

A NOVEL PROCESS FOR RAPID PROTOTYPING AND SCALABLE MANUFACTURING BY POWDER INJECTION MOLDING FOR MEDICAL APPLICATIONS

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ABSTRACT

Maetta has developed a manufacturing platform specifically designed to suit the manufacturing needs of the medical device market. Its revolutionary technology was developed for rapid prototyping and scalable manufacturing by Powder Injection Molding (PIM) for small complex shape parts made of materials typically seen in implant and instrument applications. Thriving on the design and manufacturing capabilities of conventional PIM, Maetta's technology significantly reduces cost for prototypes and small volume production by the use of its low viscosity feedstocks. This scalable technology simplifies part qualification with rapid and functional prototypes that can be directly scaled to full production volumes.

Maetta Sciences has developed a rapid prototyping and manufacturing technology to meet the specific needs of engineers and designers of small complex shape parts made of existing and new exotic alloy materials. PIM has slowly but surely gained credibility in the manufacturing community over the past years where several applications have been successfully processed for high volume applications, with only a few for low volume instrument and implant applications [1]. Maetta's revolutionary technology suites the requirements for small complex shape parts, with low to mid volume manufacturing for the medical industry. Processing guidelines and technology qualification are routinely done according to ISO 13485 standards.

The technology platform includes low viscosity feedstocks, co-specialized molding equipment and processing guidelines for prototyping and scalable manufacturing. The integrated approach is aimed at increasing its clients' product development capabilities and prototyping flexibility as well as reducing costs & time-to-market of products. Based on proprietary PIM technologies, the Maetta System enables scalable manufacturing throughout the product's life cycle.

The PIM generic manufacturing process can be divided into four key process steps being, mixing, injection molding, debinding and sintering as seen in figure 1. The first step of the process consists in creating the raw material for injection molding commonly known as feedstock. In this step, metal and/or ceramic powders are mixed with an organic

binder to create slurry that can be molded in a tool to form a part. Injection molded parts, named "green parts", are then subjected to the third step of the process, a debinding treatment, which has the purpose of extracting the binder from the molded body, leaving the powdered material in place. The debound parts, named "brown parts", have sufficient strength to be handled for the final high temperature heat treatment (sintering). In this last process step, the parts shrink to attain a high sintered density where parts maintain their shape.

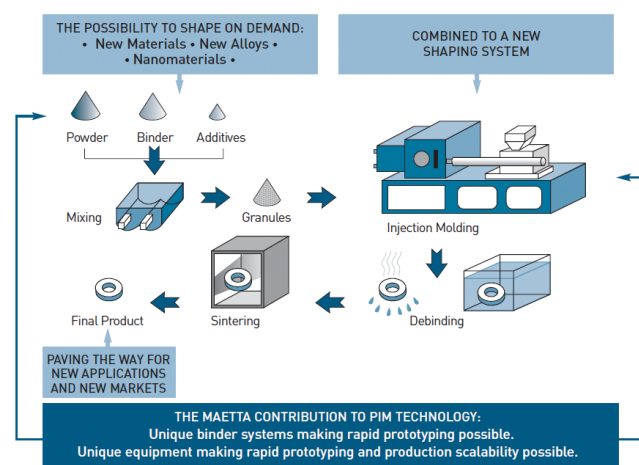
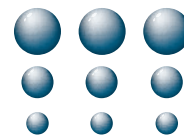


Figure 1: Processing steps of the Powder Injection Molding process.



Conventional PIM processes are usually carried out with the use of equipment and raw material/feedstock that enable high volume manufacturing [2]. Automated molding equipment and expensive tooling are typically required for prototyping parts which can radically increase qualification costs and lead-times. Maetta's proprietary low viscosity feedstocks do not require automated machines and expensive tooling for prototyping or manufacturing. The Maetta system is specifically designed for low cost rapid prototyping and is directly scalable for small to mid volume manufacturing found in orthopaedic, endoscopy and other fields of medical manufacturing.

The Maetta System is designed to rapidly assess technological feasibility with regards to the engineering drawing and specified dimensions and tolerances. PIM parts exhibit anisotropic shrinkage during the sintering step of the process. The parts rest on setters made of ceramic materials which can be shaped to support the part during the high temperature heat treatment. Friction and gravity are appreciable forces in these conditions and act upon the parts with a noticeable impact on final dimensions. Prototyping is often required for parts in order to accurately predict part shrinkage and final dimensions and assess the stability/variability of all dimensional features of a complex part with empirical data [3]. This approach is typically problematic with traditional PIM since high costs and lead-times are associated to the use of large scale production equipment.

Maetta's proprietary low viscosity feedstocks can be processed in soft tooling such as metal filled epoxy, SLA materials or aluminium tools for prototyping and production. Figure 2 presents an example of a stainless steel 316L prototype of a 5 grams part. This part is inserted into a tube for location purposes. Prototype parts were molded using a SLA cavity and were created within 10 days in which functional testing was assessed. The raw materials and processing parameters used to generate the prototypes will be used for production with high fidelity results on part characteristics such as dimensions, microstructure and mechanical properties. Based on this prototyping information, the application can be readily qualified per ISO 13485 standards and transferred to production.

Figure 3 presents another example of a stainless steel 17-4PH prototype part of a broach used in hip surgeries. A 3D CAD model of the part was created with desired features. The tooling cavity was scaled up from the 3D model to take into account the process shrink that occurs during the sintering phase in order to obtain the finished desired sintered part. In this case, the prototype tool was made of steel in which part marking features were incorporated. Figure 3 shows the typical PIM shrink that occurs between injection molded and sintered parts.

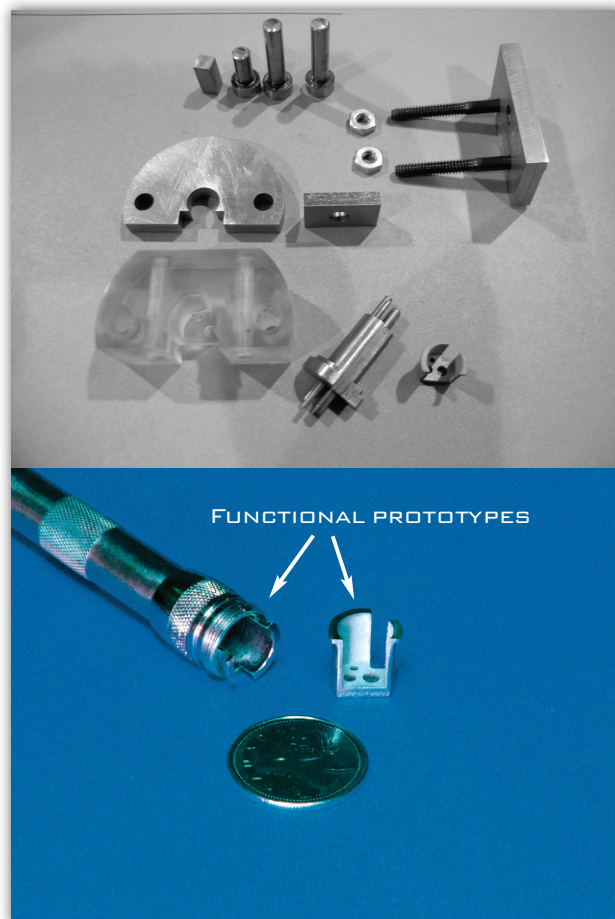


Figure 2: Example of cost effective rapid prototyping of a PIM stainless steel 316L application for part qualification.

Generating high fidelity prototypes with the use of Maetta's low viscosity PIM platform has proven itself to be strategic in part design and qualification for production. In the early stages of the life cycle of a product, the parts design and features often evolve to attain a configuration that will be processed, until the products maturity and decline phase. Working with a technology that enables rapid and low cost manufacturing in these early stages dramatically reduces the costs and efforts associated to the parts qualification. Furthermore, the preliminary work done on prototypes and small runs generate data that is considered for the qualification of larger scale production since the same raw materials and process parameters can be used.

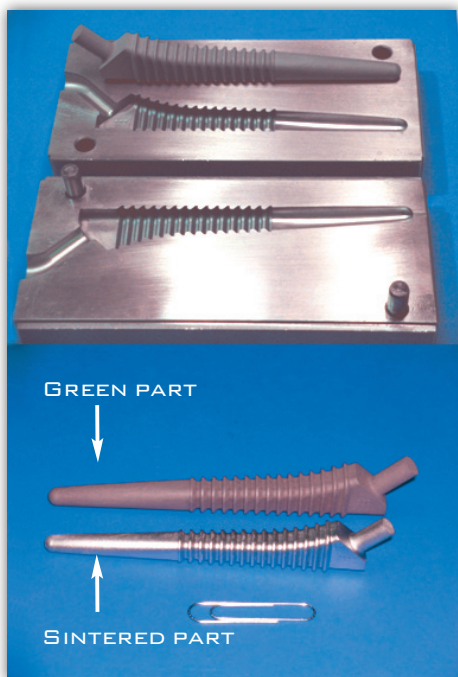
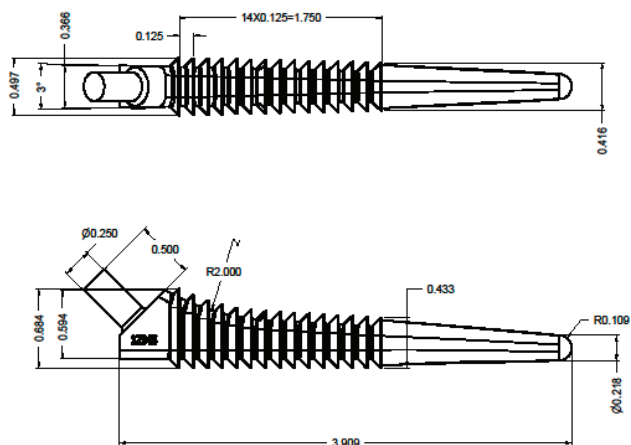
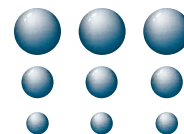


Figure 3: CAD model of the prototype, associated prototype tooling with molded part and green and sintered components

Design considerations

Part selection for PIM manufacturing is a critical step in guaranteeing a successful application. The selection criteria are based on four main considerations being the annual volume, part complexity, part dimensions & tolerances and the chosen material. Table 1 presents typical guidelines for part selection in relation with the above mentioned criteria as well as other considerations for the final parts [4].

Another interesting characteristic to consider for part selection is the effective density of a component. The effective density is the mass of the component divided by the outer volume from which machining would be done. Industry standards for parts in production indicate that the majority of manufactured parts have shapes with low effective densities, in the range of 25% of the bulk density of the material. In other words, PIM has avoided 75% mass loss for these components if they were to be machined [1].

Table 1: Typical guidelines for PIM part selection for manufacturing with the Maetta System.

Characteristic	Minimum	Maximum	Typical
Wall thickness (mm)	0.5	22.5	3
Component mass (g)	0.02	300	40
Tolerances (1σ,%)	0.03	2	0.3
Specified features (qty)	10	1 000	100
Annual production (units/yr)	50	50 000	500 – 5000
Annual production for conventional PIM (units/yr)	5000	> 1 000 000	> 50 000

Other interesting part features can be generated in PIM manufacturing such as part marking (the tooling can be manufactured with identification features such as part number, tooling revision and so on for traceability purposes). Inner cavities can be generated by co-processing two or more components or by the use of soluble cores to form features that could not be generated by other manufacturing processes. Figure 4 presents examples of 17-4PH components where parts were processed to generate net shape internal cavities. Techniques such as soluble cores and co-processing were used in these cases and enable manufacturing features that could not be done by other manufacturing processes. Numerous applications have been successfully re-designed to combine several parts of an existing assembly into one PIM component which respects form, fit and function [5]. When engineering and design efforts are conducted in the early stages of part design with PIM in mind, benefits on performance and cost reduction are optimised.

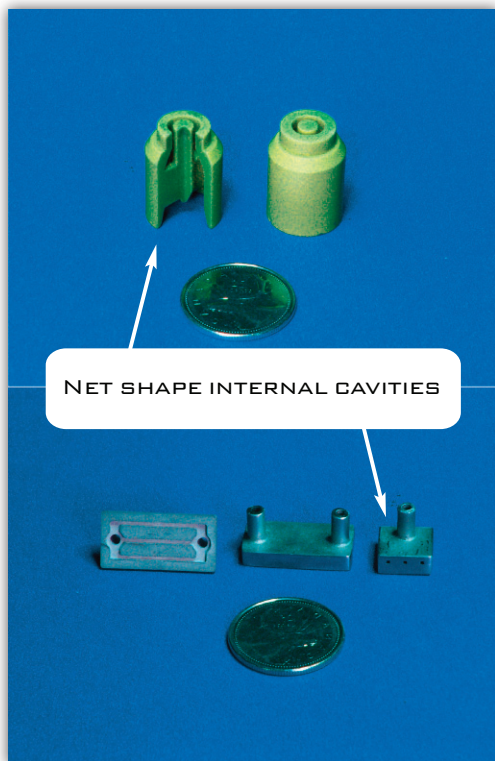
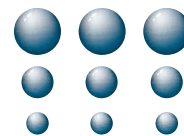


Figure 4: Examples of components manufactured with techniques to generate net shape internal cavities (top image by soluble core and bottom image by co-processing)

Materials and properties

PIM is known to be extremely versatile with regards to applicable materials that can be processed. If powdered materials are available they can conceptually be processed by PIM to obtain a finished net shape component. Powder manufacturing techniques such as atomization and milling have greatly evolved over the past years and have increased the quantity of alloys that can be successfully processed by PIM as seen in figure 5.

The Maetta System has been developed for rapid prototyping and scalable manufacturing for alloys encountered in medical devices applications. Stainless steel grades 17-4PH, 316L and 410 have been successfully developed to be processed to exceed requirements of MPIF standard 35 or ASTM B883-05 standard for ferrous MIM materials [6,7].

Other applicable materials such as cobalt-chromium alloys and titanium alloys are under development for part manufacturing on Maetta's platform.

Figure 6 and 7 present typical microstructure and mechanical properties of a stainless steel 17-4PH material once processed and heat treated. The microstructure of this material is relatively fine which is in direct relation with the presented mechanical properties. Typically, PIM materials have mechanical properties which are superior to cast material and slightly inferior to those of the wrought material [8].

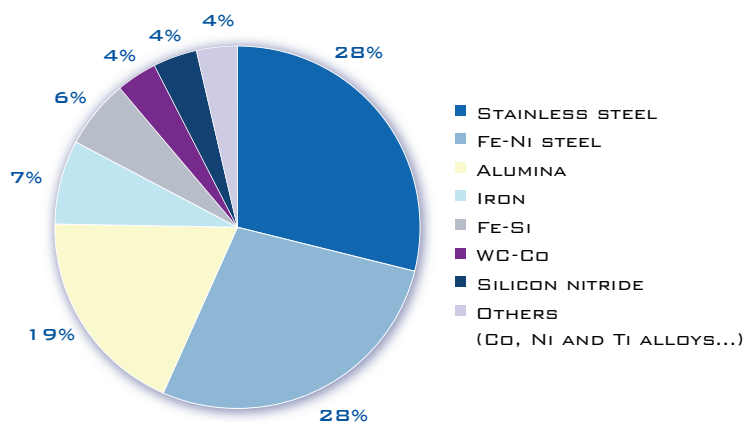


Figure 5: Relative material utilization in PIM on a weight basis [1].

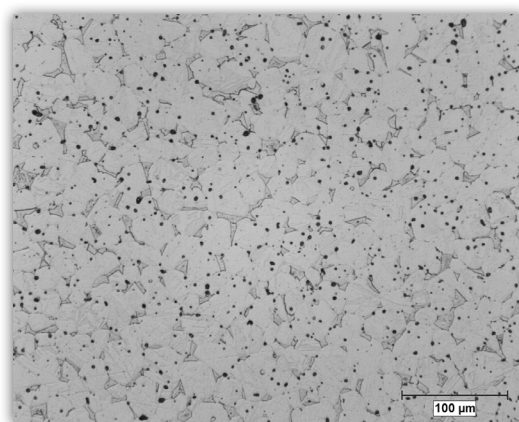


Figure 6: Typical 17-4PH microstructure once processed in the Maetta System.

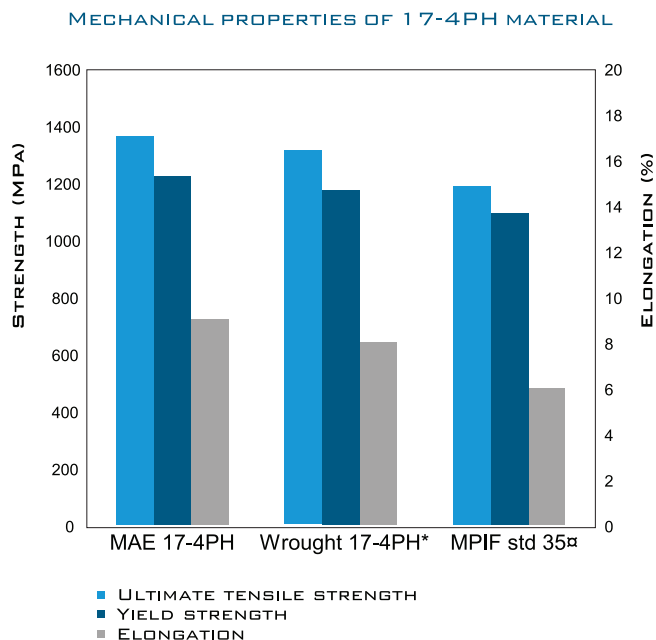
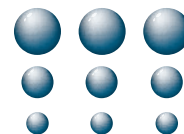


Figure 7: Comparison of 17-4PH mechanical properties once H900 heat treated; * ASTM B-564 minimum properties, \square MPIF std35 typical properties

Maetta has significantly progressed in its development program for the manufacturing of implantable materials and applications. The materials under study are titanium CpTi gr.3, Ti6Al4V and cobalt-chromium alloy F-75. The objectives of this program are to develop materials and processes that will be applicable for implantable applications and ultimately device qualification. There has been a lot of interest in the PIM and manufacturing communities concerning processing titanium and cobalt alloys for implantable applications [9-13]. There is

presently an ASTM standard under study in which standard practices and material characteristics are under investigation for Ti6Al4V [14]. Figure 8 presents an optical micrograph of Maetta's Ti6Al4V material processed by PIM.

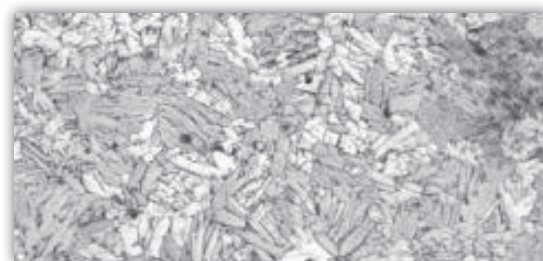


Figure 8: Ti6Al4V microstructure once processed by PIM.

Conclusion

Maetta's technology was designed to meet the requirements for small complex shape part manufacturing for low to mid volume for medical devices sector. The integrated platform combining prototyping and manufacturing equipment, raw materials and processing guidelines was specifically developed to ensure manufacturing of quality meeting the medical industry standards. The Maetta System enables scalable manufacturing throughout the product's life cycle from prototyping to production and dramatically reduces the cost of part qualification and manufacturing.

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