

# Risk of Blood Bag Lesions Induced by Standard Transfusion Devices

Johannes Raster Andreas Greinacher Linda Schönborn

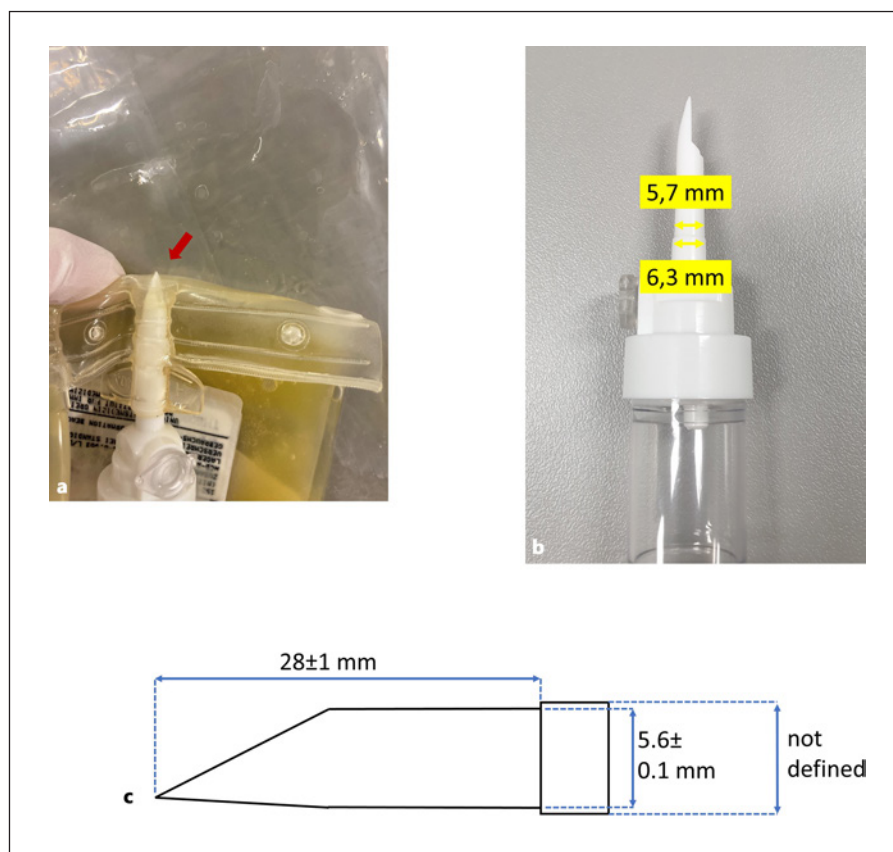
Institut für Transfusionsmedizin, Universitätsmedizin Greifswald, Greifswald, Germany

Dear Editor,

With this letter, we address a serious topic regarding the risk of bacterial contamination due to defective blood bags. At the bedside, leakage of a platelet concentrate was observed before the start of transfusion and the defective platelet concentrate returned (after a futile attempt to repair the leakage with a plaster).

The bag membrane had been punctured by the transfusion device. The tip of the transfusion device protruded the puncture resistant tubing of the blood bag by 2–3 mm (shown in Fig. 1a). The blood bag was a MCS+ apheresis set bag (Ref: 997CFE; Haemonetics, Munich, Germany).

Transfusion devices and blood bags are highly standardized. DIN EN ISO 1135-4 states the length of the



**Fig. 1.** a The protruding tip of the transfusion device puncturing the bag membrane. b The diameter of the thorn and the “stopper” of the transfusion device VH-26-EGH (Care Fusion). c Technical drawing of the thorn, measurements according to DIN EN ISO 1135-4.

thorn of the transfusion device as  $28 \pm 1$  mm while DIN EN ISO 3826-1 states that the port must be compatible with a thorn according to DIN EN ISO 1135-4 without puncturing the bag membrane [1, 2]. The norms do not consider the “stopper” at the end of the thorn that is supposed to prevent the thorn from being pushed too far into the bag (shown in Fig. 1c), which obviously happened as shown in Figure 1a. The diameter of the stopper of the transfusion device used (Ref: VH-26-EGA; CareFusion) is only 0.6 mm larger than the diameter of the thorn (shown in Fig. 1b) and the force required to overcome that barrier is negligible. The issue of poor compatibility of blood bags and transfusion devices has previously been raised, mostly regarding the force that is needed for insertion and the stability of the connection [3–5].

Punctured blood bags present a high risk for bacterial contamination of blood bags [6]. While macroscopical lesions are easily detected and the blood bag then returned, non-leaking microscopical punctures are less likely to be detected and might present an equal risk for contamination. In a field where massive and cost-intensive efforts have been implemented to minimize the risk of pathogen transmission, compatibility of transfusion

device and blood bag should be a basic requirement. We therefore recommend an adaptation of the DIN standard to also include the diameter of the stopper.

### Conflict of Interest Statement

A.G. is an advisor for MacoPharma and received funding from MacoPharma for another project.

### Funding Sources

This work was funded by the research budget of Universitätsmedizin Greifswald and the Deutsche Forschungsgemeinschaft (DFG [German Research Foundation] Grant No. 374031971–TRR 240). L.S. was supported within the Gerhard-Domagk-Research-Program by the University Medicine Greifswald. We acknowledge support for the Article Processing Charge by the German Research Foundation and the Open Access Publication Fund of the University of Greifswald.

### Author Contributions

Johannes Raster, Andreas Greinacher, and Linda Schönborn contributed to investigating the incident and writing the manuscript.

### References

- 1 Deutsches Institut für Normung e.V.: DIN EN ISO 1135-4:2016-06 Transfusionsgeräte zur medizinischen Verwendung - Teil 4: Transfusionsgeräte für Schwerkrafttransfusionen zur einmaligen Verwendung.
- 2 Deutsches Institut für Normung e.V.: DIN EN ISO 3826-1:2020-01 Kunststoffbeutel für menschliches Blut und Blutbestandteile - Teil 1: Konventionelle Beutel.
- 3 Nightingale MJ, Leimbach R. An evaluation of proposed changes to international standards for blood bags and transfusion sets to improve their compatibility. *Transfus Med.* 2008;18:281–6.
- 4 Nightingale MJ. Improving compatibility between blood packs and transfusion sets. *Transfus Med.* 2006;16(1):11–5.
- 5 Clarke G, Hannon J. Improving compatibility between blood packs and transfusion sets. *Transfus Med.* 2007;17:141. Author reply 143.
- 6 Hillyer CD, Josephson CD, Blajchman MA, Vostal JG, Epstein JS, Goodman JL. Bacterial contamination of blood components: risks, strategies, and regulation: joint ASH and AABB educational session in transfusion medicine. *Hematology Am Soc Hematol Educ Program.* 2003;2003:575–89.