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MEDICAL

INFORMATION FOR GROWTH

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TUTORIAL - Orthopaedics Market
June 2016

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IMPLANTS

2016

International conference on innovation
for orthopaedic implants and orthobiologics

12TH EDITION

IMPLANTS 2016 CONFERENCE

PARIS | FRANCE

Tuesday, June 7th 2016

Elysées Biarritz Conference Center

Two tutorials on the orthopaedic
market and contract manufacturing

Keynote speakers from major
companies



Created
and chaired by



www.implants-event.com

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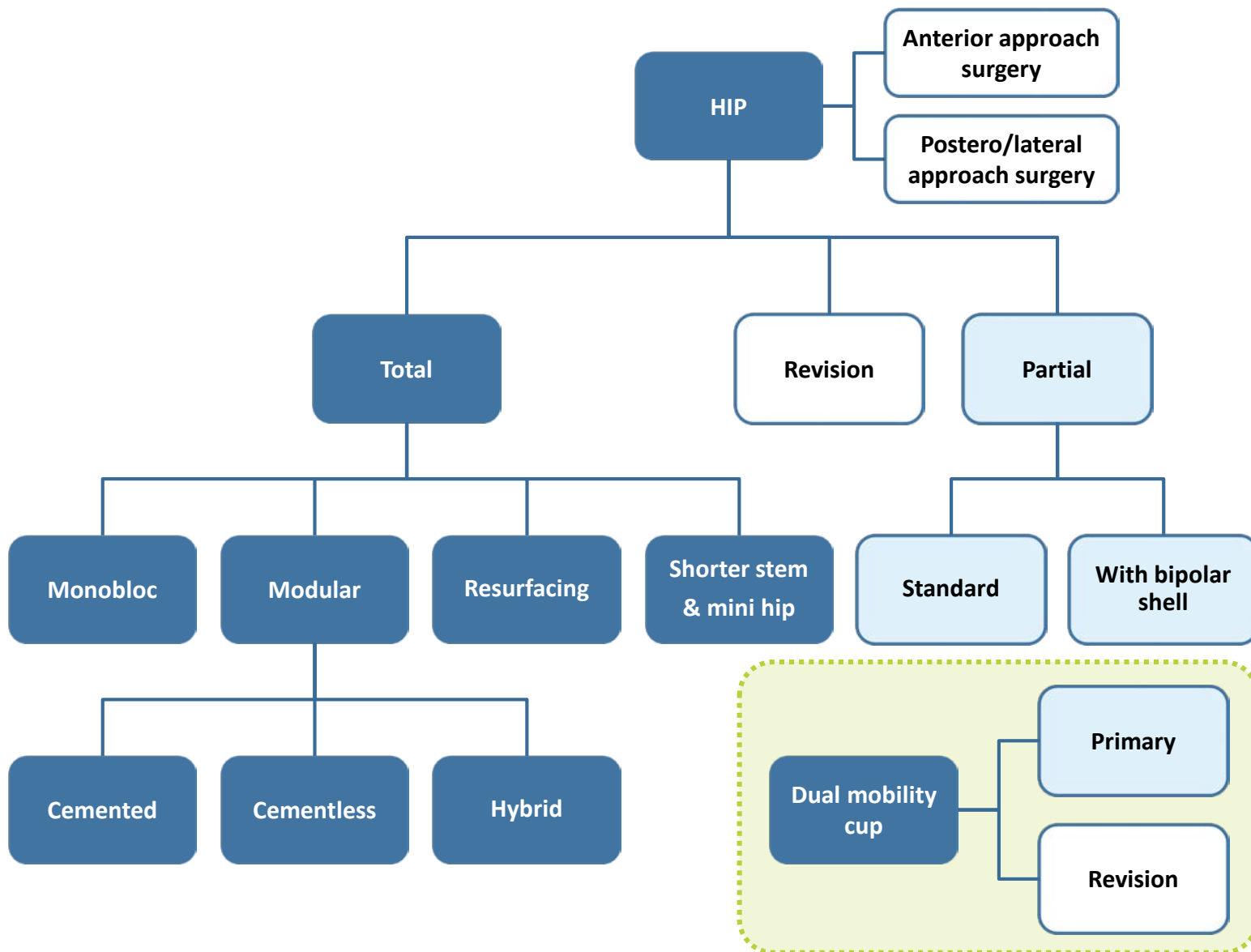
- I Worldwide orthopaedic market: dynamics, competition, drivers, limiters, ...**
 - 📄 Worldwide orthopaedic markets in 2015: hip, knee, trauma, spine, others...
 - 📄 Worldwide orthopaedic Market: products, innovations, growth, competition & trends
 - 📄 Market drivers, market limiters
 - 📄 Forecasts by 2020
- II European orthopaedic market: market share, new products in details, heavy trends, ...**
 - 📄 European orthopaedic markets in 2015: market share for hip, knee & shoulder
 - 📄 European orthopaedic Market: new products, trends...
 - 📄 Forecasts by 2020
- III Summaries**

To download the presentations:

<http://www.implants-event.com/program/presentations-2016/>

Password: biarritz_2016

Hip segmentation



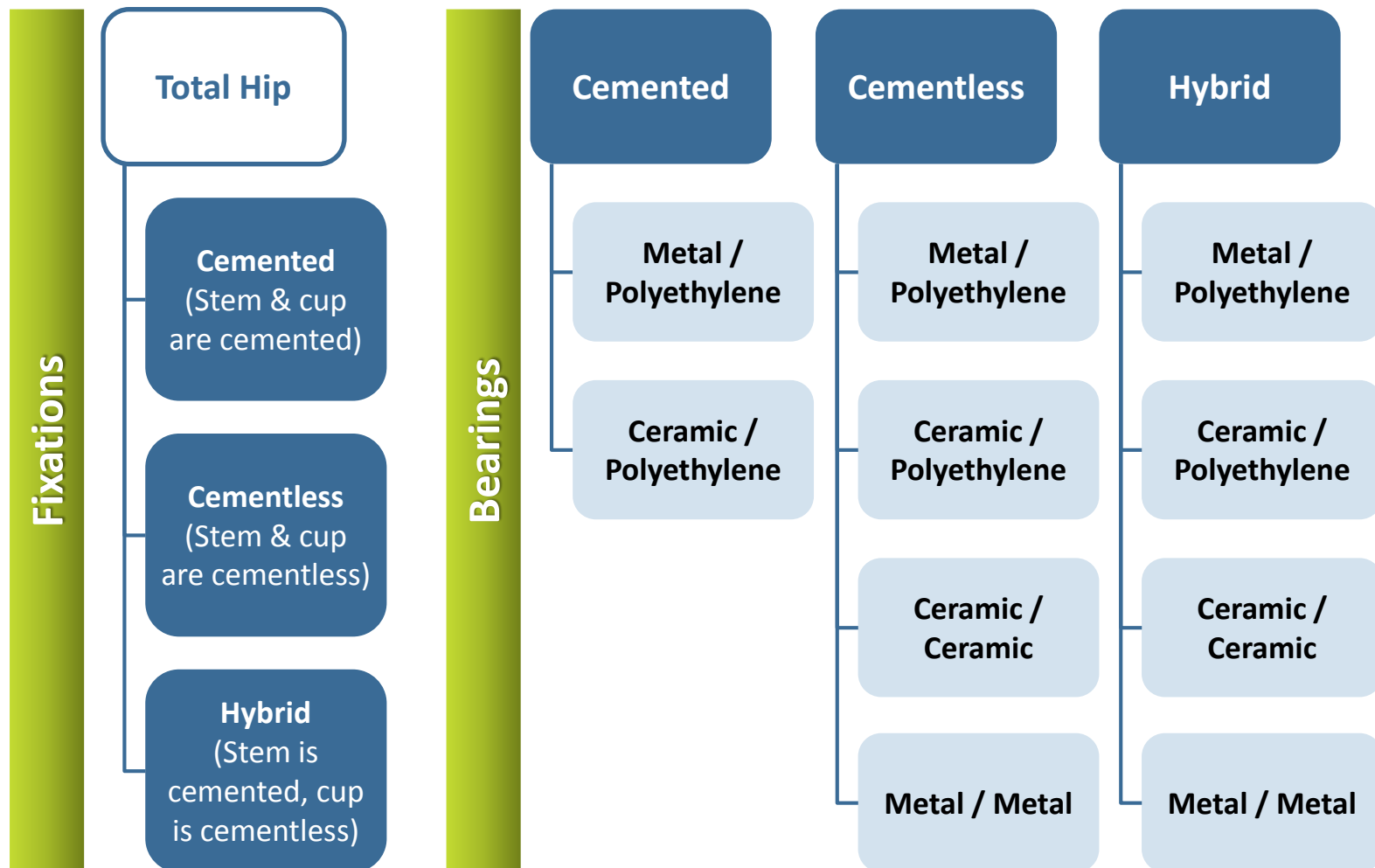
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Hip segmentation by fixations & bearings

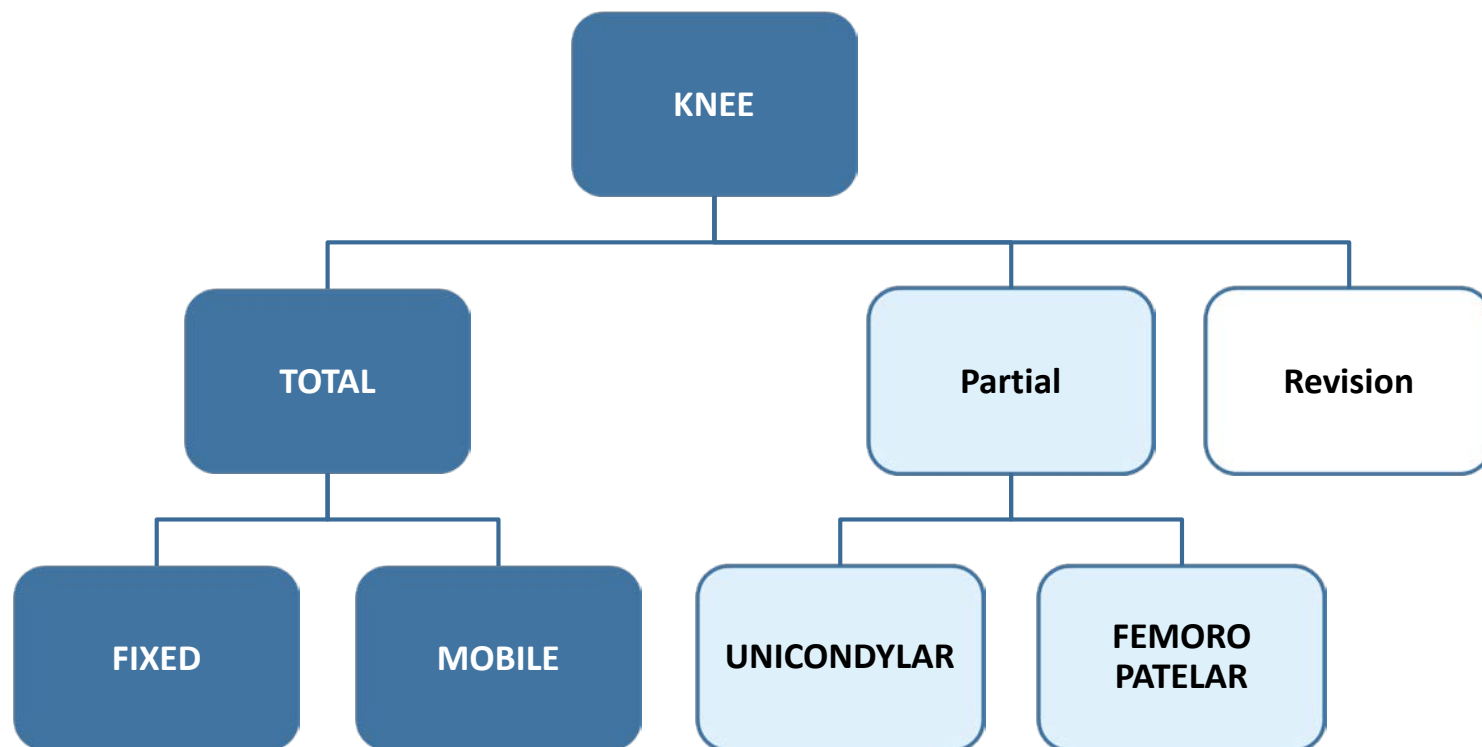


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Knee segmentation



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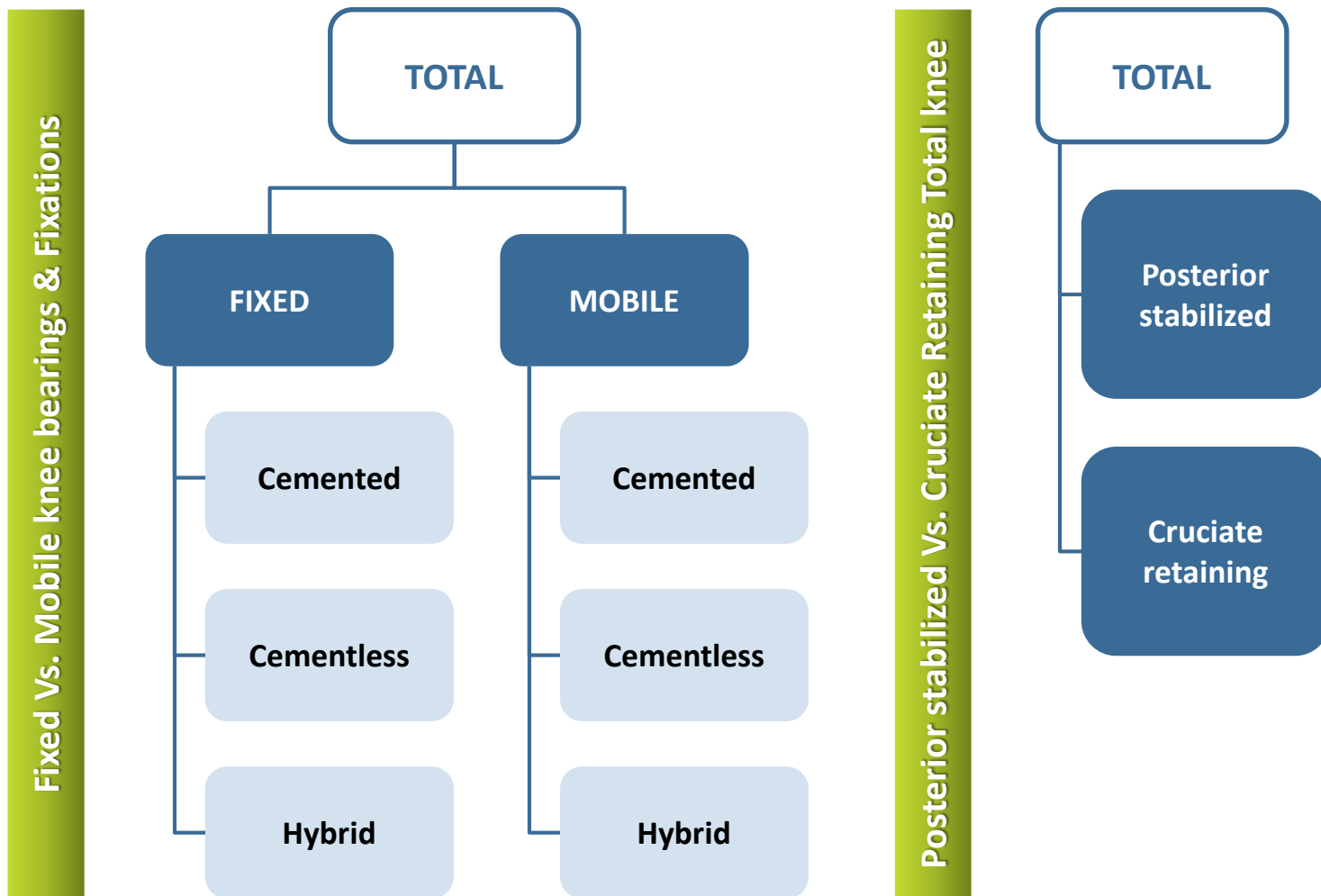
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Knee segmentation:

Fixed Vs. Mobile knee bearings, Fixations, Posterior stabilized Vs. Cruciate Retaining Total knees



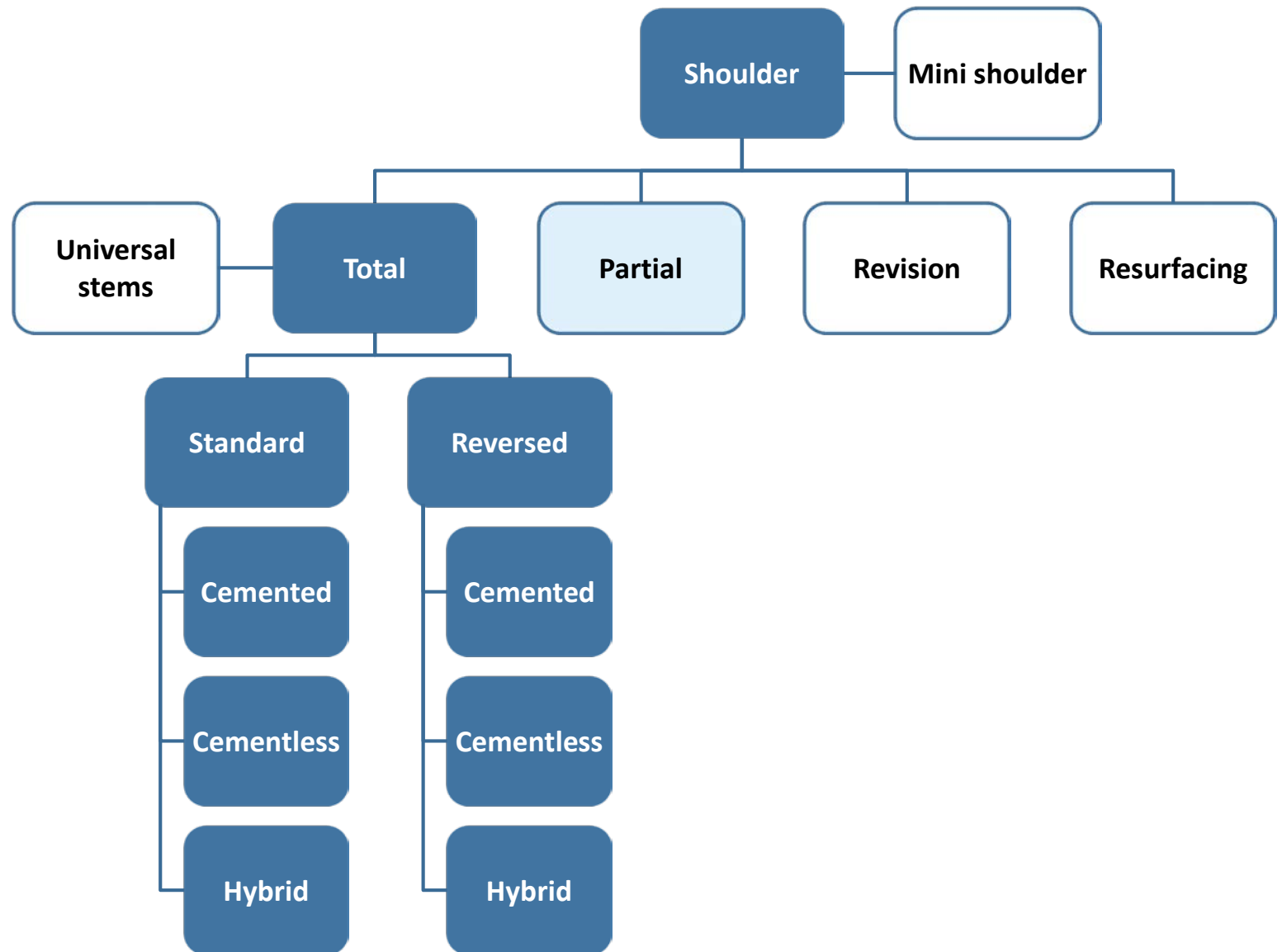
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Shoulder segmentation

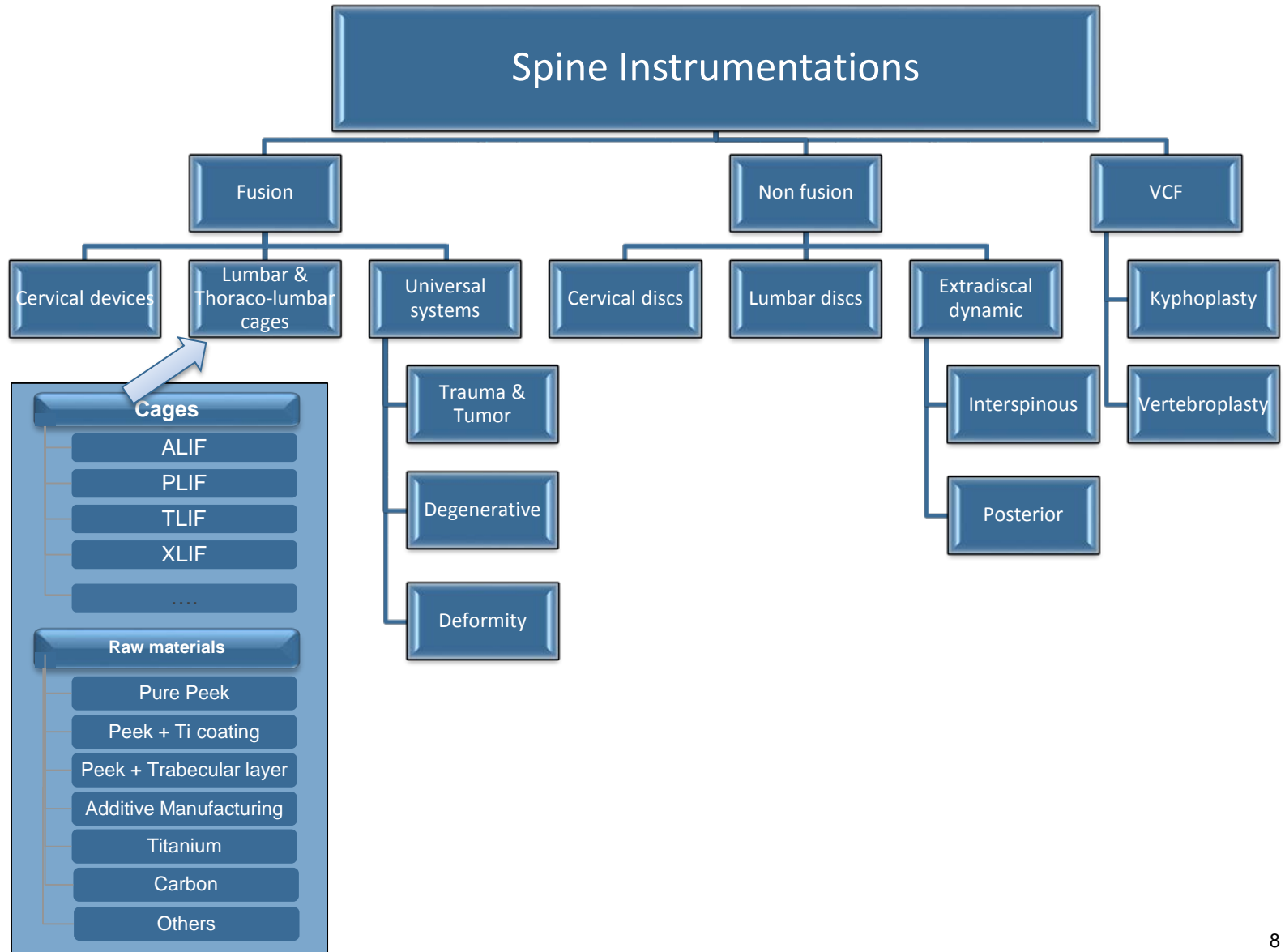


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Spine segmentation

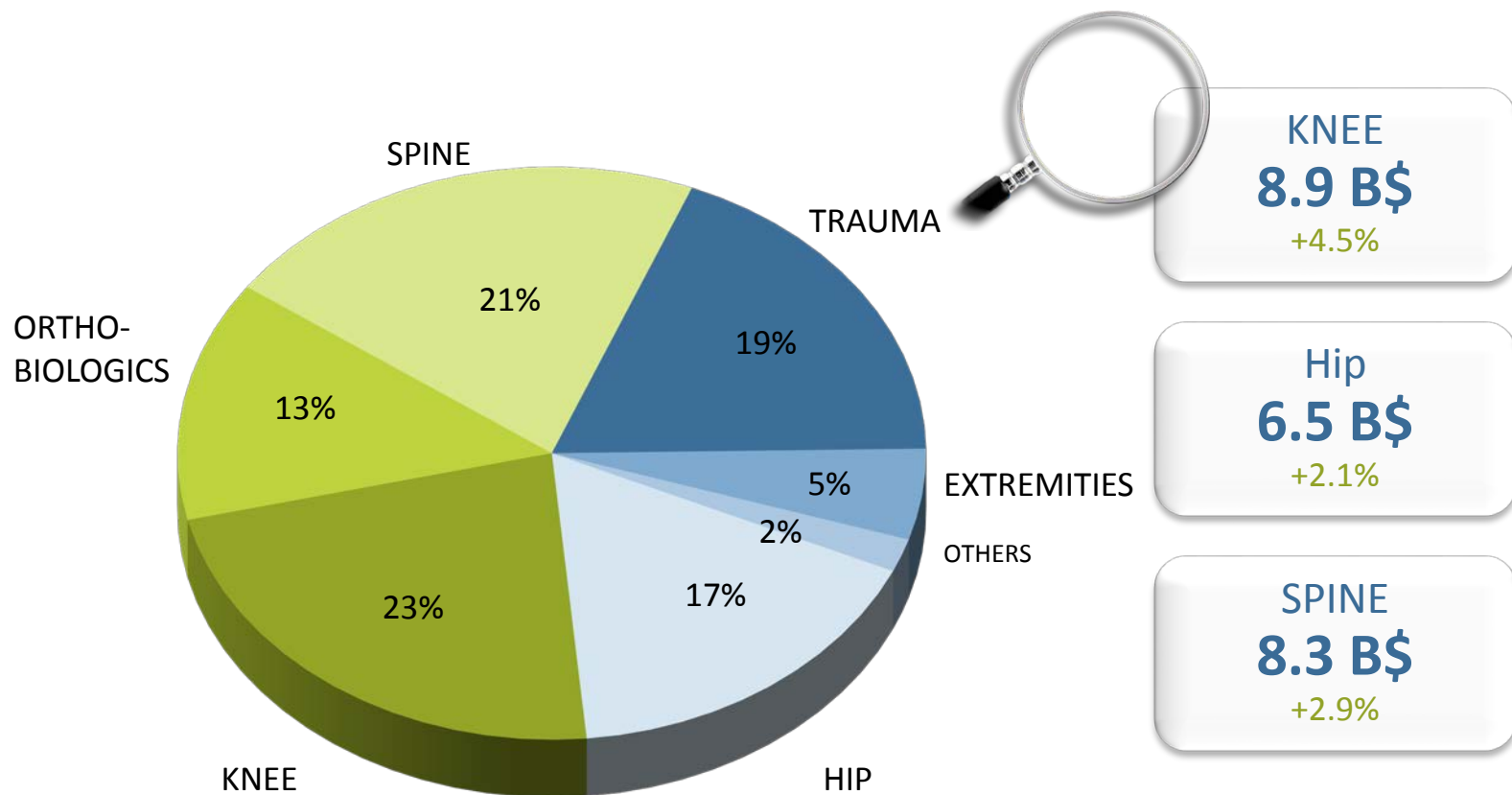


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Worldwide orthopaedic* markets in 2015: ~39 BUS\$ (+4.3%)



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Source: Avicenne research & analysis 2016

- * Not included : Power tools, Arthroscopy & soft tissue repair, sport Medicine, Neuro-stimulation
- Extremities: Shoulder, Elbow, Ankle, Foot, hand,... (excluding trauma)
- Orthobiologics: Allograft, Xenograft, Synthetic Bone, Cement, BMP, others, Cell based Product, Auto repair product, Anti Adhesion product, Hyaluronic Acid,...
- Other: Navigation, ortho. Equipment, etc..

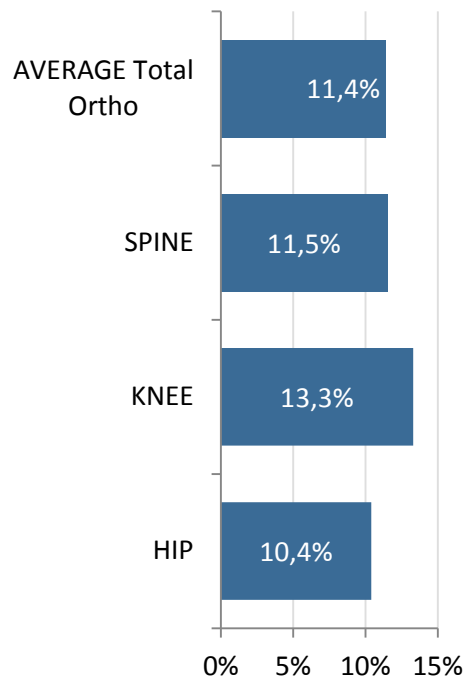
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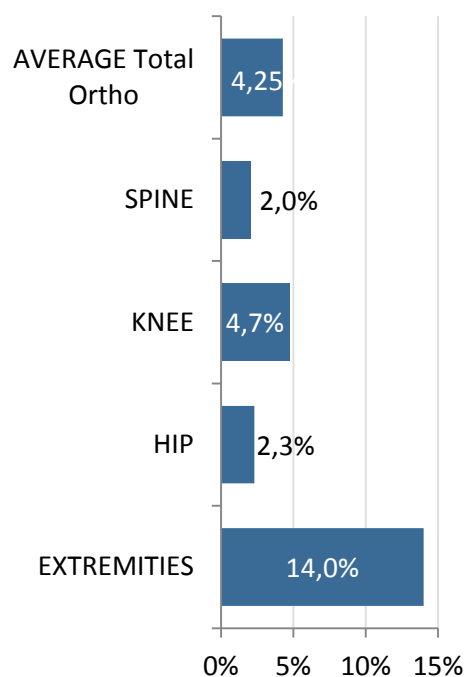
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The Worldwide orthopaedics market: Growth

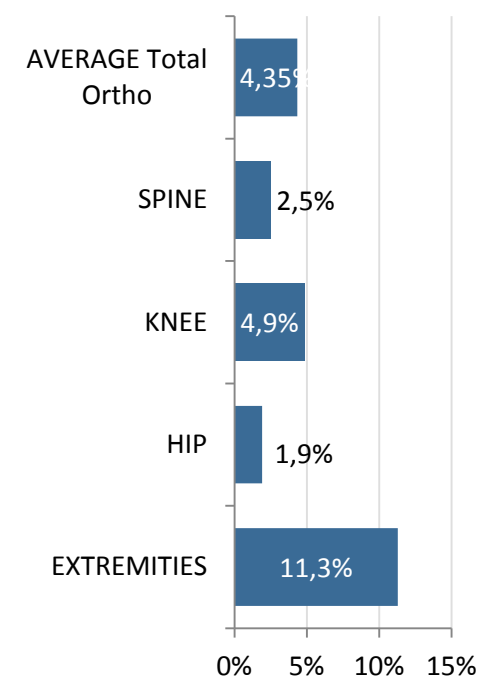
2000 - 2010 CAGR



2010 - 2012 CAGR



2012 - 2015 CAGR



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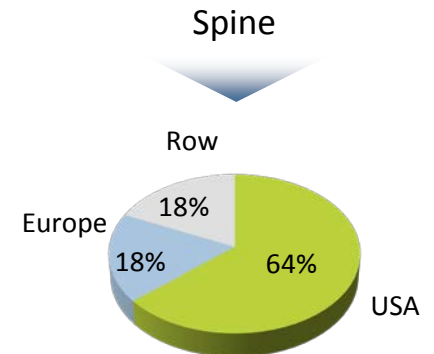
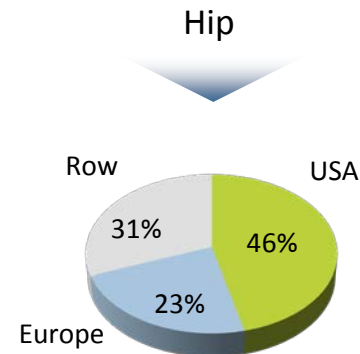
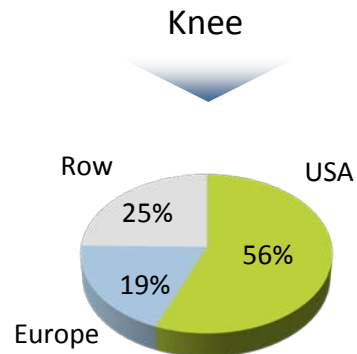
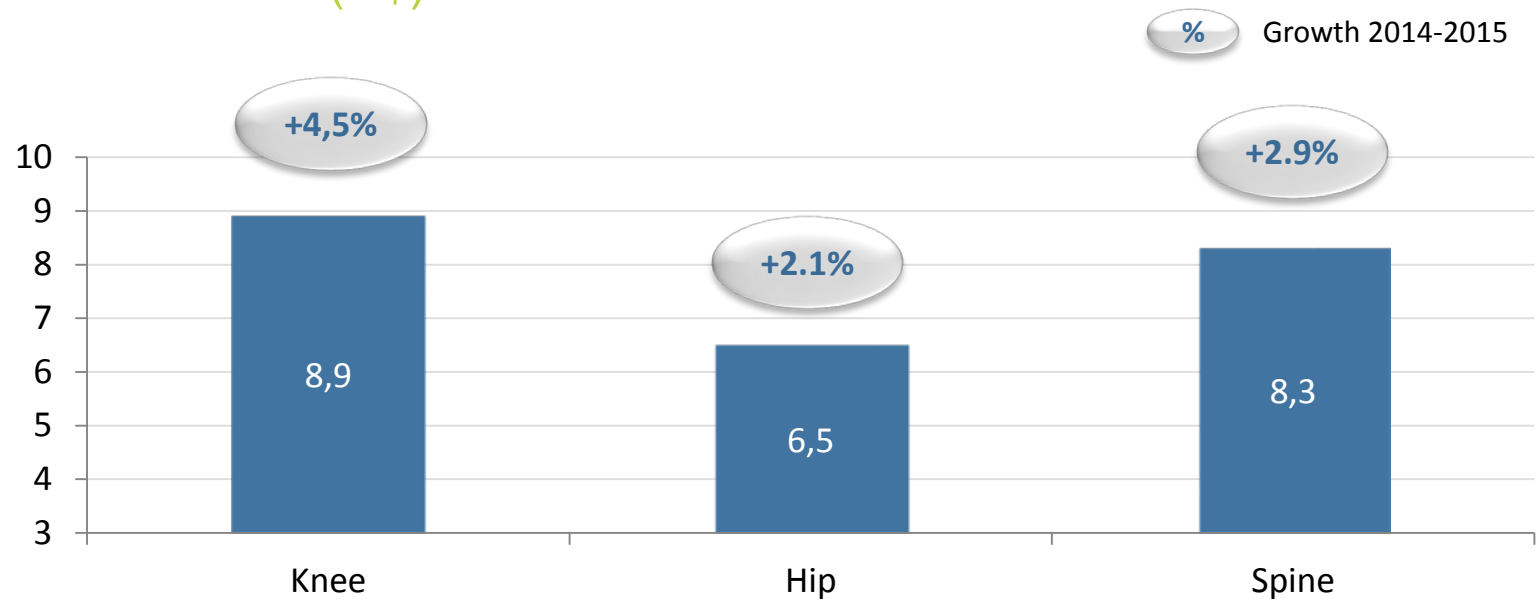
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Source: Avicenne research & analysis 2016

Worldwide implants market in 2015 in value (B\$)


Market value (B\$)

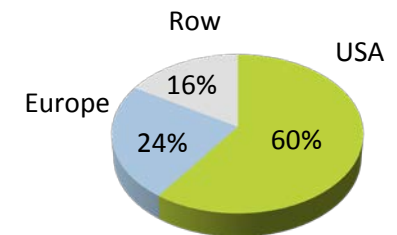
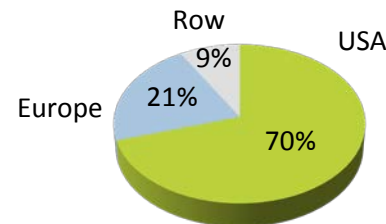
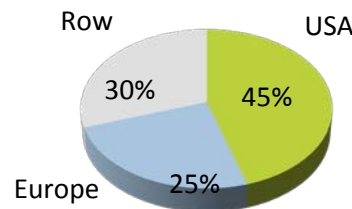
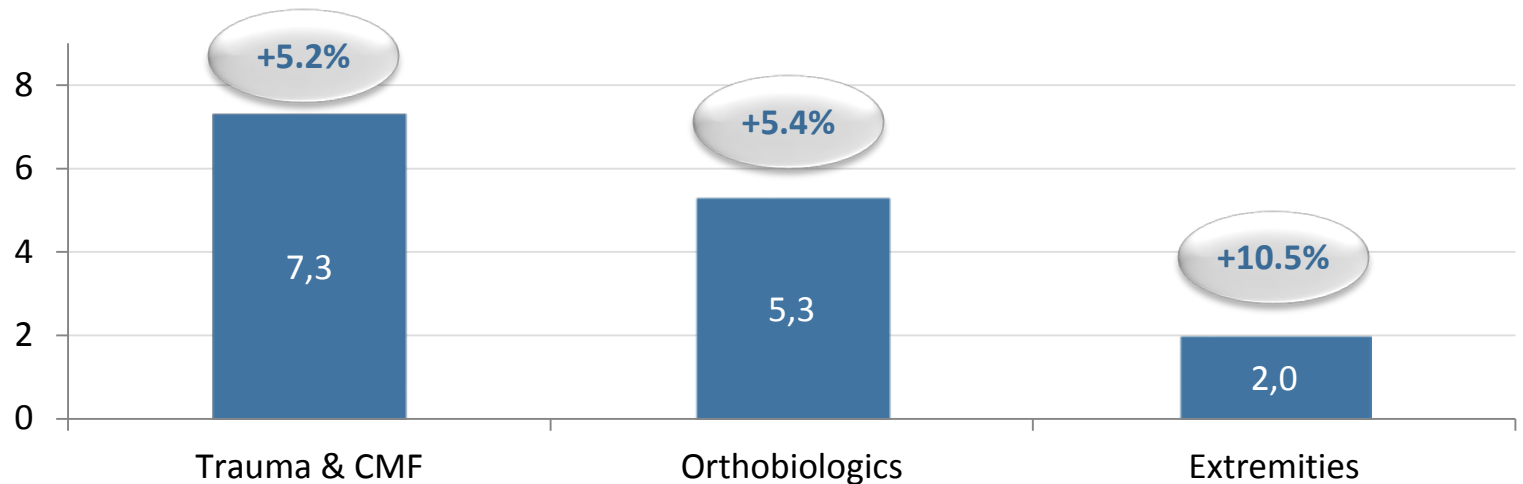


Source: Avicenne research & analysis 2016

Worldwide implants & Orthobiologics market in 2015 in value (B\$)

Market value (B\$)

 Growth 2014-2015



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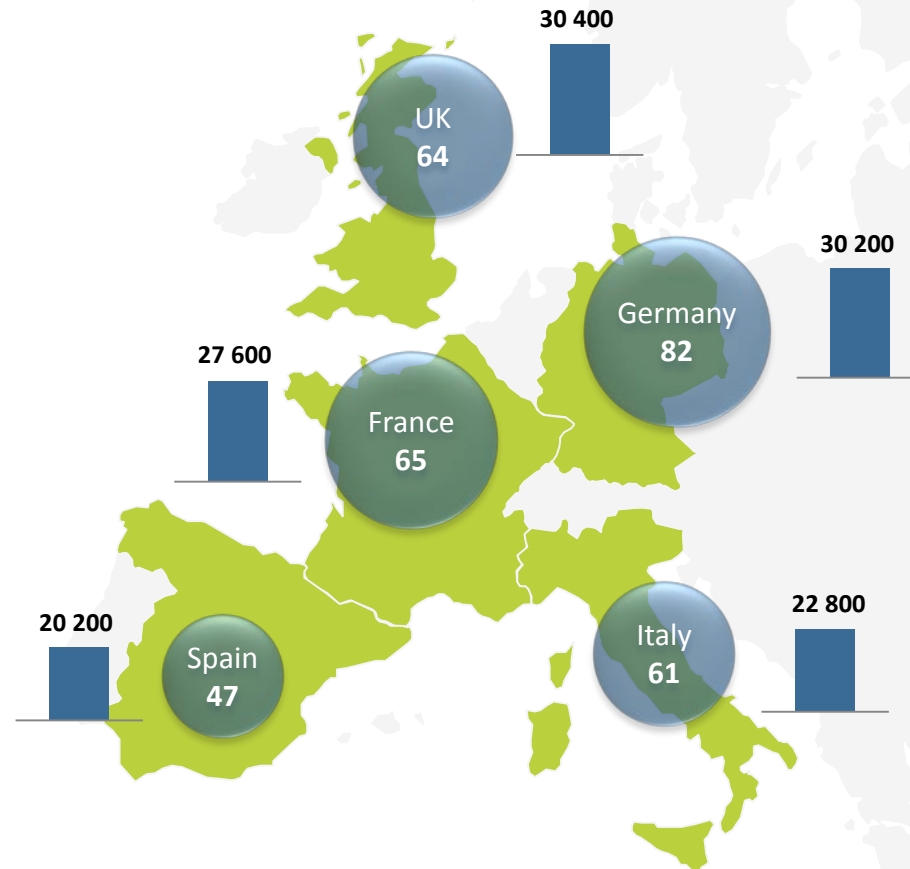
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Source: Avicenne research & analysis 2016

The countries taken into account in Europe are the 17 strongest economies

 Inhabitants in Million
 GDP per capita in US \$



Europe

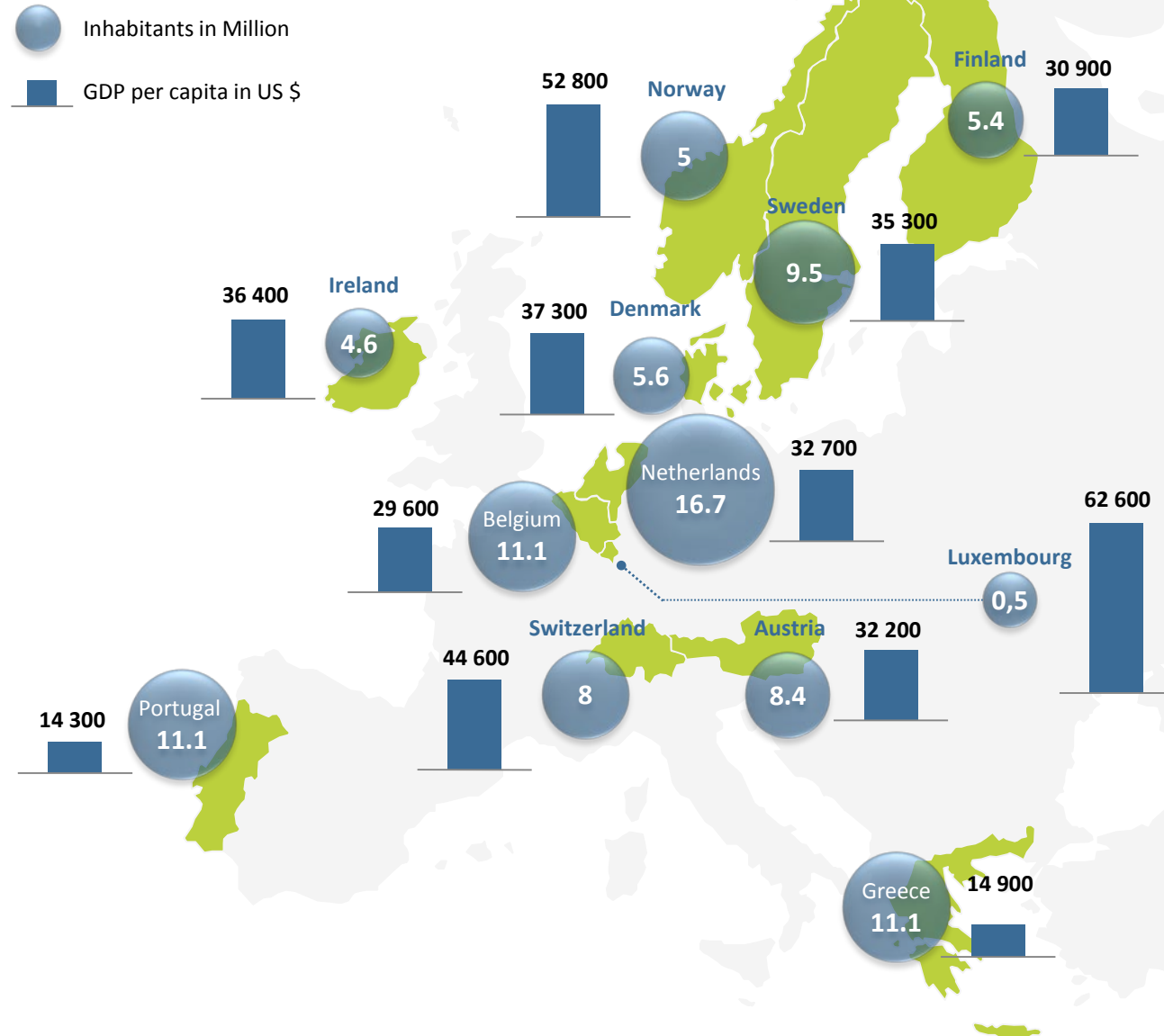
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The countries taken into account in Europe are the 17 strongest economies



Europe

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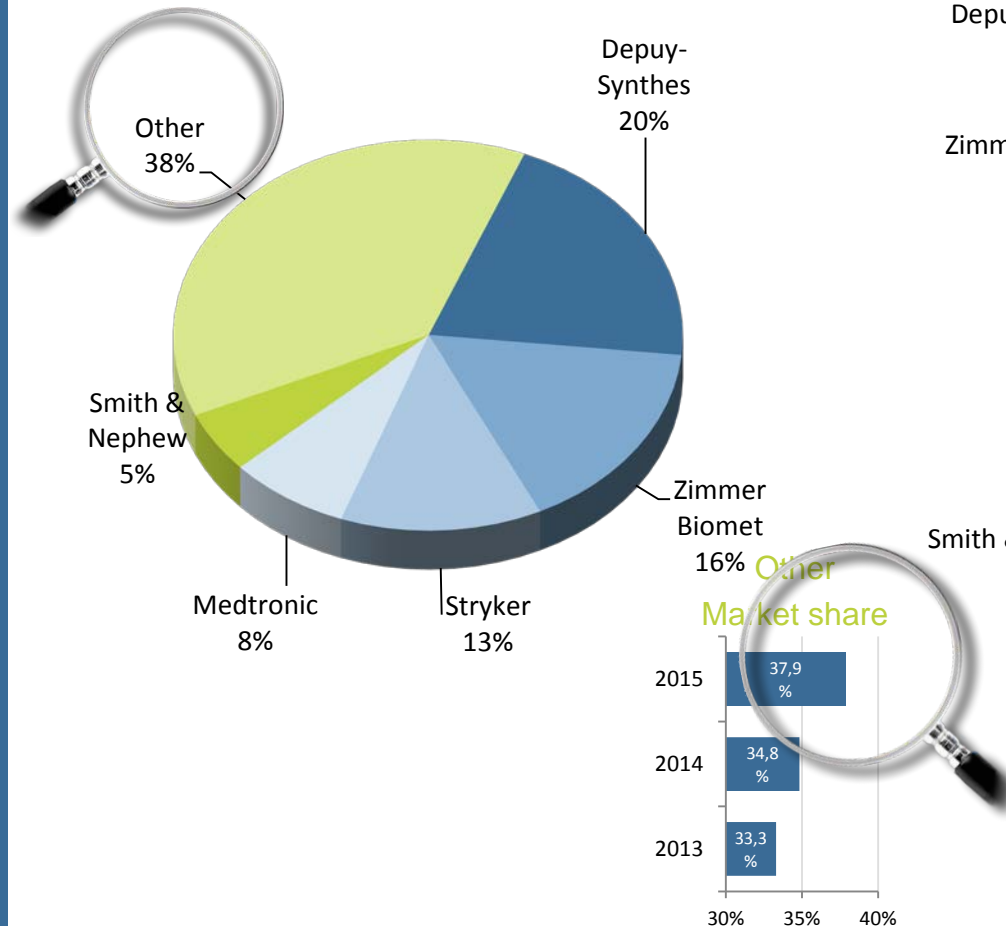
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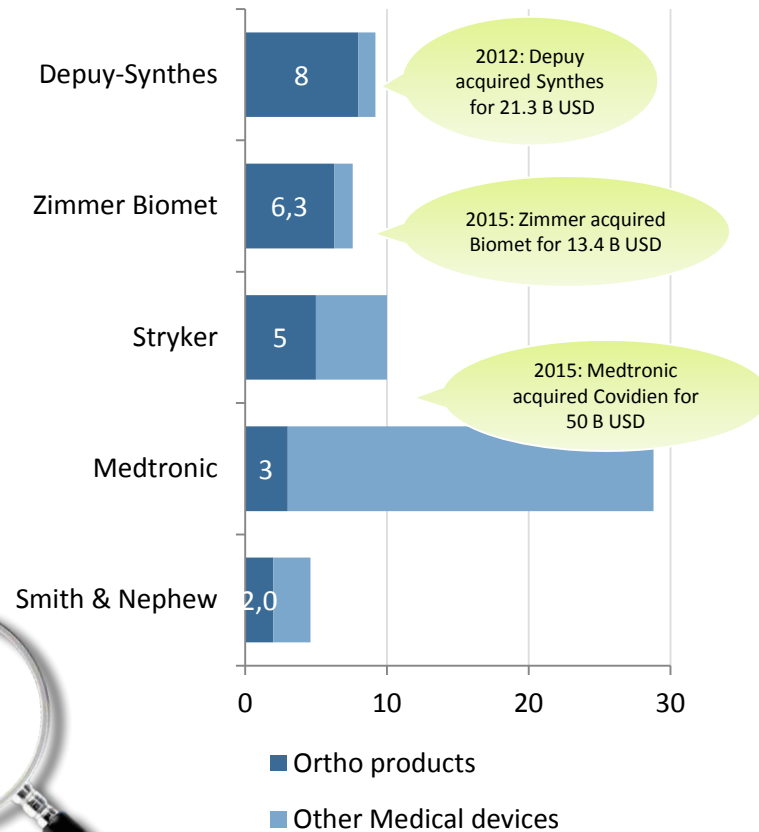
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Worldwide orthopaedic market in 2015: competition

2015 Worldwide Orthopaedic Market



2015 revenues of the Major Orthopaedic Companies (B\$)



Source: Avicenne research & analysis 2016

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Worldwide competition by product in 2015: Market share



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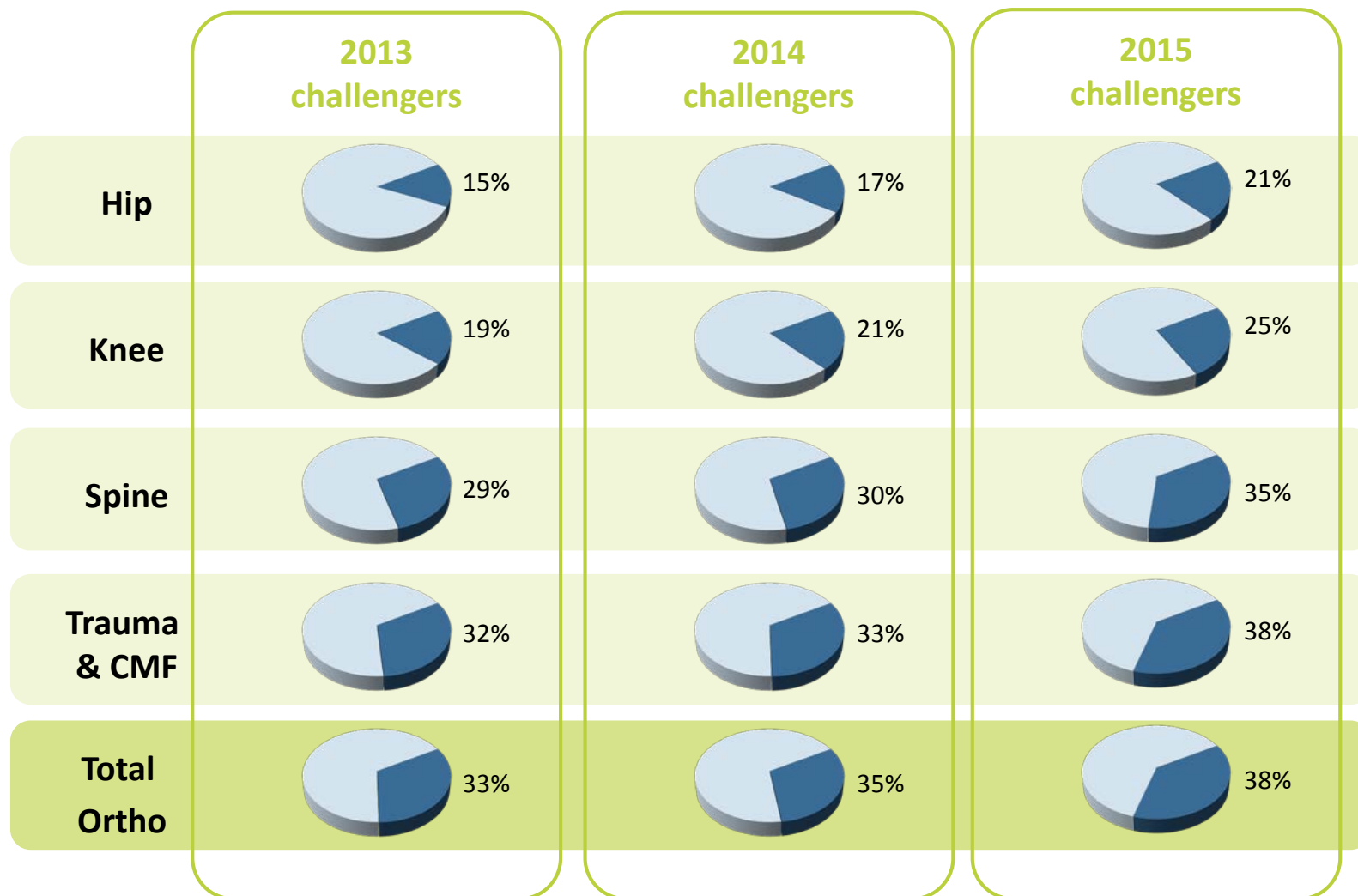
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Source: Avicenne research & analysis 2016

The challengers gained market share continuously



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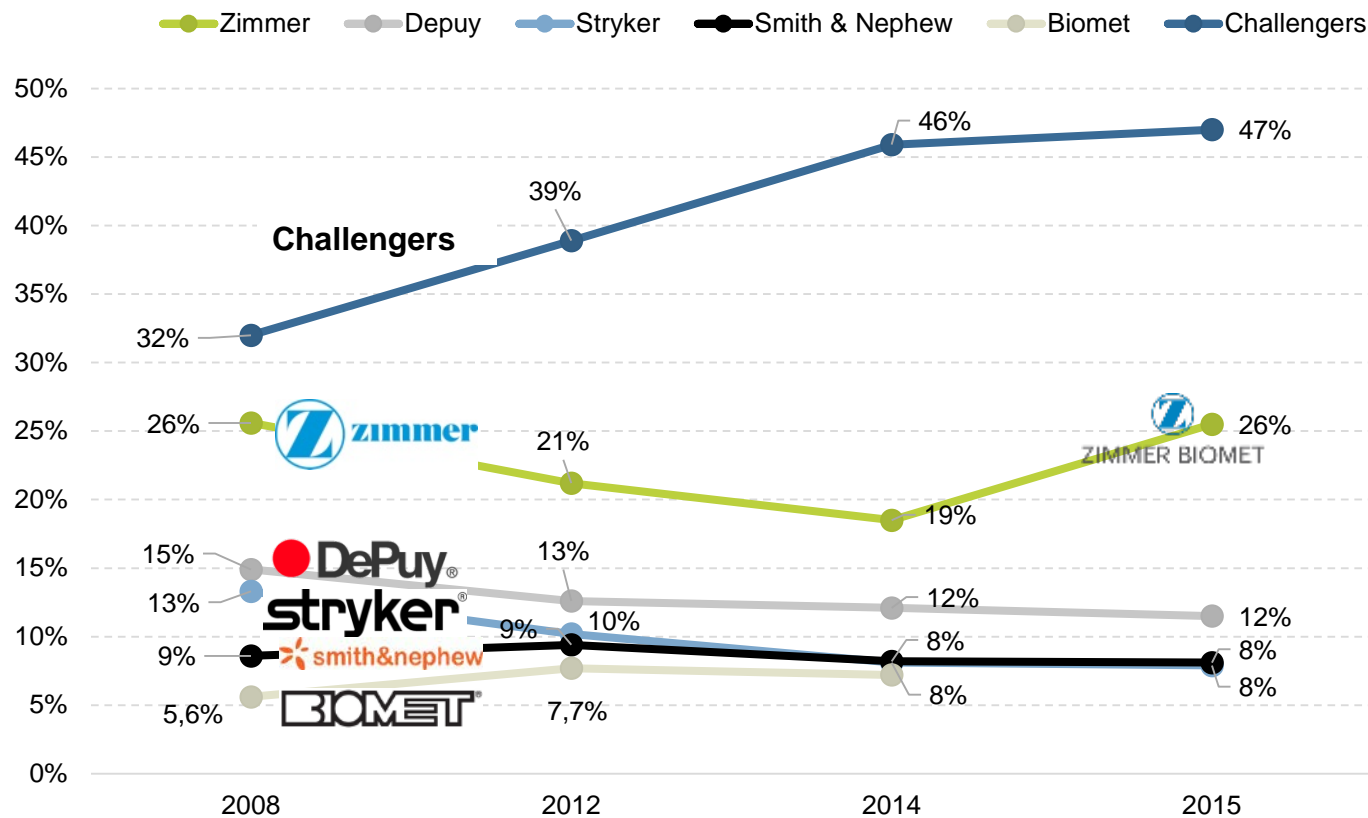
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Source: Avicenne research & analysis 2016

Hip Europe market share 2008-2015

Hip Europe market share



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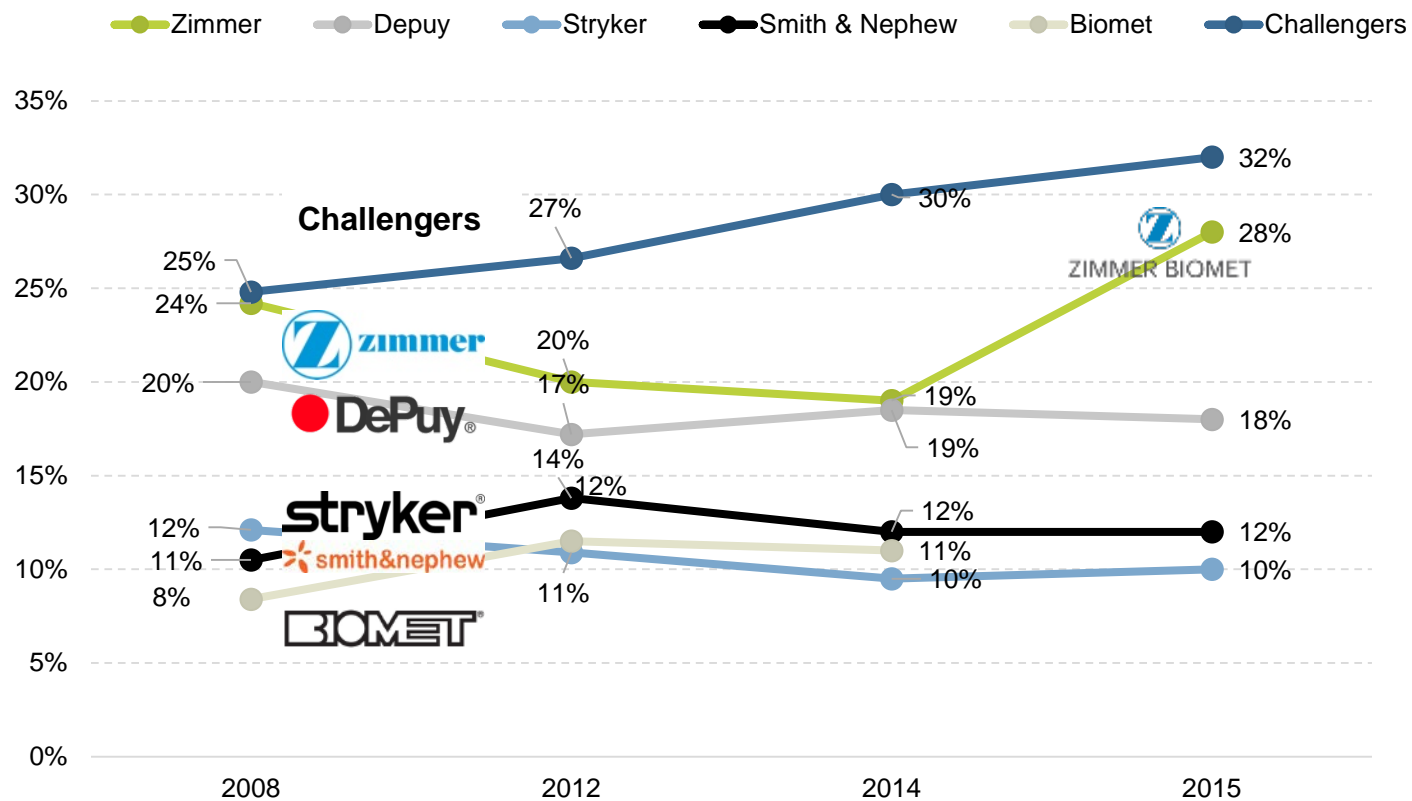
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Source: Avicenne analysis 2016

Knee Europe market share 2008-2015

Knee Europe market share



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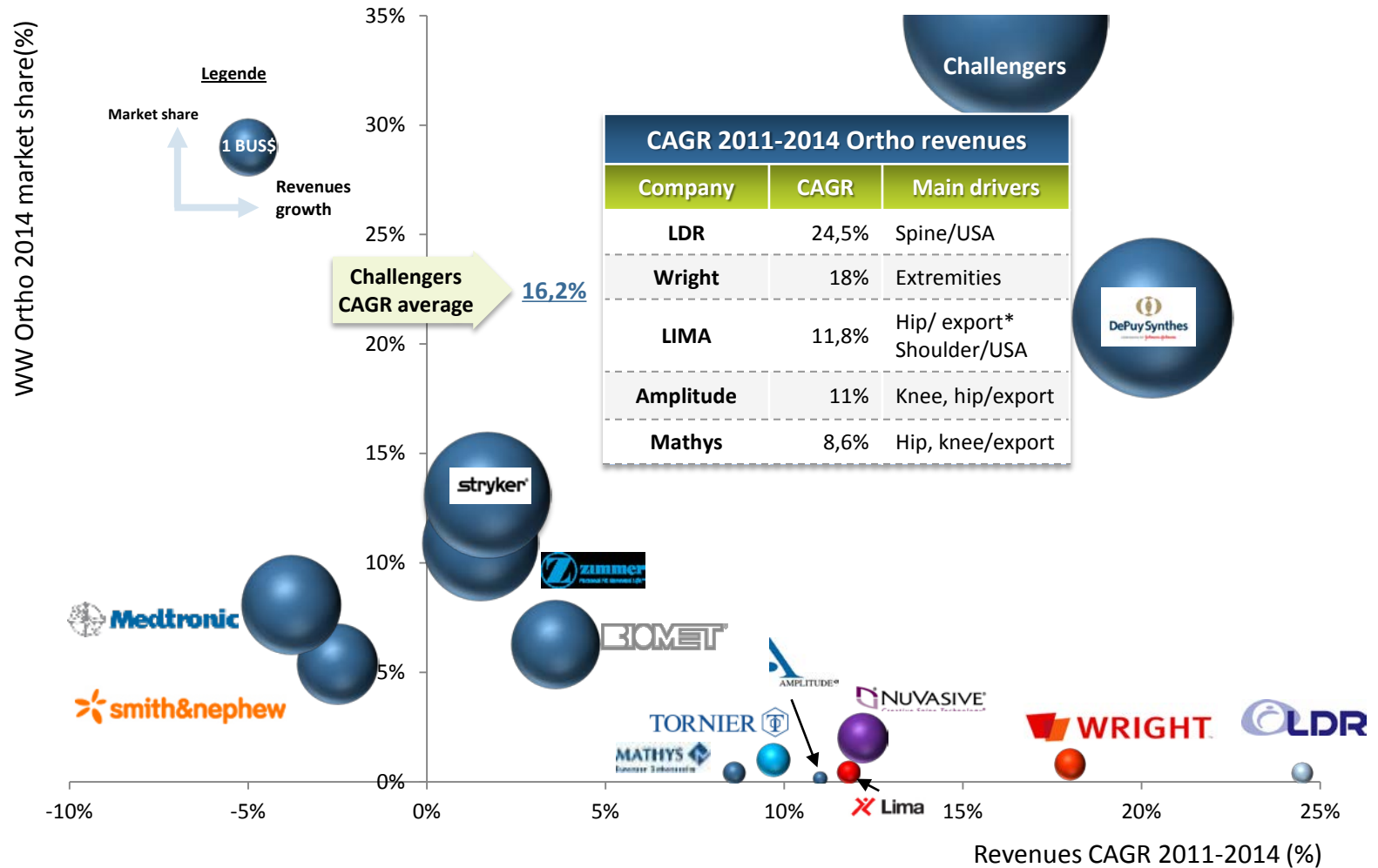
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Source: Avicenne analysis 2016

Majors Vs Challengers: Majors saved their margins & Challengers got the growth!



Worldwide orthopaedic
Contract Manufacturing
market report
2015-2020
&
Top 100 player profiles

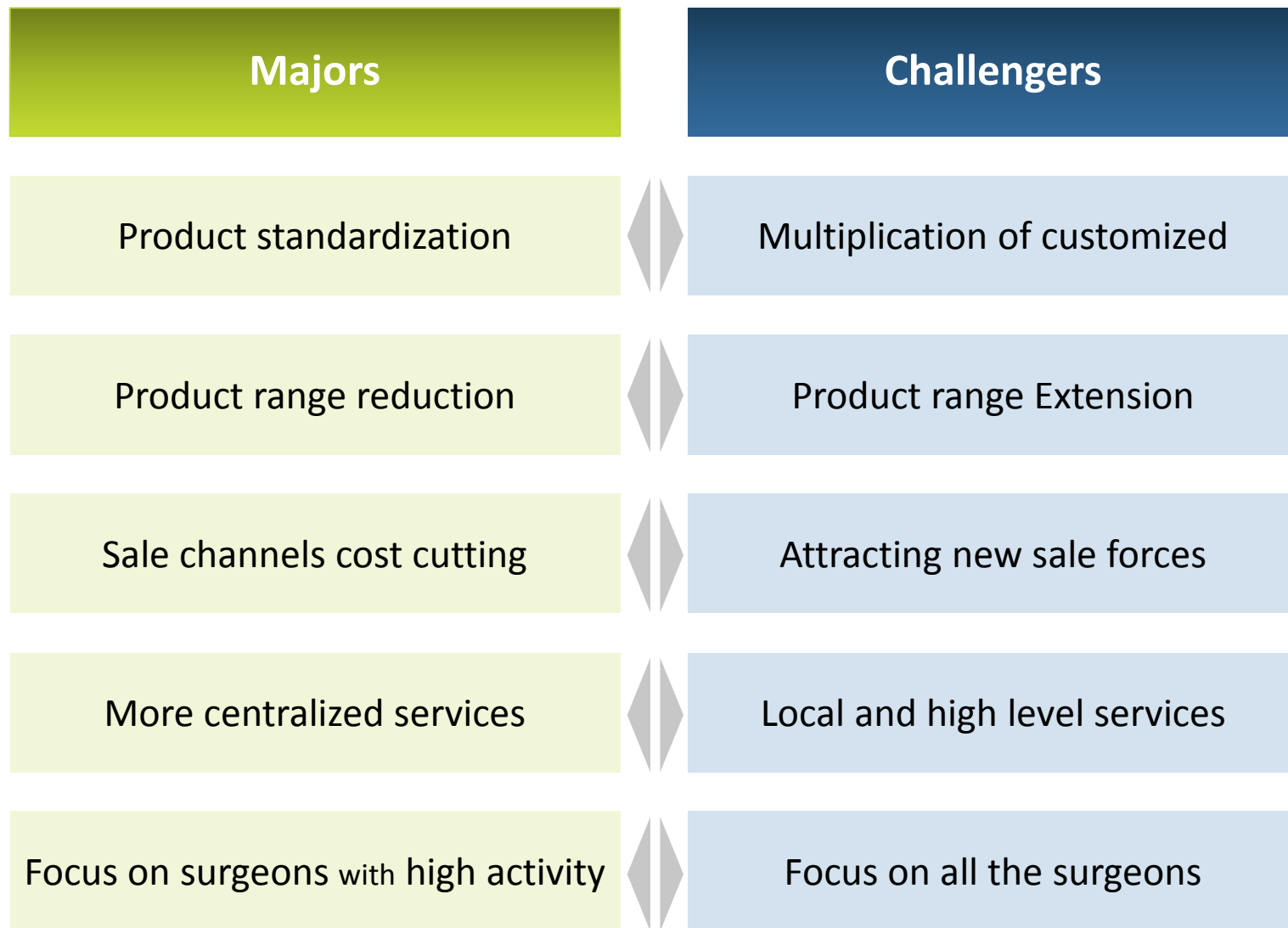
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* export: apart from their home country

Source: Avicenne, annual reports and companies June 2015

Challengers growing Vs Majors



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Source: Avicenne research & analysis 2016

Market Drivers

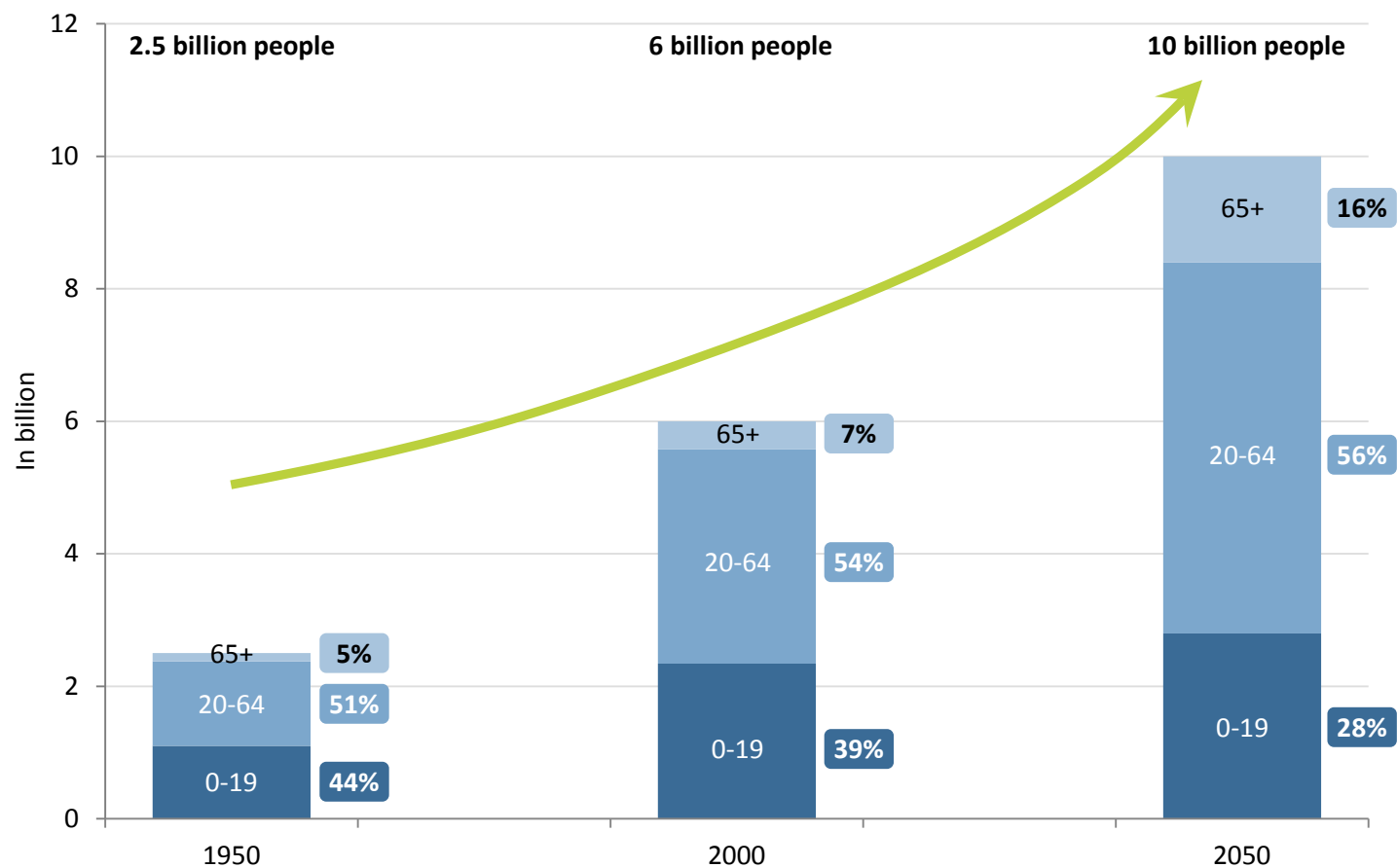
Demographic & Economic

- 📌 **Impact 1:** Population
- 📌 **Impact 2:** Inhabitants 65+ years
- 📌 **Impact 3:** Health expenses
- 📌 **Impact 4:** Obesity

New products & innovation and revision

- 📌 **Impact 1:** Product mix impact

Global population growth 1950-2050 and people over 65



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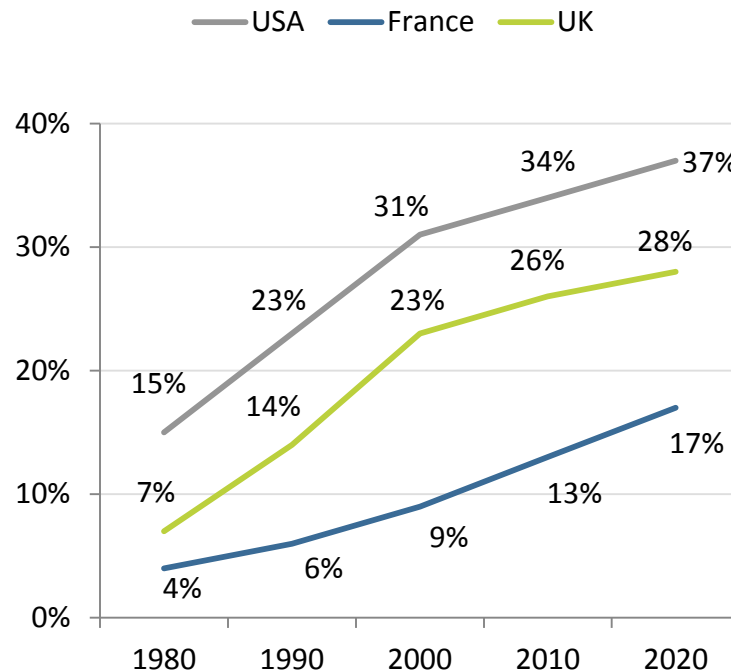
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Source: United Nations – World Population Prospects, The 2012 Revision, Smith & Nephew annual report 2014

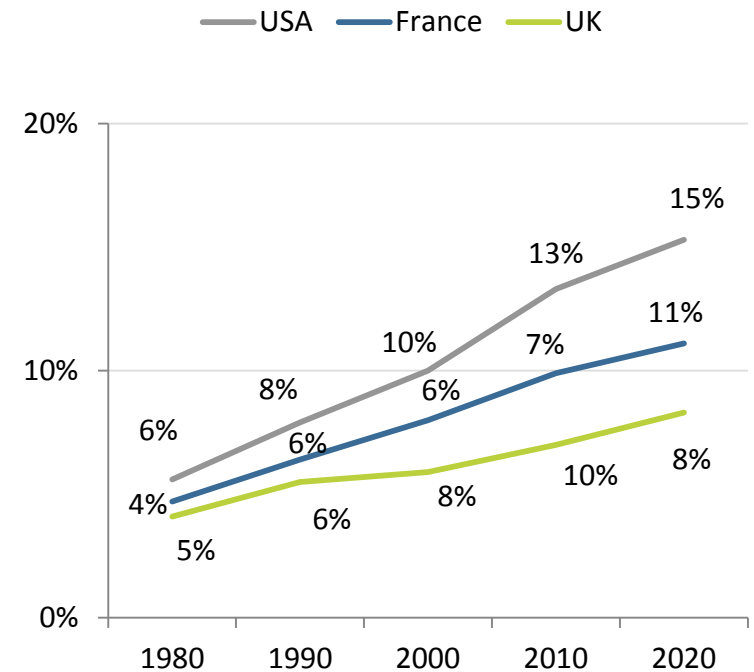
The market drivers: Demographic & Economic

Obesity in developed countries % of inhabitants



Source : OCDE

Health expenses % of GDP



Source : OCDE

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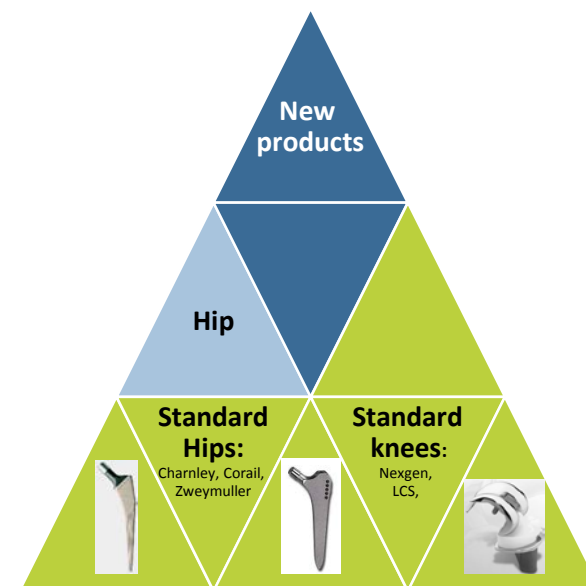
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Innovation and new products pull the market

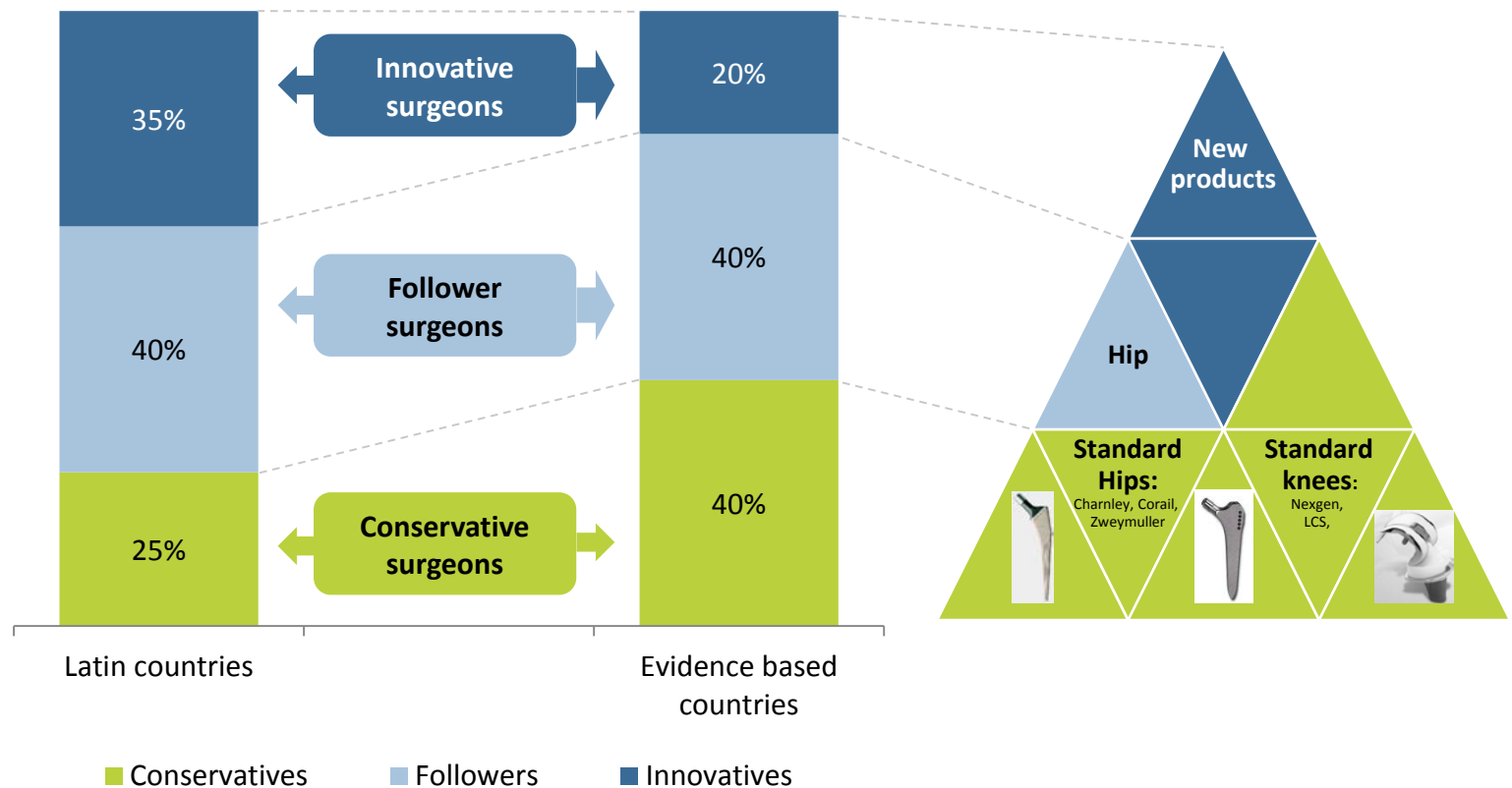
Innovation, new surgical approach, new ancillaries and instruments ... are the keys to capture new surgeons and to increase the average price. The most relevant innovations for the last two decades have been: cementless products, ceramic for hips, reversed shoulder, Trabecular products, etc.

- 📌 New products launch is at the core of the dynamic company development:
 - 📌 Innovations are boosting the market
 - 📌 They capture innovative surgeons
- 📌 Mature implants are becoming generic products and are attacking emerging country markets. Some standard products are re-boosted by minor or significant innovations.
- 📌 The most relevant innovations for the last two decades have been: cementless products, ceramic for hips, reversed shoulder, trabecular products, etc.



Innovative surgeons are looking for new products. They are lured by new orthopaedic projects. Conservative surgeons mainly use standard products with decades of clinical evidences

% of the surgeons by category in each type of country



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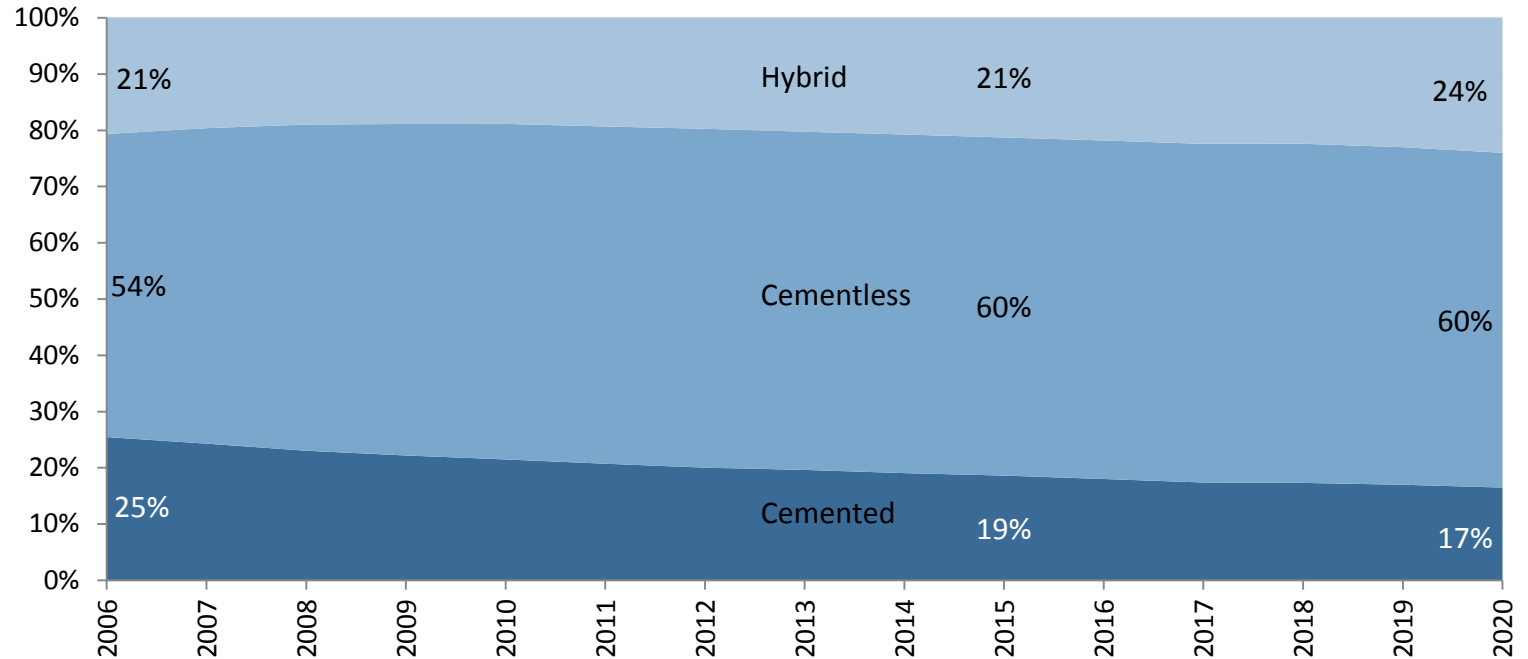
Sources: AVICENNE analysis

Product Mix pulls the market

Total hip trends 2006-2020 (in volume)

Cemented, Cementless, Hybrid

Cemented, Cementless & Hybrid ratio (% of Total hip)



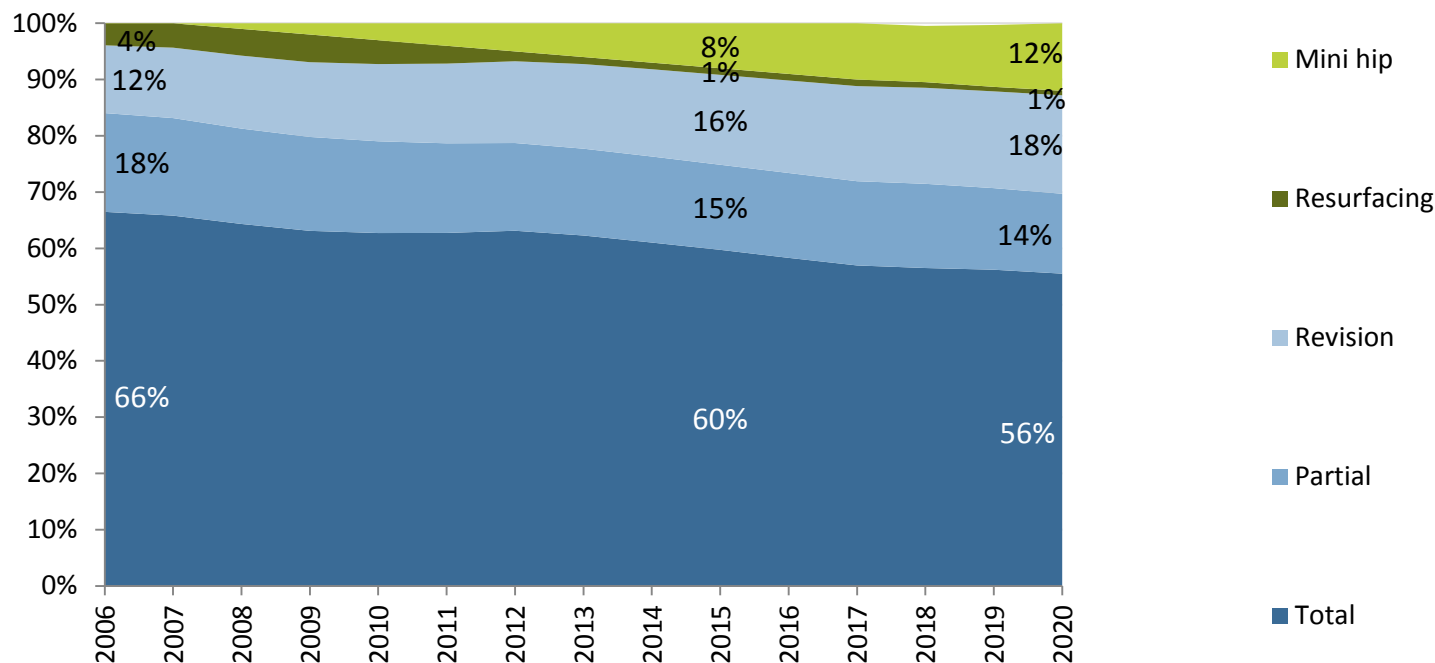
Source: Interviews & Avicenne Research & Analysis 2016

The revision driver: more and more people have more than one implant in their life

Hip implant trends 2006-2020 (in volume)

Total, Partial & Revision hip, mini hip Ratio (% of the global market)

Europe



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Source: Interviews & Avicenne Research & Analysis 2016

The market limiters (1/8)

Reimbursement

- 📌 **Impact 1:** Price decrease
- 📌 **Impact 2:** Longer Time to market

Regulatory

- 📌 **Impact 1:** Time to market
- 📌 **Impact 2:** Higher development Cost

Buying Groups

- 📌 **Impact 1:** Price decrease
- 📌 **Impact 2:** More Low-end products demand

The market limiters (2/8)

Reimbursement and pricing regulation

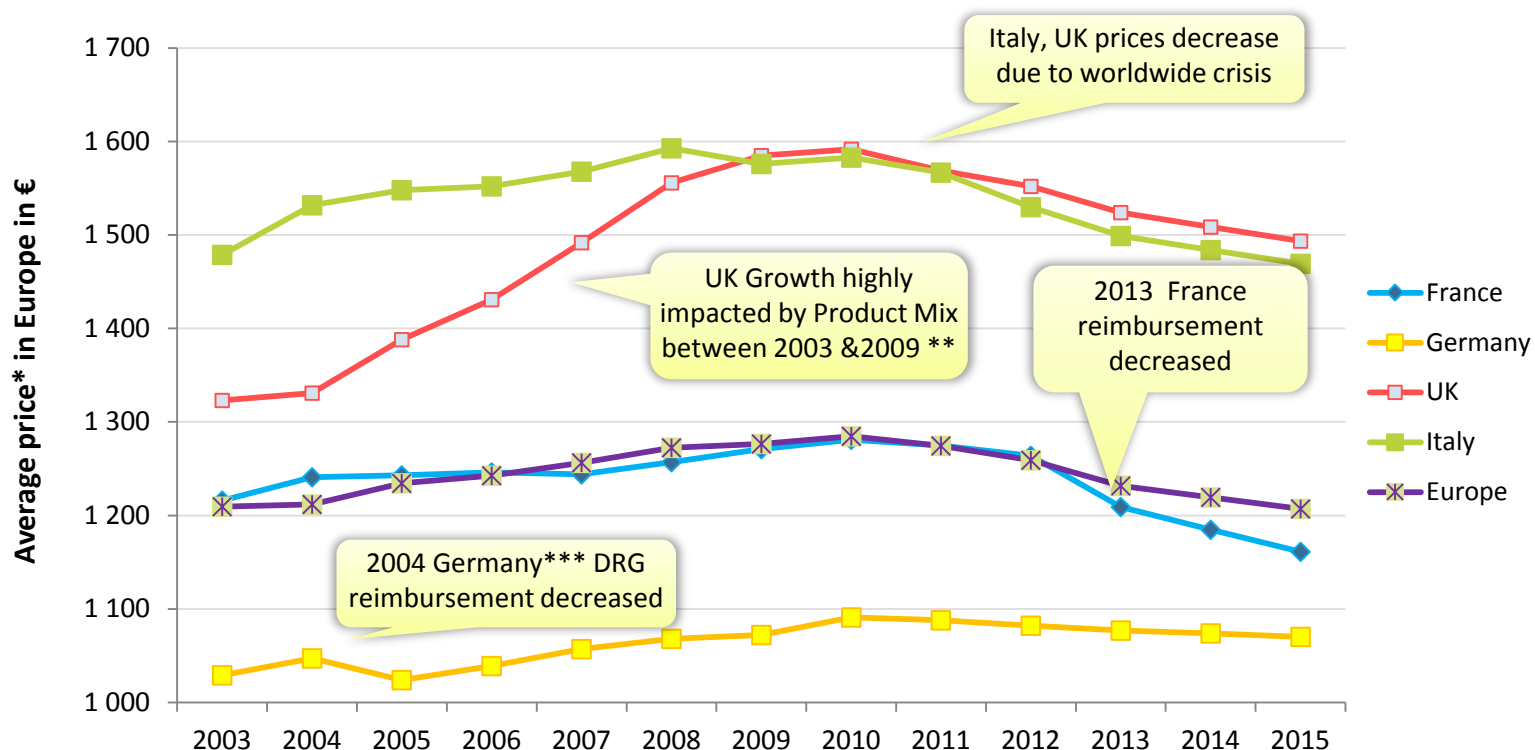
	USA	Germany	UK	Sweden	Italy	Belgium	Switzerland	France
Launch date & extension	1983	2003-2010	2002-2007	1992-1994	1994-1998	1984	2002	2003-2012
Classification system	DRG	G-DRG (derivate from Australian) system	HRG (derivate from US system)	Nordic DRG	ROD (derivate from US system)	APR-DRG (derivate from US system)	DRG (US system)	GHM (derivate from US system)
Targets	Coverage of all Medicare budgets	75% of C-DRG in 2007	Target of 100% HRG in 2006	Coexistence 50% DRG, 30% global dotation & 20% de reimbursement	Coexistence of 80%-90% ROD, 6-7% planification funds, & 3-14% extra funds		Main application: every day expenses Invest-ments supported by the "cantons"	50% T2A in public hospitals & 100% in private and public in 2012

For more than 20 years, a general concern for controlling health expenses has started in the developing countries with the introduction of the DRG type systems

The market limiters (3/8)

HIP average price* trend in Europe

After many years of constant average price growth due to product mix effect, with an increasing volume, European countries are trying to curtail the ballooning expenses. They used reimbursement price regulation to stabilize their spending.



* Average price in Europe in € = Total country market in value / total market in units, the average price is highly impacted by Product Mix effect

** In 2003 in UK, the cementless hip was the lowest rate in Europe : 17% in UK, Vs 53% in France, 4% in Germany. This figure, 17%, increased drastically!

*** In Germany, ancillaries are billed separately by orthopaedic companies and not included in this average price

Source: Avicenne European Orthopaedic market report 2015-2020

Europe

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June 2015

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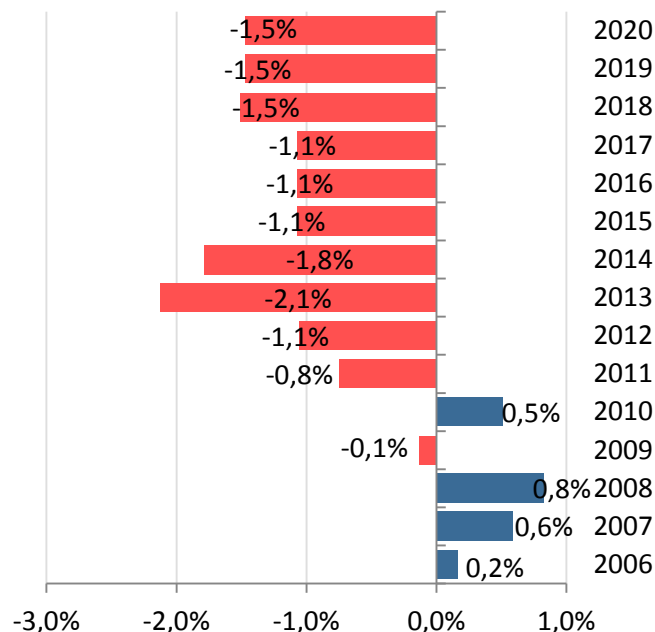
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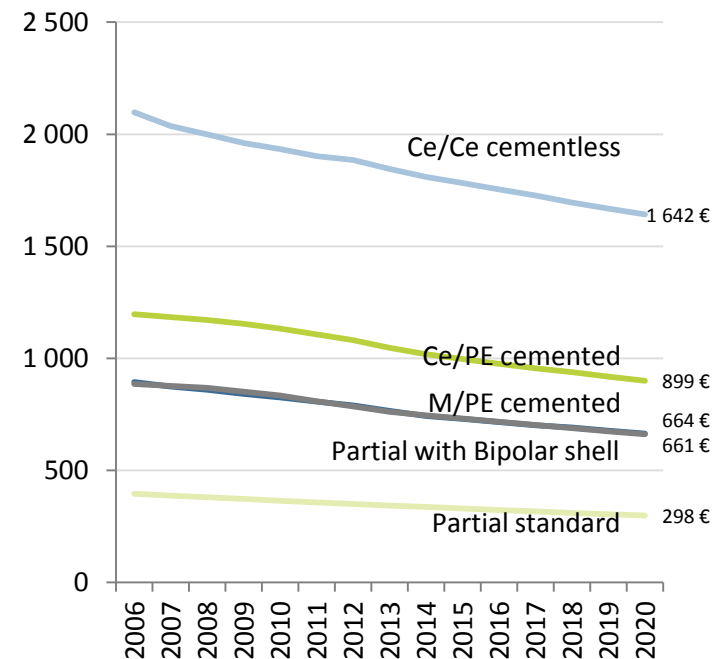
Price trends (4/8)

Average sales price trend per year for hips



Example of price decrease for each product (Euros)

Average forecasted price decrease/year from 2013 to 2020: -1.3 %



Source: Interviews & Avicenne Research & Analysis 2016

Europe

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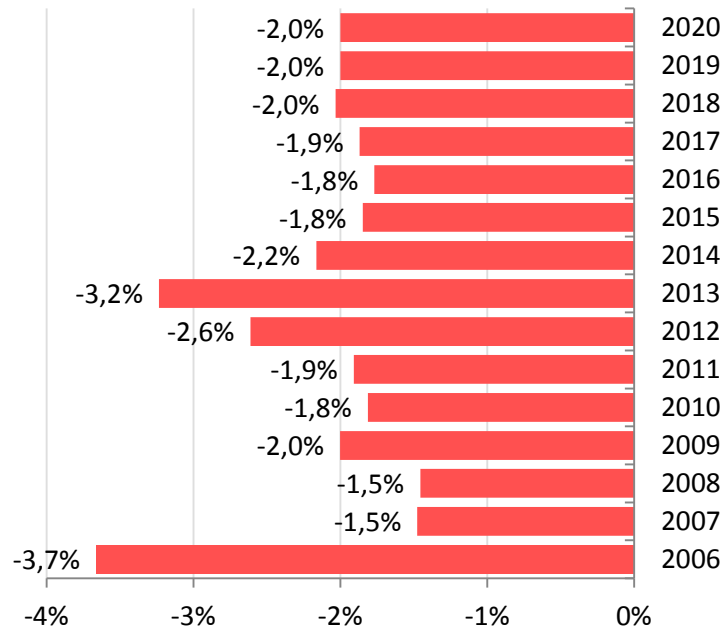
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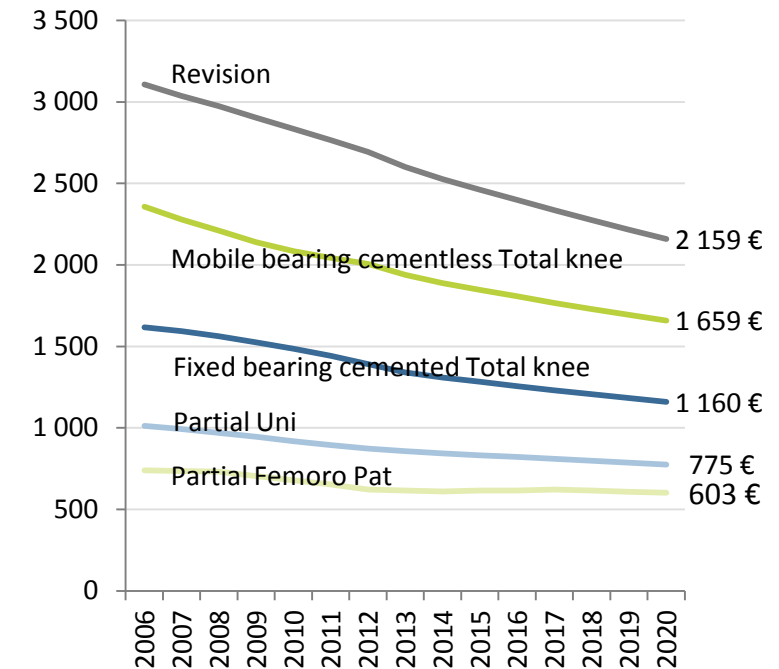
Price trends (5/8)

Average sales price trend per year for knees



Example of price decrease for each product (in Euros)

Average forecasted price decrease/year from 2013 to 2020: -1.9 %



Source: Interviews & Avicenne Research & Analysis 2016

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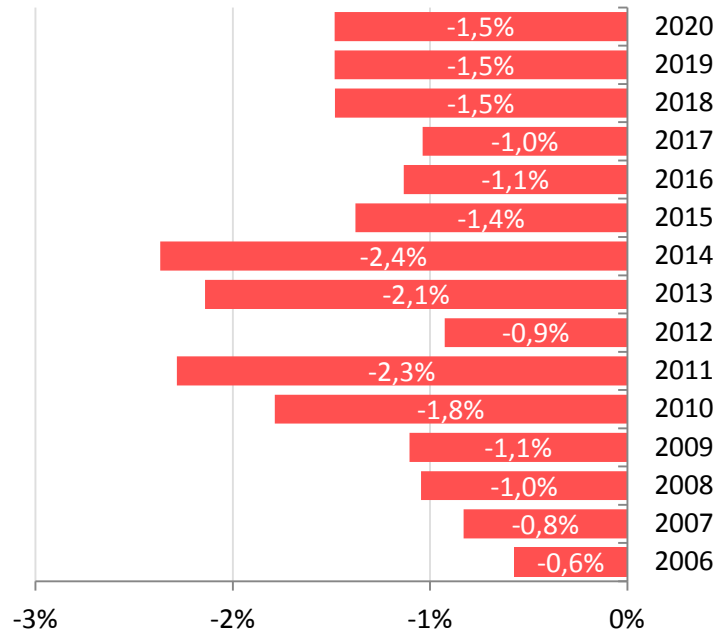
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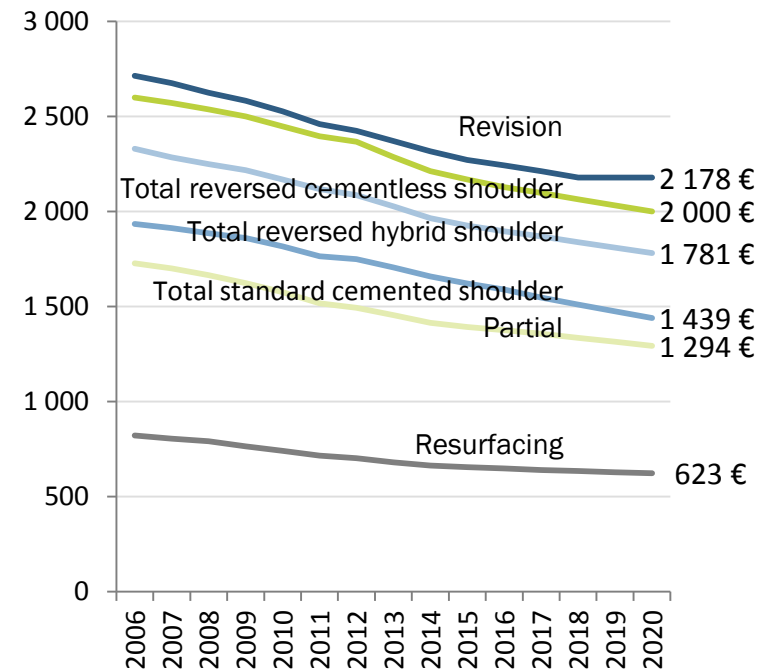
Price trends (6/8)

Average sales price trend per year for shoulders



Example of price decrease for each product

Average forecasted price decrease/year from 2013 to 2020: -1.5 %



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Source: Interviews & Avicenne Research & Analysis 2016

The market limiters (7/8)

Regulatory, Certification,...

	REFERENTS	DETAILS	IMPACT ON THE MARKET
Regulatory	European Directive 93/42	<ul style="list-style-type: none"> CE mark Clinical tests Sales authorization 	<ul style="list-style-type: none"> Additional costs Longer time to market Concentration of the product range Limitation of new product launches
	ISO 13 485	<ul style="list-style-type: none"> Medical devices vigilance system Certification of « whole production line » 	<ul style="list-style-type: none"> Longer time to market Shared risks Additional Insurance costs Change in contract manufacturing practice

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The market limiters (8/8)

Group purchasing developments in Germany drove the implant prices down... It now serves as a model in lot of other European countries

Group purchasing
was a success in
Germany...



- For example the basic knee (fixed tibial plate - cemented) is priced at 1 350 €, for some tenders a Major proposed 900 € for this basic product.
- Another Major had in his customer portfolio the “Endoclinic and DAM Group” for 4 hospitals, with 10,000 knee and hip sales per year! Average price for the knee for this customer is much less than 1 000 €.

...it was much
less successful in
France and Italy

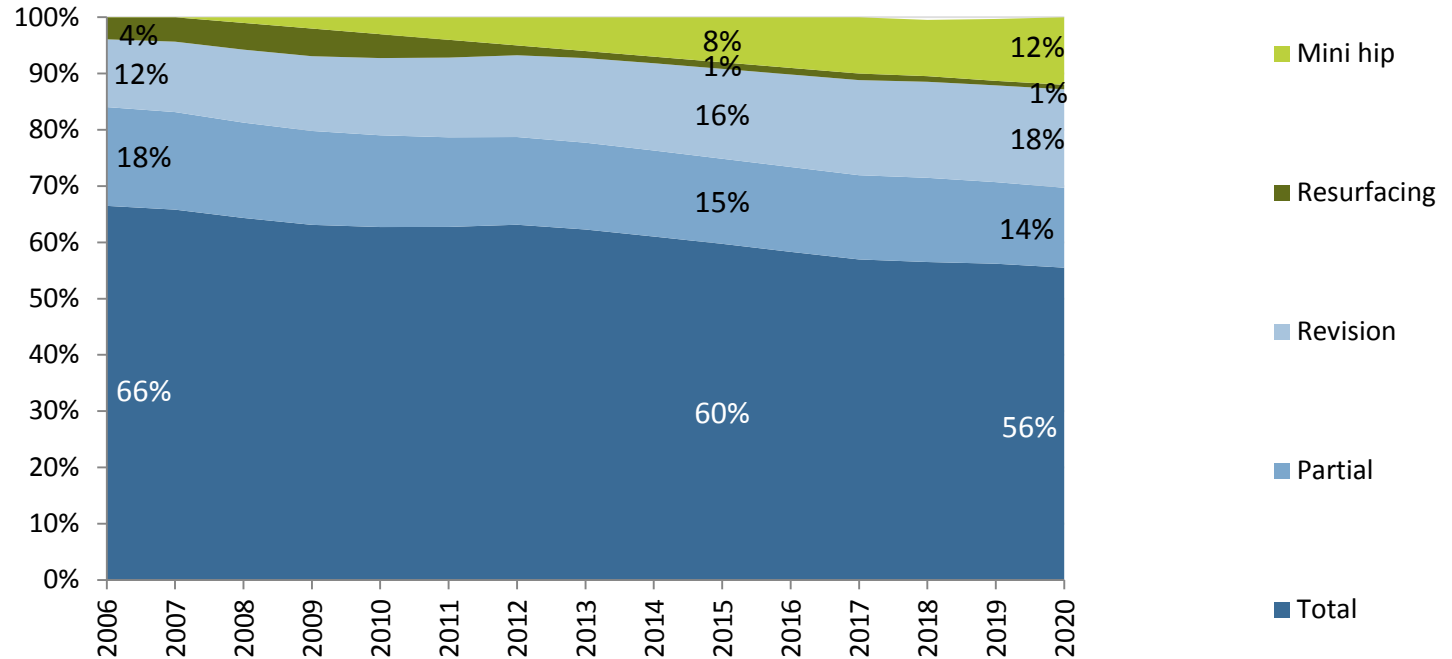


- Some private hospital groups in France like “Vitalia or Générale de Santé” have tried to centralize their implant purchasing, but it is only the beginning. The discounted price was only a few % lower and those hospitals have to share these savings with the “French Caisse d’Assurance Maladie”.
- The surgeon name reputation is considered as product marketing showcase of the private hospitals, which are making what is necessary to keep their surgeons. Hence they are not focusing on implants price reduction.
- In Italy, purchasing groups make less than 10% of the total orthopaedic market value per year and growing slowly.

The revision driver: more and more people have more than one implant in their life

Hip implant trends 2006-2020 (in volume)

Total, Partial & Revision hip Ratio (% of the global market)



Europe

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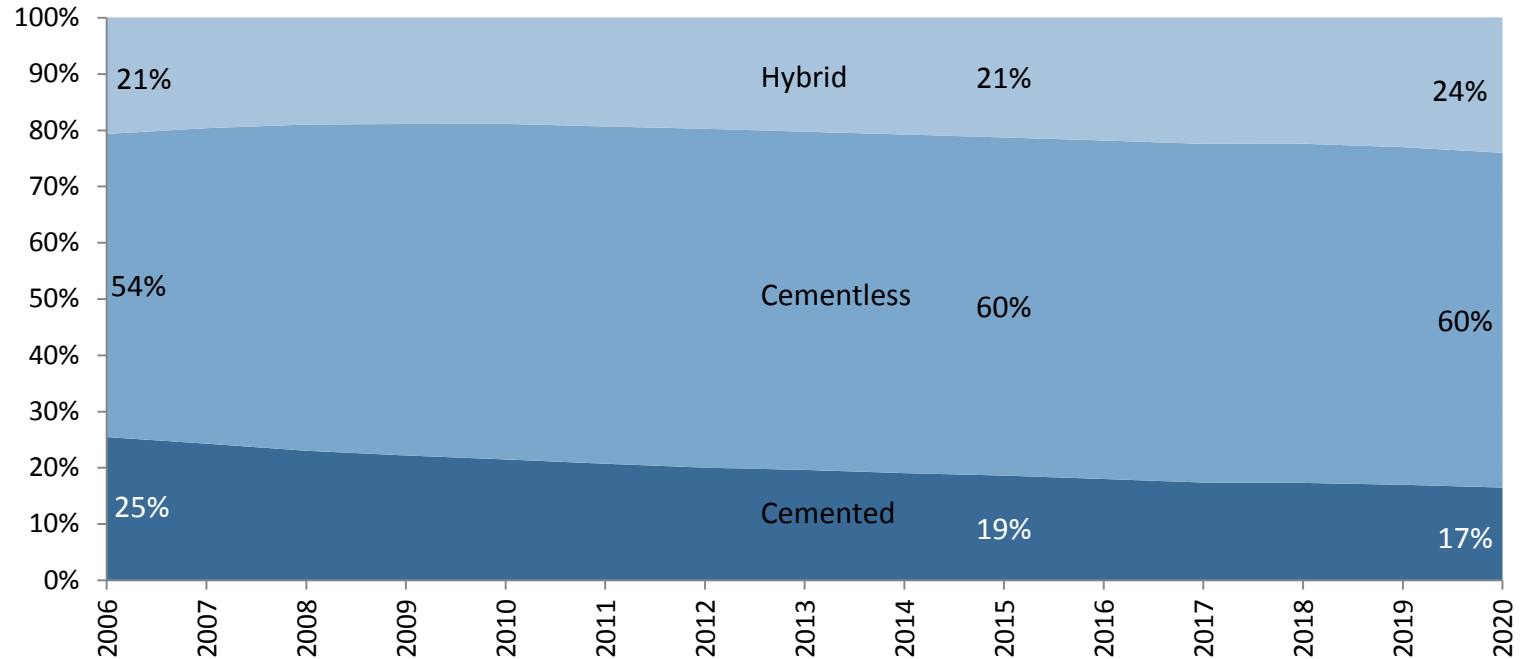
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Total hip trends 2006-2020 (in volume)

Cemented, Cementless, Hybrid

Cemented, Cementless & Hybrid ratio (% of Total hip)



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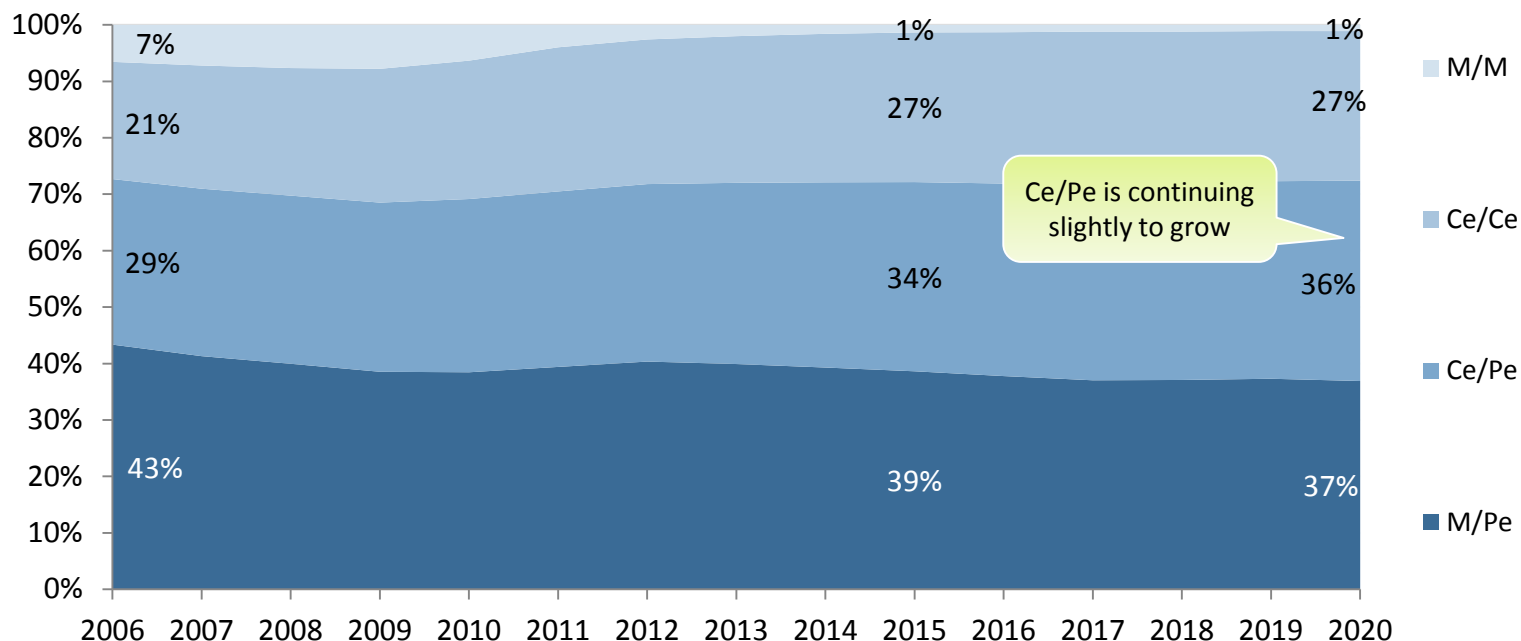
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a.madani@avicenne.com

Source: Interviews & Avicenne Research & Analysis 2016

Cementless trends 2006 – 2020

M/Pe, Ce/Pe, Ce/Ce, M/M

M/Pe, Ce/Pe, Ce/Ce & M/M ratio
(% of Cementless & Hybrid Total hip)



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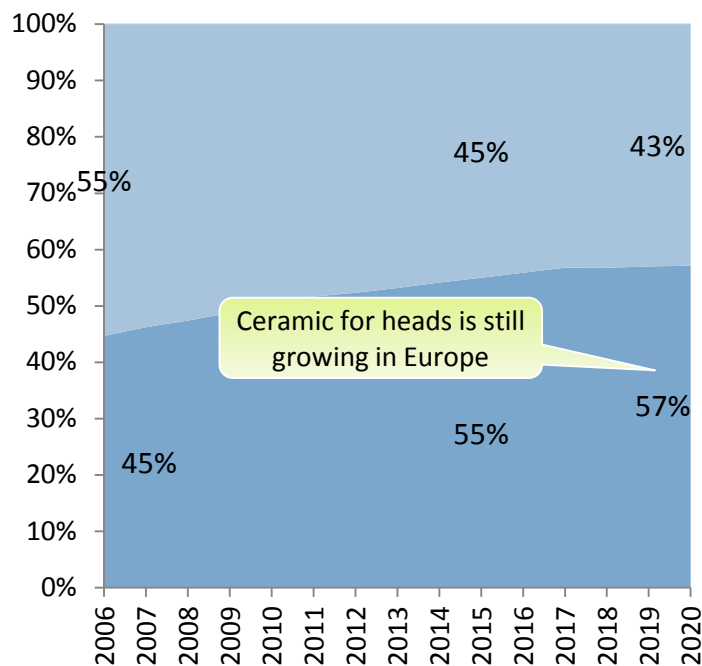
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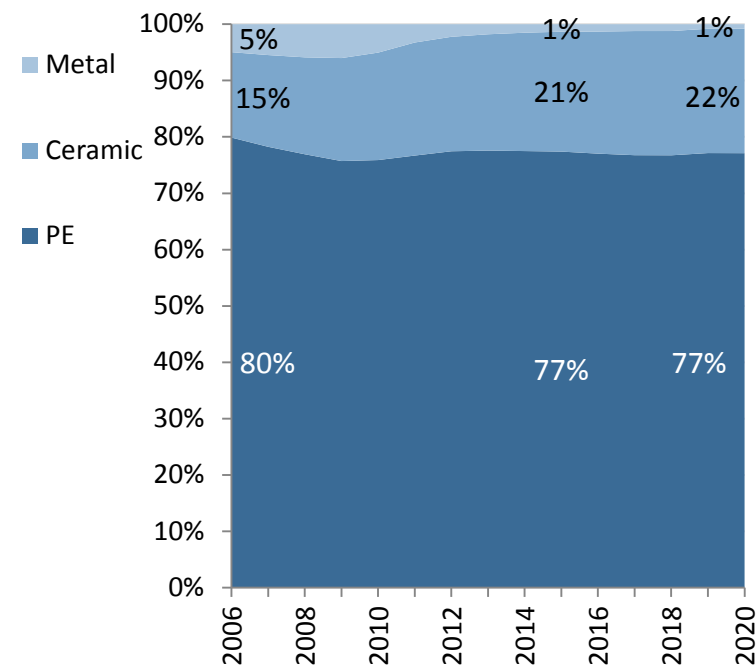
Source: Interviews & Avicenne Research & Analysis 2016

Ceramic, Metal & PE trends for Heads and Cups 2006-2020

% of Metal & Ceramic HEAD



% of Metal, Ceramic & PE CUP



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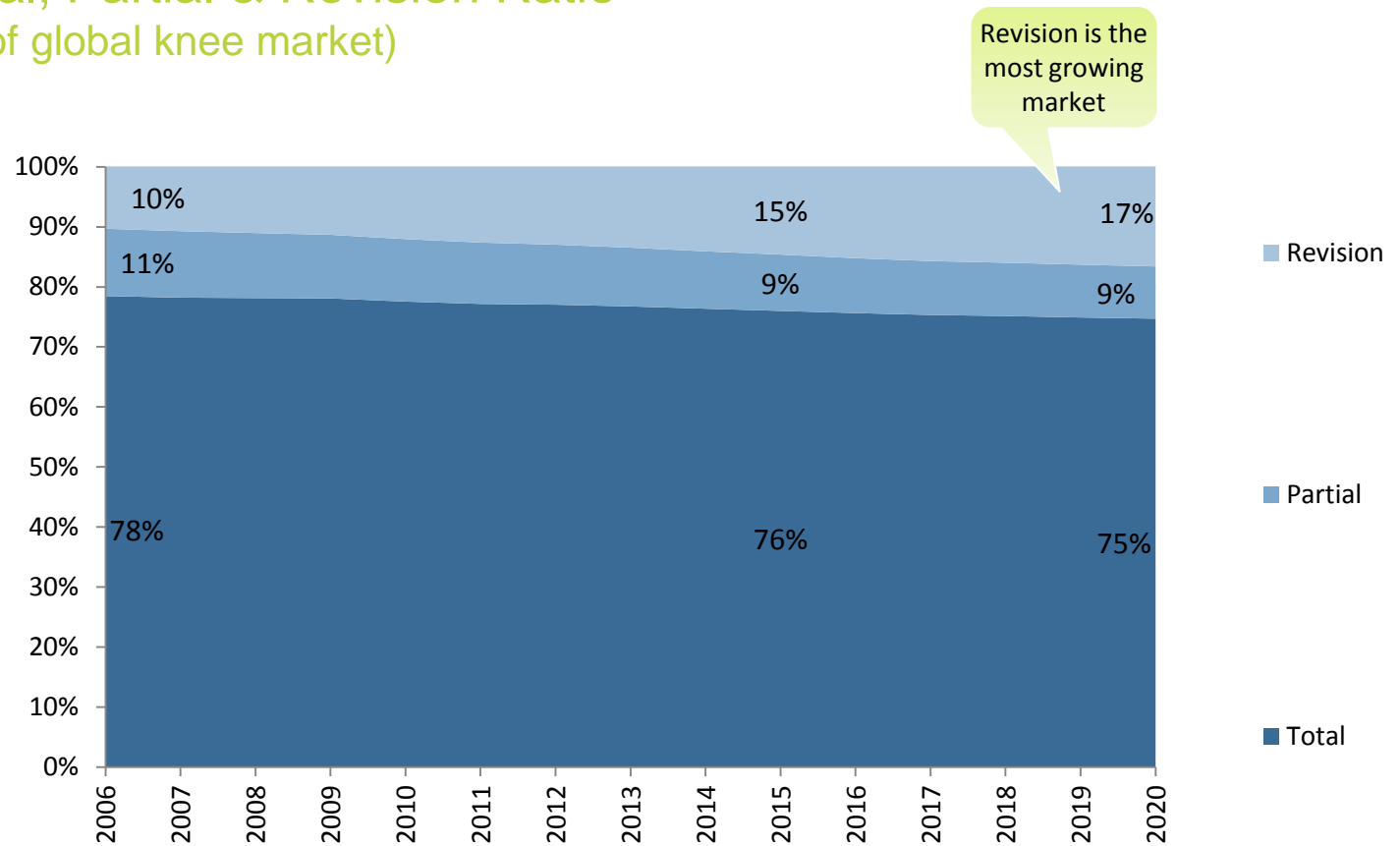
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Source: Interviews & Avicenne Research & Analysis 2016

Knee implant trends 2006-2020

Total, Partial, Revision

Total, Partial & Revision Ratio (% of global knee market)



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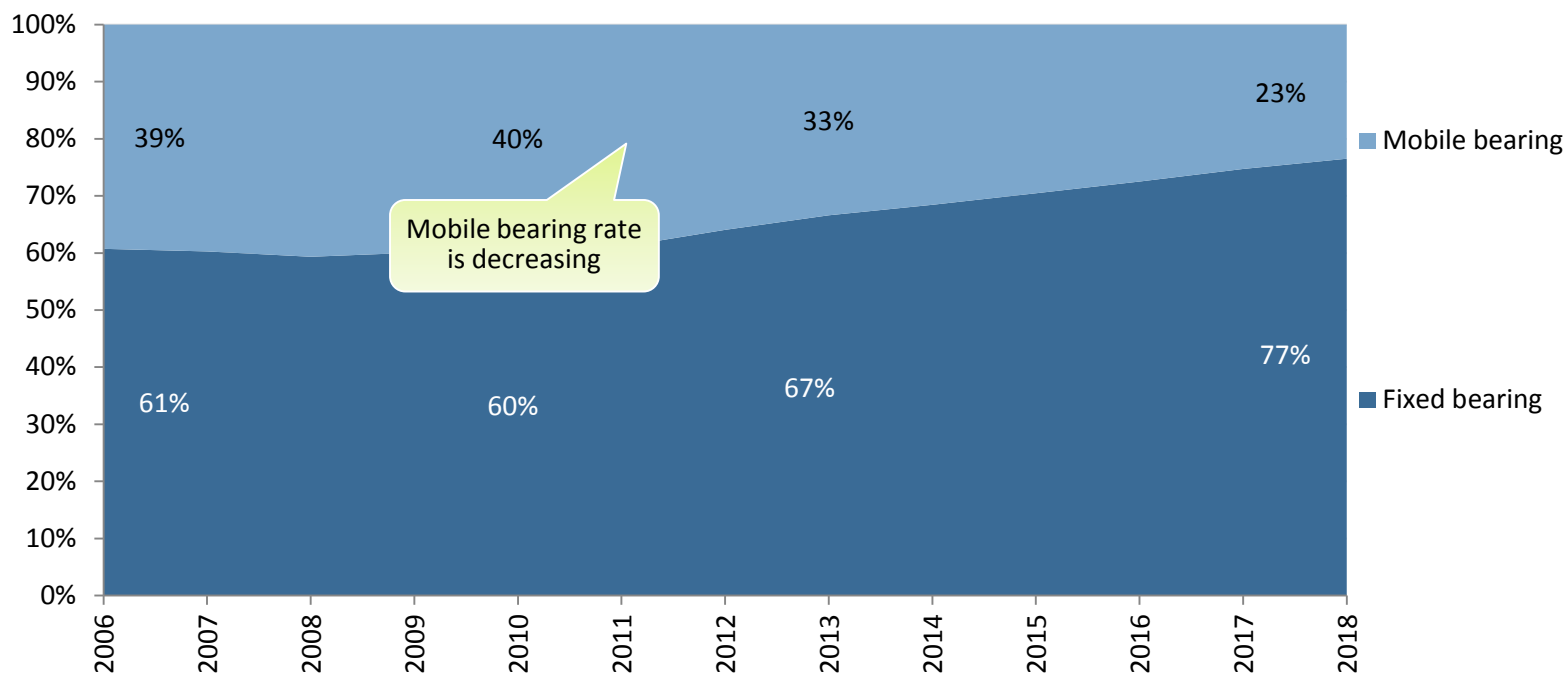
Phone: + 33 1 47 78 46 00
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Source: Interviews & Avicenne Research & Analysis 2016

Total knee trends 2006-2020 (in volume)

Fixed bearing Vs. Mobile bearing

Fixed VS Mobile bearing Ratio (% of Total knees)



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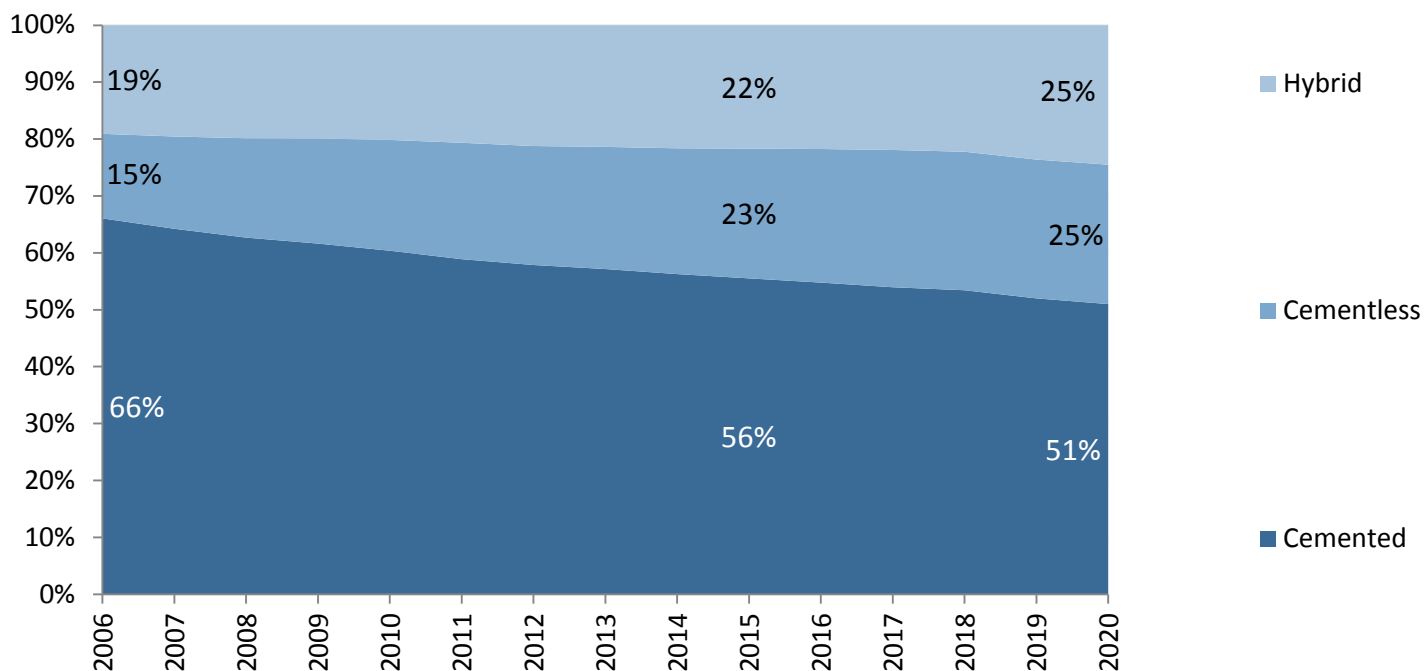
Phone: + 33 1 47 78 46 00
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Source: Interviews & Avicenne Research & Analysis 2016

Fixed bearing knee trends 2006-2020

Cemented, Cementless, Hybrid

Cemented, cementless & hybrid ratio (% of fixed bearing Total knees)



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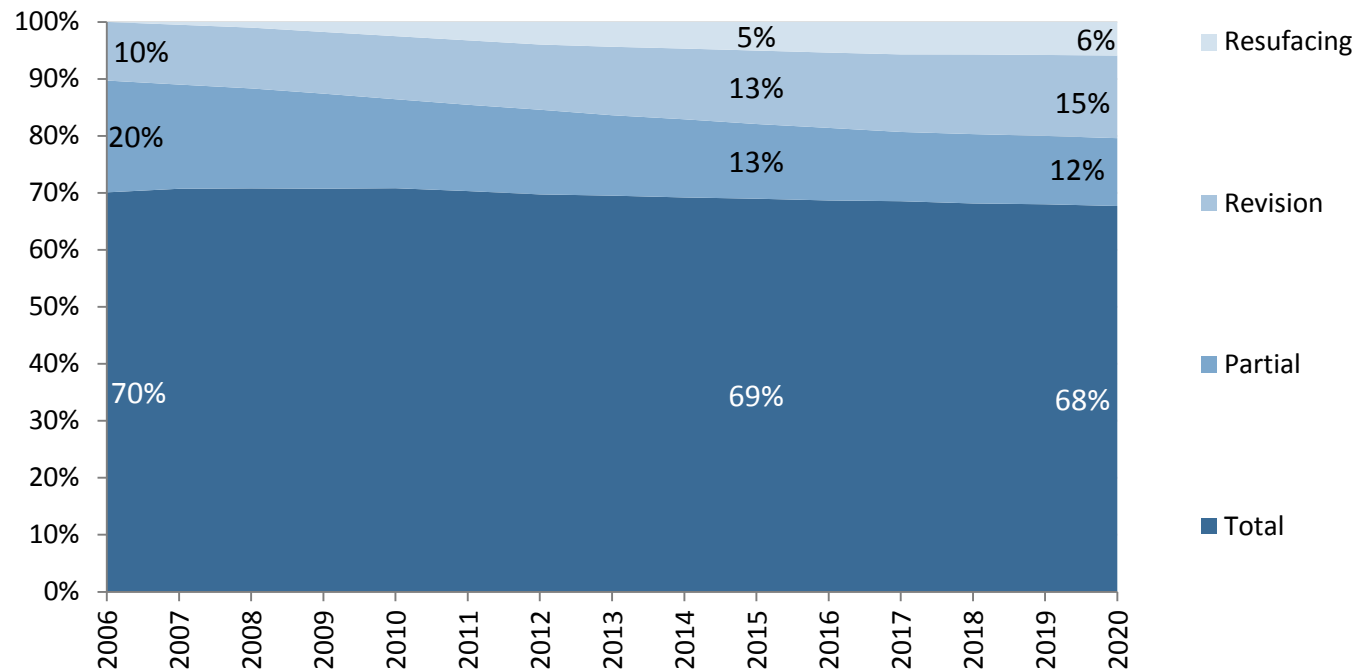
Phone: + 33 1 47 78 46 00
a.madani@avicenne.com

Source: Interviews & Avicenne Research & Analysis 2016

Shoulder implant trends 2006-2020

Total, Partial, Revision, Resurfacing

Total, Partial, Revision, Resurfacing shoulders Ratio (% of global shoulder market)



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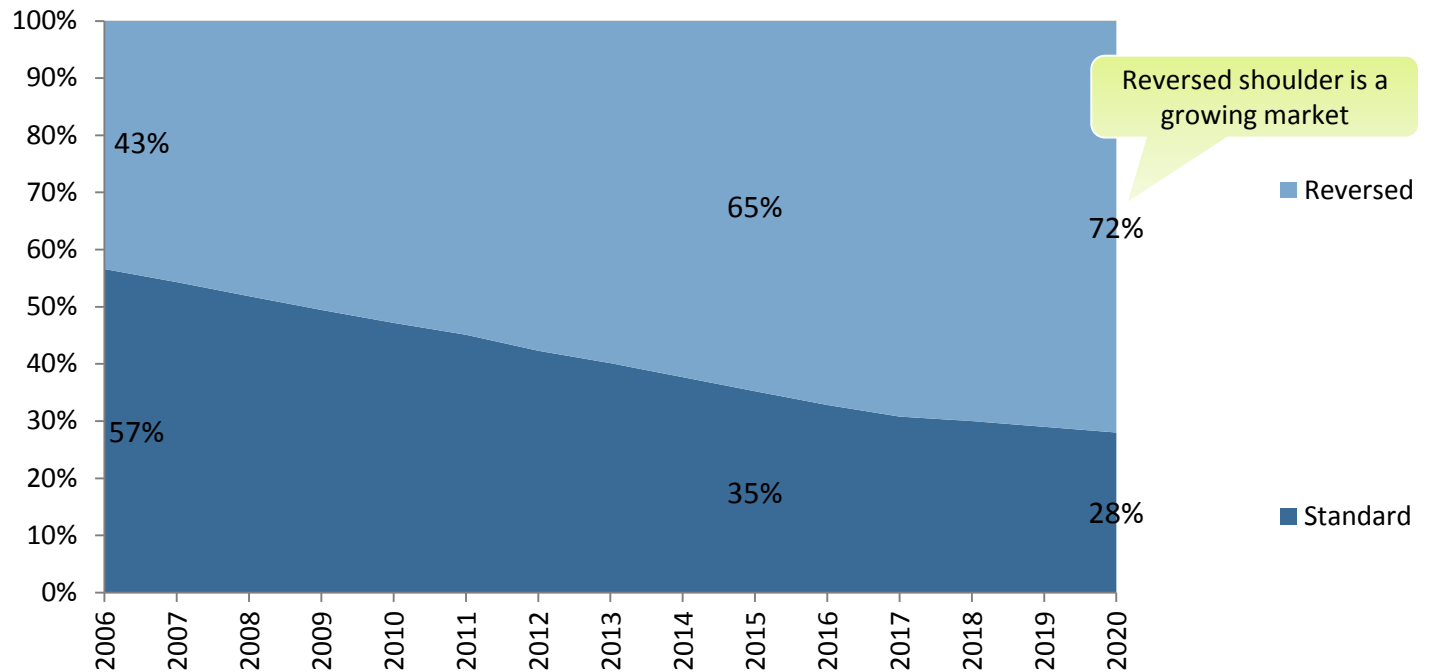
Phone: + 33 1 47 78 46 00
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Source: Interviews & Avicenne Research & Analysis 2016

Shoulder implant trends 2006-2020

Standard Vs. Reversed

Total modular Shoulder implants Standard Vs Reversed (% of global shoulder market)



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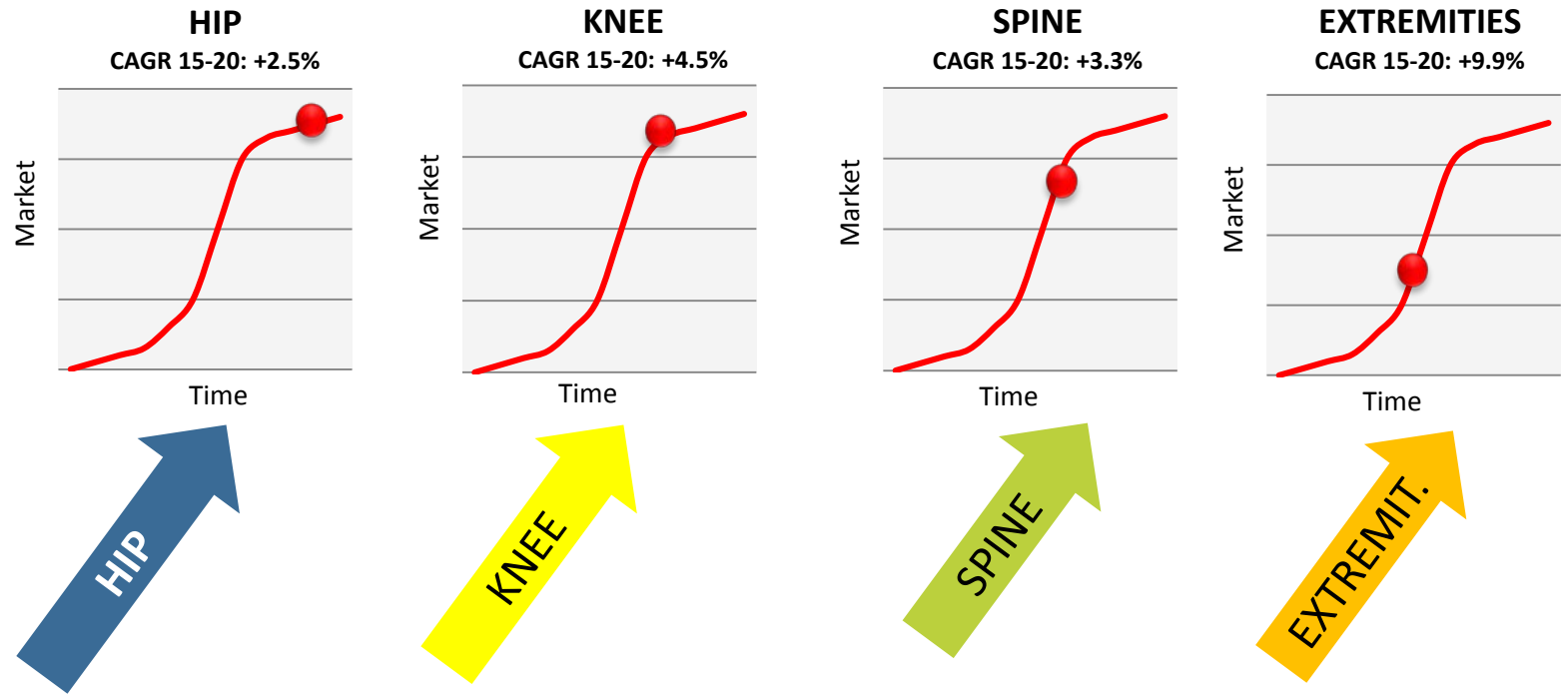
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Source: Interviews & Avicenne Research & Analysis 2016

The life cycle of the orthopaedic products: Growth forecasts by 2020



Entrance date into the mass market



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Source: Avicenne research & analysis 2016

Worldwide orthopaedic market forecasts

Worldwide orthopaedic market: CAGR 2015-2020 +4.4 %

Orthopaedics market Drivers in 2000-2010 were:

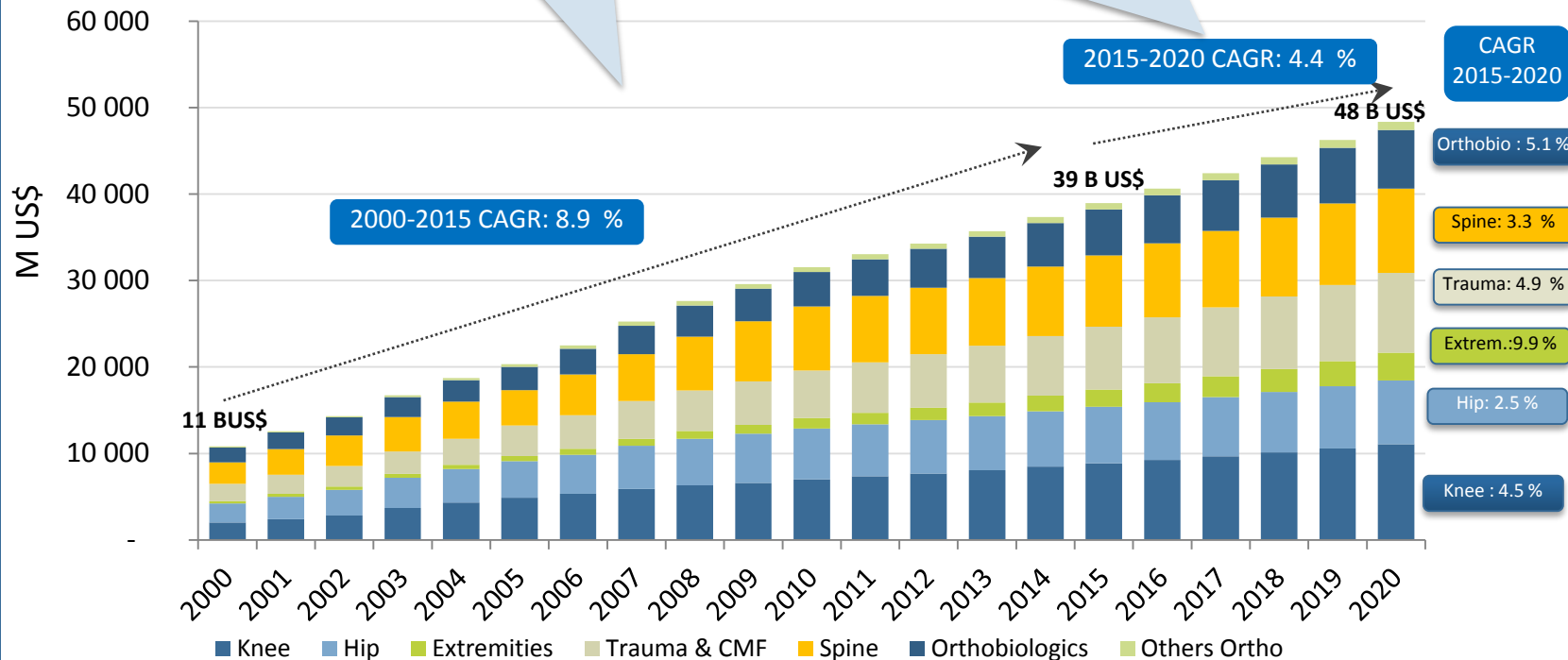
- Huge growth in hip & knee in developed countries
- USA : No price erosion, Europe slow price erosion
- Huge growth in spine procedures

Orthopaedics market Drivers: 2015-2020

- High growth in volume in emerging countries
- Orthobiologics growth in developed countries
- Extremities become multi Billion market with double-digit growth
- Trauma with historical constant growth
- Niche segments with high growth: vertebral disks, vertebroplasty, trabecular products,...

Orthopaedics market limiters : 2015-2020

- Price pressure at the end-market level
- Continuous regulatory cost increase
- Purchasing group power, in certain countries



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Source: Avicenne analysis 2016

Summary

- 1 The orthopaedics market, including hip, knee, spine, trauma, extremities and Orthobiologics accounted for more than US\$39B in 2015, with 4.3% growth.
- 2 The United States remains the largest market due to historical trends & higher sale prices. In Europe, Germany is by far the biggest market for all segments. Followed by the UK, France & Italy.
- 3 Even the 5 major companies, controlling more than 60% of the worldwide orthopaedics market, have continuously loose market share to the challengers. The challengers have gained 1 to 2% market share per year (US\$400 to 800 additional revenue), achieving US\$15B in revenue in 2015 (13 US\$15B in 2014!) .
- 4 The only way for the Majors to have two-digit growth is by acquiring rivals (Depuy & Synthes, Zimmer & Biomet, Medtronic & Covidien) .
- 5 A huge gap remains between the size of the Majors and that of the Challengers. The revenues of the Majors are 10 to 50 times bigger of the Challengers. But the Challengers are growing more rapidly, on average by 15%, due to their wider range of products, their local, high level services. They are also attracting new sales forces.
- 6 The main drivers of the orthopaedics market remain demographic & economic parameters. Product innovation, resulting in a better (or higher) Product Mix, is boosting the market.
- 7 The reimbursement trend results in price pressure. This is the main limiter of the orthopaedic market. Price erosion of mature products in orthopaedics has been a constant over the past 20 years. We do not expect a major shift, but some countries will suffer a more significant price decrease than others.

Summary

- Regulatory issues are becoming heavier and resulting in a longer time to market for new product launches, additional costs and a more limited range of products.
- Competition is fierce. In each country, the local challengers have a robust market share: Aesculap & Link for example in Germany, Lima & Adler in Italy, Amplitude in France, etc.
- Revision Implants are growing for all types of implants, cementless & Hybrid products continue to gain market share. Reversed shoulder, mini hip, Trabecular for hips and cages are examples of growing segments.
- In spite of regulatory issues & reimbursement trends, the orthopaedics market must continue to introduce innovations & new products and instruments to improve the new, less invasive and much more reliable surgical techniques.
- In 2000, this market was US\$11 B It grew to US\$39B in 2015, and it will achieve around US\$48 B in 2020.
- That represents an average of 4.4% growth in the coming years.

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THANK YOU