

9 April 2025

Osteopore secures European approval for custom orthopaedic and cranial implants

Highlights

- Osteopore secures European Union Medical Device Regulation (EU MDR) approval to supply its cutting-edge custom orthopaedic and cranial implants.
- EU MDR approval unlocks opportunities to offer high-value, custom implants to Europe, in addition to off-the-shelf implants, introducing new revenue streams.
- Regulatory clearance validates Osteopore's orthopaedic and cranial products in Europe, strengthening the Company's positioning in the market.
- The European orthopaedic market is projected to grow at a CAGR of 3.3% (2029)¹, while the cranial implant market is expected to grow at a CAGR of 9.4% (2030)².

Australian-Singaporean regenerative medicine company **Osteopore Limited** (ASX: OSX; **Osteopore** or **the Company**) – a global leader in 3D-printed biomimetic and bioresorbable implants – is pleased to announce that the Company has secured market approvals for its custom orthopaedic and cranial implants in Europe.

Osteopore has secured European Union Medical Device Regulation (EU MDR) approval for its custom orthopaedic and cranial implants to complement its previously approved off-the-shelf neurosurgical and craniofacial implants.

¹ <https://www.statista.com/outlook/hmo/medical-technology/medical-devices/orthopedic-devices/europe>

² <https://www.qyresearch.com/industry-news/5724/custom-made-cranial-implants>



Osteopore's exclusive distribution agreement with Zimmer Biomet³ – coupled with EU MDR regulatory clearance – positions the Company to supply high-value customised orthopaedic and cranial implants to the European market.

Additionally, Osteopore can provide off-the-shelf neurosurgical and craniofacial implants to the European market, unlocking new revenue streams for the Company.

By 2029, the European custom orthopaedic implant market is expected to grow at a CAGR of 3.3% with the market size expected to reach US\$15.96 billion⁴, which is primarily driven by an aging population and rising demand for advanced orthopaedic devices that enhance mobility and decrease recovery times.

The US\$368.7 million European custom cranial implant market is projected to grow at a CAGR of 9.4% by 2030⁵, which is mostly driven by the increased prevalence of cranial surgeries due to road accidents, sports injuries, and conditions such as brain tumours.

Commenting on the significance of EU MDR approvals in the context of Osteopore's European expansion, CEO Dr Yujing Lim, said:

"Securing European approvals for our custom orthopaedic and cranial implants is in step with our strategy to improve access to our high-value solutions.

"Custom cranial implant approval creates an opportunity to deepen our relationship with Zimmer Biomet, who now has access to our off-the-shelf and custom implant offering.

"Our custom orthopaedic implants have already demonstrated transformational effects on patients in earlier publications.

"With EU MDR approval, Osteopore can now boost the reach of our orthopaedic and cranial implants in Europe," said Dr Lim.

³ ASX announcement "Osteopore strikes Exclusive Distribution with Zimmer Biomet", 16 July 2024.

⁴ <https://www.statista.com/outlook/hmo/medical-technology/medical-devices/orthopedic-devices/europe>

⁵ <https://www.qyresearch.com/industry-news/5724/custom-made-cranial-implants>



ENDS

This announcement has been authorised for release to the ASX by the Board of Osteopore Limited.

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About Osteopore Limited

Osteopore Ltd. is a global medical technology company founded in Singapore and listed in Australia that commercialises products designed to enable natural bone healing across multiple therapeutic areas. Osteopore's patented technology fabricates specific micro-structured scaffolds for bone regeneration through 3D printing and bioresorbable material.

Osteopore's patent-protected scaffolds are manufactured using a proprietary manufacturing technique with a polymer that naturally dissolves over time to only allow natural and healthy bone tissue, significantly reducing the post-surgery complications commonly associated with permanent bone implants. Our 3D printing technology is unique to Osteopore.

Forward-Looking Statements

Some of the statements appearing in this announcement may be similar to forward-looking statements. You should be aware that such statements are only predictions and are subject to inherent risks and uncertainties. Those risks and uncertainties include factors and risks specific to the industries in which the Company operates and proposes to operate as well as general economic conditions, prevailing exchange rates and interest rates and conditions in the financial markets, among other things.

Actual events or results may differ materially from the events or results expressed or implied in any forward-looking statement. No forward-looking statement is a guarantee or representation as to future performance or any other future matters, which will be influenced by several factors and subject to various uncertainties and contingencies, many of which will be outside the Company's control. The Company does not undertake any obligation to update publicly or release any revisions to these forward-looking statements to reflect events or circumstances after today's date or to reflect the occurrence of unanticipated events.

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