

CeraNews

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Chinese world map, probably from 1763, private ownership

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Trend to Modular Systems

Professor Nobuhiko Sugano has been working as an orthopaedic surgeon specialized in hip arthroplasty at the Osaka University Graduate School of Medicine for the past 20 years. He is a Full Professor at the Department of Orthopaedic Surgery of the Osaka University Medical School and Head of the Department of Orthopaedic Medical Engineering. He is a member of the board of the Japanese Hip Society, the Japanese Artificial Joint Society and the Japanese Biomaterial Society. As a member of the Editorial Board of the Journal of Arthroplasty and the Journal of Computer Assisted Radiology and Surgery he stands at the forefront of scientific discussion and is one of the most experienced Japanese surgeons and scientists in the field of joint replacement.



Nobuhiko Sugano, MD, PhD

When did you perform your first THA surgery? I started THA in 1988, with alumina ceramic ball heads and polyethylene cups. At that time, polyethylene wear was recognized to be one of the most important issues and I thought that the introduction of the BIOLOX® ceramic-on-ceramic bearing was a good idea to reduce wear. I decided to introduce a custom-made hip with a modular femoral neck to manage the unique anatomy of Japanese hips with increased femoral anteversion as well as more variability. I also developed a surgical navigation system with our engineering school in 1998 and reported the minimum 5 year results of ceramic-on-ceramic bearings with the use of navigation in the JBJS Br 2007.

What are the main indications for THA in Japan? Osteoarthritis secondary to congenital hip dysplasia is the number one reason for THA in Japan. This is the main difference to other Asian countries as the incidence of hip dysplasia is much lower there.

How many hip surgeries are being performed in Japan?

In 2007, 38,355 cases of Total Hip Arthroplasty and 49,139 cases of bipolar hemiarthroplasty were performed. The growth rates of the past ten years were between 4 and 11 percent per year.

Why are bipolar systems so frequently used? They are often used in cases of osteonecrosis and femoral neck fracture because they are easier to implant. Some surgeons even use them for the treatment of the osteoarthritic hip by simply reaming the acetabulum. But in these cases we often have problems with early migration.

What are the “hot topics” of discussion at the moment? The longevity of the prosthesis has dramatically improved over the past years while early complications such as dislocation or postoperative infection remain unsolved problems. Patients also want more than only relief of pain today. They want a better quality of life, requiring more range of motion and a lesser risk of dislocation. Therefore, the articulating surfaces are a key issue. Osteolysis induced by wear particles from metal-on-polyethylene bearings motivates surgeons and implant companies to look for better articulations. Highly crosslinked polyethylene and latest generation ceramics are materials which can possibly improve survival rates. They also help to advance function, range of motion, or even a non-limited activity in daily life. Modular options for the femoral side are also a topic open to future discussion.

What are the differences in THA, in terms of anatomy and lifestyle, between Japanese and Western patients? There is an obvious general anatomical difference in hip size between Asian and Western patients and thus a limitation of the maximum possible implant sizes. Additionally the soft tissue of the Japanese is more elastic, because of a lifestyle with frequent squatting, bending and crossing the legs. Femoral anteversion and femoral head offset are also different, especially in the dysplasia patients. Because of these circumstances the risk of prosthetic impingement during daily life activities is much higher. To match the anatomy best and maximize range of motion modular systems are used more and more. The accuracy of implant positioning is possibly even more important than for Western patients. For anatomically very difficult cases custom made implants would be the best solution. Unfortunately, the Japanese Ministry of Health stopped their usage in 2002 because of regulatory approval issues.

What kind of wear couples are most commonly used in Japan? Metal on polyethylene is still the most popular choice. Most common bearing sizes are 26 and 28mm diameter due to the limitation of maximum cup sizes as the average Japanese patient's acetabulum has a diameter between 46 – 50mm. Today, some companies offer 32mm solutions with crosslinked polyethylene.

Where do you see the limiting factors of these implant systems? If we use polyethylene cups, we need to use a small diameter head like those of the Charnley system which results in a reduced ROM of implants although the Japanese patients would need a larger ROM for their daily activities.

What would a THA system specially tailored to the needs of Japanese patients look like? It should have

Approval for Japan

CeramTec opens Kyoto office

a bearing couple of a size that would fit best with the anatomical and lifestyle situation, made of fracture and wear-resistant materials without any negative biological effects. If we use metal-on-metal, head sizes between 38 – 44mm diameter for women and 50 – 54mm for men can be used. But we have to be careful when combining such ball head sizes with standard stem systems as the resulting ROM would be much greater than physiologically necessary. In extreme situations this can cause painful soft tissue impingement. Thus for younger and active patients I would appreciate a ceramic resurfacing solution as the natural femoral neck is a safeguard to prevent soft tissue impingement. For older patients standard stem systems with big ball heads are a good solution. The design of the femoral stem should be modular having an optimized anteversion and offset with a combination of different anatomical neck designs.

What are the issues discussed at the moment in regard of ceramics? Problems with polyethylene backed alumina liners with high fracture rates and failure of the metal-polyethylene or the ceramic-polyethylene interface have been published in the years 2002 and 2003, also from our group*. Survival rate was below 90 percent at ten years. Negative experiences with zirconia-on-polyethylene have also left a negative impression. On the other hand, only very few negative case reports have been published about hard-on-hard bearings with directly taper-locked alumina ceramic liners. We have excellent long term results and osteolysis is not an issue even after ten years or longer. There is a strong demand for reliable ceramics. We are looking forward to better ceramic solutions in the future.

What is your experience with bipolar systems? In my experience with self centering CoCr-polyethylene systems from the early 80's, young and active patients sometimes complained about pain. After 10 to 20 years cartilage wear and central migration of the ballhead often occurred. We have had a lot of patients with severe osteolysis and inflammatory reactions of the cartilage due to excessive polyethylene wear debris mainly caused by impingement between the neck and the cup liner's rim. This is the main issue of these bipolar systems. If you use a durable THA system you may not need a revision even after 20 years. This is the reason why in our group we abandoned bipolar systems for the treatment of osteonecrosis grade III.

*The ceramic products mentioned here were not supplied by CeramTec.

On October 1 the CeramTec Medical Products Division opened its new Kyoto office. Centrally located on the main island of Honshu, Kyoto is an important center for the electronics industry and home to 40 universities and colleges. The city's well-developed research infrastructure was a key factor behind the choice of location. CeramTec has had a long-established working relationship with the Kyoto-based Piezotech laboratory, due to its unique material testing capabilities. The office's activity focuses primarily on supporting the approval process by regulatory agencies for BIOLOX® components for the Japanese market as well as materials evaluation activity and the training of users.

Highly complex and time-consuming approval procedures have made it difficult for foreign companies to sell their products. For this reason, only very few implant manufacturers have so far managed to gain Japanese approval for the use of BIOLOX® components in their products in Japan. When the regulations governing the approval of medical products were simplified in early 2008, the management of the Medical Products Division decided to set up its own representation in this key country.

For many years, CeramTec has worked with Piezotech Japan, a materials research laboratory in Kyoto specializing in the examination and analysis of material properties and with a particular focus on load-bearing capacity, ageing characteristics and susceptibility to wear. Piezotech has developed a special microscope based on the principle of Raman spectroscopy making this the key element of a unique analysis method. The research activity of the Piezotech laboratory is solidly based on the intellectual properties of Giuseppe Pezzotti, who is known around the world for his work in this area. He holds a full professorship chair at the renowned Kyoto Institute of Technology and also leads the Research Institute for Nanoscience there. In addition, he is Adjunct Professor in the faculty of orthopaedic surgery at Loma Linda University in California and Invited Professor in the center for advanced medical engineering and informatics at Osaka University.

CeramTec – Service in Japan

- Technical support with obtaining qualification for implant systems with BIOLOX® components
- Documentation for the approval process
- Support with scientific publications
- Expert partner for all technical, medical and marketing questions on the use of ceramics in arthroplasty
- Training for surgeons, OR and sales staff
- Brochures and marketing tools

The role of the CeramTec Office in Kyoto is not to act as a sales company but rather to support implant manufacturers who use BIOLOX® products with their business operations in Japan. "We help our customers with the approval process for implants which are combined with BIOLOX® components," explains product manager Matthias Grässel, head of the Japanese office. "We also collaborate with several well-known hospitals in the areas of clinical research and documentation, where the emphasis is also on tribological results." Further services include training sessions for doctors, surgical staff and sales staff as well as the provision of brochures and marketing materials.

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High Growth Rates

China is rapidly closing the gap

Professor Kerong Dai is a life tenured professor and director of the Bone and Joint Research Center at the Shanghai Jiaotong University, Chairman of the Shanghai Medical Center of Joint Surgery and Director of the Engineering Research Center of Digital Medicine of the Ministry of Education of the People's Republic of China. CeraNews asked him about arthroplasty trends in the world's most populous country.



Kerong Dai, MD

China has rapidly caught up with the West and today belongs to the most advanced high tech countries of the world. How has arthroplasty developed? Although China is still behind the developed countries in the research and application of endoprotheses, great progress has been made in recent years and we have had our original creations in this field. For example, research on shape memory alloys used in medicine was first carried out in China early in the 1970's. The shape memory alloy implants applied in internal fixation and total hip surfacing arthroplasty were invented here and China holds the patent on this technology. By now, the application of shape memory alloys has been extended into many medical appliances such as internal stents of vessels, esophagus, urethra, and birth control rings, etc. And recently, Chinese scientists and engineers have advanced greatly in the research and development of new types of biomaterials, with good prospects for clinical use. The design and application of computer aided customized artificial joints has also made quicker progress through the introduction of modern engineering technology and concepts. On the other hand, there is still a gap between the practical needs of medicine and the translation of research results into production and the market.

What is the role of high performance ceramic components in Chinese arthroplasty? Bioceramic bearings for artificial joints are destined to be chosen as bearing couples because of their excellent tribological properties and good biocompatibility. This is the same in China as anywhere else in the world. At present, such ceramic components, including ceramic-on-ceramic and ceramic-on-polyethylene, are mostly used in patients younger than 65 years, with the limitation mainly caused by higher prices for this material. With the further development of medical ceramic technology, the advancement of surgical techniques and the extension of life expectancy, I am sure that ceramic bearings will be gradually more widely used in China.

What are the special requirements of prosthesis systems for Chinese patients? With the definite extension of life expectancy, the obvious increase of physical activity and the improvement in quality of life in China, the key point is to design and make prostheses with longer survival times. This, of course, is related to both the tribological properties and the surgical techniques. Secondly, since Asian people are accustomed to kneeling and squatting in many situations, total knee and hip prostheses with higher flexion should be designed to meet the requirements created by such movements and poses. At the same time, dislocation should also be taken into consideration and tackled, for example, by the use of femoral ball heads with large diameters. At present, most of the prostheses are designed according to anatomical data gathered from western individuals, which is quite different from the anatomy of eastern populations. This can lead to reducing the match effect and can cause a higher rate of complications. Since designs based on eastern anatomy are urgently needed, we have now accumulated a great deal of data on this aspect for these years. I believe that the next ten years will be a crucial period for the fast development of artificial joint replacement in China.

Are alternative bearing couples being used in China?

There is no difference between bearing couple systems used in China and those used abroad, including the metal-on-polyethylene, metal-on-metal, ceramic-on-polyethylene, ceramic-on-ceramic. Generally speaking, metal-on-polyethylene is used most frequently today, but I expect a growing share for metal-on-metal and ceramic-on-ceramic, probably with significant variations for different regions and different hospitals. Price will remain a factor of great influence.

What are, in your experience, the main differences in the requirements regarding the prosthesis stem in China compared with other countries? As I mentioned before, having prosthesis designs based on Chinese anatomical data would be most important. Moreover, as China is still a developing country, reducing the costs of the implants, thereby reducing the price of the prosthesis for the patients, is also very important. This would benefit both the patients and the producers since the number of implants used in China is already high and growing very fast.

How could cooperation between surgeons and industrial manufacturers help to meet these demands? When we talk about cooperation, the distribution of interests has to be considered in the first place. For the surgeon, the best curative effect is the key issue. In order to achieve long term success, benefitting the patients should also be the first goal of the manufacturer. Only when we look at it this way can we get real economic benefit. Therefore, the common target for both surgeons and producers could be the same: to achieve high efficiency for the best benefit of patients. Close cooperation between surgeons and producers is necessary. Surgeons should be the leading members of the design teams, while the producers should pay more attention to research and the clinical application of their products, collect more suggestions from surgeons and respond effectively by constantly improving their products.

Exchanging Ideas

Meeting of experts in China and South Korea

At CeramTec, we have always embraced the view that nothing is better or more effective than holding direct talks with our clients and users. That is why our company representatives in Asia have been active organizing such direct exchanges and simultaneously promoting discussion among medical experts in the field of joint replacement. At a recent round table meeting held in Seoul and two seminars in Beijing and Shanghai, the focus of discussion was on bearing couples.

Round Table in Seoul

In the framework of the Annual Congress of the International Society for Technology in Arthroplasty (ISTA), which was held in Seoul, South Korea on October 1–4, 2008, CeramTec invited leading experts in the field of arthroplasty to a round table meeting. Jun-Dong Chang (see Interview on page 6) played a leading role in organizing the round table meeting and also chaired the meeting.

The aim of the meeting was to discuss the use of bearing couples in hip arthroplasty in South Korea. In light of the fact that the considerations that play a role in decision making here are not identical to those in the west, the CeramTec team wanted to learn more about the opinions of Asian specialists, and answer the following questions: Where do we stand today? Where do we need improvement and further development?

In addition to the representatives from South Korea, Prof. Chang succeeded at recruiting guests from Japan and India to participate in the round table meeting. Four talks were given by way of introducing the subject. The animated and fruitful discussion that followed showed how important the exchange of ideas between physicians and manufacturers can be. The round table meeting proved to be an excellent platform for a very open, solution-oriented discussion, with a number of subjects being examined at length.

A consensus was reached that the introduction of BIOLOX®*delta* had very significantly reduced ball-head fracture rates. In the case of the ceramic inserts, things appear to be somewhat more complicated. Owing to the introduction of new cup designs (e.g. featuring extremely thin-walled metal shells), it has apparently not yet proved possible to achieve the same outstanding fracture-

Round table meeting in Shanghai

rate reductions for inserts that have been reported for ball heads. While the fracture rates for BIOLOX®*delta* inserts are extremely low, there is still room for improvement. The measures that have already been initiated in this regard were presented and possible measures were discussed.

In the matter of the size of bearing couple diameters, the participants generally concurred that a 36mm diameter (well implanted using a good implant system) is also entirely sufficient for Asian patients. Although very little has been reported on the subject of squeaking in South Korea, this phenomenon led to a lively discussion. A consensus was reached that squeaking is an issue that is relevant to all hard-on-hard bearing couples. The development of squeaking is complex, with prosthesis design, surgical technique and cup position all playing an important role. It is especially vital to avoid impingement in this regard.

Seminars in Beijing and Shanghai

When BIOLOX® ceramic materials were first introduced to the Chinese market 14 years ago, they were sometimes mistaken for porcelain – hardly surprising in the home of “china”. Today, high performance ceramics are regarded as one of the best solutions available in hip arthroplasty for young and active patients in China. There are hospitals in Beijing and Shanghai in which more than 1,000 ceramic-on-ceramic bearing couples and 2,000 ceramic-on-polyethylene bearing couples have already been implanted. In the interest of improving the exchange of technical and clinical information with Chinese orthopaedic surgeons, CeramTec invited Aldo Toni of the Istituti Ortopedici Rizzoli in Bologna, Italy, to China at the beginning of June 2008 to hold seminars in metropolitan Beijing and Shanghai on the subject of “Ceramic Bearing Couples: What Can We Expect? Biomechanical, Tribological and Clinical Aspects” (see page 7).

Around 20 prominent orthopaedic surgeons from a number of the country's largest hospitals participated in each of the seminars. Issues relating to the use of ceramic components (e.g. ranging from medical indication to aspects of design, surgical technique, error avoidance and complication responses) were comprehensively discussed by the speakers and the participants. The participants were especially interested in listening to Toni, who has implanted more than 5,000 ceramic-on-ceramic bearing couples in the past 20 years, relate his clinical experience and offer practical tips. The discussion also demonstrated that the Chinese specialists have gathered a tremendous amount of experience in the last few years and have developed a number of independent solutions for their patients, many of whom differ considerably in various respects from their western counterparts.



Why Asian Patients Need Different Wear Couples

Professor Jun-Dong Chang, former President of the Korean Hip Society and of the Korean Musculoskeletal Transplantation Society, is Professor and Chief of the Department of Orthopaedic Surgery at the Hangang Sacred Heart Hospital, Hallym University College of Medicine in Seoul. He is one of the most experienced orthopaedic surgeons in his country and an experienced specialist in the field of arthroplasty. CeraNews asked him about the special requirements for THA in Korea and in Asia in general.



Jun-Dong Chang, MD, PhD

Which wear couples are most commonly used for THA in Korea?

In the performance of THAs, conventional UHMW polyethylene was most commonly used in the past as the bearing surface on the acetabular side. However, high levels of wear and osteolysis have been observed in some Korean patients, due to their different characteristics compared with patients from Western countries. This led to a growing demand for alternative bearing surfaces, among which ceramic-on-ceramic couples were most commonly used for THA. The femoral head of 28mm has been widely used in Korea. Larger ball heads in 32mm and 36mm diameters are currently being introduced, and are increasingly preferred in order to decrease the incidence of impingement and instability.

You have longstanding experience with THA in Western countries and in Korea. What are the most important differences regarding wear couples?

In the Korean culture, sitting with crossed legs and in squatting positions is a common practice, both of which are rather rare in the West. The most common cause for THA in my country is osteonecrosis of the femoral head, which mainly develops in relatively young and physically active people. Due to this, impingement and liner wear are the most significant problems with regard to THA. Given this situation, there is a growing interest in bioceramics and alternative bearing surfaces. Furthermore, considering that Koreans are anatomically smaller than most Western people, the size of implants also needs to be smaller for them.

What are the limitations of the commonly used implants?

It is important to reduce the risk of impingement in THA. In addition to the surgical technique, the use of large diameter ball heads could be helpful to prevent impingement between the acetabular cup and the femoral stem. However, it may not be possible to use large ball heads because of the small acetabular bones of Korean patients. The recently introduced BIOLOX[®] *delta* wear couple with a 36mm head and a liner for a 52mm cup is a step in the right direction. But in Korea, some patients can only use cups smaller than 50mm. The other significant problem with small cups is that the liners become very thin. Korean and other Asian patients would need a THA system with a large ball head in a cup that is as small as possible.

What should the industry do to meet these demands? How could surgeons and industry cooperate to achieve progress in this field?

The most important single factor for success in THA is the bearing surface. Therefore, we have to continuously endeavor to develop a bearing surface that is not subject to wear, and is not toxic or fragile. To make progress in this field, there should be a mutual exchange of information and close cooperation between surgeons and industry. The Round Table Discussion between engineers and leading surgeons, which was organized by CeramTec during the 21st International Society for Technology in Arthroplasty Congress in Seoul was a good example. The subject was "the Asian patient and the requirements needed for wear couples to ensure the best possible treatment". I think that this first trial has contributed to progress in the field of bearing surfaces.

Big Impact

Chinese arthroplasty from a western perspective

The Istituti Ortopedici Rizzoli in Bologna is among the most renowned Institutions of its kind in Italy. Dr. Aldo Toni is the Director of the First Surgical Division of Orthopaedics and Traumatology as well as Director of the Laboratory of Medical Technology. He has implanted more than 5000 ceramic-on-ceramic bearing couples over the past 20 years and was invited to China last summer to share his experience with his Chinese colleagues. He participated in Round Table meetings in Shanghai and at the Jishuitan Orthopedic Forum (JOF) held in Beijing on June 6–8, 2008.

Which impressions did you take home from the meetings with Chinese surgeons?

I had the opportunity to view a newly emerging reality and a chance for comparison. China is entering the international stage with a big impact. This applies not only to the commercial importance of the Chinese market, but also to the excellent Chinese studies that are beginning to appear in major scientific journals in growing numbers. In the field of hip implants China has all the latest technology, the same that we have in Europe or the United States, and I have found the Chinese colleagues confident of using it properly and with really great enthusiasm.

How important are ceramics in THA in China?

The use of ceramics already seems well established. I saw Chinese surgeons present excellent cases with ceramic prostheses. The concerns related to its use are perhaps even less significant than those of Western surgeons. We must consider the average size of Asian patients, who are smaller compared to Westerners. Polyethylene liners in the small cups have to be very thin and this could cause big problems in the longer term. Ceramics offer a very good solution here.

But isn't it the case that the use of ceramic implants in Chinese patients may also pose some specific problems?

In China, just as in other Asian countries where it is common to squat or sit with crossed legs, the introduction of BIOLOX®*delta* heads with large diameters has allayed many of the concerns that could be related to the use of ceramics. Certainly, the need to reach a very large postoperative range of motion poses problems that are much greater than we normally see in the West.

Regarding your long-standing experience with ceramics, could you suggest solutions to your Chinese colleagues?

I certainly supported the use of large ceramic heads, but sometimes this may not be enough. I believe that together with the size of the head, the use of implants with modular necks could be helpful. It is my experience that modular implants reduce the risk of impingement and allow a wider range of motion without the risk of dislocation.

Can modular prostheses and ceramics be combined without problems?

Our experience shows that using modular necks leads to a 4-fold reduction of the risk of ceramics failure when compared with monoblock prostheses. I think the modularity of the stem is a great complement to ceramic surfaces.

What are your considerations as to the cases presented by the Chinese surgeons?

These are always linked to the anatomy of Asian patients which is very different from what we are accustomed to. First, the small size of the femur and the



Aldo Toni, MD

acetabulum poses problems for the sizing of the implants which are usually designed by Western surgeons and engineers using Western parameters. It is often necessary to extend the range to smaller sizes, tailored to Asian anatomical dimensions. Japanese surgeons had similar problems, and they found the computer assisted and CT based preoperative planning system that we developed at the Laboratory of Medical Technology of the Istituto Ortopedico Rizzoli very useful. With very careful planning they have reduced the risk of intraoperative fractures during the preparation of the femoral canal, especially in smaller sizes. Moreover, Asian people tend to have a much greater femoral anteversion than Western people, which can sometimes reach or even exceed 60 degrees! During surgery, it is necessary to correct this anteversion by appropriate stem design selection. My choice would be using a cone design prosthesis with a modular neck. The first takes care of the femoral anteversion and the latter may help to reach the correct length and off-set of the prosthetic hip. This is particularly important in order to avoid edge loading, stripe wear and squeaking. I want to stress again that computer assisted preoperative planning that allows a three-dimensional view of both acetabulum and femur can certainly be of great help.

Which final conclusions can you draw from your visit?

I have found great emphasis on issues related to hip prosthesis. Many of the questions that were posed to me showed that Chinese surgeons have already gained good experience in ceramic hip replacement, and that there will soon be a significant representation of them in the international scientific community.

High Performance Production

How technical ceramics are made

Apart from their shared name and history, technical ceramics and traditional ceramic crockery have next to nothing in common. On the contrary – modern high performance ceramics are characterized by extreme hardness and are practically indestructible. Their applications are almost endless, ranging from bathroom fittings to high performance engine technology and joint implants. Technical ceramics are the result of a sophisticated high-technology manufacturing process.

Preparation of the mixture

The oxides required for the manufacture of BIOLOX® forte and BIOLOX® delta are provided, preconditioned and largely in powder form, by suppliers from all over the world. Following an extensive inspection procedure they are prepared for the "spraying" process through a number of steps, which include grinding and mixing. The spraying process involves spraying the raw material, which is mixed with distilled water, into a large container filled with warm air. The end result is a fine, flour-like powder, also referred to as granules. Following an extensive inspection it is approved for the next step: the manufacture of blanks.

Manufacture of blanks

The powder is pressed into a cylindrical mold, gaining a consistency comparable to chalk. On computer-controlled lathes, the material is then given the basic shape of the ball heads and acetabular inserts. The next and most important step is the sintering process consisting of a very high temperature treatment which consolidates the loosely packed granules into a ceramic material. This initial process is followed by hot isostatic pressing, known in the industry as hipping. This very high temperature treatment is carried out under extremely high pressure (1200 bar) and it allows the individual grains of powder to be compacted into one solid, practically imporous component. The material making up the component now has the density and material properties that make BIOLOX® ceramics so successful in use. Quality assurance controls are carried out throughout these processes.

Hard machining

As BIOLOX® ceramics have a level of hardness which is almost equal to that of diamond, they can only be processed using high-quality diamond tools. Specially designed computer controlled grinding and polishing machines are used to create the final dimensions and finish throughout the ball head and the acetabular



At the automatic measuring unit the data for each insert are collected online and stored in the quality module.

insert. The bearing surfaces are then polished to a very smooth surface using ultra-fine diamond grains – this highly polished surface is a key element of the excellent wear properties of BIOLOX® ceramics. The accuracy of the process is monitored by the use of extremely precise computer controlled 3D measuring machines in order to confirm full compliance to the specifications for each single component made. Following this dimensional evaluation, all components are laser etched in order to provide them with a unique identification number and other required information such as size, neck length, etc.

Final inspection and packaging

In order to be completely sure that the components are in full compliance with the delivery specifications, an extensive inspection and testing procedure is carried out on all components. After a final 100% visual inspection – one of over 20 inspections in total – the BIOLOX® components are thoroughly cleaned in a controlled atmosphere room and subsequently packaged. The level of cleanliness of this room is at least equivalent to that of an operating theater. All of the key characteristics of BIOLOX® ceramic components are documented on a factory certificate before being sent to our customers around the world.

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