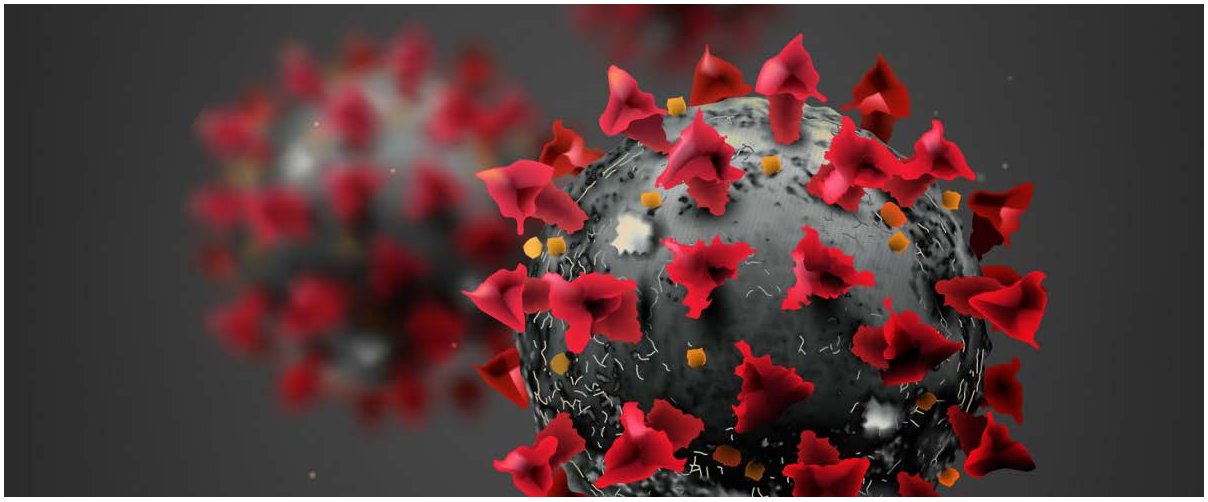
TEXERE BIOTECH
The best human tissues, for all.

PRESS RELEASE



TEXERE Biotech bone allograft products are the world first to be certified "COVID-free".

Charleroi (BE), 10 September 2020, 17:00 PM CET

Bonefide® manufacturing process for secured bone allograft has demonstrated to be COVID-19 free.

Substance of Human Origin (SoHO) such as Blood, Organs, Tissues or Cells are since many years of clinical use. There is always a concern about the risk of infection transmission and consequences to the recipients. Therefore Tissue Establishments, such as TEXERE Biotech, are striving to make them as safe as possible.

After the outbreak of a new strain of Corona virus (SARS-Cov-2 virus) provoking the COVID 19 infection was confirmed, on 11th March 2020 the WHO declared a COVID-19 pandemic with global spread. The rapid spread of the virus was overwhelming the healthcare system in Europe and posing new challenges to tissue establishments (TE) such as: safety of recipients, safety of staff in TE, precautionary measures for tissue processing, etc.

The nature of the transmission of COVID-19, the widespread spread and the experiences of epidemics previous reports of other respiratory viruses, including SARS-CoV and MERS-CoV, indicate that the COVID-19 pandemic may pose a significant risk to maintaining a sufficient level and sustainable supply of human body material. COVID-19 can affect both the population of donors and recipients, tissue bank staff and human body material demand or supply.

A recently published scientific article[1] stated: *"Although we have not fully grasped the whole features of COVID-19 and its likely host immunological reactions, pathophysiological proof of this pathogen has attracted our attention to bone metabolism. Without doubt, the deterioration of underlying diseases caused by SARS-CoV-2 infection tends to aggravate bone-forming capacity. The deficiency of ACE2, which caused by the invasion of virus, may lead to a decreased bone matrix and early muscle disorder."*

Based on current knowledge, the risk of transmission of COVID-19 via SoHO appears to be theoretical. However, the uncertainties surrounding viremia during the incubation period, at during an asymptomatic infection or after resolution of symptoms continues to be of concern regarding the viral safety of the human body material. Therefore, precautionary measures are suggested to mitigate the theoretical risk.

This was raising the question: How safe are tissue preparations in the context of SARS-Cov-2?

TEXERE Biotech decided to have an independent validation of its validated pathogen reduction Bonefide® process for enveloped viruses such as SARS-Cov-2 by a world class expert. Samples of TMBG™ grafts (*Texere Machined Bone Graft*) were sent for evaluation to TEXCell, a contract research organization that specializes in virus testings, viral clearance and safety. Virus inactivation or removal of enveloped viruses of at least 4.0 $\log_{10}$ by two steps is considered as sufficient. The final verdict confirms that the Bonefide® physical processing, chemical treatments and terminal sterilisation (by irradiation) removes/inactivates at least 11.0 $\log_{10}$ the virus. Therefore using TMBG™ graft eliminates all risks of COVID-19 transmission for both the surgeons and the patient recipient of the bone graft.

Further, due to its fully robotized process where no human intervention is taking place, Bonefide® is also eliminating all risks of cross-contamination and guaranteeing a total safety of the staff in the TEXERE Biotech processing line (since they are never in contact with the bone tissue during the processing steps).

Dr. Denis Dufrane, co-founder, commented: *"The COVID-19 pandemic has put a lot of pressure on the healthcare system and raised new challenges to tissue establishments at a time where one observed a fall of 45% in number of tissue donations. We are proud, with our Bonefide® process, that each donation will be turned in a maximum of totally safe bone grafts, and to be able to guarantee the continuity of tissue preparations while* ***eliminating all risk of virus transmission for our staff, the surgeons and their patients."***

TEXERE Biotech wishes to express its special thanks to SFPI-FPIM (the Belgian Federal Holding and Investment Company) and RW-DGO6 (the Walloon region General Directorate for Research and Technological Development) for their strong support and contribution which have made these developments possible.

[1] WHO link /Published in Med Hypotheses; 2020 Nov; 144: 110178.

About TEXERE Biotech

TEXERE Biotech (www.texerebiotech.com), incorporated in 2016, has been co-founded by three partners who have joined their various medical, industrial and robotics expertise with the vision of using advanced automated technologies (known as "smart factory-industry 4.0") to contribute to solve today's and future healthcare challenges: providing better access, improve outcomes, and lower overall costs of patient care to restore health and extend life for people around the world.

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