



Materialise Receives FDA 510k Clearance for their Acetabular Cup Orientation System

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Materialise NV (Nasdaq: MTLN), a leading provider of 3D software and sophisticated 3D printing solutions, and pioneer in medical image based guide technology, today announced that the Food and Drug Administration has cleared their hip guide system for THA surgery. The Materialise ACO guides can be used with a wide range of hemispherical cup implants on the market.

One of the most important factors for achieving a good functional outcome for THA patients is to obtain the intended cup orientation. Studies indicate that obtaining that cup orientation is also one of the most challenging aspects of THA surgery: 20 to 53% of conventional freehand THA surgeries result in a cup orientation that deviates more than 10° from the intended cup orientation.

Materialise now launches patient-specific guides that place a visual alignment pin with an orientation corresponding to the intended orientation of the cup implant. Without interfering with the normal surgical procedure of THA and adding limited additional surgery time, this pin offers a reliable visual reference to align the impactor to, independent of whether the patient is oriented accurately on the operating table. This helps surgeons achieve accurate cup orientation.

"When an orthopedic implant is placed correctly, accelerated wear and an early failure of the implant are prevented and the overall clinical outcome is significantly better," said Hilde Ingelaere, Executive Vice President - Medical, at Materialise. "This is why Materialise has invested in the development of guide systems for knee, shoulder and hip surgeries. Over the years, we've been working with a variety of orthopedic implant manufacturers in order to help surgeons achieve better clinical outcomes for their patients. With the 510k clearance of the hip guide system, even more patients will benefit from our patient-specific technology."

The hip guide system includes fast and easy to use planning software and 3D printed patient-specific surgical guides to help the surgeon to achieve accurate cup orientation. By doing so, the hip guide system helps reducing dislocation rate and impingement, and preventing accelerated wear and early failure of the implant.

"The technology does not only help to achieve reliable clinical outcome," continues Dieter Vandoren, Product Manager at Materialise, "the pre-surgical implant sizing offers important logistical advantages to hospitals and implant companies. Because of the predictability of the implant sizes needed during surgery, the amount of implant sizes that need to be available can be reduced. This is an important cost saving aspect."

For more information about Materialise's full range of solutions for orthopedics, visit <http://ortho.materialise.com/> or contact our team at ortho@materialise.com.

ACO guides are patent pending.

About Materialise

With its headquarters in Leuven, Belgium, and branches worldwide, Materialise is a provider of Additive Manufacturing (AM) software solutions and sophisticated 3D printing services in a wide variety of industries, including healthcare, automotive, aerospace, art and design and consumer products. Materialise has been playing an active role in the field of AM since 1990, through its involvement in AM for industrial and medical applications, by providing biomedical and clinical solutions such as medical image processing and surgical simulations and by developing unique solutions for its customers' prototyping, production, and medical needs. For additional information, please visit: www.materialise.com.