



SUBJECT: Safety of MTF Tissue – novel coronavirus (SARS-CoV-2)

May 1, 2020

To Whom It May Concern:

The purpose of this letter is to address questions related to the potential risk of transmission of novel coronavirus through transplanted tissues. Novel coronavirus, or SARS-CoV-2, is causing illness called COVID-19 worldwide. As a leader in the tissue banking industry, MTF Biologics is at the forefront of discussions with the FDA, CDC, and the American Association of Tissue Banks (AATB) regarding the most recent and up-to-date recommendations for screening of tissue donors for novel coronavirus.

MTF Biologics is a not-for-profit organization founded in 1987 by academic transplant surgeons dedicated to providing tissue of the highest quality and safety for transplantation. MTF Biologics has recovered over 140,000 donors and distributed over 9 million tissues to recipients over our more than 30-year history. MTF's excellent safety record is directly attributable to our commitment to the donor family and to the tissue recipients we serve. This tremendous commitment provides our customers with the assurance that this wonderful gift of human tissue is safe and of the highest quality.

Listed below are answers to several questions customers may have regarding the safety of MTF Biologics allograft tissue with respect to novel coronavirus.

**1. Has novel coronavirus been transmitted through tissue transplantation?**

No, there are no known cases of novel coronavirus transmission through transplanted tissue. However, because genetic material of the novel coronavirus can be detected in blood, body fluids, and solid organs, MTF has taken extra steps to ensure additional safety measures have been implemented through rigorous donor screening.

**2. What steps has MTF Biologics taken to ensure the elimination of novel coronavirus in donor tissue?**

MTF Biologics does not accept any donors with a medical history or diagnosis of novel coronavirus infection in the last 28 days per AATB recommendations. MTF does not accept donors with an unexplained clinical syndrome that might be consistent with infection (e.g., pneumonia of unknown cause) or donors with associated risk factors for the infection. MTF also has voluntarily added laboratory testing using PCR through collection of nasal or oral swabs in deceased donors.

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MTF Biologics also utilizes highly effective processes with disinfection steps designed to eliminate key virus types to non-detectable levels.

**3. Are tissue donors routinely tested for novel coronavirus?**

Yes. Although there are currently no screening tests cleared by FDA for the detection of novel coronavirus in living or deceased donors, there are diagnostic tests currently under FDA Emergency Use Authorization (EUA) on PCR platforms. Each deceased donor is being tested, in addition to review of other risk factors (e.g., medical history, exposure), to determine eligibility. All donors with positive results are rejected.

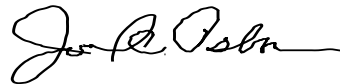
MTF is in discussion with key officials from AATB, FDA, CDC, NIH, diagnostic testing developers, and testing laboratories regarding the development of tests that could be used to screen tissue donors for novel coronavirus if deemed necessary.

Tissue recipient safety is, and has always been, the key to maintaining our customer's trust and is paramount to achieving MTF's mission. As a physician-led, science-forward organization, MTF Biologics will continue be at the forefront of any new developments with novel coronavirus screening.

Sincerely,



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Chief Medical Officer



Joel C. Osborne  
Vice President, Regulatory

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