

IOM3 Webinar
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Elastomer solutions for pharmaceutical packaging and medical devices

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Energy lives here™

ExxonMobil



NEEDS

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

SOLUTIONS

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

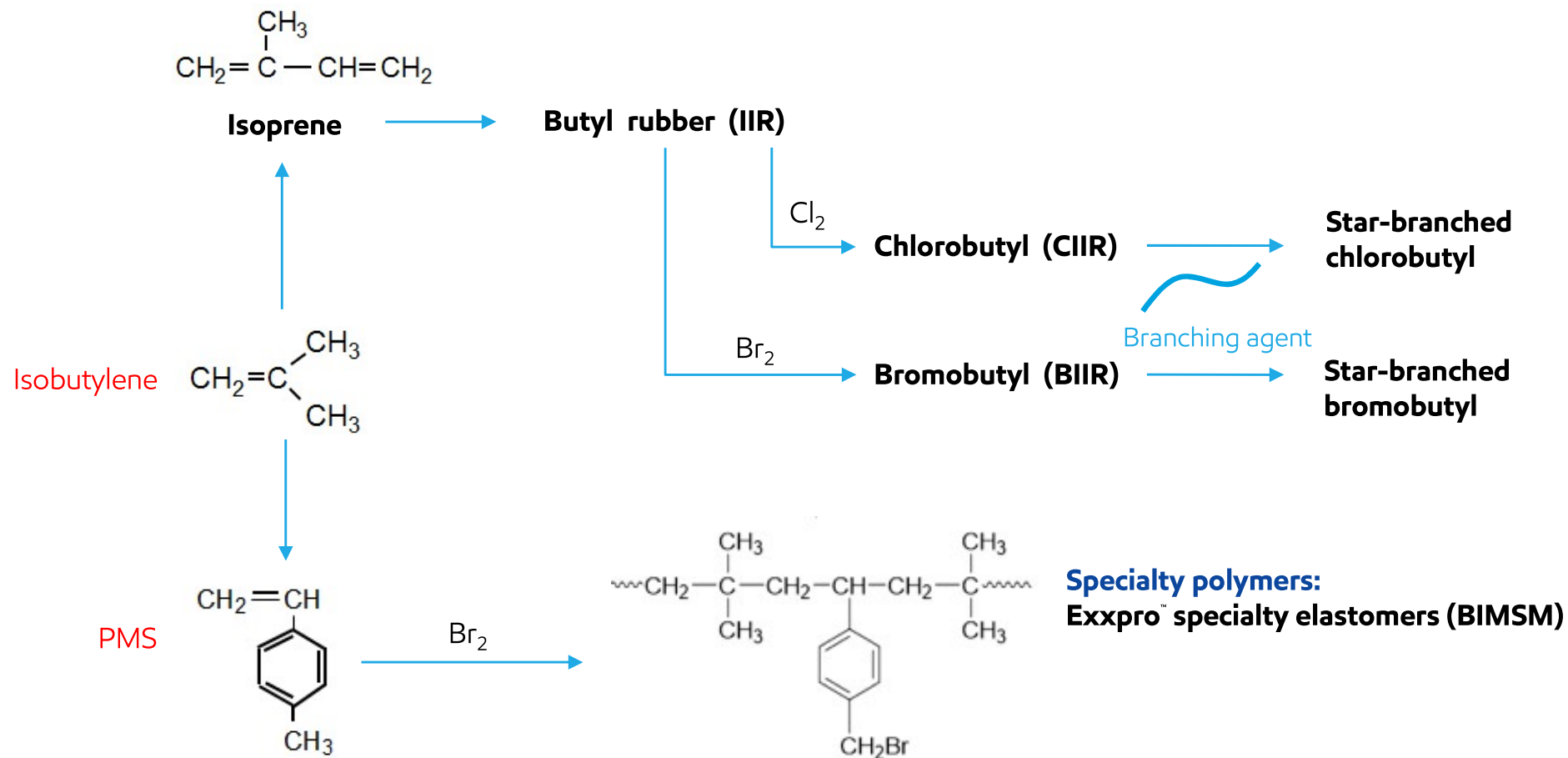
Why use butyl rubber?

- 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

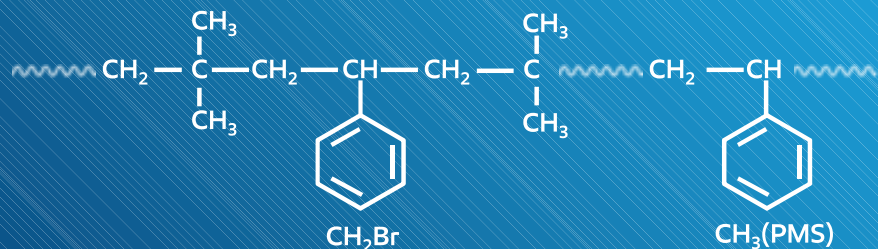


Butyl polymer family



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

Lower permeability

Pendant pMS ring

Gamma Sterilization stability

Fully saturated backbone
(no double bond)

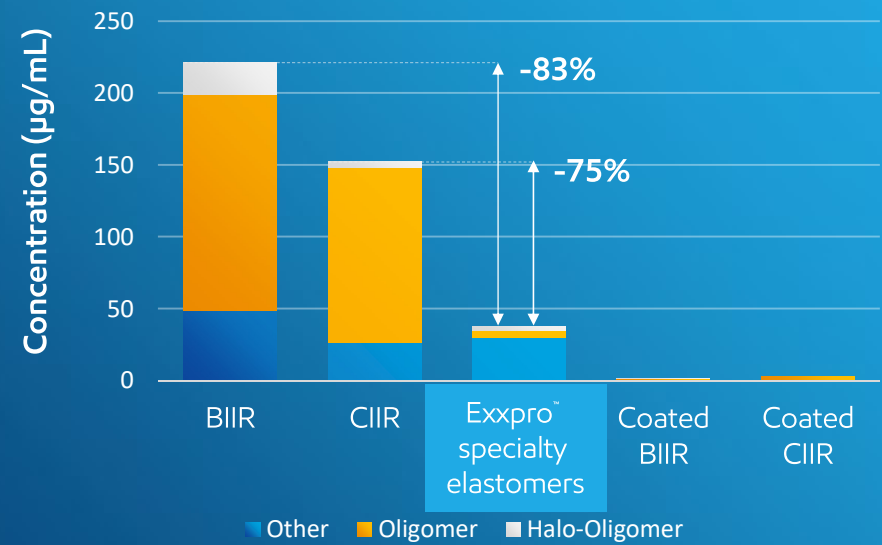
Better resistance to ozone, heat, chemicals, and weathering

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 (additives and curatives) and is not introduced by the polymer (BIIR, CIIR, Exxpro[™] specialty elastomers)

Chart data source: ExxonMobil Chemical

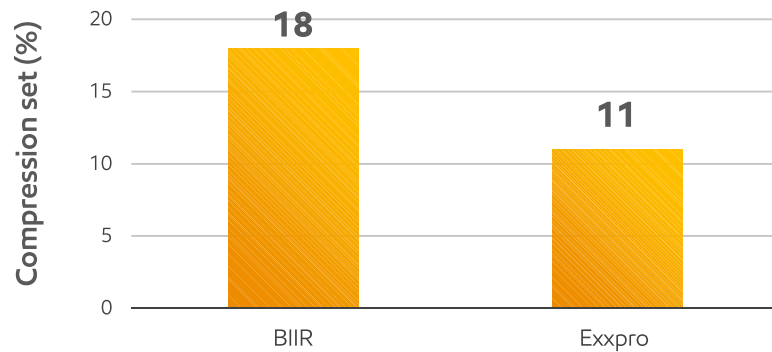
Cleanliness through sealing and low permeability

35%

Improved
compression set

15%

Reduced
permeability



* 25% deflection for 22 hrs @ 70°C

Chart data source: ExxonMobil Chemical

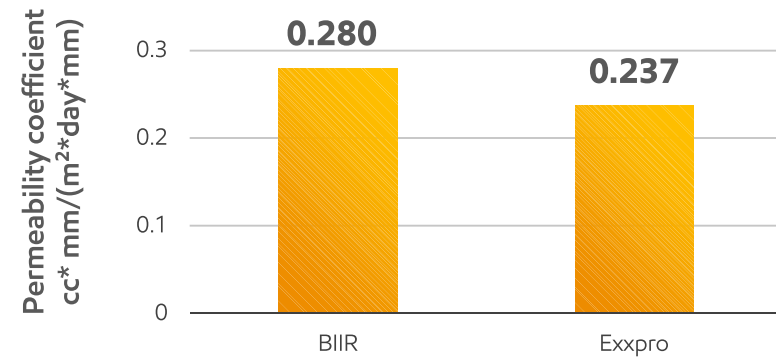
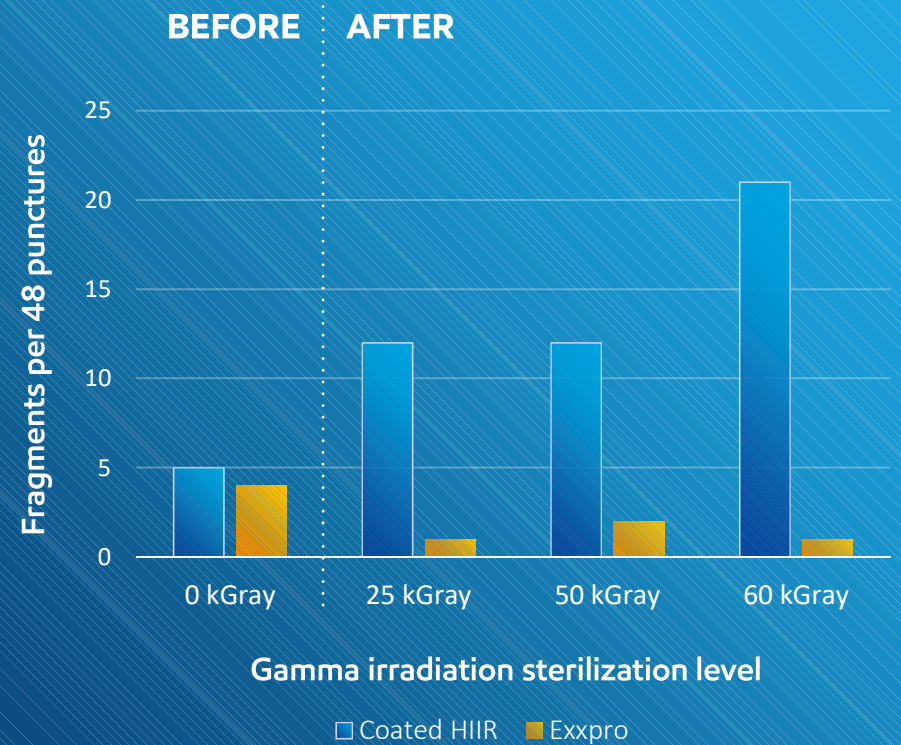


Chart data source: ExxonMobil Chemical

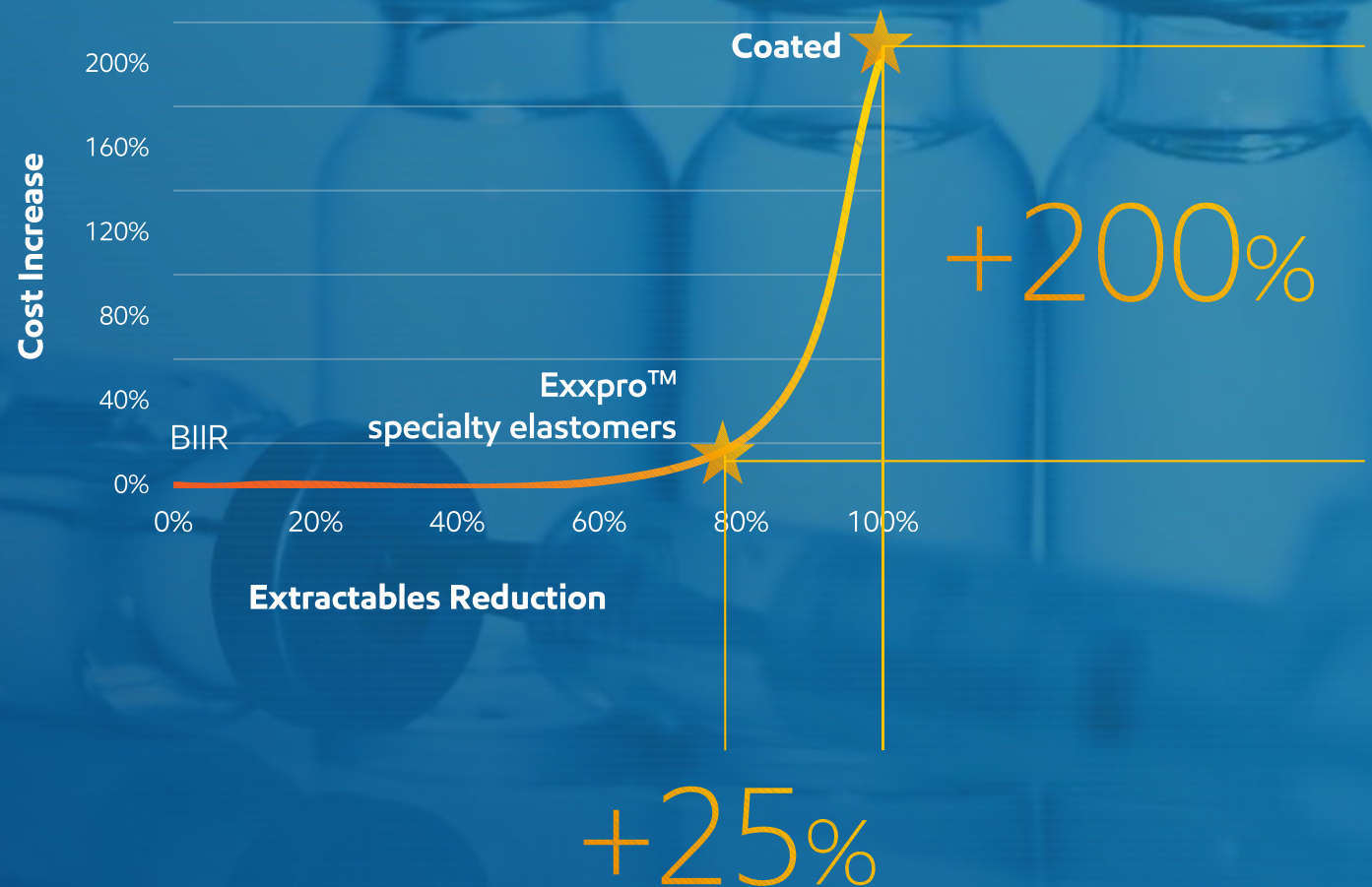
Cleanliness challenged by gamma irradiation



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



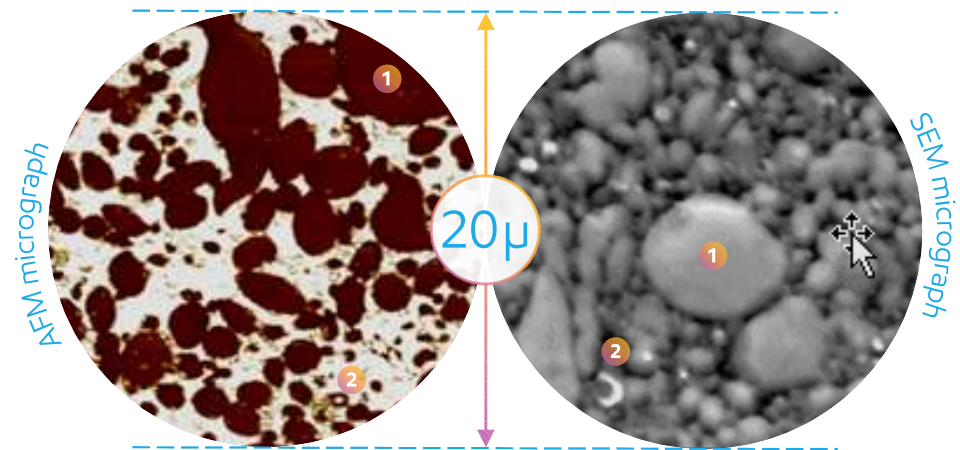


Elastomers
for medical devices:
Santoprene™ TPV

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

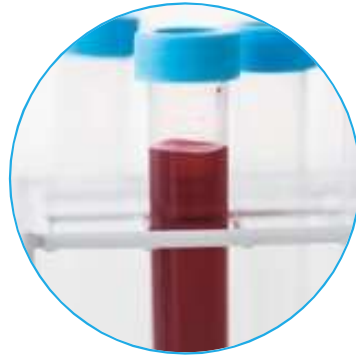
Santoprene™ TPV in medical and healthcare applications



Peristaltic pump tubing



Syringe plunger tips



Blood tube gaskets, caps, and closures



Strain relief handheld device



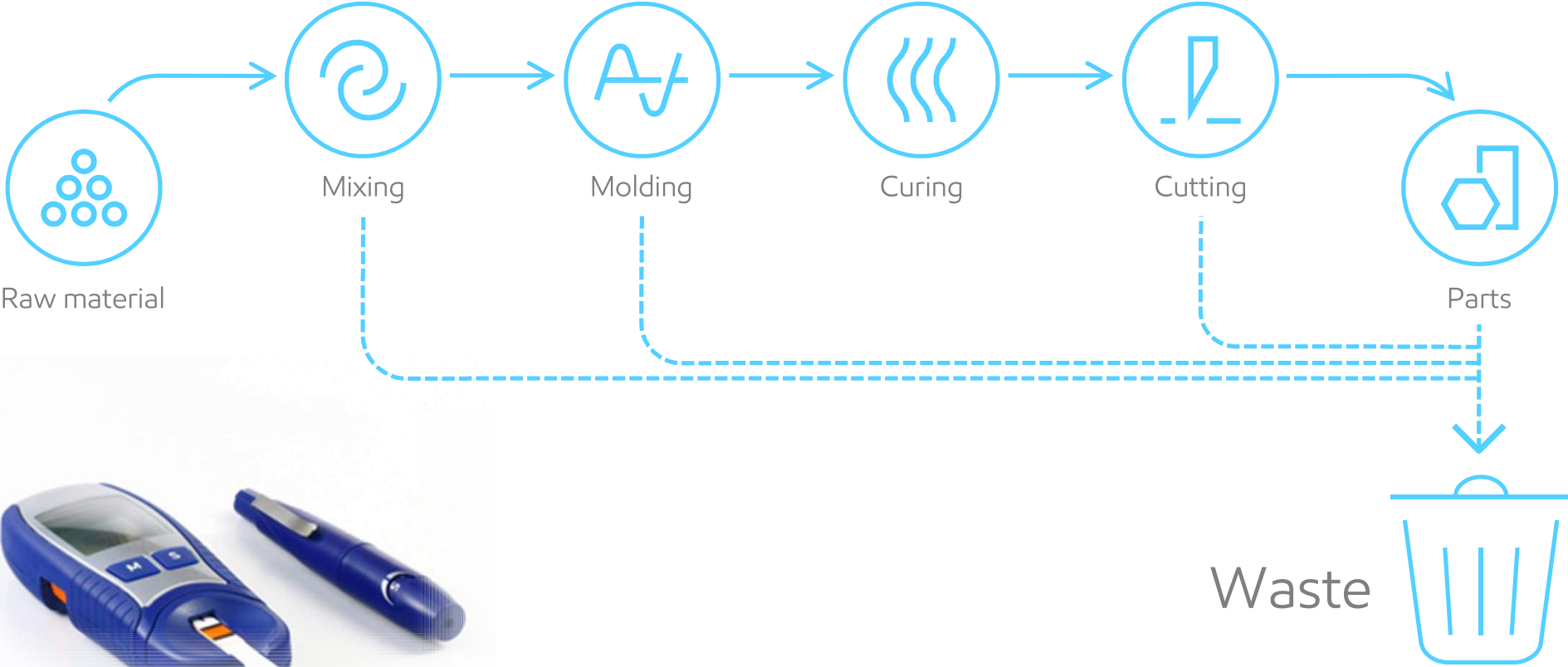
And more ...

Innovative elastomers for cost effective medical solutions

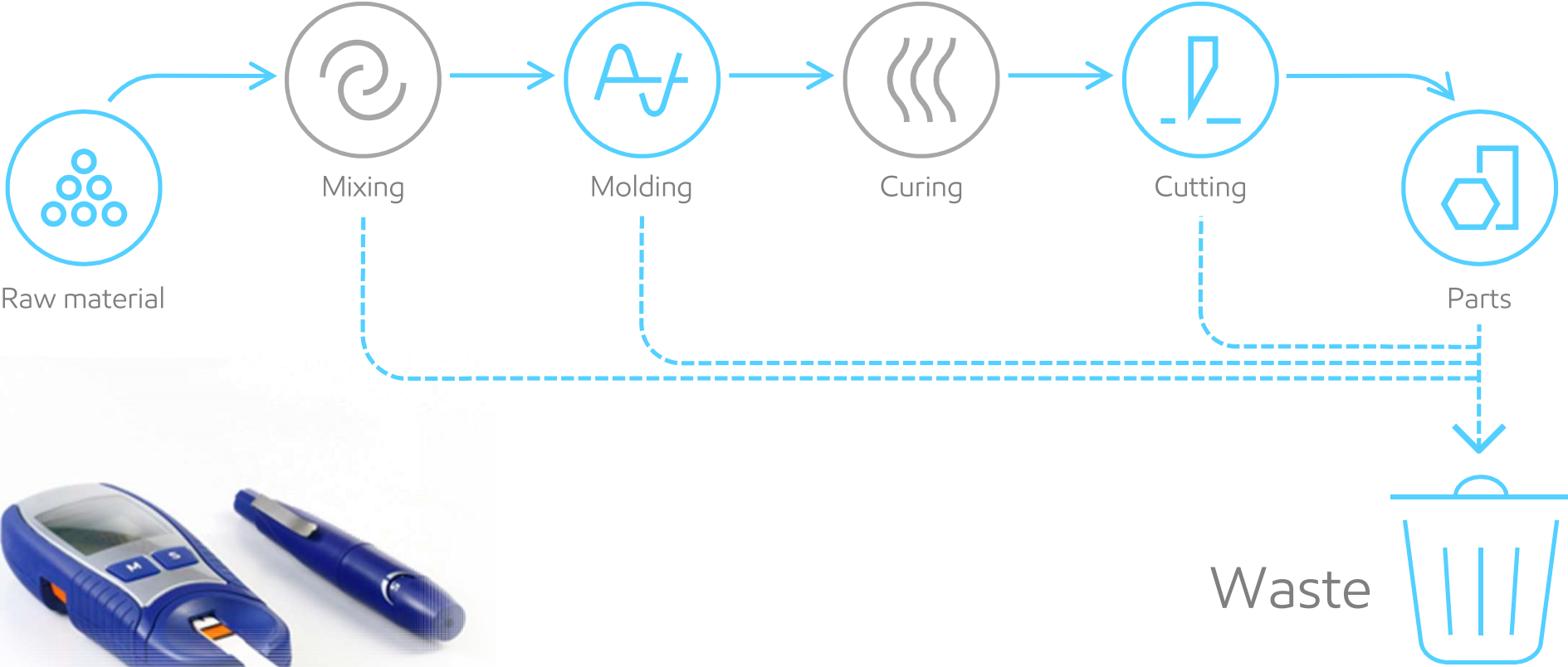
Santoprene™ TPV: What it brings to your product?



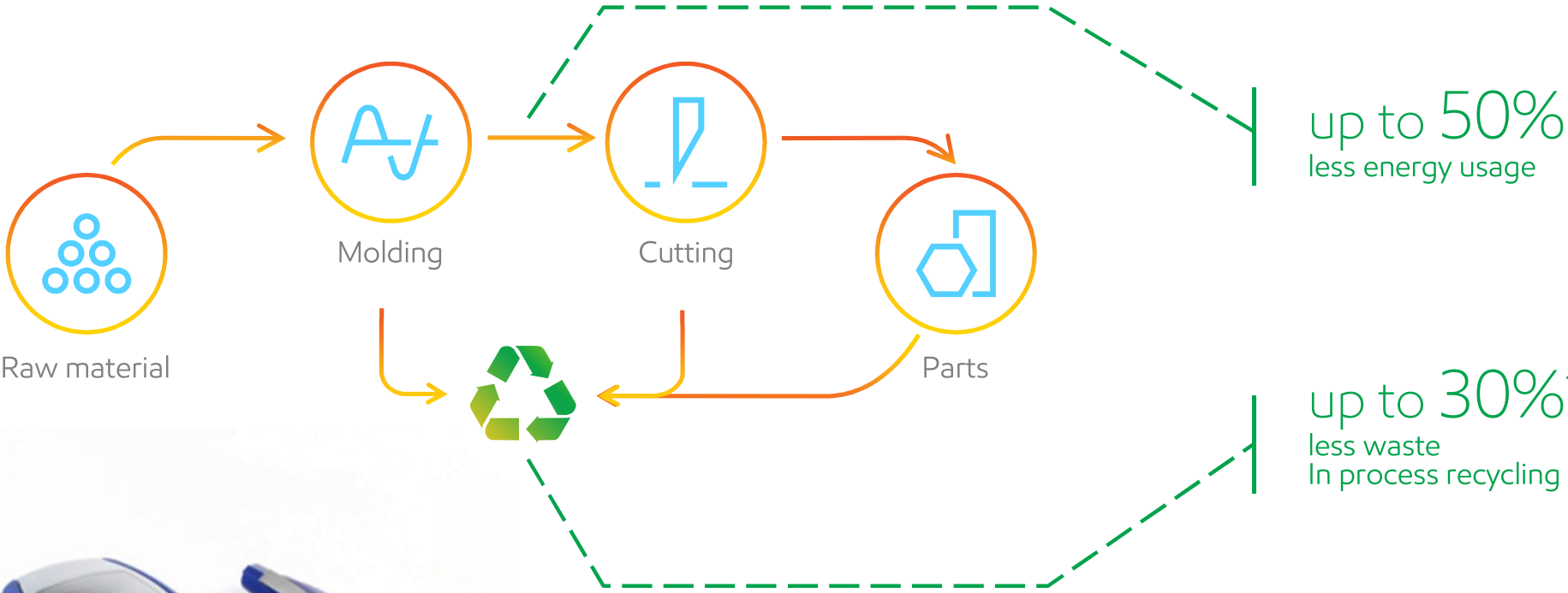
Reduced Waste | Thermoset rubber production



Reduced Waste | Thermoset rubber production



Reduced Waste | Santoprene™ TPV



*Source: ExxonMobil analysis

New Bonding capability of Santoprene™ TPV

Design flexibility, parts integration

More durable & higher quality goods

Acrylonitrile butadiene styrene (ABS)

PP

TPV

EPDM

Santoprene™ TPVs
bond to:

Poly(methyl methacrylate) PMMA

Acrylonitrile styrene acrylate (ASA)

Polycarbonate (PC)

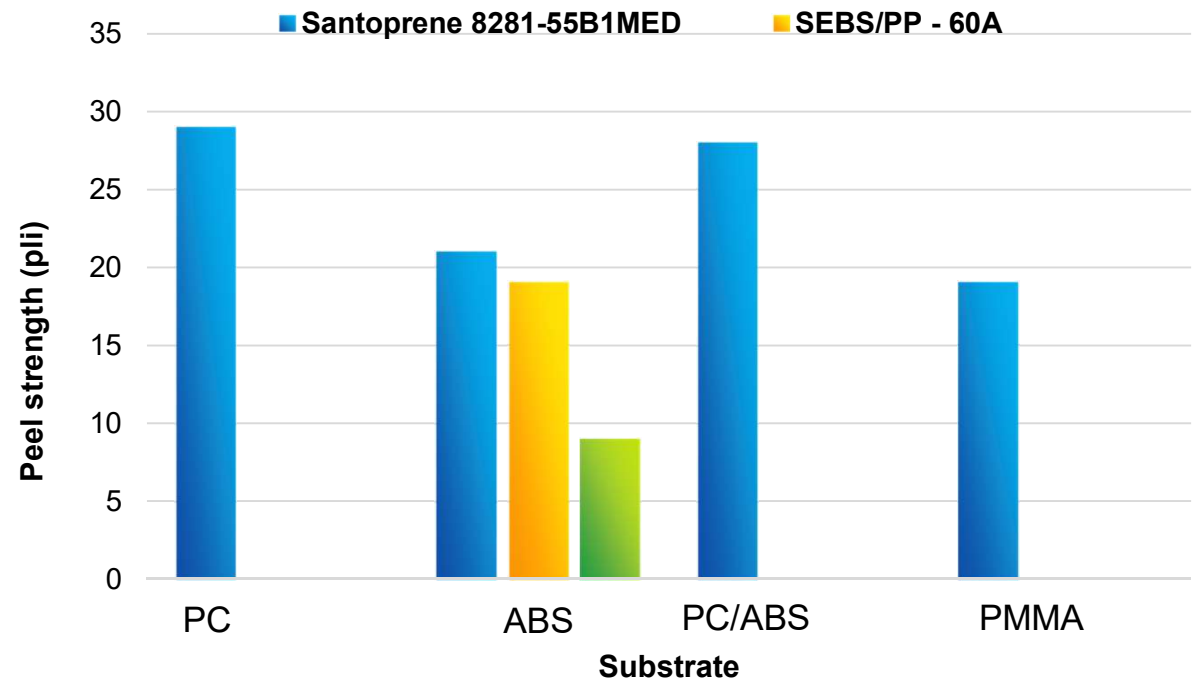
Metal

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**

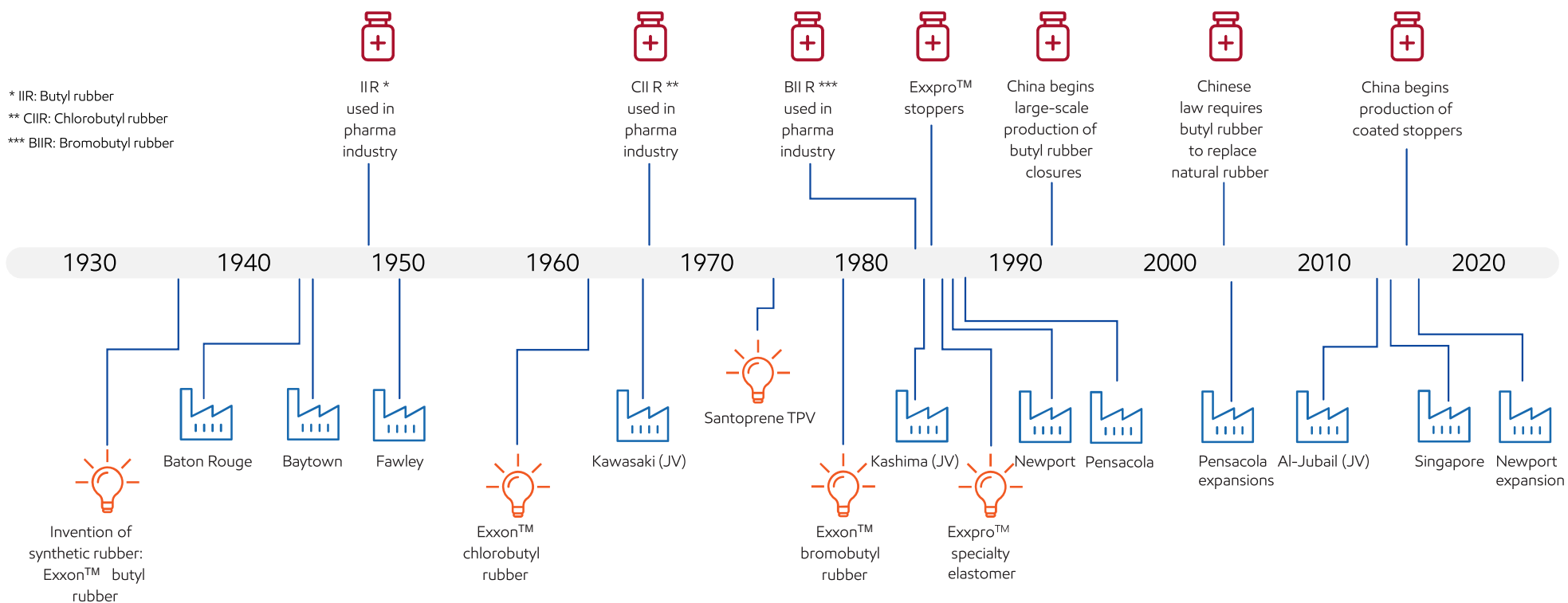
Santoprene 8281-55B1MED TPV % of original property

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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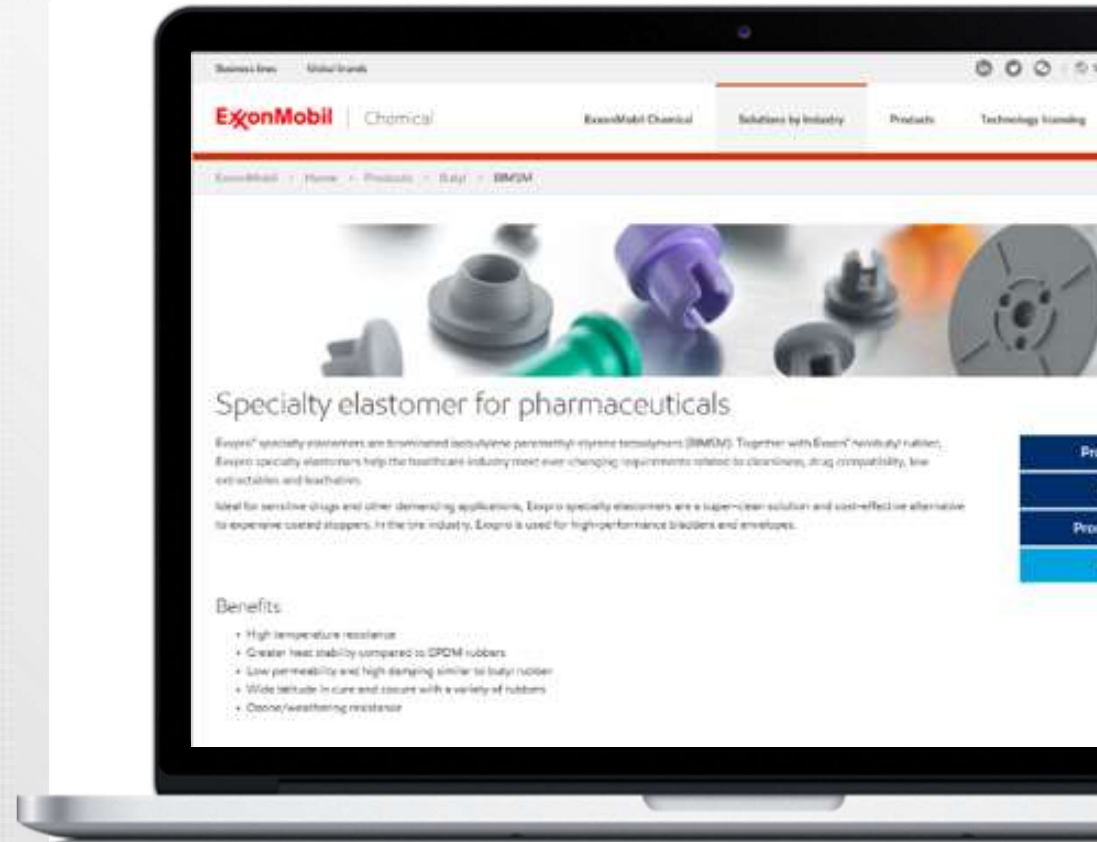
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