



Global Spine Cement

Market Report



Content

GLOBAL SPINE CEMENT



Market overview

Global

Regional

Demographics

Injectables

Market

Manufacturers

Reimbursement

COVID-19 impact



Global Orthopaedic Bone Cement Market



The global orthopaedic bone cement market is valued at approx. \$1.1bn by 2025, up from \$692.8m in 2016 (CAGR of +5.9 per cent from 2017 to 2025.)

The global market is divided into osteoporosis and trauma, with an increased market share for osteoporosis anticipated.



Key sources of growth

- Growing number of orthopaedic surgeries and spine fractures
- The rise in osteoporosis and the geriatric population
- Increasing demand for minimally invasive procedures
- Technological advancements in products



Market constraints

- Rising cost of spinal fusion surgeries
- Post-surgery complications



Vertebroplasty and Kyphoplasty



The global vertebroplasty and kyphoplasty market was valued at \$1.0bn in 2018, and is expected to grow at a CAGR of 4.6 per cent between 2019 and 2027.



Vertebroplasty

- Increasing use in developing markets due to cheaper price tag with Middle East and Africa set to rise from \$4.1m in 2016 to \$6.5m by 2023.
- Market to decline in North America (\$72m in 2016 to \$29.4m in 2023) due to a lack of demonstration of procedure efficacy and declining adoption rates.



Kyphoplasty

- Dominates the market due to better pain relief, fewer complications and a rising awareness of advantages.
- Expected to exhibit significant growth owing to changing lifestyles as people become more sedentary.
- Growth will also be driven by technological advancements and the next-gen kyphoplasty balloons, such as Arcadia by Merit Medical.



Regions



North America

The largest region, with a high cost of cement vertebroplasty, high incidence of vertebral compression fractures, rising prevalence of osteoporosis, high demand for minimally invasive surgeries, direct presence of key regional players, and strong distribution network.

A change in reimbursement policies and constant pricing pressure will hamper the vertebroplasty and kyphoplasty market in North America.

North America and Europe are expected to grow due to less pricing pressure, and as only permitted products are bought, this eliminates cheaper substitutes.

Europe

The second largest market share due to ageing population.



Asia Pacific

Growth is expected due to rapidly developing healthcare systems, adoption of advanced technologies, and ageing populations.

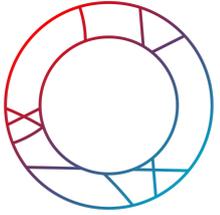
The bone cement market in APAC is expected to grow at 6.7% (CAGR 2017-2025).

South Africa

Seen as a promising market with a potential of 20,000 vertebral fractures and a market of €40m.



Demographics



The world's population is ageing.

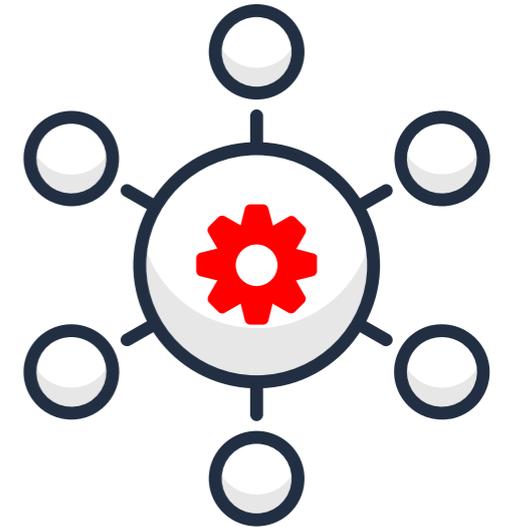
- There are approx. 962m people aged 60 or over in the world, 13 per cent of the global population (UN 2017).
- The number of older people is projected to nearly double to 1.5bn by 2050 (UN).

Changing lifestyle habits, as people become more sedentary, increase the risk of osteoporotic conditions.

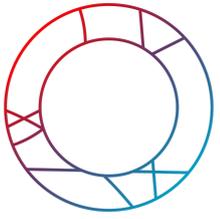
- More than 25 per cent of the world's adult population are insufficiently active.
- Levels of inactivity are twice as high in high-income countries as low-income countries.
- Insufficient activity increased by 5 per cent in high-income countries between 2001 and 2016.

An increasing number of people are experiencing osteoporotic fractures or spinal injuries.

- The International Osteoporosis Foundation (IOF) estimate there are 8.9m fractures globally every year.
- One in three women over 50 and one in five men globally will experience osteoporotic fractures.
- 61 per cent of osteoporotic breaches occur in women.
- Between 250,000 and 500,000 people suffer a spinal cord injury (SCI) every year (World Health Organisation).
- According to the National Spinal Cord Injury 2020 estimates, there are 17,810 new SCI cases and approx. 294,000 people living with SCI in the US each year.
- In the US, there are an estimated 700,000 vertebral fractures a year due to osteoporosis
- NICE estimates there are approx. 11,900 osteoporotic vertebral compression fractures per year in the UK.



Injectable Cement with Fenestrated Pedicle Screws



From 1998 to 2008, the annual number of spinal fusion discharges increased 137 per cent from 174,223 to 413,171 (US).

- Frequency, utilisation and hospital charges of spinal fusion increased at a higher rate than for other notable inpatient procedures, e.g. hip replacement, and hospital characteristics, in particular in-hospital mortality rate.
- Over the same time, the mean age for spinal fusion increased from 48.8 to 54.2 years.
- The national (US) bill for spinal fusion increased 7.9-fold.
- There were an estimated 180,000 cervical fusion procedures performed each year in the US.

Surgeons perform an estimated 400,000 instrument spinal fusions every year in the US.

- In 2012/2013 there were over 6,500 spinal fusion operations were done in the NHS in the UK.
- The procedure was developed as a way to combat the complications that can arise from spine fusion surgery.

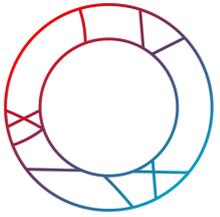
With ageing spine an increasing concern, the use of cement-augmented screw is a valuable option for fragile patients, being less invasive and with fewer complications.

- Several studies show how cement augmentation of pedicle screw fixation has become accepted as a technique to provide spine stability.

It has been reported that the procedure can increase screw pull out strength by a factor of up to 1.5 compared to surgical procedures that employ non-augmented screws.



Injectable Cement with Fenestrated Pedicle Screws: Market

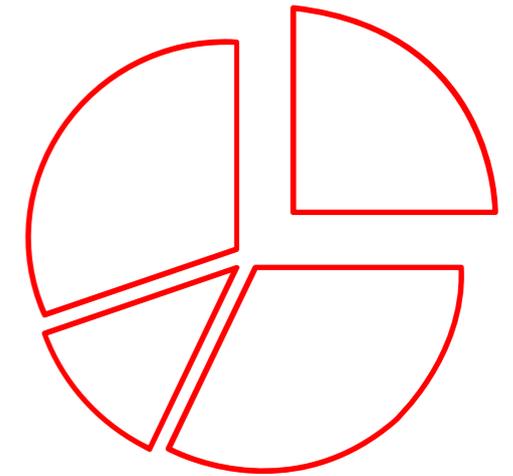


Estimates of the market vary but the global Spinal Fusion Devices Market was worth approx. \$12bn in 2020 and is expected to reach between \$13bn and \$15bn by 2026, with growth driven by advancements in surgical technology.

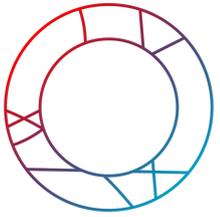
- Surgeries have become more effective as the technology has improved.

Cervical spine procedures comprise approx. \$2.6bn of global spine market. The global pedicle screw system was valued at \$3.8bn in 2018.

- Dominated by North America, given the prevalence of spinal deformities and the availability of advanced infrastructure and equipment.
- Europe was the second largest market in 2018 with the UK, France and Germany are seen as having the largest potential given the high disposable income of people and technological improvements.
- The East Asia market is expected to grow rapidly due to healthcare investments.



Injectable Cement with Fenestrated Pedicle Screws: Manufacturers



The global bone cement market is highly concentrated, and dominated by Tier-1 players (Stryker and Zimmer Biomet).

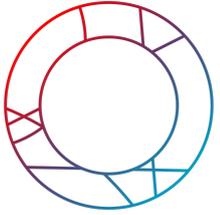
The minimally invasive spinal implants market has nearly 100 companies, most of whom have less than two per cent market share.

The pedicle screw systems market is moderately competitive and consists of several major players, for example:

- 2011 - DePuy Synthes held its European launch for the ViperCortical Fix fenestrated screw system
- 2013 - Vexim launched Interface cement to use with its SpineJack implant before being bought by Stryker in 2017
- 2015 - Safe Orthopaedics launched a range of fenestrated screws for spine surgery
- 2016 - Cement-augmented pedicle screws were first cleared by the FDA in 2016 with Medtronic's CD Horizon Fenestrated Screw Set
- 2017 - FDA approval received for VIPER and EXPEDIUM
- 2018 - CarboFix Orthopedics Ltd received FDA approval for its CarboClear Pedicle Screw system for use in spinal oncology
- 2019 - Mirus Bio LLC received FDA approval for its Europa pedicle screw system in spine deformity surgery
- 2020 - Stryker Corporation received FDA approval for its Vertaplex HV High Viscosity Radiopaque Bone Cement in March
- 2020 - icotec ag announced a partnership with G-21 to distribute their bone cements in conjunction with icotec's VADER® Pedicle Screw System in the US in December

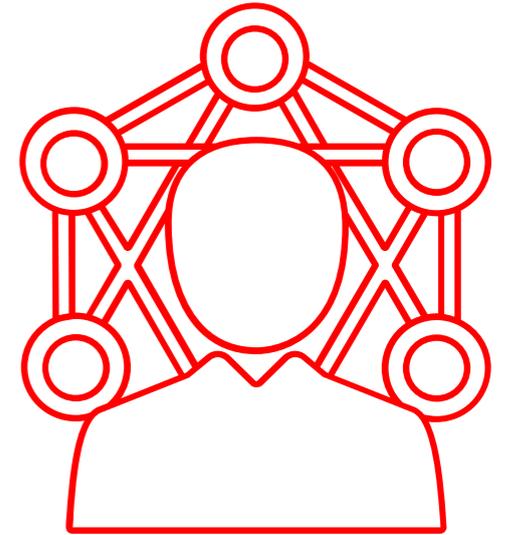


End User Market



Hospitals:

- In 2019, hospitals accounted for 61 per cent of the global kyphoplasty market.
- As the primary point-of-care for all kinds of health problems this sector is expected to hold the largest market share in the global market.
- Hospitals are estimated to generate revenue over \$501.2m (orthopaedic bone cement) by 2025.
- The number of surgeries performed in hospitals is high as compared to that in ambulatory surgical centres due to the robust hospital infrastructure in the US, Europe and developed countries.
- Patients prefer hospitals due to the availability of all levels of treatment, the number of hospital operating rooms, and a rise in awareness about different treatment support provided in hospitals for vertebral compression fractures.
- US patients favour hospitals because of reimbursement facilities provided by Medicare & Medicaid.



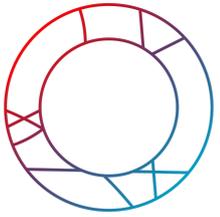
Ambulatory surgical centres

- Anticipated to witness the fastest growth over the next nine years, coming from a smaller base.

Clinics & others



Reimbursement: US



Annual vertebroplasty fell by 48 per cent from 5,744 in 2012 to 2,987 in 2017 and kyphoplasty fell by 12.7 per cent from 24,986 to 21,681 over the same time period.

Surgeon reimbursements for vertebral augmentation procedures increased by a weighted average of 93.7 per cent, primarily driven by a 113.3 per cent increase in mean reimbursements for kyphoplasty procedures from an average of \$895 to \$1,764.

The overall cost of vertebroplasty and kyphoplasty procedures is high, making them affordable for patient populations in cost-sensitive markets – cost is spread over various stages (imaging, medication, hospital care, etc.)

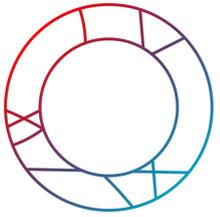
However, surgical cost of PMMA is significantly lower than that of EC. For 1-level surgeries, implant costs for use of cement was \$75 compared to \$9000 for cages.

Under the American Medical Association reference system, vertebroplasty and kyphoplasty are reported under the code CPT® 22899 - Other Procedures on the Spine (Vertebral Column).

It is projected that by 2025, 3m osteoporotic fractures will cost \$25bn a year in health related costs.



Covid-19



The demand for spinal surgery medical devices witnessed a sharp decline in demand. Zimmer Biomet reported a Q1 net sales of \$1,784bn, a 9.7 per cent decrease from 2019.

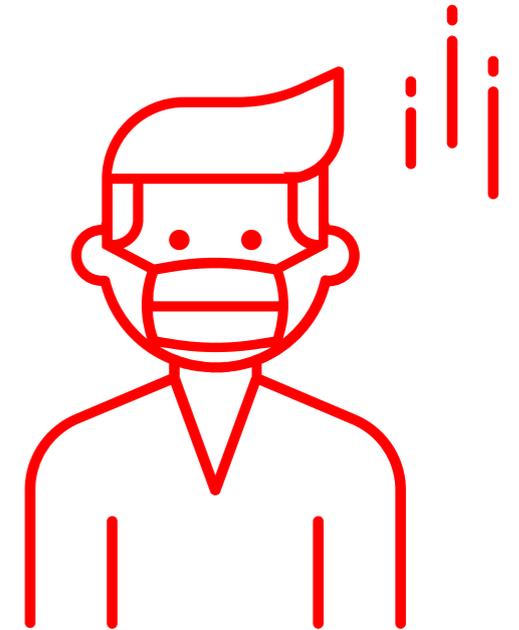
Hospitals experienced a 35 per cent decline in the operations room volume during March to July 2020, however, the robotic spinal surgeries witnessed an uptick during the COVID period.

Covid-19 has significantly affected current clinical trials and may create confounding factors in some studies, with patients not being to attend hospitals.

The silver linings are two-fold:

- The increased use of technology and virtual communications, by both researchers and patients, has increased collaboration and should streamline data collection.
- Surgeons had the opportunity to complete research projects and there has been an upturn in the amount of manuscripts submitted to peer reviewed journals globally.

Strategies need to be devised to handle the backlogs caused by the COVID-19 pandemic, in terms of both the number of surgeries delayed and the supply of materials.





THANK YOU

To access the full report with proprietary data and details regarding key players, specific market attitude and reimbursement costings, please get in touch with us.