"Proven Technology" from CeramTec: BIOLOX®delta – Know-How in Large Scale Production

Experts claim that ceramics are alive because each lot has its very own characteristics. To recognize them and to optimize the process each time remains one of the unique challenges in the production of ceramics. Of course, at the same time quality must be maximized, particularly when dealing with ceramic implants. Always meeting the required parameters, even in large scale production, calls for know-how and experience. For more than 40 years and with over 13 million implanted components CeramTec/DE has demonstrated its mastery of this skill even in production runs with a seven-digit volume per year. Uwe Kemmer, Director Production, gave Ceramic Applications an insight in the production of heads and cup inserts for hip arthrosplasty.

Fig. 1
BIOLOX® delta hip joints

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Uwe Kemmer, in charge of implant component production at CeramTec, says "you cannot buy medical grade ceramic ready made on the market. We have to manufacture our material from the raw materials and according to the formulation that we have optimized in a lengthy development process." Indeed, it took years to develop this composite which gives BIOLOX®delta[1)] its enormous strength and finish. It comprises four ceramic raw materials – aluminum oxide, zirconium oxide, strontium zirconate and yttrium chromide – which are shipped as powders to the German production sites at Plochingen and Marktredwitz.

Homogenize for one week

The production process starts with the inspection of the materials received: Each lot is sampled and – depending on the finished product made from these raw materials – 15 to 25 characteristics are tested in the company's own accredited test lab. Once the powders have passed the test, they are weighed, mixed and homogenized. The latter process may take up to a week, until the specified particle size and even distribution of the constituents in the finished material are ensured. This is followed by the addition of ultrapure water, and then the liquid bulk is sprayed through a nozzle and dried.

These steps yield an extremely fine powder which is pressed into balls or cylinders. "The special art required here is to achieve absolutely uniform compacts free of any fissures," explains Uwe Kemmer. "How to do that with the BIOLOX®delta material is part of our specific know-how." Before the compacts enter the subsequent processing steps, they are extensively tested once again: Each part is checked for accurate dimensions, density and possible fissures.

In the lingo of ceramic production, the following shaping process is called "green machining" and demands special attention as well, although at first glance the milling

1) BIOLOX® delta ball heads and inserts, BIOLOX® OPTION are registered by CeramTec's customers. They are not registered/available in all countries.

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Fig. 2
Ceramic hip joints in a 3D-simulation

and turning does not seem to differ from the machining of other materials. But this is deceiving, clarifies Uwe Kemmer: “Fixating a ceramic green compact on a lathe requires some know-how. I cannot just exert pressure until the part does not move anymore. That would destroy it. We know how to fixate it without damage.”

Precisely calculated shrinkage

For once, the actual shaping, in other words the milling and turning, is an absolutely conventional procedure. Material is machined off the compact until it has obtained its required shape. However, this shape is markedly larger than the final product, although the green machining will have produced a shape closely resembling the “final contour”. “We have to account for about twenty percent shrinkage during sintering,” says Uwe Kemmer. “In addition, during sintering the material also shrinks differently along the transverse and longitudinal axis. Since we know the corresponding values for this behavior, we can set the precise dimensions of the green compact.

Fig. 3
BIOLOX®delta hip component range

Sintering (Fig. 4) itself is a complex process once again, which for BIOLOX®delta requires three steps. The first step alone, pre-sintering, takes more than two days. The sintering kiln is slowly heated to a temperature of more than 1350 °C. At about 150 °C the organic binding agents which had stabilized the green compact will burn off. In general, the rise in temperature must follow a curve exactly calculated, and in the kiln, the heat distribution must be absolutely even.

Equivalent to 40 kg of TNT

The second step concerns the “hipping”. This term is derived from the acronym for hot isostatic pressing (HIP). Here, not only is the temperature even hotter than during pre-sintering but inert gas shielding with argon at a pressure of 1200 bar is added. “The enormous pressure ensures massive recompaction of the material and therefore a very stable and uniform crystal matrix,” explains Uwe Kemmer. The amount of energy in the kiln during operation is equivalent to 40 kg of TNT. Of course, the kiln has the corresponding safety provisions which make it quite expensive. That is why many ceramic manufacturers outsource almost 100 % of their HIP processes to service providers. We rely almost exclusively on our own HIP kilns.”

The third step is less hot and takes place in an oxygen environment to resupply the surface of the material with the oxygen atoms lost during hipping. This way, the entire component will exhibit identical characteristics of the material. And this is something to brag about: High-performance ceramic is the second hardest material in the world, right after diamond. This explains why the tools on the finishing machines must be made of that gem. Finishing ensures complete sphericity of the articulating surfaces to within a few micrometers, and the tapers get their final dimensions and shape.

Multi-testing of each component

Final polishing is preceded by elaborate testing which each component must pass, before it is labeled, packaged and made ready for shipping. Depending on the final product, the dimensions are tested according to up to twelve characteristics (Fig. 5). The measurement strategy employed here

Fig. 4
Setting of the kiln cars with BIOLOX®delta components

Fig. 5
Final dimensional control of the components

has become the standard for hip components in general. It has been incorporated into the corresponding ISO standard. "Our customers, the implant companies, seek our advice in this area. Because we are the manufacturer with the largest production runs of individual products for hip arthroplasty, we have the corresponding experience in large scale production," emphasizes Uwe Kemmer.

Also the proof testing is proprietary patented development. The finished product is subjected to a definite load far beyond anything encountered in the humane body under normal conditions. Only flawless parts will pass this test. All parts are subsequently exposed to a fluorescent fluid which creeps into the smallest fissures; UV light will then make these visible. All parts with cracks and fissures are discarded. And the final step involves a second visual inspection by specially trained staff. Speaking of which: "We spend a really big effort on training," say Uwe Kemmer. "Maybe that is the real secret of success. Because it is absolutely vital to let this complex and unique know-how come into play all the time in everyday production work."

The result of this refined production process is evidenced by the clinical outcomes and registry data. Since 2003 more than 5,5 million ball heads, more than 2 million inserts and thus over 7 million components made of BIOLOX®delta have been shipped. Therefore, in orthopedic hip-replacement implants the fourth generation of BIOLOX® high-performance ceramics excels with the largest numbers for single products. In the registries these components demonstrate a very low complication rate and good to very good clinical outcomes. They have contributed to the improved component survival rates in hip arthroplasty. Thus, BIOLOX®delta represents proven technology in the true sense of the word.