

## Interview - Zimmer Biomet sees a tricky European future



[Elizabeth Cairns](#)

Zimmer Biomet has had a hard time of it recently. Product supply disruptions dating from mid-2016 were exacerbated when a major US plant failed an FDA inspection at the end of that year, and its long-term chief executive departed last summer. In Europe, at least, the story is more positive, though here too the world's second largest orthopaedics company faces several problems.

"In the European market the arthroplasty sector is saturated, and public coverage is very good," says Dr Katarzyna Mazur-Hofsäss, president for the EMEA region at Zimmer Biomet. "Single payer healthcare systems can exert strong control over pricing." This pressure, combined with ongoing changes to European device regulations, mean that the company will have to do all it can to compete in a highly consolidated space.

### Competition

The top four orthopaedics companies occupy 70% of the market, and within that Zimmer Biomet leads in the hip and knee replacement segments. If these are combined the top four companies – a different four, with Smith & Nephew replacing Medtronic – account for 96% of all arthroplasty devices sold.

The orthopaedics market at a glance			
	Global sales (\$bn)		
Company	2017	2022e	CAGR
Johnson & Johnson	8.8	10.2	+3%
Zimmer Biomet	7.4	8.5	+3%
Stryker	6.0	7.7	+5%
Medtronic	3.0	3.3	+2%
<i>Others</i>	<i>10.7</i>	<i>13.7</i>	
<i>Total market</i>	<i>35.9</i>	<i>43.3</i>	

Source: EvaluateMedTech.

With such close competition, and the arthroplasty segment being less amenable to quantum leaps in product design than many others, Zimmer Biomet must do everything it can to give itself an edge.

"The major innovation is not around what but how," says Ms Mazur-Hofsäss. "Surgical techniques, pre-op planning, supporting surgeons through modern technology [like] artificial intelligence, robotics, augmented reality" are all ways in which Zimmer Biomet aims to keep its offering appealing to its customers. "All [these] elements have to be present: advanced products, proficient surgeons, and a very well managed care process."

The company's long-running Rapid Recovery programme is an attempt to improve the care process – and save money for the healthcare system. Instituted by Biomet in 1997, this is now in place in nearly 300 hospitals in Europe, Ms Mazur-Hofsäss says, and is designed to allow patients better care and faster passage through the hospital.

Patients meet the team, including the surgeon and the physiotherapist, before the operation, and small groups of patients are scheduled for surgery on the same day so they can support each other. The patient is then followed after discharge to monitor recovery.

### Innovation

Zimmer Biomet is in some ways more cautious than its peers. The other big ortho companies are throwing money at robotic surgery technologies specifically for orthopaedic procedures.

These moves have mostly been done through acquisitions: Stryker bought Mako Surgical way back in 2013 and things have spiralled from there, albeit with much smaller deals. Just last week J&J bought a French group, Orthotaxy, working on a system for total and partial knee replacement.

Selected deals for orthopaedic robotic surgery companies					
Date	Acquirer	Target	Tech	Deal type	Value (\$m)
Feb 2018	Johnson & Johnson	Orthotaxy	Unnamed system: knee	Acquisition	Undisclosed
Jul 2016	Zimmer Biomet	Medtech	Rosa: brain and spine	Equity stake	77.5
May 2016	Medtronic	Mazor Robotics	Renaissance: spine	Equity stake and distribution	52.0
Dec 2015	Johnson & Johnson	Verily Life Sciences	Undisclosed	Joint venture: Verb Surgical	Undisclosed
Oct 2015	Smith & Nephew	Blue Belt Technologies	Navio: knee	Acquisition	275.0
Jul 2013	Stryker	Mako Surgical	RIO: hip and knee	Acquisition	1,650

*Source: EvaluateMedTech.*

Zimmer Biomet's one foray into this area has been to take a stake in the French group Medtech, but that company's Rosa system is not intended for arthroplasty. Is it going to start to develop robotic technology for arthroplasty?

"The short answer is yes. The longer answer is that robotic surgery is in the very early stages in orthopaedics," says Ms Mazur-Hofsäss. She points out that for robotic technology to be truly disruptive it would have to replace surgeons for at least some parts of the procedures, and allow operations to be done more quickly or permit swifter recovery, thereby lowering costs.

"None of this can be done by the systems already available," she says. "That doesn't mean it's not important to innovate towards making them applicable - we're innovating like crazy."

## Regulation

There are fears, however, that coming changes to the way devices are regulated in Europe could make it harder to bring new innovations to market. The Medical Device Regulation came into force last May, but its phased implementation means that devices CE marked under the previous legislation, the Medical Devices Directive of 1993, may still be sold until May 2025. So how will this ongoing change affect Zimmer Biomet?

"I fear rather profoundly," says Ms Mazur-Hofsäss. "I don't see how these new regulations are going to improve patient safety ... Regulators must take responsibility for the practicability of their solutions."

Ms Mazur-Hofsäss is concerned that the new rules will increase the time it takes to launch a new device. Here she echoes the concerns of the lobby group Medtech Europe, of which she is a board member. She is concerned that Notified Bodies, the groups that issue CE mark approvals for medical devices, do not have the capacity to evaluate new devices within a reasonable time frame.

The UK's decision to leave the EU is another looming threat, and the lack of clarity on what might happen here is a major problem in itself.

"On Brexit this is my whole statement: I. Don't. Know." says Ms Mazur-Hofsäss, enunciating each word. The company has a manufacturing suite in Wales that employs upwards of 800 people, and it has two major European distribution centres, one in Germany and one in the Netherlands; its products cross national borders several times in different stages of their production.

"If there is a hard Brexit with no deal it will seriously affect the way we do business," Ms Mazur-Hofsäss says. Zimmer Biomet's UK plant supplies Irish as well as UK hospitals, so a hard border there would also hurt.

With the supply constraints in the US still unresolved, disruptions to the flow of products onto and within the

European market would be little short of catastrophic. Change is in the air in Europe and political factors are out of the company's control - Zimmer Biomet will have to be steered carefully in the coming years.

To contact the writer of this story email Elizabeth Cairns in London at [elizabethc@epvantage.com](mailto:elizabethc@epvantage.com) or follow [@LizVantage](https://twitter.com/LizVantage) on Twitter

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[+81-\(0\)80-1164-4754](tel:+81-080-1164-4754)

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