NeoChild®

Safe Child System™
US Patent 8,292,875

(888) 887-NICU (6428)
www.neochild.com

FACTS and AWARENESS

What is really going on with ISO 80369-3 and what you need to know...

"I don't want to see infants having the risk of being overdosed because of an 80369-3 syringe. When you hear all I have just said, can you understand why anyone would push such a piece of junk connector on people with a disability? There are no advantages to the 80369-3 connector. Only Disadvantages!! This is pushing us back to the stone age of enteral feeding methods."[1]

—**David Rowland,** Enteral Feeding Patient

"Both of these proposed designs (ISO 80369-3) fail to meet the accepted syringe dose accuracy standards on which clinicians around the world have come to rely."[2]

—**Amardeep Singh Chahal,**
BD Senior Business Director

"In light of identified deficiencies associated with connectors designed to meet ISO 80369-3, 'Canada' cannot recommend the use of these connectors."[3]

—**David Young,** Chair Canadian Mirrorl Committee

"My immune system is compromised and I worry about bacterial infection from a contaminated ENFit™ male connector (AAMI/CN3(PS):2014, E.5(b)) ."[1]

—**Wilson Bacon,** Feeding Tube User

"ISO 80369-3 also establishes a hard to clean narrow moat area in the male connector which places feeding tube individuals at risk, as bacteria and debris will accumulate in the moat causing infection (AAMI/CN3(PS):2014,E.5(b))."[1]

—**Ronald Coppinger,** Feeding Tube User

"The flow rate of ENFit™ was 2-3x slower using commercial formula. Second, when blended food was used, the ENFit™ connector clogged almost immediately while the feeding tube system I currently use does not clog."[1]

—**David Gould,** Enteral Feeding Tube User of over Three Years

"Multiple requests have been made to the ISO committee and to the FDA for hard data as to any U.S. enteral misconnections since 2011. The committee and the FDA have failed to provide any data. No data of misconnects since 2011, yet the proposed standard (ISO 80369-3) immediately creates the most high risk misconnection possible."[1]

—**Shelley Buma,** President GI Design

"If this proposed standard (ISO 80369-3) passes with the current Annex B, Table B.2 Female E1, California hospitals will be in the unfortunate position of either using 80369-3 compliant connectors and syringes or attempting to remain compliant with section 1289.7(d) of the California Health and Safety Code."[1]

—**Tabitha Hasin,** Ph.D., J.D.

1 AAMI/CN, Small-bore Connectors Committee WebEx Meeting
2 BD Letter to GEDSA
3 Canadian Mirror Committee/CSA Z298 Task Group

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"So I implore you the FDA, GEDSA, AAMI, ISO, and all 39 Nations to vote against the ENFIT 2.9mm ID product (the same inner diameter that consumer didn't want some 20 years ago because of all the problems it had then) to not go back in time. Let's move forward to the best and safest solution for people like myself today."[1]

—**Mary Slachter,** Feeding Tube User

"There is no reason to adopt the system with its known safety hazards when the existing system does not have them. Making me highly suspicious is the strong drive to adopt 80369-3 in spite of it not having a single advantage. None whatsoever. So, it should not be forced on people. In a free market, such products do NOT succeed. Unfortunately, this is not a free market. Ordinarily, medical products launch only after they have extensive confirmed data of safety and efficacy."[1]

—**Richard Reynolds,** Feeding Tube User due to Cancer

"My third comment deals with infection control and relates to 'Page 25 clause E5(b) which says that connectors should have surfaces that are easy to keep clean.' This is potentially the most deadly problem because the moat area of the male connector will be a breeding ground for bacteria. (What is) The solution to this infection control problem? Scrap 80369-3."[1]

—**David Gould,** Enteral Feeding Tube User of over Three Years

"More clogged connectors, means more connectors sold. Smaller ID connectors means more formula sold. It's a regression, not an advancement in quality of care and it (ISO 80369-3) should not be supported."[1]

—**Shelley Buma,** President GI Design

"Since December 2015, I have had 3 new tubes, 3 infections, 2 ER visits, 1 hospital stay, 5 doctor visits, and many more days in bed than I would like to count. I do believe, however, that the very deep and narrow crevice in the male piece connector on my ENFIT™ is a direct cause of these chronic infections I have been having."[1]

—**Mary Slachter,** Feeding Tube User of over Three Years

"It's irresponsible for the committee (AAMI) to now say that such a misconnection is acceptable for 80369-3 products, when in fact the FDA has called out this misconnection as a high risk deadly event. Will the deaths from such misconnections be considered acceptable collateral damage? If nothing else, the product should be labeled with a clear warning that a deadly misconnection is possible. The lives of feeding tube patients are at stake. The adoption of the standard will, by all measures, put the tried and true products on the road to extinction. The motive of the standard is a forced elimination of the connectors that keep us alive. Individuals associated with the standard have been running around saying that our funnels are unsafe. Really? My connector is unsafe? This is an utter falsehood."[1]

—**Ronald Coppinger,** Feeding Tube User

"The industry and you (AAMI) seem to think that since you have already invested so much time and money into developing 80369-3 that you simply have to force it into our lives. 80369-3 only benefits formula and medical device sellers."[1]

—**Sanford Flach,** 100% Dependent on Feeding Tubes

Additional articles and documents on ISO 80369-3 are available at www.neochild.com/iso_80369.html

Samples of NeoChild's Safe Child System™ and other products can be requested at www.shop.neochild.com

1 AAMI/CN, Small-bore Connectors Committee WebEx Meeting

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