

Luer connectors — A report to CEN CHeF from the CEN forum task group “Luer fittings”

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Summary of pages

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**Luer connectors - A report to CEN chef from the CEN forum task
group “Luer fittings”**

This CEN Report was approved by CEN on 24 November 1999. It has been drawn up by the Technical Committee CEN/CS SUBSECTOR S99.

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1. SUMMARY

Luer connectors are used in medical devices with a wide range of functions, raising the possibility of accidental cross connection between devices. We assessed the hazards arising from accidental misconnection, and reviewed adverse incidents known to have involved Luer connectors.

We considered three possible strategies for reducing the risk of misconnection being made:

- 1) The use of different male/female sequences for different applications.
- 2) The use of colour coding.
- 3) The restriction of the applications for which the use of Luer connectors is permitted.

Only the last of these offered real benefits.

2. RECOMMENDATIONS

- 1) That the use of Luer connectors is **restricted** to devices intended to be connected:

- to the **vascular system** for delivery or sampling purposes or to assist in making some sort of measurement;
- to a **hypodermic syringe** in order for the syringe or a connected device to achieve its intended purpose.

- 2) That Luer connectors should **NOT** be used:

- with devices intended to be connected to the **enteral** or **respiratory** system; specifically, they should not be used for making connections to any catheter (other than a catheter intended to be placed in the vascular system) or to components or accessories to **breathing systems**, and accessories or other devices connected to the respiratory system for the purpose of delivering gases;
- with systems intended to deliver **compressed air** or **other gases** to medical devices e.g. driving gases;
- for connections within medical device systems which are used to **control** or **monitor** the operation of that system;
- with patient-connected **drainage** devices.

- 3) That CEN, in conjunction with ISO, develops standards for **alternative connectors** for enteral and respiratory applications, including the connection between an enteral feeding set and an enteral feed container.
- 4) That the scope and titles of EN 20594-1 and EN 1707 be amended to replace the phrase "*and certain other equipment*" with one that reflects the restriction to devices connected to the vascular system.
- 5) That CEN asks relevant Convenors to review the standards (published and under development) for which they have responsibility which permit the use of Luer connectors, amending those in which the device does not fit the revised connector standard.

3. BACKGROUND

In 1997 concern grew regarding the proliferation of devices fitted with Luer connectors and the direct consequence of patient death or injury arising from the misconnection of particular devices, or the inappropriate delivery of enteral solutions, parenteral feeds or compressed gases.

Specific concerns were raised by CEN TC 205 regarding the use of Luer connectors with enteral feeding tubes and from CEN TC 215 regarding gas sampling and gas delivery systems. Supported in principle by clinical and device experts together with a knowledge of actual and anecdotal incidents, these concerns were raised with CEN BTS 3 and the Commission through the Medical Devices Experts' Group. In November 1997 the problem was aired at the final CEN BTS 3 Healthcare Forum and the newly created CHeF steering group set up a Forum Task Group (FTG) to debate the problem.

Membership of the FTG was by invitation; CHeF ensured that there was appropriate representation drawn from users, device manufacturers, European Standards bodies and European regulators. The FTG met on three occasions between January and October 1998.

The FTG was asked to review the current evidence relating to real and potential problems arising from the misconnection of devices utilising Luer fittings, and to make recommendations regarding the application of Luer fittings to medical devices in order to reduce potential hazards arising from their misconnection.

The remit of the FTG did not cover the design of the Luer connector itself; existing standards adequately specify constructional requirements. The security of the connectors is adequate for the intended purpose providing they have been correctly manufactured and are used appropriately.