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TUTORIAL – Contract Manufacturing Market

June 2016

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Contract Manufacturing market value chain: The Major OEMs have a different outsourcing strategy Vs the challengers. The challengers outsource almost all their products.

Contract Manufacturers

Implants

Instruments

Cases & Trays

Orthopaedic companies OEM

Revenues in 2015:
39 B US$

5 majors
& Several hundreds challengers

Hospitals & Clinics

TECOMET, ORCHID, PARAGON MEDICAL, Greatbatch, AVALIGN, lisi, Marle, CoorsTek Medical, TEGRA Medical, IN'TECH MEDICAL, NORWOOD Medical

DePuy Synthes, ZIMMER BIOMET, stryker, Medtronic, smith&nephew, NUVASIVE, AESCULAP, GLOBUS MEDICAL, Lima, serf dedienne santé, WRIGHT, MATHYS European Orthopaedics, MBA, LDR, AMPLITUDE, LINK, Corin

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OEM Contract Manufacturing strategy: Zimmer Biomet

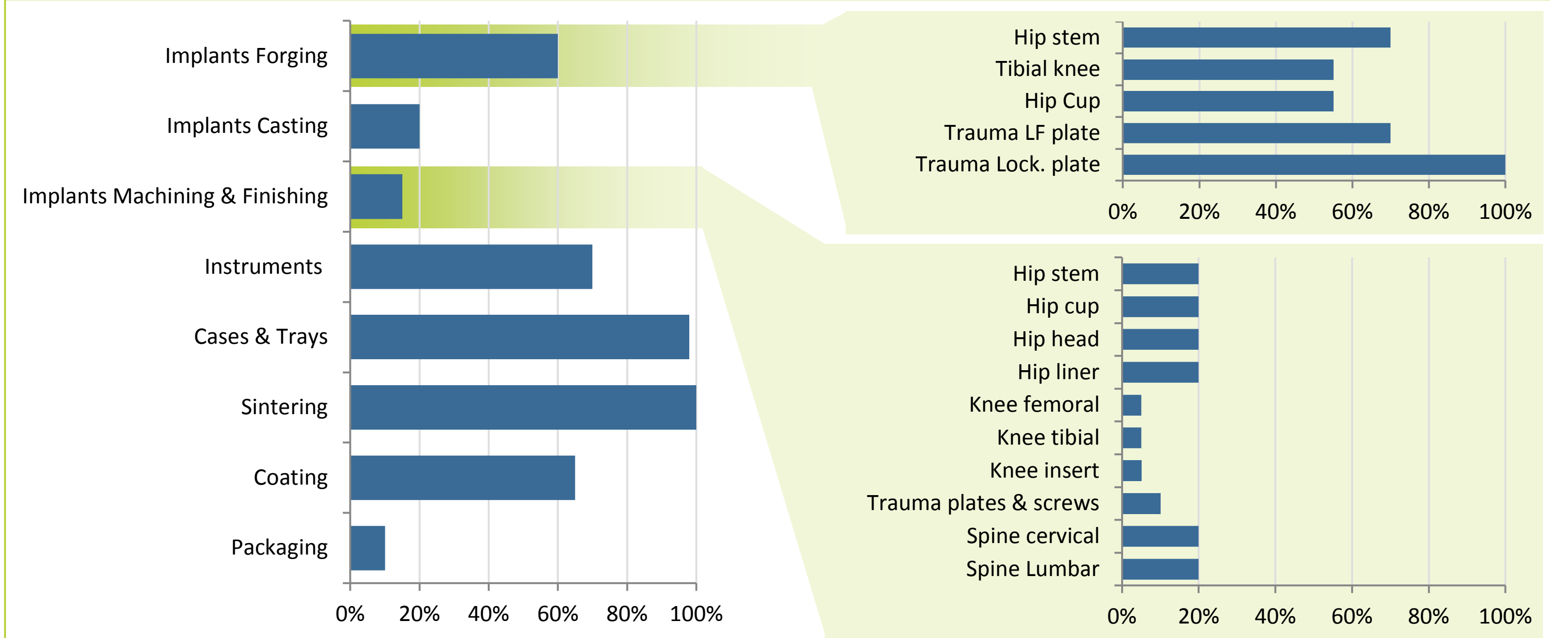
ZIMMER BIOMET

Casting: In-House → Warsaw (USA)

Forging: Winterthur (CH) – Berlin (Gr)

Machining & other facilities: Warsaw, Dover, Parsippany, Jacksonville, Palm Beach (USA) - Winterthur (CH) - Bridgend (UK) – Shannon, Galway (Ir) - Valence (Fr) - Valencia (Spain) - Ponce (Puerto Rico) - Beijing, Jinhua, Changzhou (China)

Contract Manufacturing Rate



Source: Avicenne 2016

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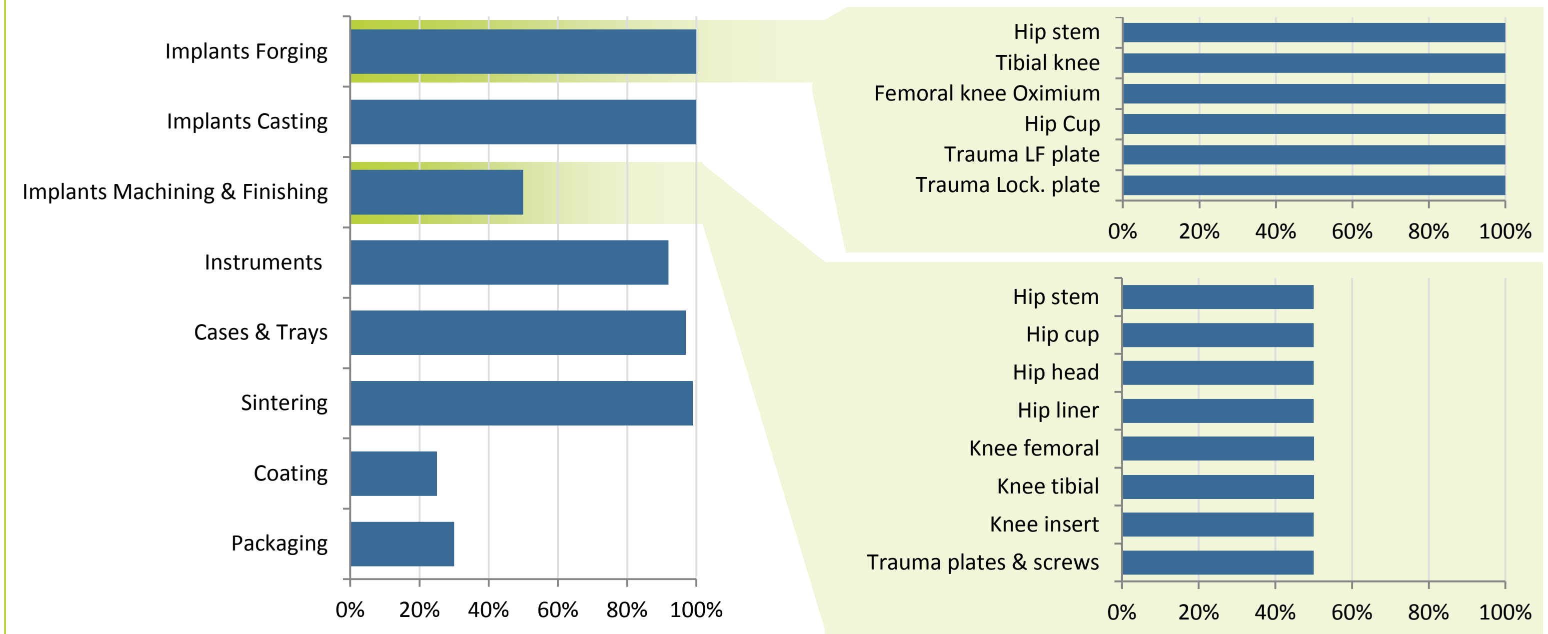
OEM Contract Manufacturing strategy: Smith & Nephew

- **Casting:** No In-House casting
- **Forging:** No In-House forging
- **Machining & other facilities:** Memphis, Oklahoma City (USA) - Calgary (Canada) - Aarau (CH) - Warwick (UK) - Tuttlingen (Gr) - Beijing (China) – Sangameshwar (India)

Contract Manufacturing Rate



Source: Avicenne 2016

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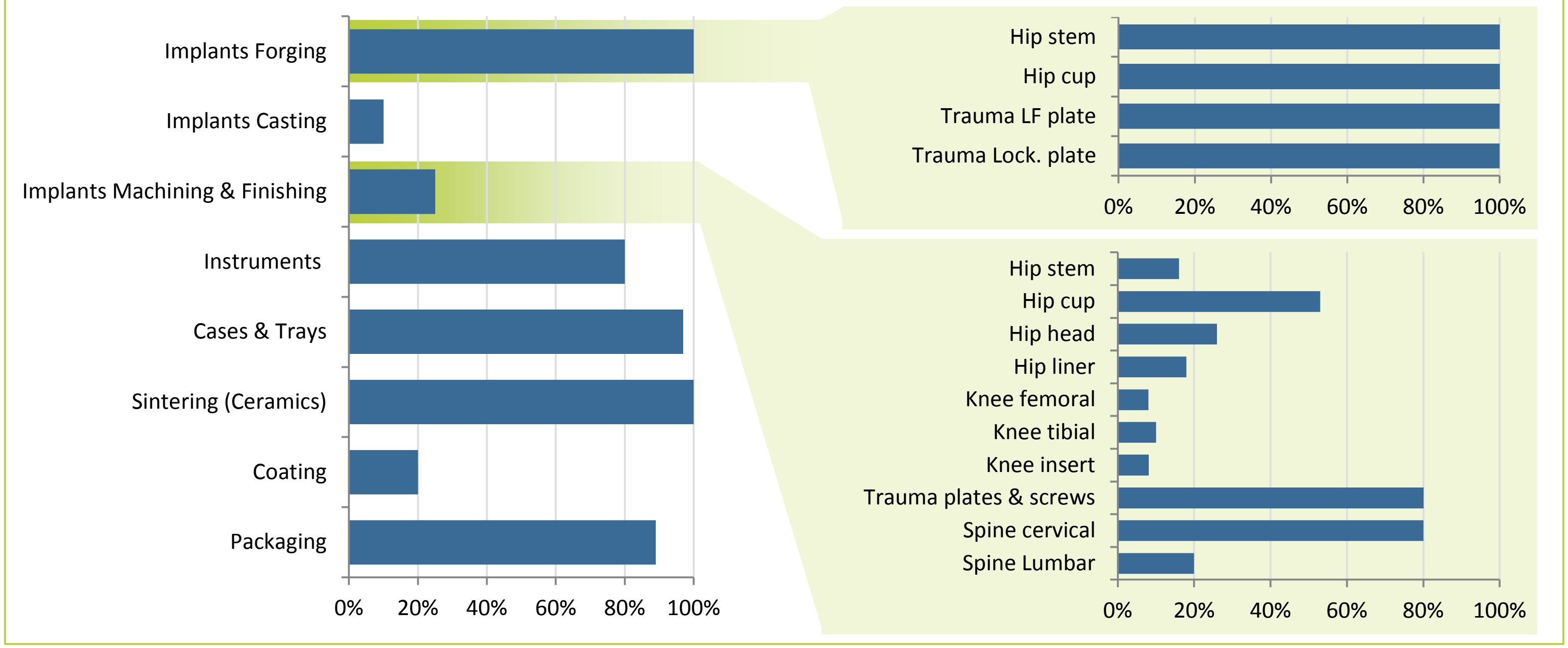
OEM Contract Manufacturing strategy: Stryker

stryker

- **Casting:** In-House → Mahwah (US) - Limerick (Ir)
- **Forging:** No In-House Forge
- **Machining & other facilities:** Mahwah, Kalamazoo, Malvern, Ft. Lauderdale (US) - Cork, Limerick, Carrigtwohill (Ir) - Cestas, Rennes (Fr) - Kiel, Fribourg, Stetten (Ger) - Changzhou, Suzhou (China) - Selzach, Neuchatel (CH)

Contract Manufacturing Rate



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OEM Contract Manufacturing strategy: Depuy-Synthes

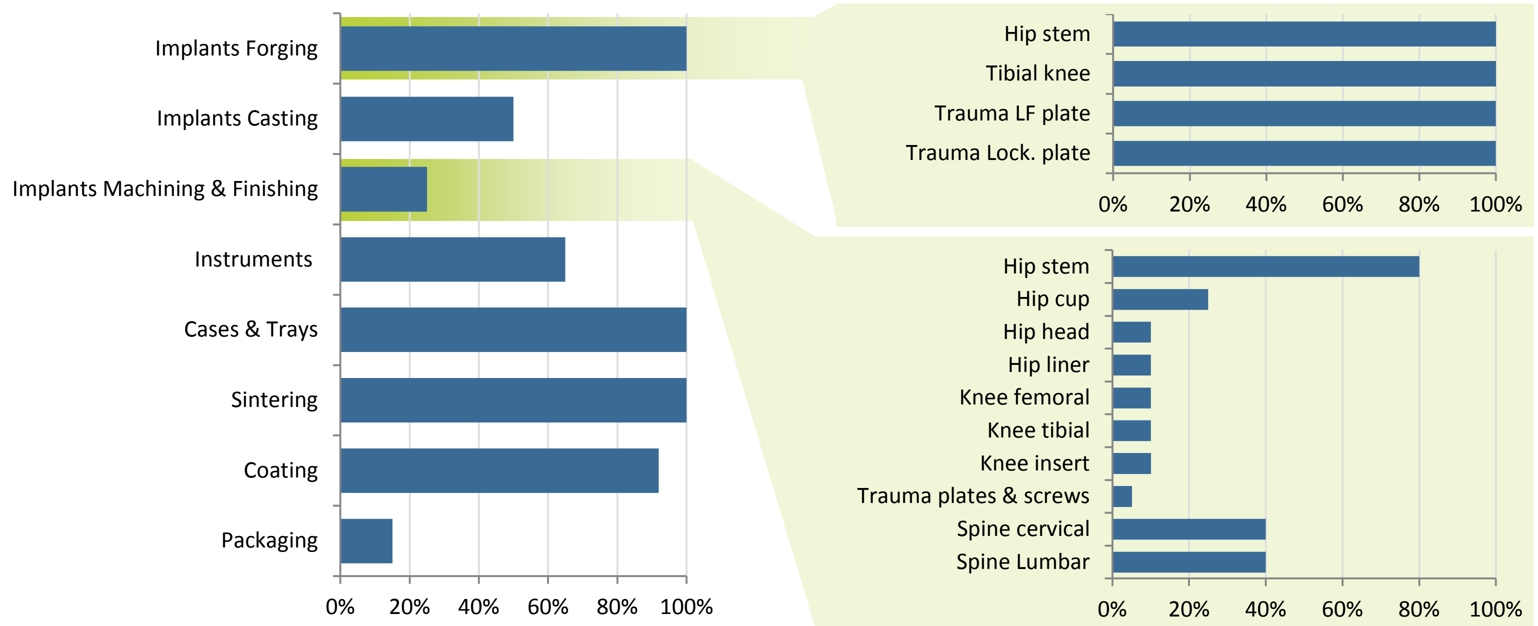
DePuy Synthes

Casting: In-House →Raynham (US), Leeds (UK), Cork (Ir)

Forging: No In-House Forge

Machining & other facilities: Warsaw, Raynham (US) - Leeds (UK) - Cork (Ir) - Suzhou (China) & Synthes: 10 facilities in Europe and 4 in US

Contract Manufacturing Rate



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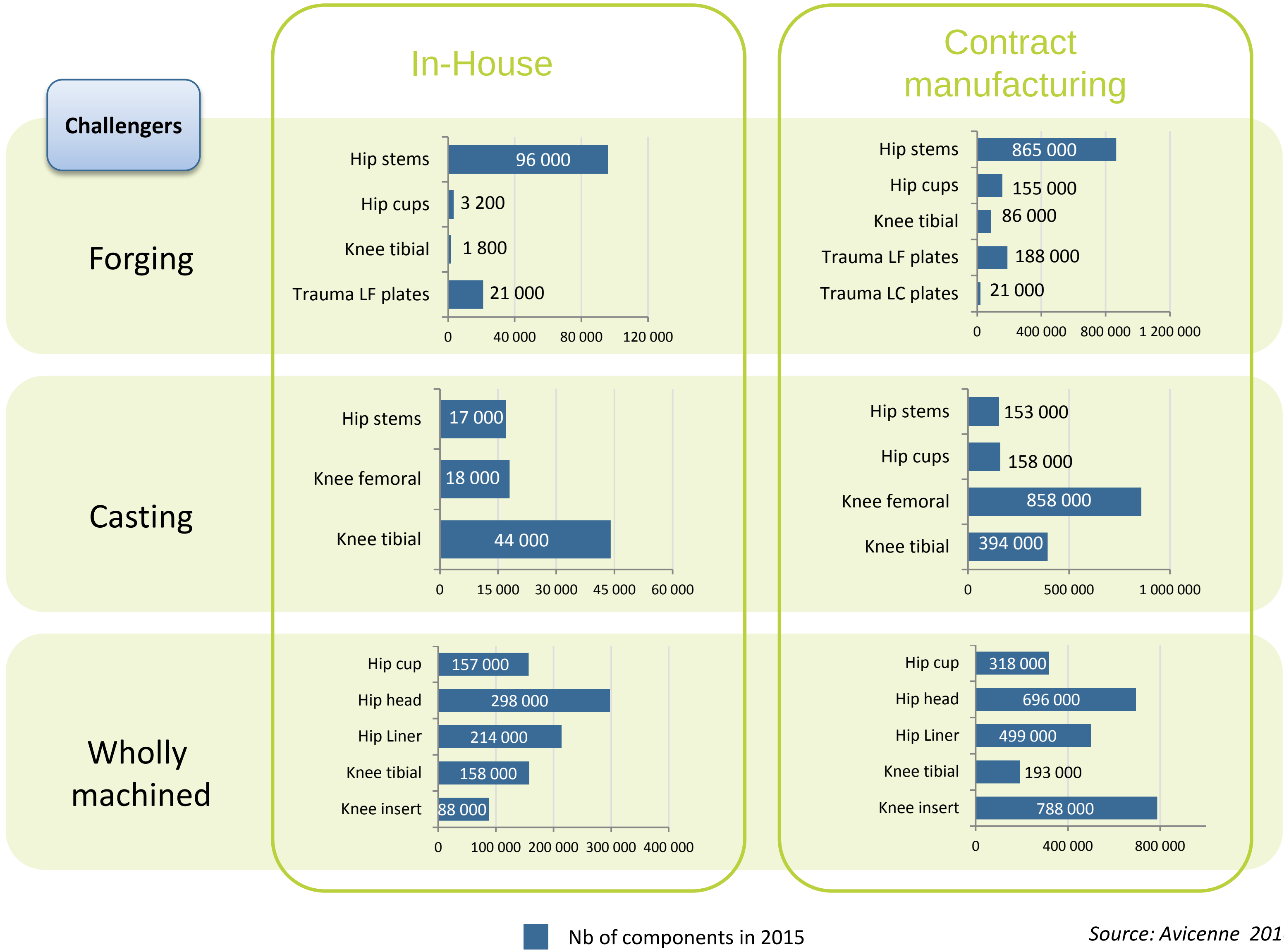
OEM Contract Manufacturing needs: Challengers



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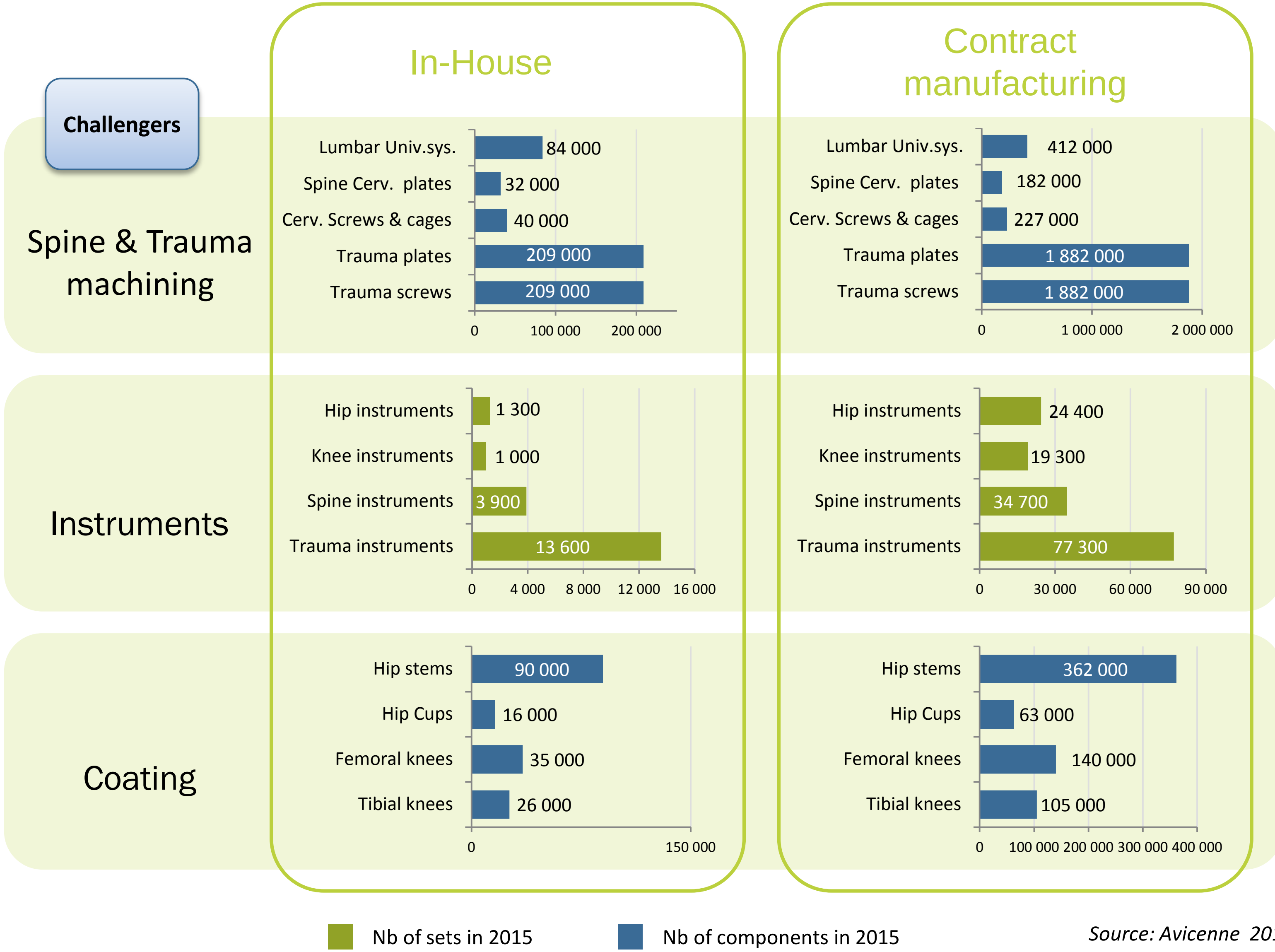
OEM Contract Manufacturing strategy: Challengers



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Contract Manufacturing product segmentation: 11 segments & 40 sub-segments

- Product segmentation
  - Forging
    - Hip stem
    - Hip cup
    - Femoral knee (special forging)
    - Tibial knee
    - LF plates
    - LC plates
  - Casting
    - Femoral knee
    - Tibial knee
    - Hip cup
    - Hip stem
  - Hip machining
    - Stem
    - Cup
    - Head
    - Liner
  - Knee machining
    - Femoral
    - Tibial
    - Insert

- Product segmentation
  - Spine,Trauma machining
    - Spine lumbar & cages
    - Spine cervical plates
    - Spine cervical & cages
    - Trauma internal plates
    - Trauma screws & Others
  - Instruments machining
    - Hip
    - Knee
    - Spine
    - Trauma
  - Cases & Trays
    - Hip
    - Knee
    - Spine
    - Trauma
  - Coating
    - Stem
    - Cup
    - Femoral
    - Tibial

- Product segmentation
  - Ceramics
    - Head
    - Liner
  - MPS
    - Hip
    - Knee
    - Spine
    - Trauma
  - Others

Source: Avicenne 2015

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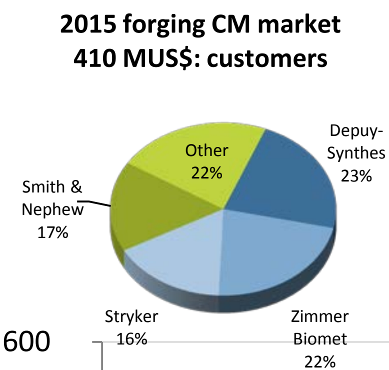
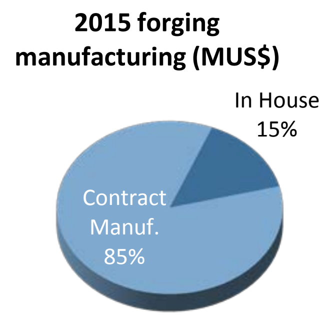
Forging Contract Manufacturing market 2015-2020

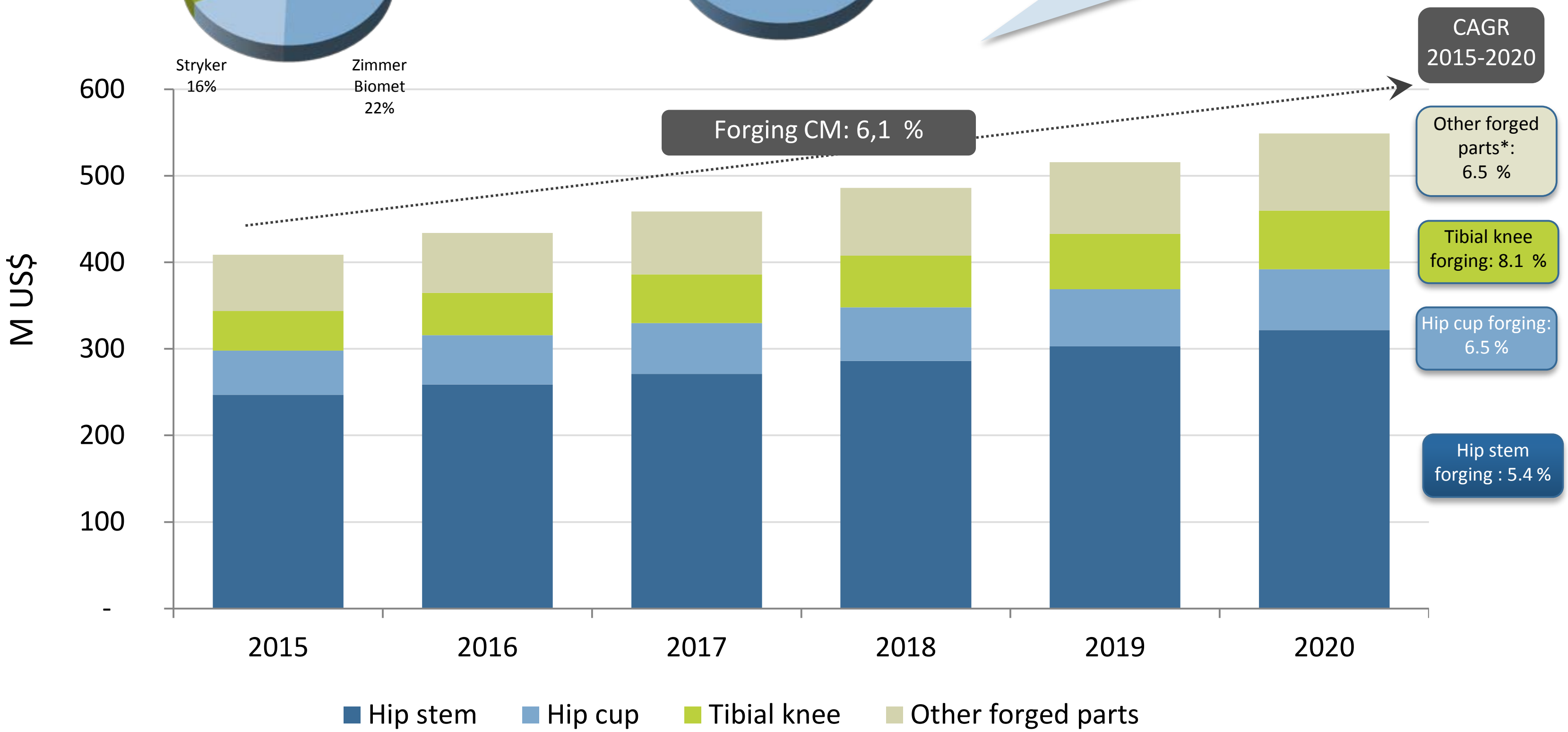
Forged stems represent 60% of the total forging Contract Manufacturing market.





Forging Contract Manufacturing Drivers:

- Very high outsourcing rate
- Reasonable assumption: Switch of the remaining In House part
- Very moderate price erosion
- Growth in tibial knee forging
- Growth in vertebral disks & trauma components forging



*Other forged parts: mainly Trauma locking Plates, Trauma LF Plates & vertebral disks

Source: Avicenne analysis 2016

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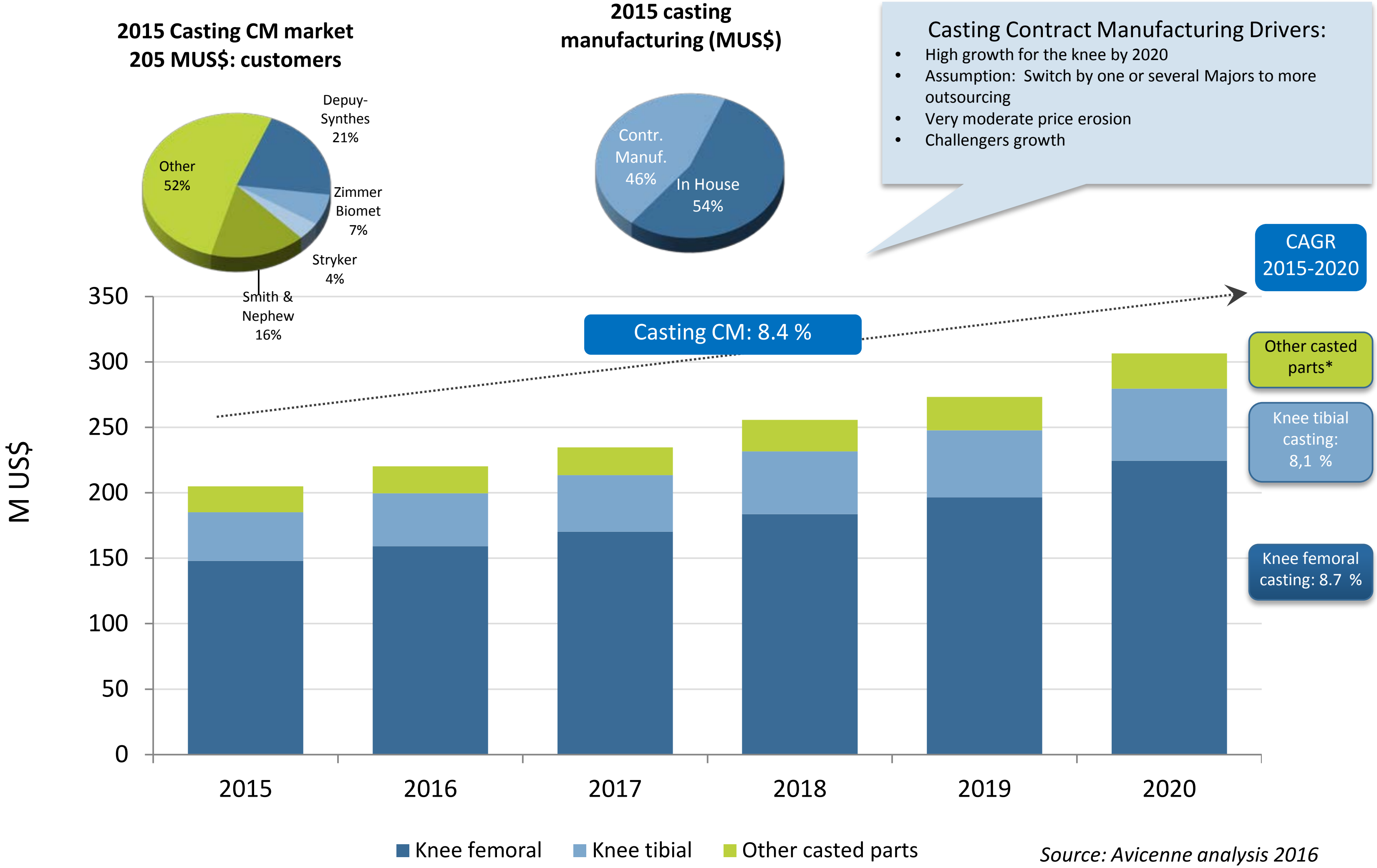
Casting Contract Manufacturing market 2015-2020

Knee femoral cast parts represent more than 70% of the total casting Contract Manufacturing market. In-house manufacturing is bigger than Contract Manufacturing.



Casting Contract Manufacturing Drivers:

- High growth for the knee by 2020
- Assumption: Switch by one or several Majors to more outsourcing
- Very moderate price erosion
- Challengers growth

Source: Avicenne analysis 2016

**Other casted parts: Hip cups & hip stems casted*

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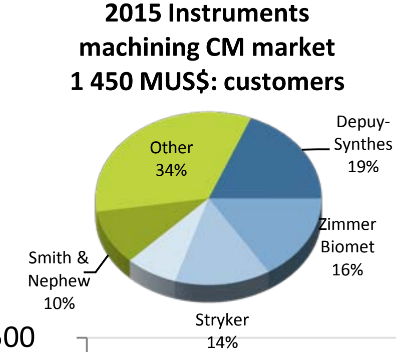
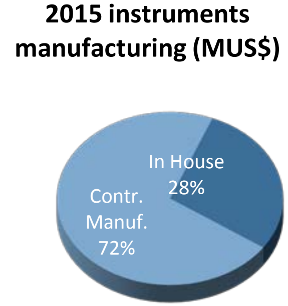
Instruments Contract Manufacturing market 2015-2020

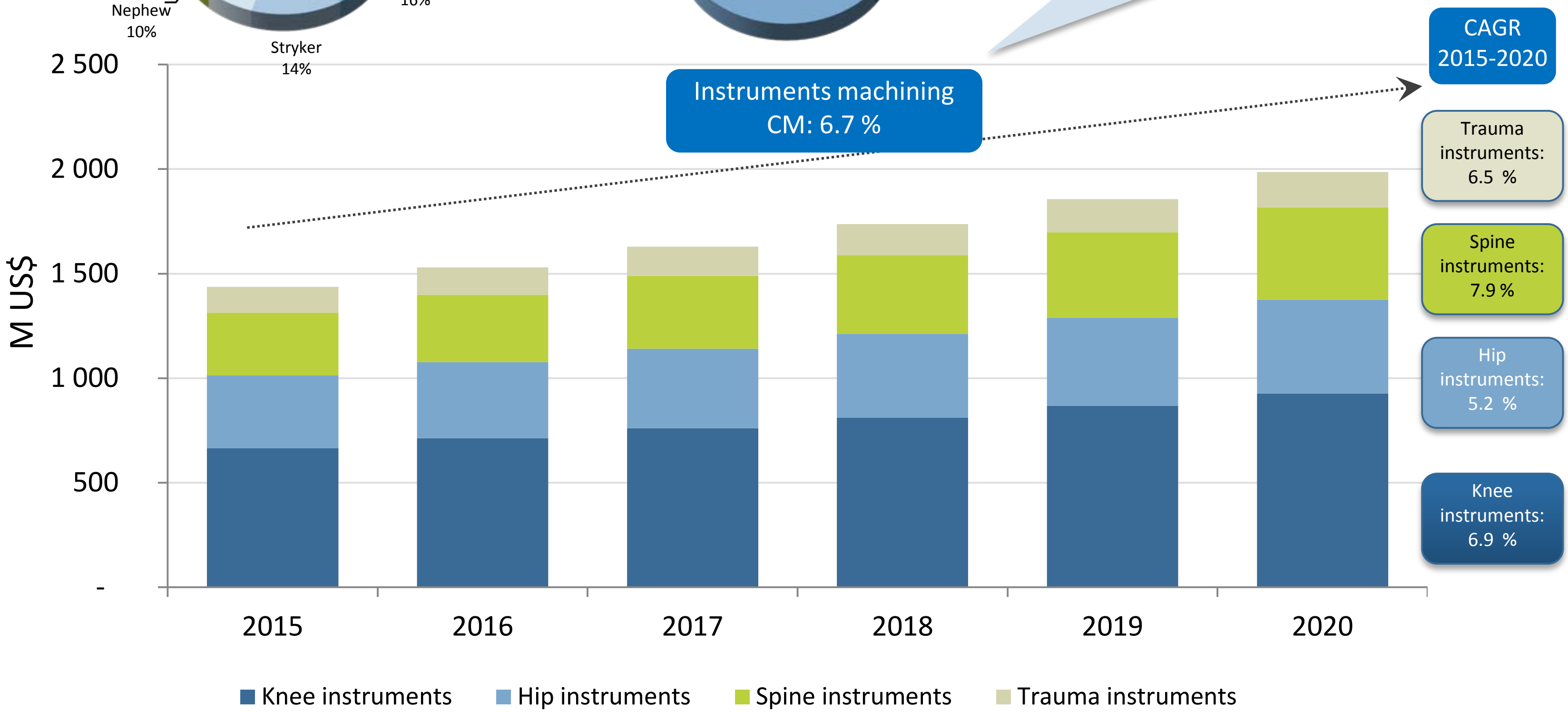
Manufacturing customized instruments is highly complex and mainly outsourced. Certain simple instruments are still made In-House or supplied from LLCs.





Instruments machining Contract Manufacturing Drivers:

- Growth in the knee segment by 2020
- Spine : Procedures growth
- Logical assumption : Part switch by certain spine & trauma Majors to more outsourcing
- Moderate price erosion
- Challengers growth



Source: Avicenne analysis 2016

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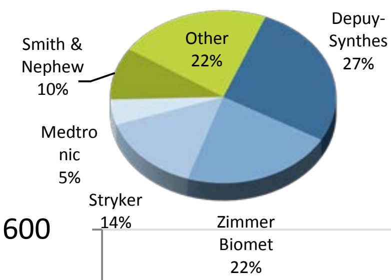
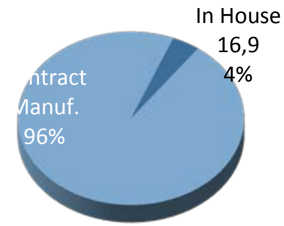
Cases & trays Contract Manufacturing market 2015-2020

Cases & trays follow the same dynamics as instruments. Almost completely outsourced

Cases & trays CM market 410 MUS$: customers

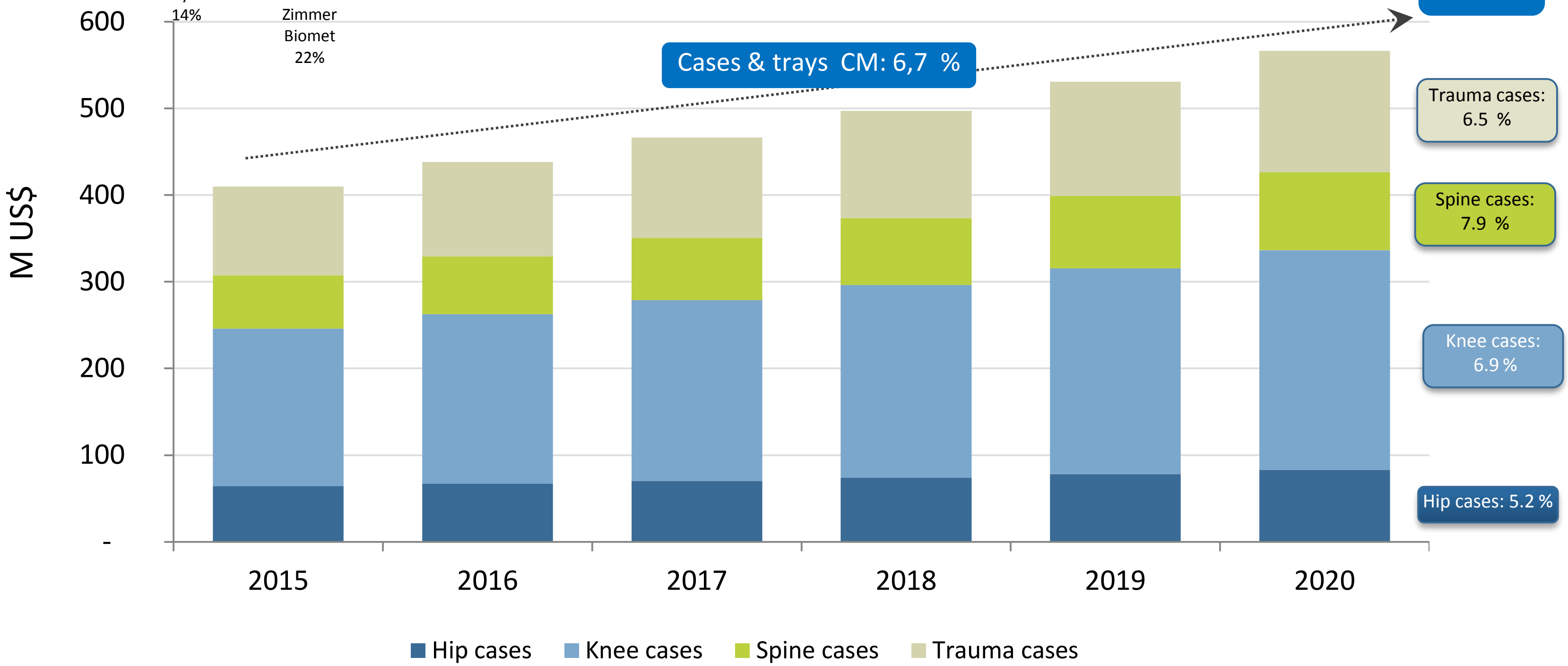


2015 cases & trays manufacturing (MUS$)



Cases & trays Contract Manufacturing Drivers:

- High outsourcing rate
- Cases & trays follow Instruments dynamics
- Small price erosion
- Knee & spine procedures growth
- Challenger dynamics & trend toward average decrease in surgeon procedures



Source: Avicenne analysis 2016

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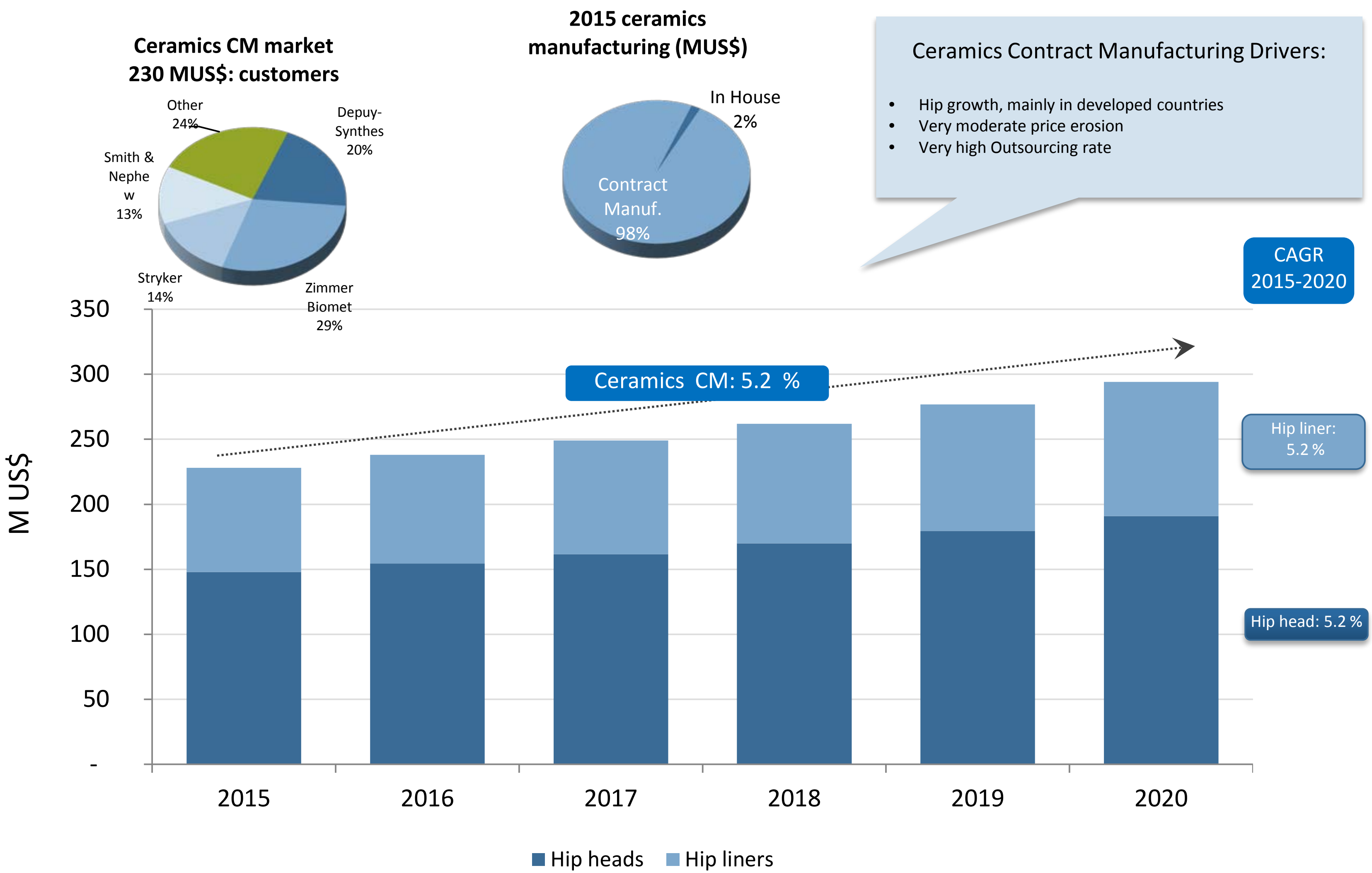
Ceramics Contract Manufacturing market 2015-2020

Ceramics is almost fully outsourced. Slow growth in the hip segment limits the growth in ceramics.

Ceramics Contract Manufacturing Drivers:

- Hip growth, mainly in developed countries
- Very moderate price erosion
- Very high Outsourcing rate



Source: Avicenne analysis 2016

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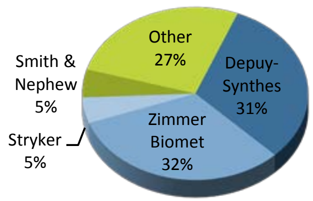
Coating Contract Manufacturing market 2015-2020

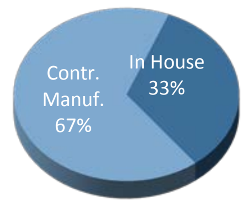
OEMs often making the monolayer & non-complex coating In-House.

Zimmer Biomet & Depuy-Synthes almost entirely outsource

2015 coating CM market
175 MUS$: customers

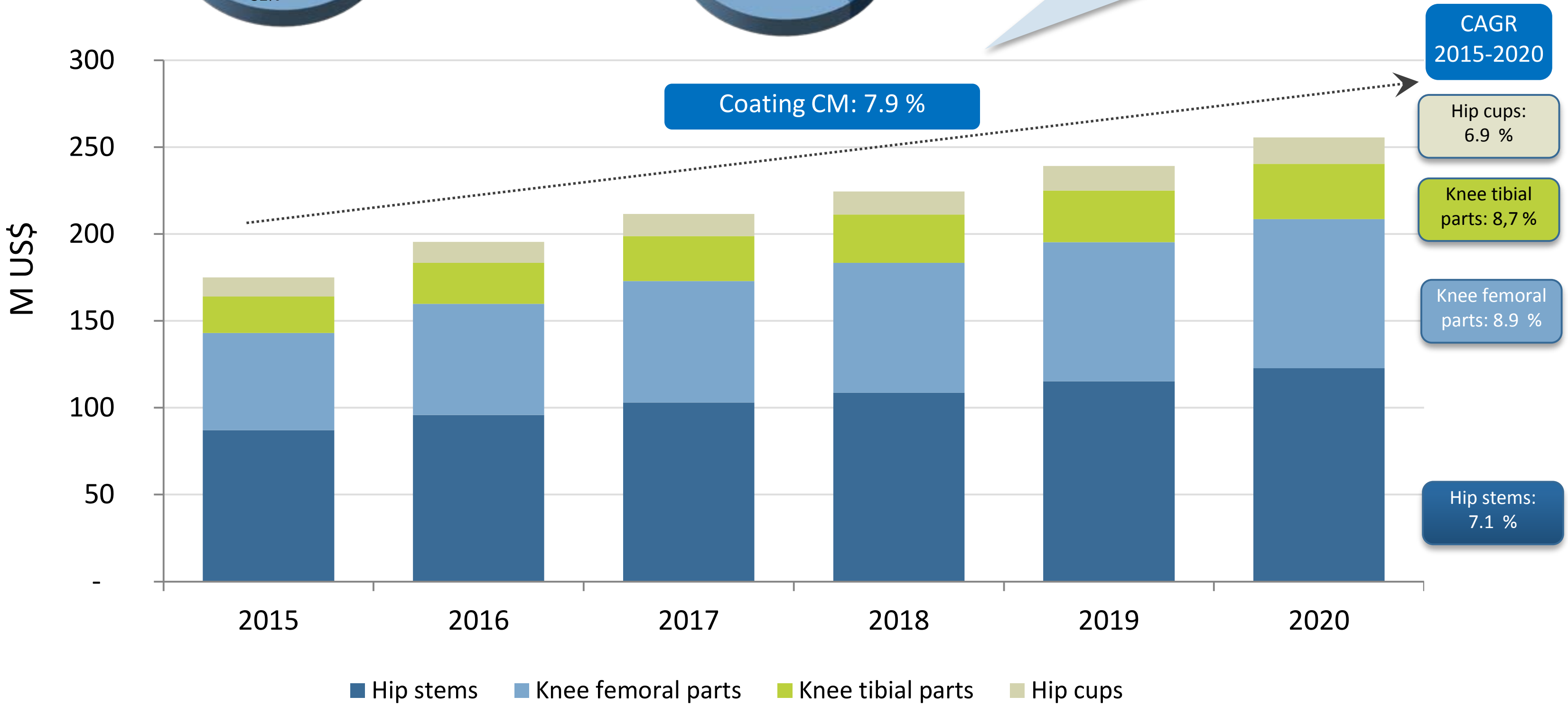


2015 coating (MUS$)



Coating Contract Manufacturing Drivers:

- Growth in the knee segment by 2020
- Trend toward Cementless, even in emerging countries
- Moderate price erosion
- Challengers growth



Source: Avicenne analysis 2016

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Contract Manufacturing market value chain: the Major OEMs have a different outsourcing strategy than the challengers. The challengers outsource almost all their products.

Contract Manufacturers

Implants
2.5 B US$

Instruments
1.4 B US$

Cases & Trays
0.4 B US$

Orthopaedic companies OEM

Revenues in 2015:
39 B US$

5 majors
& Several hundreds challengers

Hospitals & Clinics

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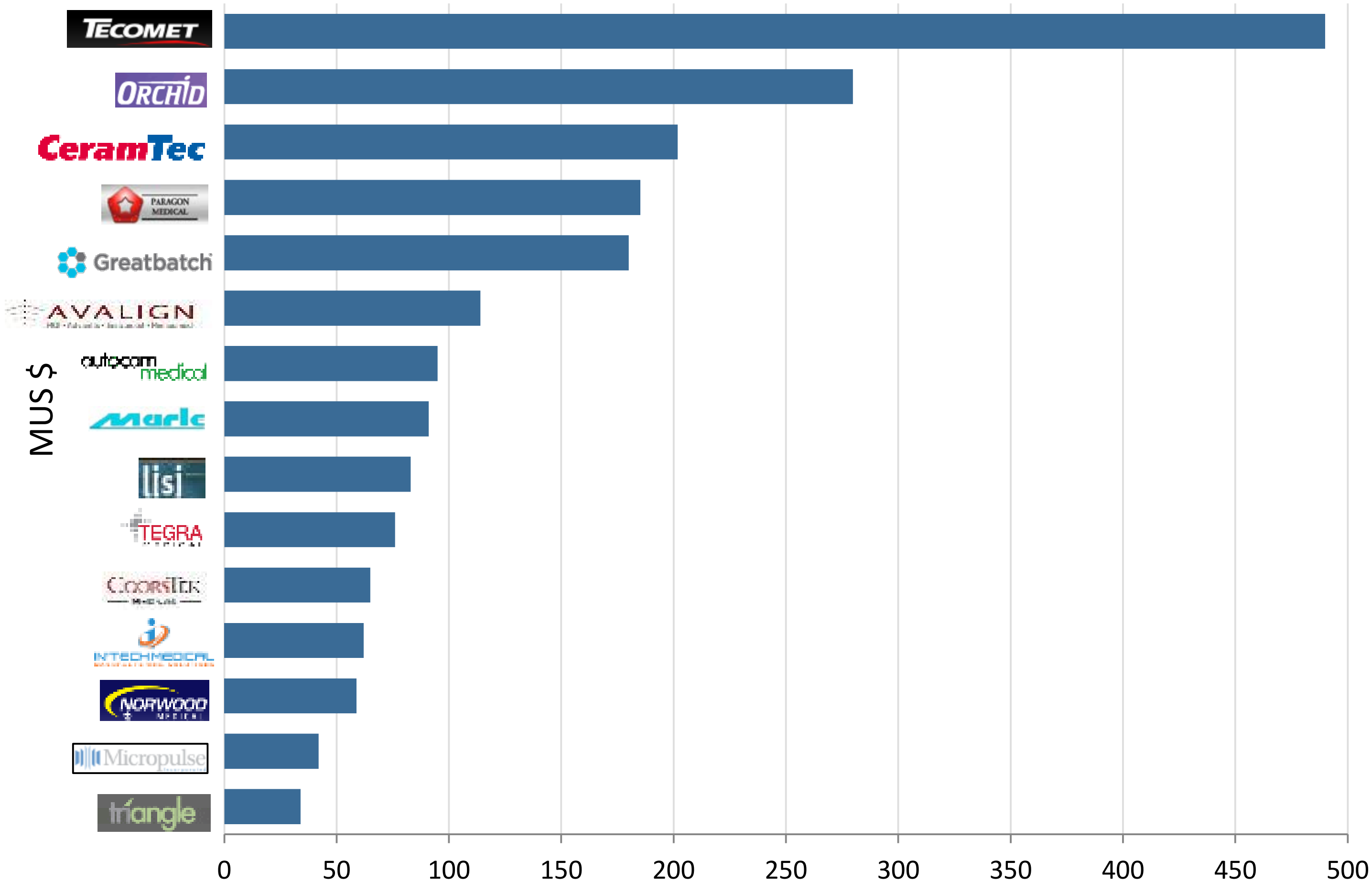
Contract Manufacturers worldwide revenues in 2015 (in M US$): Top 15 made 48% (43% in 2014) of the ortho contract manufacturing market



Source: Avicenne 2016

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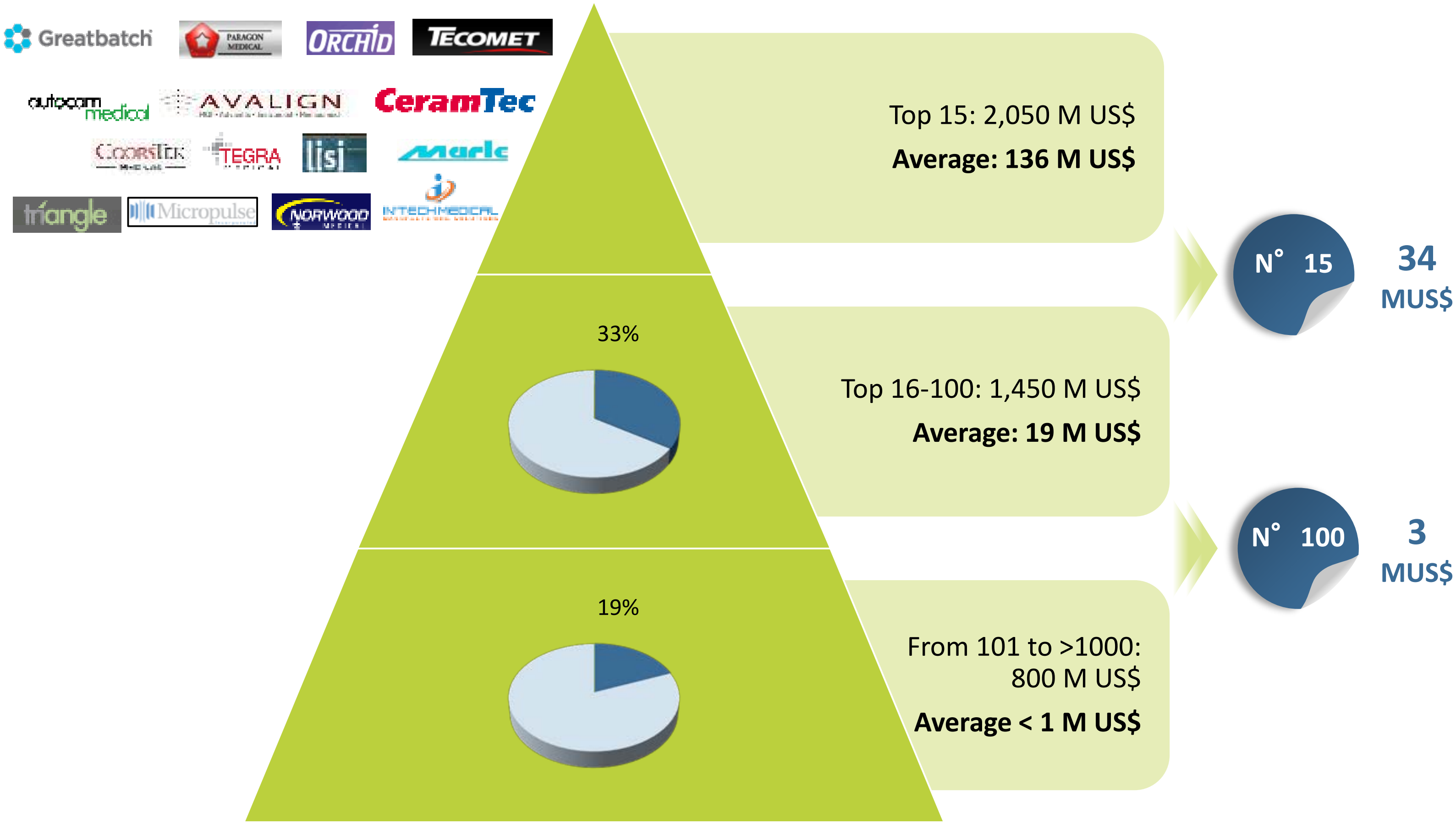
Contract Manufacturing competitor ranking & dispersion



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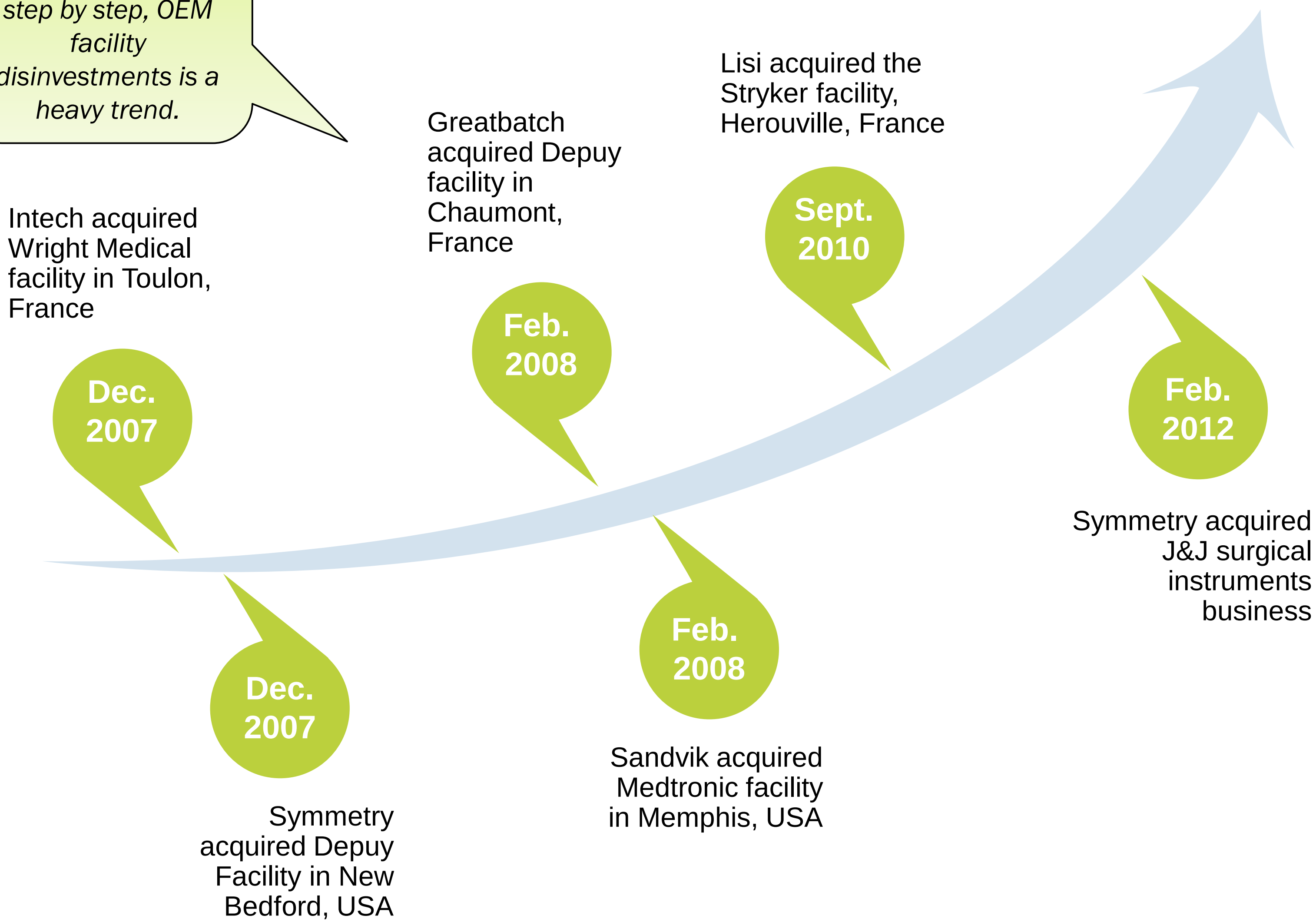
Heavy trend: The OEM facility disinvestments

Even though it is being accomplished step by step, OEM facility disinvestments is a heavy trend.



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Orthopaedic Contract Manufacturing concentration by acquisition

TECOMET
- **2014** 3D Medical
- **2014** Symmetry
- **2012** Teleflex
- **2011** Kemac Technology
- **1963** Tecomet

SYMMETRY Medical
- **2011** Surgical Instruments Codman & Shurtleff
- **2008** DePuy OEM Bedford Facility
- **2007** SSI/UCA
- **2007** TNCO
- **2007** Clamonta
- **2006** Everest Metal
- **2006** Riley Medical
- Merger: **2003** Symmetry / **2003** Mettis Ortho

Symmetry acquired by Tecomet

ORCHID
- **2015** Alhenia & Cam Bioceramics China
- **2012** Sandvik
- **2008** Azary Technologies
- **2007** MPS & Keller & 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

Sandvik acquired by Orchid

Greatbatch Medical
- **2015** Lake Region
- **2014** CCC Medical Devices
- **2013** MicroPower
- **2012** NeuroNexus
- **2008** Depuy Facilities
- **2008** PRECIMED
- **2007** EAC & Ouan Emerteq &Intellisensing & Enpath Medical & Biomec Inc.
- **2004** NanoGram
- **2002** Globe Tool
- **2001** Sierra-KD
- **1998** Medical Components
- **1998** Hittman Materials
- **1977** Wilson Greatbatch

Source: Avicenne analysis 2016

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The risk of moving to LLC by 2020: Developed countries & Low Labor Cost countries

	Trend by 2020	Level of moving to LLC
Generic orthopaedic instruments	Massively outsource In LLC	
Complexes & customized Orthopaedic instruments	Massively outsource Stay in USA & Europe	
Implants forging & casting	Stay in USA & Europe More outsourcing for the Majors	
Implants hip & knee machining	Few % go to the major OEM facilities in LLC	
Spine & trauma implants machining	Depuy-Synthes & Medtronic will stay In-House. Other players outsource more and more in LLC	

Source: Avicenne 2015

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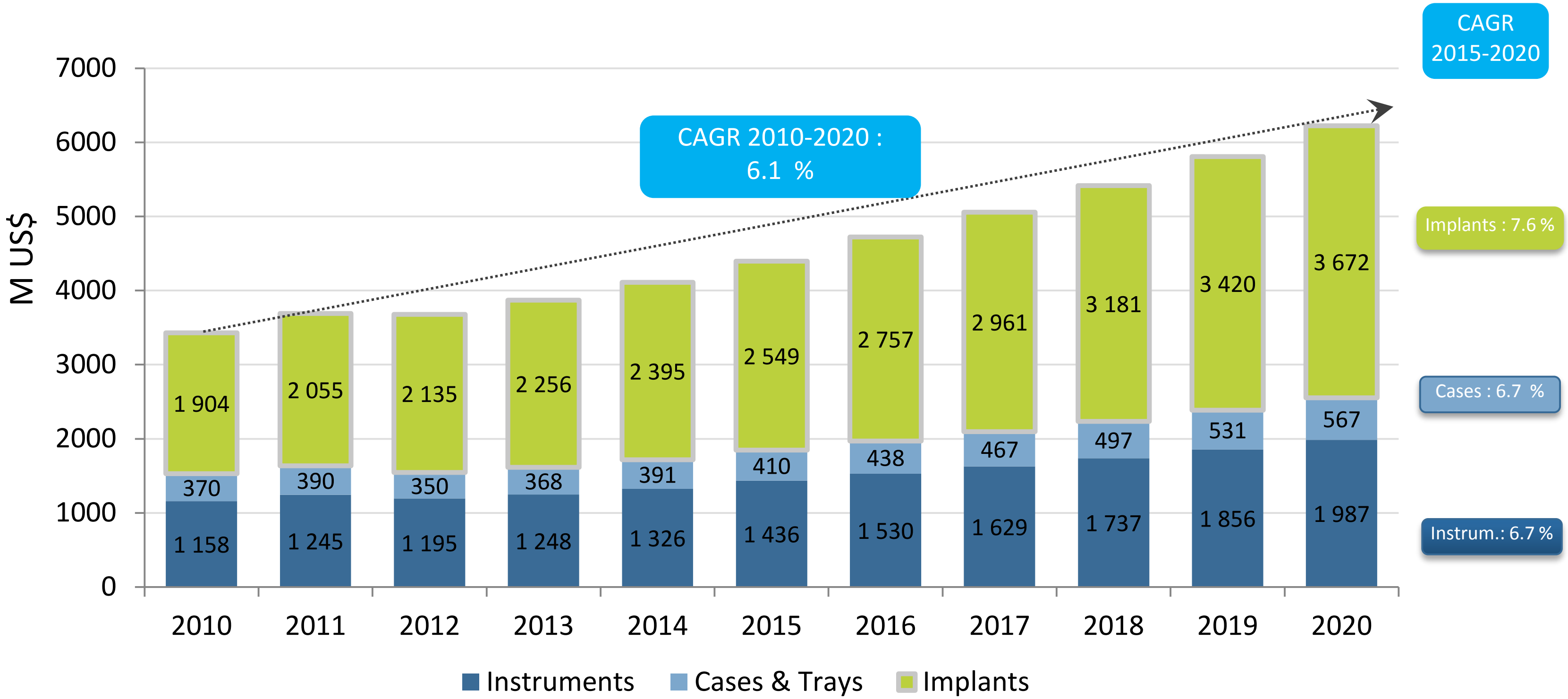
Contract Manufacturing market historical revenues & forecasts (M US$)

Implants will grow more rapidly than the instruments & cases & trays. The stable CM market in 2011 & 2012 slowed the market dynamic. In the period, 2015-2020 CM market growth will accelerate.



Source: Avicenne research & analysis 2016

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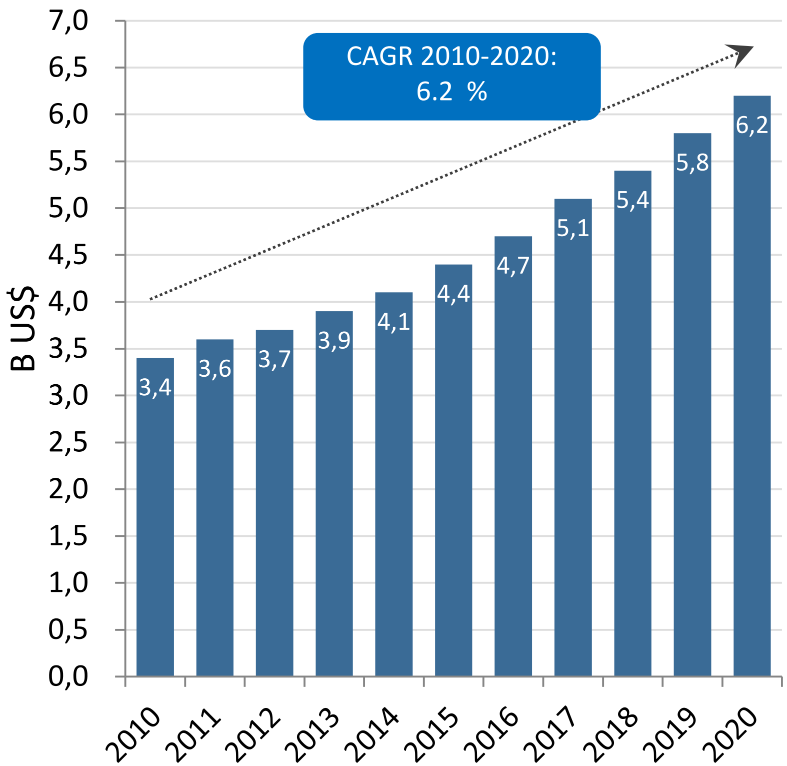
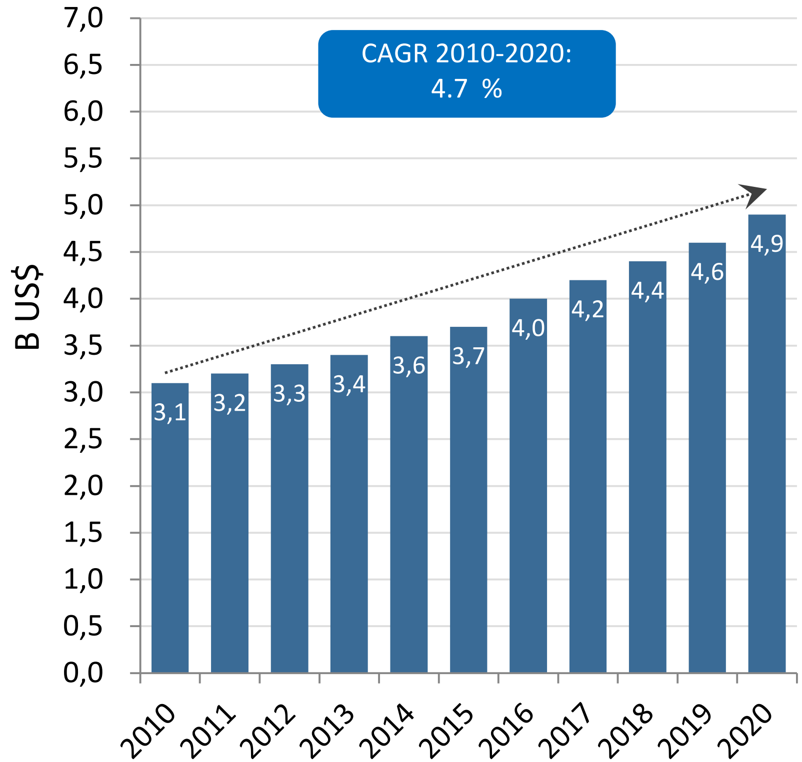
The Orthopaedics Contract Manufacturing market is growing faster than In-house manufacturing.

In- house manufacturing is growing linearly; the Contract manufacturing will be more dynamic.

2010-2020 Orthopaedics Contract Manufacturing (B US$)



2010-2020 Orthopaedics In-house Manufacturing (B US$)



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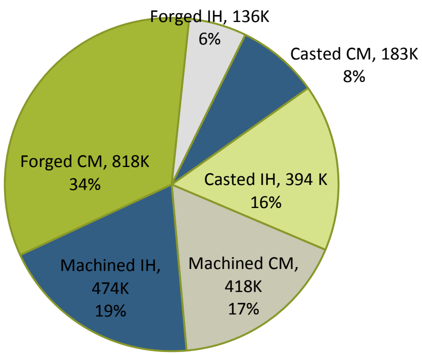
Additive Manufacturing represented in 2015 only a small % of all orthopaedic products manufactured

Additive Manufacturing is a new technology, which today is adapted only to the manufacture of small parts (and small series). Revision cups and several trauma and spine implants can be switched to Additive Manufacturing

- The main benefits of Additive Manufacturing for orthopaedics is the Bone ingrowth capabilities. It also enables the manufacture of complex metal parts, simultaneously and for different sizes, shapes and design. In the industrial field (mainly aeronautics) the Additive Manufacturing users are looking for weight reduction or advanced cooling.
- Additive Manufacturing enables the manufacture of complex metal parts, simultaneously and for different sizes, shapes and design.
- Zimmer, one of the Major orthopaedic companies, penetrated this market 15 years ago with a proprietary technology acquired from IMPLEX, thereby opening the trabecular structure market with an investment of several hundred million US$.
- Italy for Additive Manufacturing is the most advanced market: Challengers like Lima Corporate and Adler Ortho have invested massively in this technology, following Zimmer, the historical player. The main trabecular products are hip cups, sold by several thousands in Italy each year, and followed by other products like shoulder implants, knee tibial plates, mini-hip stems, etc…
- Additive Manufacturing focuses today mainly on cementless cups (especially revision) and cages for spine.
- Today, if the orthopaedic industry use around 1 500 tons of Titanium per year, Additive Manufacturing uses less than 50 tons of titanium per year for Orthopaedic purposes. (< 3% of the total).
- CMF implants will also be produced by AM due to their complex profiles and small dimensions.

2,4 million units Hip cups manufactured worldwide by processes



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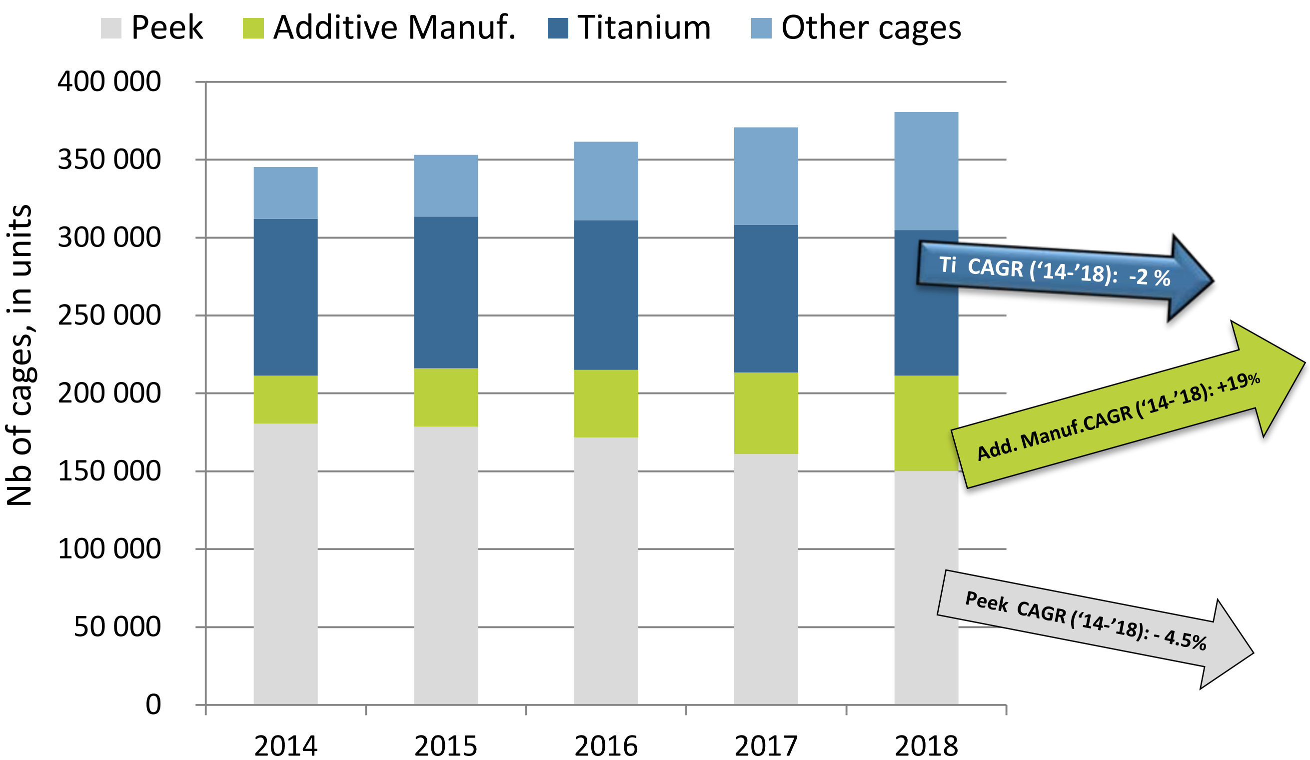
Cages Raw Materials in the five main countries in Europe: When Peek and Titanium lose market share, Additive Manufacturing cages will increase dramatically

in Europe, when Peek cages lose market share (-4.5% CAGR by 2018) and Titanium cages also decrease by 2% in the five main countries, Additive Manufacturing & Trabecular cages will increase by 19% and achieve 61,000 units in 2018.



Source: Avicenne analysis 2015

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Executive Summary (1/3)

- To manufacture implants, instruments & related products, orthopaedic companies in 2015 spent, 3.7 B US$ In-House and paid their contract manufacturers 4.4 B US$ (+6.2% Vs 2014)
- In the orthopaedic Contract Manufacturing market, Challengers are the n° 1 customer. In 2015 they accounted for 1.680 MUS$ due to their higher rate of outsourcing, followed by Depuy-Synthes, who accounted for 830 M US$, then Zimmer Biomet (625 M US$), Stryker (600 M US$) and Smith & Nephew (470 M US$).
- Medtronic spent only 180 M US$ because their manufacturing strategy is mainly oriented to In-House made.
- Instruments are the largest segment, with revenues of 1.4 BUS$ for Contract Manufacturing, followed by spine & trauma machining (820 M US$) and cases & trays (415 M US$). In 2015 forging Contract Manufacturing accounted for 410 M US$ & casting for 200 M US$.
- OEMs are demanding more and more that their Contract Manufacturers reduce costs and sometimes that they follow them to certain LLC countries to set up facilities there.

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Executive Summary (2/3)

- The Majors want to drastically reduce the number of their Contact Manufacturers. The response to this need is Contract Manufacturing market concentration.
- The risk of moving to LLC countries will be mainly limited to generic instruments and spine & trauma implants machining.
- Even though it is being accomplished step by step, OEM facility disinvestment is a heavy trend. When the Majors find a long term solution to outsource a “heavy or difficult function” they go for it!
- If the history of Orthopaedic Contract Manufacturing is set to feature more and more facility disinvestment by the Majors, the strategic question for the next few year is, “What other main services will be disinvested by 2020? Casting or the machining of certain products?”
- Bucking this strategic trend for disinvestment, a few rare, specific cases show that some players in the spine market want to internalize a small proportion of their manufacturing. In our view, this will not modify the general evolution in Contract Manufacturing, which is set to remain the dominant trend for outsourcing.

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Executive Summary (3/3)

- The Contract Manufacturing market benefits from the main orthopaedic drivers; population ageing and product mix evolution. It also has its own intrinsic drivers: OEM implant facilities disinvestment and the growth of the challengers' market share, which is drastically impacting this market, due to their high outsourcing rate.
- By 2020, the Contract Manufacturing market will still be growing faster than In-House.
- Contract Manufacturing remains a robust market with 7.4% CAGR by 2020. Implants will grow more rapidly than instruments and cases & trays.
- Today, if the orthopaedic industry use around 1,500 tons of Titanium per year, Additive Manufacturing uses less than 50 tons of titanium per year for Orthopaedic purposes. (< 3% of the total).
- CMF implants will also be massively produced by AM due to their complex profiles and small dimensions.
- Market growth 2015-2020 for Metal Additive Manufacturing will be between 18% and 30%, according to several industry forecasts. Orthopaedic applications will be one of most dynamic segments.

THANK YOU