

Automated Vial Torquing Machine



Sponsor: AlloSource

Director: Dr. Maureen Lynch

Team 1: Blaire Rodriguez, Abdullah Alkhalidi, Evan Blake, Ben Piquard, Grant Hupp, Jared Moya, Nebiyu Tadesse

Contents

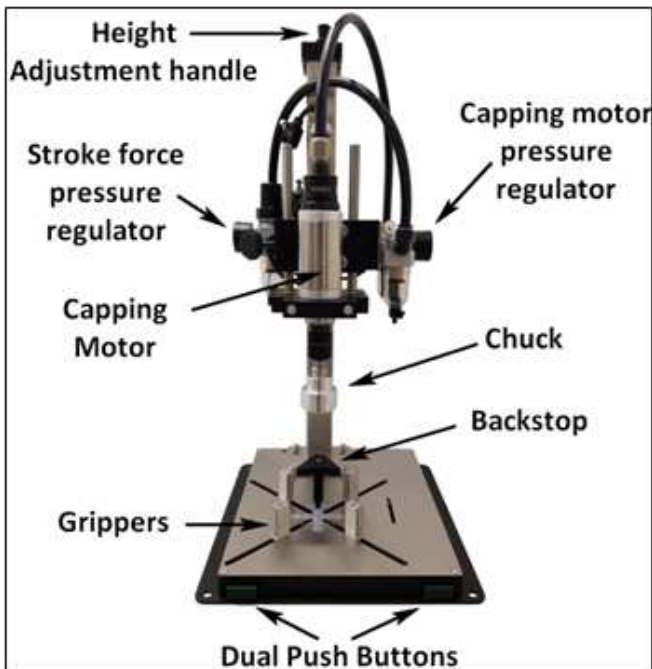
Executive Summary	03
Project Background	04
Design Overview	05
Testing	07
Challenges and Final Outcome	09

Executive Summary

The demand for tissue and organ donors is at an all-time high and continues to rise. AlloSource, the sponsor of Team 1, provides tissue donations to those in need. These tissue donations, known as allografts, are processed in an aseptic, clean room environment in which vials are filled with tissue before being capped and sent off. These vials must be torqued to a certain specification to prevent outside air contamination and maintain the sterile integrity of the donations.

Project High-Level Goals:

- Torque Standard - Vials are torqued to 23 +/- 1 in.lbs
- Automation - Vials are torqued with minimal to no operator interaction
- Assembly - Assembly and disassembly in under 10 minutes.
- Lightweight - Turntable delivery assembly shall stay under 10 lbs.
- Size - The full assembly shall fit within an area of 2 ft x 3 ft
- Sterile - Designed to withstand steam sterilization conditions of up to 272°F



Kinex Capper SA-2000-DPB

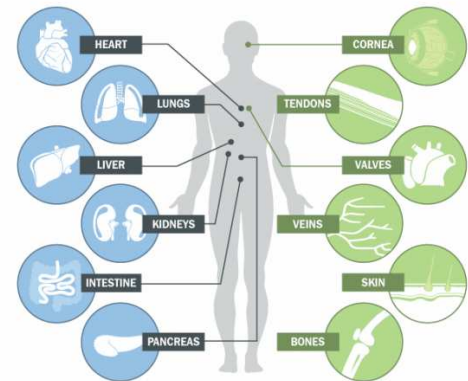
AlloSource's current process to cap these vials involves technicians using a torque wrench to manually tighten them. Consequently, they have come across technicians incurring wrist motion injuries due to the repetitive nature of the task. To mitigate these safety concerns, AlloSource acquired a semi-automated torquing device from Kinex Cappers. This machine however was not user-friendly and still required too much operator interaction.

The main goal of our project this year: Minimize ergonomic safety risks and increase product throughput by retrofitting AlloSource's Kinex Capper.

Project Background

An allograft procedure is an essential medical process that involves the transplant of bone or tissue from one person to another. This is very useful when a person encounters a bone, skin, or soft-tissue injury and could potentially serve as a life-saving procedure. Since this product deals with materials that will have direct bodily human contact, it is of utmost importance that everything remains aseptic throughout the handling stage. The current procedure AlloSource uses to process their allografts involves technicians manually tightening caps to a torque specification. This process is tedious and a cause for ergonomic concern of the technicians.

LIFESAVING & HEALING ORGANS & TISSUES



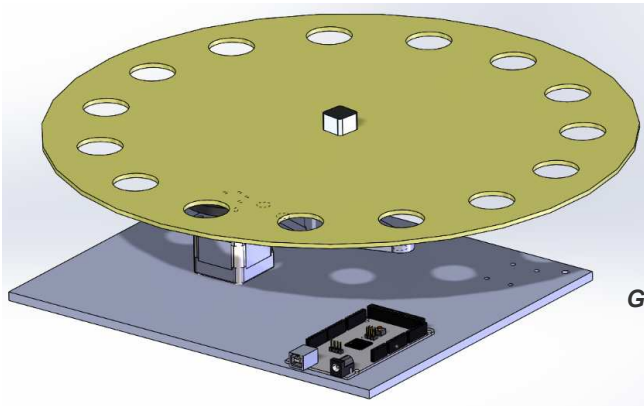
Available Organ and Tissue Donations



An Aseptic Room at the AlloSource Facility

An automated method is preferred to mitigate these adverse health risks. Not only would this decrease the amount of work-related injuries, but also streamline the vial torquing procedure. This could result in increase throughput and productivity. This report will describe the mission behind the project, provide a design overview of the prototype broken down, define analysis processes to come, and lastly, will clearly state and justify project budget and timeline.

Design Overview

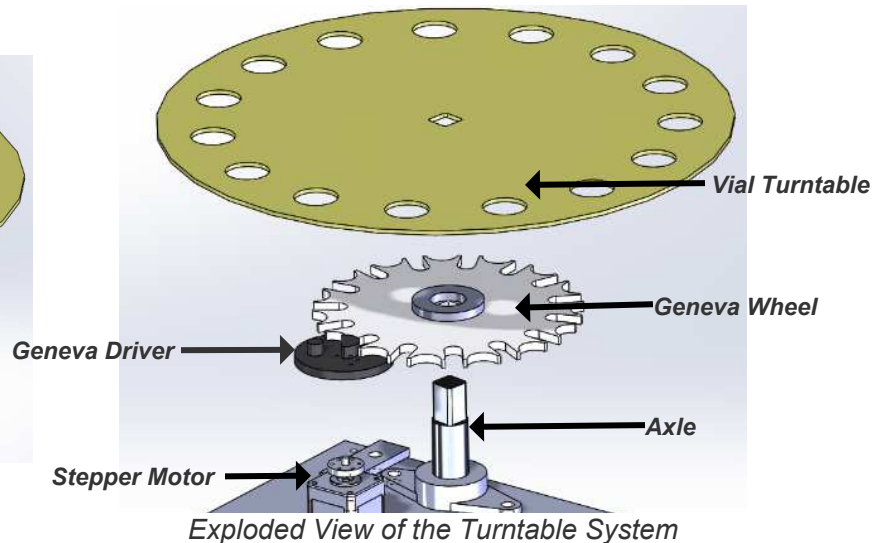


Turntable System mounted on Baseplate

The objective of this project is to modify the Kinex Cappers SA-2000-DPB machine in order to automate the capping process as well as maximize throughput. AlloSource needed the entire machine to fit on the 24" by 36" table, while also being able to withstand the cleaning techniques already in place to ensure a clean room environment.

To achieve this goal, the team explored different options to ensure precise vial placement. Different gripping methods, a conveyor system, and switches were all feasible solutions.

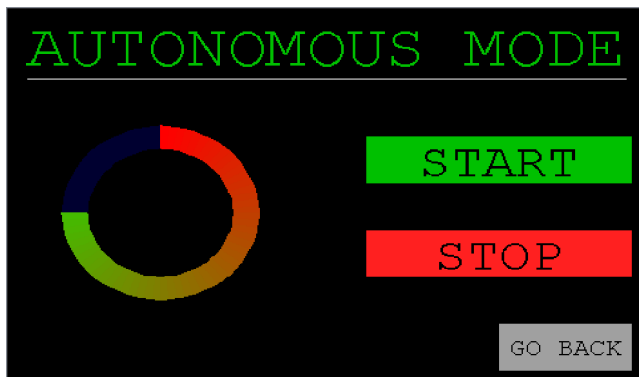
In the end, we chose to design a Geneva wheel style drive mechanism with interchangeable turntables.



Using the disk to hold multiple vials, the fixture will rotate the disks allowing the Kinex Capper to rapidly torque multiple vials. Team 1 decided to design a 16" diameter disk manufactured out of Polysulfone thermoplastic that can house up to 15 vials. This design and material fulfilled both the size and sterile constraints, while minimizing the weight.

To properly position the vials under the capping head repeatedly, we utilized a Geneva wheel--a unique drive mechanism where every full rotation of the driver gear indexes the wheel to discrete positions only dependent on its geometry. The driver gear is driven by a stepper motor in order to achieve precise open-loop control.

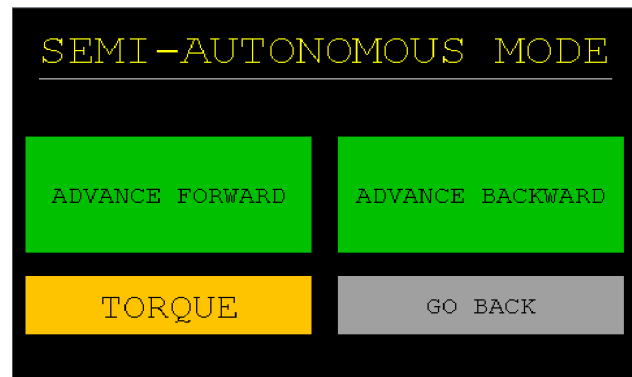
Design Overview



Fully Autonomous Mode Selection Display

In order to give the user an easy interface with the machine, a graphical user interface (GUI) was developed and displayed on a 3.5-in TFT Touch Screen. For the controller, the Arduino Mega was used to incorporate the ATmega 2560 chip from Atmel. We selected this microcontroller due to its low cost, Flash Memory and RAM size, and its large support community.

The GUI offers two different modes:: Fully-Autonomous and Semi-Autonomous. The Fully Autonomous Mode gives the technician the option to put a full turntable on and let the machine go through and torque each of the holes containing a vial by just pressing the "START" button. The progress is displayed on the gauge and a "STOP" button is also incorporated just in case the user wants to stop at any stage of the process.



Semi-Autonomous Mode Selection Display

The Semi-Autonomous mode was created to give the technician individual feed control. The page offers 4 buttons, main ones being the "Advance Forward", "Advance Backward" and "Torque". The "Advance Forward" and "Advance Backward" buttons just advance the disk by one hole clockwise and counter-clockwise respectively. The "Torque" button initiates the torquing process.

The stepper motor drives the geneva wheel and the torquing process is initiated by the solenoid. The stepper motor is controlled using the A3967 Microstepping Driver and the solenoid is controlled using the RFP30N06LE N-Channel MOSFET.

Testing

Desired Outcomes

This Test Plan will be divided into two main sections:

- [1] Specification Tests
- [2] Functionality Tests

These two types of tests will provide Team 1 with the data necessary to confirm that the specifications agreed upon with AlloSource are satisfied and that the custom mechanical, electrical, and software components are fully functional.

Data Analysis & Reporting

The specification tests, unless otherwise noted, all have measurable values that are defined in each test sub-section. Each test will confirm that the proper relationship with the collected data and defined specifications agree with each other and if not, the proper design or manufacturing changes will be implemented until the specifications are met. The functionality tests will ensure proof of concept and will help Team 1 catch any design flaws or interference present on sub-assembly and full-assembly levels.

Revised Test Plan

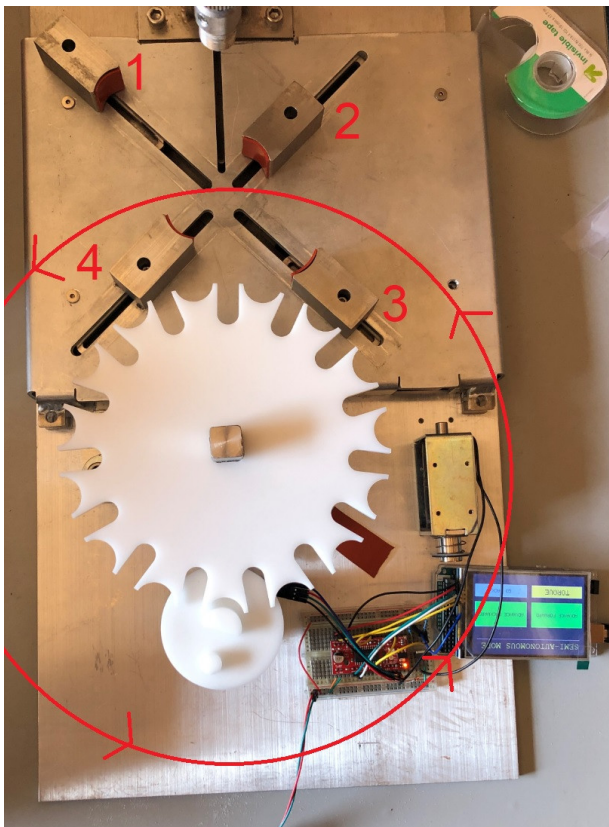
Due to COVID-19 and lack of resources, Team 1 was unable to fully execute the initial Test Plan. The following tests were affected:

- Vial Torquing and Indication Test** _____ no longer viable without further manufacturing
- Automation Inspection** _____ can no longer test with technicians, but still viable
- Assembly Test** _____ can no longer test with technicians, but still viable
- Lightweight Test** _____ viable once full assembly complete
- Size Inspection** _____ viable once full assembly complete
- Sterility Test** _____ viable once full assembly complete

Testing

Vial Pathway Clearance

The Vial Turntable was designed with the idea that all four vial grippers would be able to grip the vial from the furthest placement. However, after running the Full Assembly Functionality Test, the grippers needed to be placed in a specific orientation to achieve proper vial grip and torque actuation. The vials follow the circular path shown in red. For a clear path, grippers 1 and 3 needed to be pushed all the way back while 2 and 4 are placed so that the vial will be both gripped and able to clear with no mechanical interference.



Annotated Top View of Full Assembly

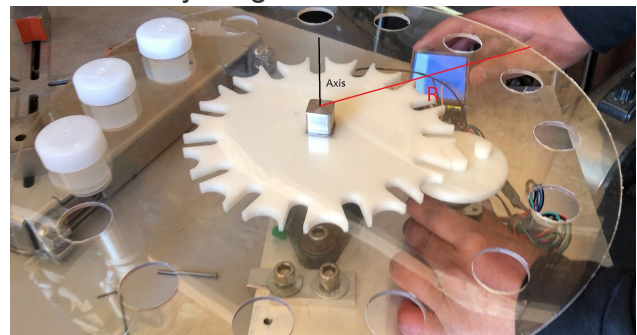
Motion Testing

During the Full Assembly Functionality Test, the stepper motor angular velocity was too fast, causing jolting in the system during Vial Turntable rotation. The team added extra weight onto the geneva wheel and realized that the weight of the Vial Turntable was not the issue. It was determined the moment of inertia of the Vial Turntable was too large for the stepper motor to overcome, due to the disk's large diameter.



Geneva wheel with 2.5-lb additional load

The initial stepper motor angular velocity was set to **150 rev/min**, but was changed to a more conservative value of **19 rev/min**. This change allowed the Vial Turntable to turn with no jolting.



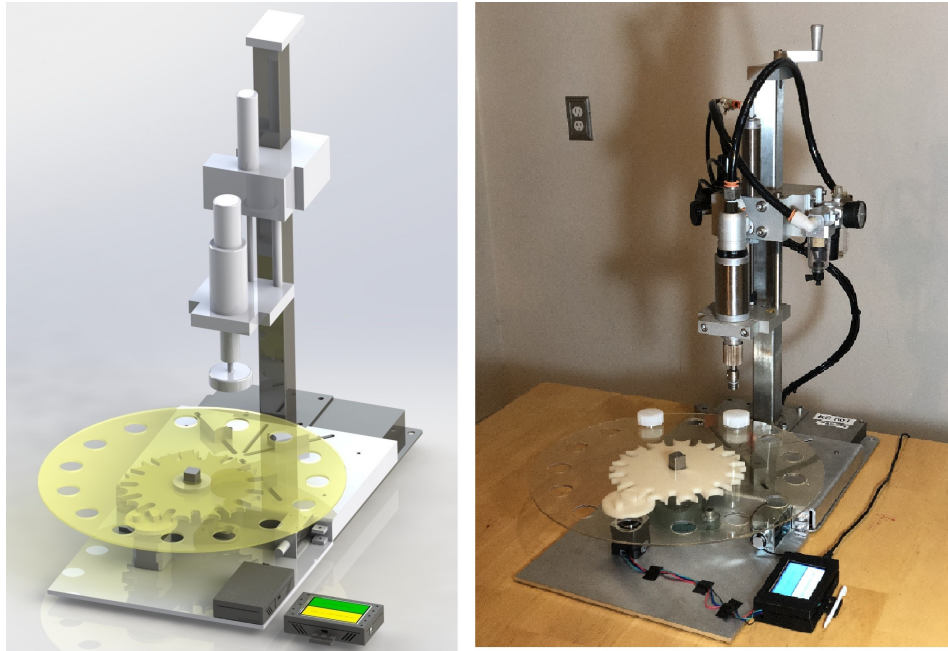
Moment of Inertia (Disk)

$$I = (1/2)MR^2$$

where, $M = \text{mass}$

$R = \text{radius}$

Challenges and Outcome



Kinex SA-2000-DPB capping machine retrofitted with Team 1's automated delivery system. Render on the left, actual assembly on the right

There were two overarching challenges of this project - to specify and deliver a design which conformed to clean room standards; and to retrofit the existing machine with unitize-able systems. This implied several requirements: resilient raw materials, ease of assembly and disassembly, and the ability to interface with the capping machine's existing and proprietary designs. The design materials had to be capable of withstanding multiple cycles of high temperature, high pressure, and strong chemical cleaners without degradation. Along with this, the entire assembly had to be easily assembled and disassembled for these sanitation measures.

The final outcome was a success and resulted in an efficient and reliable automated system, capable of increased throughput with minimal operator interaction. The team was able to execute on the goal of mitigating the ergonomic risk associated with the current process in place. The design incorporates interchangeable 'turntables' which stage 15 vials at a time. These turntables can be pre-loaded and quickly changed out to expedite the capping process. This will allow technicians to stage many of these turntables for hands-free capping.

The system includes a 'fully-autonomous' and 'semi-autonomous' mode which the technician can choose from the human-machine interface touchscreen. This will either process an entire turntable or allow the technician to cap one-by-one for a partially filled disk.