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2012 , March 29th
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STRASBOURG

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INNOVEZ DANS LES IMPLANTS ORTHOPEDIQUES

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Executive Summary

- AVICENNE company short presentation
- Worldwide Orthopaedic Markets in 2010
- European Orthopaedic Market in 2010
- The Market Drivers & Limiters
- Trend of Orthopaedic Contract Manufacturing
- Contract Manufacturing market
- Contract manufacturing market & Competitor trends

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AVICENNE team

- Foundation of the company: 1992
- Orthopaedic : Main activity
- HQ: Paris
- Our team:
  -  Ali MADANI - Paris
  -  Christophe PILLOT- Paris
  -  Jean-Philippe SALVAT- Paris
  -  Amir YASSARI - Vienne
  -  Eri UHEHARA - Paris
  -  Mat MIRIN - San Diego

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AVICENNE marketing reports

"European Orthopaedics Market"

July 2010 12th edition

- First publication in 1993
- Yearly up-date
- Hip, knee, shoulder
- Based on +80 interviews
- 650 pages & 800 graphs detail the European Market in Germany, France, Italy, Spain, UK, and other countries

Available immediately

"Trends, Developments & Dynamics of the European Spine Market"

Sept. 2011 6th edition

- Première publication en 2000
- Publication annuelle
- Système universels, cages…
- 70 interviews d'acteurs dans le domaine du rachis
- 400 pages & 300 graphs détaillant le marché européen du rachis en Allemagne, UK, France, Italie, Espagne, Belgique et Suisse

Available immediately

"European Orthopaedic Contract Manufacturing detailed analysis and Profiles"

Feb. 2012 edition

- Les 100 plus importants sous-traitants européens de l'orthopédie
- Analyse détaillée par fiche individuelle
- L'évolution des revenus sur plusieurs années, activités et savoir faire, principaux clients, principaux actionnaires, détails dans l'orthopédie…
- Comparaison avec les sous-traitants majors américains

Available immediately

"Orthopaedic patent watch"

Yearly edition

- 4 segments surveillés : hanche, genou, trauma et biomatériaux
- Publication du bulletin de veille tous les 2 mois
- 50 brevets présentés par numéro de façon claire et avec schéma
- Ces éléments permettent :
  - D'identifier les tendances en matière de R&D
  - De connaitre les choix technologiques du concurrent

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Implants 2012: The international Rendez-Vous of European Orthopaedic actors

IMPLANTS event

- Founded and chair by AVICENNE since 2005
- + 40 international speakers
- + 70 booths
- + 600 attendees
- + 100 business meeting

Exhibition

Conferences

Created and Chair by avicenne MEDICAL INFORMATION FOR GROWTH

IMPLANTS
8th INTERNATIONAL OUTSOURCING & SOLUTIONS FOR ORTHOPAEDIC IMPLANTS AND BIOMATERIALS **CONFERENCE & EXHIBITION**

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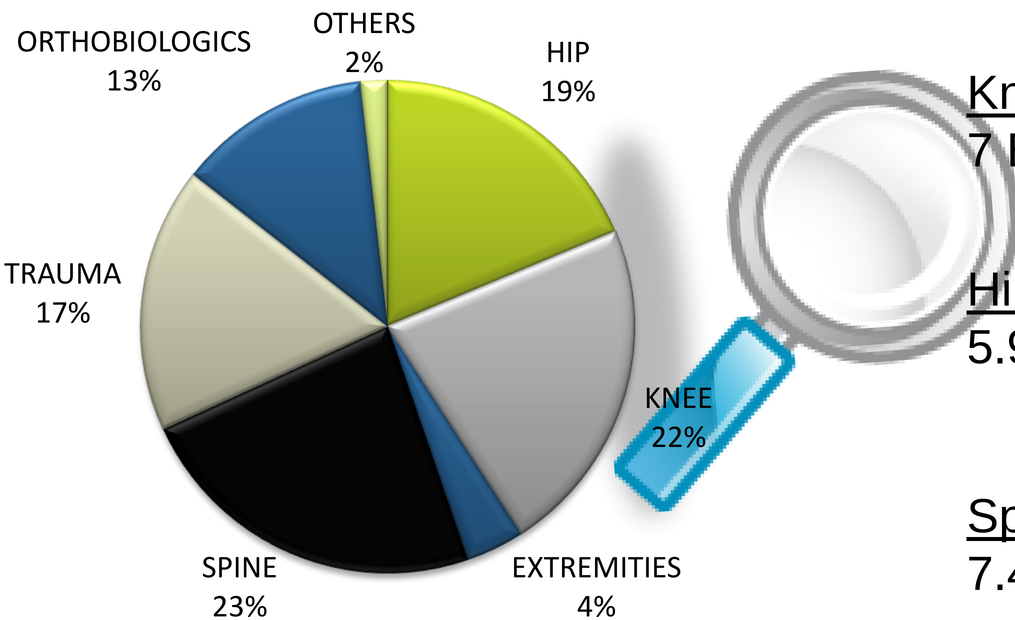
Worldwide Orthopaedic Markets in 2010: ~32 B$



Knee
7 B$ **+6%**

Hip
5.9 B$ **+4%**

Spine
7.4 B$ **+6%**

Source: Avicenne data compilation 2011

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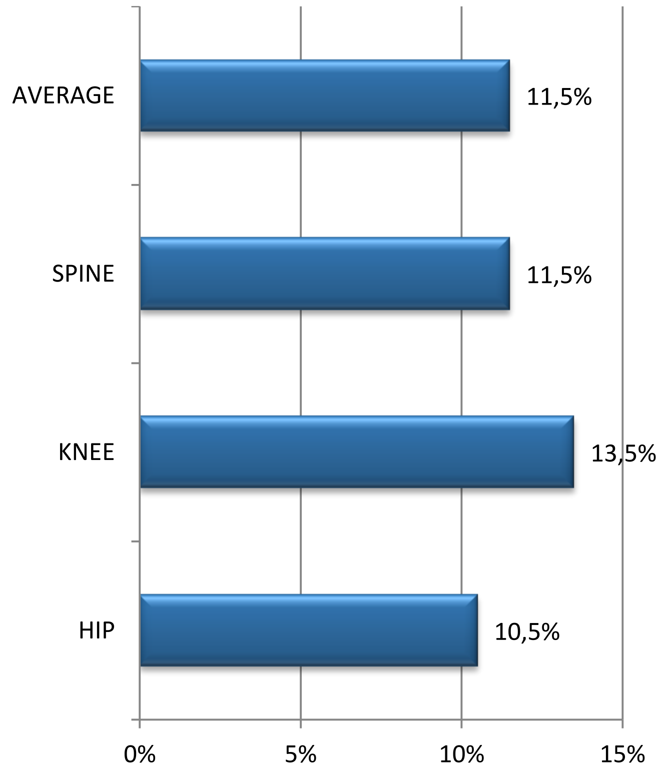
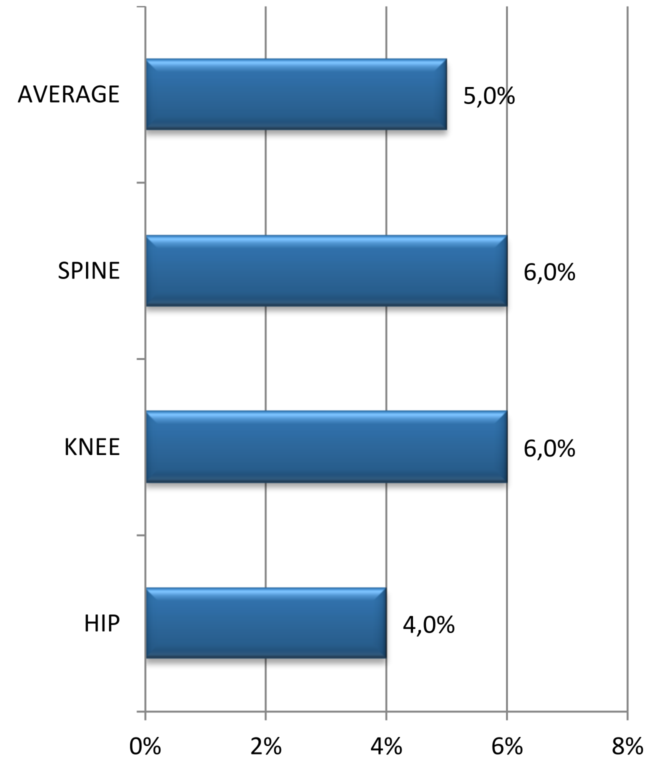
The Worldwide Orthopaedic Market

2000 - 2010 CAGR



2009 - 2010 Growth



Source: Avicenne data compilation 2011

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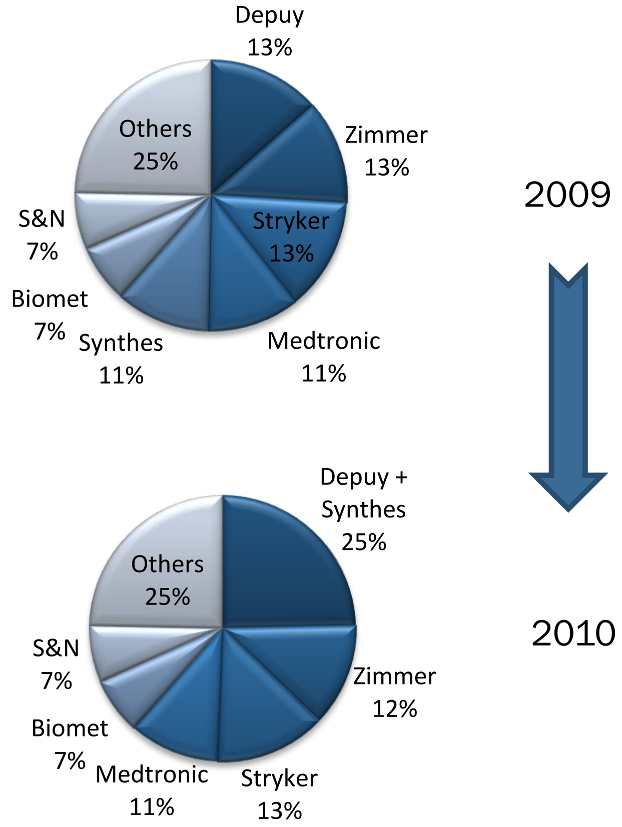
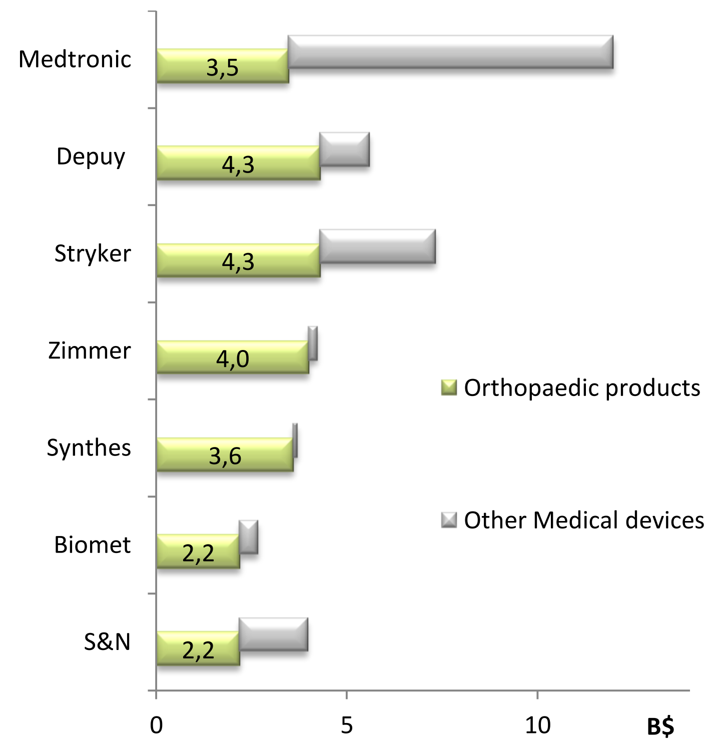
Worldwide Orthopaedic Market in 2010

2009-2010 Worldwide Orthopaedic Market



2010 revenues of the Major Orthopaedic Companies (B$)



Source: Avicenne data compilation 2011

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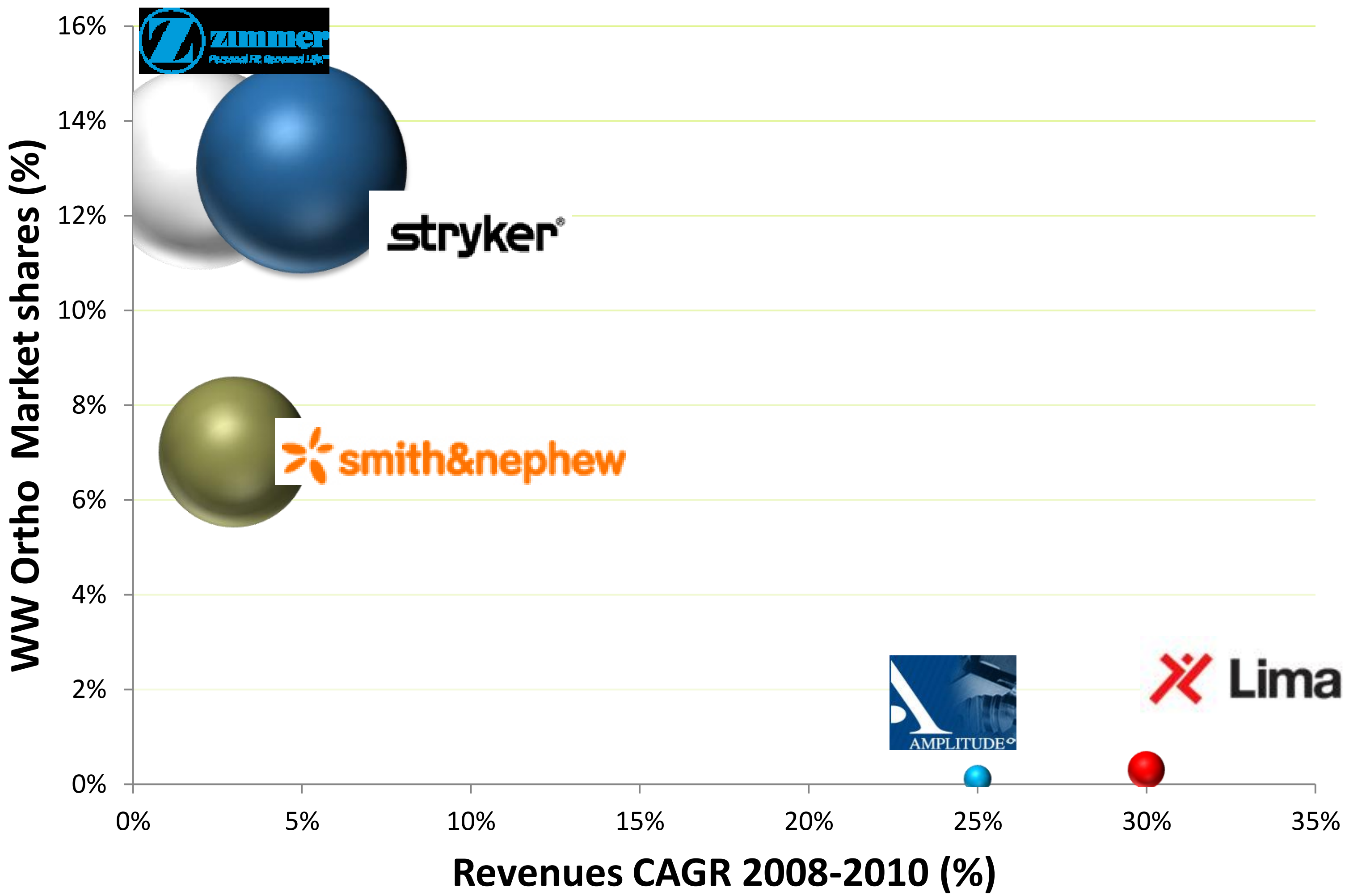
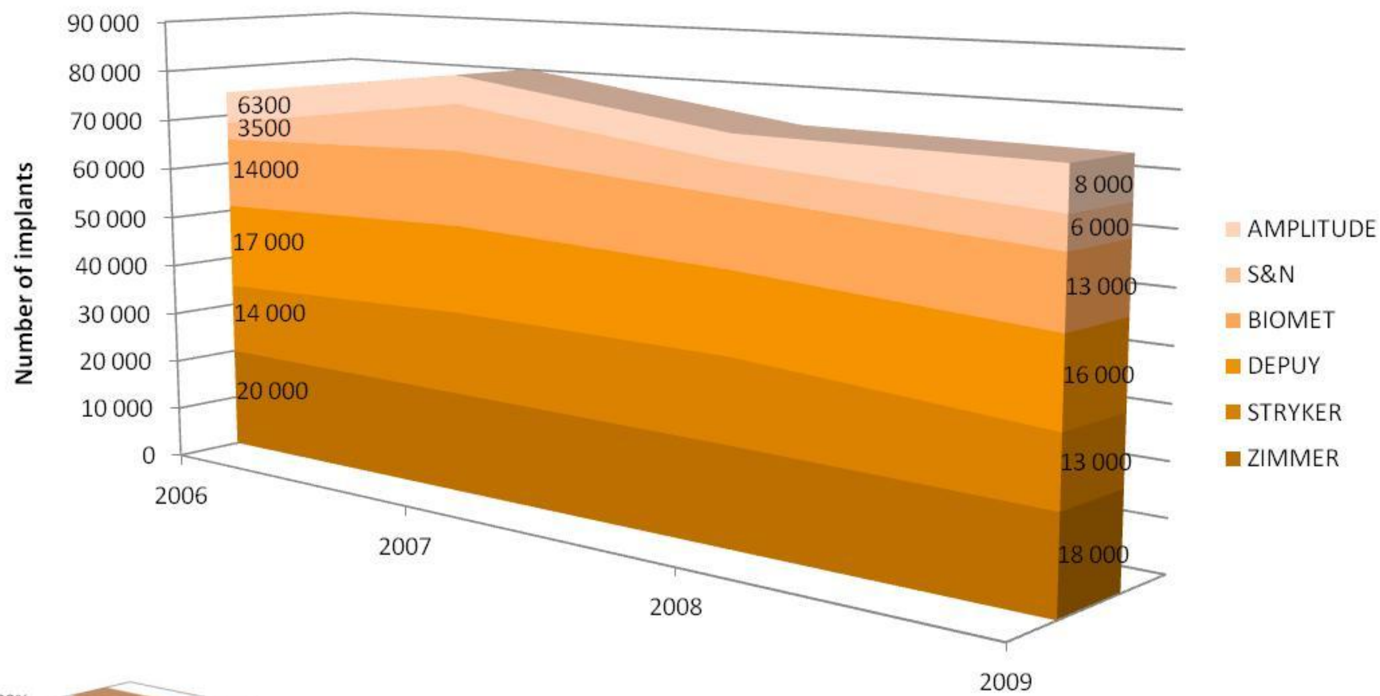
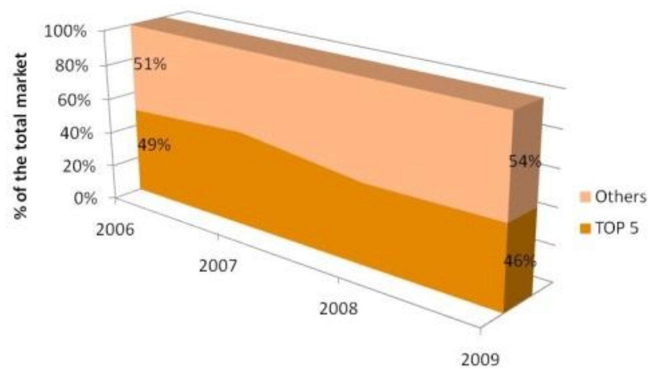
Majors Vs Challengers: Majors save ranking & Challengers the growth!



Source: Avicenne , annual reports and companies

Example of Hip in France: Top 5 and other competitor market shares





Source: Avicenne report, European Orthopaedic Market July 2010

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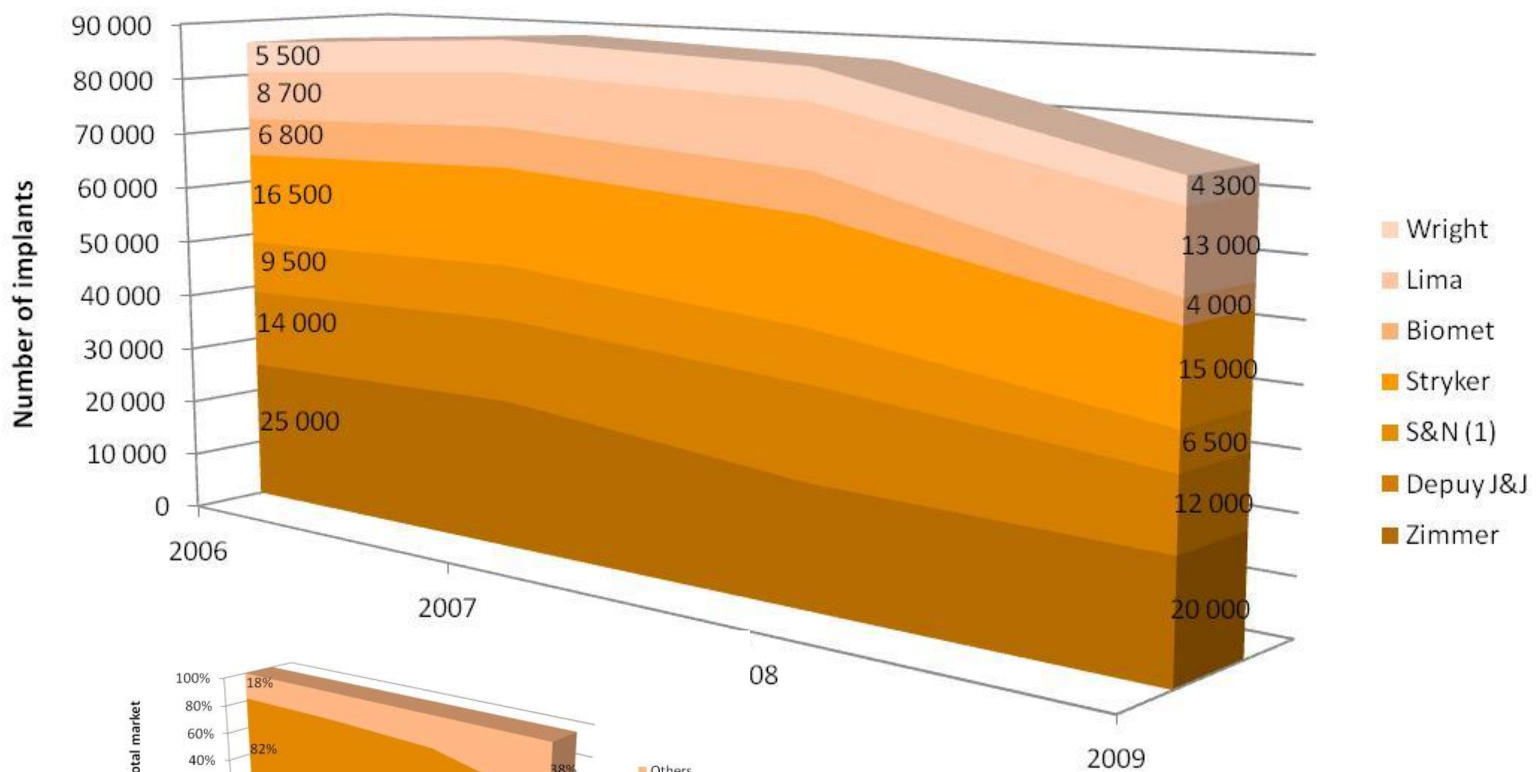
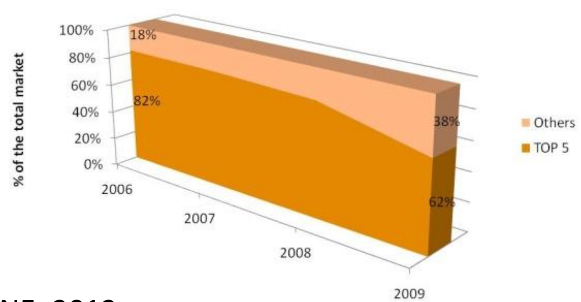
2006-2009, example of Hip trends in Italy: majors lost market shares





Source: Avicenne report, European Orthopaedic Market July 2010

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Challengers growing Vs majors

Majors		Challengers
• Product standardization	⟷	• Multiplication of customized
• Product range reduction	⟷	• Product range Extension
• Sale channels cost cutting	⟷	• Attracting new sale forces
• More centralized services	⟷	• Local and high level services

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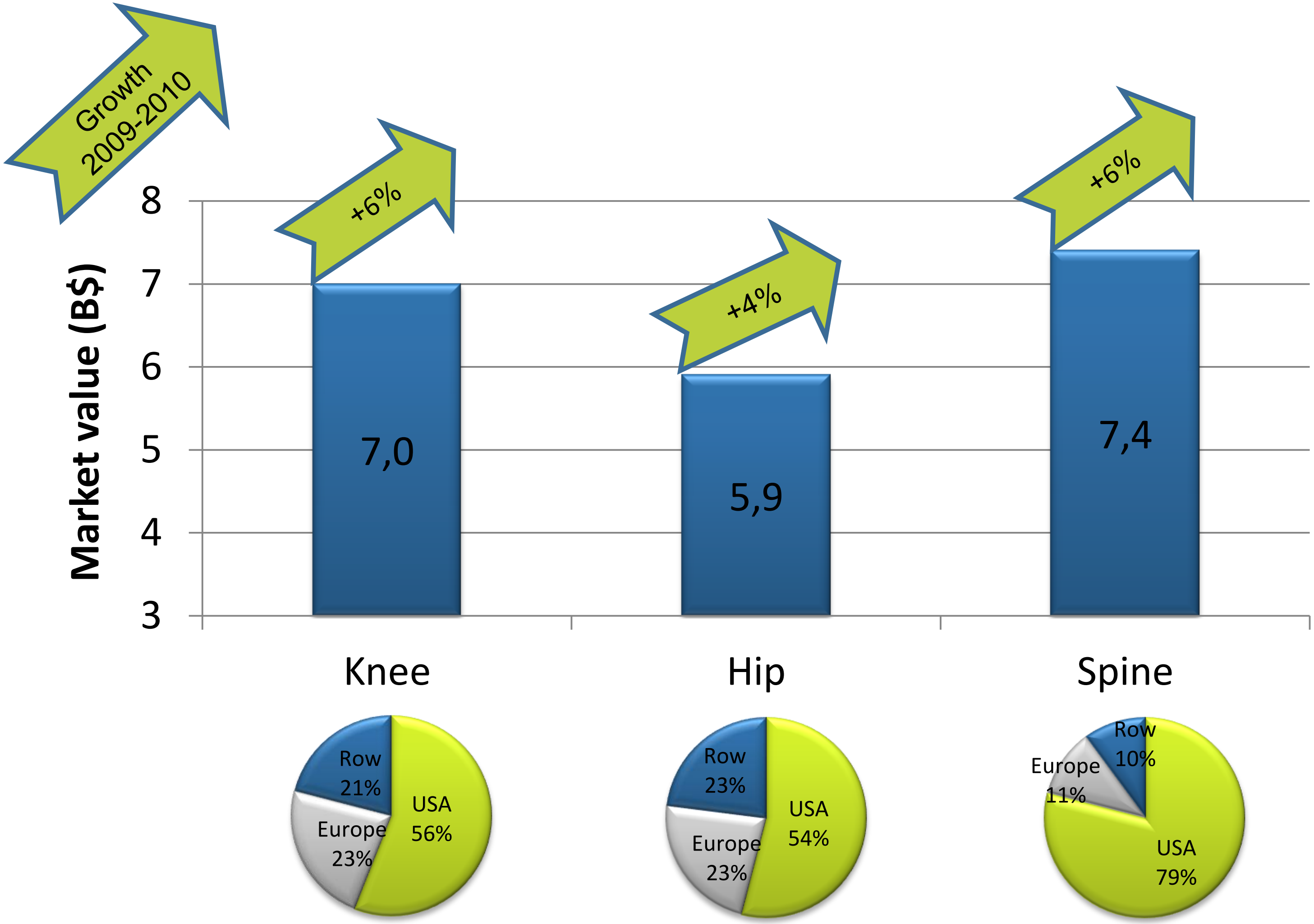
Worldwide Implants Market in 2010 in value (B$)



Source: Avicenne data compilation 2011

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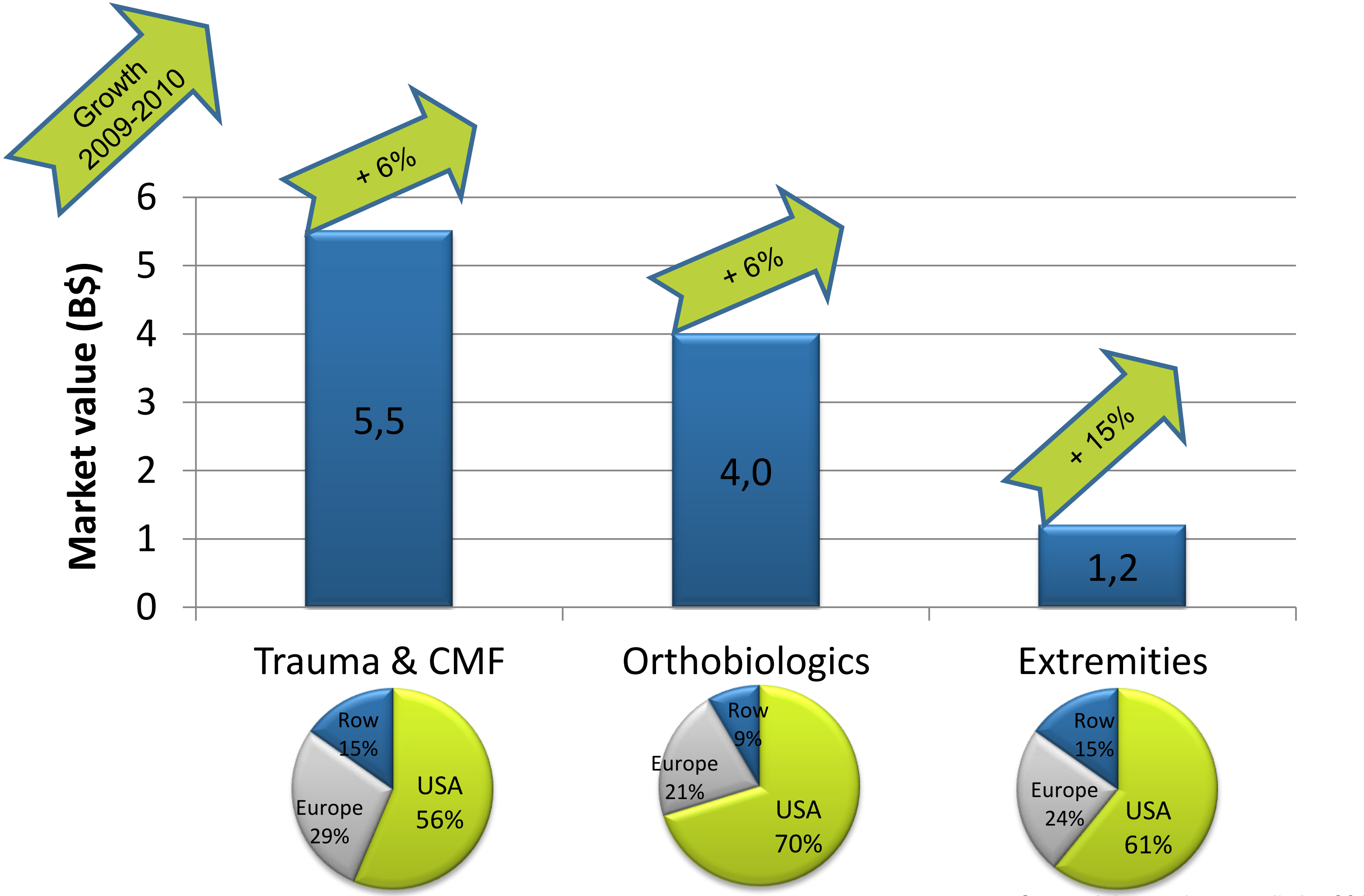
Worldwide Implants & Orthobio. Market in 2010 in value (B$)



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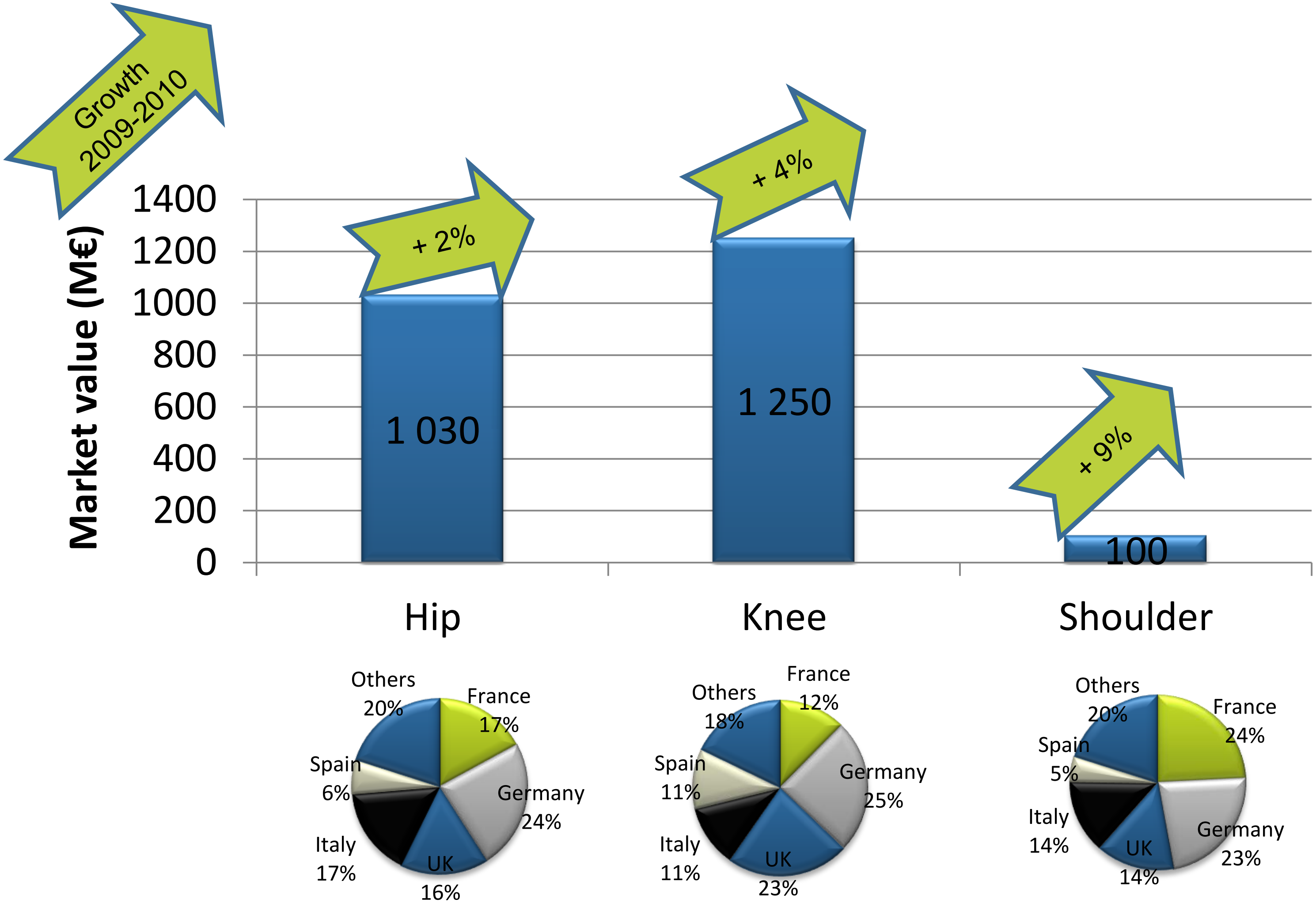
European Implants Market in 2010 & Growth (2009-2010) in value (M€)



Source: Avicenne data compilation 2011

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Knee, Hip & Spine Implant Markets: Big 5 & Challengers Market Shares in Europe

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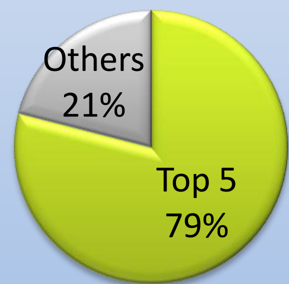
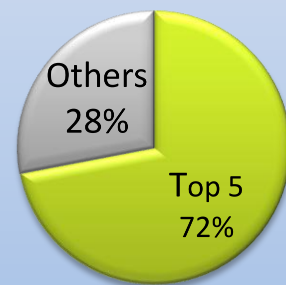
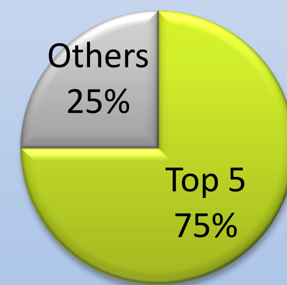
Europe	KNEE	HIP	SPINE
European Market 2010 in M€ - 14 countries	1.250 M€ 24% of WW market	1.030 M€ 23% of WW market	630 M€ 11% of WW market
Growth per year 2009/2010	+4%	+2%	+9%
Top 5* and Challengers market shares			

*Top 5 hip & Knee: Zimmer, Depuy, Stryker, Biomet, Smith & Nephew

Top 5 Spine: Medtronic, Synthes, Stryker, Depuy, Zimmer

Source: Avicenne data compilation 2011

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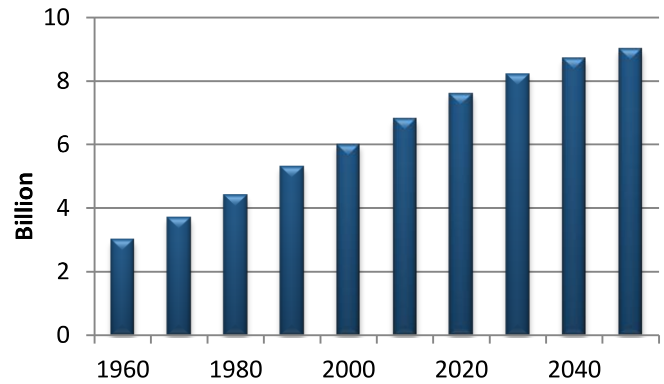
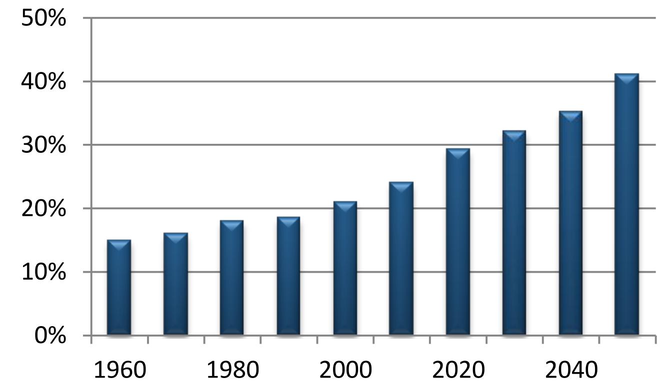
The Market Drivers (1/3)

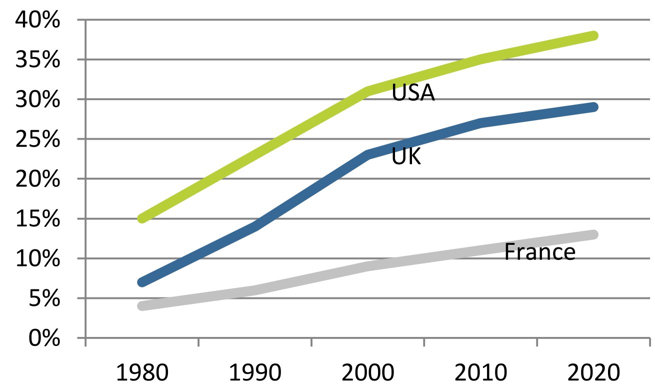
Worldwide population in Billion (Source: UN)



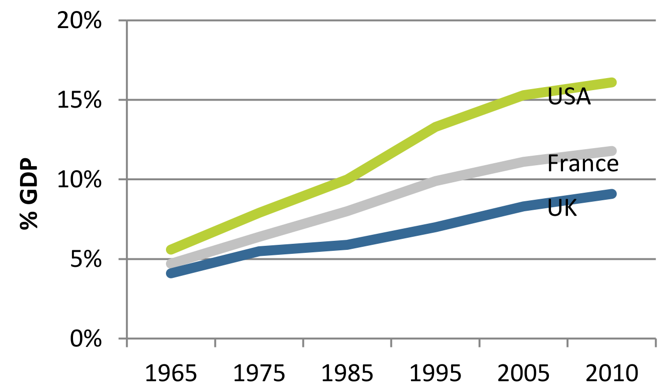
Inhabitants > 65 years example of France (Source: Insee)



Obesity in developing countries % of inhabitants (Source: OECD)



Health expenses: % of GDP (Source: OECD)



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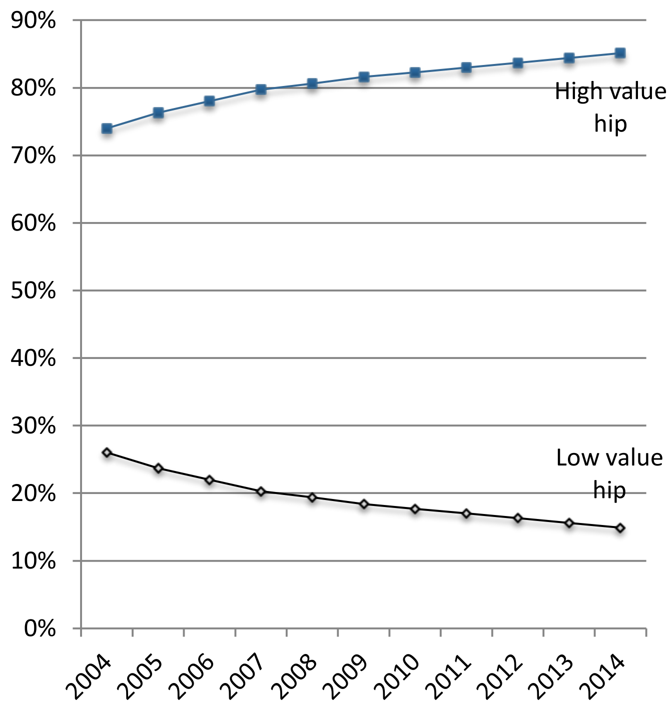
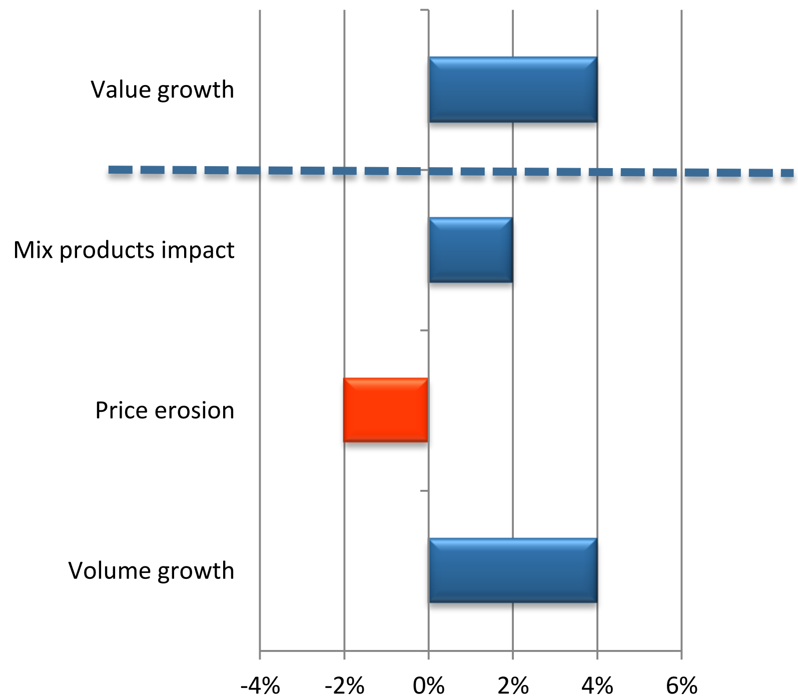
The Market Drivers (2/3)

Mix products impact: Example of high value hip (in volume)



The volume growth and mix products growth balancing the price erosion



Source: Avicenne data compilation 2011

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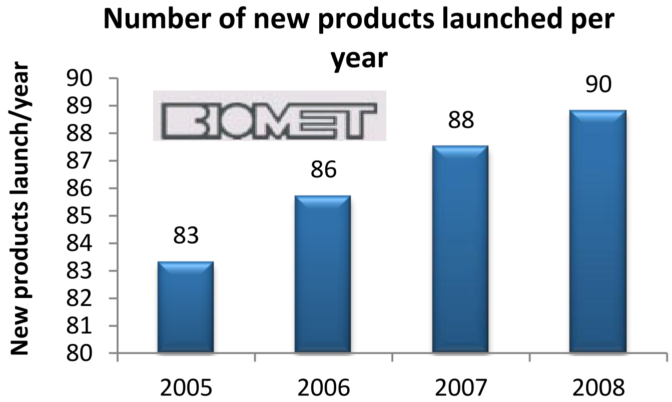
The Market Drivers (3/3)
Innovations & New Products

Innovations & new products driving the market

- Customized instruments
- Minimally Invasive Implants and Instruments
- Cementless products
- Orthobiologic products
- High end materials (Ceramic, …)
- …..

In the past 9 years, BIOMET introduced 800+ new products in the market



Zimmer Patient Specific Instruments

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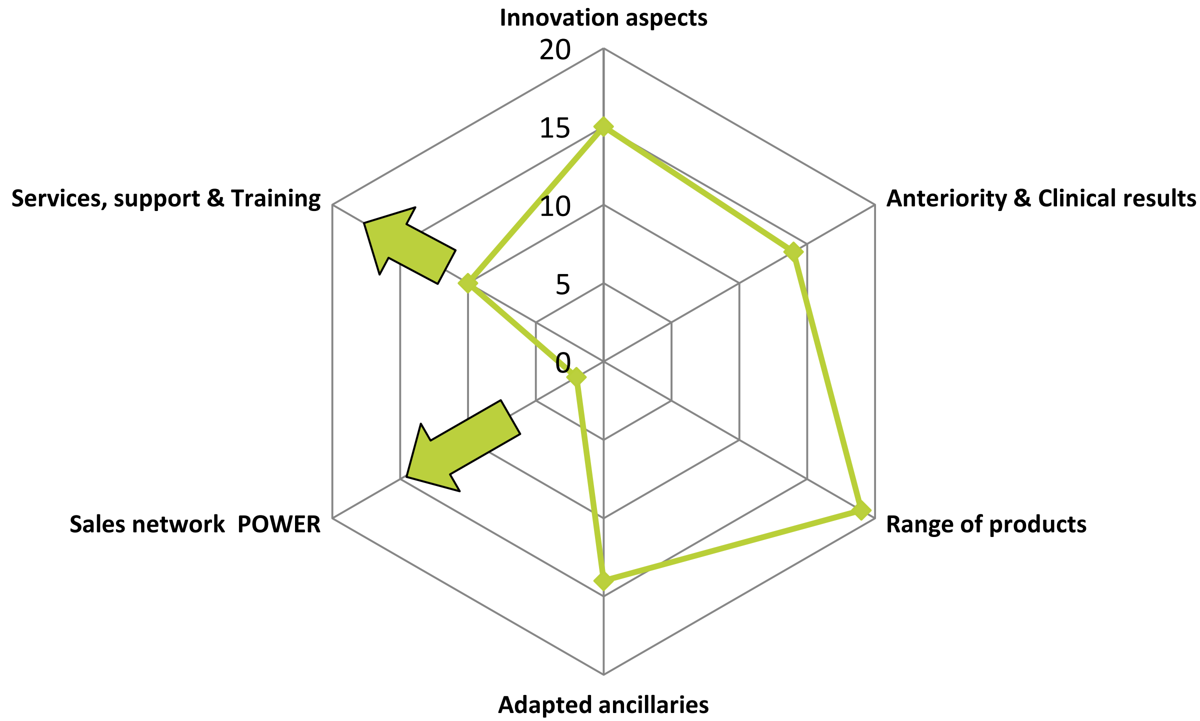
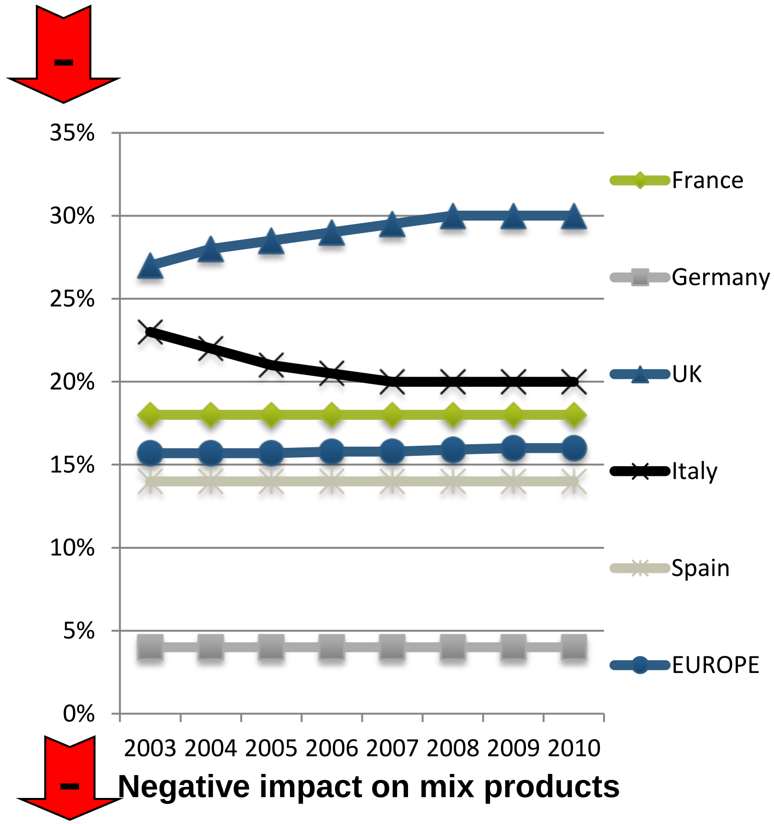
New product sucess kees



Example of Product-Mix in Hip Market Structure

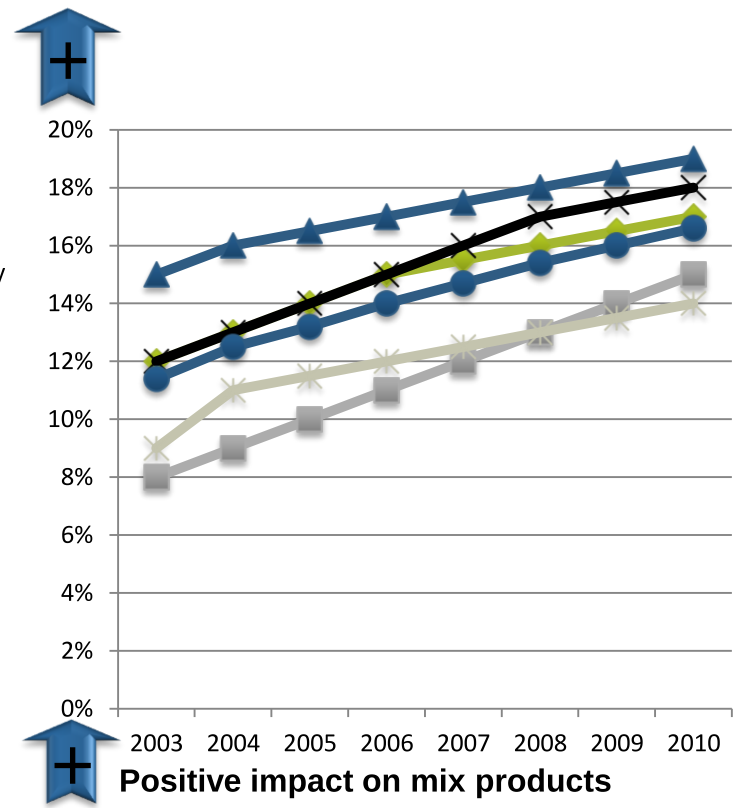
More Partial prosthesis -> negative impact on mix product
More Revision prosthesis -> positive impact on mix product

Partial prosthesis rate
(% of the global market)



Negative impact on mix products

Revision prosthesis rate
(% of the global market)



Positive impact on mix products

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The Market Limiters (1/2) REGULATIONS, Certification…

Regulation in Europe

REFERENCE	DETAILS	IMPACT ON THE MARKET
European Directive 93/42	• CE mark • Clinical tests • Sales autorization	• Additional costs • Longer time to market • Concentration of the product range • Limitation of new product launches
ISO 13 485	• Medical devices vigilance system • Certification of « whole production line »	• Longer time to market • Shared risks • Additional Insurance costs • Change in contract manufacturing practice

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The Market Limiters (2/2)
Reimbursement and Pricing Regulation

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

	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 Australien) 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 Investments supported by the "cantons"	50% T2A in public hospitals & 100% in private and public in 2012

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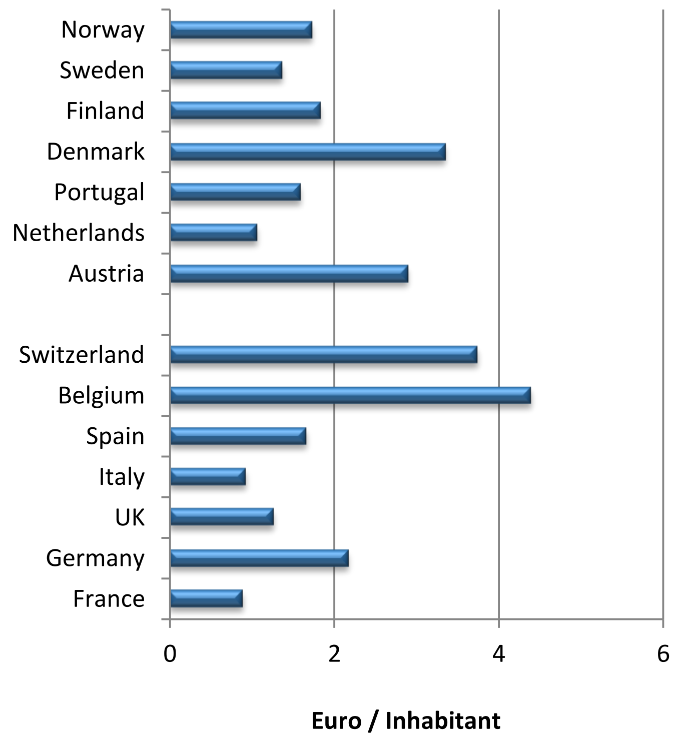
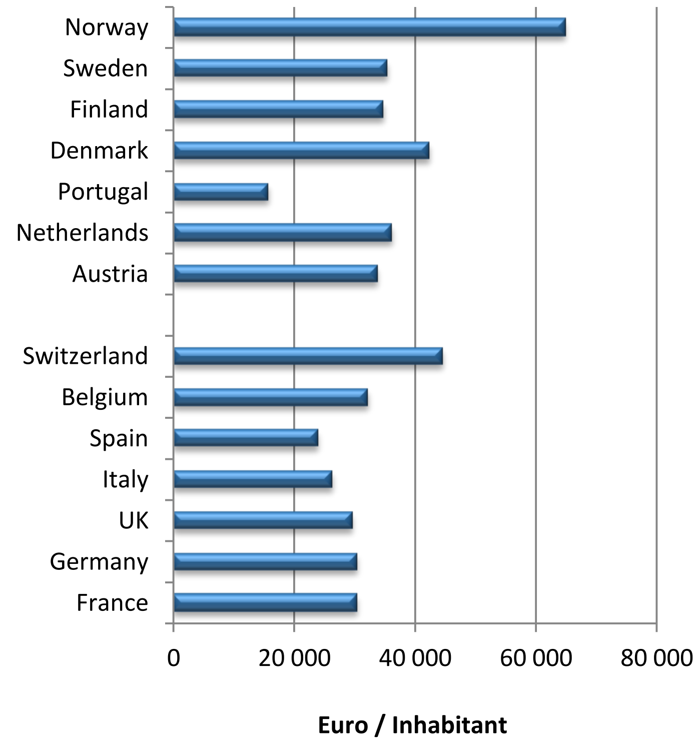
Regulations limit Market Growth: Example of Spine expenses per inhabitant in Europe

The reimbursement policy in each country influences drastically the market

€ / inhabitant for Spine in 2010



GDP (in €) / inhabitant in 2010



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Trend of Orthopaedic Contract Manufacturing

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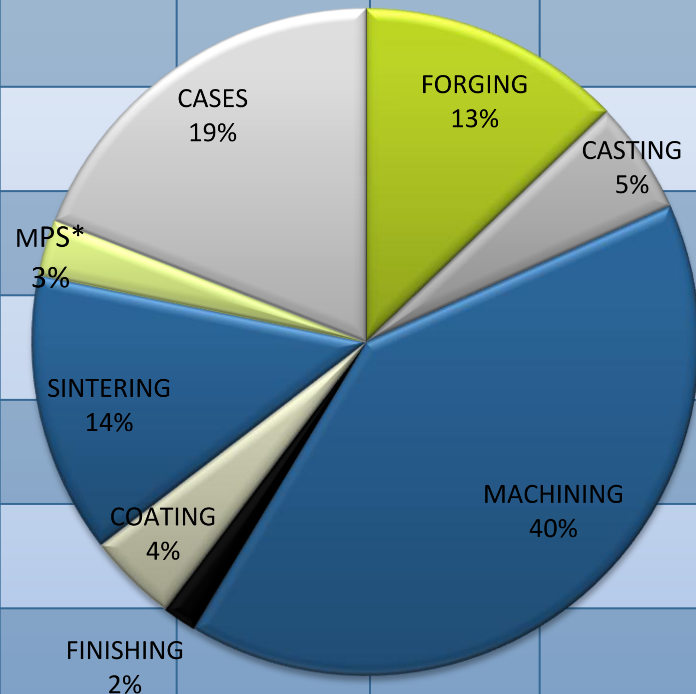
Contract Manufacturing segmentation

Orthopaedic Contract Manufacturing Market by Services

	HIP	KNEE	SHOULDER	SPINE & TRAUMA	INSTRUMENTS	CASES
FORGING						
CASTING						
MACHINING						
FINISHING						
SINTERING						
COATING						
MARKING, PACKAGING STERILIZATION						



MPS: Marking, Packaging & Sterilization*

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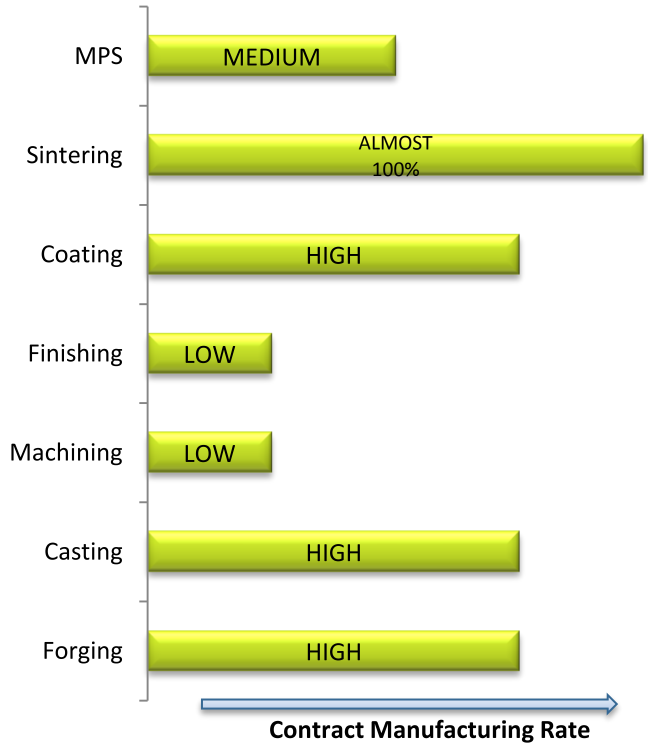
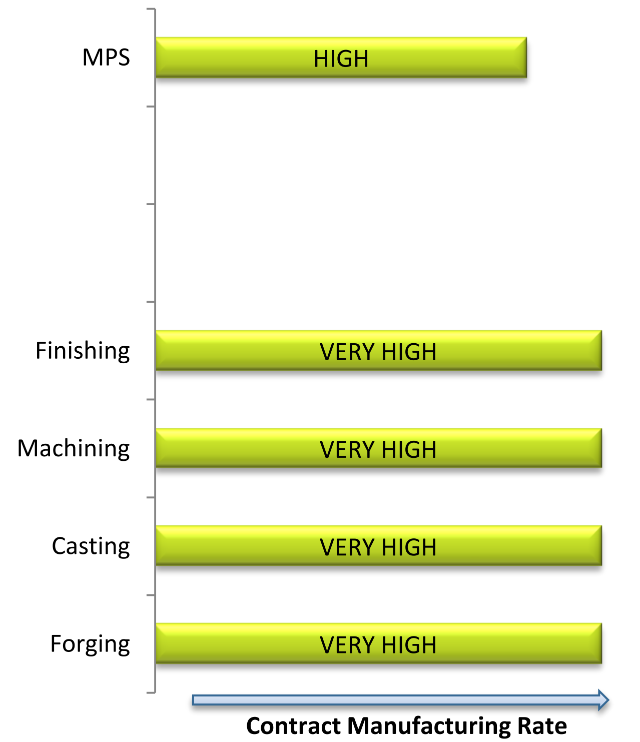
Orthopaedic Contract Manufacturing rates for the Majors

Contract Manufacturing rate for IMPLANTS



Contract Manufacturing rate for INSTRUMENTS



Source: Avicenne data compilation 2011

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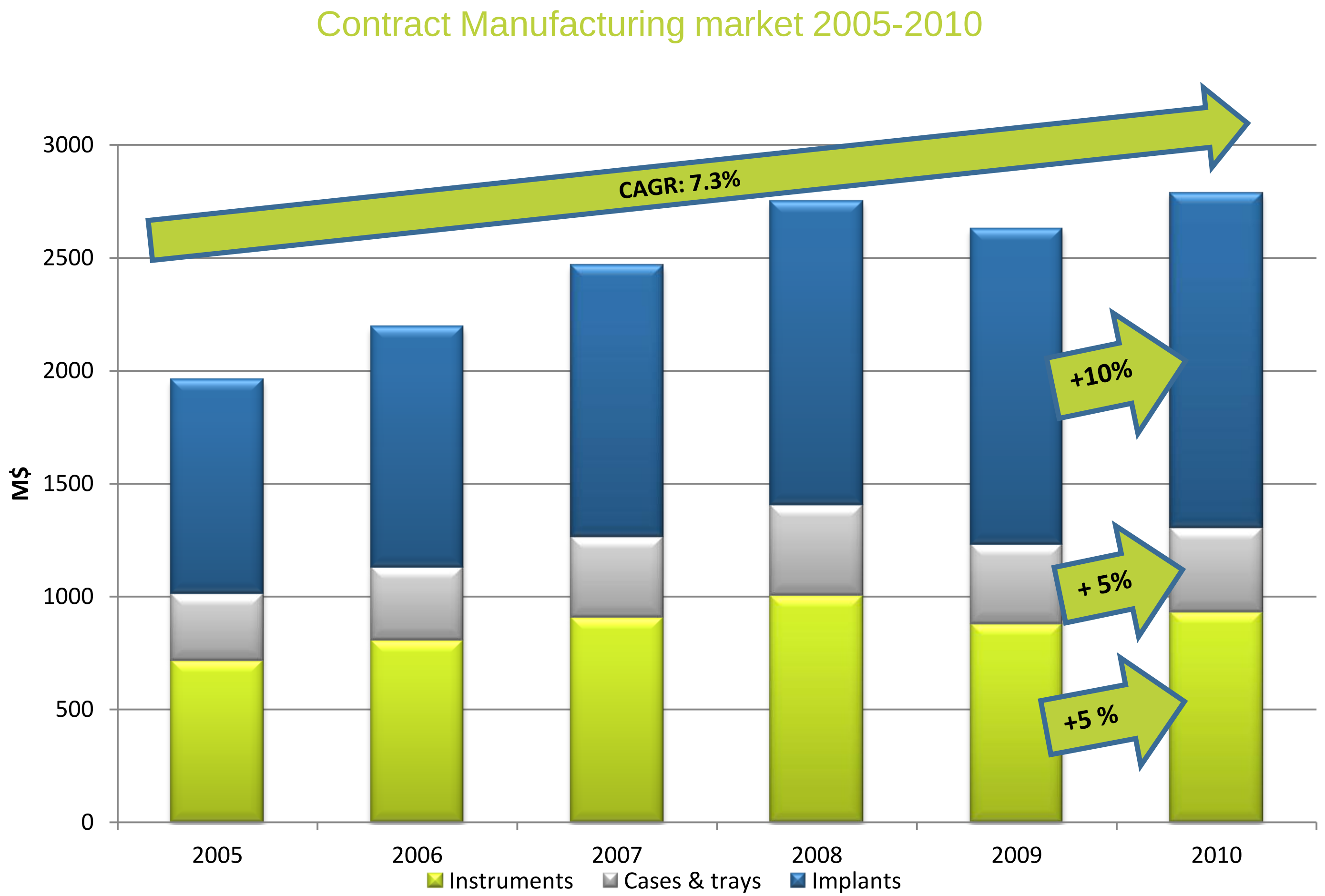
Contract Manufacturing market[1]: 2,8 Billion US$ in 2010



(1) Note: Excluding Sintering

Source: Avicenne data compilation 2011

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Mouvements and Signals for Contract Manufacturing market: OEM Side (1/2)

We are expecting other “disengagements” from the major OEM

- **December 2011-> Symmetry acquired surgical instruments business of Johnson & Johnson for 165 M$ in cash**
- **September 2010 -> STRYKER sold his Herouville facilities to LISI Group**
- **February 2008 -> DEPUY sold Chaumont facility in France to Greatbatch**
- **February 2008 -> Medtronic sold his manufacturing operation in Memphis to Sandvik**
  “We are selling off the specialty instrument operation because we feel someone else can do it better…“
- **December 2007 -> DEPUY: New Bedford facility sold to Symmetry**
- **December 2007 -> IN’TECH acquired Wright Medical Facility in Toulon, France**

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Mouvements and Signals for Contract Manufacturing market: OEM Side (2/2)

China, India and Brazil: New Eldorado to produce Instruments and Implants?

- **2010-> SMITH & NEPHEW: New Beijing Facility - 11.000 m²**
  Smith & Nephew announced new plant in Beijing for instruments and parts of implants. Smith & Nephew maintaining operation capacity in Memphis and Switzerland and the Beijing plant is dedicated to provide added capacity to supply local market and orthopaedic instruments for export. Smith & Nephew Linhe in operation since 2008 for orthopaedic instruments (will be closed in 2011).
- **2009-> BIOMET: Jinhua Facility - 9.600 m²**
  400 employees - Dedicated to instruments (hip, knee & Trauma)
- **2008-> DEPUY: Suzhou Facility in China - 11.000 m² - 100 M $ investments**
  Depuy has started operations at its first Chinese facility in the Suzhou Industrial Park in Eastern China (Instruments) 500 employees.
- **2008-> BIOMET: New Facility in China in Changzhou High-tech District**
  The company began production in Jinhua, China 4 years ago (Instruments)-> 200 employees, 7.400 m², 18 M$ investments.
  "I won't tell you that all of our instrumentation (production) is going to China," said Jeff Binder. "But a significant percentage of it is being transferred to China for a significant cost savings."
- **2010-> SANDVIK: New facility in India Poona**
- **2010-> The Contract manufacturers following the OEM: PARAGON (in Changzhou)**

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Estimated % of instruments made in BRIC countries by certain major OEMs

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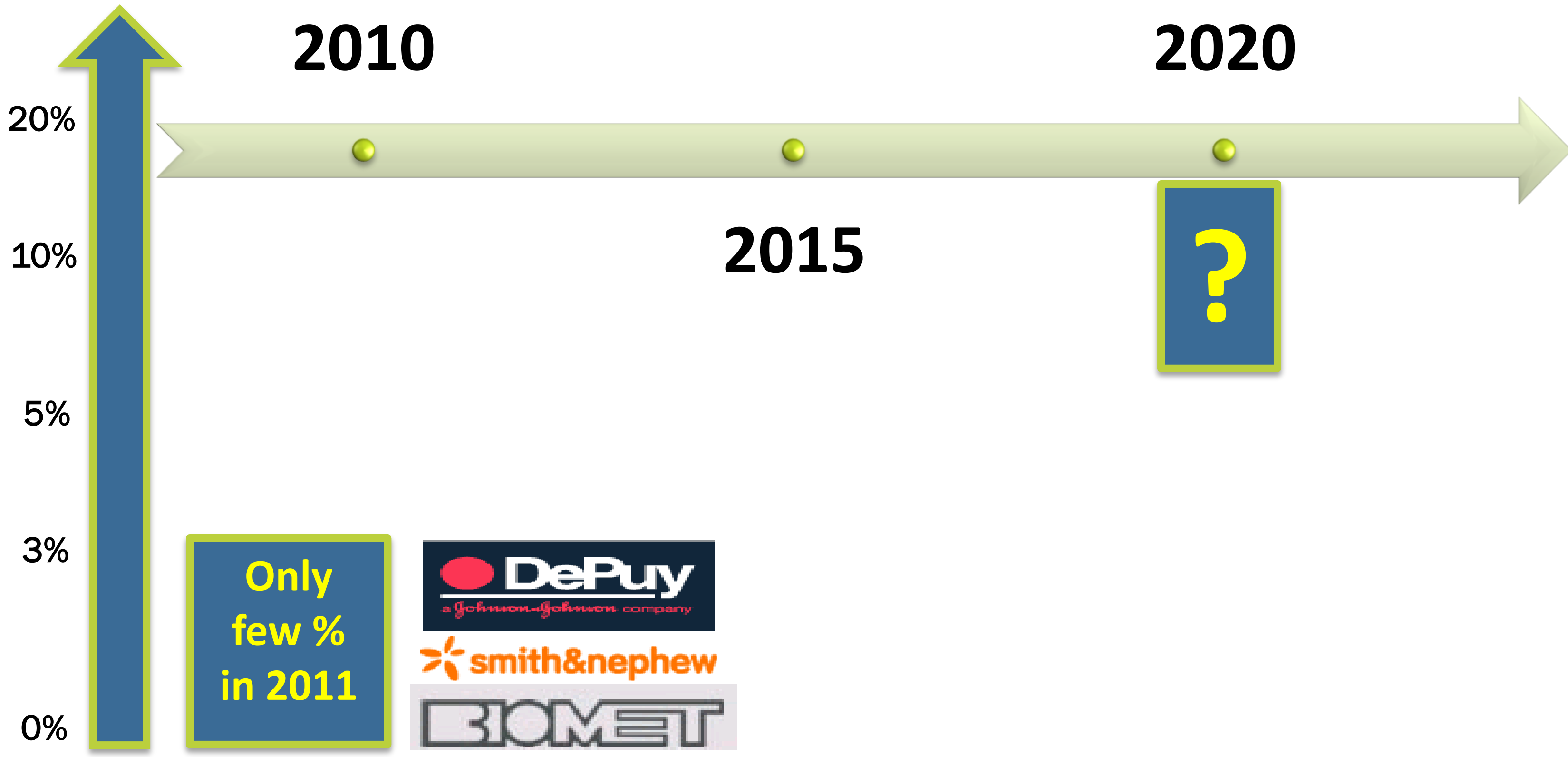
Estimated % of instruments manufactured in BRIC countries in worldwide annual production for DEPUY, SMITH & NEPHEW and BIOMET



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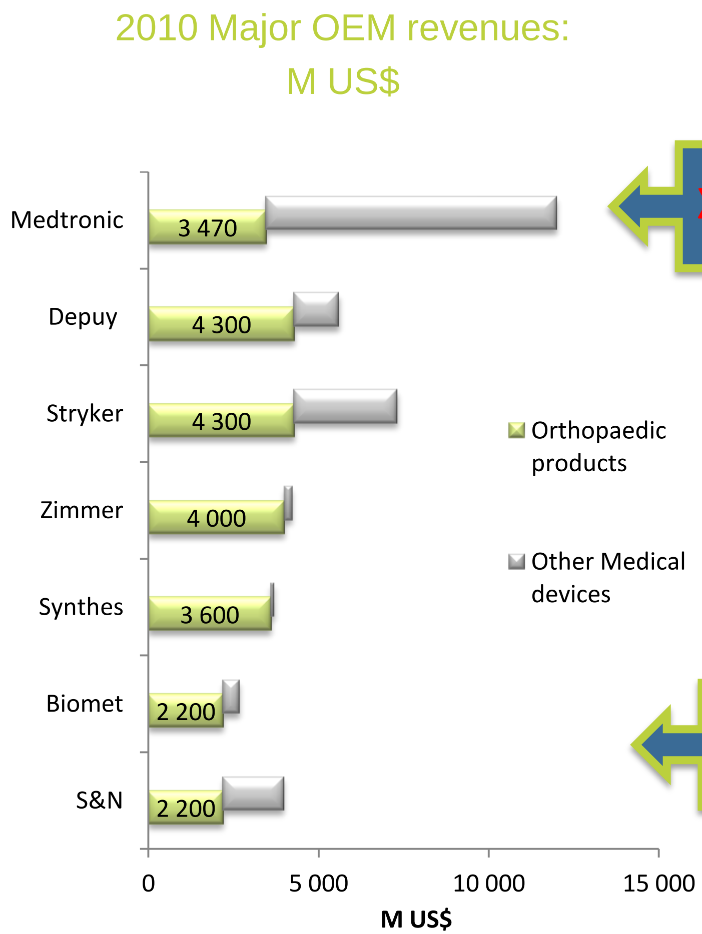
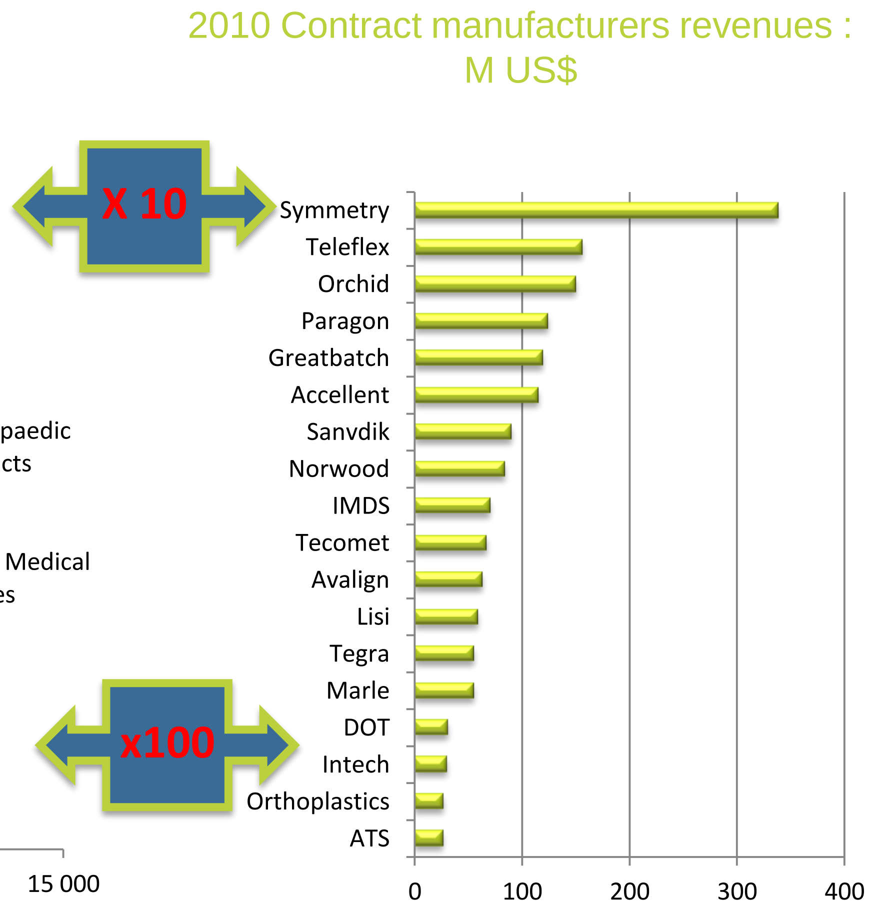
The Orthopaedic suppliers are relatively small, compared to OEM





Source: Avicenne data compilation 2011

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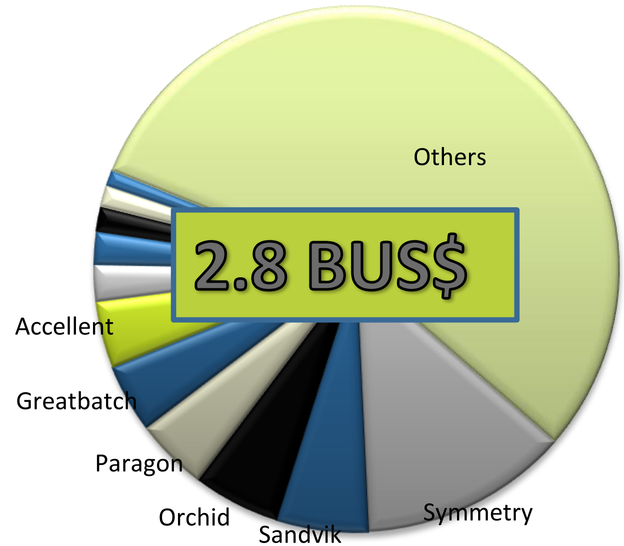
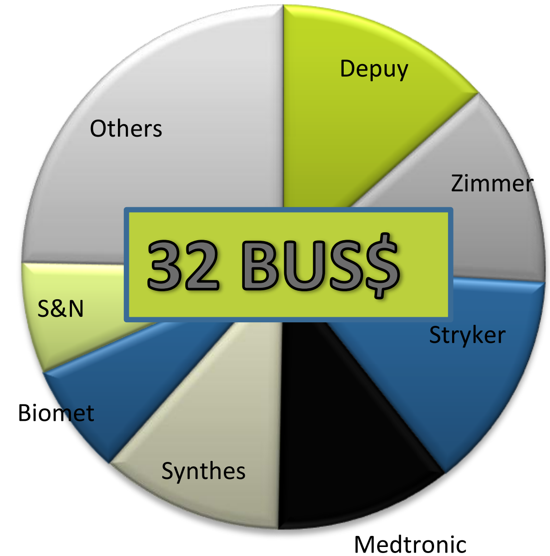
Contract manufacturers expecting more concentration and a critical size

Contract manufacturing market in 2010:
2.8 BUS$

Orthopaedic market in 2010:
32 BUS$

CONCEPTION → FORGING OR CASTING → MACHINING → FINISHING → COATING → MARKING → PACKAGING → STERILIZATION → MARKETING SALES





Source: Avicenne data compilation 2011

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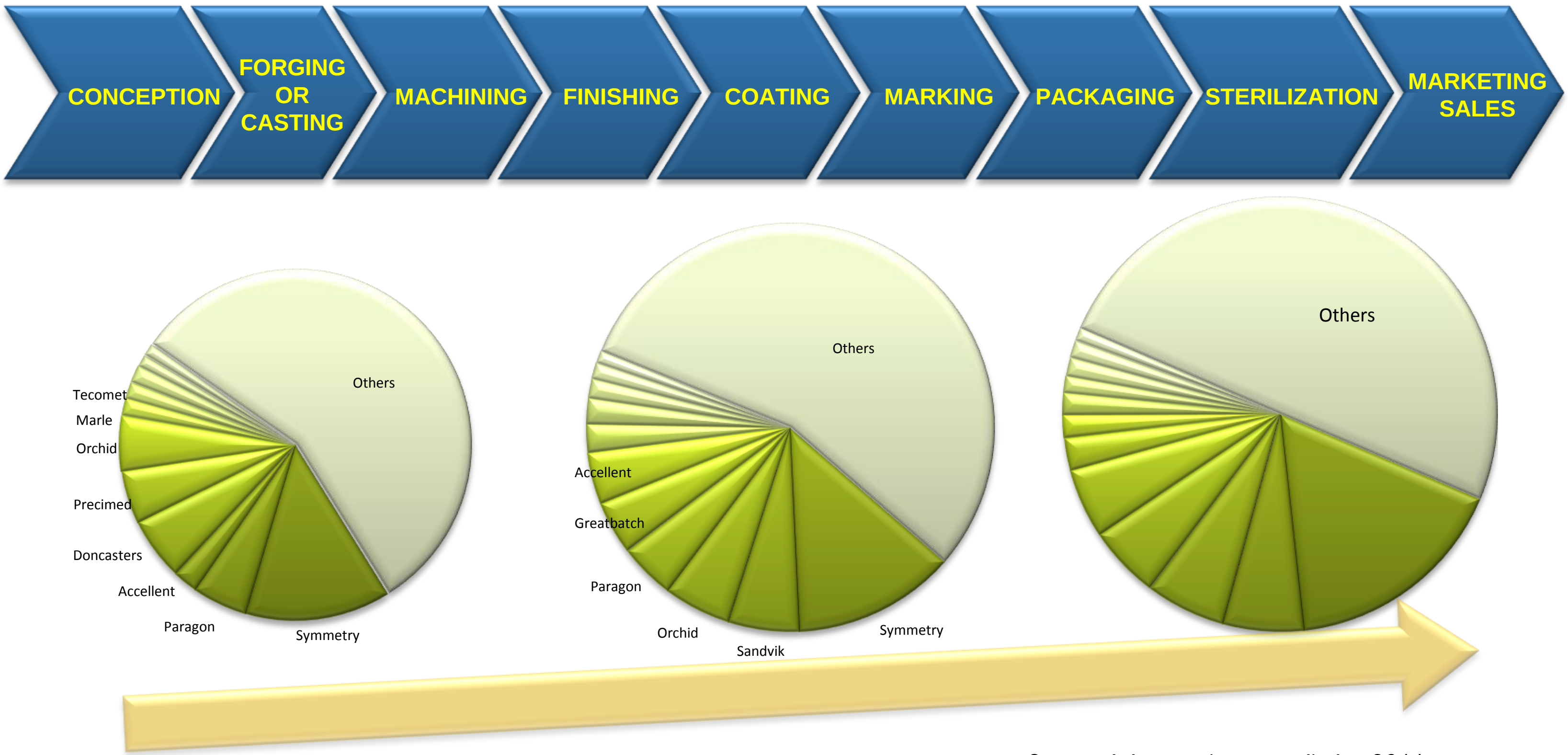
The orthopaedic Contract Manufacturing competitor response: Concentration

Contract manufacturing market in 2006

Contract manufacturing market in 2010

Contract manufacturing market in 2015



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Orthopaedic Contract Manufacturing competitor response: Concentration by acquisition

SYMMETRY
- 2008 DePuy OEM Bedford Facility
- 2007 SSI/UCA
- 2007 TNCO
- 2007 Clamonta
- 2006 Everest Metal
- 2006 Riley Medical
- Fusion: 2003 Symmety / 2003 Mettis Ortho

ORCHID
- 2008- Azary
- 2007- MPS
- 2007- Keller
- 2007- Anzon
- 2006- McDee
- 2005- Bio-Coat
- 2005- Bio-Vac
- 2004- Unique Design
- 2003 Stro Met Inc
- 2001 HY-VAC
- 1992- Stealth Technologies
- 1977- Unique Instruments

SANDVIK
- 2008 Eurocut
- 2008 Medtronic Memphis Facilities
- 2007 JKB Medical Tech
- 2007 Doncasters

GREATBATCH
- 2008- Depuy Facilities
- 2008 PRECIMED
- 2007 EAC
- 2007 Ouan Emerteq
- 2007 Intellisensing
- 2007 Enpath Medical
- 2007 Biomec Inc
- 2004– NanoGram
- 2002– Manufacturing
- 2002– Globe Tool
- 2001– Sierra-KD
- 1998 – Medical Components
- 1998 – Hittman Materials
- 1977 – Wilson Greatbatch

LISI MEDICAL
- 2010 Stryker Herouville Facilities
- 2008 INTERMED
- 2007 Jeropa USA
- 2007 Hugueny
- 2007 Seignol

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Contract manufacturing market value chain

Contract Manufacturers

Implants
1.5 B $

Instruments
0.9 B$

Cases & Trays
0.4 B$

Orthopaedic companies
OEM

Revenues: 32 B$

7 majors
Few 10 challengers

Hospitals & Clinics

Source: Avicenne data compilation 2011

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Take Home Messages (1/3)

OEM are looking for Contract Manufacturers who recognizing mutual interdependancy and targeting common goals

COMMON IMPROVEMENTS

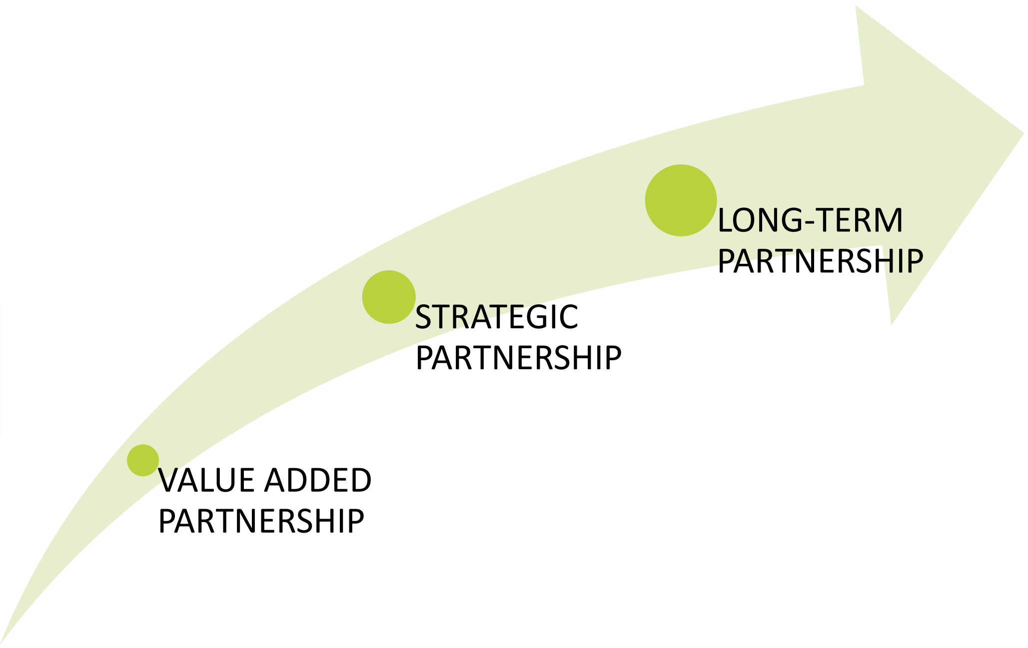
LONG TERM PLANNING

SERVICES

SHARING RISKS

ROBUST SUPPLY CHAIN

RELIABILITY



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Take Home Messages (2/3)

- **Concentration in the orthopaedic market continuing**
- **Concentration in the Contract Manufacturing market continuing**
- **The OEM sold their facilities to the contract manufacturers, we are expecting this trend for the future**
- **If China is becoming the new investment place for manufacturing generic instruments in short and mid term, we don't think the main part of implants and customized instruments will switch from Europe or US to BRICS countries**

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Take Home Messages (3/3)

- The Challengers Vs Majors: a double digits growth for challengers … Majors are losing market shares
- As soon as the OEM find the right supplier he starts to outsource
- OEMs need structured suppliers ready to:
  - Deliver within shorter time frames and enable flexibility
  - Be efficient in terms of less waste and thus reducing manufacturing costs
  - Share with them more responsibility and risk concerning regulatory constraints

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