Field Safety Notice

(1) No-React® BioConduit (NRAC),
(2) No-React® BioPulmonic Conduit (NRPC),
(3) No-React® Injectable BioPulmonic (NRIP),
(4) No-React® BioMitral (NRM),
(5) No-React® BioAortic (NRA)
FSCA-002-22

Date: 2022-07-14

Attention: Distributors of BioIntegral Surgical Heart Valves outside of the EEA/UK **only**

Devices: bioprosthetic heart valves (1) No-React® BioConduit (NRAC), (2) No-React® BioPulmonic Conduit (NRPC), (3) No-React® Injectable BioPulmonic (NRIP), (4) No-React® BioMitral (NRM), (5) No-React® BioAortic (NRA)

Update: *All holds or restrictions related to mycobacterial investigation have been LIFTED. There are no restrictions on any products.*

While concerns were raised by some that viable Mycobacteria chelonae could be present in devices, the multi-laboratory EU/Canadian investigation to date has not shown any positive growth in culture on dozens of sterilized devices tested, of any type of organism. Canadian labs have yet not been able to duplicate positive staining and PCR test results, complicated by the fact that no growth was observed (i.e., inadequate DNA to test). As of the date of this bulletin, our experts investigate the proper positive controls to be used (e.g., inadequate recovery, known glutaraldehyde interference). BioIntegral continues to work with labs internationally to understand and use the most accurate test methods and the investigation is ongoing.

By relevant investigative routes carried out to date, BioIntegral Surgical devices do not seem to have deviated from Standards of Conformity with regards to biocompatibility, sterility, pyrogenicity or storage. Concerns about DNA in device tissues must be put into the context as all sterile, fixed tissues harvested from live animals are likely to include the presence of a variety of DNA fragments, regardless of source or manufacturer.

Advise on action to be taken by the user: no hold / restrictions on any products outside the EEA/UK.

Transmission of this Field Safety Notice: This notice needs to be passed on all those who need to be aware within your organization (distributors) or to any organization where the potentially affected devices have been transferred outside of the EEA/UK.

Please transfer this notice to other organizations (e.g., distributors' customers) on which this action has an impact outside of the EEA/UK.

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