

**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**
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**Date:** 2022-07-14

**Attention:** Distributors of BioIntegral Surgical Heart Valves

**Devices identified in previous notice:** 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) in April 2022.

**Update:** 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. In addition, the presence of *M. chelonae* originally identified was put in doubt by Canadian PCR labs. Canadian labs have not been able to duplicate positive staining and PCR test results, particularly since no growth was observed (i.e., inadequate DNA to test) and our experts considered it likely that proper positive controls were not used for the original testing (e.g., inadequate recovery, known glutaraldehyde interference). 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.


A summary of the test results and a discussion can be found [here](#).

**Advise on action to be taken by the user:** N/A

**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.

Please transfer this notice to other organizations (e.g., distributors' customers) on which this action has an impact.



S. Gabbay, MD  
Medical Director and CEO