Greater Freedom of Movement
Thanks to a Large Ball Head

With the development of the highly cross-linked and extremely wear-resistant Durasul™ polyethylene (PE), Sulzer Orthopedics made a breakthrough in hip replacement technology. The use of Durasul PE in artificial hip cups allows the use of ball heads with greater diameters than before. For the patients, this means greater stability of the joint and distinctly greater freedom of movement.

The size of the conventional ball heads used in hip implants today is a compromise between wear of the joint cup and mechanical stability of the joint. The wall thickness of the PE insert must be sufficient to guarantee an adequate life expectancy of the prosthesis, in spite of the wear that was up until now unavoidable (approximately 0.2 mm per year). Because of that, a minimum insert thickness of 6 mm is required, which means that with the present-day cups only joint heads with diameters of 22 to 28 mm can be used. Compared with larger ball diameters (Fig. 1), the risk of the ball head jumping out of the cup is increased. This so-called dislocation, which occurs in up to 10% of all cases, is the second-most frequent complication with the use of hip implants. The aim of designing artificial hip joints which come closer to matching the human anatomy required a technological breakthrough.

LARGER JOINT HEADS THANKS TO DURASUL
The newly developed Durasul (see box on p. 26) allows the PE insert thickness to be reduced so that ball heads of up to 38 mm diameter can be used. This increases the displacement distance that would ultimately lead to dislocation of the joint (Fig. 2) and helps increase the stability and range of motion.

MORE QUALITY OF LIFE
For the great majority of total hip implants, the result for the patient is drastic reduction of hip pain,
making it possible to lead a largely normal life again. However, until now, the problem with hip implants is the limited life expectancy due to loosening of the prosthesis, which is caused to a large extent by the wear of polyethylene occurring in the cup. In addition, particularly in the first few months after the operation, dislocations of the hip joint can occur – a very unpleasant complication for the patients that can make a second operation necessary. Caution is indicated for activities such as getting into and out of an automobile or when standing up from any sitting or even kneeling position. With the large-caliber and therefore much more stable artificial ball heads, the incidence of the two most important complications with total hip prostheses are drastically reduced (Fig. 3*).

**WEAR IS NOT MEASURABLE**

In a series of tests carried out in the biomechanical laboratory of the Massachusetts General Hospital (MGH), no wear of the Durasul PE was measurable even after 20 million cycles in the hip simulator. This test loading is equivalent to approximately twenty years life in vivo. The tests were carried out with joint heads made from cobalt-chromium, with diameters of up to 46 mm and a PE layer thickness of only 3 mm (Fig. 4*). Through the development of Durasul, Sulzer Medica is today the first supplier of artificial hips with 38-mm heads without measurable wear in the cup.

**GREATER STABILITY**

Investigations show that the leverage effect of the neck of prosthesis at the rim of the cup is the most

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2*  The new ball head of the Durasul hip system has, with the same cup size, a larger radius \(X\) than the heads that have been used up until now \(Y\). The increased displacement distance provably makes a dislocation more difficult.

3*  For people with hip implants, standing up and sitting down are not always simple activities. A stable hip prosthesis gives the patient more security and therefore a better quality of life.
frequent cause of dislocation. Larger joint heads increase the range through which bending of the joint – without contact between the neck of the prosthesis and the cup – is possible; this further reduces the dislocation risk.

At the beginning of the year 2000, Sulzer Medica received FDA approval for the commercial introduction of the Durasul Large Diameter Head System in the US market. The Durasul tribological combination was introduced in various European countries in the first half of 2000, on the basis of clinical testing in three phases. The clinical testing is accompanied by two scientific studies carried out in parallel and covering a period of ten years, and a third study which concentrates on retrieval analysis in the case of a revision. The Durasul tribological combination with the 38-mm ball head will be introduced in Europe at the beginning of 2001.

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**FOR MORE DETAILS**

Sulzer Orthopedics Inc.
Manfred Menzi
9900 Spectrum Drive
Austin, TX 78717
USA
Telephone +1 (1)512-432 95 93
Fax +1 (1)512-432 95 49
E-mail manfred.menzi@sous.com

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**DURASUL: WEAR-RESISTANT POLYETHYLENE THANKS TO ELECTRON IRRADIATION**

The arrangement of the molecular chains in the plastic material, polyethylene (PE), is half crystalline and half amorphous. The resistance to wear of the material increases if the molecular chains can be cross-linked with one another. In 1986, Sulzer introduced the gamma irradiation of PE, which under laboratory conditions reduced the wear by half. However, in this procedure the cross-linking takes place mainly in the amorphous part, while the structure in the crystalline area remains unchanged. Furthermore, through the irradiation unsaturated free radicals are formed, which over time may lead to embrittlement of the material through oxidation.

The electron irradiation, which is very important in the manufacture of the Durasul PE, temporarily reduces the crystalline structure of the PE and makes cross-linking possible. After a final heat treatment, practically no unsaturated radicals can be detected, and the crystallinity of the material is restored in the course of a very long cooling process. As a result, the outstanding mechanical properties of the material are permanently retained.

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4. In contrast to conventional polyethylene (PE), in laboratory measurement tests Durasul PE shows no measurable wear, but even an increase in weight. This effect results from the absorption of fluids and also occurs with conventional material, but in the latter case it is compensated by the loss of material through wear.