

In vitro evaluation of a new safety connection for the administration of enteral nutrition: ENLock



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Background

New "EN-Lock" standard connectors (between administration tube and enteral feeding catheter-EFC-) and "EN +" (between nutrition bag and administration tube) are designed to secure enteral nutrition (EN) administration and avoid mysconnections. These connectors will coexist for a while with devices not equipped with them. Compatibility data would be necessary for their safe use.



Purpose

The purpose is to *in vitro* evaluate the compatibility between devices having or not these connectors.



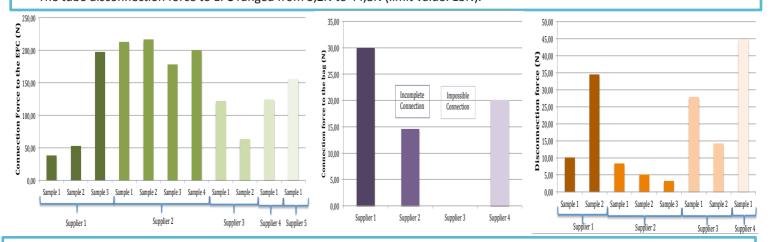
Materials and Methods

The evaluation focused on 12 EFC references from 5 suppliers (Teleflex, Vygon, Kimberly Clark, Ansell, Nutricia), 4 nutrition bags from 4 suppliers (Nutricia, Nestlé, Fresenius, Realdiet) and one administration tube with EN-lock connection at both extremities (Nutricia). Following the NF-EN-1615 and 1618 norms, five tests have been realized in triplicate on each reference.

Test	Evaluated characteristic	Purpose of the evaluation	Method	Normative reference	-
1	Leak test between administration tube and EFC	Presence of leakage at the connection	 Eosin solution, Simulated pressure of 50kPa for 2min in connectors. Spots on filter paper revealed leaks. 	NF-EN-1615 NF-EN-1618	EFC clamped without EN-Lock clamped with 500 mL of eosin diluted EN-Lock connection Spots on filter paper
2	EFC connector deformability test of the EFC connection	Percentage of change of the dimensions of the connection of the probe	Measure inner and outer diameter after one connection/disconnection a day during 30 days with a caliper.	/	
3	Penetration test: EN-lock/EFC	Maximum force of penetration	Using a dynamometer, exerting a linear force and measuring the maximal force for connection.	/ 1	2
4	Penetration test: En +/bag	Maximum force of penetration	Using a dynamometer, exerting a linear force and measuring the maximal force for connection.	/ 2	
5	EFC connexion resistance test	Maximal force for disconnection	Using a dynamometer exerting a linear traction and measuring the maximal force for disconnection.	NF-EN-1615 NF-EN-1618	1

Results

- ✓ No leak was detected.
- ✓ The changes of the EFC connector internal and external diameters tested were respectively up to 30% and 6%,
- ✓ The tube connection force to the EFC ranged from 37.8N to 216.2N,
- ✓ The tube connection force to the bag ranged from 14,6N to 20,1N. Two suppliers' bags cannot be connected to the EN + device,
- ✓ The tube disconnection force to EFC ranged from 3,2N to 44,8N (limit value: 15N).



Conclusions

Important deviations exist within suppliers. Some feeding lines don't meet specific EN norms devices particularly as regards the maximal disconnection force so their use with incompatible devices can be risky.