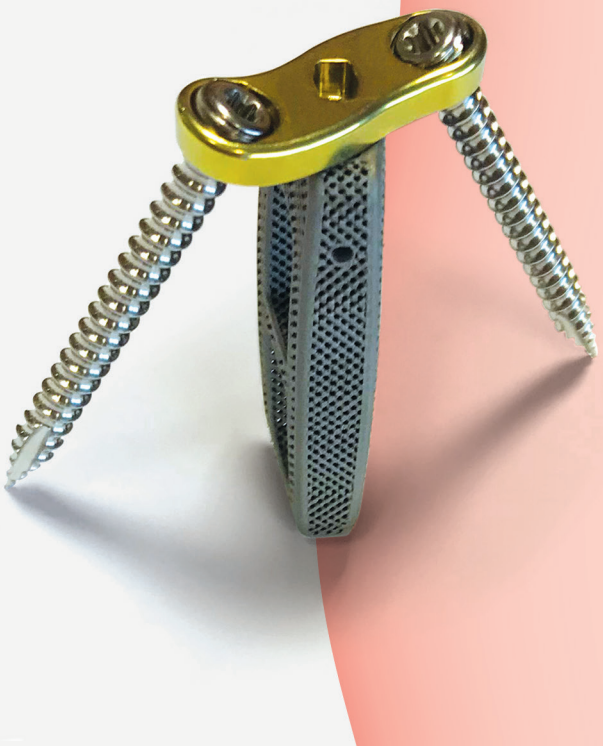
Clariance

PRESS RELEASE :

# 510(k) clearance of the lateral Interbody Idys®-LLIF 3DTi



*Clariance, a French company specialized in spine surgery, announces the 510(k) clearance of the lateral interbody Idys-LLIF 3DTi.*

**Chicago & Beaurains, May 17th, 2021 -** Clariance, specialists in spinal implants, announces that they have obtained 510K clearance from the U.S. FDA (Food and Drug Administration), which was received in April for their Idys®-LLIF 3DTi device. The first U.S. surgery using this implant was performed at the end of April in Dallas, TX by Dr. Tolhurst.

This is their 15th 510K clearance received, completing Clariance's anterior and lateral range alongside the Idys®-ALIF, Idys®-ALIF TiVac, Idys®-ALIF 3DTi and Idys®-ALIF ZP 3DTi. In addition, Clariance is also introducing their own lateral retractor and patented ClarView technology.

The Idys-LLIF 3DTi combines simplicity, fluidity, and efficiency. This system is composed of a lateral cage, plate, and two screws. The plate has been designed in the same spirit as the Idys®-ALIF, allowing the surgeon to insert the screws with the ideal angulation for each individual case and to treat several levels without creating conflict between the screws.

The plate connection and screw-locking system require no additonal instrumentation, allowing for a continual workflow.

The Idys-LLIF 3DTi has been developed for both transpsoas and anterior-to-psoas (ATP) lateral approaches.

Clariance's retractor also reflects the company's goal to simplify this surgical procedure and facilitate the surgeon's approach.

For more information about Idys®-LLIF 3DTi, visit www.clariance-spine.com

**Thierry Manceau, CEO of Clariance,** added, "By completing our range, the Idys®-LLIF 3DTi and its retractor definitively establish our strategy for the anterior and lateral approach. These solutions allow us to meet every surgeon's need. They have been designed to facilitate the surgical procedure and make the anteriolateral approach accessible to an ever-growing number of practitioners. We define ourselves as spinal architects. This product reflects our involvement and commitment, and is another step on the road to fulfilling our ambitions."

The Idys®-LLIF 3DTi is Clariance third device to be entirely produced using 3D printing, along with the Idys®-ALIF ZP 3DTi and the Idys®-TLIF 3DTi. True to their commitment to practitioners, this implant and its retractor were designed in collaboration with an international group of French and American surgeons.

"Practitioners are our primary source of inspiration," adds Thierry Manceau. "Despite current circumstances, we feel it was essential to continue our collaboration in order to produce a complete solution that provides surgeons with everything they need to adapt the lateral approach to the individual patient being treated."

## About clariance

Clariance is a French company specialized in the design, production, and distribution of spinal implants. Since 2007, the company has obtained more than 28 international approvals (FDA 510K, CE certifications) for their implants, which have been used in over 125,000 surgeries worldwide to date. As true architects of the spine, the Clariance Group aims to develop groundbreaking solutions to improve clinical outcomes. To do so, each product is developed in close collaboration with international teams of surgeons. Additionally, the company maintains full control over the manufacturing process and is supported by an Executive Committee with over 35 years of experience in the medical device market.

For more information about Idys®-LLIF 3DTi, visit **www.clariance-spine.com**

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