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Study on the Molding of the Instrument in the Complex Thin-Wall Medical Device with Polymer Material Structure

Tianbiao Huang[1*], Nuoying Feng[2], Yifan Tang[1]

[1]*Zhejiang Ocean University Donghai Science and Technology College, Zhejiang, China*
[2]*Zhejiang Huachang Hydraulic Machinery Co., Ltd, Zhejiang, China*
**corresponding author*

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Abstract: China has poured a lot of heart and soul into the development of medical device industry, but up to now, Chinese medical device industry in the high-end product field, the competitiveness of local enterprises is still vulnerable. This Papers is in order to optimize the use of polymer materials for medical equipment for the rational exploration of a shortcut. In this paper, the application of Ug tool software, Moldflow tool software, AutoCAD tool software and other tools are used in the design, manufacture, simulation analysis of polymer materials used in medical devices; It can be used for reference in the design, manufacture and simulation of medical equipment with the same kind of polymer materials. In this paper, according to moldflow analysis software study on used to determine, the injection molding mold location, cavitation distribution, weld lines, maximum deformation of the products. This article has certain reference value to the design and production of the same kind of products.

1. Introduction

About 15% of the medical devices in China's primary medical and health institutions were manufactured before or after the 1970s, and 60% before the mid-1980s. With the acceleration of the global integration process, China's medical device market will grow rapidly in the next 10 years or even longer. The Chinese government has put forward the goal of creating a high place for life and health science.[1] It has poured a great deal of effort into the development of the medical device industry, and has continuously increased its efforts to support the medical device industry.[2] But to this day, the Chinese medical device industry in the high-end product field, the competitiveness of local enterprises is still vulnerable. Especially in the medical equipment polymer molding technology talent shortage, equipment is not perfect, the standard is not unified, with the western manufacturing power has already realized the polymer molding mold standardization, the intellectualization, the integration, to achieve resource sharing, greatly shorten the design cycle, reduce the production cost of the advanced production level there is still a big gap.[3-4] In this paper, a medical instrument cover, such as figure 2, is studied, By using Moldflow simulation software, the inner structure of the cover was optimized and the polymer injection mould for medical apparatus was designed as shown in figure 1.

2. Selection of Component Materials

The cover of medical instrument is instrument article, as shown in figure 1,the requirements of non-toxic harmless to the human body, product appearance quality requirements, do not allow to leave obvious traces and flow, flying edge and other defects; And should have a certain wear resistance and corrosion resistance, working size stability, medium precision, mass production; injection conditions for high temperature, high pressure, it has higher strength requirements for mold as shown in figure 2. Therefore, the use of polycarbonate materials with good. The properties and applications of common plastics such as Acrylonitrile Butadiene Styrene, polypropylene, polyethylene, polyvinyl chloride is compared, Due to their poor mechanical properties, and molding shrinkage is not easy to shape, even toxic harmful to the human body, so do not choose. So selection of the polycarbonate with good heat resistance, excellent stability, non-toxic and harmless to human body is selected.[5]

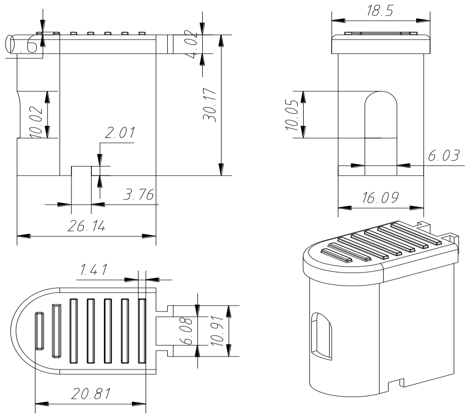


Figure 1: The cover of a medical instrument

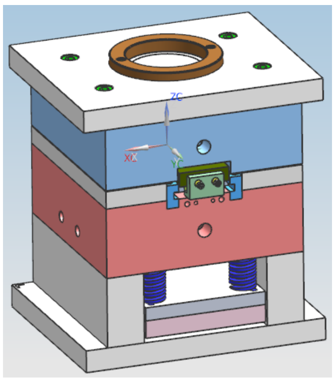


Figure 2: The mould for the cover of an instrument box of a medical instrument

3. Analysis of Plastic Parts Structure Technology and Selection of Equipment

3.1. Analysis of Gating System for Polycarbonate Polymer Molding

The finite element model of a certain type of medical device cover is established by Moldflow, an advanced gate locator algorithm for the above gate designs is presented in figure 3 to verify the accuracy of the gate design position to minimize flow resistance, and Moldflow analysis to determine the optimal gate position. For the thin-walled plastic parts of the instrument cover such as figure 1, the main defects in the forming process are warping deformation and insufficient filling. The deformation degree in each direction can be analyzed in advance by the analysis of Moldflow software as shown in figure 4, the results of this kind of analysis have become more and more accurate, so the data can be used to modify plastic parts or injection molds in a timely manner.

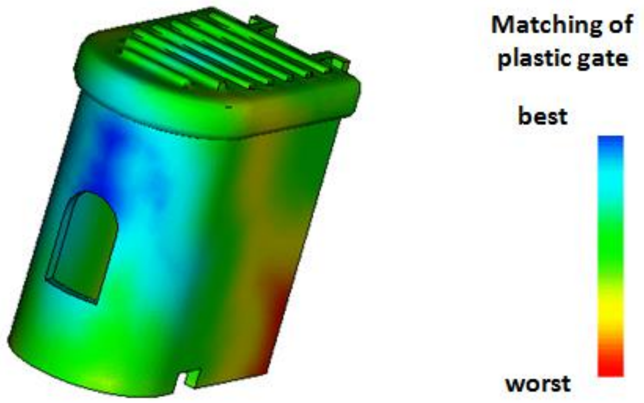


Figure 3: Gate matching of gating system

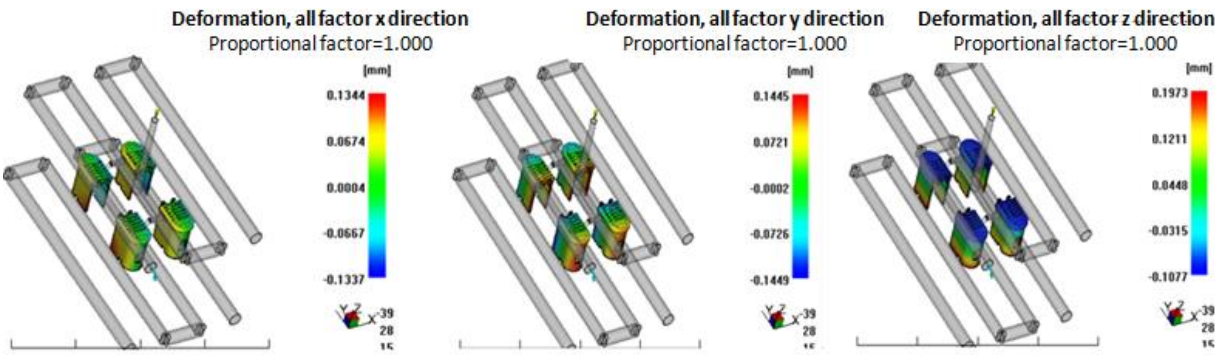


Figure 4: Analysis of the deformation of thin-walled plastic parts in different directions

It can also help engineers and technicians to effectively predict the bad conditions such as Air Holes and weld lines that may occur in the molding process of plastic parts, to determine the optimum injection pressure, holding pressure, clamping force, mould temperature, melt temperature, injection time, holding time and cooling time as shown in figure 5 for injection molding of the best plastic products [6], to improve the success rate of a trial mold, and finally achieve the goal of reducing production costs and improving production efficiency.

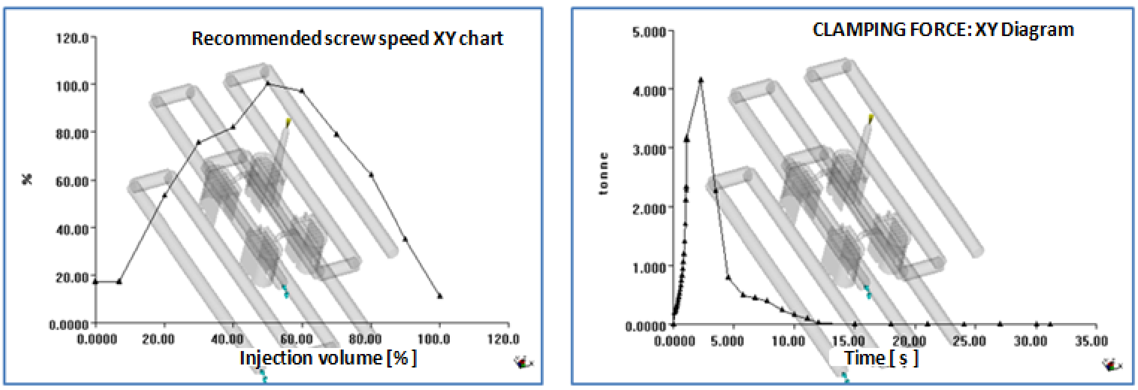


Figure 5: Analysis of process parameters before or during injection

3.2. Dimensional Accuracy Analysis of Plastic Parts

As shown in figure 1, there is no special requirement for the dimensional accuracy of the cover of a medical device, all dimensions are undimensioned. Undimensioned dimensions of polycarbonate plastics are classified to MT5 [5]. major dimensioned tolerances are specified as follows unit: mm.

Plastic part outline size (reduced size after wear), mark one-way negative deviation: Figure.1.

$30.14\pm0.28\rightarrow30.17\pm0.28\Rightarrow30.45^{0}_{-0.56}$ Class A

$16.09\rightarrow16.09\pm0.19\Rightarrow16.28^{0}_{-0.38}$ Class A

$18.5\pm0.22\rightarrow18.5\pm0.22\Rightarrow18.72^{0}_{-0.44}$ Class A

$30.77\pm0.28\rightarrow30.77\pm0.28\Rightarrow31.05^{0}_{-0.56}$ Class A

$4.02\pm0.12\rightarrow30.17\pm0.12\Rightarrow4.14^{0}_{-0.24}$ Class A

$13.07\pm0.16\rightarrow13.07\pm0.16\Rightarrow13.23^{0}_{-0.32}$ Class A

$1.21\pm0.20\rightarrow1.21\pm0.20\Rightarrow1.41^{0}_{-0.40}$ Class B, Wall thickness dimension etc.

Internal dimensions (increased size after wear) of plastic parts, marked with one-way positive deviation:

$7.04\pm0.14\rightarrow7.04\pm0.14\Rightarrow6.9^{0.28}_{-0}$ Class A

$4\pm0.12\rightarrow4\pm0.12\Rightarrow3.88^{+0.24}_{0}$ Class A

$13.67\pm0.16\rightarrow13.67\pm0.16\Rightarrow13.51^{+0.32}_{0}$ Class A

$2.01\pm0.2\rightarrow2.01\pm0.2\Rightarrow1.99^{0.4}_{0}$ Class B etc.

Dimensions of center distance of holes in plastic parts dimensions with constant relative position after wear, marked with two-way equivalent deviation:7.04±0.24 Class B etc.

3.3. Surface Quality Analysis of Plastic Parts

Surface quality of plastic parts. According to GB 14234-1993, the range of Surface roughness for injection molding of polycarbonate is R_a0.025~1.6um, so the value is R_a=0.8. According to the characteristics of polycarbonate, the internal Surface roughness of plastic parts are not required.

3.4. Analysis of the Structure and Technology of Plastic Parts

a. the plastic part has a large drawing angle to ensure the normal demoulding.

b. Demoulding slope. Refer in "***plastic molding process and mold design***" for plastic parts made of polycarbonate, the declination of the die cavity is 35'-1°20', the declination of the core is 30'-40', take half of the die cavity, the declination of the core is 35'. [5]

c. the plastic part belongs to the plastic part of the box cover and has uniform wall thickness, and conforms to the minimum wall thickness requirement.

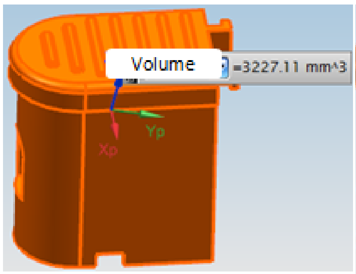
To sum up, the structure of the plastic parts is of moderate complexity, reasonable structure technology; the precision of the plastic parts is moderate, the size of the die parts can be guaranteed in the processing; the molding requirements of the plastic parts can be guaranteed.

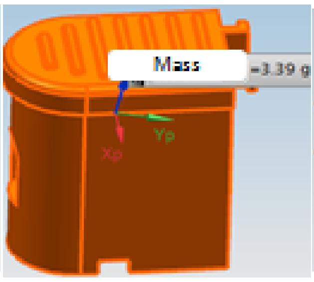
3.5. Initial Selection of Equipment Based on Maximum Injection Volume

According to design experience, it is usually guaranteed that the injection quantity required for the product is less than or equal to 80% of the maximum injection quantity allowed by the injection machine. Otherwise, the defects such as incomplete shape, loose internal structure or reduced strength of the product will be caused, and the injection volume is too large, the injection volume utilization ratio of the injection machine is too low, and the electric energy is wasted, furthermore, prolonged exposure of plastics to high temperatures can lead to the decomposition and deterioration of plastics. Therefore, it should be noted that the maximum amount of injection that can be handled by the injection machine should normally be greater than 20% of the rated injection amount.

3.5.1 UG Software Query the Physical Parameters of Plastic Parts (Including: Volume, Mass, Projection Area, etc.)

According to the 3-D model of the parts in Ug tool software as shown in figure 6; figure 7; figure 8; According to in Ug tool software, the volume, quality and projection area of the plastic parts can be obtained directly by using UG tool software:





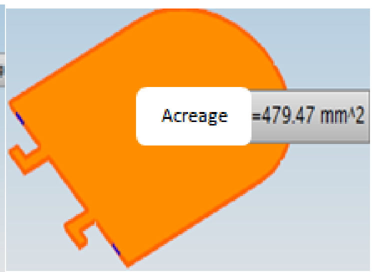


Figure 6: Volume of plastic part   Figure 7: Plastic quality   Figure 8: Projection area

3.5.2 Calculate the Quality of the Plastic Part

The purpose of calculating the quality of plastic parts is to select the injection machine and determine the number of die cavity. The density of polycarbonate plastics obtained from schedule 1 of Reference [5] is calculated by changing the density with 3D software as shown in figure 7:

$$M_{total} = 4 \times M_{Single} \approx 13.56\text{g} \quad (1)$$

According to the shape and size of the plastic part, the shape of the plastic part is the box cover body, the maximum length is 26.14 mm, the width is 16.09 mm, the height is 30.17 mm, and the size is smaller. Therefore, the instrument box covers plastic parts molding we use a four-piece mold structure.

Plastic parts need injection amount (including the quality of the condensate, the preliminary estimate is) for 35g each time.

3.5.3 Calculate the Total Volume (Total Mass) of Each Injection into the Mold

$$M_{total} = 4 \times M_{Single} \approx 12908.44mm^3 \quad (2)$$

$$V = \frac{M}{\rho} = \frac{35}{1.05} = 33.3\text{cm}^3 \quad (3)$$

Usually guaranteed that the injection quantity required for the product is less than or equal to 80% of the maximum injection quantity allowed by the injection machine.

$$\frac{V}{80\%} = \frac{33.3}{0.8} = 41.6cm^3 \quad (4)$$

Therefore, the maximum injection volume of the selected injection molding machine should be greater than or equal to, by consulting the table in reference [5], the types and technical parameters of commonly used domestic injection molding machines, the primary selection, the types of screw injection molding machines, meet the injection machine less than or equal to the maximum allowed injection machine, the late choice in the mold base is much larger than the priority injection machine. Finally, the thickness of the mould base 301mm, does not meet the model of screw injection molding machine mold maximum thickness, so the last choice, injection machine. The main parameters of the injection machine are shown in table 1.

Table 1: Main parameters of injection machine

Theoretical injection quantity /cm ³	200	Mold max trip /mm	260
Screw diameter /mm	65	Maximum thickness of mold /mm	406
Injection pressure /Mpa	109	Minimum thickness of mold /mm	165
Injection trip /mm	230	Template size /mm	523× 634
Inject time /s	5	Pull rod space /mm	400
Plasticizing ability (g/s)	7	Radius of nozzle ball /mm	SR18
Mold clamping force /KN	2540	Nozzle orifice diameter /mm	Φ4
Injection mode	Screw type	Diameter of locating hole /mm	Φ125

3.6. Selection of Injection Molding Machine Based on Maximum Clamping Force

Because the force produced by injection pressure in the mold cavity will cause the mold to expand along the parting surface, so in order to avoid the overflow and expansion of mold, when the melt filled the mold cavity, the mold locking force of the injection machine must be & GT Effect of Melt in cavity on moving die.

a. the projection area of a single plastic part on the parting surface A_1.

As shown in figure 8, the three-dimensional software analysis shows that: $A_1 \approx 479.47mm^2$.

b. projected area of melt plastic on parting surface during molding A.

The plastic parts of the instrument box cover are molded with a mold structure of four parts, and the projected area of the condensate on the parting surface is estimated to be about $1000mm^2$, so.

$$A = 4A_1 + 1000 = 4*479.47 + 1000 = 2917.88 < 645*10^2 mm^2 \quad (5)$$

c. the force exerted by Melt Plastic on the moving die during molding F

$$F = AP = 2917.88 \times 34.2 = 99791.5N = 99.8KN \quad (6)$$

$$F = \frac{AP}{K} = \frac{99.8}{0.8} = 124.75kN < 2540KN \quad (7)$$

In the formula: p :Average molding pressure of a plastic melt on a cavity, the polycarbonate (PC) viscosity is higher [5]. the unit pressure required for the molding of the polycarbonate (PC) mold cavity is p =34.2 Mpa. [5]

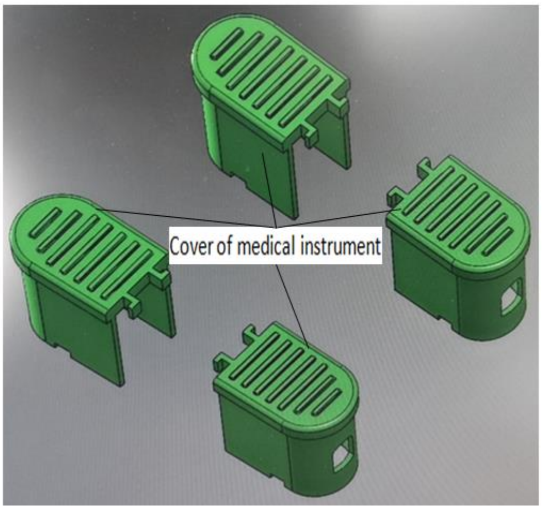
K —factor of safety

d. according to the principle that the clamping force must be greater than or equal to the force acting on the moving mould by the melt in the mould cavity [5]. the clamping force of the screw injection machine of the model is, meet the requirements.

3.7. Injection Process Parameters of the Cover of the Instrument

The injection molding process for the cover of the instrument is shown in table 2.

Table 2: Injection molding process cards for instrument cover

<table>
<tr><td>Component</td><td>Instrument Box Cover</td><td>Material Trademark</td><td>Polycarbonate</td><td>Facilities No.</td><td>G54-S-200</td></tr>
<tr><td>Assembly drawing No.</td><td>none</td><td>Material quota</td><td>none</td><td>Number per molded part</td><td>4 pieces</td></tr>
<tr><td>Part No.</td><td>none</td><td>Single piece mass</td><td>39.44 g</td><td>Clamp No.</td><td>none</td></tr>
<tr><td colspan="3" rowspan="14">
</td><td rowspan="3">Material drying</td><td>equipment</td><td>Infrared oven</td></tr>
<tr><td>temperature°C</td><td>95~105</td></tr>
<tr><td>Time h</td><td>3~4</td></tr>
<tr><td rowspan="4">charging barrel temperature °C</td><td>charging barrel Zone 1</td><td>160~175</td></tr>
<tr><td>charging barrel Zone 2</td><td>185~195</td></tr>
<tr><td>charging barrel Zone 3</td><td>205~215</td></tr>
<tr><td>spray nozzle</td><td>190~205</td></tr>
<tr><td colspan="2">Mold temperature°C</td><td>85~120</td></tr>
<tr><td rowspan="3">time</td><td>Injection s</td><td>3~7</td></tr>
<tr><td>dwell pressure s</td><td>5~10</td></tr>
<tr><td>Cool s</td><td>5~15</td></tr>
<tr><td rowspan="3">pressure</td><td>Injection pressure MPa</td><td>50~85</td></tr>
<tr><td>dwell pressure MPa</td><td>45~65</td></tr>
<tr><td>Backpressure MPa</td><td>3~8</td></tr>
<tr><td rowspan="2">aftertreatment</td><td>temperature °C</td><td>Infrared oven 80~100</td><td rowspan="2">time rating</td><td>Assist min</td><td>0.5</td></tr>
<tr><td>Time h</td><td>0.4~1</td><td>Single piece min</td><td>0.5~1</td></tr>
</table>

3.8. Mainstream Design

The dimensions of the injection molding machine nozzles, it can be seen that the radius of the nozzle ball is R = 18 mm and the diameter of the nozzle hole is d = 4 mm. According to the relationship between the main flow channel and the nozzle of the mold. [7]

$$R = R_0 + (1-2)mm \qquad \mathrm{d} = d_0 + 0.5mm \tag{8}$$

The spherical radius of the main channel is r = 20mm, and the diameter of the small end of the main channel is d = 5mm.

The main channel is designed to be conical, its cone angle is $\alpha = 2°$, Surface roughness $Rz = 0.4\mu m$, polishing along the axial direction, in order to facilitate the casting system condensate from which smoothly fall off. At the same time, the ARC transition is designed at the discharge end of the main flow passage, and r = 3mm is taken to make the melt smoothly enter the flow passage.

3.9. Design of Tributaries

The shape and size of the sprue are related to many factors of the plastic part. The plastic part is made of polycarbonate (PC) with complex shape, thin and uniform wall thickness. Combined with the structure of the plastic part, the side gate is adopted. In consideration of the pressure loss, a circular diversion channel with cross-section is adopted. The diameter of the sprue is d = 4mm, the length of the sprue depends on the location of the gate, and the end extension acts as a cold cavity.

3.10. Point Gate Design for Gating System

The gate design mainly needs to solve the gate type, the feed gate position determination, the gate size determination and so on.

(1) selection of point gate type

In order not to affect the surface quality of the plastic part as much as possible, the structure of the plastic part, the position of the parting surface determined, the plastic forming property, the point gate analysis, and in order not to complicate the mould structure, it is determined that the side gate is used as the mould for forming the plastic part.

(2) determination of point gate size

The gate size requirements, design gate size in turn. Side Gate width b = 1.2 mm, height h = 0.8 mm, length l = 2mm, end radius r = 1.83 mm. [5]

3.11. Cold Material Cavity Design

Using the more common z-shaped pull rod now in use, this pull rod is fixed on the push rod fixing plate.

3.12. Flow Ratio Calibration

The limit flow ratio Φ = 120 ~ 180 can be found by consulting "***plastic molding process and mold design***" and in "***plastic molding process and mold design***", when the flow ratio exceeds the allowable value Φ, insufficient filling will occur. The flow ratio K is calculated as follows: [5]

$$K = \sum_{i=1}^{n} \frac{li}{ti} = \frac{75.5}{2} + \frac{64.9}{4.99} \times 2 + \frac{28}{4} \times 8 + \frac{2}{1.2} \times 8 = 133.1 \qquad (9)$$

It can be seen that the general limit flow ratio Φ value is much greater than 50.58, so the plastic limit flow ratio meets the molding requirements.[5]

4. Design of Exhaust and Air Entraining Systems

Because the wall thickness of the plastic part is even and thin, the air displacement is small, at the same time, the side gate die structure is adopted, which belongs to the medium and small-sized die, the air can be discharged by using the gap of parting surface, the utility model can also make use of the mating clearance between the movable core, the movable insert and the template to exhaust gas.[7] Although the plastic part belongs to the thin shell plastic part, and there is gap between the cavity and slide block as shown in figure 9 and the pull rod for air entrainment, vacuum negative pressure will not be formed in the process of opening and demoulding, so the air entrainment system is not designed.

5. Complex Structure Large-Scale Thin-Walled Medical Equipment Polymer Molding Die Assemble

Study on the molding of the instrument in the complex thin-wall medical device with polymer material structure, take the injection molding of the cover of a medical instrument as an example as shown in figure 9.

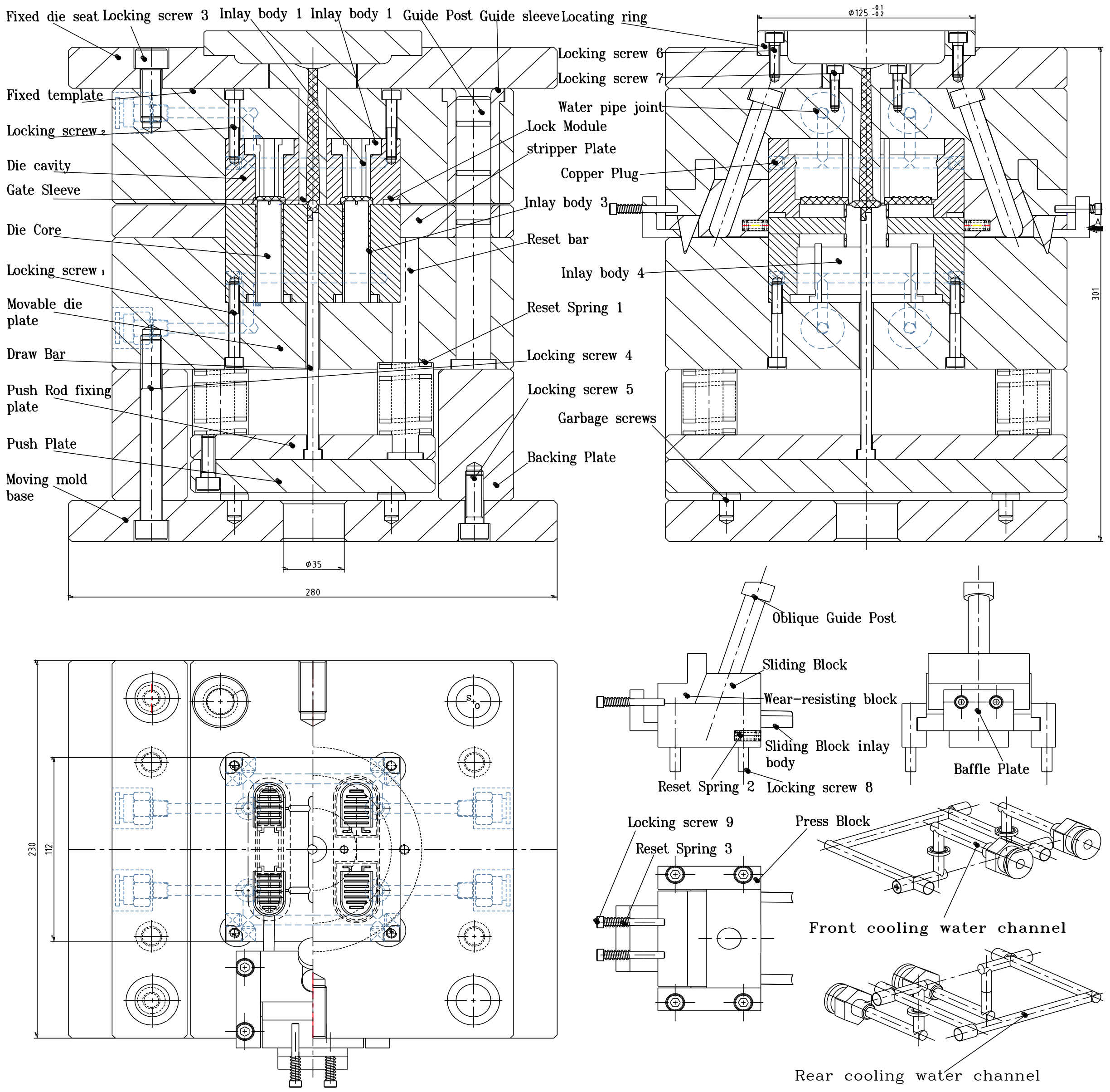


Figure 9: Assembly drawing of a forming die for the lid of a medical instrument

The technical requirements for the forming die of a medical instrument box cover are as follows:

a. The Oblique Guide pillar core-pulling mechanism is adopted, and the push rod is reset first to avoid interference. The ejection stroke of the die is 40.5 mm;

b. The main parting surface is perpendicular to the center line of the contact surface which is separated from the plastic part and the condensate of the pouring system. The horizontal parting surface of the moving fixed die should be occluded, and the fitting clearance of the parting surface of the die after assembly is not more than 0.02 mm;

c. The gap fit between the guide pillar and the guide sleeve hole is h7/f7, and the transition fit between the guide pillar and the fixing plate of the guide sleeve and the template is h7/k6, h7/n6;

d. The first-degree mold note whether the plastic bag can fill the cavity, whether there is a flash, ejection mechanism is normal work, ejection after the workpiece is deformation, if there is not appropriate, repair mold try again;

e. The surface shall not be scratched or damaged

f. each fastening screw must not appear loose and so on, and ensure that the screw end face should not be higher than the template end face;

g. The ejector Rod, the pull rod and so on should have reasonable clearance when cooperating with the core mold kernel, not only to ensure that there is no flash, but also to ensure that it is not stuck in the working process.

6. Conclusions

This design research is carries on the injection molding mold design to the medical instrument box cover plastic part. In the calculation of the die. In the aspect of design, the shape and size characteristics of plastic parts are analyzed firstly, and then the selection of injection machine model, parting surface, pouring system and plastic part size are determined, combining the analysis of Moldflow software can help engineers to effectively predict the molding of plastic parts, modify plastic parts or injection molds in time, set up equipment data, effectively shorten the product development cycle and mold design cycle and improve the reliability of mold design. As shown in figure 9, it is not only convenient to process and replace, but also suitable for fitting after R & D, paving the way for future development. The optimization of side core-pulling mechanism and push-out mechanism of inclined guide pillar can improve the success rate of test die and reduce the production cost, so as to shorten the design cycle of injection mold and improve the production efficiency. According to the determined single parting surface of the die. Select the standard mould base; finally draw the general assembly drawing of the mould and the parts drawing of cavity, core and slanting top. In the process of drawing, the main application of UG, Moldflow, AutoCAD software, to provide reference for peers.

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