


Welcoming and Introduction of SPECTARIS

Facts and figures of an industry caring for our future health

Marcus Kuhlmann, SPECTARIS e.V.

Networking Mission

Japan 2018: Healthcare – Production Technology, Medical Technology and Photonics

Tokyo, Japan, June 4th 2018

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SPECTARIS – German Hightech Industry Association - History

- Founded in 1881 „German Society for Mechanics and Optics“
- Due to the growing international cooperation the "European Industry Association for Precision Mechanics and Optics" (EUROM) was founded in 1960
- In 2002, the Association was renamed “SPECTARIS. German Industry Association for Optical, Medical and Mechatronic Technologies“
- In 2004 the office moved from Cologne to Berlin
- SPECTARIS mainly represents small and medium-sized enterprises - more than 90% are SMEs

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SPECTARIS – Structure

- Based in Berlin with more than 400 members in four industry sections

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The SPECTARIS industry association Medical Technology:

- represents the interests of around 170 manufacturers of medical technology goods and medical auxiliary devices, plus Homecare-Provider of the respiratory home therapy
- Focus on capital equipment, no consumables!
- Our member companies produces products for diagnosis and surgery, for the medical care system, for facilities for hospitals, for respiratory home therapy and devices for rehabilitation and orthopedics
- predominantly small to medium sized enterprises – SME´s
- with a quite a few world leaders like Karl Storz, Aesculap/B Braun, Carl Zeiss Meditec, Dräger
- Services focus on the business areas
  - Regulatory Affairs
  - Reimbursement
  - Compliance
  - Market Access with mainly supporting Export Business
  - Hygiene and Processing
  - Research funding
  - Marketing, Financing

} Lobbying

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SPECTARIS Photonics

SPECTARIS is the active voice of the European photonics industry regarding the RoHS regulations

- RoHS exemptions for the use of lead and cadmium in glass and optical filters have been reached that are valid till 2021 at least
- New substances for RoHS restrictions are on the candidate list which are relevant of the photonics industry
  - Antimontrioxid – used in the glass production
  - Indium phosphide – used in optoelectronic semiconductor devices (LEDs, sensors)
  - Beryllium metal – used in metal springs
  - Nickel sulphate/sulfamate – used in the production for Nickel coatings
- SPECTARIS and its corporate association members work on technical statements to avoid the listing of those substances in regard to the photonics industry.

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The German Medical Devices Industry – Opportunities and Challenges in Japan

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The German Medical Technology Industry

turnover | employees | companies

€29.2 billion turnover	133k employees	1.258 companies
€27.6	130k	1.229

2016 2015

» Data refers to companies ≥ 20 employees
» Including small businesses: 26.21 billion EUR turnover, 12.550 commercial enterprises, 200.230 employees (2015)
» Retail trade with medical/orthopedic products: 52.000 employees (2014)

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Health expenditure in % of gross domestic product - TOP 10

Country	Expenditure
1. USA	17,1 ⇧
2. Sweden	11,9 ⇧
3. Switzerland	11,7 ⇩
4. France	11,5 ⇧
5. Germany	11,3 ⇧
6. Austria	11,2 ⇧
7. Netherlands	10,9 ⇩
8. Belgium	10,6 ⇧
9. Canada	10,4 ⇧
10. Denmark	10,3 ⇩
China	**5,5** ⇩
OECD average	**~9,3** ⇧

Japan: 10,2%
India: 4,7%
Europe: 10,0%

Source: EMERGO, Statistisches Bundesamt, SPECTARIS e.V.

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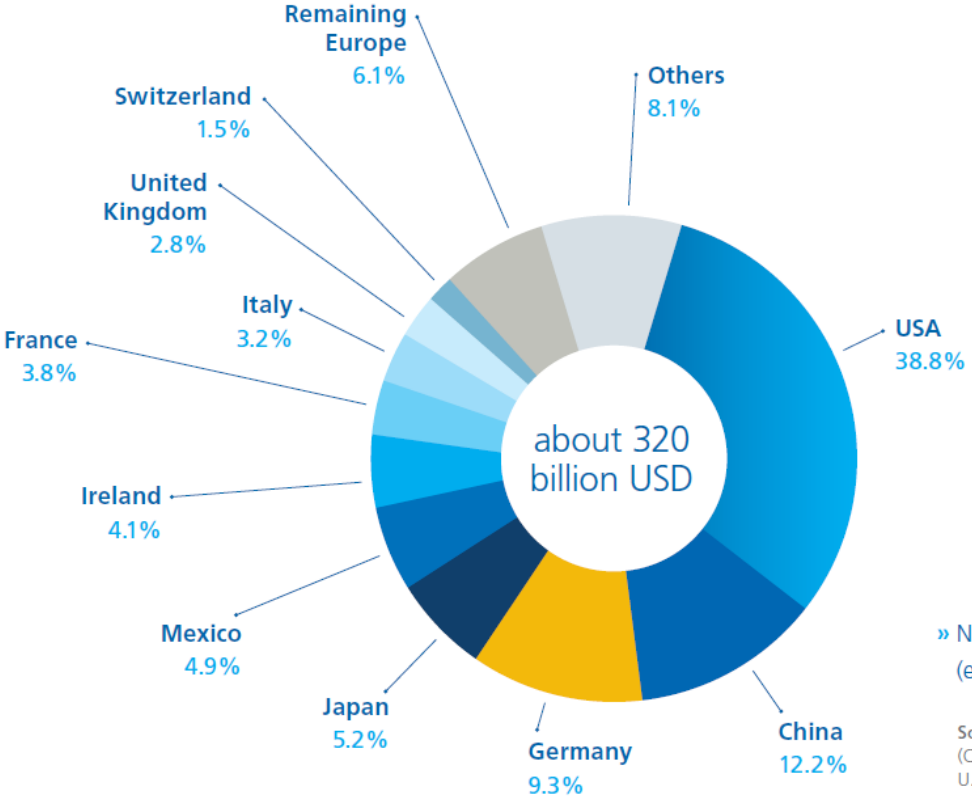
Medical Technology worldwide

Germany is the third largest producer



» Note: Data refers to Year 2015 (excluding IVD)

Sources: SPECTARIS (Calculated on the basis of data of GTAI, U.S. CommercialService and Eurostat)

www.spectaris.de

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Medical Technology Industry in Europe

Germany ranks No. 1

» Note: Data refers to the respective total turnover of the local manufacturers in 2015 (excluding IVD)

» Remaining Europe: 9 billion EUR

» Total Europe: 90 billion EUR

Sources: Eurostat, SPECTARIS

51% of the German Medical Technology are exported to European countries

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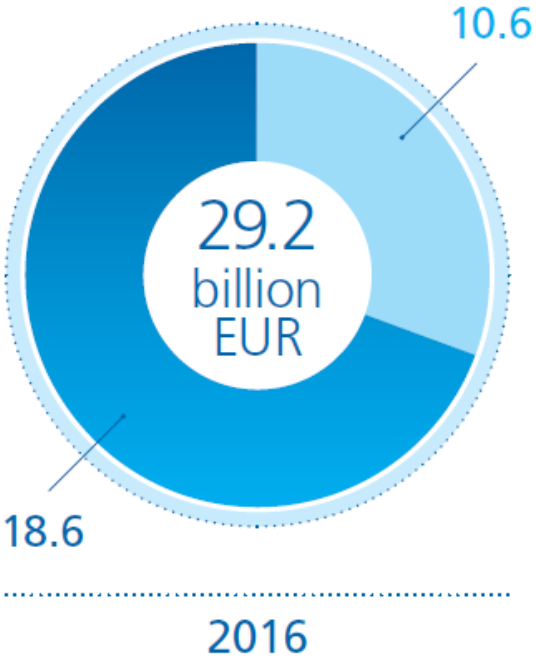
The German Medical Technology Industry

innovative | medium sized | export-oriented



Export turnover Domestic turnover

Sources: Federal Statistics Office. Eurostat, SPECTARIS

- R&D quota: ~9%
- Export quota: 64%
- Medium sized industry (<250 employees): 92% of the companies
- Sales growth p.a. 2011–2016 (CAGR): +5.0%

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One of the most innovative industries in Germany

Research and Development	Share
R&D expenditure to turnover	9,1%
R&D workforce ratio to total employees	15%
Turnover of innovative products (younger than three years)	31%

Source: SPECTARIS e.V.

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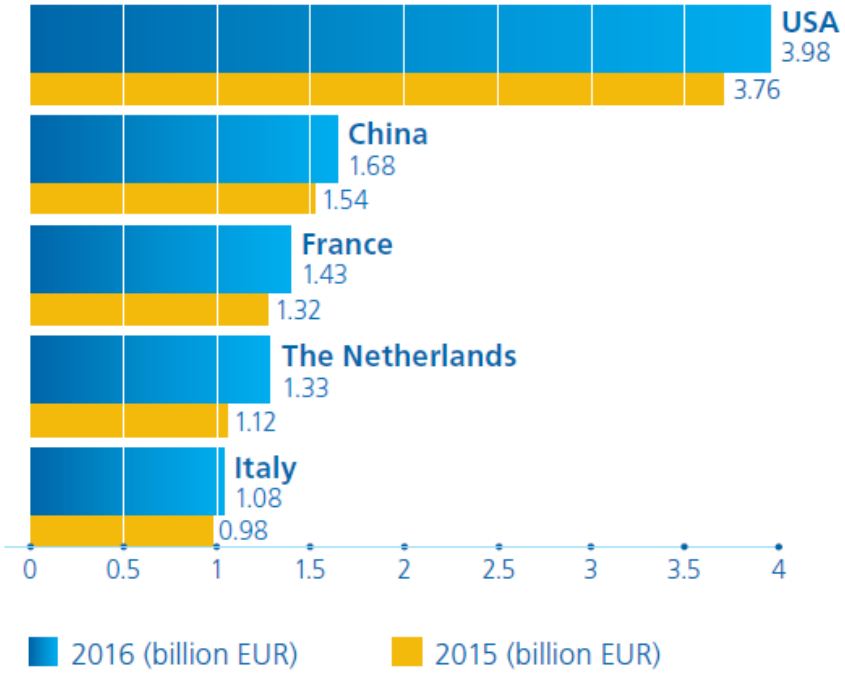
The German Medical Technology Industry

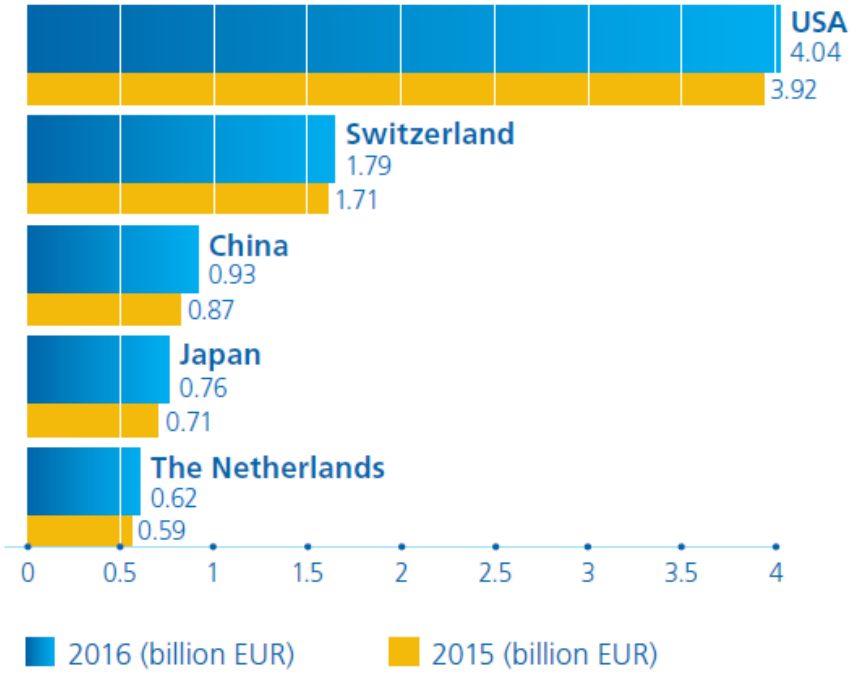
exports | imports

Top 5 target countries for German exports



Sources: Federal Statistics Office, SPECTARIS

Top 5 countries of origin for German imports



Sources: Federal Statistics Office, SPECTARIS

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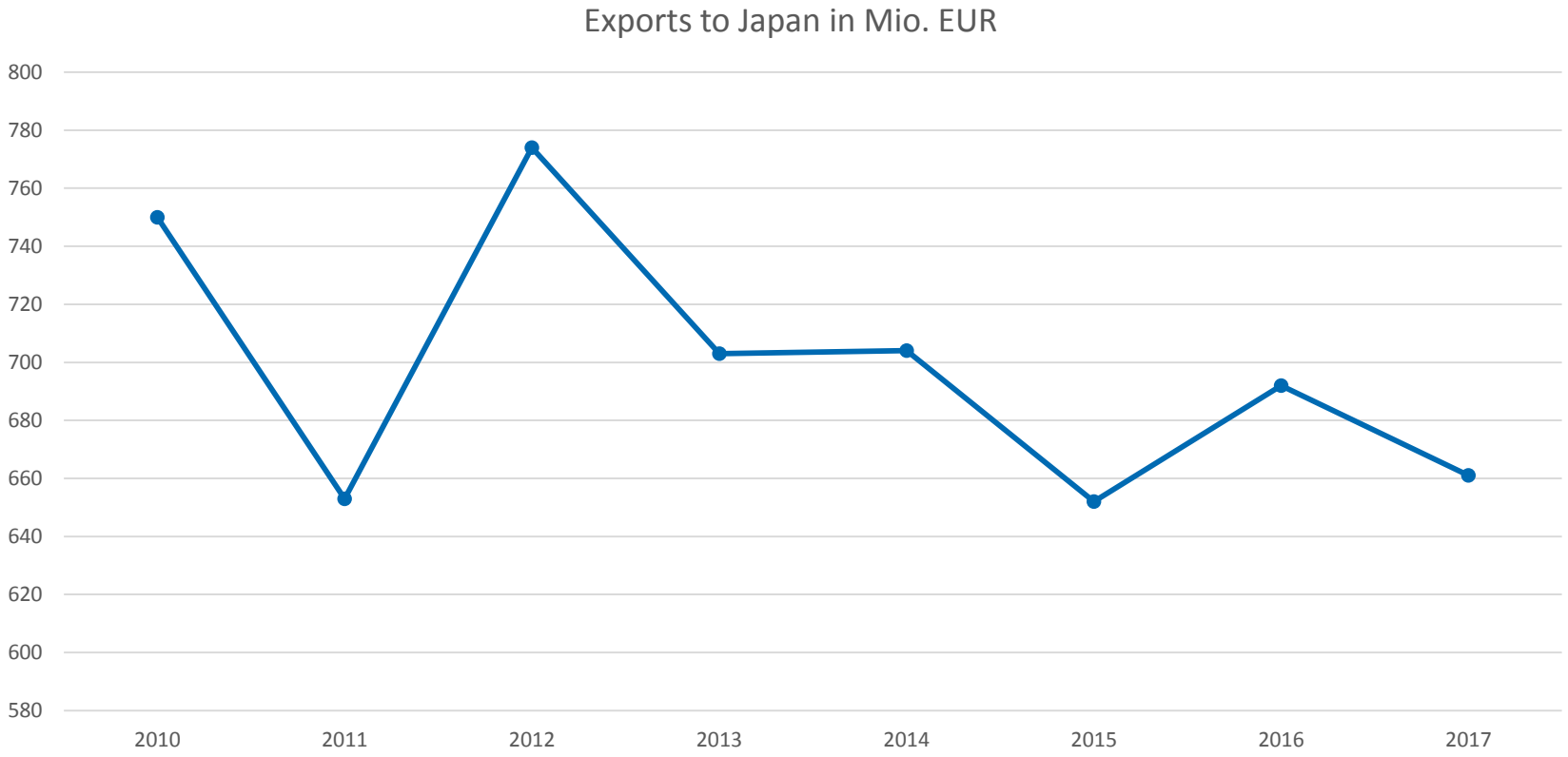
Germany - Japan: Medical Technology Export



Source: eurostat

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Japan – Germany: Medical Technology Import/ Export

Germany – Japan trade	2017	Change 2017/2016
TOP 9 – Exports to Japan	661 Mio. EUR	- 4,5%
TOP 4 – Imports from Japan	760 Mio. EUR (2016)	+ 7,0%

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Most important export medical devices and technologies from Germany to Japan in 2017

- Radiology equipment: Magnetic Resonance Imaging (MRT), Computer Tomography Apparatus (CTA) (213 Mio. EUR)
- Surgical Instruments (71 Mio. EUR)
- Dental apparatus and equipment (54 Mio. EUR)
- Pacemakers for stimulating heart muscles (46 Mio. EUR)
- Single use equipment like syringes, needles etc. (32 Mio. EUR)
- Endoscopy (30 Mio. EUR)
- Implants for orthopaedic purposes (27 Mio. EUR)

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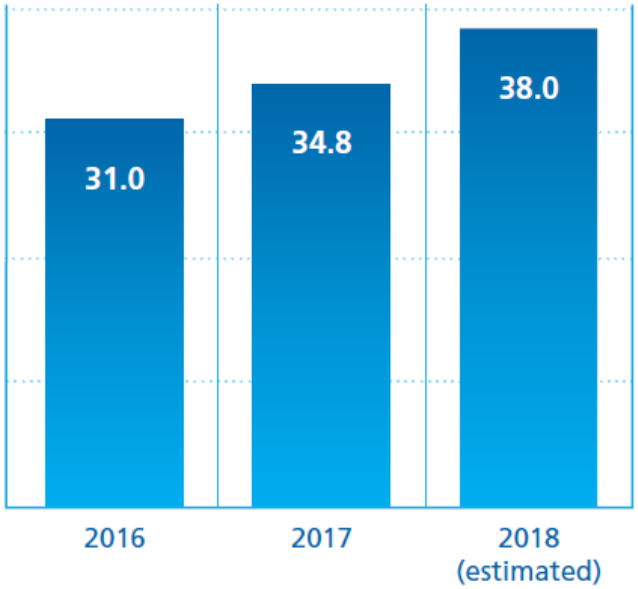
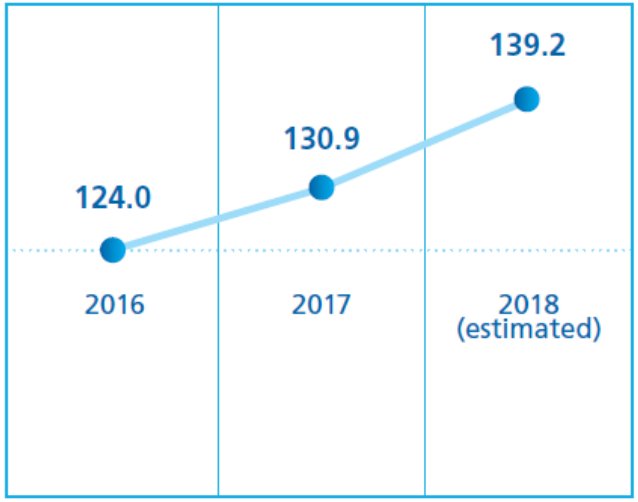
The Photonics Industry in Germany (1/2)

The German photonics industry in numbers

Total revenue (bn. EUR)



Employees (thousand)



Source: 2016 Optech Consulting, 2017 ff. SPECTARIS estimate

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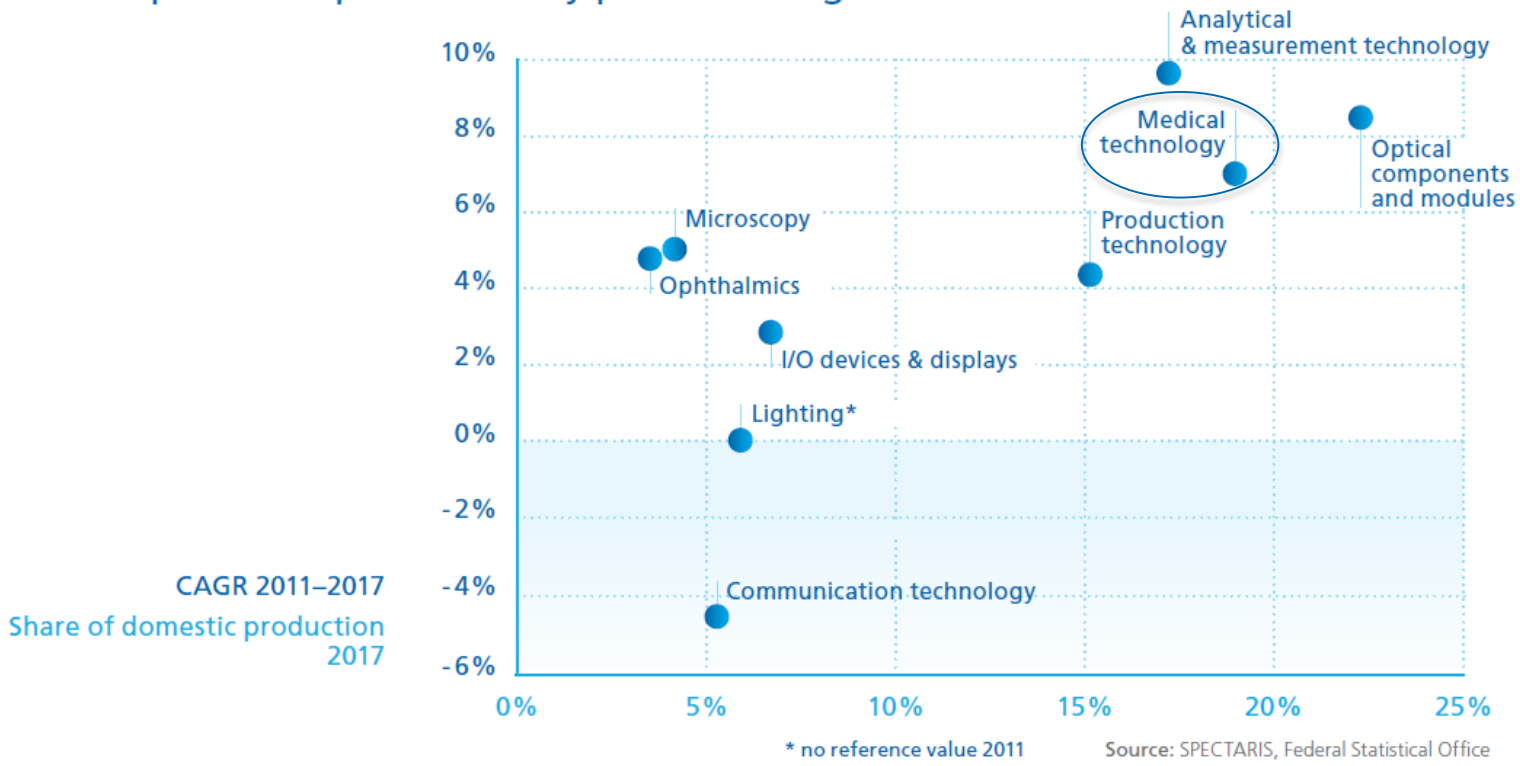
The Photonics Industry in Germany (2/2)

Domestic photonics production by product categories



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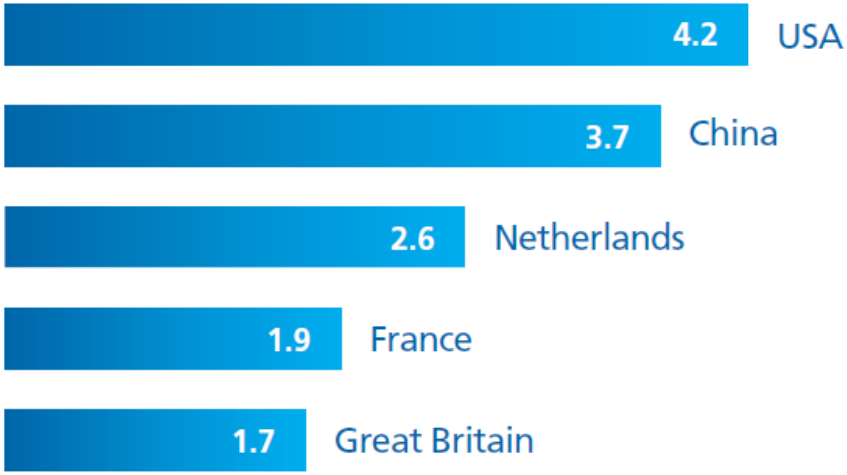
Global Photonics Market (1/2)

Top 5 target countries for German photonics exports (bn EUR)



The USA and China are the most important target countries. Within Europe, the Netherlands are ahead.

Source: SPECTARIS, Federal Statistical Office

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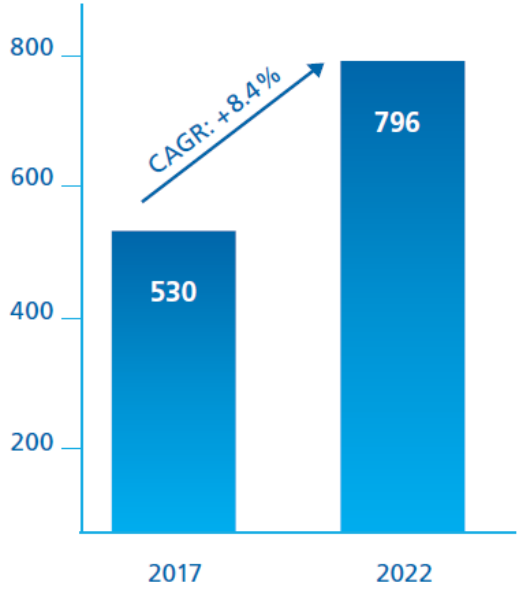
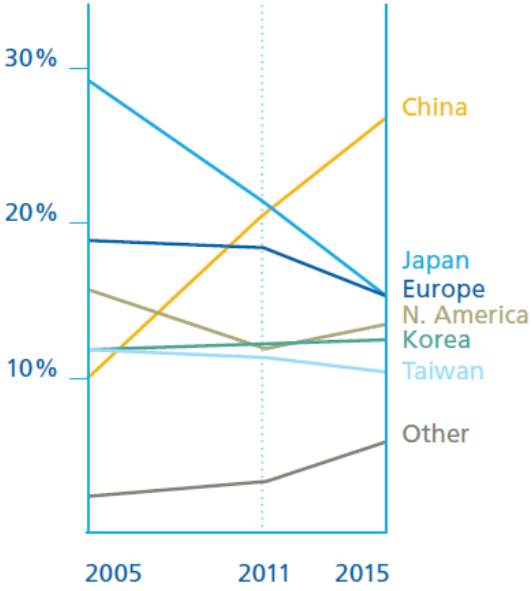
Global Photonics Market (2/2)

Global photonics production volume (bn USD)



Source: MarketsandMarkets

Photonics production volume share



Source: Photonics21 (Optech Consulting)

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Opportunities for German Medical Industry in Japan (1/2)

- Japan has one of the biggest medical device market in the world
- Market volume at US$ 28.1 billion in 2016, projected to grow steadily through 2020, when it should reach over US$ 31.7 billion, despite a cautious growth of the Japanese economy over the last few years
- Healthcare expenditures have grown up to 10.2% (of GDP)
- Japan has a huge domestic manufacturing market
- But: majority of the medical devices used in the Japanese healthcare system is imported from other markets

Source: emergo, Germany Trade and Invest 2017

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Opportunities for German Medical Industry in Japan (2/2)

- Despite Japan´s reputation as a hub of technological innovation, there is still opportunity for foreign manufacturers in the medical device sector
  - Japanese exports of medical technology: US$ 5.7 billion (2016)
  - Japanese imports of medical technology: US$ 18.1 billion (2016)
- Japan has a very large aging demographic: over 25% of the Japanese population is older than 65, and: high spending capacity!
- Which products are needed? Strong demand for interventional cardiology equipment, pacemakers, orthopedic implants, homecare, preventative care, and innovative technologies

Source: emergo, Germany Trade and Invest 2017

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Industry challenges in Japan (1/3)

Complex regulatory process

- Japanese regulatory process can be lengthy and expensive and is very complex
  - An importeuer has to classify the imported medical device into risk classes from 1 (low risk for patients) to 4 (very high risk for patients) => authorization by the Pharmaceuticals and Medical Devices Agency (PMDA)
  - All regulations and documents are published almost exclusively in Japanese
  - PMD Act imposes strict requirement and clinical standards for foreign manufactures => an experienced regulatory partner with a presence in Japan is essential!
- Reimbursement restrictions obstruct imports: medical innovations are only limited refundable

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Industry challenges in Japan (2/3)

Local competition

- Foreign manufacturers can expect hefty competition from domestic manufacturers
- Japan is home to leading consumer technology companies that also design medical devices such as Canon, Toshiba, Panasonic, Olympus, Pentax among others
- Greatest competition is in diagnostic imaging, therapeutic and surgical equipment, biophenomena measuring and monitoring systems, home therapeutics, dialyzers, and endoscopes.
- Germany is one of the most important importeuer for medical devices but has a growing competitor in China

Complex sales structures

- Sales structures are complex and intransparent
- SME usually need a local dealer/partner that has personal connections to stakeholders, especially doctors

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Industry challenges in Japan (3/3)

New EU-Japan Economic Partnership Agreement will entry to force in 2019

- tariffs on industrial products will be fully abolished, for instance in sectors where the EU is very competitive, such as chemicals, plastics, cosmetics as well as textiles and clothing
- Already in November 2014, Japan adopted the international standard on quality management systems (QMS), on which the EU QMS system for **medical devices** is based. This should reduce the costs of certification of European products exported to Japan considerably
- Procurement: EU companies will be able to participate on an equal footing with Japanese companies in bids for procurement tenders in the 48 so-called 'core cities' of Japan with around 300.000 to 500.00 inhabitants
- SME´s: a specific chapter will enable smaller companies to benefit fully from the agreement, notably through increased transparency. Lack of access to information can represent a trade barrier, particularly for smaller firms.
  - Both the EU and Japan therefore commit to setting up a specific website to provide information relevant to smaller companies on how to access their markets.
  - There will also be dedicated small business contact points to manage the issues raised in this chapter and to deal with issues relevant to smaller companies in other areas of the agreement.

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Thank-you for your attention!

あなたの注意をありがとう

Anata no chūi o arigatō

Vielen Dank für Ihre Aufmerksamkeit!

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