



“We are proud of our partnership with Helix to update the ACE Connector system for enteral feeding. They developed a new design that was both compliant with the new ISO 80369-3 standard and offers an excellent solution for our customers. The new design is easy to use and effective for clinician and patient use.”

**Sharon Steeves**

Product Development Manager  
Dale® Medical

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Dale® ACE 485 Connector® with ENFit™ Connection System

Original Dale® ACE 475 Connector®

Dale® ACE 485 Connector®  
with ENFit™ Connection System

 **PROJECT OBJECTIVES:**

- Review the new ISO 80369-3 regulation and the current Dale ACE patent
- Explore design options to meet the new ISO requirements
- Prototype to evaluate and verify
- Develop documentation package for production

 **PRODUCT SOLUTIONS:**

- ISO 80369-3 ENFit compatible reduces misconnections
- Designed to physically prevent administration of enteral formula in any line other than 80369-3 ENFit compliant enteral tubing systems
- Works with all ENFit type small bore feeding tubes, PEG/PEJ tubes, most G/J tubes, and enteral feeding sets

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HELIX DESIGN

BECAUSE INNOVATION MATTERS



PATIENT-ACCESS END



SYRINGE (CURRENT)



SYRINGE (Standard Tip)

Syringes to administer medicine, flush, hydrate, or bolus feed through enteral tubes will now require a precise enteral-specific fitment.

OR



SYRINGE (Low Dose Tip)

To ensure small volume dosing accuracy, syringe sizes of 5mL or smaller may require an ENFit Low Dose Tip.

### ENFit Enteral System Connector Changes

The new design standard impacts the entire enteral feeding system



FEEDING TUBE (CURRENT)



TRANSITION SET (TEMPORARY)

Allows fitment to current feeding port until new ENFit enteral feeding tubes are available



FEEDING TUBE (FINAL)

Changing from male—the stepped or Christmas tree connector—to the new ENFit female connector. The feeding tube port for the administration set will change from female to male.

Text/Graphics courtesy of StayConnected.org



Dale® ACE 485 Connector® with ENFit™ Connection System

Updated system offers enhanced protection for the clinician and patient. The system infuses nutrients, medications, fluids, irrigates, controls flow, and checks gastric residuals.

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## HELIX'S APPROACH:

- Brainstorm with design and engineering teams
- Prepare preliminary engineering CAD concepts
- Generate mock-ups and test models
- Prototype concepts and identify areas of opportunity for refinement
- Produce production CAD assembly, BOM, and 3D database