CASE STUDY

Vertical Integration Speeds Scale-up for US Launch of Orthopedic Implant

CUSTOMER SITUATION

A midsize European orthopedic company was seeking support for the US expansion of its artificial cervical disc, which had been on the market in Europe for about 6 years.

The customer was looking for a single-source supplier that could handle every step of the operation, from procuring raw materials to delivering a sterile product ready for use. It also needed a partner willing to invest in the development of facilities that could scale to accommodate rapid growth. In addition, the customer was looking for a supplier that was well-versed in US Food and Drug Administration (FDA) regulations.

The customer felt that Viant, an end-to-end partner with strong orthopedic expertise, met these requirements.

VIANT SOLUTION

The Viant team invested time to thoroughly understand the customer's market segment, challenges, and strategy for penetrating the US market. Team members also collaborated closely with the customer on DFM to ensure that the product met quality and technical requirements.

Viant provided end-to-end solutions for this orthopedic implant, including:

- Fabrication and subassembly of metal components such as cobalt-chrome plates
- Fabrication and subassembly of polymer components, including UHMWPE and PEEK
- Finishing
- Assembly and sterile packaging

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Viant made major investments to support the growth of this product, including hiring new associates and purchasing machining, polishing, cleaning, and packaging equipment. Viant also created a new manufacturing cell dedicated to cleaning and polishing operations, which increased capacity by 30%. The production cell:

- Facilitated communication between operators, improving quality
- Simplified the polishing operation
- Reduced WIP by a factor of 5
- Reduced lead time for the end customer

Viant team members were committed to supporting the customer through each step of the PMA submission to the FDA. Viant successfully passed FDA PMA inspection and subsequent FDA inspection without violations or observations.

RESULTS

The customer successfully launched the implant in the US, delivering 3500 units in the first year with good clinical results. Viant supported the customer and product from launch to scale with no quality or service issues. The product experienced extremely high growth, and Viant was able to successfully support volumes that were 60% above the minimum long-term agreement (LTA) volume.

This product is a market leader in the high-growth artificial cervical disc space, part of the growing motion preservation segment within the spine market.

3500
UNITS DELIVERED
TO THE US
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60%
CAGR
SUPPORTED

NO
QUALITY OR SERVICE
ISSUES

VIANT™
WE'RE IN IT FOR LIFE.