DIPLOMA THESIS

Concept Development of a Capsule Manual Opening Device

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STATUTORY DECLARATION

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Kurzfassung

Die Schwierigkeit des Schluckens von Standardtabletten und Kapseln ist ein zunehmendes Problem bei der Bereitstellung besonders höher dosierter Medikamente für Patienten/innen. Eine Alternative ist die Verabreichung von kleinen Multipartikeln, die zur Einnahme in Nahrung oder Getränke gemischt werden können. Dennoch gibt es viele Patienten/innen oder Pfleger/innen, für die das manuelle Öffnen von Hartkapseln eine Herausforderung oder sogar ein unüberwindbares Hindernis darstellt. Diese Arbeit befasst sich mit der Entwicklung eines semimanuellen Gerätes zur Unterstützung der Öffnung von Hartkapsel. Nach einer Analyse der aktuellen Situation und potenzieller Probleme, denen verschiedene Benutzer/innen beim Öffnen der Kapseln gegenübersehen, wurde eine Reihe möglicher Lösungen entwickelt. Diese Arbeit begnügt sich mit den zwei vielversprechendsten Konzepten, welche mittels 3D Druckverfahren realisiert wurden. Während der Prototyping-Phase sind die Geräte hinsichtlich ihrer Funktionsweise mehrmals optimiert worden, bis das höchste annehmbare Leistungsniveau erreicht war. Schlussendlich wurden die finalen Konzepte basierend auf den 3D-Modellen bezüglich ihrer Kapselöffnungsleistung getestet und die Ergebnisse bewertet.

Schlüsselwörter: Schluckprobleme, Kapseln, semimanuelle Öffnung, Konzept Entwicklung

Abstract

Swallowing difficulties of standard tablets and capsules is an increasing issue in delivering especially higher dosed medicines to patients. An alternative is the administration of small multi particulates that can be sprinkled on food or beverages for intake. Still, there are many patients or care givers to whom the opening of hard capsules could be a challenge and sometime a real barrier. This thesis focuses on the engineering concept development of a semi-manual capsule opening device. After analyzing the situation and the potential problems various users face when opening the capsules, a number of possible device based solutions were created. The various solutions were narrowed down to the two most promising concepts, which were then 3D printed. During the prototyping phase devices were optimized several times until highest acceptable level of performance was achieved. In the end, final §D printed concepts were tested regarding their capsule opening performance.

Keywords: swallowing issues, capsules, semi-manual opening, concept development.

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1 Introduction

The effective delivery of healthcare in an aging society is a major challenge for the coming decades due to the baby boomer generation coming into age. Patient managed pharmaceutical drug therapy is and will remain the major health intervention to treat and manage chronic diseases. The increasing life expectancy and higher age of the older patient generations correlates with a high degree of multimorbidity and functional impairments [1, 2]. This also includes a higher prevalence for swallowing dysfunction, which limits the administration of solid oral dosage forms by a swallowable dosage form size, especially for the high dosed drugs like metformin or antibiotics. The use of multiple “multiparticulates” and mini-tablets have been shown to overcome the issue a single large monolytic dosage form, especially when they are introduced into small portions of soft food or beverages. This form of administration is called “sprinkle” whereby the multiparticulates are filled in capsules or sachets containing the precise and entire dose strength.

The objective of this Master Thesis was the conceptualization and feasibility testing of a semi-manual capsule opening device simple enough to be use by patients and manufactured on commercial level. A brief description of the problem is given as well as the motives for creating the capsule opening device. The approach towards the semi-manual opening device concept being chosen as well as the selection and optimization of the concept is being described in this chapter.

1.1 Task and Goals

This thesis focuses on the engineering concept development of a semi-manual hard capsule opening device. The goal was to develop a simple and easy to handle capsule opening tool by a semi-manual opening mechanism taking into account the patient and user factors as well as manufacturability and commercialization.

The approach to the problem addressed in this thesis includes different research tools from literature research to engineering concept development and preliminary mechanical and functional assessment. While usability testing with patients was not foreseen in this work, the ease and intuitive use of the capsule opening device was considered as a guiding principle.

A number of possible solutions had to be identified based on the analysis of the situation and the potential problems various users have when opening the capsules. The potential concepts should be derived from a broad and open-minded search within the consumer packaging industry, pharmaceutical devices operating with capsules (e.g. inhalation devices). For the identified concepts, manual or semi manual opening tests should be performed to evaluate different opening behaviors. The various solutions had finally to be narrowed down to the two most promising concepts to be 3D printed for further optimization and final concepts testing with regard to their capsule opening performance and predicted usability.

1.2 Problem Description

Older persons and persons with several co-existing disease conditions (multimorbidity) are the patient population receiving most of the drug products and are consequently exposed to complex medication schedules (polypharmacy). These patients are more likely to develop swallowing dysfunction, which affect the safe swallowing of solid oral dosage forms. Especially for higher dosed drugs the size of standard tablets and capsules can lead to critical issues impacting drug safety and therapeutic outcomes. Swallowing difficulties could also affect smooth and safe oral medication administration. There is increasing evidence that swallowability issue increase the risk for non-adherence due to omission of the medication or medication errors due to inappropriate alteration of the medication like tablet crushing [3].

To prevent inappropriate drug alteration or drug omission, an alternative to a large monolytic tablet or capsule is the development of sprinkle formulations to overcome the size related swallowing issues. One of the most promising approaches is the use of small multi particulates or mini-tablets that can be dispersed in food or beverages for intake. To achieve correct dosage of the medicine, a precise dose of multi particulates or mini-tablets is filled into two piece hard capsules which are then opened by the patient or care giver before the administration.

Recently, new capsules were developed dedicated to the sprinkle application (e.g. Coni-Snap® Sprinkle) in order to address the needs of the rapidly growing population with swallowing difficulties. The difference to the standard capsules (e.g. Coni-Snap®) was achieved through modifications of the locking ring to reduce the opening force required to separate cap and body [4]. However, there are still many patients or care givers to whom the opening of capsules could be a challenge or even a barrier. This is mainly due to the fact that capsule opening by hand is more complex than just pulling ca and body apart. Capsules often carry high doses of medication (500 mg to 1000 mg) and the body of the capsule is generally filled to 90 % requiring good grip strength, dexterity and coordination to avoid the risk of spilling when opening by hand.

The capsule opening device should resolve the issues derived from the manual opening of the capsules and allow opening also by patients or care-givers with limited hand functioning. In principle, the capsule opening device should reduce the manual operations by the users to the placement of the capsule intuitively in the right direction, activate the device by a “push” or “turn” operation (semi-manual) to open the capsule and then lifting the device to pour out easily the content into the soft food or beverage placed in front of them. The empty cap and body of the capsules will be released either through another “push” or “turn” or can be removed easily by hand and discarded.

2 Capsule Specifications

The concepts were developed for the Coni-Snap® Sprinkle capsule size 0 produced by Capsugel. The concept will also be suitable for other capsule sizes by adapting the dimensions of device to the specific dimensions of the capsules sizes. For the purpose of this work the use of one capsule size (capsule size 0) was deemed sufficient to prove the mechanical performance of a capsule opening device concept. The main specifications of the capsule are provided in Table 1 and were the basis the design work as well as the decisions made during the development. Dimensions and information about the capsule are taken from [5].

2.1 General Specifications

Coni-Snap® Sprinkle capsule is specifically designed to meet the needs of patients with swallowing difficulties for example pediatric or multimorbid patients with swallowing issues. It is meant to support the oral administration of drug by simply sprinkling the contents on soft food. Unlike the strong locking mechanism in standard hard capsules, which requires sufficient grip strength, dexterity and coordination to reopen, the sprinkle capsule has a closure that needs less force to open and allows smooth separation of the two parts, cap and body. The new locking mechanism therefore enables easier and safer opening for all patients and care-givers [4]. Figure 1 shows the appearance of the capsule, while figures 2 and 3 show the detailed design of the capsule.

Figure 1: Coni-Snap® Sprinkle capsule; (1) capsule body, (2) capsule cap [4]

Capsule consists of two hard gelatin pieces in the form of cylinders. The shorter, blue piece, is capsule cap, and the longer, white part, is known as capsule body. The capsule cap has a slightly larger diameter so that the body can be inserted for closing. The body of the capsule is filled with small units of drug particles from where they are released after opening.

2.2 Capsule Design Features

The capsule is easier to open due to its specific design of the capsule locking mechanism. While the traditional capsules are closed by fitting two closing rings (one in the upper part of the body and one in the upper part of the cap) together (Figure 2), the cap of the sprinkle capsules only possesses six dimples that fit into the closing ring of the body (Figure 2). After closing of the standard as well as the sprinkle capsules, the edge of the body touches the cap inner shell wall preventing any leakage from the closed capsule. Being mechanically stronger, rounded ends make the capsule more resistant to deformation [5].

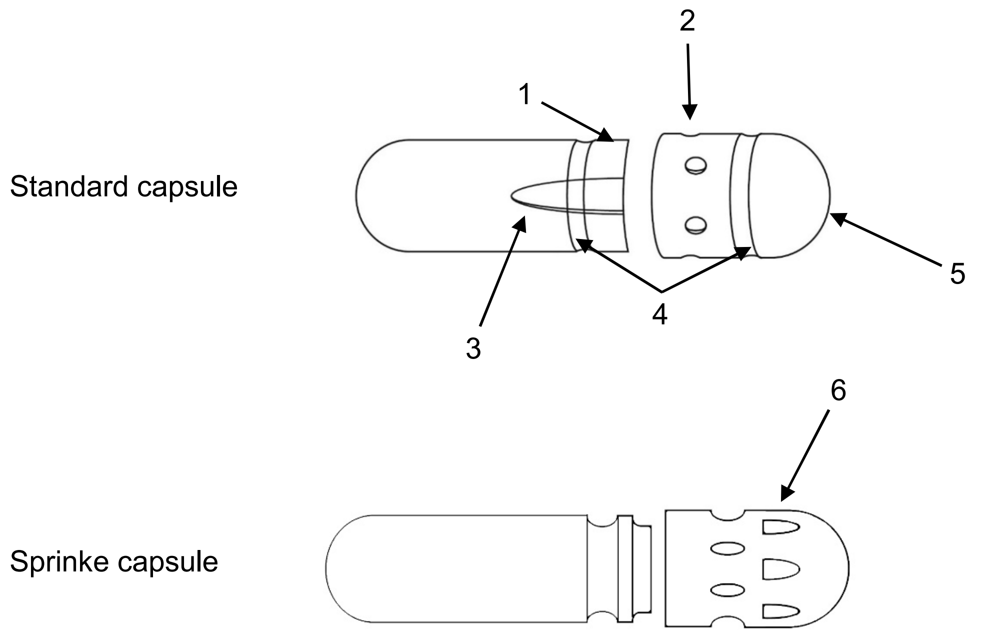


Figure 2: Capsule design features; (1) tapered rim, (2) elongated dimples, (3) air vents, (4) locking rings, (5) rounded end, (6) locking dimples [4, 5]

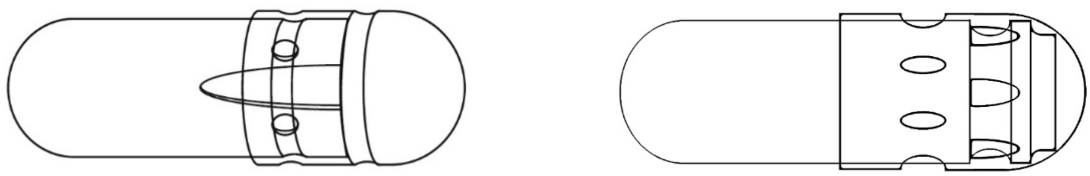


Figure 3: Capsule closing positions in standard and in sprinkle capsules [4, 5]

With capsules designed with the Sprinkle closing mechanism the patient needs to overcome lower lock forces when opening from the locked position of the capsule. The dimples of the cap positioned over the indented ring of the body still provide enough force for the capsules to stay closed after filling and during transport (Figure 3) [4].

In general, capsules are available in sizes from 5 to 000 [5]. The capsule opening devices were designed for the size 0 whose dimensions are given in Table 1.

Table 1: Capsule dimensions [5]

Coni-Snap® sprinkle capsule size 0	
Body length [mm]	18.44
Cap length [mm]	10.72
External body diameter [mm]	7.34
External cap diameter [mm]	7.64
Overall closed length [mm]	21.7

3 Approach

The process of concept development went through following phases: Understanding the problem statement, defining requirements, research, idea generation, evaluating ideas, prototyping, and testing. Each of the phases is shortly described in following subchapters.

3.1 Problem statement

The starting point for the thesis was the review of the reasons for developing a capsule opening device. The basic components and the users were analyzed to generate an understanding of the underlying environment necessary to define the requirements.

3.2 Defining Requirements

The goal was to develop easy to handle and simple semi-manual opening mechanism. Based on the research a list of product requirements was created. In addition to the list of requirements, a weighing scale was defined for each requirement representing their importance. Table of requirements presented in Chapter 4 serves as a guideline for product design and development as well as for the easier evaluation of ideas.

3.3 Research Phase

In this phase, research was conducted to get a better overview on the elements that have to be respected in the concept development. Specifications of the capsules were gathered and potential problems users might face while opening the capsule were analyzed. The research phase provided the knowledge needed for defining the requirements.

3.4 Idea Brainstorming

This was a phase of developing ideas by creative approach towards problem solving. Idea generation was guided by the previously defined requirements and a broad survey of similar packaging or device tools from the consumer industry. During the brainstorming process, multiple ideas were created of which the two most promising ones are presented in Chapter 4.

3.5 Idea Evaluation

In this phase, the generated ideas were filtered by filling up the product requirements table. Pros and cons of the concepts were highlighted for easier decision making. At the end, the list was narrowed down to the two most promising concepts.

3.6 Prototyping

Two most promising concepts were taken to be further developed. Sketches were made in Adobe Photoshop CC while Catia V5 was used for 3D modelling of the solutions. Models were then 3D printed and tested.

3.7 Testing the Concepts

The prototypes were manually assembled to be tested regarding the mechanical performance. After the testing, some parts of the devices needed optimization and adjustments. Improvements were conducted until highest acceptable level of efficiency and functionality was obtained. Efficiency of final concepts was tested on a number of repeated usages, whose results are presented in Chapter 5.

4 Screen of Potential Solutions

The most promising potential device concepts for opening the capsules that came up during the brainstorming process are presented in this chapter. The results of the defined requirements according to which solutions were evaluated and ranked are summarized below.

4.1 Requirements

For any device development it is of great importance to consider the interface with the final user. In this respect, the device should not add additional complexity to the opening procedure. The device functioning should build on the reasonably easy to open mechanism of the capsule and replace the manual opening by a mechanical, semi-manual opening mechanism. That is why easy to handle and efficiency of opening was weighted with the highest priority. The simplicity of the opening mechanism is a precondition for successful product prototyping and assembly as well as for later manufacturing costs and commercialization. Capsule opener should be robust and durable if the device is to be used for at least 120 openings reflecting the maximum number of drug units per drug product. Easy insertion without capsule deformation and effortless ejecting should be provided. Cutting or destroying of the capsule is to be avoided as being considered as a risk for overall user experience. Since the initial evaluation was being made before the prototyping phase, the important factor was estimating the ability of the device to really open a capsule – based on initial designs and assumptions. Compactness is weighted the lowest as the main focus of this thesis is on the capsule opening mechanism and barely on the exterior device of the device.

Table 2: Device requirements and their priority of importance (in %)

Requirement	Weight
Estimated efficiency	22%
Ease of handling	17%
Ease of capsule insertion	14%
Mechanism simplicity	13%
No cutting of the capsule	12%
Robustness	9%
Ease of capsule removal	8%
Compactness	5%

4.2 Initial Concepts

During the brainstorming it occurred that the gelatin capsules can be easily opened with the grip of a rubber. Rubber has good adhesion properties with hard gelatin capsule shells upon low contact forces and without deformation of the capsule shells. The core of all solutions is based on this cognition.

4.2.1 Concept 1 – Capsule Keychain

This solution is in the form of a keychain. It consists of a two-piece hard case with rubber holders in the interior of the device (Figure 4). The capsule is placed inside and safely stored until needed. The concept has appearance and is colored like the capsule to remind the user in which position capsule should be placed. Upon opening the device, the capsule is opened as well due to each part of a capsule being held in opposing rubber holders.

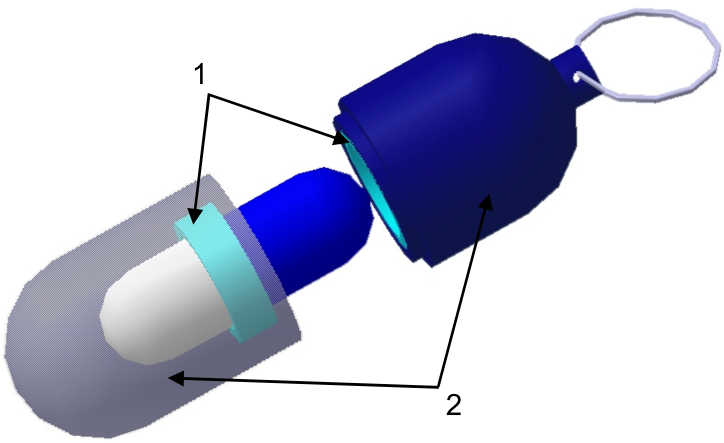


Figure 4: Capsule keychain concept; (1) rubber holders, (2) hard case

Removal of the capsule after usage would be rather difficult due to the possibility of the capsule for being pushed too deep in the rubber holders. Implementing a spring driven ejection mechanism would not be simple enough to meet the requirements of the solution. While the concept is mainly suitable for a single capsules, it would be limited for the routine use of medication for which the device concept in this thesis is intended. However, this concept might be highly suitable for “urgency medication” which dissolve quickly in the mouth for buccal absorption (e.g. nitrates for angina pectoris).

4.2.2 Concept 2 – Rubber Finger Gloves

The simplest device that was identified was the use of simply two rubber glove on thumb and forefinger (Figure 5). Rubber enables easier holding and opening while preventing potential slipping with very low grip strength required.

Constantly putting gloves on and off requires dexterity and can be a difficult procedure for patients with impaired functioning.

Figure 5: Rubber finger gloves concept

Similar to the finger gloves, a user can attach rubber stickers to the fingers (Figure 6). Stickers are not a long-term solution due to its limited life cycle. Nevertheless, it is more user-friendly than the gloves.

Figure 6: Rubber finger stickers concept

Rubber stickers and gloves could solve the problem of potential slipping of the capsule, but they do not meet the need of the capsule being opened by a mechanism and not directly with the fingers. Despite the lack of presenting a mechanical opening of the capsule, such concepts would require education and user training to be successfully applied by patients.

4.2.3 Concept 3 – Rubber Holder

This solution is based on the rubber ring with the plastic case around for easier handling (Figure 7). To open a capsule, the user needs to place the body of the capsule into the rubber ring and pull off the cap manually. The rubber ring facilitates holding the body of the capsule and provides easier opening of the cap. Furthermore, the body being held in the plastic holder provides simpler and more stable holding of the body during the opening and prevents that particulates can fall out during opening. Moreover, the opened capsule can be pour into food or beverages more easily for administration. After the usage, the body of the capsule is being removed manually out of the rubber.

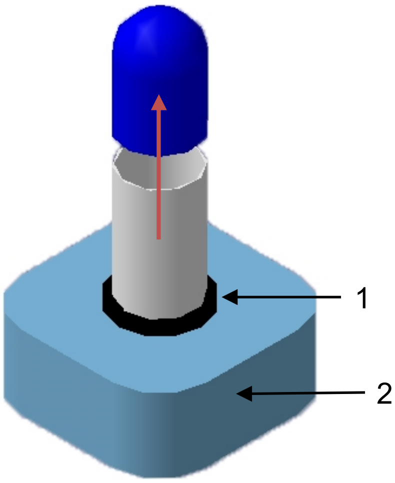


Figure 7: Rubber holder concept; (1) rubber ring, (2) plastic case

The potential problem is pushing the body of the capsule too deep into the rubber ring, which could make it difficult to remove it later. In addition, this concept bears the risk that user would push the cap into the holder and particles would fall out, when removing the body. After the testing of the concept, it was concluded that the optimal height of the capsule body in the rubber ring for the easier removal would at least be around 10 to 12 mm (body height of the capsule is 18.44 mm).

Even this concept is very simple and easy to produce; the opening mechanism would still be manual and require certain grip strength and dexterity of the user. Another limitation of this concept would be the transferability to smaller capsule sizes as this would require increasing fine motoric capabilities.

4.2.4 Concept 4 – Rotating Gears

This concept is based on the rack and pinion mechanism. A rack and pinion gears system consists of two gears. The round gear is known as the pinion and the straight gear is the rack.

Racks are connected with the lever (Figure 8). After putting the capsule in the rubber holder, the user needs to push the lever down. Being pushed down with the lever, racks start the rotational motion of the pinions. Pinions are fixed so they are rotating only around their axis. Pinions should be made out of rubber for better adhesion with the capsule. Load of the pinions on the capsule and friction between them while rotating pushes the cap through the hole of the device.

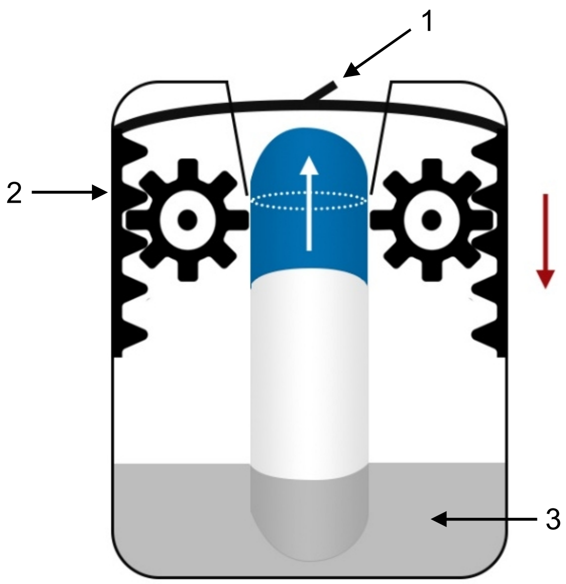


Figure 8: Rack and pinion mechanism concept ; (1) lever, (2) rack and pinion mechanism, (3) rubber holder

This mechanism is recognized as the most promising and innovative one. This idea is taken to be finalized and 3D printed.

4.2.5 Concept 5 – Revolute Joint

This concept is based on the simple revolute joint mechanism. A revolute joint has one degree of freedom and provides single-axis rotation function. The device consists of a two-piece plastic housing connected with the revolute joint (Figure 9). In the interior of the housing, both at the top and the bottom, there is a rubber holder.

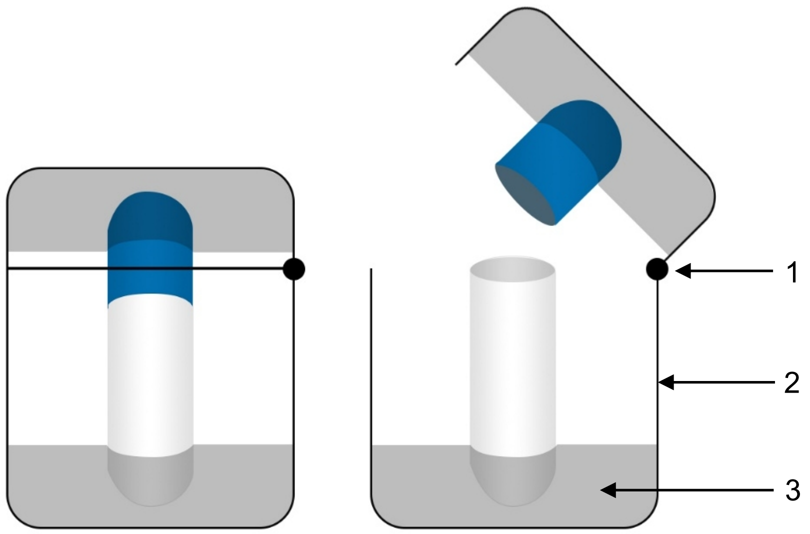


Figure 9: Revolute joint concept; (1) joint, (2) plastic housing, (3) rubber holder

Once the capsule is placed with the body side into the bottom rubber holder, the device needs to be closed whereby the cap is captured by the rubber holder of the top housing chamber. To open a capsule, the user simply needs to open the device again, moving the joint. Since the cap of the capsules is fixed in the top chamber, the movement of the joint opens the capsules as rubbers are holding the cap and the body of the capsule.

Recognizing the simplicity of this concept, it is taken to be further developed and 3D printed.

4.3 Requirement Score Table

The five previously explained concepts were evaluated with regard to the defined requirements and ranked with criteria weighting. Grades from 1 to 10 express how much each concept meets the criteria, whereby 1 means unmet and 10 fully met. Grades were multiplied with each criteria weight and summed up to a final score. Highest scores indicate products that meet the requirements the most.

All grades were assigned according to free estimation since there were no tangible prototypes in this phase. Table enables better overview of the final concepts and helps in the evaluation process. It needs to be emphasized that decision for the final concept was not only based on the weighted sum table. Highlighting pros and cons, research and innovative factor and simplicity were some of the criteria for choosing the most promising solutions.

As it can be seen from the Table 3, concepts 4 and 5 had the highest overall score and meet most of the criteria best.

Table 3: Concepts scores according to requirements

	Criteria								Weighted sum
	Estimated efficiency	Ease of handling	Ease of capsule insertion	Mechanism simplicity	No cutting of the capsule	Robustness	Ease of capsule removal	Compactness	
	22%	17%	14%	13%	12%	9%	8%	5%	
Concept 1	8	7	7	10	10	7	3	10	5.84
Concept 2	6	5	8	10	10	6	10	9	7.57
Concept 3	8	7	9	10	10	8	7	10	8.49
Concept 4	9	9	9	8	10	8	9	10	9.13
Concept 5	9	9	9	10	10	8	7	10	9.05

5 Concept Development and Testing

This chapter centers on the tangible prototyping of two concepts. The first concept is based on the rotation of rubber cylinders. The core of the second concept is in the revolute joint mechanism. In the upcoming paragraphs, both concepts were explained in details, as well as their optimization process. At the end of the process each concept were 3D printed and assembled for real testing. Results were based on fifty performed capsule opening tests.

5.1 Concept 1

This concept is based on the initial idea of the rack and pinion mechanism (known as Concept 4 in the Chapter 4). During the 3D modeling it occurred that implementing the rack and pinion mechanism is rather complicated in such a small device. Especially the need to open the device to remove the body would be very challenging with connecting racks to the lever and not the most dexterous solution. The prototyping and assembly process clearly revealed the importance of simplifying the mechanism of opening to its most. It became obvious that for the opening process of the capsule, a flat surface touching the cap, rather than just the teeth of a gear would be a much better option. That is why rack and pinion mechanism is replaced with two spur gears with same size and same number of teeth. Rubber rollers are pushing the cap out during the opening process and are placed on the gears.

5.1.1 Constraints

During the concept prototyping following limitations were taken into the consideration:

1. **Unavailability of materials:** During the 3D printing of the device, rubber material was not available. The rubber holders, which were supposed to be 3D printed, are made by cutting the pen’s rubber cap which were not the perfect fit. Rubber cylinders were made out of plumbing rubber rings. This reflected mostly during the testing phase.
2. **Inaccuracy of 3D printer:** Small size of the device required small gears. Level of precision needed for 1 mm small gear’s teeth could not be perfectly accomplished. It needs to be taken under consideration the unwanted excess of the material during the 3D printing. This could affect the basic functionality of the mechanism, which is why premade gears were purchased. Therefore, the whole design of the device was built around the existing gears.
3. **Design simplification:** Design had to be simplified to allow easier assembly process.

5.1.2 Optimization of Concept 1

The optimized device consists of bottom and upper housing, handle, two gears, two rubber cylinders and rubber holder. Rubber holder is placed in the bottom case while the opening mechanism is fixed in the upper housing (Figure 10).

Gears are attached to the small cylinders in the upper housing, around which they are rotating (Figure 11). Handle is attached to one of the gears and goes through the rubber roller. Plastic cylinder is attached to another gear around which is rubber roller as well.

On top of the upper housing there is a hole through which the cap of the capsule is ejected during the opening process. Bottom case contains only the rubber holder, which holds the capsule body during opening process.

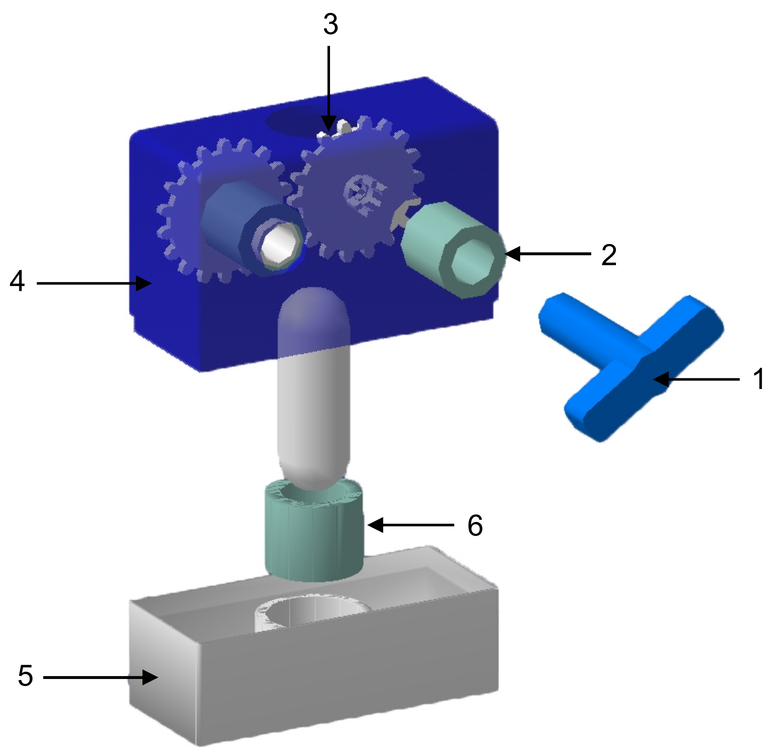


Figure 10: Concept 1 design; (1) handle, (2) rubber cylinder, (3) gear, (4) upper case, (5) bottom case, (6) rubber rollers

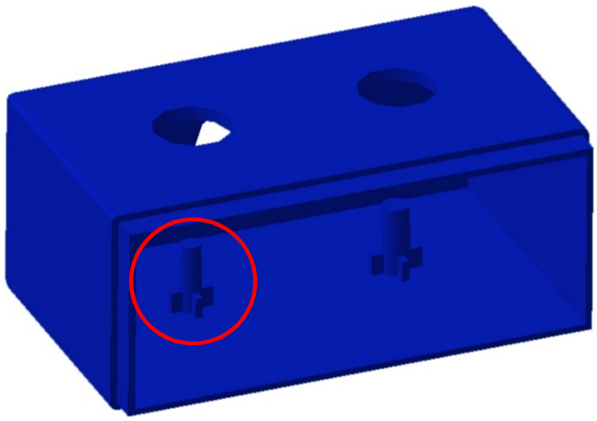
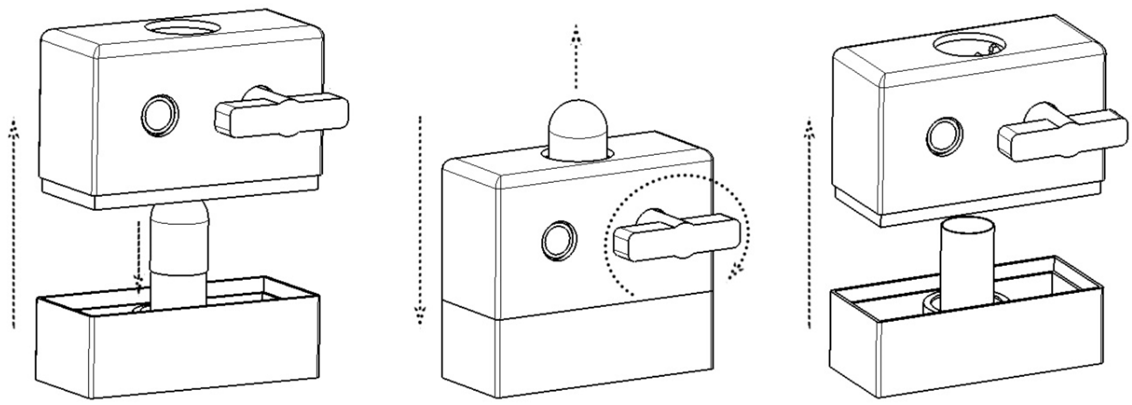


Figure 11: Concept 1 upper housing with gear holders

The device consists of two main pieces, upper and bottom housing. After opening the device, a capsule needs to be placed in the rubber holder in the bottom case. Once the capsule is placed and fixed, the device needs to be closed again and the handle rotated in the clockwise direction. Rotation of the rubber rollers separates the cap from the body. Once the cap is ejected out through the hole in the upper housing, the user needs to open device again to pour out the capsules content on food or in beverages before removing the body from the rubber. (Figure 12)



Open the device and place the capsule in the rubber holder.

Close the device and rotate the handle in the clockwise direction.

Open the device and remove the body from the rubber holder.

Figure 12: Concept 1 usage instructions

5.1.3 Opening Mechanism of Concept 1

Before the opening, cap and the body are in the closed position. The mechanism of the device needs to overcome these lock forces to separate the capsule. This chapter explains simplified forces applied on the capsule during the opening.

Friction between the capsule and the rubber assures there is no sliding between. During the opening of the capsule three forces applies. F1 is the force, which pulls the cap up during the rollers rotation and separates the cap from the body. F1 is equal to product of the role pressure on the capsule (the load with which the rolls press against the capsule), p, contact surface (multiplied by two as there are two rollers), A, and the friction factor, μ (5.1).

$$F1 = 2pA\mu \tag{5.1}$$

F2 is the lock force of the capsule, which resists the movement of the cap.

F3 force is the sum of the capsule weight, Fg, and the friction force between the body and lower rubber holder, resisting the movement of the capsule (5.2).

$$F3 = Fg + Ftr \tag{5.2}$$

Condition F1>F2+F3 must be conducted to enable pulling the cap up separating her from the body (Figure 13).

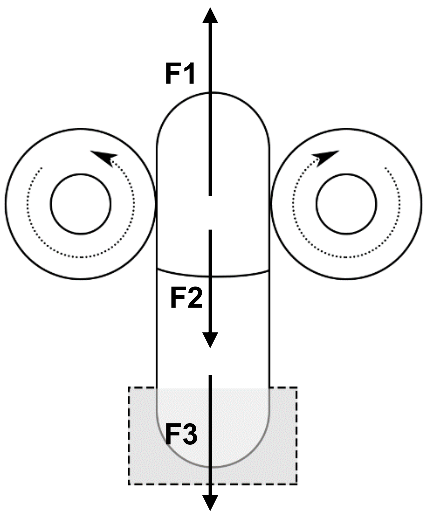


Figure 13: Forces applied on the capsule in Concept 1

5.1.4 Design and Materials of Concept 1

Materials used in prototyping were plastic and rubber. Capsule holders in ring shape and rollers are made of rubber. Housing of the device and the handle were 3D printed (Figure 14). Material used for 3D printing was Polylactic Acid (PLA), which is a type of polyester. With total volume of the 3D printed elements being 4.81 cm^3 and the density of PLA 1.25 g/cm^3 [6], calculated weight of the parts is 6.05 g.

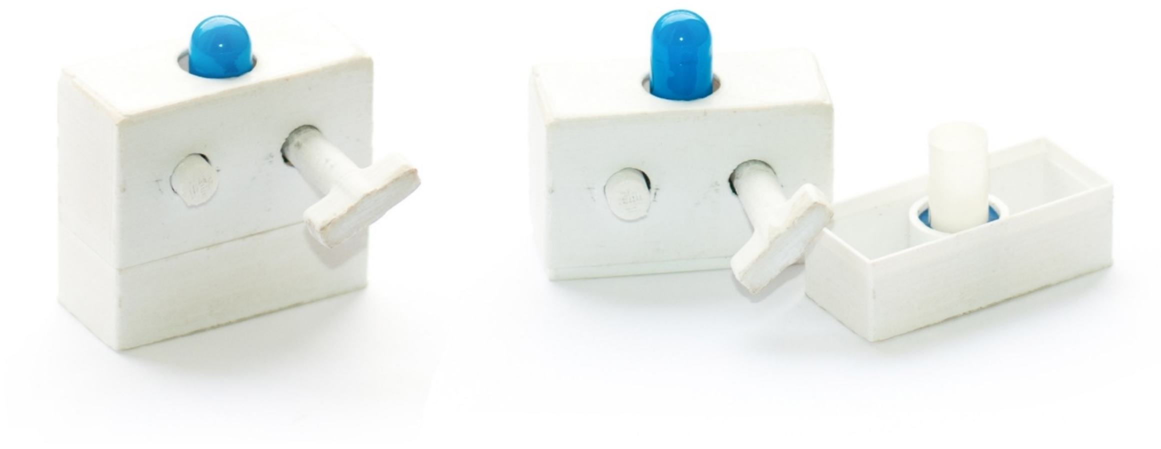


Figure 14: Concept 1 prototype

Device is designed to fit easily in one's hand. Figure 15 shows dimensions of the housing with the shell thickness of 1 mm. For more intuitive usage lower housing could be colored in white while upper one is blue to follow the capsule design.

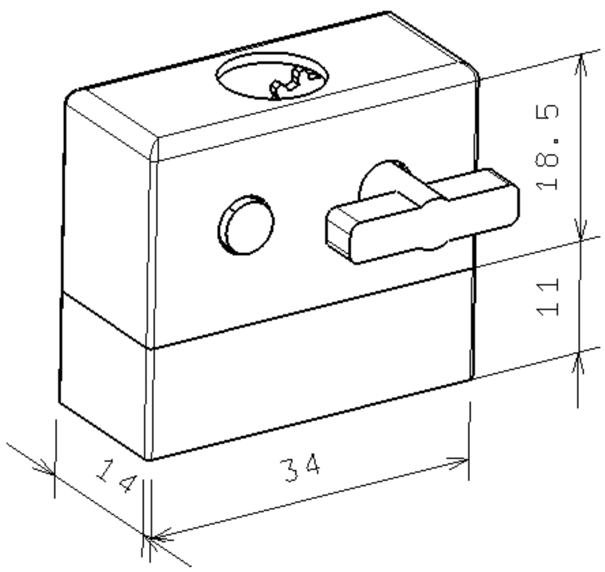


Figure 15: Concept 1 housing dimensions

5.1.5 Concept 1 Testing

This chapter shows the testing procedure and results based on two test scenarios. Each testing scenario was conducted 50 times.

5.1.5.1 Test Scenarios

The concept was tested on two test scenarios:

I. Putting the capsule from the top:
   1. Put the capsule through the hole on the top.
   2. Rotate the handle in counterclockwise direction.
   3. Stop when the capsule reaches the rubber holder in the bottom.
   4. Rotate the handle in clockwise direction.
      Expected result: Capsule cap is separated from the body, while body remains in the rubber holder.

II. Putting the capsule from the bottom:
   1. Open the device.
   2. Put the capsule in the rubber holder.
   3. Close the device.
   4. Rotate the handle in the clockwise direction.
      Expected result: Capsule cap is separated from the body, while body remains in the rubber holder.

5.1.5.2 Test Results

Table 4 contains the number of successful and failed tries with the success rate at the end.

Table 4: Concept 1 test results

	No. of successful tries	No. of failed tries	Success rate
Scenario 1	45	5	90%
Scenario 2	50	0	100%

Two types of failures occurred during the test scenario 1. Due to the hole on the top housing being bigger than the external capsule diameter, there is a slight chance that capsule is not positioned right (vertically) at the beginning. This can disable the rollers to pull the capsule down. During the testing, this type of failure occurred four times. Rubber not holding the body of the capsule tight enough causes the cap not to be separated. This type of failure occurred once and might be cause by insufficient rubber introduction forces or non-vertical downwards movement. During the test scenario 2 no failure occurred.

Table 4 shows the success rate of the opening mechanism only; still some observations during the test process need to be emphasized.

Even though test scenario 2 has a 100% opening mechanism success rate, the usage of the device is more inconvenient. User has to open the device twice as more than in the scenario 1. Also, body of the capsule is more tightly held in rubber which makes it a bit harder to pull it out afterwards.

5.1.5.3 Meeting the Requirements

Previously shown test results are focused only on the efficiency of the opening mechanism. Device requirements table was filled for both scenarios and shows how device meets the initially set requirements. Efficiency criteria was taken from the previously made test results. Other criteria are self-estimated based on personal observations and serve only for an approximate comparisons.

Table 5: Concept 1 requirements scores after testing

	Criteria								Weighted sum
	Efficiency	Ease of handling	Ease of capsule insertion	Mechanism simplicity	No cutting of the capsule	Robustness	Ease of capsule removal	Compactness	
	22%	17%	14%	13%	12%	9%	8%	5%	
Scenario 1	9	8	8	8	10	6	8	10	8.38
Scenario 2	10	7	8	8	10	6	7	10	8.35

5.1.6 Concept 1, Version 2

Second version of the Concept 1 uses the same opening mechanism but differs in the diameter of the hole on the top housing and misses the rubber holder in the bottom one. The hole has the same diameter as the body of the capsule allowing the capsule to be introduced into the device through the body part until the larger diameter of the cap hits the device surface. This assures that only the body of the capsule can get through as the cap is a bit wider than the hole (Figure 16).

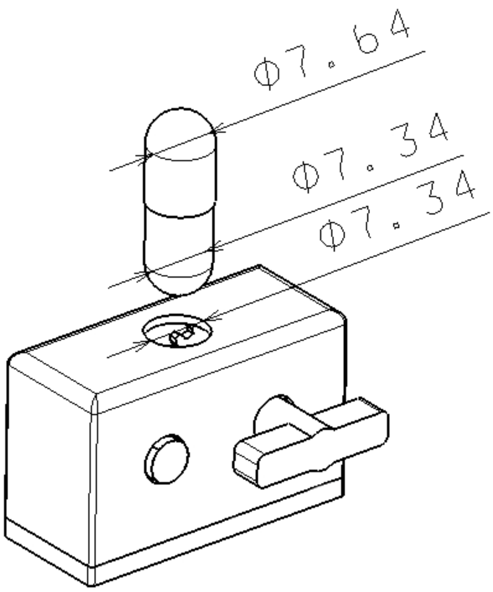


Figure 16: Concept 1, Version 2 design

Rubber holder for the body part is not necessary as the smaller diameter stops the cap from moving downwards. In this concept, the device is meant to be used just by rotating the handle. To pull the body down and to separate the cap the handle should be rotated in the counterclockwise direction. While the body touch the bottom of the housing, the edge of the open body end is aligned with the surface of the upper housing, the cap falls apart and the content of the body can be sprinkled out. Afterwards, the capsule body is supposed to be ejected back through the same hole rotating the handle in the clockwise direction.

Version 2 was 3D printed and analyzed (Figure 17). During the opening process, body is being a bit squeezed between the rollers, which makes the ejection hardly possible. Since this was a single 3D printed device, further improvements can be achieved by higher precision parts to avoid this issue.

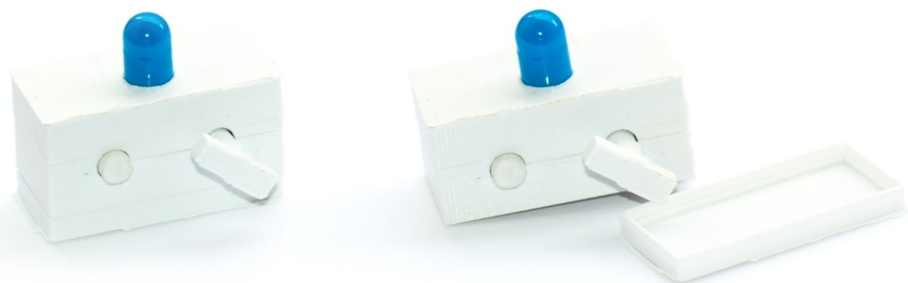


Figure 17: Concept 1, Version 2 prototype

5.2 Concept 2

This concept uses the simple revolute joint as an opening mechanism. This chapter shows the three iterations to the final solution with the test results of the final one.

5.2.1 Constraints

During the concept prototyping following limitations were taken into the consideration:

Unavailability of materials: During the 3D printing of the device, rubber material was not available. The rubber holders, which were supposed to be 3D printed, are made by cutting the pen's rubber cap, which were not the perfect fit. This reflected mostly during the testing phase.

5.2.2 Optimization of Concept 2

Concept 2 was optimized several times. In this chapter different versions that led to the final concept are presented.

5.2.2.1 Version 1

This concept consists of a two piece housing connected with the revolute joint, and two rubber rings that serve the purpose of capsule holders (Figure 18). Revolute joint enables single axis rotation. Bottom housing is set to be fixed and serve the purpose of holding the capsule. Upper housing is movable and is used to remove the cap from the body.

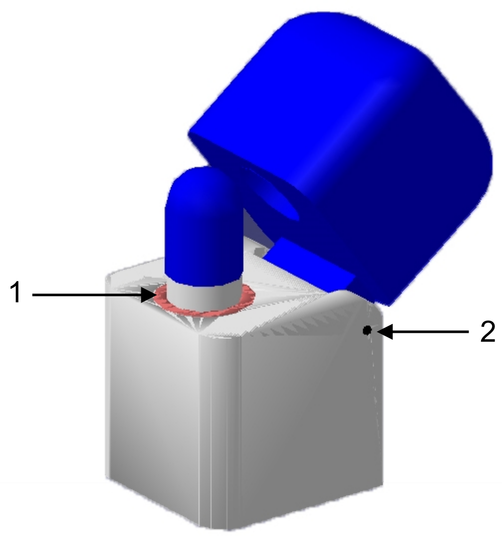


Figure 18: Concept 2, Version 1 design; (1) rubber holder; (2) revolute joint

Once the device is opened, the body part of the capsule needs to be placed in the rubber ring of the bottom housing. Closing the device sets the cap of the capsule in the upper rubber ring. Due to the different diameter of cap and body, the two rubber holes differ in diameter, making it very difficult to introduce the cap part into the rubber ring of the bottom housing. Additionally the use of color cues of the capsule and the device could facilitate intuitively the correct use. When device is closed, capsule should be placed in two opposing holes. To open a capsule, user simply needs to open the device again as the forces holding the cap and the body are higher than the forces required to separate cap and body.

After 3D printing of the model (Figure 19), several problems were spotted. It is impossible to close the device with the capsule in the bottom ring, unless the body was pushed too deep. Pushing the body too deep disables easy removing afterwards.

Figure 19: Concept 2, Version 1 prototype

5.2.2.2 Version 2

The new design has a different approach in placing the capsule into device. Bottom housing is shorter with a hole going through the whole housing. In this concept capsule should be placed from the bottom through the hole (Figure 20). This approach decreases the number of openings and closings and is simpler to use. With this type of housing, the problem of impossible closing is fixed.

The upper case has a conical hole for easier removing of the cap. One possible idea is to make the whole device out of rubber. This approach could allow the squeezing of the capsule after the usage.

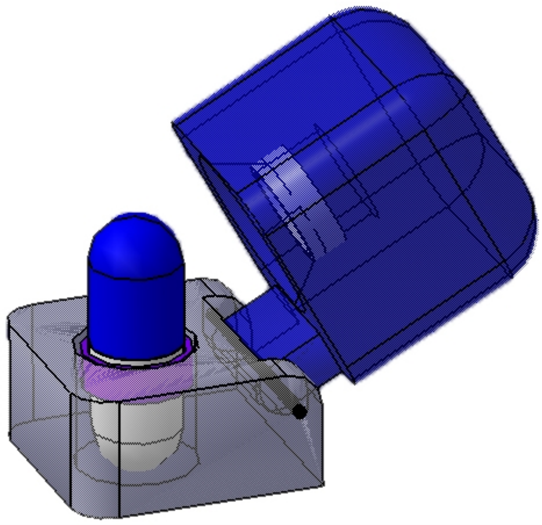


Figure 20: Concept 2, Version 2 design

After analyzing the 3D printed model (Figure 21), it is concluded that conical hole is not effective as expected. Cone of the hole is too large and therefore rubber holder placed to high. During the opening, rubber holder is not able to grip the cap enough.

Figure 21: Concept 2, Version 2 prototype

5.2.2.3 Version 3

Figure 22 shows the third iteration of the Concept 2. Upper housing is shorter than in previous two iterations to assure easier cap removal, which was a major problem. Designed like this, the device enables putting the capsule through one of the holes.

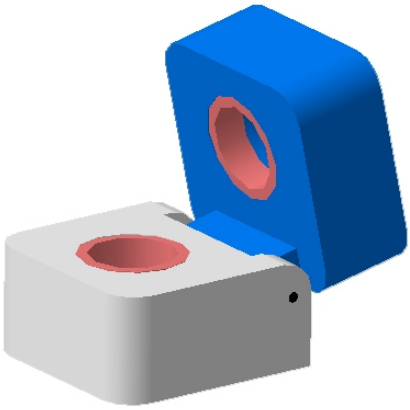
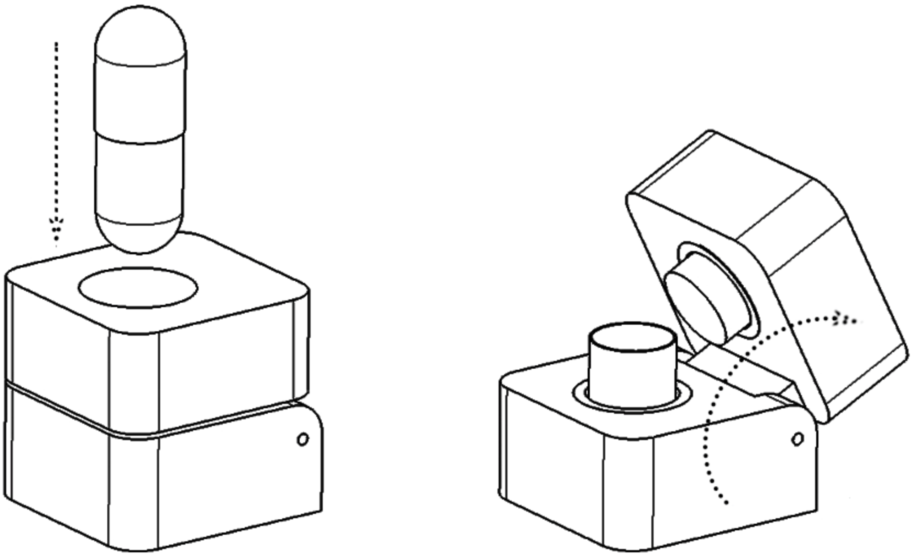


Figure 22: Concept 2, Version 3 design

Both housings contain a hole in which rubber rings are placed. It needs to be emphasized that rubber holders are shorter than the housing. Shorter rubber holders enable easier capsule removal after the usage, but are still strong enough to hold the parts during the opening process. Housings are connected with the revolute joint.

Figure 23: Concept 2, Version 3 prototype

To open a capsule, user needs to slide the capsule through one of the holes and pull up the upper housing (Figure 24). Capsule is separated due to body and cap being held in opossing holders. To overcome locking force of the capsule only the finger force has to be applied with the friction between rubber holders and capsule as enabler. After the usage cap and body should be removed manually.



Slide the capsule through the hole. *Pull up the upper housing.*

Figure 24: Concept 2, Version 3 usage instructions

5.2.3 Concept 2, Final Version

In the final concept, conical ends were added for the easier releasing of the capsule halves (Figure 25). Both the opening mechanism and capsule insertion procedure are equivalent to those of Version 3. Due to the conical end of the holes, the two concepts differ in the method of removal of the previously opened capsule.

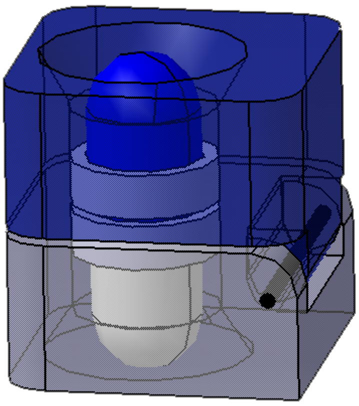
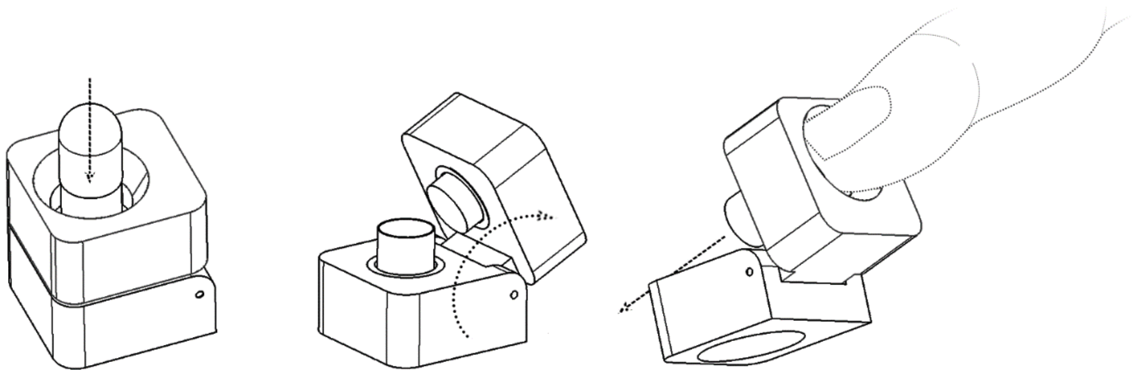


Figure 25: Concept 2, Final Version design

Conical ends on both holes allow fingers a further and an easier access to the capsule tips enabling easier removing of the used capsule by finger push (Figure 26).



Slide the capsule through the hole.

Pull up the upper housing.

Push the capsule halves after the administration.

Figure 26: Concept 2, Final Version usage istructions

5.2.3.1.1 Design and Materials

During the prototype process two materials were used, rubber and plastic. Ring holders are made out of rubber. Upper and bottom housing were 3D printed out of PLA (Figure 27). With total volume of the 3D printed parts being 6.02 cm^3 and the density of PLA 1.25 g/cm^3 [6], calculated weight of the elements is 7.5 g.

Figure 27: Concept 2, Final Version prototype

Figure 28 shows the dimensions of the housing. Concept was designed to be easily handled with fingers. To know when the capsule is placed accurately the height of the device approximately fits to the height of the closed capsule. Housings were again meant to be differently colored to follow the capsule design.

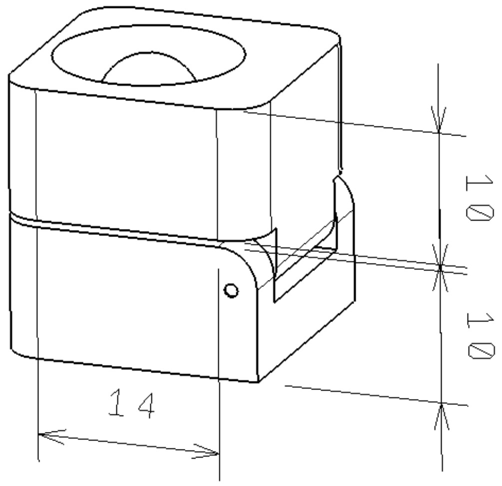


Figure 28: Concept 2, Final Version housing dimensions

5.2.4 Concept 2 Testing

This chapter contains testing results based on 50 opening tests.

5.2.4.1 Test Scenarios

Efficiency of the opening mechanism was tested on the following test scenario:

1. Slide the capsule through the upper hole.
2. Pull up the upper housing.
   Expected result: Capsule is separated with each part being placed in opposing rubber holder.

5.2.4.2 Test Results

Table 6 shows the success rate of the opening mechanism calculated from the number of successful and failed tries. Testing was conducted 50 times.

Table 6: Concept 2 test results

	No. of successful tries	No. of failed tries	Success rate
Concept 2	43	7	86%

One type of failure occurred during the test process in which the upper housing pulls the capsule unopened. This type of failure occurs due to the capsule not being pushed deep enough and therefore not properly placed in the bottom rubber holder. With the 7 failing tests success rate is 86% which is a good indicator this concept has a great potential. One possible culprit are the not perfect fit of the rubber holders, which were taken from the pen for the need of prototyping. It is to assume that fine tuning can optimize the mechanism.

5.2.4.3 Meeting the Requirements

Device requirements table shows how device meets the initially set requirements (Table 7). Table was filled both for Version 3 and Final Concept. Efficiency criteria was taken from the previously made test results. Other criteria are self-estimated based on personal observations and serve only for an approximate comparisons. Since the two concepts differ only in the type of a hole, all criteria except ease of capsule removal are assumed to be equal. Conical ends of the holes noticely improved the ease of capsule removal.

Table 7: Concept 2 requirements scores after testing

	Criteria								Weighted sum
	Efficiency	Ease of handling	Ease of capsule insertion	Mechanism simplicity	No cutting and of the capsule	Robustness	Ease of capsule removal	Compactness	
	22%	17%	14%	13%	12%	9%	8%	5%	
Concept 2, Version 3	8.4	9	8	10	10	7	7	10	8.67
Final Concept 2	8.4	9	8	10	10	7	9	10	8.85

6 Conclusion

With increasing age and morbidity, swallowing problems of standard tablets and capsules is an increasing issue in delivering especially higher dosed medicines to patients. In case the tablet or capsule cannot be swallowed intact, an alternative is the use of small multi particulates or mini-tablets that can be dispersed in food or beverages for intake. Coni-Snap® Sprinkle capsules are designed to meet the needs of a rapidly growing population with swallowing difficulties by a much easier opening compared to the standard Coni-Snap® capsules. Still there are many patients or care givers to whom the opening of capsules could be a challenge or is even impossible.

The objective of this thesis was to develop a semi-manual capsule opening devices to resolve issues with manual handling and opening the capsules. Devices are designed to place the capsule intuitively in the right direction and to open the capsule by “pull” or “turn” operation. Two most promising approaches were introduced. During the prototyping phase devices were optimized several times until highest acceptable level of performance was achieved.

The first approach uses the turn of a handle for opening the capsule. Concept 1 is based on the rubber rollers, which are pulling the cap off the body during the rotation. After opening the device, a capsule is placed in the rubber holder in the bottom case. Once the capsule is placed and fixed, the device is closed again and the handle rotated in the clockwise direction. Once the cap is ejected out through the hole in the upper housing, the user opens the device again to pour out the capsule’s content.

The second approach is based on “pull” operation. Final concept consists of two-piece hard housing connected with revolute joint. Each housing contains two holes with conical ends and rubber holders inside. To separate the capsule halves, capsule is simply slid through the upper hole and upper housing pulled up. After the usage, capsule halves are ejected by finger push through the conical ends.

Test results show 90% and 100% success rates (depending on type of usage) of Concept 1 and 86% success rate of Concept 2, which is a great indicator of mechanisms potential. Success in meeting the requirements such as efficiency, ease of handling, ease of capsule insertion, and mechanism simplicity was rated with 8.38/10 for Concept 1 and 8.85/10 for Concept 2.

Due to the limitations (unavailability of materials and perfectly fit parts) during the prototyping, the highest level of optimization could not be accomplished. This concepts will be enhanced and optimized by a higher precision of components and selected materials once put on the commercial path.

Beside the achieved high efficiency of performance, all proposed semi-manual opening device concepts are based on a 2-6 plastic parts and 2-4 rubber parts. The assembly in this thesis was done by hand without requiring special equipment. Thus, the proposed concepts can be considered being simple from a manufacturing standpoint as well as relatively cost effective for commercial purposes.

The semi-manual opening device development was purely focused on the mechanical part of the device and its efficiency to open the capsule. It should be noted that the usability of the device will also be guided by the ergonomic design, which was not part of this thesis. It can be expected that the ergonomic design can further address specific needs of different patient population. Since the housing of the proposed devices is very small, the device concepts allow a versatility of ergonomic designs, without increasing the complexity of the device. These patient centered ergonomically design semi-manual opening devices will have to be developed through usability studies in the relevant patient populations.

In summary, the proposed semi-manual capsule opening devices provide different concepts of which two concepts achieved the expected requirements. Optimization through higher precision parts can further increase the semi-manual capsule opening efficiency to 100 %. The semi-manual opening devices are characterized by a small mechanical housing, which will allow a high degree of freedom in the ergonomic design development to address intuitive use by different patient populations. The simplicity of the semi-manual opening device provides the bases for commercial viable manufacturing of the device.

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Notations

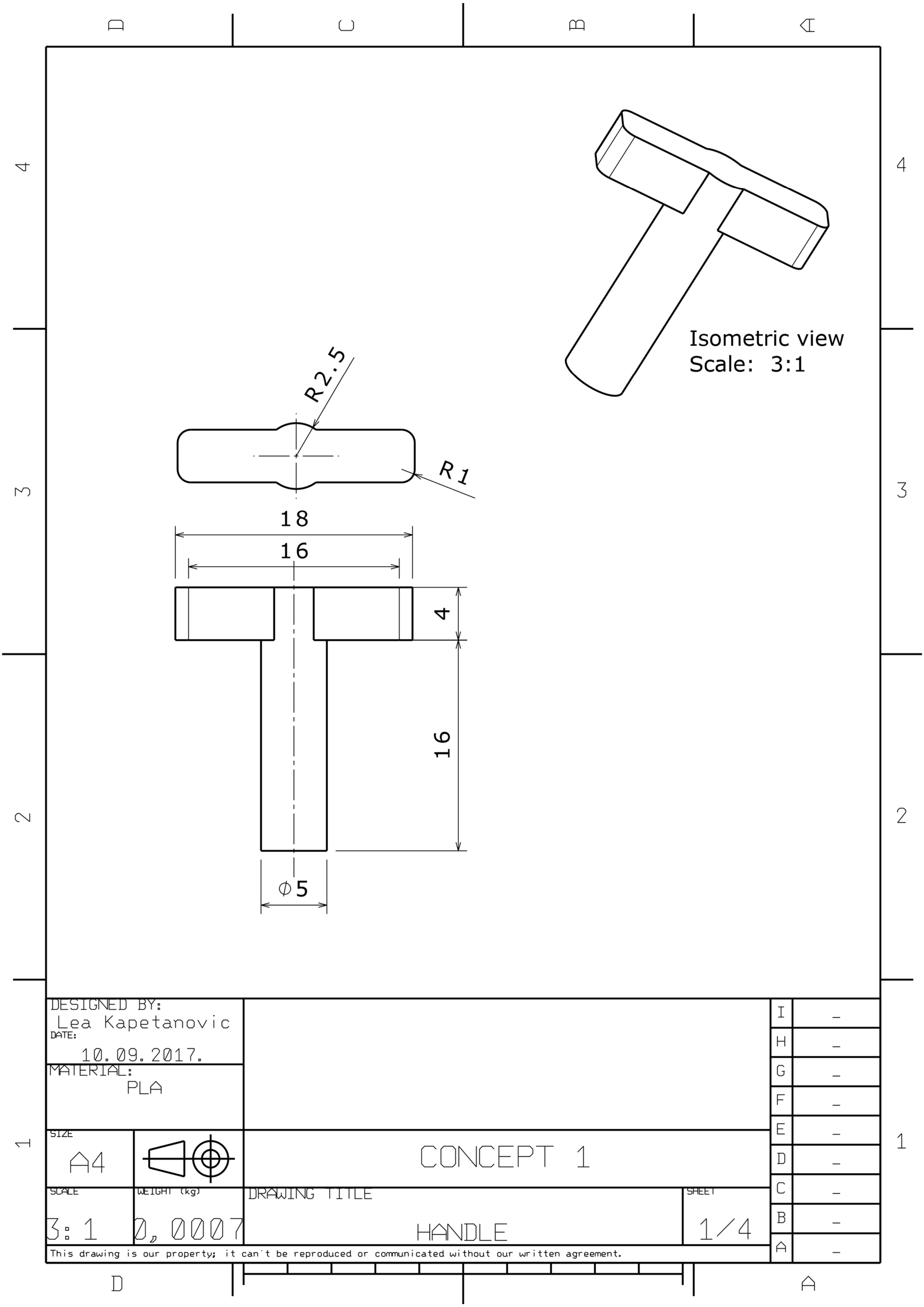
cm^3	cubic centemeter
g	gram
F	force
Fg	weight
Ftr	friction force
mm	milimeter
p	pressure
μ	friction factor

Appendix

Appendix 1: Final Concepts Drawings

This appendix consists of following drawings:

1. Concept 1:
   1.1. Handle
   1.2. Plastic roller
   1.3. Lower housing
   1.4. Upper housing
2. Concept 2:
   1.1. Upper housing
   1.2. Lover housing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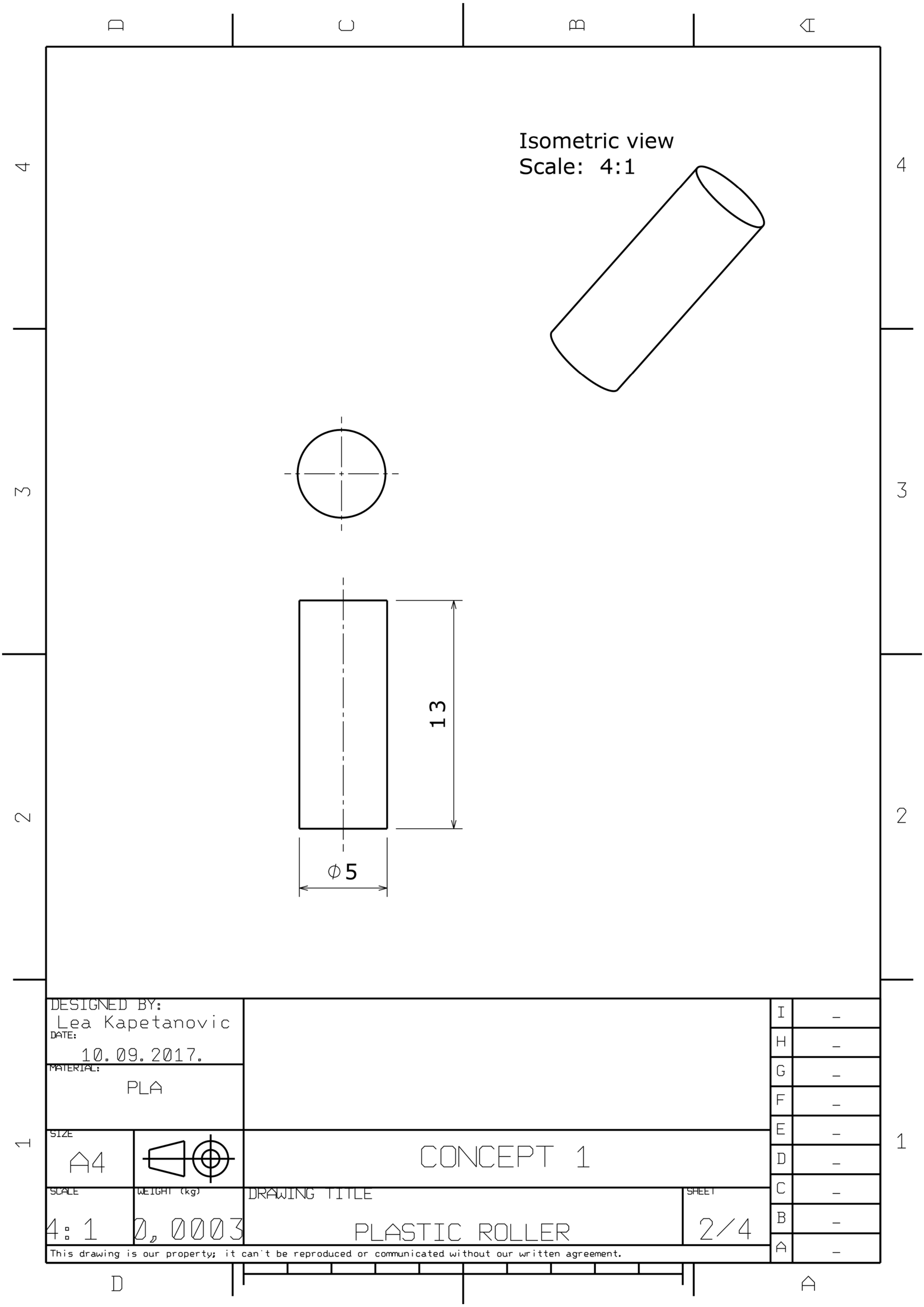
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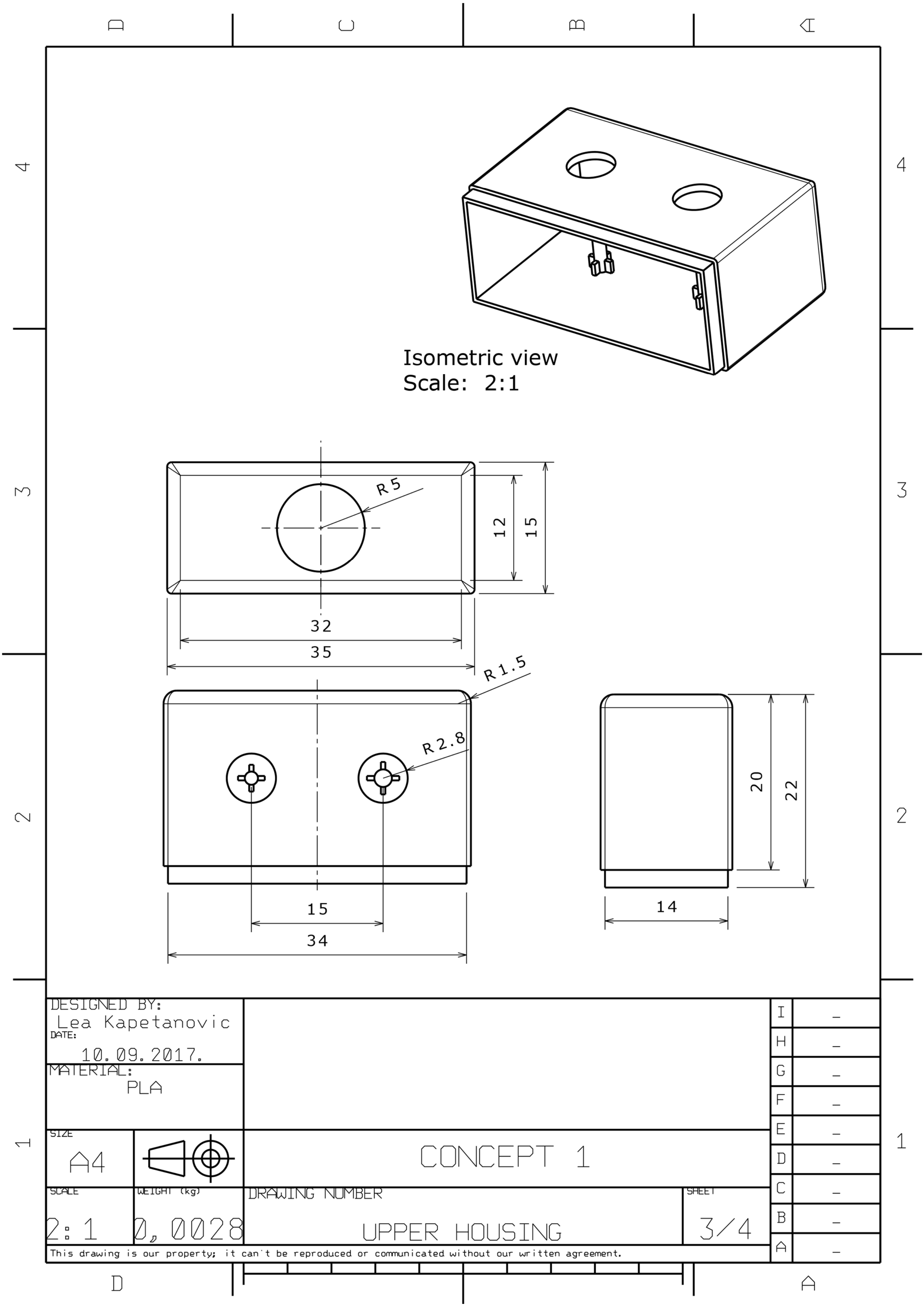
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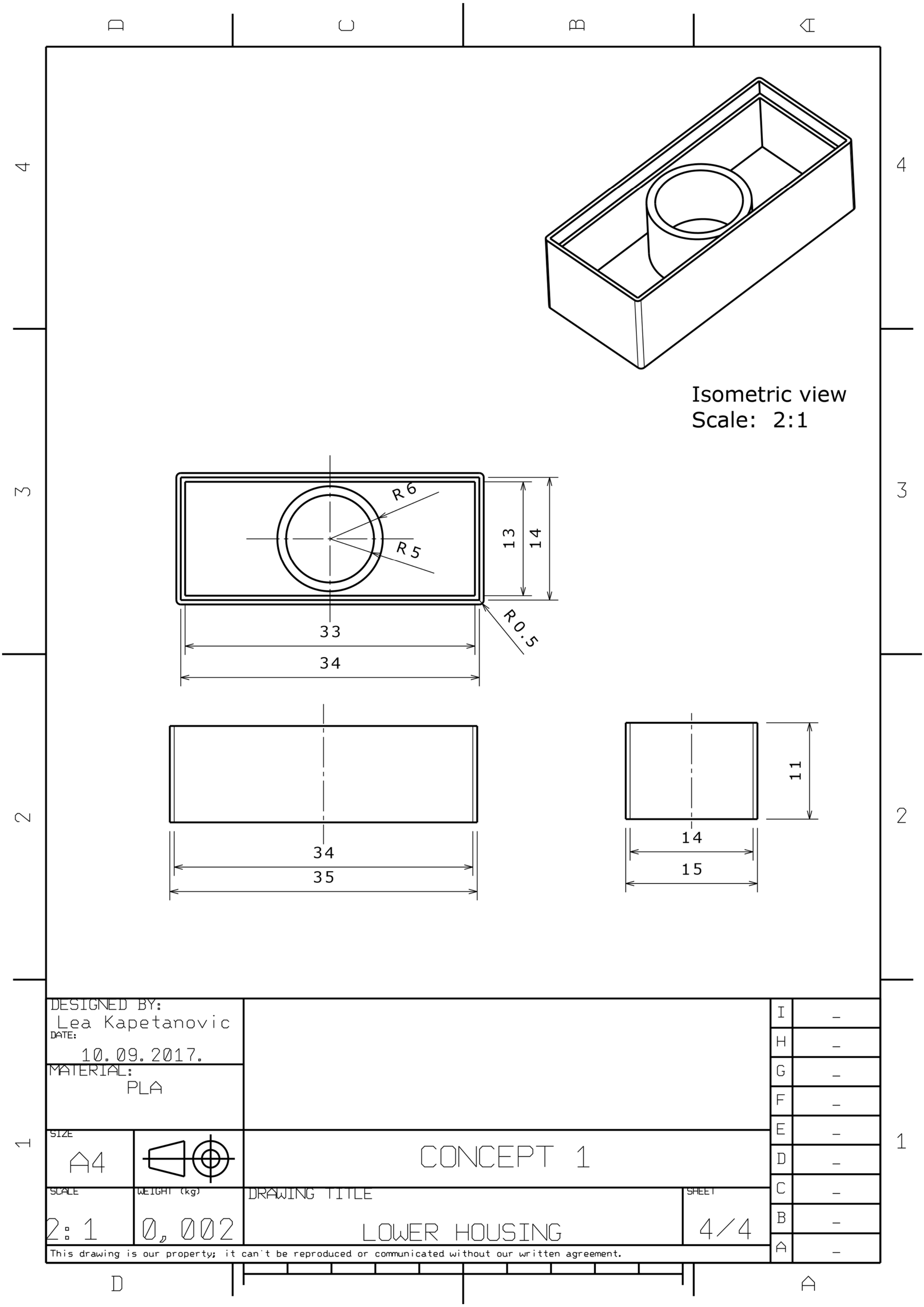
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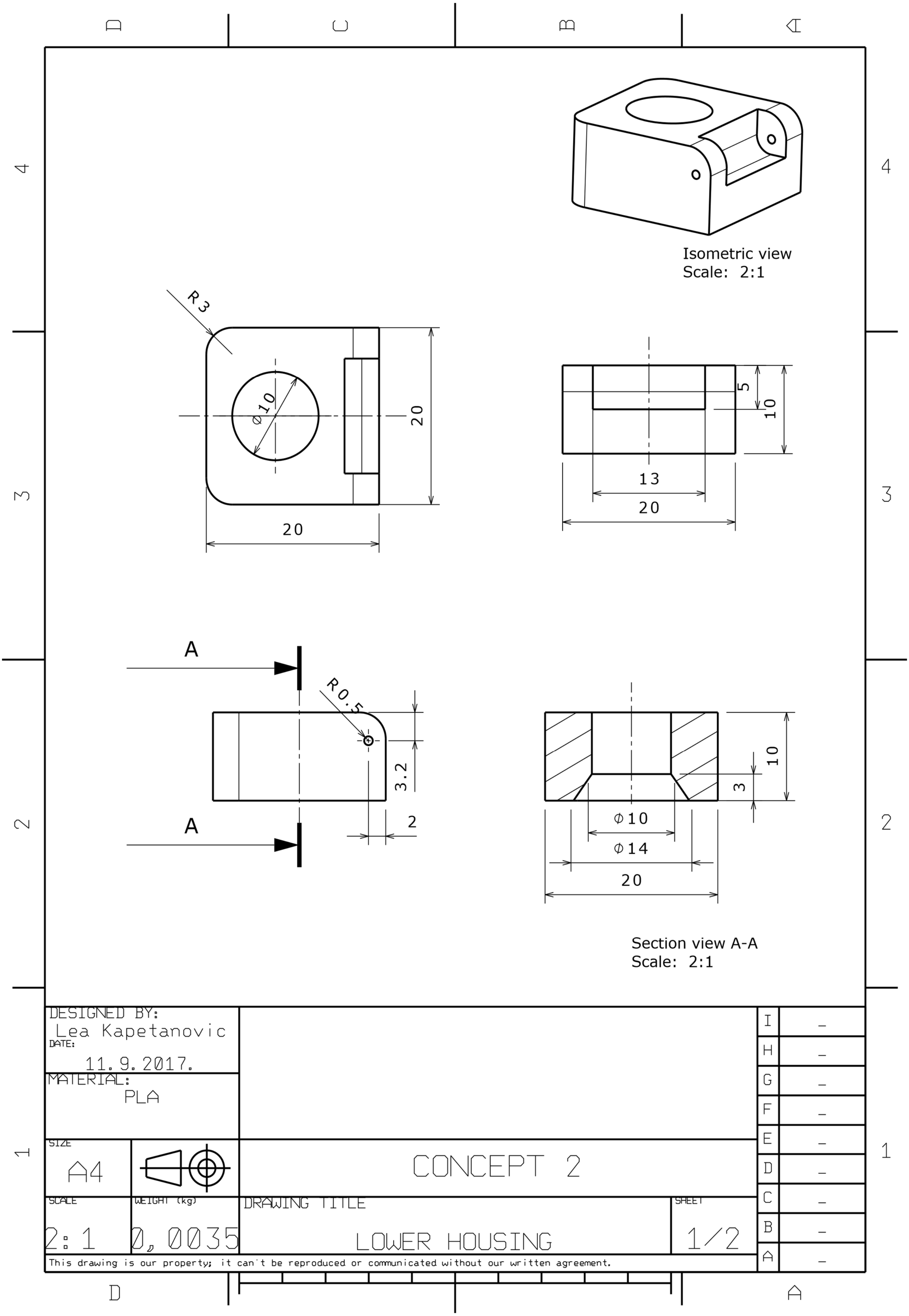
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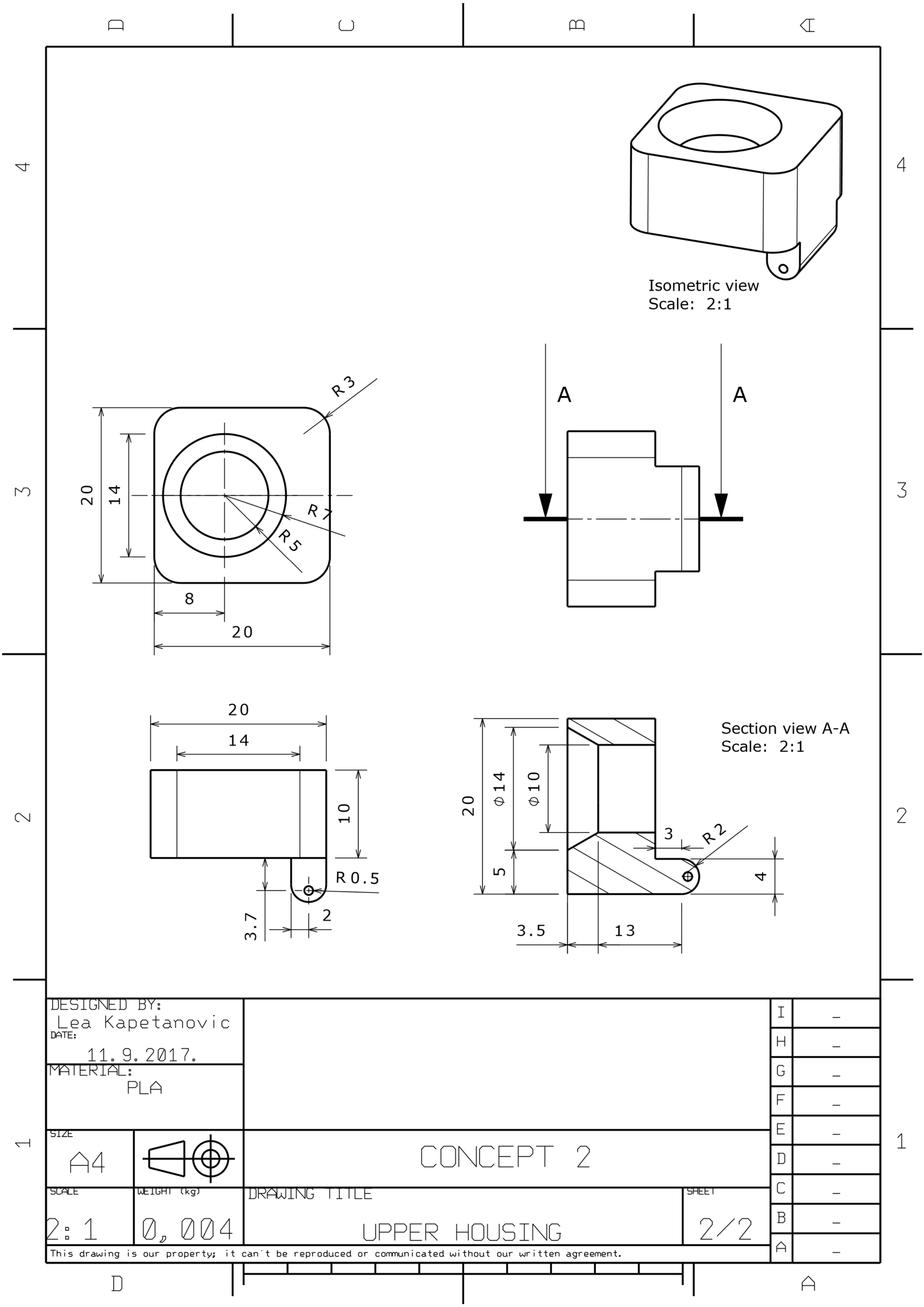
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