

DSM Biomedical

私たちのビジョン

持続可能な科学を通じて世界の医療を解決する

Our Vision

Solving our world's healthcare needs through sustainable science

NUTRITION • HEALTH • SUSTAINABLE LIVING



DSM

BRIGHT SCIENCE. BRIGHTER LIVING.

毎秒1個、世界中の誰かが、DSMの医療用材料を
含んだ医療機器使用します。

Every second, a patient receives a medical
device containing a DSM Biomedical
material

毎年世界中で何百万人もの患者が恩恵を受けています

Millions of patients benefiting
annually worldwide



DSM Biomedicalとは

人類の寿命は年々伸びています。しかし、どれだけ洗練された設備も老朽化していくように、人間の身体も老化し、治療が必要となる時がきます。高齢化に対応した需要が急激に高まる時代がまもなくやってくるでしょう。より多くの人が活動的な人生を過ごすための体の酷使、あるいは逆に運動不足になったり、偏った食生活や、糖尿病の蔓延など、さまざまな健康問題が予想されます。

バイオメディカル (Biomedical) ~ 機器の質を向上させ、患者ケアを向上させる

DSMの医療用材料の強みは、マテリアルサイエンス (とりわけポリマー) およびライフサイエンス分野両方の専門を兼ね備えているという特徴にあります。その結果生まれたものが、非常に長い期間にわたって体内での使用が可能となったバイオメディカル製品です。

DSMの医療用材料は、超強力縫合糸、人工心臓、ペースメーカー、人工関節 (肩、大腿骨、膝)、コンタクトレンズに至るまで、医療機器に幅広く利用されています。さらに、革新的なドラッグデリバリーシステム、インプラントの埋め込みを容易にするコーティングなども挙げられます。DSMは、再生医療をはじめとした、生活を一変させる先進的な治療へ目を向けています。DSMは、今後も医療機器・製薬関連企業の方々が安全でよりよい患者ケアを提供できるよう、努めていきたいと考えています。



DSM Biomedicalの医療用材料紹介

ポリウレタン、超高分子ポリエチレンファイバー、親水性コーティング



ポリウレタン/TPU (Bionate®, CarboSil®, PurSil®, BioSpan®)

弊社ポリウレタンは耐久性が格別に優れており、インプラントの寿命を延ばすことができます。さらに、生体適応性と生物学的安定性が証明された素材でもあり、体内で長期間使用した場合の安全性が保証されています。FDAには7つのMaster fileがある。

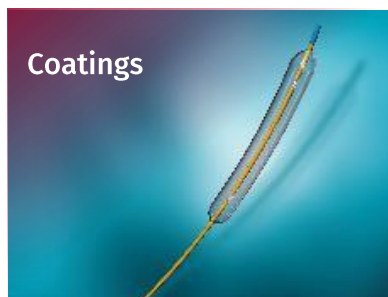
実績: 30年以上の臨床実績。心臓弁、脳や心臓ペースメーカー用リードケーブル1400万個以上に材料提供。持続血糖測定器 (CGM) には年間1000万個以上に材料提供。



超高分子ポリエチレンファイバー UHMWPE Fiber/Dyneema Purity®

世界で最も強力な繊維、Dyneema Purity®は、低プロファイル、やわらかさ、摩擦耐性という特長によって、複雑な低侵襲手術での使用に理想的な素材です。

実績: 15年以上の整形・心臓血管領域で臨床実績。整形分野では標準的な材料 (Gold Standard) になります。



親水性コーティング

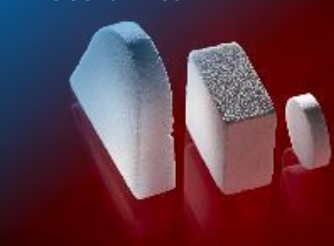
カテーテル (特に尿道カテーテル)、ガイドワイヤー、その他外科用機器への弊社親水性コーティングの使用が増えてきています。潤滑性に非常に優れていることで、装置を体内に挿入しやすくなります。

実績: 年間7500万個以上の医療機器に使用。

DSM Biomedicalの医療用材料紹介

生体機能性セラミック、コラーゲン、細胞外組織

Bioceramics



生体機能性セラミックス

先進的な人工骨を設計・開発・製造しています。形状は粉末、ブロック、パテ状など。コラーゲンやファイバーグラスなどを混ぜ、優れた特徴を有しています。

実績: 年間15万個以上の人工骨を製造。整形分野でのトップサプライヤー

Collagen

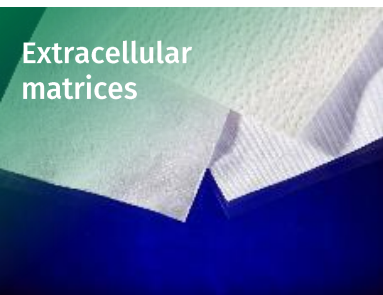


コラーゲン

業界最高クラスの弊社医療用コラーゲンは安全かつ取り扱い性にすぐれ、組織修復、止血デバイスや人工骨に使用されます。心臓血管、歯科、整形および創傷が主な応用分野です。

実績: 25年以上の臨床実績。4000万人以上に弊社コラーゲンが埋め込まれている。テルモ社のAngio-Seal™は弊社(元Kensey Nash社)が20年以上前に設計・開発。

Extracellular matrices



細胞外組織 (ECM)

DSM OPTRIX™製法により、自然本来の軟部組織を保持しつつ、抗原性物質を除くことができます。スポーツ医学、形成、歯科、外科が主な応用分野です。

実績: 10年以上の臨床実績。25本の論文で報告されている。

DSM Biomedicalの医療用材料紹介

ドラッグデリバリー、ポリマー成型品、細胞濃縮装置

Drug delivery

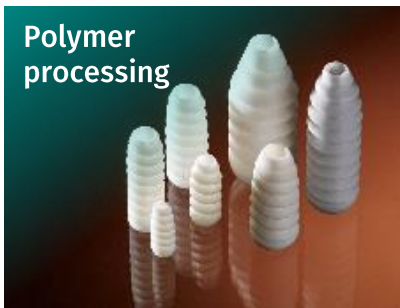


ドラッグデリバリー用ポリマー

埋め込み式長期徐放性ドラッグデリバリーに適した生分解性ポリエステルアミド (PEA) および非分解性ポリウレタン (TPU) を展開しています。

実績: ヨーロッパで販売されているドラッグイレーティングステント (Svelte社) には弊社PEAが使用されている。Aerie Pharmaceuticals 社はPEAを用いた加齢黄斑変性治療用インプラントを開発中。避妊リングには脂肪族性TPUが使用されている。

Polymer processing



ポリマー成型品

整形分野 (特にスポーツ医学) にて低侵襲および加速治療用ポリマー加工品を提供しています。

実績: 30年以上の臨床実績。年間50万個以上のポリマー成型品を製造。

Cell concentration



細胞濃縮装置 (PRP/BMC)

血液や骨髄液中の細胞 (例えば血小板) を3分以内に、7倍程度に濃縮することができる、世界最高クラスの持ち運び可能装置を製造している。

実績: FDA 510K、CEマークに続き、PMDAの承認を2019年取得。

PRPシステム 承認番号: 23100BZI00005000

DSM Biomedical

Our Vision

Solving our world's healthcare needs
through sustainable science

A division of Royal DSM

Exton, PA
Geleen, The Netherlands
Berkeley, CA
Greenville, NC
Shanghai, China
Tokyo, Japan



Why partner with DSM?

Unrivalled experts in biomaterials, committed partners driving sustainable innovation in healthcare

Experienced

30+ years of experience working with the world's leading device and pharmaceutical companies

Strategic

Strategic partner with an approach driven not only by market dynamics, but the unique needs of every customer

Breadth

Unparalleled breadth of product portfolios, proprietary manufacturing & processing capabilities, world-class IP, and extensive regulatory experience & expertise

Solutions

Solutions and support recognized for quality, reliability and performance in multiple markets

Innovation

Over 1,800 DSM scientists and engineers working on technology solutions every day

Invested

DSM invests over \$500 million in research annually

Purpose-led, Performance-driven and Market-proven

Global presence

~450 employees



Quality Control & Assurance

DSM Biomedical is committed to developing, manufacturing and delivering high quality, innovative, and cost-effective medical products with a focus on continuous improvement and customer satisfaction through compliance with the applicable regulatory requirements and maintenance of an effective Quality Management System.

- State-of-the-art facilities include dedicated application labs and world-class analytical departments
- cGMP compliant manufacturing facilities
- Compliance with regulatory requirements
 - FDA registered
 - ISO 13485: 2016 Certified
 - MDSAP Certified
 - EU MDR Compliant Quality System
- Trusted partner: Regularly audited by both customers and governing bodies with positive outcomes



The infographic features a header image of three business professionals in a meeting. Below the image is the DSM logo with the tagline "BRIGHT SCIENCE. BRIGHTER LIVING.™". The main content is organized into two columns of icons, each with a title and a commitment statement. The icons represent: Customer needs (two people with arrows), Consistency (three arrows pointing to a target), Vigilance (an eye), Environment (a hand cleaning a surface), Accountability (a person with a checkmark), and Traceability (a barcode with a magnifying glass). At the bottom, the text "NUTRITION • HEALTH • SUSTAINABLE LIVING" is displayed.

My Customer Commitments

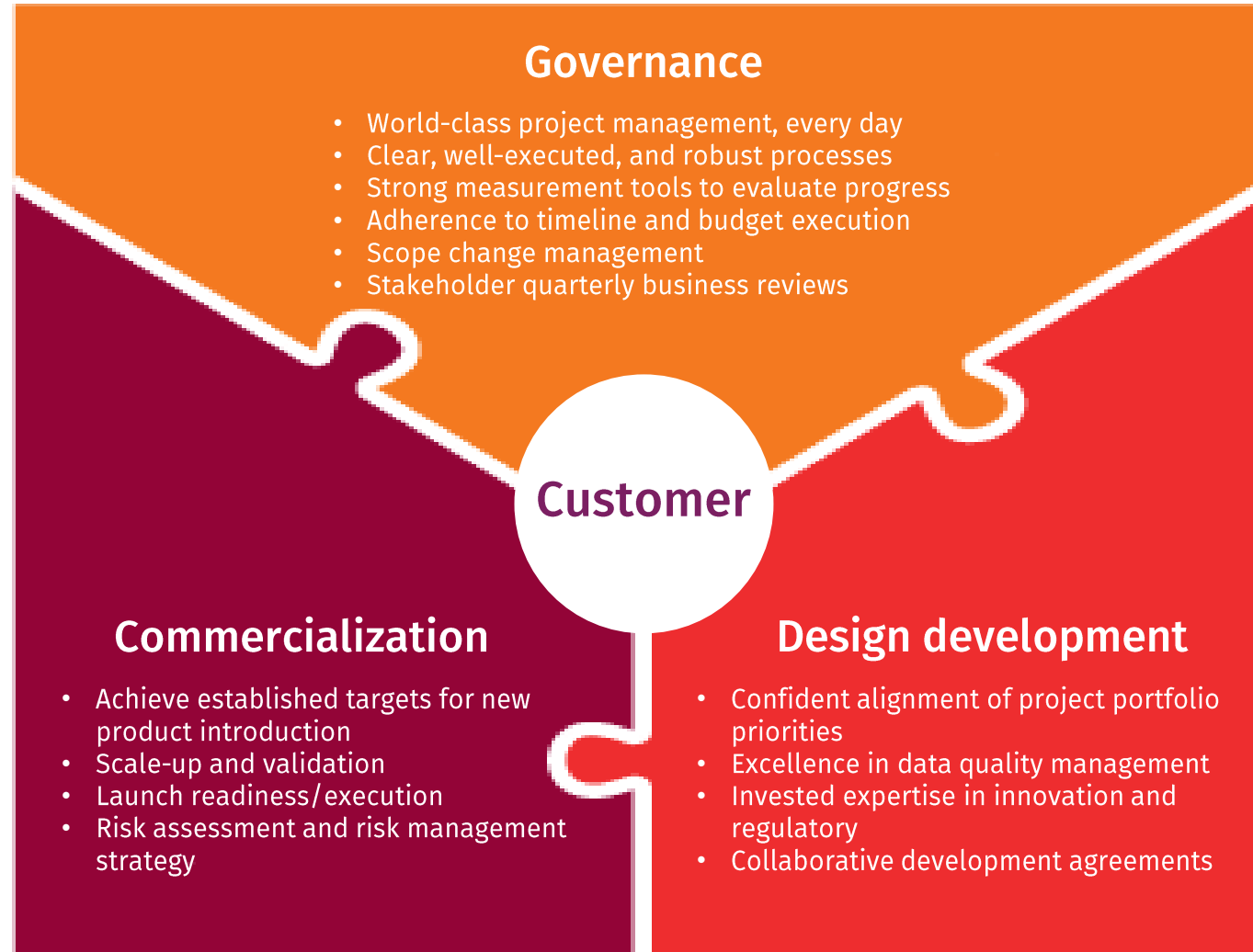
DSM
BRIGHT SCIENCE. BRIGHTER LIVING.™

 Customer needs I know and respond to customers' needs	 Consistency I will safeguard process and product consistency
 Vigilance I will be vigilant on quality and always react immediately if needed	 Environment I will keep a clean, safe, and organized environment
 Accountability I will take my responsibility for Quality	 Traceability I will ensure traceability of my work

NUTRITION • HEALTH • SUSTAINABLE LIVING

Program management at DSM

A strong foundation for commercialization



DSM Materials Science Center is world class in material science

DSM enterprise-wide shared resource

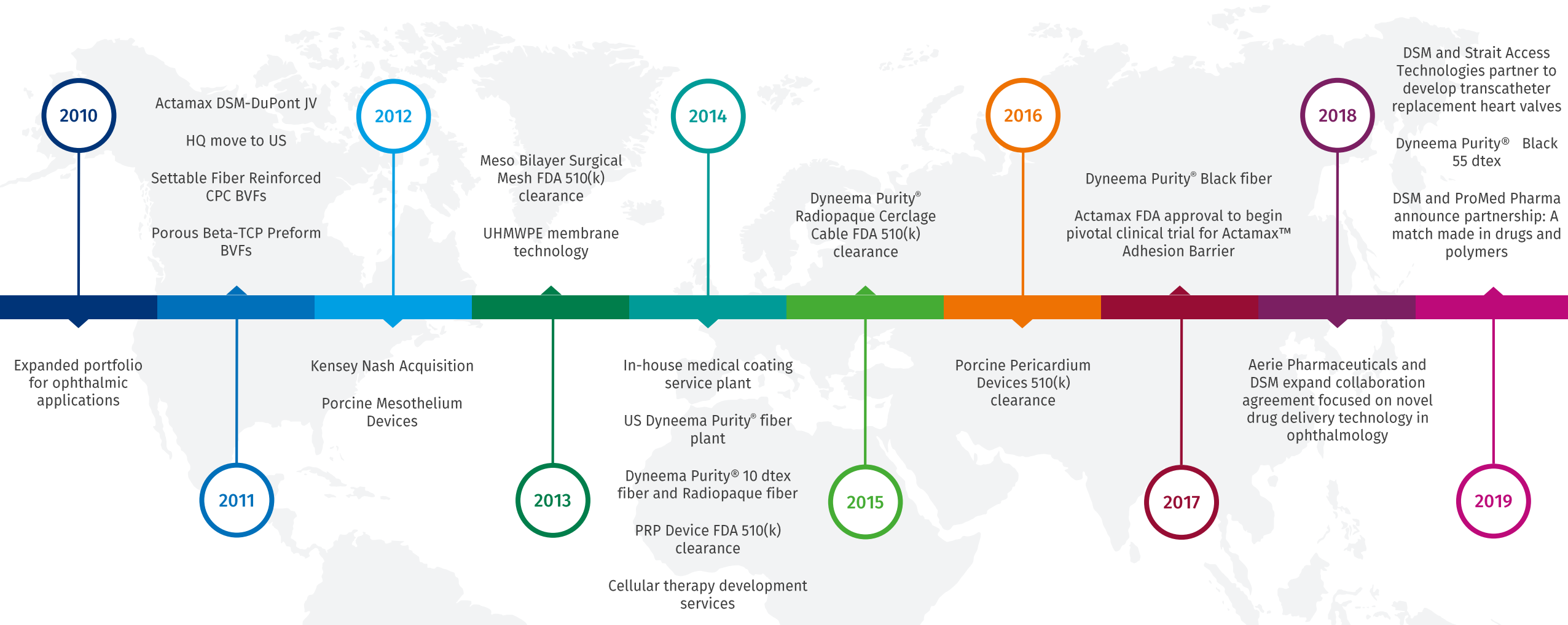
- Research
- Application
- Product and business development
- Manufacturing optimization
- Approximately 300 scientists



Shanghai, China

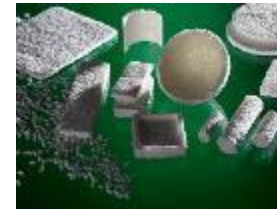
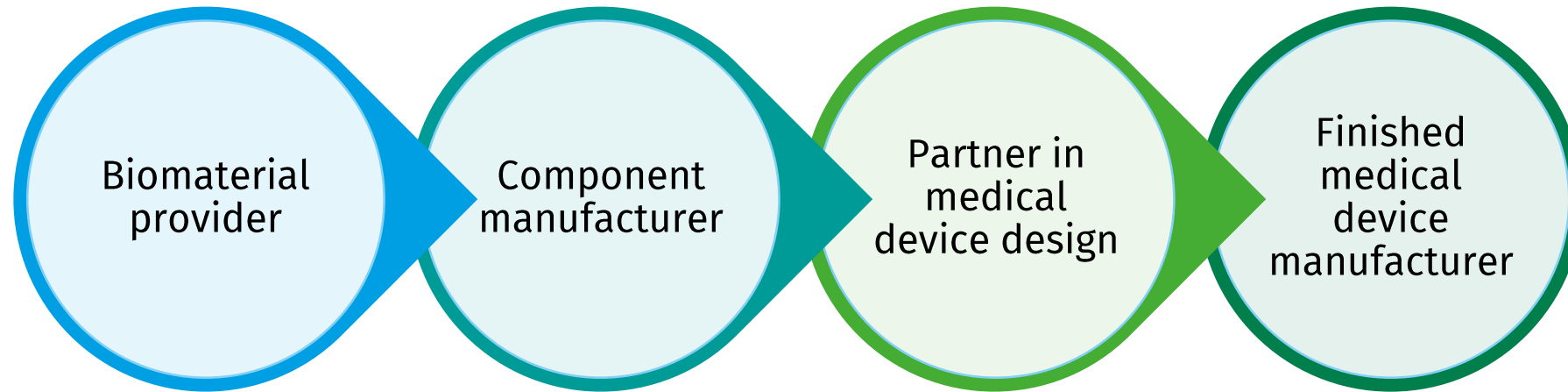


Last 10 years of biomaterial innovation and partnering



DSM solutions at all levels of the value chain

From biomaterials to finished devices



Developing with our partners is our way to innovate

Engaging in long-term innovation roadmaps

- We team up with your innovation group to discuss long-term needs
- Based on those insights, we can deliver the innovations you need in time, at the right cost and with high quality
- We design our products based on science and with sustainability in mind
- We support the performance of our solutions with solid data (including pre-clinical and where needed, clinical data). This can also be done in a partnership sharing the risks and value.
- We invest in proprietary biomaterial platform solutions which can be tuned to your needs



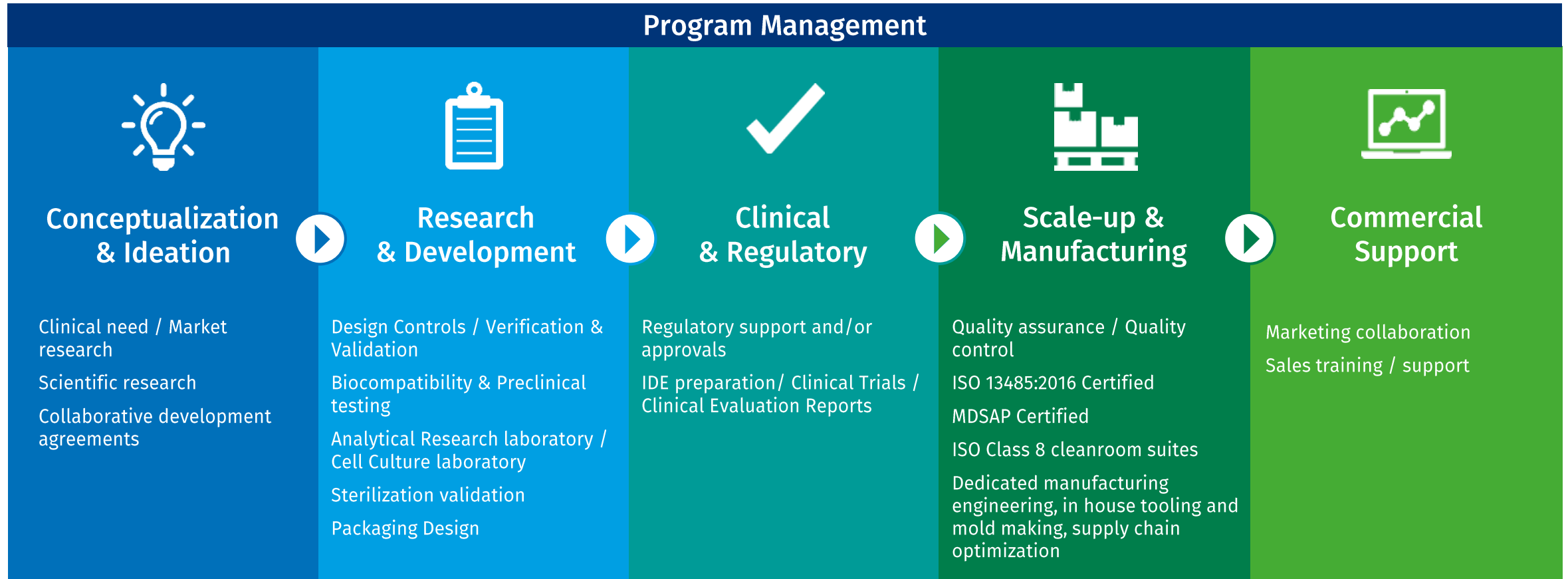
Our new products are designed with sustainability in mind



Developing game-changing science across three defining societal areas

	Improve	Enable	Advocate
Nutrition & health	<p>Reducing occupational safety incidents</p> <p>Promoting health & well-being in our own workforce</p>	<p>Enabling sustainable & healthy living for all</p>	<p>Partnerships to address sustainable & affordable healthcare solutions</p>
Climate & energy	<p>Reducing our own carbon footprint</p> <p>Stepping up our use of renewable electricity</p>	<p>Enabling low-carbon economy to support our customers ambitions from raw materials to finished products</p>	<p>Advocating climate action & building the movement for a low-carbon economy</p>
Resources & circularity	<p>Unlocking more value from the limited resources that are available</p>	<p>Enabling the transition toward a circular & bio-based economy</p>	<p>Advocating the transition from a linear to a circular and bio-based economy</p>

Partnering with DSM from concept to commercialization

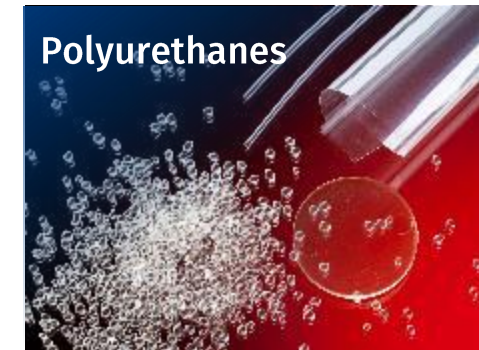
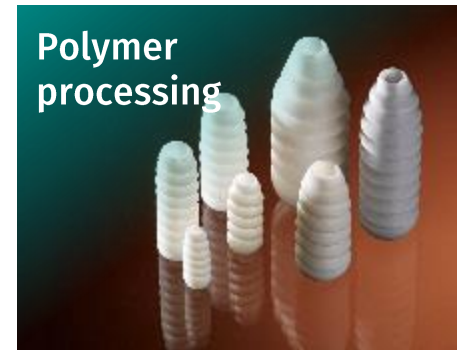
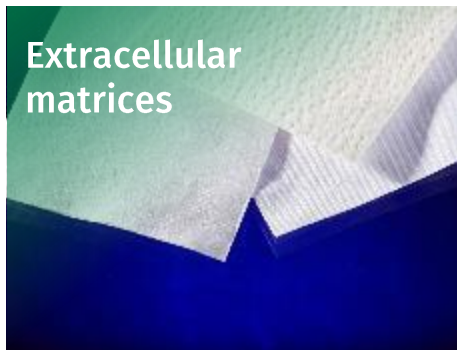
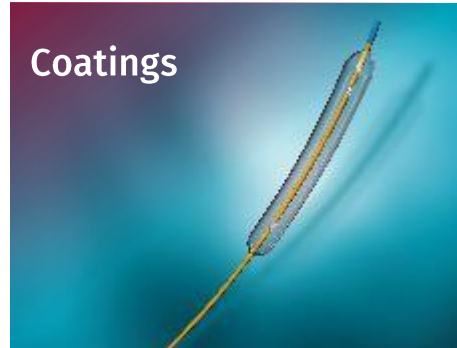
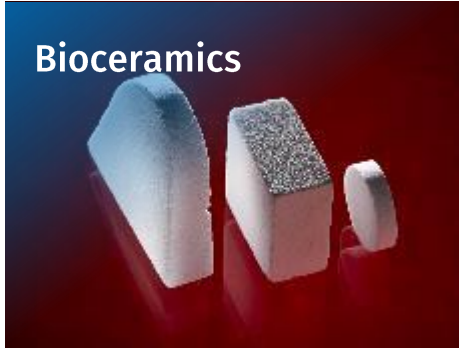


An accomplished Global Leadership Team



Broadest portfolio of biomaterial solutions

Supported by a solid science foundation



Bioceramics

Developing best in-class bone-graft substitutes and novel biomaterial offerings to enable design freedom in fusion

- Tunable scaffold combinations
- Full range of bioceramic material options
- Multiple configurations
- World-class development and manufacturing facility
- MDSAP certified

150k+ synthetic
bone grafts
manufactured
every year

Leading
manufacturer of
biocomposite
orthopedic
fixation



Cell concentration

LAVA™ cell concentration technology: The most portable cell concentration device consistently delivering a highly concentrated output in one-fifth the time as conventional devices

- Greater than 7X platelet concentration¹
- Lightest weight and most portable device
- Available in configurations to create platelet concentrates from bone marrow aspirate and/or peripheral blood

Less than
3 minute
processing time

5" x 5"
footprint
Less than 4 lbs.
fully loaded

Low 3.2%
variance for
output
predictability¹

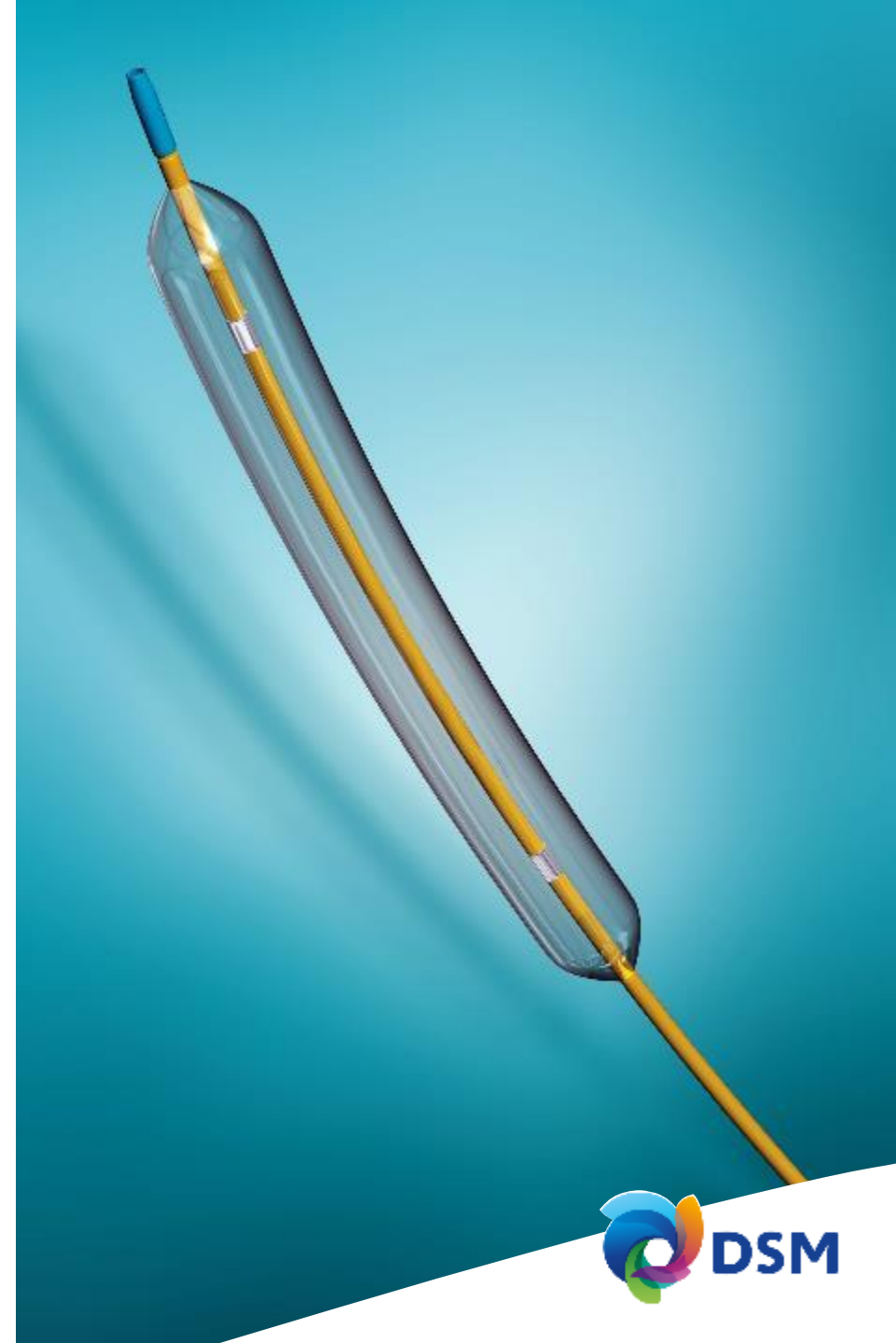


Coatings

Developing the next generation of hydrophilic coatings by transforming today's industry-leading processes into tomorrow's sustainable solutions for medical device development

- Application development and technology transfer to ensure consistent coating performance and turnkey manufacturing processes for our customers

Over 75 million
catheters
coated each
year



Collagen

A best-in-class medical-grade collagen platform, trusted for its safety, performance, and ability to enhance your custom medical device offerings

- Creates best-in-class handling with your devices
- Known for its tissue repair, cell proliferation and hemostatic properties
- Customizable architecture, resorption time and mechanical properties
- Available as raw materials, device components and finished devices
- Proven applications in cardiovascular, dental, orthopedics and wound management

Implanted in
40+ million
patients
worldwide

Over 25 years of
clinical use



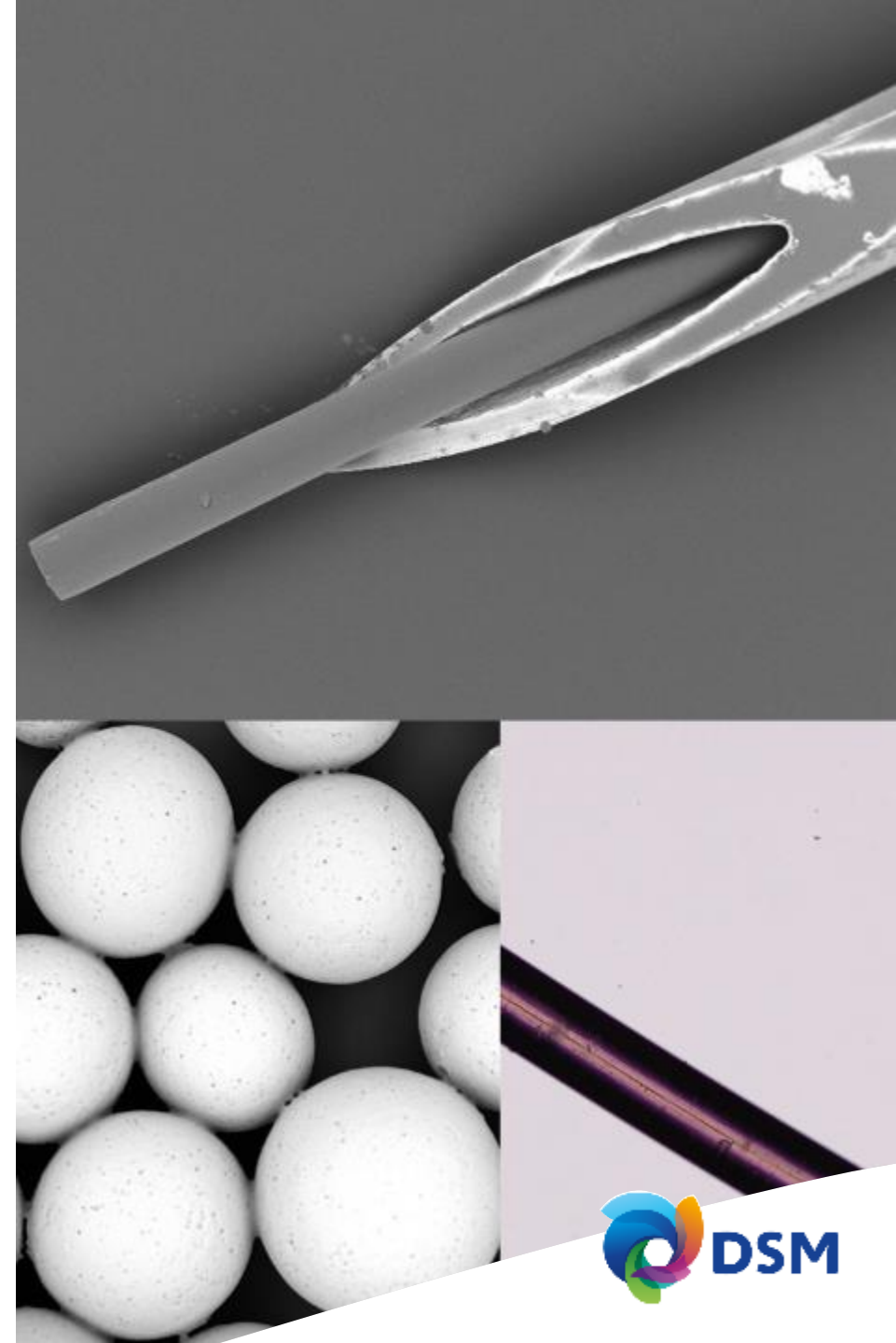
Drug Delivery Materials: Polyesteramide (PEA)

Enabling product innovation in sustained drug delivery with the development of customized solutions with tunable properties to suit the active pharmaceutical ingredient (API), the physiology of the delivery site, and the desired target profile of the end-product

- Proven material platform solutions for sustained drug elution, while allowing ease of processing with active pharmaceutical ingredients.
- Available support during feasibility, development/implementation, and product manufacturing

Bioresorbable
platform

Shown to
provide
additional IP
protection for a
product



Extracellular Matrices

Our broad selection of extracellular matrices (ECM) can be added to your portfolio with ease and efficiency. Feel secure because it's DSM.

- Supply chain security of working with a trusted global leader
- OPTRIX™ PROCESSING - Designed to be as close as possible to the way nature made it, DSM's proprietary processing selectively and thoroughly removes antigenic materials while maintaining the natural structure and biochemical makeup of the tissue

3 distinct
tissues for
customized
handling

25 peer-
reviewed
articles

Sold
commercially
for more than
10 years



Polyethylenes

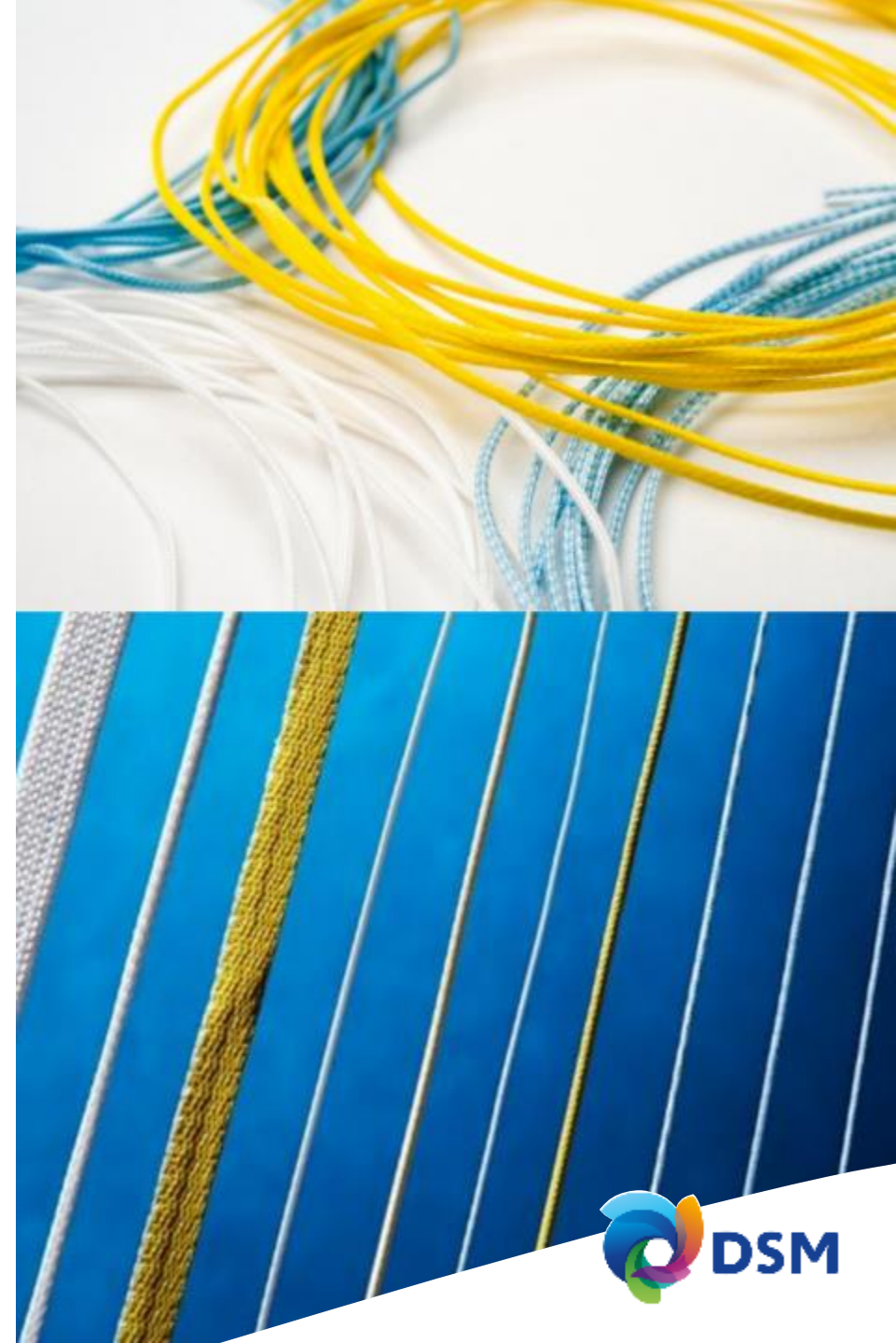
Together, we're creating sustainable solutions to unmet clinical needs with the world's most innovative, high-performance fiber

- Offering the widest range of colors, sizes, and functional attributes
- Only medical-grade UHMWPE fiber in full compliance with today's ASTM standard
- Dedicated manufacturing facility in cleanroom environment with ISO 13485 certified QMS

in clinical use in
orthopedics and
cardiovascular
for 15+ years

inventor of
high-strength
UHMWPE fibers
made by a gel-
spinning
process

Gold standard
for high-
strength
orthopedic
sutures



Polymer processing

Pioneering innovative biomaterial solutions that facilitate less invasive surgical repair and accelerate healing to optimize clinical outcomes for orthopedic applications

- Internally funded R&D
- World-class quality system
- cGMP manufacturing options

30+ years of
experience

500k molded
parts
manufactured
annually

100+ scientists
and engineers
dedicated to
improving the
processing of
polymers



Polyurethanes

The industry's most trusted biomaterial solutions, customized to support today's needs and tomorrow's innovations

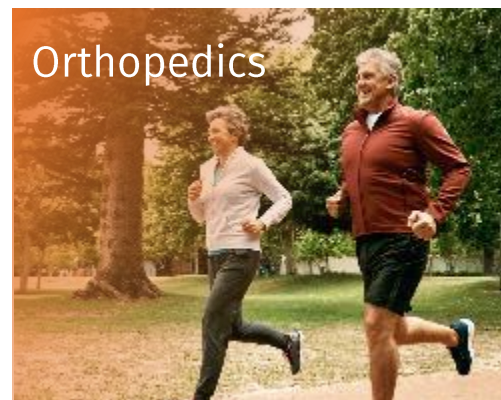
- 30+ years of clinical history serving the medical device industry
- Bionate® PCU, CarboSil® TSPCU, PurSil® TSPU, BioSpan® SPU
- Tailored surface properties
- Range of mechanical properties

Over 14 million
cardiac/neuro-
stimulation
leads implanted

7 master file
families at FDA

Over 10 million
continuous
glucose
monitoring
devices used
annually

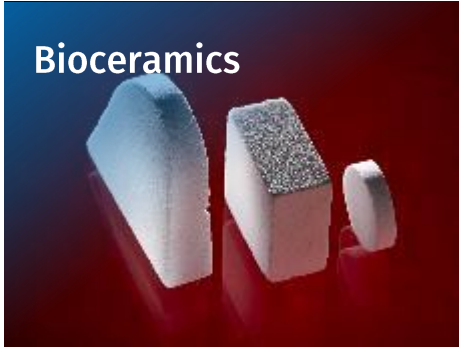
Markets we serve



Our offering to the Orthopedic Market

Biomaterial applications

Bioceramics



- Bone graft substitute
- Cartilage repair device

Cell concentration



- Bone Marrow Concentrate (BMC) system
- Platelet Rich Plasma (PRP) system

Collagen



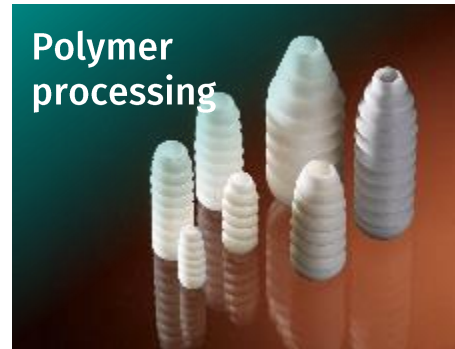
- Bone graft substitute
- Cartilage repair device
- Collagen coated suture
- Meniscus repair device

Polyethylenes



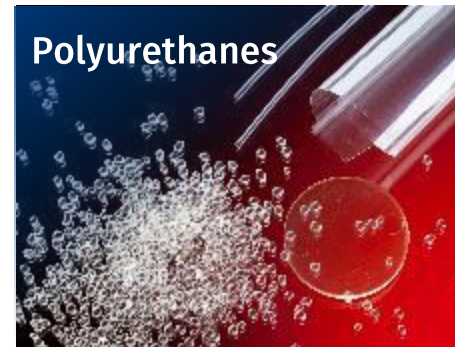
- ACL loop
- Articulating joint implant
- Cerclage cable
- High strength suture
- Meniscus repair device
- Orthopedic fixation
- Soft tissue repair

Polymer processing



- Cartilage repair device
- Meniscus repair device
- Resorbable plate
- Resorbable screw

Polyurethanes



- Articulating joint implant
- Motion preservation device
- Spinal disc replacement

DSM has a solution to treat bone fractures

Bone graft substitutes (Collagen & Bioceramics)

ColOSSIS™ fast-setting, drillable calcium phosphate cement can be combined with biologic fluids, such as autologous blood or bone marrow, then delivered to fill bony voids or gaps of the skeletal system. ColOSSIS™ cement can remodel bone while providing the strength needed for a stable healing environment.



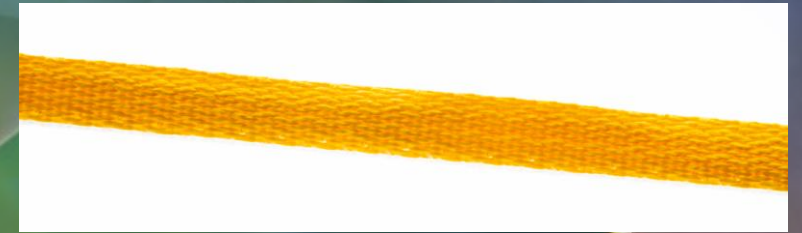
150k+ synthetic
bone grafts
manufactured
every year

DSM has a solution to treat bone and spine fractures

Polyethylene solutions for orthopedic fixation

Dyneema Purity® Radiopaque high-strength fiber is used in cerclage cables during the surgical treatment of fractures. The pliant cables minimize intraoperative and postoperative risk of damaging nerves, and its flatness reduces the risk of trauma to fragile bone.

The incorporation of radiopaque materials into the cable means it can be seen on fluoroscopy and conventional X-ray images, which allows for improved visualization of the cable both during and after the procedure.



in clinical use in
orthopedics for
15+ years

Only medical-
grade UHMWPE
fiber in full
compliance with
today's ASTM
standard

DSM has a solution to preserve motion in patients undergoing cervical disc replacement surgery

Polyurethane solutions for cervical discs

Bionate® PCU provides elasticity, tensile strength and biostability to the device nucleus. The discs are designed to mimic the spine's natural disc's structure and movement, including up and down, side to side, backward, forward, and rotation.

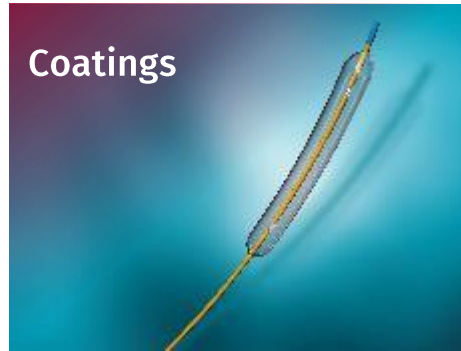
30+ years of
clinical history
serving the
medical device
industry

Tailored surface
properties



Our offering to the Cardiovascular Market

Technology applications



Coatings

- Atherectomy device
- Bare metal stent (BMS) delivery system
- Central venous catheter
- Drug coated balloon
- Guidewires & introducer sheaths
- IVUS and OCT imaging catheters
- PTCA and PTA balloon catheters
- Transcatheter aortic valve replacement (TAVR), delivery system



Collagen

- Collagen coated graft
- Vascular closure device



Drug delivery

- Drug eluting stent



Polyethylenes

- Embolic protection device
- High-strength vascular suture
- PTA balloon, reinforcement
- Surgical annuloplasty ring
- Surgical tissue valve
- Stent graft
- Transcatheter heart valve



Polyurethanes

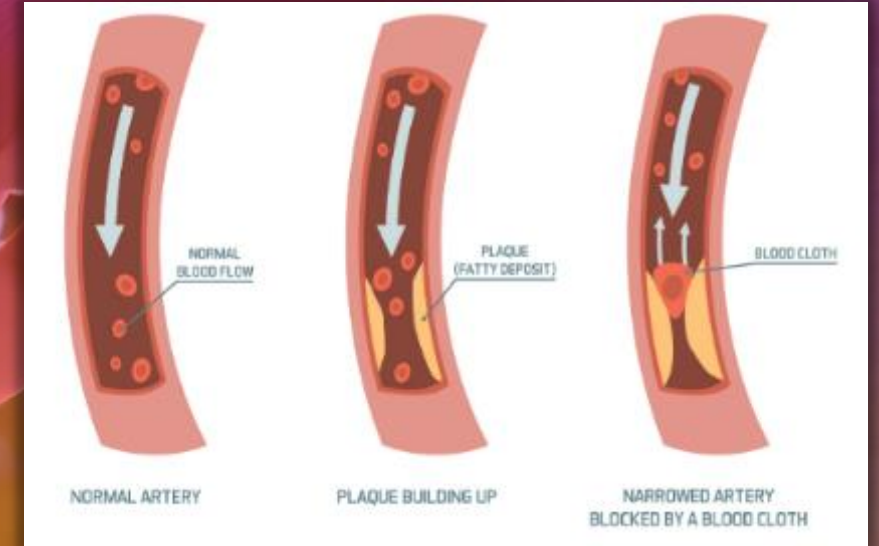
- Cardiac assist devices, such as artificial hearts, pacemakers and ventricular assist devices
- Embolic protection device
- Leads for pacemakers, Implantable cardiac defibrillators and CRT devices
- Transcatheter heart valve
- Peripheral vascular stent
- Stent graft

DSM has a solution to help assess heart vessel damage

Coating solutions for catheters

ComfortCoat® coating provides the perfect balance of lubricity and durability for catheters

- DSM's ComfortCoat® material is used to coat the tip of a catheter on an ultrasound probe used during an Intravascular Ultrasound (IVUS) to look at the vessel from the inside. By gathering information on the vessel from inside of it, physicians can better assess lesions and better place stents.
- As catheters need to be slippery enough when in blood to pass through vessels without damaging the vessel and durable enough to work inside vessels on a beating heart without damaging the ultrasound probe, ComfortCoat® coating provided the perfect balance of lubricity and durability for catheters



Over 75 million
catheters coated
each year

DSM has a solution to restore proper heart function

Polyethylene solutions for heart valves

Dyneema Purity® polyethylene high-strength fiber is used in heart valves during the Transcatheter Aortic Valve Replacement (TAVR) procedure

It's used as a tissue substitute due to its durability, abrasion resistance, flexibility, long-term biocompatibility, and its low profile



Clinically used in
cardiovascular for
15+ years

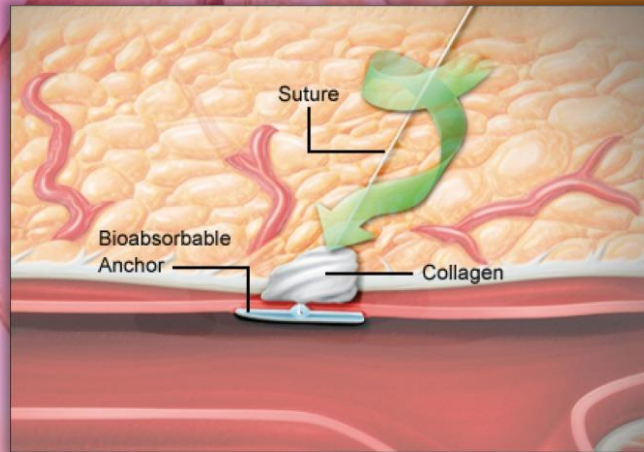
DSM has a solution to assist patients undergoing a catheterization procedure

Collagen solutions for puncture closure

Uniquely formulated collagen provides rapid but safe hemostasis after cardiac procedure



Terumo's Angio-Seal™ Vascular Closure Device



> 2-million
patients
annually

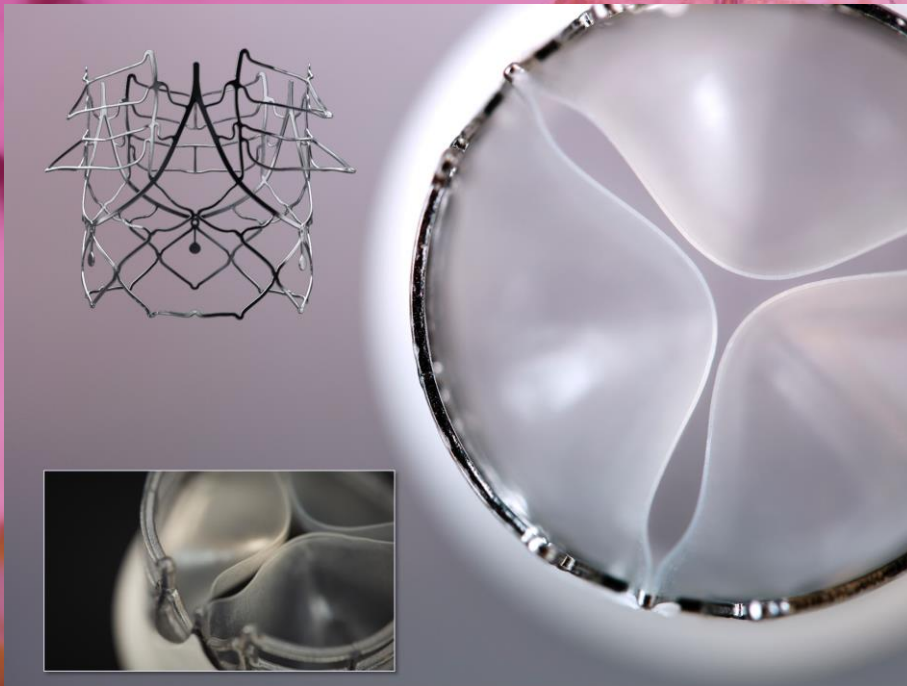
Reduction in
hospital stay
time

Remodels quickly
leaving nothing
in patient

DSM has a solution to help treat rheumatic heart disease

Polyurethane solutions for heart valves

CarboSil® TSPCU gives the valves durability and also dispenses with the need for anticoagulants



Strait Access Technologies (SAT) Heart Valve

30+ years of
clinical history

7 master file
families at FDA

Tailored surface
properties

Our offering to the Pharma Market

Technology applications

Drug delivery



Bioresorbable

- Drug eluting stent
- Sustained drug release to treat retinol disorders

Polyurethanes



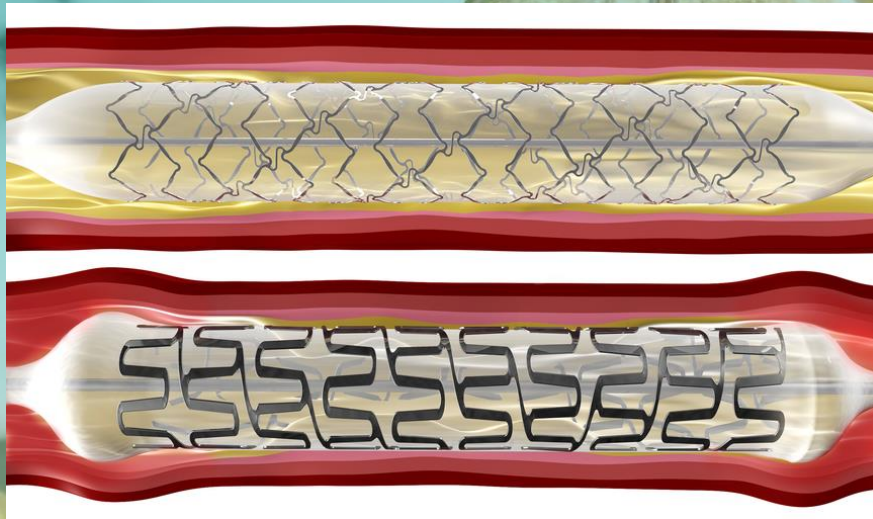
Biostable

- Reproductive health devices

DSM has a solution to treat heart disease

Drug delivery solutions for drug eluting stents

Proprietary poly(esteramide) (PEA) bioresorbable polymer used as a drug carrier designed to provide high mechanical integrity and optimize healing, while delivering desired drug dosages to the local tissue



Svelte's Slender IDST™ DES

Bioresorbable
platform

Sustained drug
elution

Ease of
processing with
active
pharmaceutical
ingredients

DSM has a solution to treat vision impairment

PEA drug delivery system as a platform for the development of long-acting formulations of bioactive ingredients

Approximately 1.3 billion people around the world suffer some form of vision impairment. About 80% is considered avoidable. A key success factor in any eye therapy is the application of the right dosage of medicine in the right place over time.

With our alternative to traditional eye drug delivery systems, we are helping people to live healthier lives.



Bioresorbable platform

Sustained drug elution

Ease of processing with active pharmaceutical ingredients

DSM has a solution to prevent unwanted pregnancies

Polyurethane solutions for contraceptive device

Aliphatic polyurethane is used as polymer excipient and have been shown to have better drug storage and release characteristics compared to the EVA polymer. Aliphatic polyurethanes have the advantage of low temperature process ability and more flexibility in the molecular structure allowing for easier diffusion of API's.



Biostable
platform

30+ years of
clinical history

Tailored surface
properties

Every second,
a patient receives a
medical device containing
a DSM Biomedical material

Millions of patients benefiting
annually worldwide



BRIGHT SCIENCE. BRIGHTER LIVING.™



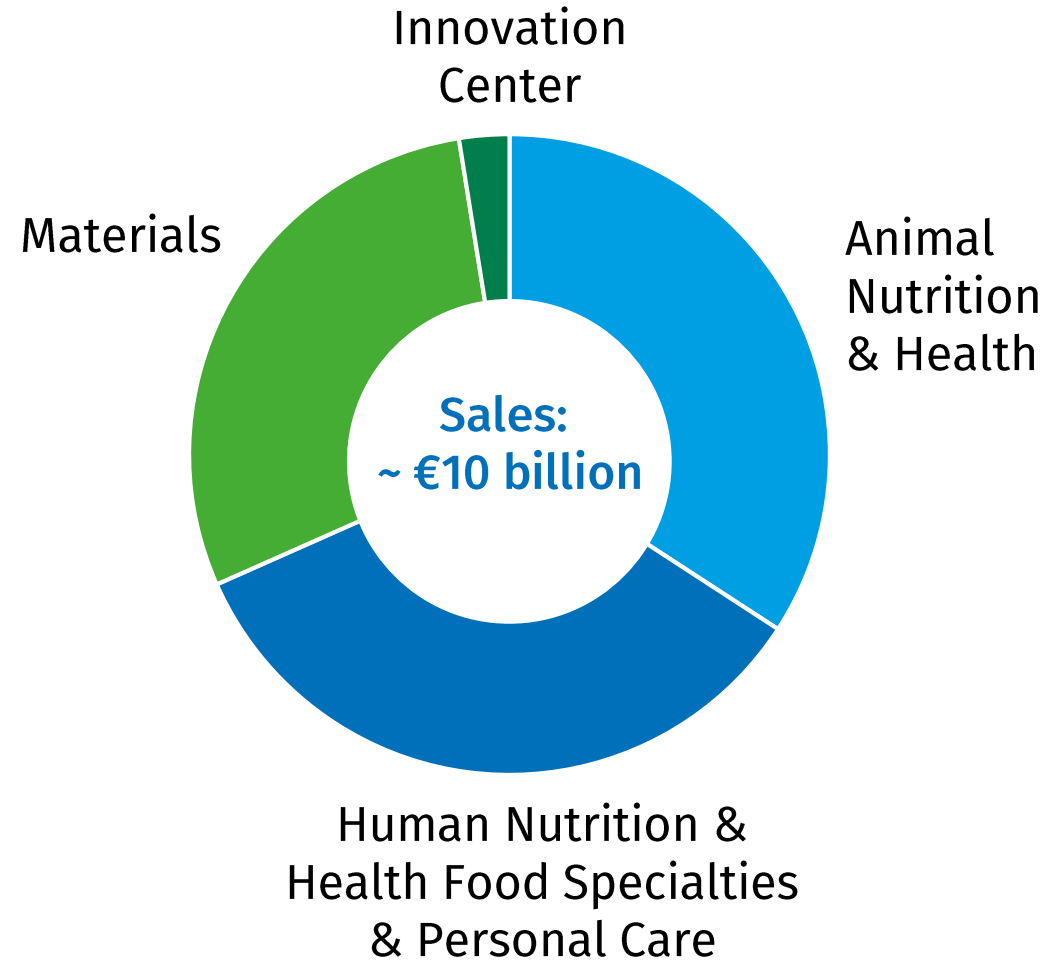
DSM at a glance

*Purpose-led science to address
the world's challenges in nutrition,
health and sustainable living*

DSM at a glance

2019 numbers

- Global company with 43% of sales to high-growth economies
- Intrinsically innovative with 21% of sales from products launched in the last 5 years
- Highly engaged workforce across the world of ~23,000 employees
- Purpose-led strategy aligned with the UN Sustainable Development Goals



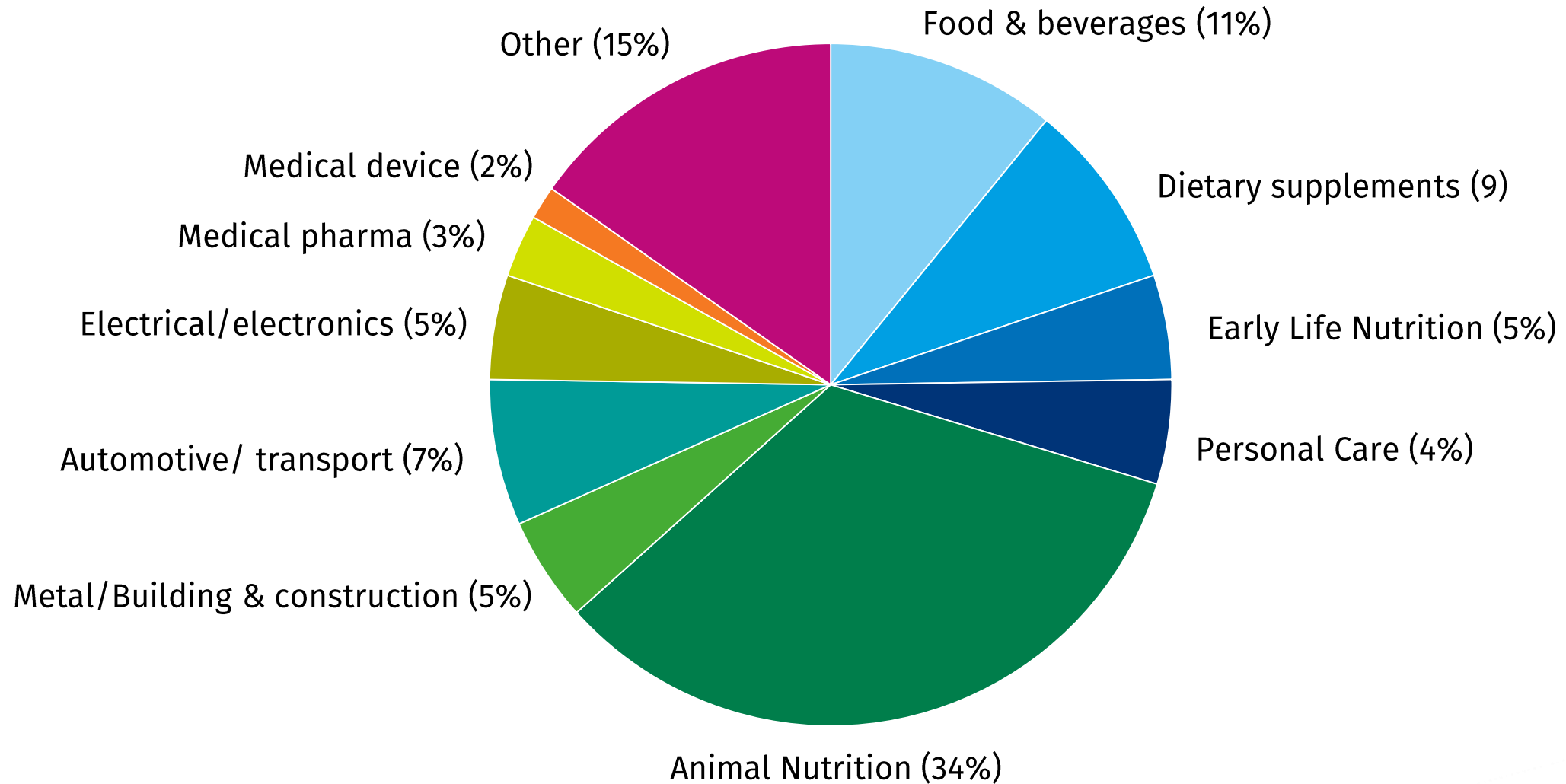
DSM global workforce

~23,000 Employees incl. JVs/associates



Products & solutions for a wide range of end-markets

Net sales by end-use markets (in %)



DSM is well aligned with sustainable development goals

Nutrition
& Health



Climate
& Energy



Resources
& Circularity



Case study examples

Other DSM businesses

Expanding our digital capabilities in personalized nutrition

- Vitamins, nutritional lipids and minerals are essential for human health and well-being, and a balanced and nutritious diet is key to prevent diseases. There is a growing interest worldwide in personalized nutrition tailored to consumers' specific health goals and needs.
- Our personalized nutrition partnerships help individuals take responsibility for their health, reducing their exposure to a wide range of non-communicable diseases and helping to lower healthcare costs.



Combating skin cancer through innovative approaches to UV protection

- An astonishing 3 million cases of skin cancer are diagnosed each year. In the US alone, more than 2 people die of the disease every hour. Despite the known risks, however, many people do not protect themselves adequately from the harmful effects of the sun's ultra-violet (UV) rays.
- Our UV filters and sensory modifiers offer protection from the suffering associated with sun-related skin cancer. To help raise awareness of the importance of sun protection, we have been working with the professional cycling team, Team Sunweb, to showcase a powerful example of men building sun protection into their daily safety routine.



How cows can help us fight climate change one burp at a time

- Methane is a greenhouse gas which, contributes to climate change. Ruminants (mainly cows) emit about 20% of all methane gasses globally.
- A quarter of a teaspoon per cow of our feed additive per day inhibits the enzyme that triggers methane production in a cow's stomach and reduces methane emissions by ~30%, significantly reducing the environmental footprint of dairy and beef products, a key source of protein around the world.



A cleaner future for China's shipping industry

- We are helping the Chinese shipping industry to reduce annual VOC emissions by leading the transition to waterborne container coatings, which contain up to eight times fewer VOCs than their solvent-borne equivalents.
- As a result of this initiative, 99% of containers manufactured in China have been produced using waterborne coatings since April 2017.



Omega-3 rich in EPA and DHA from natural marine algae

- Fish is an important source of nutrition. Oily fish – and especially salmon – is also a rich source of the two-essential omega-3 fatty acids EPA and DHA, which are vital for brain, eye and heart health.
- DSM and Evonik have joined forces to create Veramaris® an algal oil containing EPA and DHA for fish feed. This way we help to conserve wild fish stocks and enable the aquaculture industry to grow sustainably.



Fully recyclable carpets & mattresses

- Most of the bulkiest waste items in the world are made of complex combinations of materials glued together so as not to come apart. Mattresses and carpets eventually end up in landfill or else have to be incinerated as they cannot be recycled.
- Niaga®, focuses on the redesign of everyday products for full recyclability.



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