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**TDK Conference**  
**Molding Simulation of a Unique**  
**Spinal Implant**

**Name:**

**Eng. Batoul Wanous**

**Supervisor:**

**Dr. Gyorgy Czel**

**Neptun code:**

**X3H2KJ**

**Date:**

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- Abstract

This research is based on a new design for a unique spinal implant, specifically between the two vertebrae (L4 and L5). Using the NX Siemens CAD software and adopting the dimensions of a previous implant that was produced using a milling machine, with the aim of reproducing it in the future with PEEK (polyether ether ketone) using an injection molding machine (IMM) in order to reduce the production cost and the cyclic time. Despite the available transforaminal lumbar interbody fusion (TLIF) spine implants, improvements are needed to create ideal TLIF spine cage implants. This study aims to improve the spine implant, which can adjust to the direction and small size of insertion that match the spine size of patients, and the designed implant must withstand the body load. A molding simulation model was created to design this implant using Moldex 3D software to evaluate the proposed design before performing injection molding. This simulation provides insights into how different design parameters, material properties, and process conditions affect the molding process and the quality of the resulting part, which enables us to improve manufacturability, reduce the likelihood of defects occurring, and proactively address potential problems (such as weld lines, air traps or sink marks that may affect product quality).

**Keywords:** NX Siemens, Moldex 3D, Spinal Implant, PEEK, Injection Molding Machine.

## ● Introduction

Spine is a very flexible structure that may twist and curve in multiple directions. The complex of approximately twenty bones that make up the spinal column is designed to store and protect important components of the nervous system. A motion segment in the spine consists of the two neighboring vertebrae and the intervertebral disc, and all these components facilitate natural spinal motions [1]. However, spinal disorders such as degenerative disc disease, spondylolisthesis, deformative disorders, trauma, and tumors occur, which may result from factors including trauma, disease and degenerative conditions caused by injury and aging. These spinal disorders typically result in symptoms including pain, nerve damage, and a partial or complete loss of mobility. Pain can be treated through surgical procedures in which damaged discs are removed and replaced with implants inserted between adjacent vertebrae, thus restoring normal spacing and alignment. Typically, these implants are combined with materials that encourage bone growth to facilitate bone fusion and stabilization. These devices create new solid bone mass, providing weight-bearing support and holding the vertebral segment at a biomechanically restored height. These implants help reduce pain by relieving irritation and pressure on the spinal nerves [2].

Since the 1800s, related research has focused on finding the perfect biomaterial for spinal implants. The ideal biomaterial should be compatible with the implanted bone, biologically inert, have high stiffness, tensile strength, fatigue strength, and low imaging artifacts. Commonly used materials include titanium and polyetheretherketone in many shapes, like screws, rods, cages, and plates [3].

When spinal surgery first began, implants were made mostly of stainless steel and titanium using traditional machining methods like milling and turning. These early implants were mostly used for stability and fusion, and their design was simple.

However, in the 1980s, a new age of biomaterials was brought, when titanium alloys, cobalt-chromium alloys, and improved stainless steels with better biocompatibility and mechanical qualities were introduced [4].

The introduction of computer-aided design (CAD) and computer-aided manufacturing (CAM) software in the 1990s transformed the design and manufacture of implants by facilitating the creation of intricate and highly precise geometries. Additionally, the implementation of computer numerical control (CNC) machinery has enabled the productive fabrication of intricate implant configurations from a variety of substances, including titanium and polymers like PEEK [5].

Injection molding is a manufacturing process widely used to produce many plastic elements; however, it has not been used to directly produce spinal implants. Rather, other manufacturing methods are commonly used for spinal implant production, such as machining, or additive manufacturing (3D printing). Spinal implants which are made of materials like titanium or polyether ether ketone (PEEK) require high precision and excellent biocompatibility, and this cannot be easily achieved with injection molding machines [4].

Despite of the fact that the injection molding is a mass technology connected 10000 of production number, unique designed and low numbering products could be also possible by this technology. Nevertheless, PEEK is an extremely costly material (1 kg is equivalent to 200 euros). When it is manufactured using milling machines, a rod that requires an extrusion is needed, which weakens the covalent bond. This lengthy process takes 3.5 hours to produce a single piece, and 2/3 of the material is wasted.

However, if we use injection machines to produce it—a transparent technology—we will not waste any, and it will be produced in a matter of seconds from a raw material that requires no preparation before the injection process, strengthening the material.

I aim to design the appropriate implant size and geometry that is fit for injection molding and for human applications. I hope in the near future another engineer will create an inter-changeable mold cavity for implants to make it simpler the size changing of the product which is fit for low series implant production.

To manufacture an implant using injection machines, it is necessary to conceptualize and create a mold that satisfies the medical device industry's strict criteria for accuracy and exceedingly small tolerances. A virtual mold simulation is incorporated into the design process to evaluate and optimize processes and tools. With 3D simulation, I defined: tool design, runner placement, the gating system, filling behavior, packaging, cooling, and solidification. This will improve productivity, efficiency, and the quality of components, instilling considerable assurance prior to the release of the design.

After designing many versions of spinal implants and a lot of changing in parameters and shape, and many simulations running, here I will show the last version of the spinal implant as well as I will show the 3D printed sample of this spinal implant and will analyze the results after last version of molding simulation for this specific designed implant.

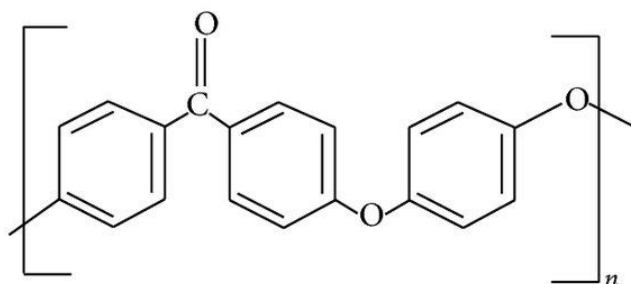
# 1. Literature Review

## 1.1 Background about PEEK:

PEEK or polyetheretherketone, belongs to a family of polymers called "aromatic polyketones" (more accurately "polyaryletherketones" or PAEKs).

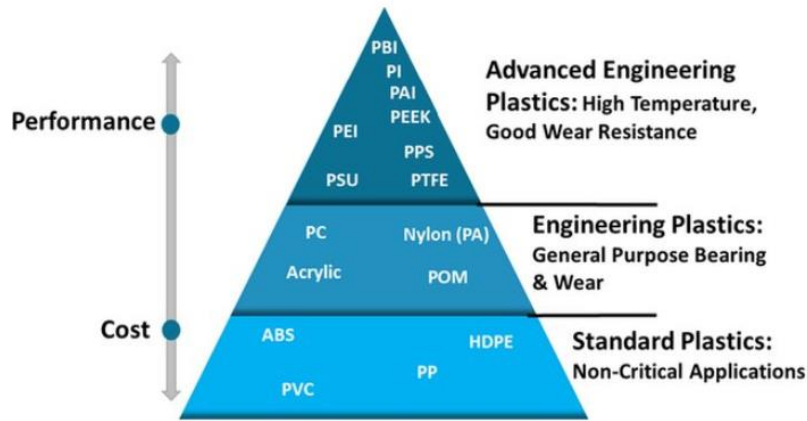
Semi-crystalline polyaryletherketone polymers (PAEKs) are biomaterials widely used in processing technologies, such as extrusion, injection molding, compression molding, or powder coating. Within PAEKs for medical implants, PEEK is widely recognized (Vitrex/Invibio, Solvay, Evonik) and used, benefiting from a solid history and an advanced ecosystem. In addition to the excellent properties (thermomechanical, chemical resistance and tribological) of other PAEKs, polyetheretherketone (PEEK) stands out as a polymer renowned for its impressive thermal and chemical stability, robust mechanical performance, and favorable tribological characteristics. These attributes stem from its aromatic polymer chain structure and its semicrystalline nature, influenced by its thermomechanical processing history. Due to the combination of these properties, coupled with ease of manufacturing, PEEK has found a niche in the medical field due to its biocompatibility and transparency to radiation. And PEEK is a versatile material for various mechanical components (piston parts, pumps, and bearing mechanisms).

The P comes from the Greek “poly” meaning many, so many EEKs make PEEK. This “repeat unit”, shown in the square brackets below, is replicated many times – on average somewhere between 200-300 times – to make a single PEEK polymer chain. The regular structure of the repeat unit means that PEEK molecules can partially crystallize, and crystallinity provides a combination of wear, creep, fatigue, and chemical resistance [6].



**Figure 1.** Chemical structure of PEEK [7].

As we can see from the Plastics Pyramid below which is an at-a-glance plastic material selection guide, among high performance polymers, PEEK is one of the best heat-resistant materials up to 260°C, with a heat distortion temperature of 160°C. Excellent thermal stability and almost same strength are maintained even after 5000 hours of operation at 260°C. Even under the harshest environments, PEEK has a long lifetime [8].



**Figure 2.** The plastics pyramid [9].

In the 1990s, researchers explored the in vitro biocompatibility and stability of various members of the polyaryletherketone (PAEKs) family. and PEEK has stood out as a promising candidate to take the role of metals in bone implant applications. PEEK is resistant to radiation, hydrolysis, and flame and is extremely stable chemically and biologically. PEEK's molecular structure's benzene ring gives it rigidity, and the ether bonds provide enough toughness to make it extremely resistant to cyclic stress. More significantly, PEEK's elastic modulus ( $\sim 3$  GPa) is similar to that of human bone (3~17 GPa), which means it can effectively reduce the risk of osteoporosis and address the "stress shielding" problem in surgical sites [10].

A company called Thornton-Cleveleys suggested using PEEK as a biomaterial for commercial purposes in 1998. Since then, PEEK's exceptional qualities in mechanical strength, thermal/chemical stability, and nontoxicity have attracted more attention in the biomedical industry [11] [12]. These days, PEEK is highly sought-after as a substitute material for the widely used Ti and its alloys. Applications in biomedical devices, including dental implants, intervertebral fusion devices, fixation devices, skulls, knee joints, and hip joints, are growing [13].

The afore-mentioned molecular structure of PEEK makes the material extremely hydrophobic. Such a hydrophobic surface reduces cellular adhesion and inhibits tissue regeneration, and as such, PEEK is classified as a bioinert material [14]. Even though PEEK has been thoroughly studied for use in hard tissue implant applications, its bioinertness and lack of osteointegration continue to be significant drawbacks, which frequently result in implant loosening and even premature failure.

The study demonstrates that femtosecond laser technology can improve the bioactivity of Polyetheretherketone (PEEK) by introducing submicro structures on the surface of PEEK. These structures, when treated with hydroxylation, create a micro-submicro structure and a hydroxyl group on the surface of FPK (FPKH). This structure enhances surface properties such as roughness, hydrophilicity, surface energy, and protein absorption [14].

PEEK is used in medical devices as a replacement for titanium, with different polymer variants, sources, and cell types. Previous studies show PEEK is cellularly compatible with the substance, but no current study reflects its current state. In a study by Sagomonyants, implantable-grade PEEK

forms were compared with commercially pure titanium grade A using a human bone model. Preimplant osteogenesis involves adherence, proliferation, differentiation, protein creation, and calcium phosphate deposition.

The polymer is a semi-crystalline polymer possessing regions of amorphous and crystalline phases that present themselves at the surface. The crystalline content varies due to previous thermal processing. For injection-molded PEEK, crystallinity is typically 30–35%. PEEK crystals consist of spherulites (approximately 25–40  $\mu\text{m}$  in diameter) formed from thin lamellae (50–60  $\text{\AA}$ ). Changes in crystallinity will be present due to the manufacturing process chosen (injection molding or machining), but also within these routes, the processing temperatures, hold time, cooling rate of the part, and subsequent annealing will be influential. Injection molding may also form a perimeter skin that may differ from the bulk material.

The study found that osteoblasts spread well on PEEK and that PEEK is cytocompatibility with osteoblasts. Smoother, injection-molded PEEK variants demonstrated better initial cell adhesion, while rougher variants were significantly lower than controls. CFR-PEEK stimulated osteoblast differentiation, while unfilled injection-molded PEEK surface had a higher proliferation rate but less bone matrix protein signals, indicating less differentiation [15].

In injection molded composites, the mold geometry has been considered as the most important parameter to determine the fiber orientation state. Many complex geometries, such as discs and dogbone tension bars, have been studied, but the most studied case is rectangular molds with edges. In all the mentioned cases, three layers were observed: in the upper and lower skin layers, the fibers were aligned along the direction of melt flow, while in the core they were oriented transversely.

Although different thermoplastics with different fiber contents that were treated under different conditions were used, layered structures were obtained. This demonstrates that restrictions must be imposed on the melting flow by the template which is more important than the fundamental rheological aspects of polymeric melting.

Material variables and injection conditions also play a role in the formation of layered structures, as it has been shown that by changing the polymer matrix and the right parameters, the size of each layer and the direction of the fibers in the layer can be modified, which in some cases helps in the disappearance of the core.

The microstructure analysis of injection-molded short-fiber PEEK samples revealed a layered structure with high fiber alignment along the melt flow direction. Carbon fibers exhibited greater susceptibility to attrition during manufacturing compared to glass fibers. Mechanical testing through tensile and ultrasonic methods indicated that PEEK/carbon fiber composites exhibited higher fiber-matrix shear strength and critical length values than PEEK/glass fiber composites. The superior adhesion of carbon fibers to the PEEK matrix suggests PEEK's enhanced interfacial properties with fibers compared to other thermoplastics [16].

## 2. Injection Molding Design:

Injection molding is a common method for mass production and is often preferred over other processes, given its capability to economically make complex parts to tight tolerances. It is necessary to design, manufacture, and commission an appropriate injection mold before any parts can be molded. The productivity and quality of the molded parts are directly influenced by the mold design. The injection mold is a multi-component, complex system that is exposed to numerous cycles of stress and temperature. In mold design, trade-offs are common. For example, cheaper molds can occasionally lead to lower-quality products or ineffective molding processes [17].

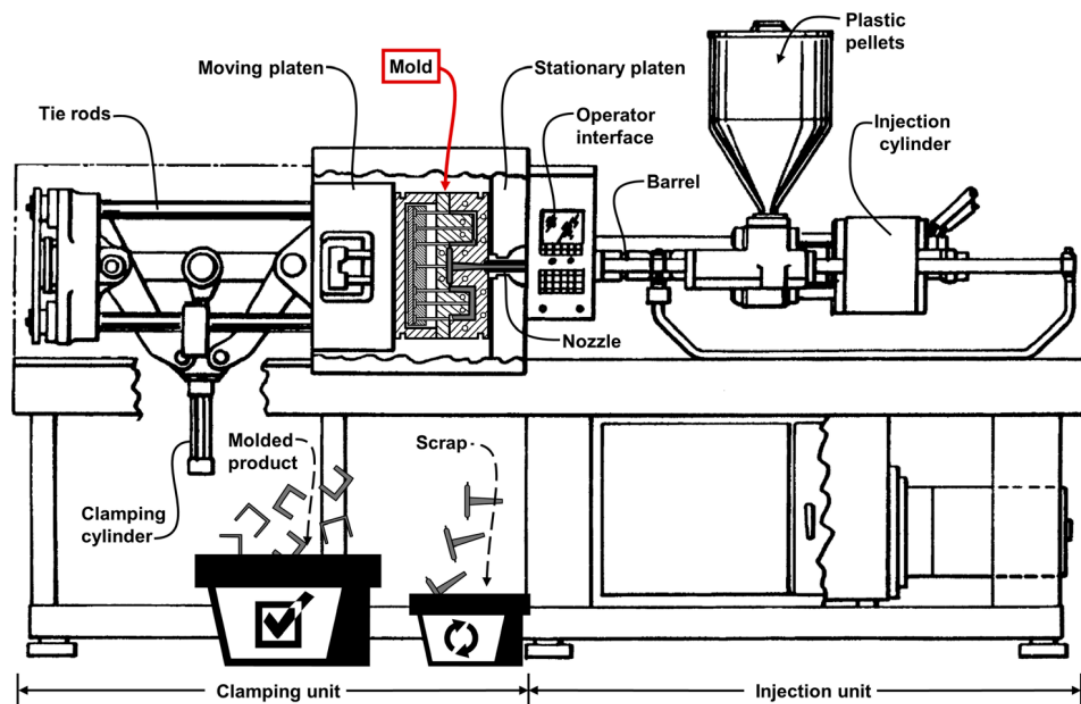


Figure 3. Injection Molding machine [17].

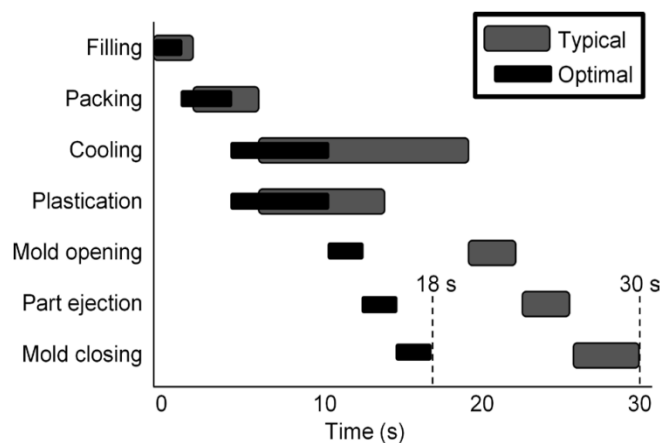
The mold is typically connected to and moves with the machine platens so that the molded parts are formed within a closed mold, after which the mold is opened so that the molded parts can be removed. The mold is typically connected to and moves with the machine platens so that the molded parts are formed within a closed mold, after which the mold is opened so that the molded parts can be removed.

The "heart" of the mold is the mold cavity, where each molding cycle produces the molded part(s) by injecting and solidifying polymer. The majority of injection molding processes typically involve the steps of plastination, injection, packing, cooling, and ejection, though they can vary greatly in terms of design and functionality. During the plastication stage, a screw within the barrel rotates to convey plastic pellets and form a "shot" of polymer melt. Through the combined action of heat

conduction from the heated barrel and internal viscous heating brought on by molecular deformation as the polymer is forced along the screw flights, the polymer melt is plasticized from solid granules or pellets. Subsequently, the plasticized shot of polymer melt is pushed into the mold during the filling stage by the molding machine's nozzle and pistol grip. The molten resin forms the molded product(s) as it passes through one or more gates, a feed system, and one or more mold cavities [17].

Additional material is injected into the mold cavity during the packing stage as the molten plastic melt cools and contracts after the mold cavity has been filled with the polymer melt. The volumetric shrinkage of plastic varies depending on the material's characteristics and the needs of the application; however, during the packing stage, the molding machine usually forces an extra 1 to 10% melt into the mold cavity. The cooling stage gives the resin in the cavity more time to solidify and become sufficiently rigid for ejection after the polymer melt stops flowing. Then, in order to grant access to the mold cavities, the molding machine actuates the moving platen and the attached moving side of the mold. Before the mold closes and the next molding cycle begins, the molded part(s) are usually removed via an ejection system that consists of moving slides and pins within the mold.

The filling time, which makes up a tiny portion of the cycle, is frequently chosen to reduce the injection pressure and molded-in stresses. To minimize the packing time, which is of moderate length, a shot weight stability study is frequently conducted, culminating in the polymer melt freezing off in the gate. The cooling phase of the molding process typically takes up most of the cycle time because the low thermal diffusivity of the plastic melt restricts the rate of heat transfer from the polymer melt to the cooler mold [17].



**Figure 4.** Injection molding process timings [17].

### 3. Designed Implant Description:

#### 3.1 Determining the Size and 3D model of the implant:

This unique spinal implant was designed with NX Siemens software using specific dimensions. Optimal condition for fusion to replace lumbar intervertebral discs and to fuse the adjacent vertebral bodies together at vertebral levels L4–L5, as shown in Figure 5.

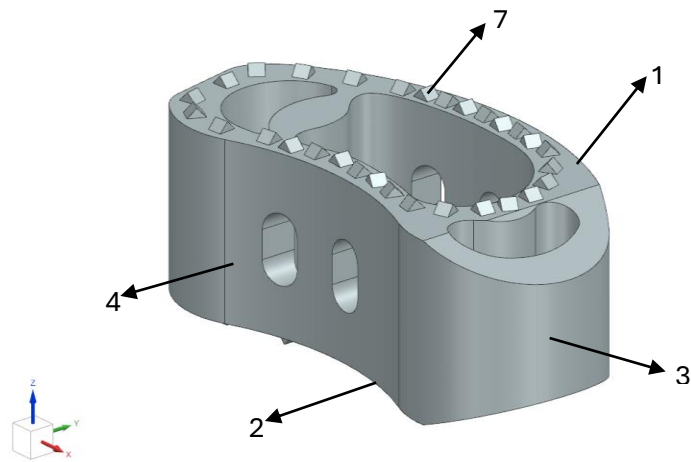
It has a banana-like, bean-like, crescent, c-like, curved or slightly curved c-like shape that facilitates contact with the cortical bone, and it is typical of implants used in a TLIF procedure, transforaminal lumbar interbody fusion it is a fusion procedure which involves a posterior and lateral approach to the disc space. To gain access to the disc space, the facet joint may be removed, whereby access is gained via the nerve foramen.



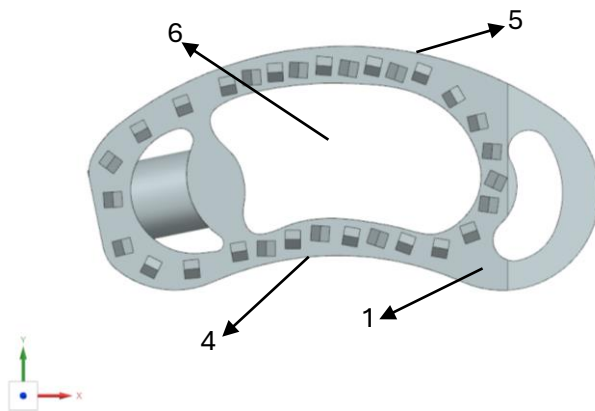
**Figure 5.** L4 and L5 in Spine [18].

This uniquely designed spinal implant has one sidewall (4) having a concave outer surface and the opposite sidewall having a convex outer surface, interconnected by generally curved end walls. This end wall defines a peak-like tip and forming a ramp-like surface with the top and the bottom surfaces of the end wall. And this shape is generally configured for use as a TLIF cage. The top end plate and the bottom end plate, each of which have a bone-engaging surface, called pyramidal teeth. It also has axial windows on the sides.

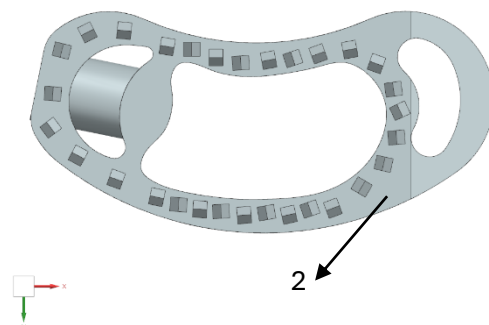
### 3.2 3D Model Figures:



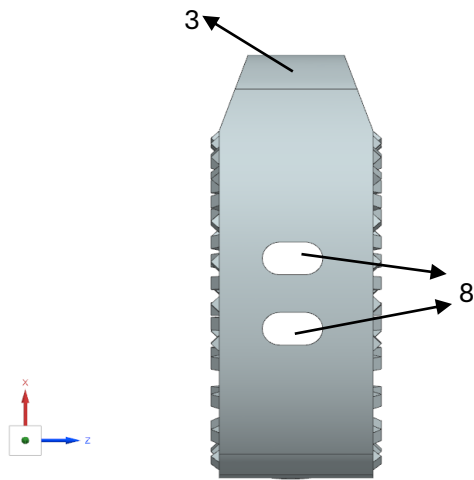
**Figure 6.** Isometric view of the Spinal Implant.



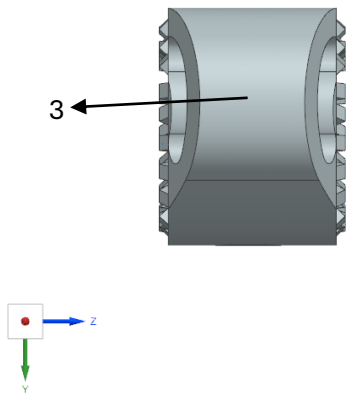
**Figure 7.** Top view of the Spinal Implant.



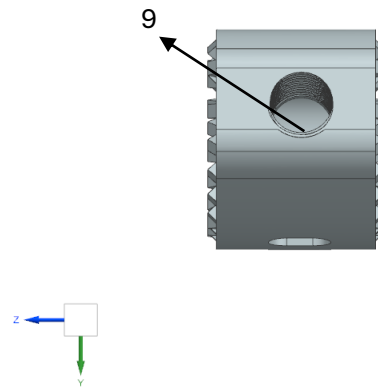
**Figure 8.** Bottom view of the Spinal Implant.



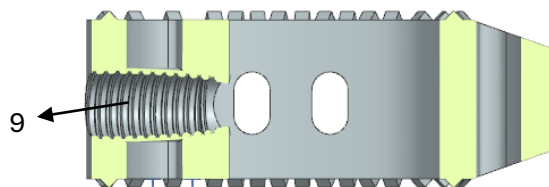
**Figure 9.** Side view of the Spinal Implant.



**Figure 10.** Front side view of the implant.



**Figure 11.** back side view of the implant.



**Figure 12.** Sectional view of the implant.

### 3.3 Figures description:

1. Top end plate: have a bone engaging surface.
2. Bottom end plate: also have a bone engaging surface.
3. End wall: bullet nose design for self-distraction for easy insertion. And it is forming with the top and bottom surfaces of the end wall a peak-like tip.
4. Side wall: concave outer surface.
5. Side wall: convex outer surface.
6. Axial window: accommodates more autogenous bone graft substitute to allow fusion to occur through the cage.
7. Pyramidal Teeth: It is called serrated teeth, these teeth-like structures are designed to provide better stability and fixation of the implant within the bone. Also, it can promote osseointegration, which is the process when the bone grows into the surface of the implant.
8. Oval-shaped holes (windows): facilitating bone graft placement during spinal fusion surgery, bone graft material is often placed around the implant to promote fusion between the vertebrae. promoting osseointegration.  
These windows also serve to reduce the implant's stiffness and imitate the natural mechanical properties of bone.
9. Screw: to insert and direct the implant in right position.

### 3.4 3D model implant specific parameters:

The length L, height H, and width W, is:

$$L = 41.47 \text{ mm}$$

$$H = 14 \text{ mm}$$

$$W = 19.81 \text{ mm}$$

It has a big hole in the middle and another two holes around it, with same thickness all around between the inside holes and between the holes and the side wall, which is:

$$t = 3 \text{ mm.}$$

These holes exist to avoid bulk material, which is not good for injection molding machining.

This implant also has an M6x10.9 screw, which was created to allow the surgical to hold the implant and directed into the correct position.

## 4. Prototyping of the spinal implant:

In order to execute the 3D design of the spine cage, an additive manufacturing technique commonly known as stereolithography (SLA) was conducted. A Photon Mono X 6Ks (Anycubic photon) with LCD-based SLA technology that has faster printing speeds, and a larger volume was utilized. The previously determined solid model file in .stl format was converted to photon file by the Anycubic photon Workshop program to transferred to the SLA machine. We printed the implant model with scale: 100%. The Photon Mono-X 6Ks machine uses Standard Colored UV Resin. The gray resin has a low viscosity and has mechanical properties. After the printing process was finished, we washed the 3D printed implant for 3 minutes, and for polymerization, we cured it in UV light for 5 minutes.



**Figure 13.** 3D printed spinal implant (Top view).



**Figure 14.** 3D printed spinal implant (Isometric views).

## 5. Part design considerations:

With the use of simulation technology, it is possible to forecast product behavior before the first prototype is built, which can reduce project risk and increase project efficiency while also lowering costs and improving performance. Additionally, it can speed up design iterations, enabling more rapid and intelligent decision-making.

Purposeful simulations require accurate material characterization, which provides insight into the engineering plastics' behavioral characteristics even in the absence of abundant data. Advanced injection molding simulations improve quality, reduce scrap, and avoid expensive tool revisions by optimizing tooling. The simulation should be used to determine gate locations to ensure a part fill with a pressure that is well within the machine's capabilities. With this technique, various aspects of the injection molding process, such as filling, welding lines, air traps, and warpage, can be predicted.

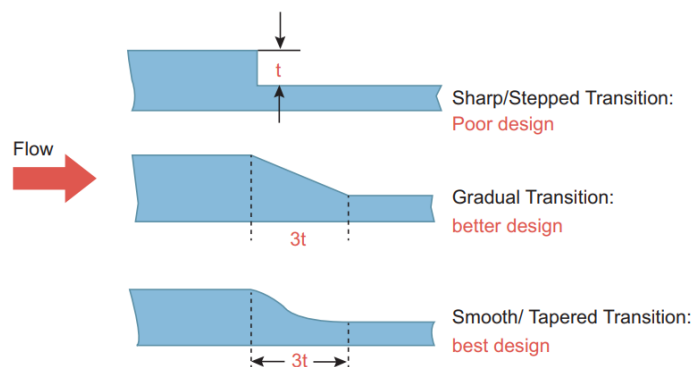
Process simulation is a powerful tool to troubleshoot molding issues and part performance issues. That's why we use it in this project to optimize the implant and ensure a successful injection process.

The mold simulation process was performed using Moldex 3D software, which is considered a world leading program in the plastic mold industry. It predicts potential manufacturing defects, validates part/die design, reduces mold development costs, improves manufacturability, shortens time to market, and significantly increases business value.

And we will go through all the steps of the simulation process:

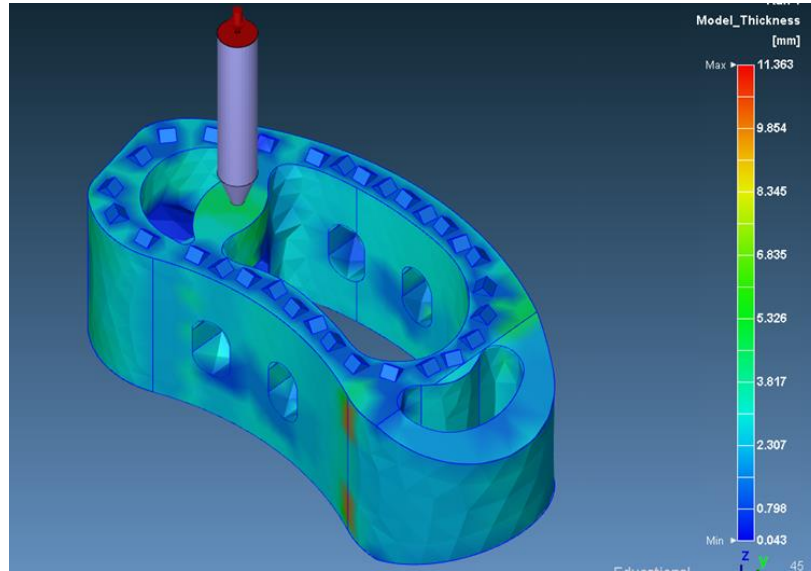
### 5.1 Part Design:

The golden rule for designing parts is to ensure a uniform distribution of wall thickness. Plastics are poor conductors of heat, and wall thickness affects cooling efficiency and thawing behavior during the packaging stages. A drastic change in thickness is the worst design because it lacks a transition zone for shrinkage during molding. Gradual change is best if variation in thickness is necessary, but uniform thickness is, of course, best, as shown in Figure 15.



**Figure 15.** The recommended design of transition region [19].

In the case of the piece, however, a compromise must be made between the correct design guidelines of functionality and technology, so at certain points where functional surfaces are located, the wall thickness will increase or decrease. We kept almost a uniform thickness all around the part, Where  $t = 3$  mm. As shown in this Figure below.



**Figure 16.** Uniform thickness for the part.

The recommended wall thickness for injected molded PEEK is between 1.0 and 3 mm. With its excellent mechanical strength, PEEK can support relatively thin walls while maintaining sufficient part strength. A uniform wall thickness is recommended, but PEEK parts can have walls with different thicknesses as long as those thicknesses do not change abruptly [20]. By this, we met the condition of uniform thin wall thickness.

## 5.2 Wall Thickness versus Flow Length

Because flowability is influenced by part thickness and flow length, the flow length to wall thickness ratio Equation is frequently used in product design to assess the quality of a design. It is defined as:

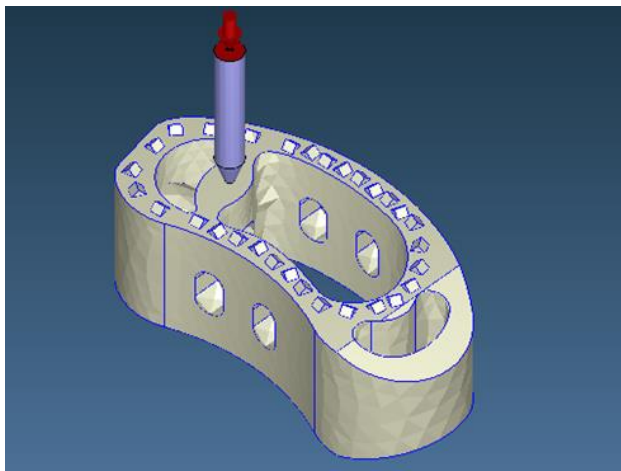
$$\frac{L}{t} = \frac{\text{Flow length from gate to end}}{\text{Average wall thickness}} = \frac{31 \text{ mm}}{3 \text{ mm}} = 10.33$$

A key consideration in molding design is the ratio of flow length to wall thickness. Melts find it easier to fill if the ratio is less than 100. The ratio of most parts is between 100 and 200. However, a ratio greater than 200 calls for design changes to prevent flaws in thin-wall components. Filling becomes challenging at ratios higher than 300, necessitating the use of high-flowable plastics or high-speed injection molding equipment. Creating a unique material or utilizing high-speed injection molding equipment can aid in overcoming these difficulties.

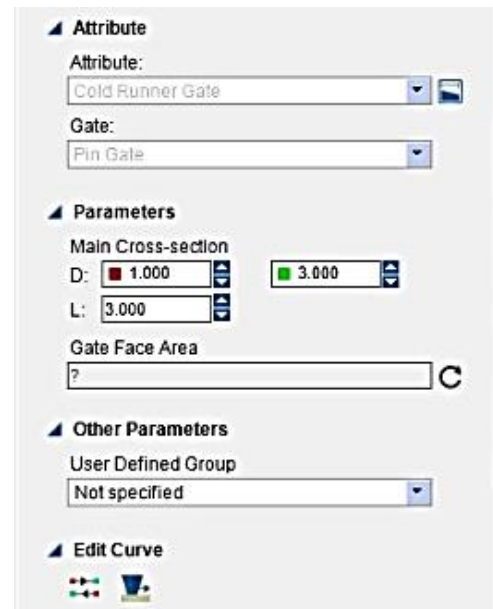
## 6. Determination of parameters for molding simulation:

### 6.1 Gate Design:

Given that a narrow gates cross-section results in a high injection pressure, gates should be erected in thick-walled areas to prevent significant pressure drops and improve pressure maintenance. The appearance quality is the priority of gate location design, followed by smoothness of flowing. As already mentioned, the L/t ratio is very critical, and enough gates should be included according to the flowing properties of the used plastics. In this version of running, we decided to put the gate in a thick position, and after that Moldex 3D software automatically generated the runner.

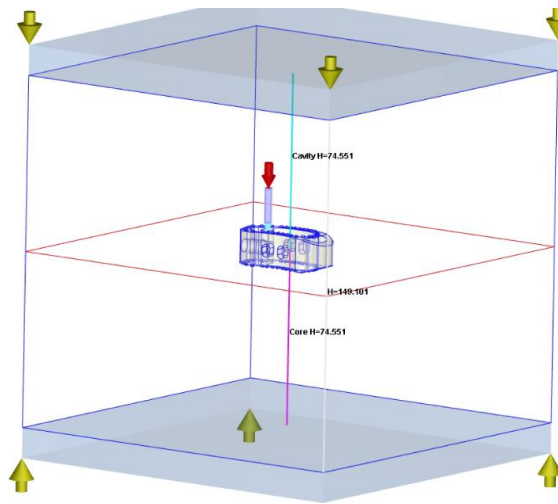


**Figure 17.** Gate position and parameters.



### 6.2 Virtual mold geometry:

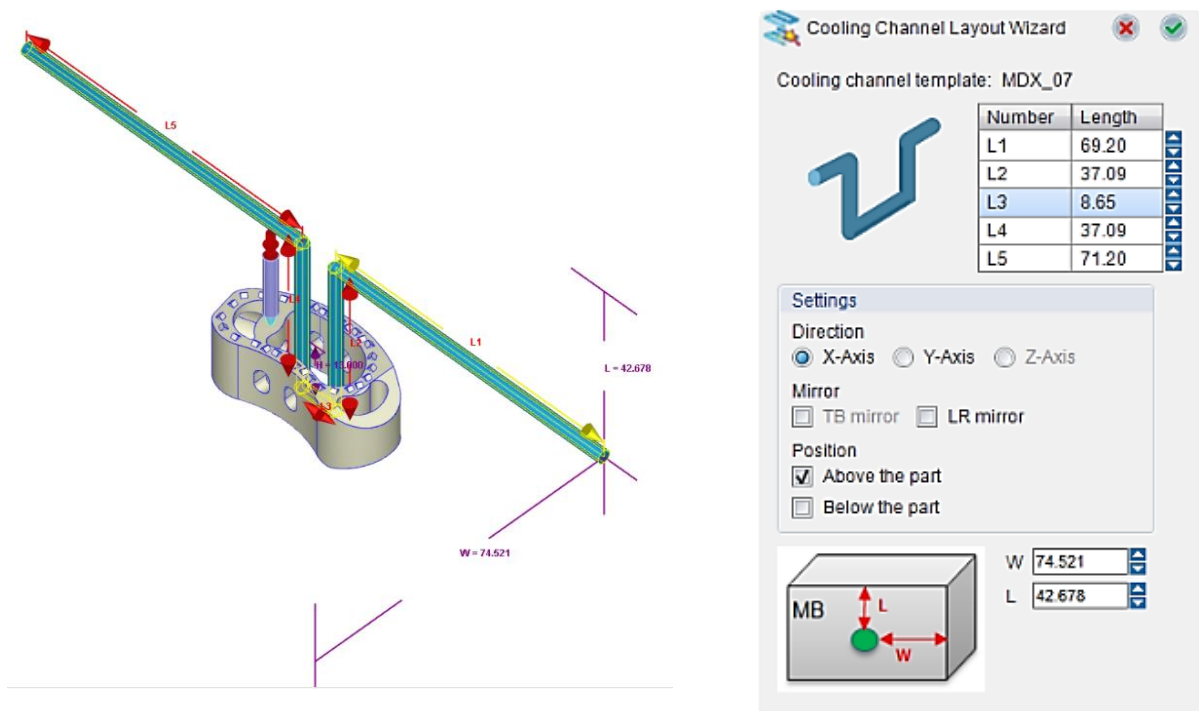
The dimensions of the mold were determined as: 149.10x149.10x149.10 mm x mm x mm x mm.



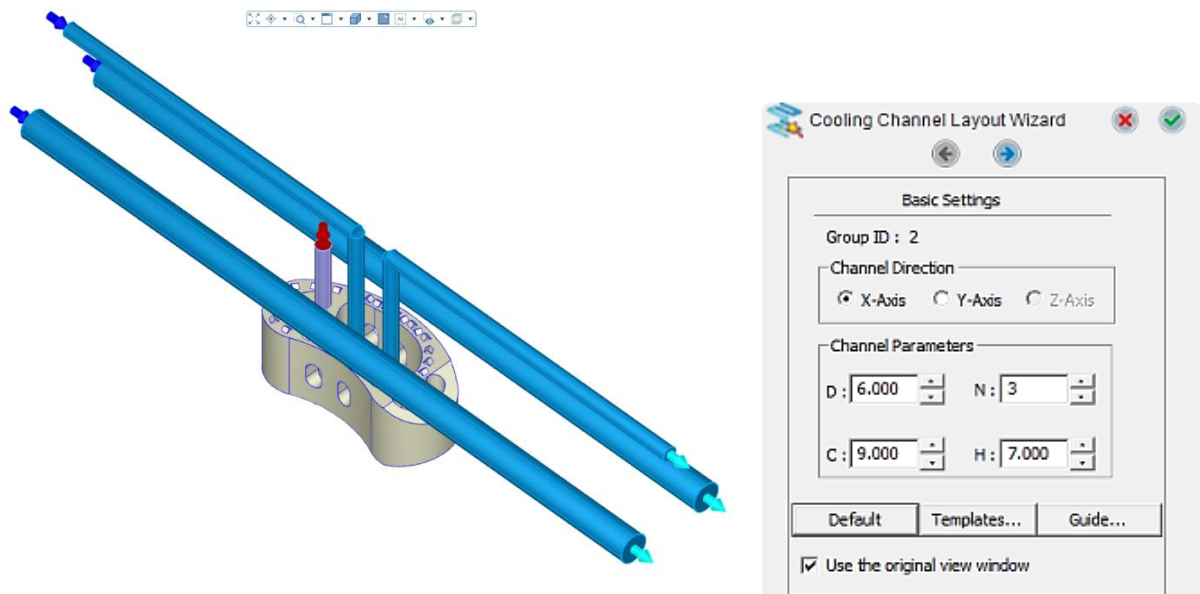
**Figure 18.** Mold geometry (Isometric view).

### 6.3 Design of cooling circuits:

Now, for cooling channels a u-shape tube was chosen to cool the core,  $d = 2$  mm. and another two long tubes parallel to the part with diameter  $d = 4$  mm.



**Figure 19.** U-shape cooling channel and its parameters.



**Figure 20.** Long tube cooling channel and its parameters.

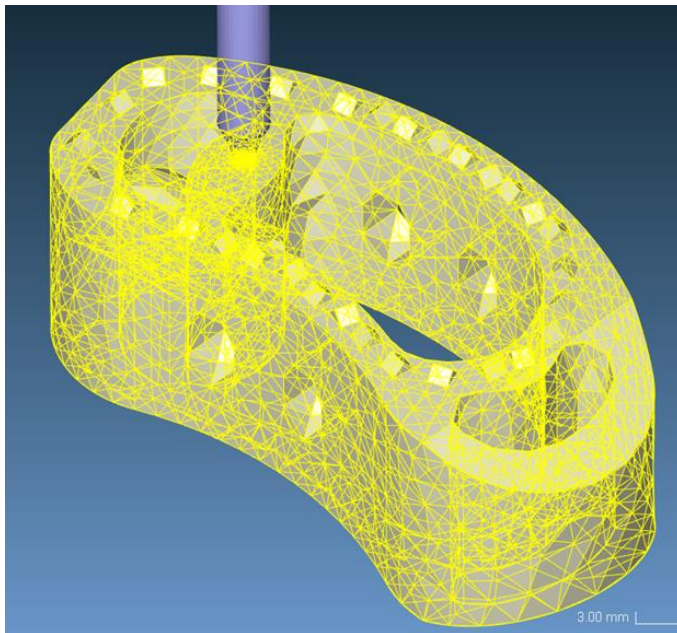
## 7. Simulation of Molding Process

### 7.1 Mesh generates:

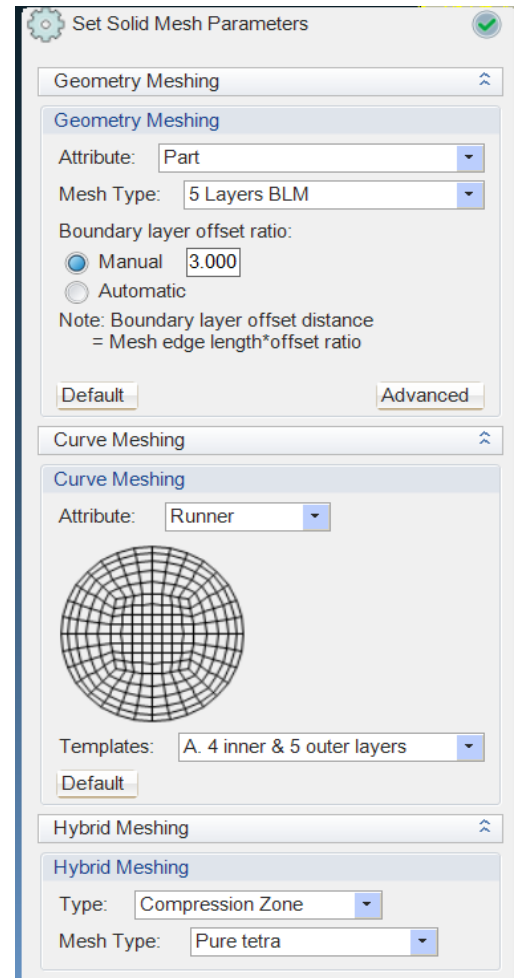
We chose Solid mesh type. And after this mesh was generated with these parameters shown on the table below.

**Table 1.** Mesh parameters.

| Mesh parameters            | Item Data |
|----------------------------|-----------|
| Mesh Type                  | solid     |
| Solid Mesh Element Count   | 216,786   |
| Part Elements              | 32,791    |
| Surface Mesh Element Count | 3,500     |



**Figure 22.** Mesh model.



**Figure 21.** Set solid mesh parameters.

## 7.2 Material type:

From the Moldex 3D library we can choose which material we want and which grade.

In this project we are focusing on PEEK material, which is used for human implantation due to its biocompatibility. So, in this running the chosen material name is: VICTREX POLYMER PEEK 150CA 30, Which is 30% carbon fiber reinforced PEEK.

From Victrex company we can see the datasheet for this grade of PEEK.

**Table 2.** Technical data sheet for VICTEX PEEK 150CA30 [21].

### VICTREX™ PEEK POLYMER 150CA30

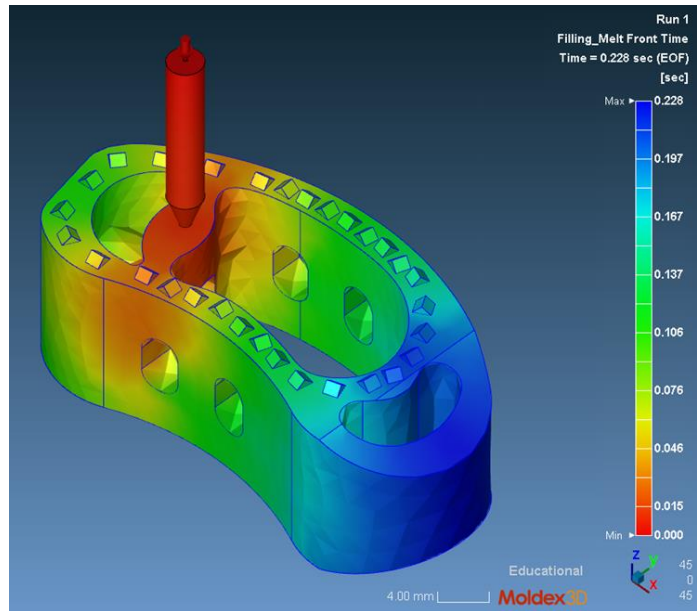
| General Information                                                                                                                                                                                                                                                             |               |                   |                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|-------------------|-----------------|
| Product Description                                                                                                                                                                                                                                                             |               |                   |                 |
| High performance thermoplastic material, 30% carbon fibre reinforced PolyEtherEtherKetone (PEEK), semi crystalline, granules for injection moulding, easy flow, colour black.                                                                                                   |               |                   |                 |
| Complex geometries with thin cross sections or long flow length where higher strength in a static or dynamic system is required. Excellent wear resistance, low coefficient of friction, low coefficient of thermal expansion. Chemically resistant to aggressive environments. |               |                   |                 |
| Material Properties                                                                                                                                                                                                                                                             |               |                   |                 |
| Physical                                                                                                                                                                                                                                                                        | Nominal Value | Unit              | Test Method     |
| Density (Crystalline)                                                                                                                                                                                                                                                           | 1.40          | g/cm <sup>3</sup> | ISO 1183        |
| Spiral Flow <sup>1</sup>                                                                                                                                                                                                                                                        | 14.0          | cm                | Internal Method |
| Molding Shrinkage <sup>2</sup>                                                                                                                                                                                                                                                  |               |                   | ISO 294-4       |
| Across Flow                                                                                                                                                                                                                                                                     | 0.50          | %                 |                 |
| Flow                                                                                                                                                                                                                                                                            | 0.10          | %                 |                 |
| Water Absorption (Saturation, 23°C)                                                                                                                                                                                                                                             | 0.30          | %                 | ISO 62          |
| Water Absorption - Saturation (100°C)                                                                                                                                                                                                                                           | 0.45          | %                 | ISO 62          |
| Mechanical                                                                                                                                                                                                                                                                      | Nominal Value | Unit              | Test Method     |
| Tensile Modulus (23°C)                                                                                                                                                                                                                                                          | 28000         | MPa               | ISO 527-1       |
| Tensile Stress                                                                                                                                                                                                                                                                  |               |                   | ISO 527-2       |
| Break, 23°C                                                                                                                                                                                                                                                                     | 270           | MPa               |                 |
| Break, 125°C                                                                                                                                                                                                                                                                    | 170           | MPa               |                 |
| Break, 175°C                                                                                                                                                                                                                                                                    | 105           | MPa               |                 |
| Break, 275°C                                                                                                                                                                                                                                                                    | 60.0          | MPa               |                 |
| Tensile Strain (Break, 23°C)                                                                                                                                                                                                                                                    | 1.5           | %                 | ISO 527-2       |
| Flexural Modulus (23°C)                                                                                                                                                                                                                                                         | 24000         | MPa               | ISO 178         |
| Flexural Stress                                                                                                                                                                                                                                                                 |               |                   | ISO 178         |
| 23°C                                                                                                                                                                                                                                                                            | 380           | MPa               |                 |
| 125°C                                                                                                                                                                                                                                                                           | 275           | MPa               |                 |
| 175°C                                                                                                                                                                                                                                                                           | 130           | MPa               |                 |
| 275°C                                                                                                                                                                                                                                                                           | 65.0          | MPa               |                 |
| Compressive Stress                                                                                                                                                                                                                                                              |               |                   | ISO 604         |
| 23°C                                                                                                                                                                                                                                                                            | 300           | MPa               |                 |
| 120°C                                                                                                                                                                                                                                                                           | 200           | MPa               |                 |
| 200°C                                                                                                                                                                                                                                                                           | 70.0          | MPa               |                 |
| Impact                                                                                                                                                                                                                                                                          | Nominal Value | Unit              | Test Method     |
| Charpy Notched Impact Strength (23°C)                                                                                                                                                                                                                                           | 6.0           | kJ/m <sup>2</sup> | ISO 179/1eA     |
| Charpy Unnotched Impact Strength (23°C)                                                                                                                                                                                                                                         | 45.0          | kJ/m <sup>2</sup> | ISO 179/1U      |
| Notched Izod Impact Strength (23°C)                                                                                                                                                                                                                                             | 7.5           | kJ/m <sup>2</sup> | ISO 180/A       |
| Unnotched Izod Impact Strength (23°C)                                                                                                                                                                                                                                           | 40.0          | kJ/m <sup>2</sup> | ISO 180         |
| Hardness                                                                                                                                                                                                                                                                        | Nominal Value | Unit              | Test Method     |
| Shore Hardness (Shore D, 23°C)                                                                                                                                                                                                                                                  | 87.5          |                   | ISO 868         |
| Thermal                                                                                                                                                                                                                                                                         | Nominal Value | Unit              | Test Method     |
| Deflection Temperature Under Load                                                                                                                                                                                                                                               |               |                   | ISO 75-2/Af     |
| 1.8 MPa, Unannealed                                                                                                                                                                                                                                                             | 339           | °C                |                 |

## 8. Evaluation Simulation Results:

### 8.1 Filling:

#### 8.1.1 Melt front time:

Filling melt front time shown in Figure 23, which has a colored scale with min time value (0 sec) where the gate is located, and max time value (0.23 sec) it is in blue color and this is last area will be fill, meaning that it took 0.23 seconds to fill all the mold cavity.



**Figure 23.** Filling - Melt front time (Filling process).

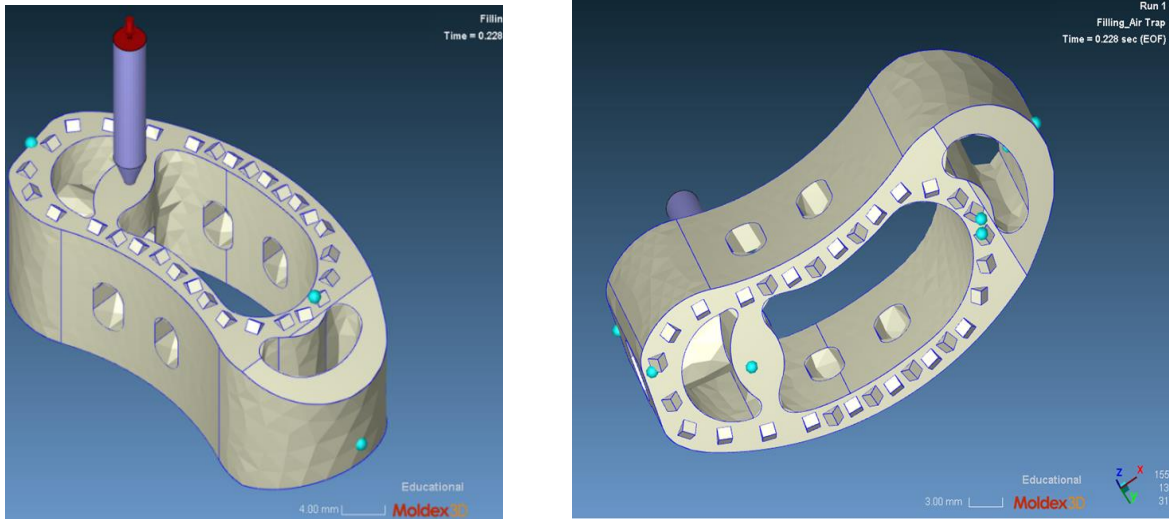
Filling parameters are in **Error! Reference source not found..**

**Table 3.** Filling parameters.

| Filling                | Item Data              |
|------------------------|------------------------|
| Filling Time           | 0.23 sec               |
| Melt Temperature       | 385 °C                 |
| Mold Temperature       | 190 °C                 |
| Max Injection Pressure | 250 MPa                |
| Injection Volume       | 4.5791 cm <sup>3</sup> |

### 8.1.2 Air traps:

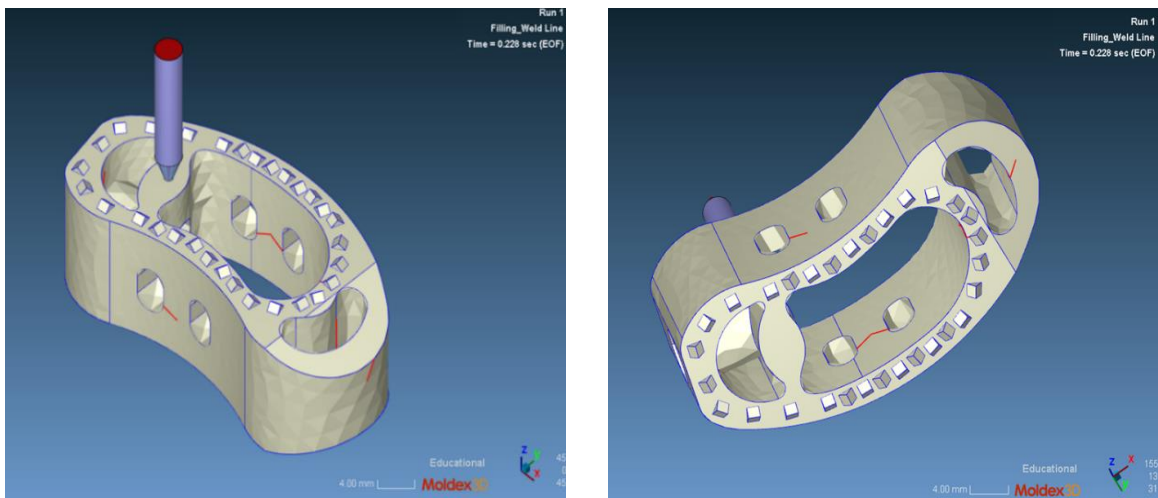
Air traps are shown in Figure 24, Air traps are localized regions within mold cavities where air becomes entrapped during the injection process. The molten plastic resin displaces the air present in the cavity, leading to the formation of isolated pockets of air that remain trapped. As a result, this gives rise to the presence of bubbles or voids within the molded part.



**Figure 24.** Filling - Air traps (Isometric and bottom view).

### 8.1.3 Weld lines:

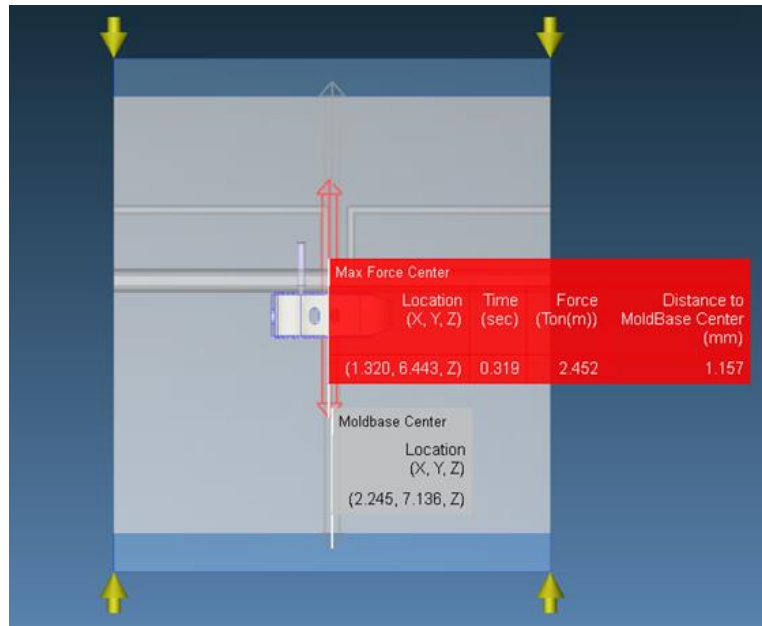
Welding lines, also known as flow lines, are seams in injection-molded parts formed when molten plastic resin meets and combines, visible as faint marks on the part's surface. From welding lines shown in Figure 25, we can see that we don't have vertical welding lines, which is considered an advantage. But the disadvantage is that we have a welding line next to the end plate and this happened because of melting connections at this point.



**Figure 25.** Filling - Weld lines (Isometric and bottom view)

#### 8.1.4 Clamping force:

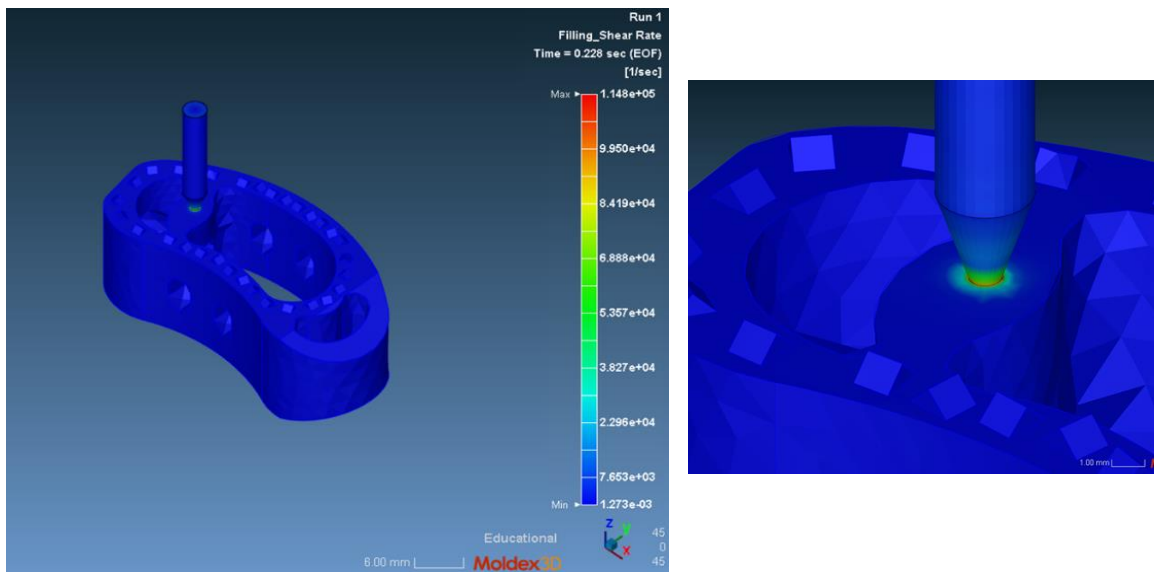
Clamping force is perpendicular to the part as shown in Figure 26, this is the force applied to hold the two halves of the mold together during injection process, and its value  $F = 2.452$  Ton.



**Figure 26.** Filling - Clamping force.

#### 8.1.5 Shear rate:

The shear rate is equal for the part, less shear rate means better. And max shear rate is in the shooting point. As shown in Figure 27.



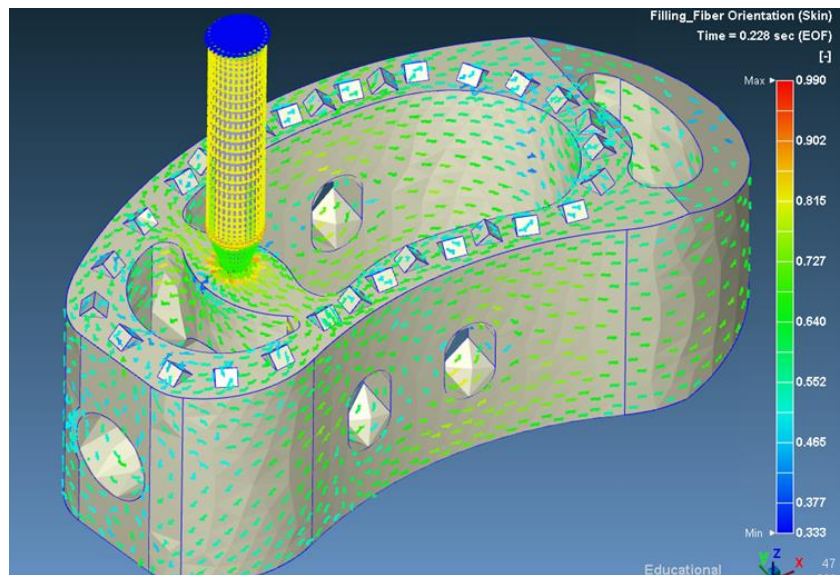
**Figure 27.** Filling - Shear rate and Max. shear rate.

### 8.1.6 Fiber orientation:

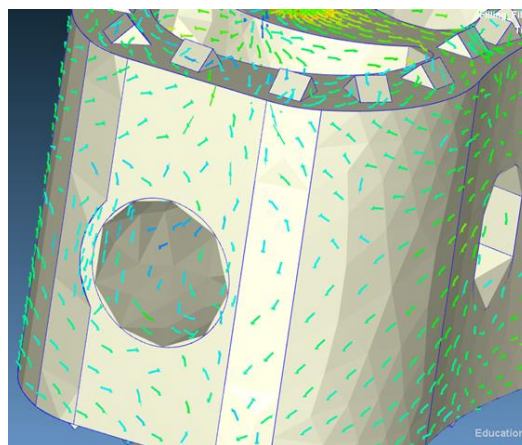
The chosen material from VICTREX has 30% carbon fibers, we can see the fiber orientation in Figure 28, which provides information about the distribution of fiber orientation within the implant during the molding process. The range of fiber orientation values depicted in the color gradient is indicated by the scale in the Figure. It shows the minimum (0.333) and maximum (0.990) fiber orientation values. These values are unitless and indicate the degree of alignment or orientation of the fibers within the material.

Each color indicates a different level of fiber orientation. Dark blue corresponds to the minimum fiber orientation, while red represents the highest orientation.

Other colors (light blue, green, and yellow) represent increasing levels of fiber orientation, with higher percentages indicating larger areas of the surface with aligned fibers.



**Figure 28.** Filling - fiber orientation.



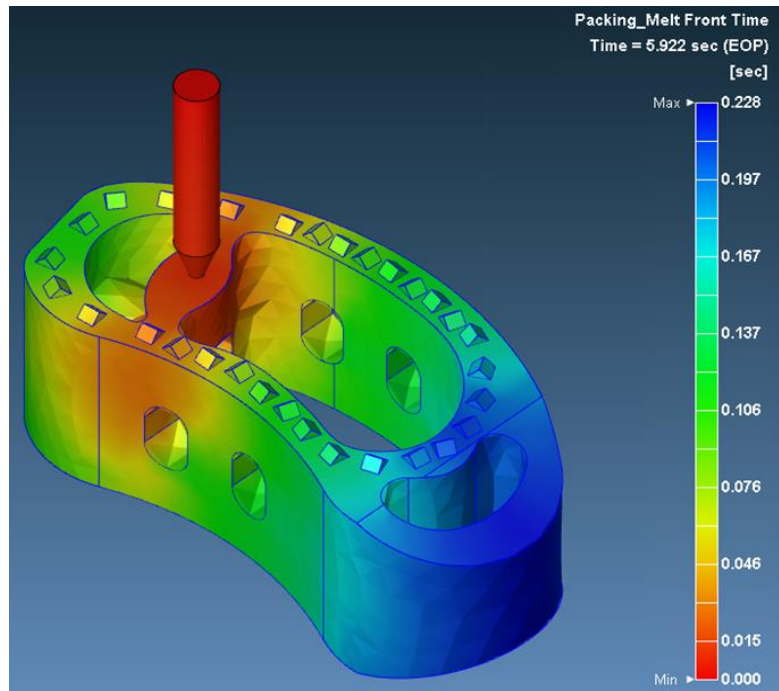
**Figure 29.** Filling - fiber orientation around the hole.

## 8.2 Packing:

### 8.2.1 Melt front time:

Packing melt front time is: 5.69 sec. and Packing max Pressure is 250 MPa. Figure 30 shows the packing melt front time. The color scale in this figure indicates the distribution of melt front arrival times across different regions of the molded implant during the packing stage of the molding process.

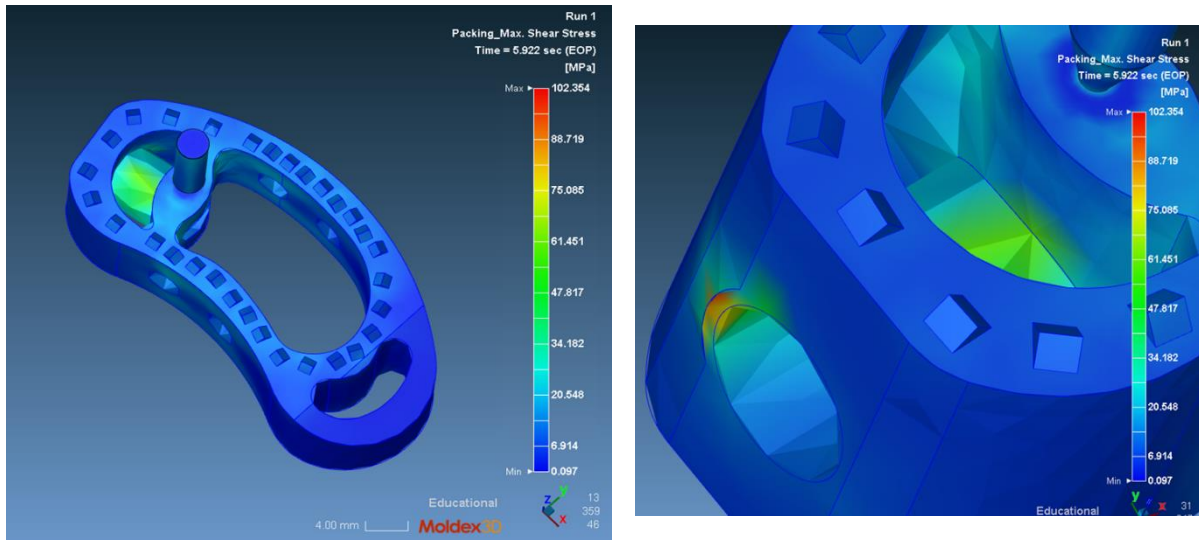
The current color distribution shows the differences in packing melt front arrival times across various regions of the implant. Warmer colors (red, orange, and yellow) represent earlier arrival times, these regions may experience more effective packing and material consolidation, while cooler colors (green and blue) represent later arrival times, and these regions may have less optimal packing conditions



**Figure 30.** Packing – packing melt front time.

### 8.2.2 Packing shear stress:

Shear stress at the current instant is shown in different colors according to the stress level. Shear stress is one of the sources of the residual stress in molded parts. If the shear stress is not distributed evenly, it will cause some dimensional problems. Too high a shear stress level will result in stress-induced problems in the molded part. And as we can see from Figure 31 the scale shows max value of shear stress (102.354 MPa), and min value is (0.097 MPa). The maximum shear stress is next to the screw-hole part as shown in the figure, which records the peak value of shear stress during the passing filling time.



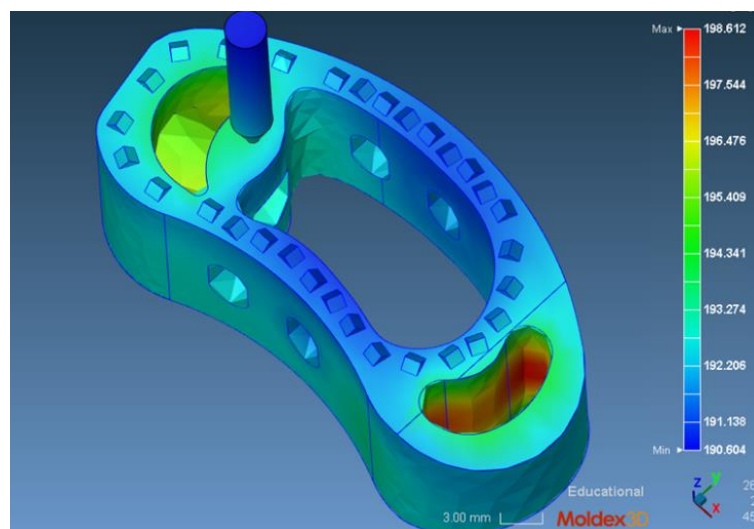
**Figure 31.** Packing – packing shear stress, and max shear stress.

### 8.3 Cooling:

#### 8.3.1 Cooling Temperature:

The color scale in Figure 32 represents the temperature distribution across different regions of the molded implant. This scale ranges in color from blue, which represents areas with the lowest temperatures, to red, which indicates higher temperature values.

This highlights areas of potential concern, such as regions experiencing slower cooling rates in the side hole in the nose region, which attains the highest temperatures during the cooling process. potentially due to restricted airflow or thicker material sections. On the other side, where the hole is a screw, there are intermediate temperature levels; this area may experience slightly slower cooling rates compared to surrounding regions.



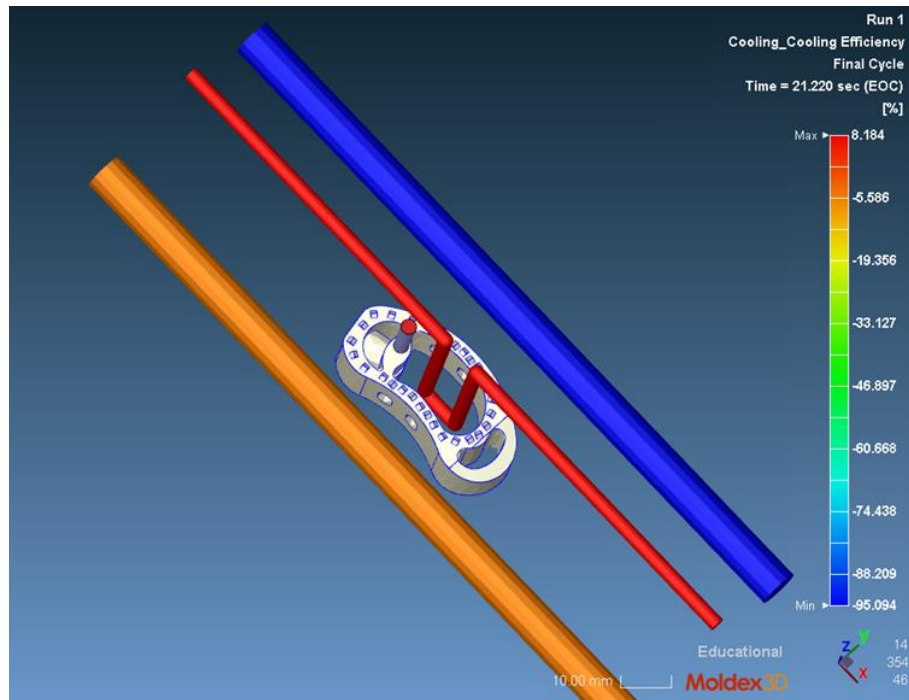
**Figure 32.** Cooling – cooling temperature.

### 8.3.2 Cooling efficiency:

The cooling efficiency provides insights into how effectively each cooling channel within the mold withdraws heat from the molded implant during the cooling process. This scale ranges in color from blue, which represents areas with the lowest cooling efficiency, to red, which indicates areas with the highest cooling efficiency. As shown in Figure 33.

So, the U-shaped cooling tube, which has a red color, indicates the highest cooling efficiency, where heat withdrawal from the surface of the cooling channel is most effective.

For the other two long tube cooling channels, the tube with an orange color experiences relatively high cooling efficiency. while the tube with the blue color shows the lowest cooling efficiency, where heat withdrawal from the surface of the cooling channel is less effective.



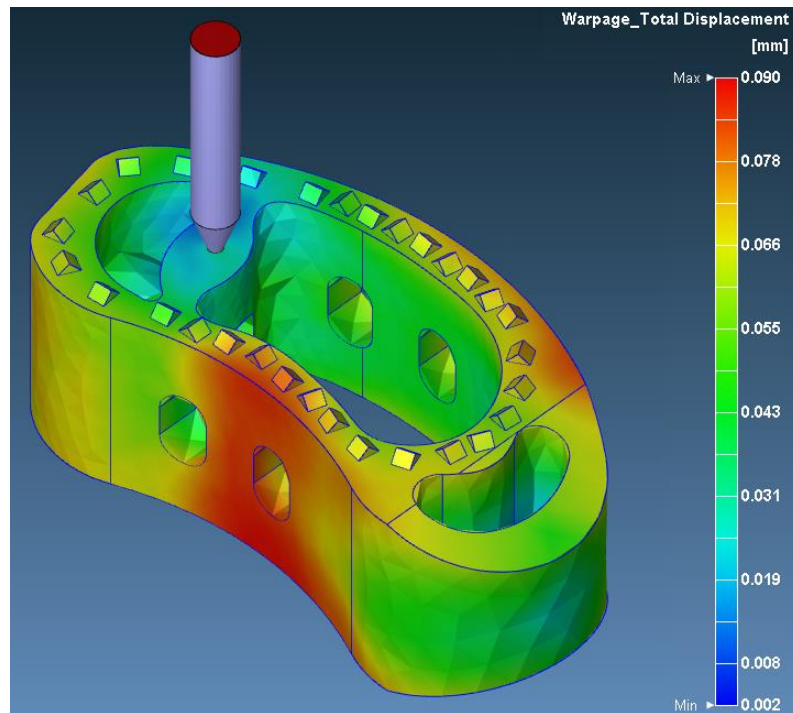
**Figure 33.** Cooling - cooling efficiency.

## 8.4 Warpage:

### 8.4.1 Total displacement:

Total displacement provides information about the magnitude and distribution of displacement across the molded implant during the warpage process. This scale ranges in color from blue, which shows regions with the lowest total displacement values, to red, which indicates regions with the highest total displacement values. As shown in Figure 34.

Which shows the length of the total displacement vector after the part is ejected and cooled down to room temperature. As we can see the maximum deformation is 0.090 [mm], which we consider good, because the element is stable in dimensions.



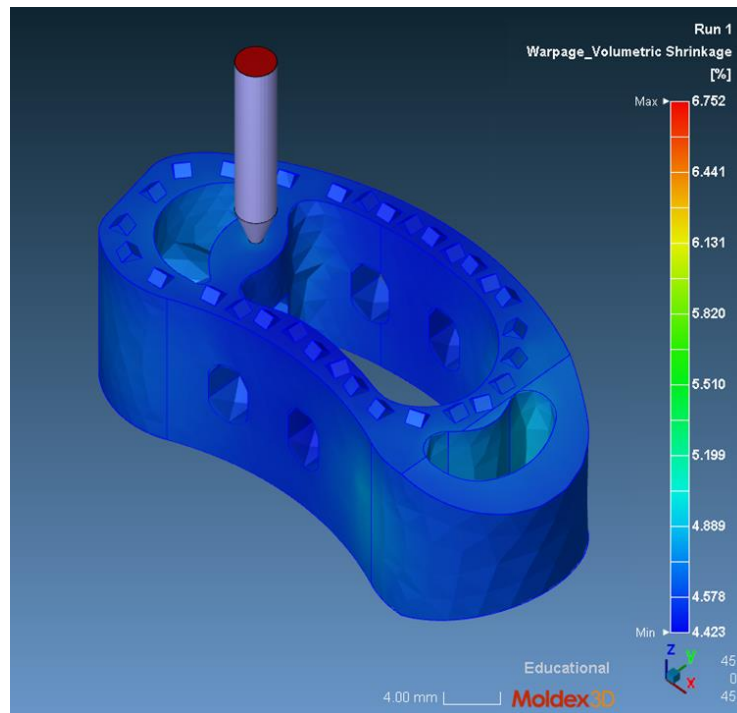
**Figure 34.** Warpage - total displacement.

### 8.4.2 Volumetric shrinkage:

The volumetric shrinkage provides information about the percentage of volume change experienced by the molded implant during the warpage process. This scale ranges in color from blue, which shows regions with the lowest volumetric shrinkage values, to red, which indicates regions with the highest volumetric shrinkage values.

This data shows the volumetric shrinkage percentage of molded part due to pressure-volume-temperature (PVT) change as the part is cooled down from high temperature, high pressure condition after packing stage to room temperature, ambient temperature conditions. While non-uniform volumetric shrinkage will lead to warpage and distortion of demolded parts.

So, we can see that this volumetric shrinkage is uniform. As shown in Figure 35.



**Figure 35.** Warpage - Volumetric shrinkage.

## Conclusion:

In this thesis work, a new design for a spinal implant was designed with NX Siemens software, which could be used in spine fixation. A molding simulation process was done with Moldex 3D software to predict the molding process behavior and the potential problems while producing it with injection molding machines. With the manufacturing process in mind, it was necessary to choose a material that could match the properties of medical applications, and PEEK was the perfect fit. In making the implant model, it was necessary to have the best possible product design so that it wouldn't complicate the mold simulation process. In this phase, there were lots of ups and downs in trying to figure out what the best design for the implant might be.

I did models modifications to reach the appropriate geometry and technology fit design. Two basic designs, and many simulations running, were conducted earlier. However, only one design and one simulation iteration were presented in this TDK thesis work.

This simulation version is characterized by filling time (0.23 sec), packing time (5.69 sec), cooling time (15.03 sec), cycle time (26.22 sec). Melt Temperature: 385 [°C], Mold Temperature: 190 [°C], Max Injection Pressure: 250 [MPa], Ejection Temperature: 296 [°C], Max. Clamp Force: 2.5 [ton].

After analyzing the results of this simulation for this specific design, we decided to do another simulation process, which we will consider for it all the previously mentioned problems.

Such as: - Sharp welding angles found at some places, and welding lines became visible.

- Some air traps were found, which are not serious problems but may cause voids or surface defects.
- Big shrinkage in the hole screw part, and next to some other parts.

To solve these problems, first I will modify the designed implant a little bit, after that I will do another simulation running, and will change the gate position, or maybe increase the gates number. Also, I will try to increase the filling time.

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