



BD
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bd.com

Dear Valued Customer:

October 2016

Availability of BD ISO connectors for Neuraxial applications (80369-6)

The purpose of this communication is to provide you with an update on BD's activities to launch devices with new ISO 80369-6 compliant neuraxial connectors incorporating the NRFit™ design. BD is an industry innovator, committed to developing and manufacturing medical devices with small bore connectors (i.e. intravenous, enteral & neuraxial) that are safe for patients and meet the needs of practitioners.

As you may know, a new ISO standard governing enteral connectors is being developed in parallel to ISO 80369-6 for neuraxial products. In the enteral space, after a design was settled on by ISO and industry began planning for launch, BD learned of important patient safety concerns about dose accuracy from the clinical community—concerns that required a second look at the planned enteral connector design.

To prevent a similar last minute discovery of a design issue with ISO 80369-6 neuraxial connectors, BD conducted an extensive clinical community evaluation of the planned design. This global initiative included anesthesiologists from 17 countries who stepped through simulated neuraxial procedures using BD ISO 80369-6 compliant prototypes on anesthesia mannequins.

BD is pleased to report that the results of the global study were very positive and we are now moving forward with the manufacturing and other changes needed to launch the new ISO 80369-6 compliant products.

The scope of the ISO changes encompasses 100+ BD products and it is important that the ecosystem is rolled out carefully to ensure no disruption of patient care. BD's launch plan for the full BD ecosystem of compliant neuraxial products is as follows:

- NRFit Spinals starting in Q2 2018
- NRFit Epidurals starting in Q3 2018

This product introduction will provide the capacity necessary to ensure a steady stream of products to all BD customers.

To ensure continuity of care, the ISO standard anticipates a phased transition to the new design over a 5-year period.¹ As a result, BD will continue to offer our existing range of products during this transition.

Please contact your local BD representative should you have any questions regarding this matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'M. Jacobsen', with a stylized flourish at the end.

Martin Jacobsen, M.Sc. (Econ.)
Senior Global Product Manager, WW Anesthesia & -Enteral

¹ Applicable law or regulations in your location may require a more accelerated transition.