

Hydrix client & investee company Gyder Surgical receives TGA approval

Hydrix Limited (ASX: HYD) (Hydrix or the Company) is pleased to announce that its long-term client and venture investee company, Gyder Surgical (Gyder), received regulatory approval from the Therapeutic Goods Administration (TGA) of Australia to market and sell its GYDER® Hip Navigation System.

Highlights

- GYDER® Hip Navigation System approved by the TGA to be included on the Australian Register of Therapeutic Goods (ARTG)
- Gyder Surgical to commence commercial sales in Australia
- ARTG listing triggers Hydrix Ventures equity-in-kind milestone payment, increases investment by \$0.33m to \$1.76m

Sujit Dike Chief Executive Officer of Gyder Surgical commented:

“The GYDER® Hip Navigation System (HNS), is a non-invasive (pin-less) and image-less smart navigation system for total hip replacement using the anterior approach.

“We are excited to receive the regulatory approval from Australia’s TGA. It is a major milestone and an important step forward in our journey to make available our patented technology to orthopaedic surgeons in Australia to improve patient outcomes.

“We believe that there is a strong appetite for intuitive, efficient, easy-to-use, and cost-effective enabling technologies that improve surgical accuracy during hip arthroplasty.”

Gavin Coote, Executive Chairman of Hydrix Limited commented:

“It is very rewarding to have developed this world first product and technology innovation for Gyder Surgical, and to have successfully managed the TGA regulatory application process.

“We look forward to supporting Sujit and the Gyder Board with future product developments and as investors through our Hydrix Venture investment.”

-ENDS-

Authorisation: This announcement has been authorised for release by the Board of Hydrix.

Contact Details: For more information, please contact:

Company Enquiries:

Gavin Coote
Executive Chairman
info@hydrix.com

+61 3 9550 8100

Legal Enquiries:

Alyn Tai
Partner, Holding Redlich
Alyn.Tai@holdingredlich.com

+61 3 9321 9834

Media Enquires:

Rod North
MD, Bourse Communications
rod@boursecommunications.com.au

+61 3 9510 8309

About Hydrix Limited

Hydrix Limited (ASX: HYD) is a powerful product innovation company. Hydrix's purpose is to enhance the health, safety, and well-being of a billion lives. The company leverages its powerful product innovation capability across three business segments: Services: design, engineer and deliver world first products and innovation; Ventures: invest in high potential MedTech clients; and Medical: distribute disruptive cardiovascular products.

About Gyder Surgical

Gyder is an Australian medtech company specialising in non-invasive orthopaedic navigation solutions. The GYDER® Hip Navigation System is a computer controlled, non-invasive surgical tool to aid navigation during total hip arthroplasty via the anterior approach. It is designed to provide real-time guidance and assist the surgeon in positioning the acetabular cup in the intended orientation during primary or revision total hip arthroplasty. Incorrect positioning of the acetabular cup during total hip replacement can lead to potential dislocations, cup loosening ultimately leading to failures, impingement, excessive liner wear & osteolysis, limited range of motion, abnormal gait, and limb length. Improved cup placement accuracy has significant potential to reduce post-surgery complications, thereby improving patient outcomes and lowering health system cost burden. The system is an open system that provides surgeons flexibility to use their preferred implant system.