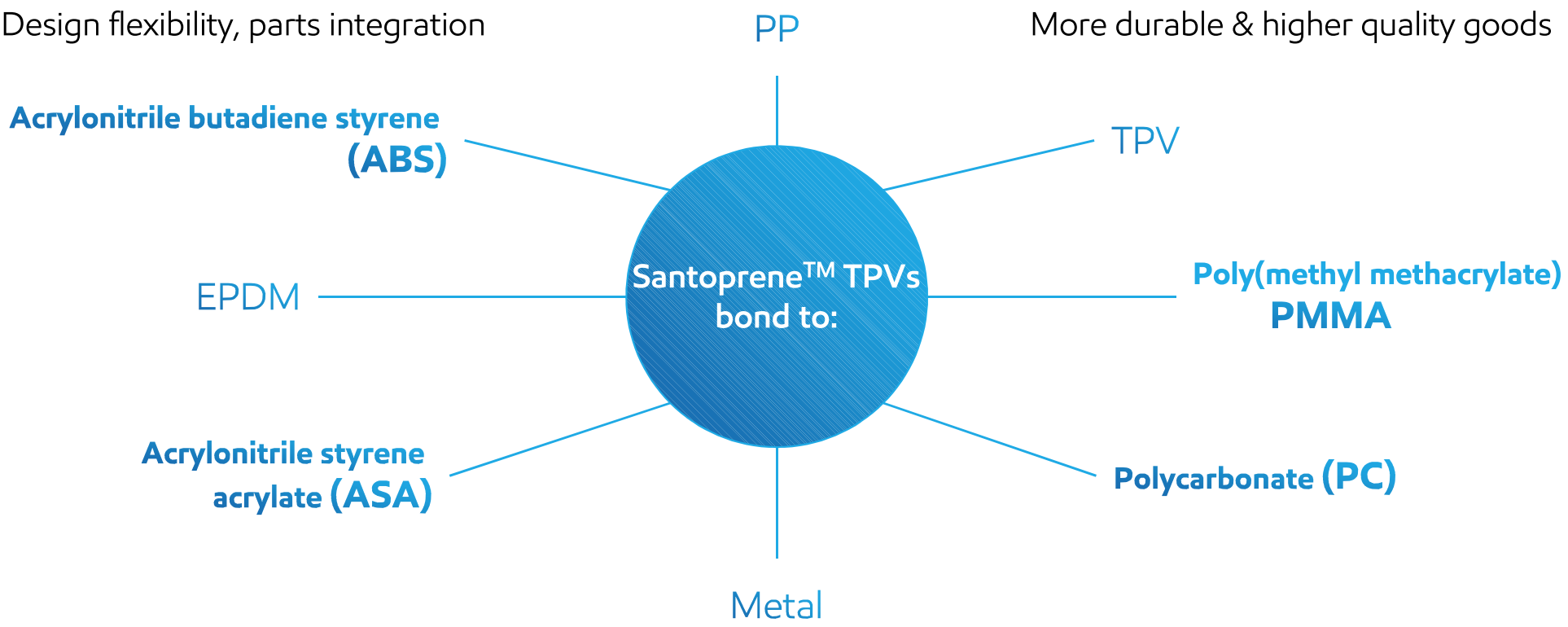
up to 30%*
less waste
In process recycling

*Source: ExxonMobil analysis

New Bonding capability of Santoprene™ TPV

Design flexibility, parts integration

More durable & higher quality goods

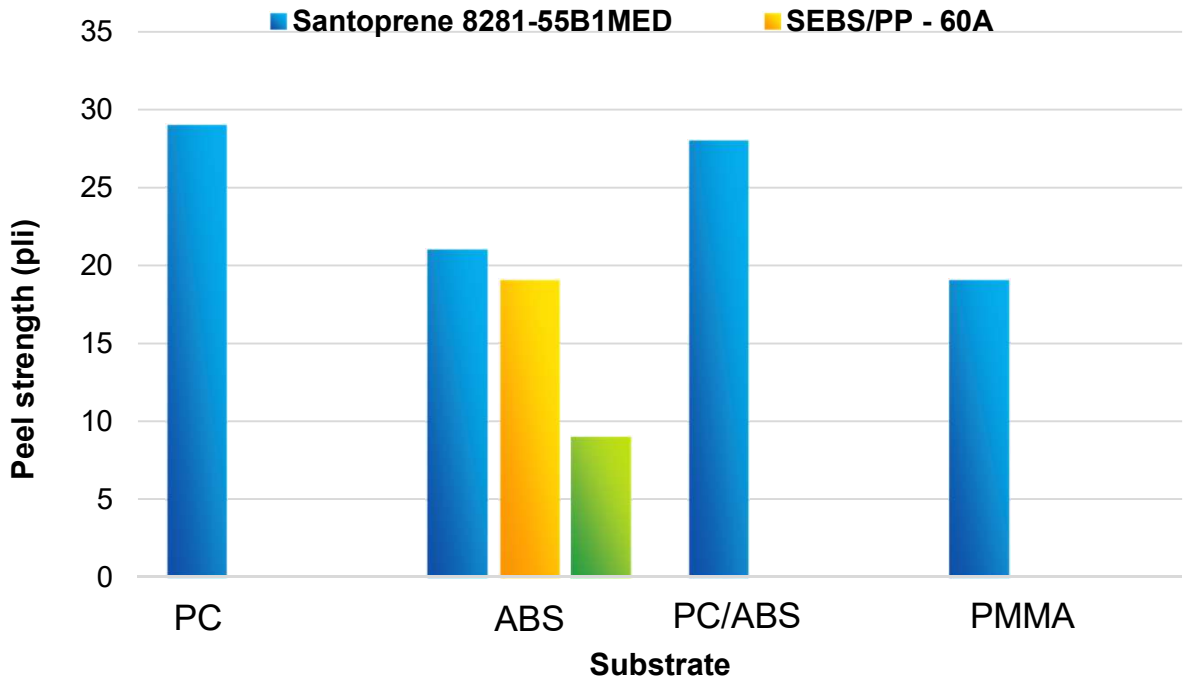


Improved customer use experience

Ease of manufacturing, lower processing costs

Adhesion to various Engineered Thermoplastic Substrates

Santoprene™ TPV B1MED series exhibits highest bond strength on many ETP substrates



T-bars tested per modified ASTM D1876. Adhesion samples were insert molded @ 257°C (495°F) at 3mm

Property retention after steam and gamma sterilization

Santoprene™ TPV B1MED series displays high retention of properties after gamma and steam sterilization study

	Santoprene 8281-55B1MED TPV % of original property		
Sterilization Method	Tensile strength	Elongation @ break	Hardness
Steam – 6min, 132°C, 5 cycles	93%	97%	93%
Gamma – 50kGY dose	102%	97%	98%

Testing conducted on injection molded plaques. Tensile testing as per ASTM D412 and hardness as per ASTM D2240

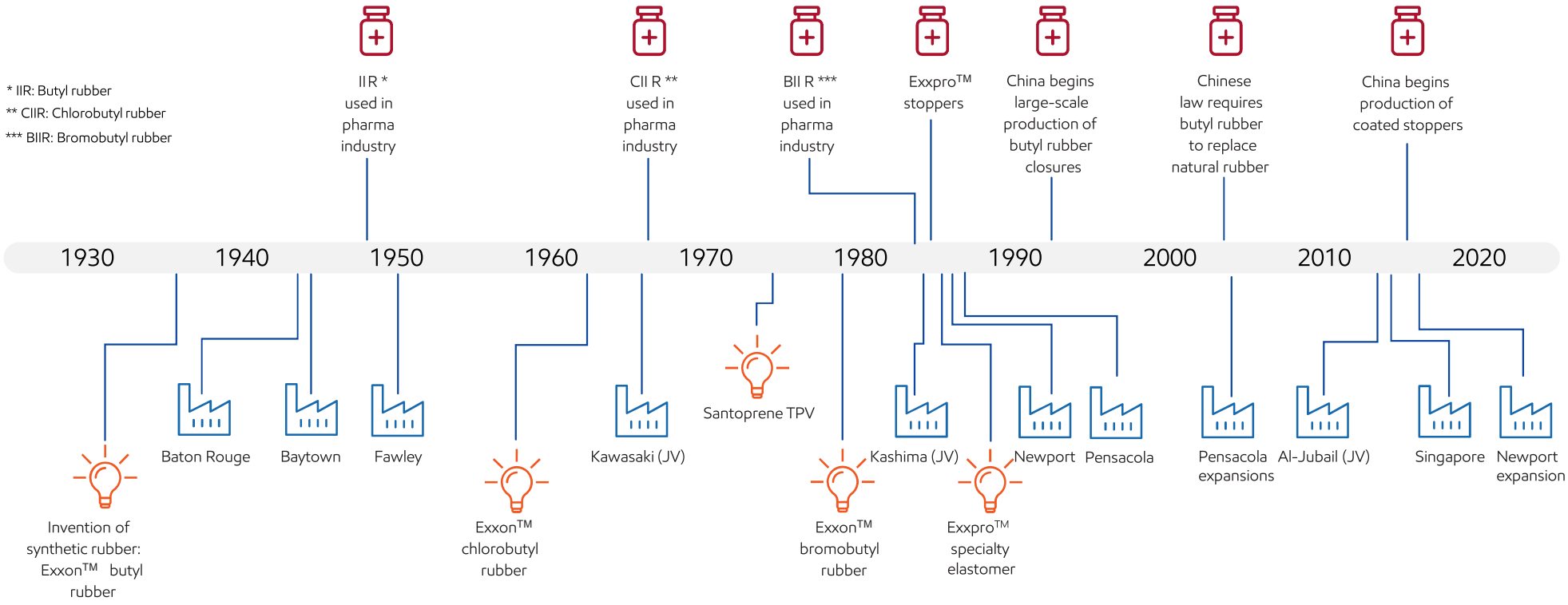
Property retention in various environments

Santoprene™ TPV B1MED series displays high retention of properties in various environments

		Santoprene 8281-55B1MED TPV % of original property		
Aging environment	Test method	Tensile strength	Elongation @ break	Hardness
Water – 168h, 23°C	ISO 1817	99%	102%	102%
10% IPA – 168h, 23°C	ISO 1817	125%	123%	100%
Bleach – 168h, 23°C	ISO 1817	97%	112%	104%
IRM 901 Oil – 168h, 23°C	ISO 1817	94%	102%	91%
Heat aging – 168h, 100°C	ISO 188	86%	100%	92%

Testing conducted on injection molded plaques. Tensile testing as per ASTM D412 and hardness as per ASTM D2240

ExxonMobil portfolio
Historical innovation in pharmaceuticals



Summary

Exxpro™ specialty elastomer provides additional benefits.

Santoprene™ thermoplastic vulcanizate (TPV) is ideal candidate for medical device applications such as tubing, seals and gaskets.

Thank you

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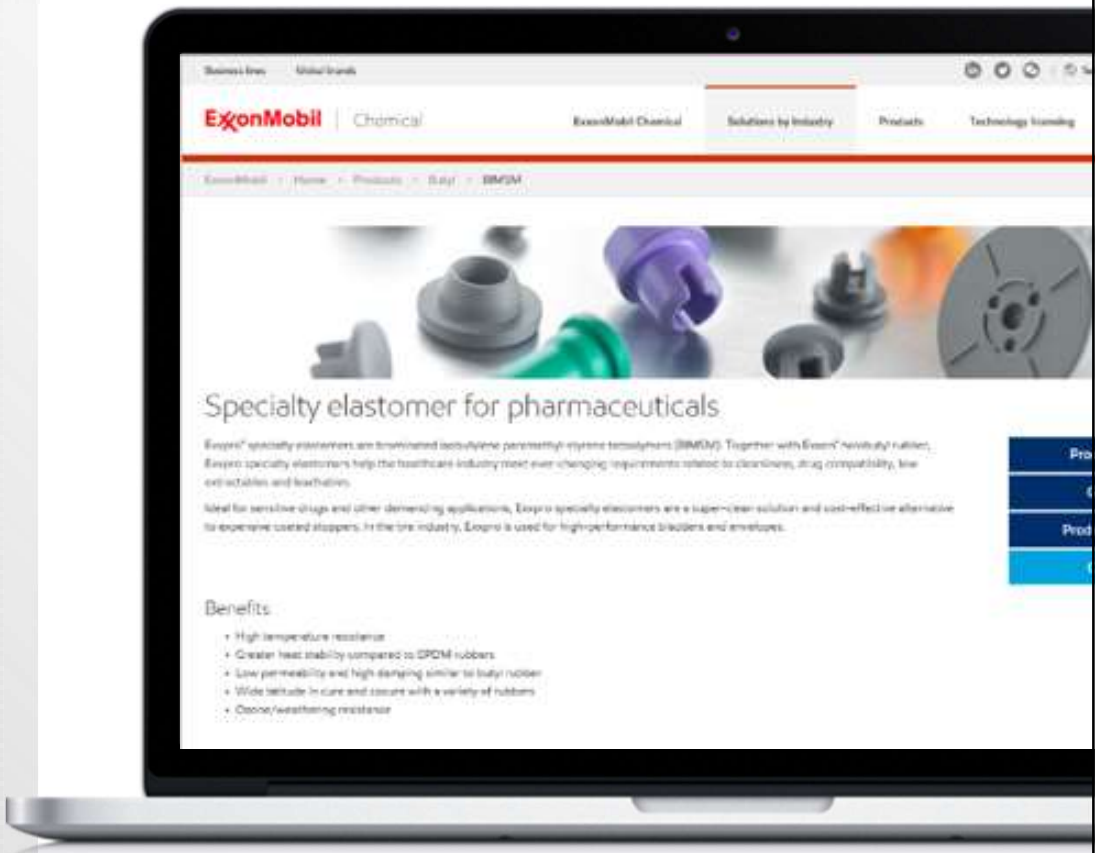

[Pharmaceutical stoppers & seals]

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