Eliminating Contrast Leakage in Bayer's CT Injector System

Hannah Avery, Anagha Chandra, Morgan Kontor, Raahul Sriram, Michelle Wu

Department of Biomedical Engineering, Department of Chemical Engineering, Department of Materials Science and Engineering
Carnegie Mellon University, Pittsburgh, PA

Clinical Need

- Contrast materials improve the image quality of computed tomography (CT) scans.
  - Contrast media temporarily changes the way the x-rays interact with the body[1].
- Bayer produces and sells CT injectors and tube sets which together inject contrast into patients (Figure 1).
- Clinical problem is there is a contrast fluid loss when the multi-patient tube set (MPDS) and the single-patient tube set (SPDS) are disconnected following the injection of the contrast (Figure 2).
- This is a significant issue for consumers due to increased costs and hazardous conditions.
- Results in hospital employees needing to clean up the excess contrast materials, both on the injector and on the floor around it.
- This leads to Bayer's customers switching over to competitive systems.

Figure 1 (above). Bayer's CT injector

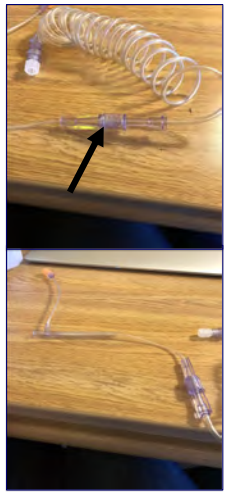


Figure 2 (right). Bayer CT injector tube sets. Top: SPDS which is replaced after each patient. Bottom: MPDS which is used for up to 60 times. The arrow points to the interface where the leak occurs

Needs Statement

- Project goal was to design a valve that fixes the dripping issues while not adding significant costs to Bayer or the customer.
- Proposed solution needs to meet two requirements:
  1. Eliminate the leaking of contrast material or reduce it to no more than a total of 0.15 mL
  2. Add no additional steps to the operating procedure

Design and Test Results

Swabbable Valve

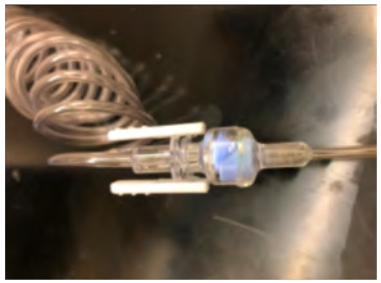
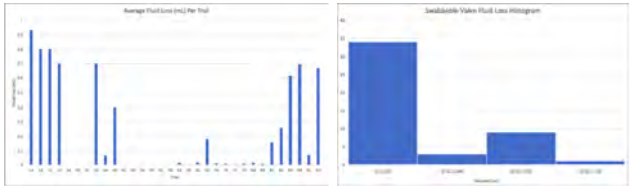


Figure 3. Swabbable valve prototype

- Silicone-type material situated around the MPDS luer.
- When the SPDS is inserted into the MPDS, the material depresses and provides a straight fluid pathway (fluid can flow).
- When SPDS is removed the material returns to its initial state and forms a barrier to prevent any leaks (Figure 3).

Test Results: 10 prototypes, 8 functional
Different test procedures denoted as A-D

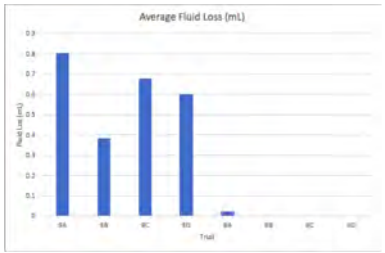


Compression Activated Spring Clamp

Figure 4. Spring clamp prototype

- Depresses (or pinches) the tubing so that fluid is not able to flow.
- A compression spring is captured in between two injection molded parts.
- In the resting state the tubing will be pinched shut to prevent flow.
- Applying a fluid pressure to the inside of the tube will cause the spring to compress and fluid will be able to flow freely through the tubing (Figure 4).

Test Results:



- 1 prototype
- 2 settings-determines amount of fluid pressure needed to compress spring
  - 9 threads (1 atm)
  - 8 threads (9 atm)

Market Analysis

- This new design will be implemented into the sale of new MPDS
- Cost to produce each design
  - Swabbable Valve-$400,000 for injection molding tools
  - Spring-$195,000 for injection molding tools
  - $1.16 per part for spring and screws
- Expected sales in 2018
  - 425,000 MPDS
  - 3.25 million SPDS
- 560,000 CT scans/yr lost in Europe due to this dripping issue.[2]

Regulatory Pathway

Because this product is for overseas markets, this must go through the approval process in the EU, Asian countries, and South American countries. In Europe, the product would fall under Medical Devices Directive (MDD) 93/42/EEC. It would be considered a Class I device that is provided sterile and/or has a measuring function (low/medium risk).[3]

Future Work

Given that the presented design prevents the dripping of excess fluid, there is not significant motivation for changes to the overall design. However, work could be done to improve upon the consistency and usability of the device. This includes variations to the material and design of the latching mechanism on the swabbable valve. Additionally, the knob on the top of the spring design can be refined to be of additional assistance to the operator.

Acknowledgments

The authors thanks Dr. Conrad Zapanta for review and suggestions on the content of the poster and project. We'd also like to thank Mike McDermott and Ian Menego from Bayer for all of their guidance on this project. Finally, we'd like to thank Abraham Umo our TA.

References

[1] "CT scan." *Mayo Clinic*, Mayo Foundation for Medical Education and Research, 25 Mar. 2015, www.mayoclinic.org/tests-procedures/ct-scan/basics/definition/prc-20014610.
[2] Bayer Design Opportunities Presentation
[3] "European Medical Device Classification." *Emergo*, https://www.emergobyul.com/services/europe/european-medical-device-classification

Carnegie Mellon University
BIOMEDICAL ENGINEERING
BAYER