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CONNECTORS

Whither the Luer; Can Old Tech Find a Second Life?

page 36

Strategies for Start Ups
page 32

User Interface Lessons
page 42

The Life and Death of the Luer

Luers were once critical medical technology advances that saved lives. Have these low-cost components outlived their usefulness?

JIM BROWN

The common luer—once a simple fits-all solution—now creates considerable complications in increasingly complex medical environments. Widespread use of the luer connector has become too much of a good thing. For more than 110 years its simple design made the luer economical to manufacture and easy to use. Today, its simplicity threatens patient health and physician outcomes.

The luer connector design allows direct or functional connection between unrelated delivery systems, including vascular, enteral, respiratory, epidural, and intrathecal medical devices, as well their components and accessories. Multiple connections between medical devices and tubing are common in patient care.

Despite its modern-day difficulties, the luer has a rich history. Luer connectors got their start in 1896 when Karl Schneider, an instrument maker for the H. Wulfing Luer Company of Paris created an all-glass syringe that consisted of a glass cylinder and glass plunger with no additional "packing" material to create the seal between the plunger and cylinder. A variety of syringes and related products with Luer-type connectors appeared in the company's catalogs in the early 1900s for a variety of applications, from hypodermic and intravenous injection to urethral and uterine instillation.

In this original locking form the male and female parts, each featuring a 6% taper, allowed a clean press fit. The simple design created a strong hold that could be accomplished in a variety of materials—glass, metal, and eventually, plastic.

The next major development solved the problem of keeping needles firmly fixed to syringes when pressure was applied during injection. In 1930, a patent for the Luer-Lok connection was granted to Fairleigh S. Dickinson, cofounder of Becton Dickinson. The addition of locking flanges addressed the Luer's tendency to pop open under pressure and enabled users to connect the needle to the syringe by twisting to engage interlocking cams.

The Luer-Lok connector locks and unlocks with a twist and remains locked. Due to these features, this simple, effective and economical connector gained attention in a wide variety of medical applications. (Roughly 20 years after the Luer-Lok patent was issued, the luer lost its proper-name status. Except for specific references to events after 1950, luer-lock and luer are lowercased.)

Before and after development of the Luer-Lok, various tapered connectors found expanded use in medical applications particularly involving syringes:

- The 1925 S. Maw, Son, and Sons catalog includes a Rose's "antrum instrument" for use in nose and throat surgery. A tapered connector is used to attach the cannula.
- A 1930s Charles Lentz & Sons catalog includes a variety of lachrymal syringes for irrigating the tear ducts and nasal instruments with tapered connections for washing and suction.
- The Allen & Hansburys Ltd. catalog included a "Record" syringe with needles. Record and Luer connectors coexisted until the 1980s.
- The 1943 V. Mueller & Company catalog illustrated a variety of connectors for medical applications, including the Luer-slip (trademarked by Becton Dickinson), Luer-Lok, small French slip, large French slip, standard thread, Record slip, 606 hose end, and ¼ in. tubing.

In 1954 Becton Dickinson introduced a disposable glass syringe for a test of the Salk polio vaccine. Over a period of three weeks the syringes were used to vaccinate more than 1 million children in 44 states. One year later, Roehr Products introduced Monoject, the world's first disposable plastic syringe. In 1961, Becton Dickinson introduced Plastipak, a disposable plastic syringe. However, because many believed sterilization of reusable syringes was economical

Image courtesy of COLDER PRODUCTS CO.

Air Show Disaster Elevates Luer Connector

In August 1988, three jets from the Italian Air Force display team collided at the U.S. Ramstein Air Base air show Flutag '88. Three pilots died and flaming aviation fuel and debris resulted in 67 spectator deaths. About 500 people sought hospital treatment following the event, including 346 spectators with serious injuries.

Compounding the magnitude of the disaster were the lack of coordination between civil and military authorities, and the incompatibility of the luer and Record connectors used on intravenous catheters by the American military and German paramedics. Largely in response to the Ramstein disaster, the luer style became the global standard and the Record connector fell into disuse. However, a single standard wasn't codified until 1995.

Over the next couple of decades, luers became the standard connector in enteral and gastric, urethral and urinary, limb cuff inflation, and neuraxial device applications. Their ease of use and low cost moved the product from clinical settings to home-based care environments. This continued expansion counter intuitively weakened its foundation as a simple solution for a complex world.

The connections were simple and secure — and potentially very risky. The European Committee for Standardization (CEN) Report CR 13825 in 2000 stated, "In a coronary care unit there are as many as 40 connectors on the devices used with a single patient."

With the same connector being used simultaneously in vascular, enteral, respiratory, epidural, and intrathecal applications, the possibility of misconnections between these applications has always existed. The probability of misconnections grows exponentially with increased applications and types of users, and the consequences can be deadly. That's why new standards mandating separate, incompatible connectors for different applications are nearing adoption.

While hundreds of millions of procedures are performed each year without incident, any misconnections are still far too many. And the widespread use of standard luer connectors is the reason for misconnections. Devices, components, and materials that are used within a specific application will continue to come from different suppliers, so standardization within, but not across, applications will be the best solution.

The process of developing new standards for small-bore connectors began in 1996 when the Association for the Advancement of Medical Instrumentation (AAMI), stated that "enteral feeding tubes should not be Luer Lok compatible." In 1997 the standard designated BS1060-3 stated "Luers should not be used with NIBP [non-invasive blood pressure] systems."

AAMI, with a broad range of industry, healthcare organization, FDA, and academia participants, worked to develop two standards. The first disallows compatibility of enteral and parenteral connectors. Specific dimensions, tests, and acceptance criteria for a new enteral connector were to be expressed in a second standard. AAMI/ANSI ID 54 is still in effect today and recognized by FDA but without any additional FDA action; no second standard has been developed.

In 2000, CEN BTTF 123 was formed in Europe to address the issue. In 2006 it proposed that a joint working group (JWG) be formed for "the development of standards for small-bore connectors for liquids and gases in healthcare applications under the Vienna agreement with ISO TC 210 administrative lead." Responsibility was officially moved to ISO TC210 JWG4 in 2007.

JWG4 subsequently released ISO 80369-1:2010, which "provides the methodology to assess non-interconnectable characteristics of small-bore connectors based on their inherent design and dimensions in order to reduce the risk of misconnections between medical devices or between accessories for different applications and to reduce the risk of misconnections between medical devices with 6% Luer connectors, and all other non-Luer (6%) connectors that will be developed under future parts of this series of standards."

and comparably safe, there was little demand for the products.

The fate of the reusable syringe was sealed when Dr. Albert Weiner was convicted on 12 counts of manslaughter in December 1961 after a dozen of his patients died of hepatitis that was attributed to the reuse of infected syringes. Demand for disposable syringes skyrocketed, and within a year, disposables secured one-third of the U.S. needle market. The mass production of plastic luer-type syringes, in turn, led to the growing use of plastic luer connectors in a variety of applications. That expanded interest and use could now lead to its contraction in the medical marketplace.

Expanding Use of the Luer

Advances in thermoplastic technology allowed manufacturers to mold plastics in precise parts and dimensions, making luer connectors easier to manufacture. They were rapidly adopted in a variety of medical applications. In 1961, for example, a method for percutaneous transvenous catheterization was described as using "dialysis tubing fixed to a Luer-lock at the end of the venous catheter."

During the 1960s industry consolidation survivors Abbott Labs, Baxter, and B Braun dictated fit, form, and function of intravenous (IV) connectors. They settled on the luer and luer-lock connectors and agreed on dimensions and materials as they moved away from metal and glass. Connecting metal and glass together could result in cracks, leakage or entrainment of nonsterile air, leading to infection.

The luer style was selected because it was reliable, and inexpensive to manufacture and purchase. It also had a simple design that worked with few complications and allowed device manufacturers to make items that would easily connect with other products.

Subsequent Developments

Indwelling catheters, such as the peripherally inserted central catheter (PICC) line, drove the development of new luer-type connectors. The female connectors on the indwelling catheter represented an open system that was capped using a closed-end male luer-lock connection—essentially a cork. The cap could be removed to provide access, but it provided an opening for infection. The alternative closed-system connectors were permanently capped with a rubber injection port through which a needle could be inserted to draw blood or introduce medication. The closed injection port used a male luer connector attached to the female luer at the end of the indwelling catheter.

When the ANSI Luer Taper Standard was issued, it was the first-ever parenteral device connection standard (Other standards from the EU and Japan came later.). The nonstandardization of materials and dimensions had resulted in deaths, injuries, misconnections,

and taped connections. The new standard allowed an approximately five-year phase-in period to develop new molding machines and use existing inventory.

In the 1980s, rising concern over needle sticks as a cause of hepatitis and HIV transmission led to the development of needleless technologies. Blunt plastic cannulae replaced metal needles as a means of entering the closed system through the rubber port. Luer-activated devices (LADs) performed a similar function, creating a leakproof seal that opened automatically when a suitable luer-based connector was attached to it.

In complex IV systems, stopcocks allow delivery of various materials to be turned off and on without opening the system, providing individualized control over multiple materials being introduced through the same line. These modular systems, largely created using lures, allowed a level of control over the delivery of drugs, blood, and other materials and reduced the opportunity for infection.

Applications in which luers are no longer allowed will see significant change. And as medical applications advance, so must the connector industry's progress.

At the same time, luers were being used to connect gas delivery lines for applications such as limb cuff inflation. Patients in operating, recovery, and emergency rooms could have dozens of luer connections delivering a variety of gases and liquids.

By the late 1960s, the luer had largely supplanted the more slender Record connector due to the marketing dominance and technological leadership of U.S. companies' IV (parenteral) products. U.S. dominance of the IV market in terms of IV bottles, IV bags, kits and trays, and the associated sets and devices, all revolved around the use of the parenteral luer.

The luer connector had become the *de facto* standard in the U.S. by 1980, however, most European users employed the Record (sometimes referred to as Rekord) connector. Interestingly, the luer was not formally defined as a standardized small-bore (inside diameter less than 8.5 mm) connector until 1986 (It is defined in ISO594-1 and ISO594-2 and described as a "conical fitting with a 6% taper for syringes, needles, and certain other medical equipment.").

The luer's place in medical history was solidified following investigations of an August 1988 midair collision at the U.S. Ramstein Air Base (See the sidebar "Air Show Disaster Elevates Luer Connector").

What the Future Holds

Luers have a long, storied history and possibly a replicated future, but there will be changes in form and function, if not fit. National committees and international working groups are driving the changes, as are researchers and users. The question of what the future holds for the simple luer might be answered in the new options manufacturers are offering.

What was once a simple solution in a simple time is now being replaced with a more appropriately straightforward method: matching connectors for each media and purpose. Even where general luers may still be used, they likely will see design changes. Applications in which luers are no longer are allowed will see significant change. And as medical applications advance, so must the connector industry's progress.

Connector manufacturers are adopting unique closure and fitting applications including color-coding, audible signals (a click when the match is right), and radio frequency identification (RFID). Matching-color sets can reduce the risk of mistaken connections. Textured closures can simplify and ease the mating process. Audible indicators clarify whether the proper closure has been made. RFID signals warn of misconnections, declare good connections, and record the findings. Colors, textures, and connection options are just a few of the possibilities being considered to meet stricter requirements and also retain the luer's low-cost appeal.

Given safety concerns and new standards that restrict their use, luers will either decline in use or change dramatically from a design that has seen few alterations throughout its lifetime. The popularity of new and different connectors such as quick-disconnect couplings continues to rise, because these advances offer greater protection and confidence in accuracy and closure success.

Manufacturing innovations are making these critical safety options more accessible and affordable as luers are phased out of many medical environments where standards risk mitigation call for safer and new approaches. Luers might still be used for vascular access; however, the focus is on new connector designs that specifically address the prevention of misconnections in other applications.

Certainly it is the buyers' and the manufacturers' responses to the standards committees that spell the fate of the luer. ISO 80369 will test the industry's willingness to turn from a tested, but now questioned, low-cost technology toward new, potentially more costly, but safer connection options. Likely the widespread use of luers will diminish. No one technology will replace them. The fun part will be to see what comes next.

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