Design and Product Rationale
Contents

Product Rationale

BI-MENTUM™ Dual Mobility Concept 2
Heritage and Clinical Results 3
Head to Cup Ratio 5
Range of Motion 6
Jump Distance 7

Design Rationale

BI-MENTUM Acetabular Cup Features 8
BI-MENTUM Acetabular Liner Features 12
Comprehensive Cup Platform 13
BI-MENTUM™ Dual Mobility Concept

**DUAL MOBILITY**
1. Femoral head (ceramic or metal) – mobile polyethylene liner articulation
2. Mobile polyethylene liner – metal cup articulation

**THIRD ARTICULATION**
3. Femoral neck – retentive part of mobile polyethylene liner

**TWO concepts**
Designed to reduce wear according to the Charnley concept of low friction arthroplasty.1 Enhance stability according to the McKee-Farrar concept of large diameter femoral heads.1

**Natural MOVEMENT**
The dynamic mechanism of action of the 3rd bearing allows the activation of the 2nd articulation with a natural single smooth movement and enhanced Range of Motion.

**STANDARD RANGE OF MOTION**
Primary movement occurs between Femoral head – polyethylene insert articulation, allowing the mobile polyethylene liner to sit in its natural position within the metal cup

**EXTREME RANGE OF MOTION**
Secondary movement occurs between polyethylene insert – metal cup articulation when the third articulations between femoral neck and polyethylene liner is activated
Heritage and Clinical Results

Heritage

Currently available evidence indicates that a dual mobility implant is becoming a leading treatment option to address instability for complex primary total hip replacement.²⁻⁴

To further enhance the DePuy Synthes portfolio, a strategic co-operation and supply agreement has been formed with Société d’Etude, de Recherche et de Fabrication (SERF) to exclusively launch the SERF NOVAE® SunFit TH Dual Mobility System under the brand name BI-MENTUM™ Dual Mobility System.

SERF is the original developer of the dual mobility implant with over 40 years of clinical experience.⁵

NOVAE Dual Mobility cups

<table>
<thead>
<tr>
<th>Year</th>
<th>NOVAE Model</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1979</td>
<td>NOVAE-1</td>
<td>Tripod Fixation</td>
</tr>
<tr>
<td>1998</td>
<td>NOVAE E</td>
<td>Hemispherical cup +3 mm cylindrical rim</td>
</tr>
<tr>
<td>2000</td>
<td>NOVAE Sunfit</td>
<td>Pressfit only fixation with Alumina and Hydroxyapatite coating</td>
</tr>
<tr>
<td>2007</td>
<td>NOVAE TH</td>
<td>Circumferential Macrostructure and Titanium + Hydroxyapatite Coating</td>
</tr>
<tr>
<td>2018</td>
<td>BI-MENTUM Dual Mobility Cup</td>
<td>Identical Press-fit design, features and coating as NOVAE TH</td>
</tr>
</tbody>
</table>

BI-MENTUM Dual Mobility Cup / NOVAE equivalence table

<table>
<thead>
<tr>
<th>BI-MENTUM Dual Mobility Cup</th>
<th>BI-MENTUM Press-fit Cup</th>
<th>BI-MENTUM Plus Cup</th>
<th>BI-MENTUM Revision Cup</th>
<th>BI-MENTUM Cemented Cup</th>
<th>BI-MENTUM Polyethylene Liners</th>
<th>BI-MENTUM Reinforcement Cage</th>
</tr>
</thead>
<tbody>
<tr>
<td>SERF Equivalent</td>
<td>NOVAE SUNFIT TH</td>
<td>NOVAE E TH</td>
<td>NOVAE COPTOS TH</td>
<td>NOVAE STICK</td>
<td>NOVAE CI E liners</td>
<td>NOVAE K E Cross</td>
</tr>
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</table>
Heritage and Clinical Results

Clinical Results

Ten-Year Clinical and Radiological Outcomes of 100 Total Hip Arthroplasty Cases with a Modern Cementless Dual Mobility Cup


A single-centre prospective study of 100 consecutive primary THAs using the press-fit Sunfit TH® dual mobility cup and a cementless straight stem.

93 patients (43 females, 50 males) with a mean age of 71.81 years (range: 40-94 years). 4 patients were lost to follow-up and 19 died with their implants still in place. The mean follow-up was 10.03 years.

Mean Harris Hip score significantly improved from 56 ± 15.2 pre-operatively to 93 ± 8.4 (p<0.001) and the mean Postel Merle d’Aubigné score significantly improved from 11.8 ± 2.1 pre-operatively to 17 ± 1.6 post-operatively (p<0.001).

There were no cases of aseptic loosening, dislocation or intra-prosthetic dislocation.

This study reports excellent survivorship rates of 100% at 10 years follow-up with revision for aseptic loosening considered as the endpoint.
A larger femoral head diameter increases the head to neck ratio. This can improve range of motion, jump distance and reduce the occurrence of prosthetic neck impingement to the acetabular cup. This in turn helps reduce the risk of dislocation.¹

The large diameter mobile liner in the BI-MENTUM Dual Mobility System is 6 mm smaller than the outer diameter of the acetabular cup. The 6 mm is derived from the 3 mm wall thickness.

BI-MENTUM Dual Mobility System head to cup ratio compares favourably to a conventional bearing as shown below.

*52 mm PINNACLE Hip solution used as example as this is the smallest cup size to provide a 36 mm metal or ceramic on polyethylene bearing
Range of Motion

Although stability and “potential” range of motion increases with bearing diameter, there is little improvement in clinical range of motion for heads greater than 37 mm to 41 mm because bony impingement becomes the governing factor.

BI-MENTUM Dual Mobility System provides:
- 37 mm diameter mobile liner in the smallest Pressfit cup (43 mm)
- 41 mm diameter mobile liner at a size 47 mm cup
- Cup size range from 41-43 mm to 69mm

(Note this is based on the Pressfit fixation range; a 41 mm can also be provided in the Plus fixation option)

BI-MENTUM with CORAIL® AMT Collarless Stems (Range of Motion (ROM) calculated as FE and AA sweep angle)
Jump Distance

Definition of jump distance: is the distance a femoral head must travel to dislocate after impingement. The greater the jump distance, the greater the stability of the hip; thus, helping to reduce the risk of dislocation.\textsuperscript{10}

Jump distance is dependent on the combination of head size, depth of the cup and degree of inclination of the cup.

The chart below shows jump distance for both BI-MENTUM 51 mm Cup / 28 mm head and PINNACLE ALTRX 52 mm Cup / 36 mm head for different inclination angles.

Jump Distance for different implant types, sizes and inclination angles\textsuperscript{11}
Design Rationale

BI-MENTUM Acetabular Cup

Acetabular Cup Features

The BI-MENTUM Dual Mobility Construct is an acetabular cup consisting of a forged stainless steel cup and a mobile polyethylene liner to be used in combination with DePuy Synthes ceramic or metal head and DePuy Synthes stems with a polished neck.

Cementless BI-MENTUM Dual Mobility Cups are coated with plasma-sprayed titanium (150 +/- 30μm) and hydroxyapatite (70 +/- 20μm). All cup variants have a polished bearing surface with a 3 mm cylindrical extension which increases jump distance compared to a hemispherical bearing.

- A macrostructure of concentric rings increases the surface area with the aim of improving primary fixation.
- The external pole of the cup is slightly flattened (~0.5 mm), with the aim of reducing stresses at the base of the acetabulum and preventing the cup from being forced out of the acetabulum, which may lead to better cup impaction and pressfit at the equator of the cup.
Fixation

A band of raised structures at the equator of the cup (ridges) in three areas: ischium, pubis and ilium contribute to the implants primary stability and aids the mechanical press-fit fixation of the device.

Dislocation Resistance

All BI-MENTUM Dual Mobility System Cup variants have a polished bearing surface with a 3 mm cylindrical extension which increases jump distance (AB) compared to a hemispherical bearing.

The dislocation risk decreases when the AB distance increases

NOTE: AB distance depends on head diameter, depth of the cup and the degree of inclination of the cup
BI-MENTUM Acetabular Cup

Fixation

BI-MENTUM Plus and Revision Dual Mobility Cups have the same macrostructure and coating as the BI-MENTUM Pressfit Dual Mobility System. These variants allow for additional fixation through the use of cortical screws and anchoring pegs, the revision cup also has an obturator hook for additional fixation.

BI-MENTUM Plus and Revision Dual Mobility Cups are anchored in the acetabulum using the tripod principle: 1 peg in the ischium, 1 peg in the pubic bone and cortical screws in the ilium through flanges.

BI-MENTUM Revision Dual Mobility Cups also utilise an obturator hook to ensure anatomical re-centering and provides additional mechanical support.
**BI-MENTUM™ Dual Mobility Cup** are grit blasted and have radial, circumferential and longitudinal grooves to aid primary anchoring and rotational stability in the cement mantle. Cemented cup can be used alone or in combination with the BI-MENTUM Reinforcement Plates.

**BI-MENTUM Reinforcement Plates** have a cruciform shape with an obturator hook and ischial flange designed to accommodate up to four screws.

- The plates are both sided (Left and Right) and size specific.
- The plates have an outer diameter (OD) designed to fit with BI-MENTUM cemented cups with OD 7 mm smaller than the plate e.g. a 50 mm BI-MENTUM Reinforcement Plate accommodates a 43 mm BI-MENTUM cemented cup.
- Spacers on each arm of the plate help to maintain a uniform cement mantle.
The unconstrained polyethylene (PE) liners are made from conventional UHMWPE (GUR1050). When articulating within the polished stainless steel cup, a PE liner transfers reduced torque to the cup when compared with hard on hard bearings.12
**Comprehensive Cup Platform**

<table>
<thead>
<tr>
<th>BI-MENTUM Size (OD/mm)</th>
<th>BI-MENTUM Pressfit</th>
<th>BI-MENTUM Plus</th>
<th>BI-MENTUM Revision</th>
<th>BI-MENTUM Cemented</th>
<th>22mm PE liner</th>
<th>28mm PE liner</th>
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<tbody>
<tr>
<td>41</td>
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Pegs, Screws and Hook can be used in combination with the BI-MENTUM Pressfit
Ti Plasma / HA Coating to provide additional fixation
References


7. Laurendon L, Philippot R, Boyer B, Neri T, Farizon F. Ten-Year Clinical and Radiological Outcomes of 100 Total Hip Arthroplasty Cases with a Modern Cementless Dual Mobility Cup. Surgical Technology International. 2018 Apr; 32: 985


11. Data on File. DePuy Synthes Internal Test report 103469937


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