

# BIOLOX® Ceramic-on-Ceramic

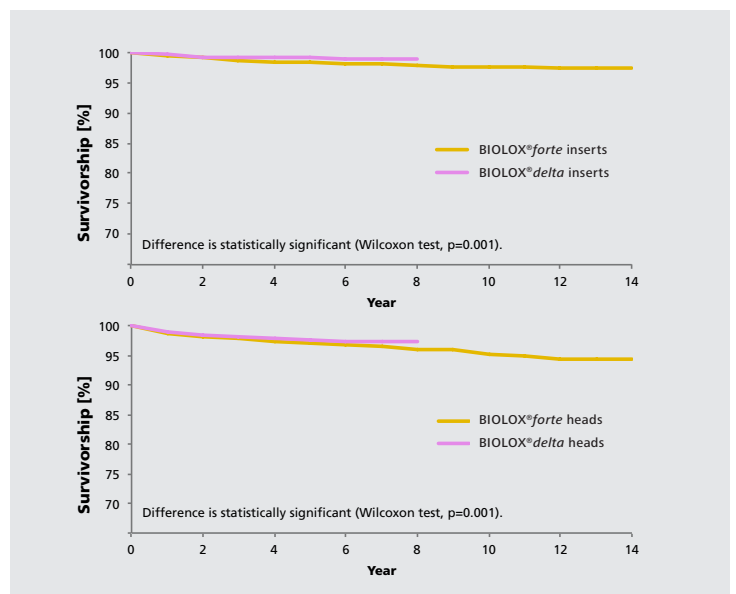
- CoC bearings show excellent mid- and long-term clinical results\*
- CoC bearings have the lowest wear characteristics of all articulations\*
- Osteolysis is extremely rare in CoC bearings\*
- Safe in terms of metal ion release\*
- Fretting/corrosion at the modular taper interface is mitigated\*
- No known risk of allergy for CoC bearings\*
- A pathogenic reaction to ceramic particles is very unlikely\*
- Ceramics may impart a lower incidence of PJI\*
- Excellent short and mid term clinical and functional outcomes with CoC large bearings\*
- Over 3 millions implanted CoC bearing couples worldwide (assumption for CoC worldwide)\*
- Ceramic bearings are safe, effective, and highly successful solution for revision THA\*



\*References available on file at CeramTec GmbH on request.

## CoC bearings have excellent mid- and long-term clinical results

| Reference  | Survival rate %<br>(revision for any reason) | Follow-up<br>in years |
|--|--|-----------------------|
| Toni et al. Hip Int. 2017 <sup>8</sup>             | 93%  | 17,40                 |
| Kang et al JoA 2015 <sup>9</sup>                   | 98,90%                                       | 15,00                 |
| Steppacher et al SemArthrop 2011 <sup>10</sup>     | 97,20%                                       | 14,00                 |
| Kusaba et al DKOU 2013 <sup>11</sup>               | 98,20%                                       | 14,00                 |
| Lee et al Sem Arthrop 2013 <sup>12</sup>           | 96,20%                                       | 13,00                 |
| Kim et al Int Orthop 2013 <sup>13</sup>            | 99%  | 12,40                 |
| Imbuldeniya et al ISTA 2013 <sup>14</sup>          | 96,50%                                       | 11,50                 |
| Lee et al JBJS 2010 <sup>15</sup>                  | 99%  | 10,00                 |
| Kusaba et al SemArthrop 2011 <sup>16</sup>         | 97,60%                                       | 10,00                 |
| Hsu et al SemArthrop 2011 <sup>17</sup>            | 96,30%                                       | 10,00                 |
| D'Antonio et al CORR 2012 (System 1) <sup>18</sup> | 100%   | 10,00                 |
| D'Antonio et al CORR 2012 (System 2) <sup>19</sup> | 98,60%                                       | 10,00                 |
| Yoon et al CORR 2012 <sup>20</sup>                 | 98,90%                                       | 10,00                 |
| Chana et al BJJ 2013 <sup>21</sup>                 | 96,50%                                       | 10,00                 |
| D'Antonio et al CORR 2014 <sup>22</sup>            | 97%  | 10,00                 |
| Epinette & Michael Jarthrop 2014 <sup>23</sup>     | 98,60%                                       | 10,00                 |
| Yoo et al JoA 2013 <sup>24</sup>                   | 96,90%                                       | 9,80                  |
| Wang et al Arthrop. Today 2016 <sup>25</sup>       | 97,30%                                       | 9,40                  |
| Tozun et al Int Orthop 2014 <sup>26</sup>          | 97,80%                                       | 8,20                  |
| Choy et al ClinOrthopSurg 2013 <sup>27</sup>       | 98,10%                                       | 7,80                  |
| Kim et al. JoA 2017 <sup>28</sup>                  | 99,70%                                       | 7,80                  |
| Kim et al Int Orthop 2014 <sup>29</sup>            | 100%   | 7,40                  |
| Kang et al JoA 2014 <sup>30</sup>                  | 97,90%                                       | 6,50                  |
| Aoude et al JoA 2015-online <sup>31</sup>          | 98,50%                                       | 6,00                  |



Regional Register of Orthopaedic Prosthetic Implantology (RIPO), 1<sup>st</sup> January 2000 – 31<sup>st</sup> December 2013  
Evaluation based on figures from RIPO for CeramTec GmbH

## Prevalence of bearings

|  | CoC   | CoP   | MoP   | MoM  |
|--|-------|-------|-------|------|
| Germany <sup>1</sup>                       | 8%    | 61%   | 31%   | <1%  |
| France (private hospitals) <sup>2</sup>    | 43%   | 22.4% | 35.2% | 1.2% |
| France (public hospitals) <sup>3</sup>     | 32%   | 11.2% | 54.8% | 2%   |
| UK <sup>4</sup>                            | 16.5% | 22.4% | 59.4% | 0.7% |
| Italy (Region Emilia-Romagna) <sup>5</sup> | 62%   | 26%   | 11%   | 1%   |
| Korea <sup>6</sup>                         | 86%   | 13%   | 1%**  | 0%** |
| Australia <sup>7</sup>                     | 25.6% | 23%   | 44.6% | 6.8% |

\*\*Estimation

## Osteolysis is extremely rare in CoC bearings

- Most recent studies report **NO** osteolysis in the mid to long term when CoC bearings are used  
*Choy et al 2013<sup>32</sup>*  
*Kim et al 2014<sup>33</sup>*  
*Imbuldeniya et al 2013<sup>34</sup>*  
*Murphy et al 2013<sup>35</sup>*  
*Tozun et al 2014<sup>36</sup>*  
*Lee et al 2013<sup>37</sup>*

- CoC bearings in revision surgeries can reduce or even halt the progression of osteolytic lesions

*Jack et al 2013<sup>38</sup>*  
*Kim et al SICOT 2011<sup>39</sup>*  
*Park et al AAOS 2011<sup>40</sup>*  
*Yoo et al JoA 2013<sup>41</sup>*

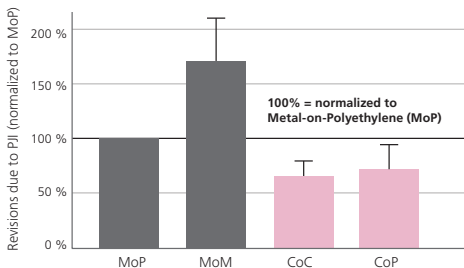
## Ceramic bearings are a safe, effective, and highly successful solution for revision THA

| Study                          | Number of hips | Index Revisions due to Aseptic Loosening (%) | Mean followup in years (range) | Bearing Used for Revision  | Fractures (%)   | Kaplan Meier Survival (Re-Revision)                 |
|--------------------------------|----------------|--|--------------------------------|--|-----------------|---|
| Hannouche et al. <sup>42</sup> | 110            | 83%  | 9.3 (5 to 27)                  | COC, 28% (31/110);<br>C-PE, 58% (64/110);<br>M-PE, 14% (15/110); | –               | 83.1% "revision for mechanical failure" at 10 years |
| Chang et al. <sup>43</sup>     | 42             | 64% (27/42)                                  | 5.4 (3.2 to 8)                 | COC, 100% (alumina)  | –               | 100% (no re-revisions)                              |
| Yoo et al. <sup>44</sup>       | 64             | 59% (38/64)                                  | 9.8 (7.0 to 13.1)              | COC, 100% (alumina)  | –               | 96.9 % at 7 years                                   |
| Jack et al. <sup>45</sup>      | 165            | 98%  | 4.8 (2.1 to 12.5)              | COC, 100%<br>(100 alumina, 65 delta)                             | 2 alumina heads | 96.6% femur,<br>94% acetabulum at 8.3 years         |
| Khatod et al. <sup>46</sup>    | 629            | 14.3%  | 5                              | C-PE (13.7%)   | –               | 86.8% at 5 years                                    |

Table 1: Summary of clinical outcomes reported for ceramic bearings in Revision THA

## Risk for revision for infection is lowest in case of CoC bearings

### Periprosthetic Joint Infection (PJI) 9 Registries; 827,306 THAs<sup>a-1</sup>



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