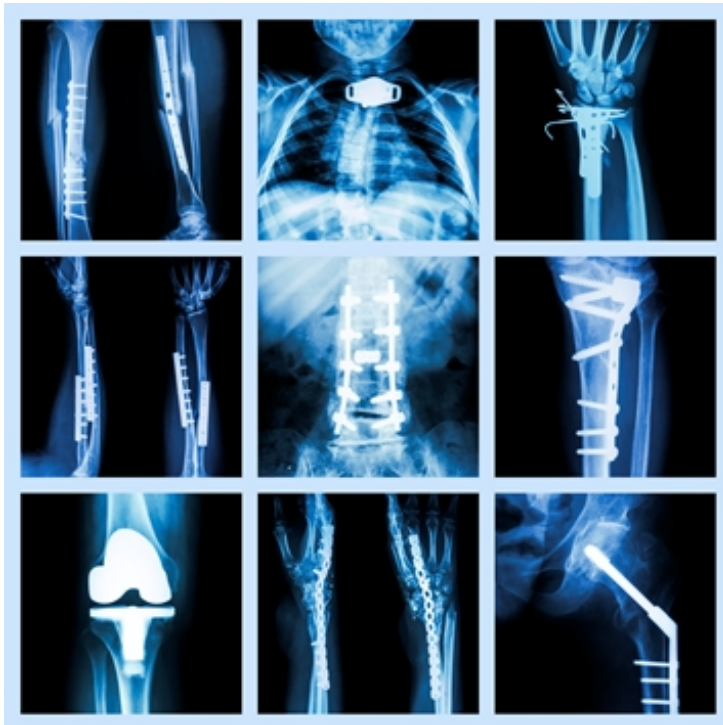


Trauma fixation market set for marginal growth

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The global trauma fixation market, which includes internal and external fixation devices to treat and manage bone fractures and covers 39 markets, is set to experience a minor increase from approximately \$6.4 billion in 2015 to \$7.4 billion by 2022, at a Compound Annual Growth Rate (CAGR) of 2.2%, according to research and consulting firm GlobalData.

The company's latest report states that global reimbursement and regulatory limitations, as well as the preference for locally manufactured implants in emerging markets, are demanding obstacles which are curbing potential growth.

Ms Jennifer Ryan, GlobalData's Analyst covering Medical Devices, explains: "Medical device regulation has slowly developed into a more rigorous and taxing process, especially for companies attempting the premarket approval path, which requires heavy development and financial commitment to prove the efficacy and safety of a new product."

Proving the efficacy of orthopedic devices has also been a challenge facing companies trying to bring new products to market.

The US 510(k) regulatory process requires that manufacturers demonstrate a device is substantially equivalent to a predicate device before approval is given by the Food and Drug Administration (FDA).

For orthopedic devices, this is a lengthy process, as it can take years before device success or failure is evident.

The trauma fixation segment, where much of the innovation revolves around materials research and biodegradation, faces particular difficulty.

Ms Ryan continues: "Developed nations have seen decreasing orthopedic reimbursement rates in recent years, driven by a desire to maintain low healthcare costs in the face of the rising number of fraction fixation procedures. In turn, this has forced manufacturers to lower implant prices in order to stay competitive.

"Emerging markets are also suffering from the effects of poor reimbursement as inadequate insurance coverage and the high costs of surgery are keeping patients from using fixation devices. Improved reimbursement and healthcare access in these countries will permit market growth as patients are able to adopt more robust treatment methods."

Although these barriers serve to slow market growth, the global demand for trauma fixation devices remains due to the growing elderly population, the rising number of motor vehicle accidents as emerging markets urbanize, and increasing prevalence of fracture risk factors such as obesity and osteoporosis.