



Build Your Success with our Foundation

Additional Information Regarding COVID-19, Tissue Products (HCT/P) and RMTB's commitment to ensuring safety.

General Tissue Safety Protocols:

The AATB has provided on their website (www.aatb.org, under bulletin 21-1) the following information on COVID-19 highlights from FDA Communication on January 4, 2021 (www.fda.gov, Updated Information for Human Cell, Tissue, or Cellular or Tissue-based Product (HCT/P) Establishments Regarding the COVID-19 Pandemic):

- FDA continues to work closely with CDC and other federal and international agencies to monitor the coronavirus disease 2019 (COVID-19) pandemic caused by the virus, SARS-CoV-2.
- Respiratory viruses, in general, are not known to be transmitted by implantation, transplantation, infusion, or transfer of human cells, tissues, or cellular or tissue-based products (HCT/Ps).
- To date, there have been no reported cases of transmission of COVID-19 via these products.
- Routine screening measures are already in place for evaluating clinical evidence of infection in HCT/P donors.
- FDA does not recommend using laboratory tests to screen asymptomatic HCT/P donors.
- FDA is aware that some HCT/P establishments in the U.S. are considering additional donor screening and testing measures in response to the COVID-19 pandemic.
- The HCT/P establishment's responsible person must determine and document the eligibility of a cell or tissue donor (21 CFR 1271.50). Based on information available at this time, establishments may wish to consider, whether, in the 28 days prior to HCT/P recovery, the donor
 - cared for, lived with, or otherwise had close contact with individuals diagnosed with or suspected of having COVID-19 infection; or
 - had been diagnosed with or suspected of having COVID-19 infection; or
 - had a positive diagnostic test (e.g., nasopharyngeal swab) for SARS-CoV-2 but never developed symptoms.
- COVID-19 vaccines are complex biological products intended to be administered to millions of individuals to prevent COVID-19. Recently, vaccines for the prevention of COVID-19 have become available under emergency use authorization (EUA) issued by the FDA.
- Based on information available at this time, those who have received non-replicating, inactivated, or RNA-based COVID-19 vaccines are not precluded from donating HCT/Ps.

RMTB's commitment:

- All donors are screened at the time of donation for their potential of exposure to the COVID-19 virus. During RMTB's evaluation of donor eligibility, medical and social questions provided by the family are reviewed along with all available medical records.
- All donors that have been tested for COVID-19 have had negative or non-reactive testing either thru nasal swabs or blood testing.
- RMTB requires all donors to be tested for COVID-19, all tissue is processed aseptically in a manner to ensure the safety of the tissue and is terminally sterilized via gamma irradiation with a SAL 10^{-6} , which is known to inactivate all viruses.

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Build Your Success with our Foundation

Additional Information Regarding Tuberculosis (TB) or Mycobacterium Tuberculosis Transmission (MTB) and RMTB's commitment to ensuring safety.

General Tissue Safety Protocols:

The AATB has provided on their website (www.aatb.org, under bulletin 23-6) information on requirements and Recommendations for Reducing Risk of Mycobacterium Tuberculosis transmission.

Information regarding adverse events including death have recently been reported extensively within the news and other government agencies (i.e., CDC) regarding TB due to MTB transmission. These events are **directly related to products containing viable cells** utilized within the orthopedic and dental industry. The current events are associated with one singular manufacturer and all potential facilities or individuals who may have received these tissues have been notified.

RMTB's bone allograft's **DO NOT** contain viable cells.

RMTB's commitment:

- All donors are screened at the time of donation of ever having tuberculosis or if they have had a recent positive test for tuberculosis. Additional screening questions have been added to allow for a more robust screening of tuberculosis.
- All tissue is processed aseptically in a manner to ensure the safety of the tissue and is terminally sterilized via gamma irradiation with a SAL 10^{-6} , which is known to inactivate all viruses and viable cells.

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