Eastman™ medical polymers for luer design

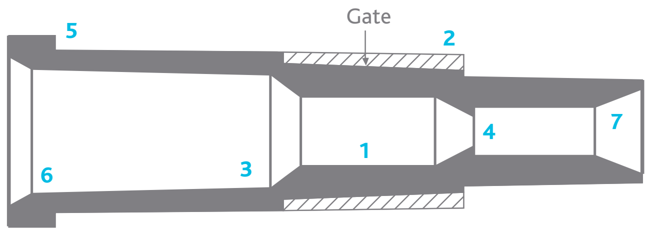
At first glance, luer components are small and relatively simple. However, the demands placed on these parts are severe and a high level of engineering goes into successful applications.

The tooling for luers can also be quite complex: male luers typically require an unscrewing core, and female luers require the use of small-diameter core pins, which are difficult to cool properly.

Figure 1 shows seven features that have been designed into a female luer. They provide a robust design that holds up under the demands of operating in an intravenous line.

Some luer device manufacturers intentionally oversize the female luer to move the maximum engagement area away from the outside edge of the part, as shown in Figure 2. When assembled, the resultant hoop stresses are highest in a thicker region where there is more material to resist the force and where weld lines are stronger.

Figure 1. Female locking luer: optimized design



1 Large gate leads into thick section, allowing circumferential flow of hot melt into a strong weld line.

2 Ribbed finger grips permit the use of a large gate while hiding gate vestige.

3 "Choked" section causes a cylindrical flow pattern to form, flowing toward female end of part with no weld line.

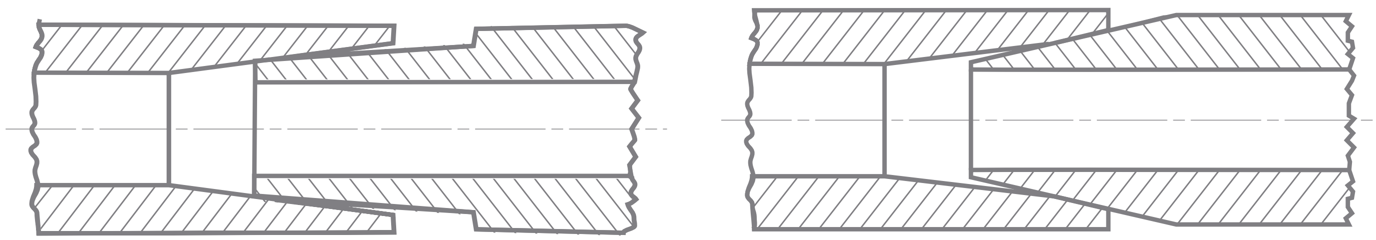
4 Tubing stop is designed to minimize thick section and facilitate assembly.

5 Maximum wall thickness of 1 mm (0.040 in.) is allowed by ANSI/ISO standards to improve polymer flow and strength.

6 The thread locks located opposite the gate provide added strength in coldest flow zone. Tapered lead-in reduces mating stresses.

7 Generous lead-in for easy tubing assembly.

Figure 2. Overcoming high tensile stresses in luer fittings



Mismatched luer tapers with male part oversized at the tip of engagement. Probability of trouble is low.

Mismatched luer tapers with male part undersized at the tip of engagement. Probability of splitting the female part is high.

Potential sources of luer failure

There are many reasons a luer may fail. The "top 10" reasons are:

1. Circumferential (hoop) stress is inherent with tapered connectors.
2. Wrong material choice (too brittle) or contaminated material.
3. Material improperly dried before molding or high residence time in barrel.
4. Parts cold-molded, creating excessive orientation with weakness in the hoop direction and at the weld line.
5. Chemical attack by alcohol or fatty hyperalimentation solutions containing glycerol and lipids.
6. Luer taper exerts a wedging action, enhanced by lipid, lubricant, wetness, or overtorquing.
7. Polypropylene adapters invite overtorquing to overcome slippery surfaces.
8. Sterilization processes, both radiation and ETO, affect physical properties.[1] One hundred percent ETO can craze high-stressed parts.
9. Dimensional mismatch between male and female tapers.
10. Pretreatment of components with incompatible solutions, solvents, or freon wash can initiate microcrazing.

[1] *While sterilization processes, radiation, and ETO affect physical properties of many clear materials, they do not significantly affect Eastar copolyesters.*

Like other components, luers should be designed with uniform wall thickness. Figure 3 shows an example of a part that was designed with a large variation in wall thickness. One problem that occurred was the inability to properly fill and pack out the part without voids forming in the thick region. These voids could not be removed by optimizing the molding process. Since the part was gated into the thin [0.75-mm (0.030-in.)] section, opening the gate was not effective. The thin section would freeze off before the gate, preventing the rest of the part from packing out properly. The thin wall was, in effect, the "gate." The voids were finally eliminated by coring out the thick section. Had the coring not been successful, another option would have been to move the gate to the thick area or to increase the thickness of the thin section.

Figure 3. The importance of uniform wall thickness (heparin luer lock example)

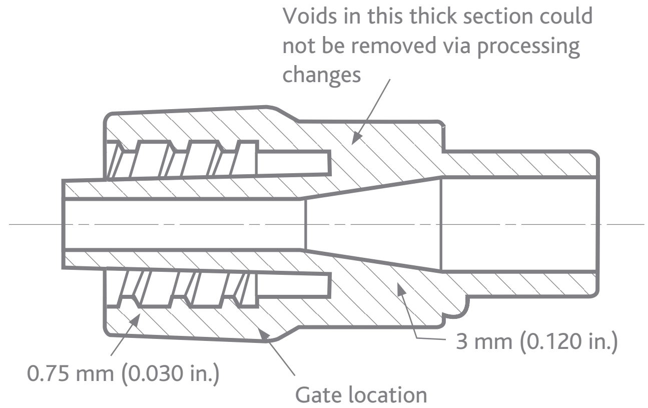


Table 1 illustrates the applicability of several resins for luer connectors. Note the data for polyesters, which are materials supplied by Eastman.

Table 1. Material selection criteria for luer connectors

Material choice	Elongation range, % to break	Sensitive to alcohol and most solvents	Radiation resistance	Fracture mode—brittle (B)*/ ductile (D)	Is polymer hygroscopic (requiring drying)?	Primary reason to use/ not use
Styrene	2–5	Yes	Excellent	B	No	Too brittle
Impact Styrene	5–10	Yes	Excellent	D	No	Difficult tubing bond, clarity poor
SAN	1–2	Yes	Excellent	B	No	Too brittle
Acrylic, Impact	1–2	Yes	Fair/good	B	No	Long history of use in luers w/limited elongation
Modified Acrylic	5–25	Yes	Fair/good	B/D (both available)	No	Good clarity
Clear ABS	25–35	Yes	Good	D	No	Good choice
Rigid PVC	10–25	Resistant	Good	D	No	Good choice, color compromise
Polycarbonate	100	Yes	Good	D	Yes	Good choice
Polysulfone	100	Yes	Good	D	Yes	Good choice, color compromise
Polyesters/Copolyesters	200	Resistant	Excellent	D	Yes	Good choice, slow cycling
Nylon	100	Resistant	Fair	D	Yes	Difficult tubing bond
Polypropylene	700	Resistant	Fair/poor	D	No	Difficult bonding; widely used in syringes, needle hubs, and lab fittings
Polymethylpentene	100	Resistant	Poor	D	No	Low radiation tolerance
Cellulosics	50–100	Yes	Good	D	No	Too soft, heat deformation
Rigid Urethane	50–75	Resistant	Excellent	D	Yes	Good choice, but radiation induces color
Polycarbonate-Polyester Blends	100–150	Yes	Good	D	Yes	Good choice, cycles well, balanced properties

*(Brittle = <25% elongation to break)

Notes

1 Clarity is an issue in luers, sufficient to observe the flow path. All materials listed allow visualization of bubbles.

2 Freon washing, 100% ETO, oils, plasticizers, and solvents are potential stress-crack agents, especially when molding stress is present.

3 Each material has an elongation at which craze and cracking initiates. The difference between crazing and cracking is only a matter of size and time. Crazing usually occurs slowly and does not result in failure; the opposite occurs in cracking.

4 Cost of material is not tabulated (minor compared to the price of failure).

5 There is no substitute for testing parts as molded and processed for retention of physical properties.

6 Polymers are subject to development and improvement that can affect future selection criteria.

7 Female luers are inherently weakest in the hoop direction. Make sure that testing includes hoop stress and deformation in the hoop direction. The use of any polymer with less than 25% elongation is inviting failure in female luers by sacrificing functional safety margin.

Some of the material in this publication has been modified from J. A. Stubstad, Antec 1992 Proceedings.

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