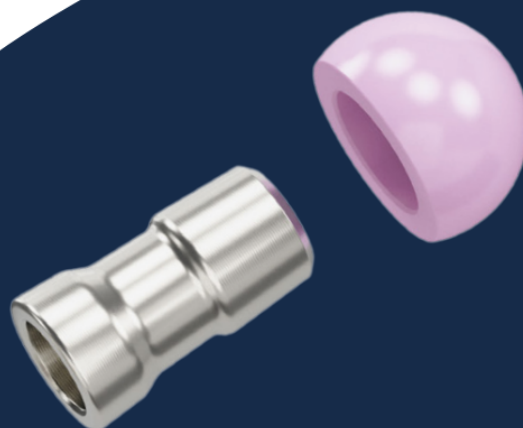




# BioBall® Adapter System

## Claims

**THE POWER**

**TO ADAPT**

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## 1. BioBall® Adapter System - Claims

| Category                   | Title                                           | Advantage                                                                           | Description                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------|-------------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Clinical                   | Preservation of Well-Fixed Stems                | Retention of well-fixed femoral stems in revision procedures                        | The BioBall® Adapter System supports retention of well-fixed stems, which can reduce the need for more invasive revision procedures.                                                                                                                                                                                                                            |
| Clinical                   | Reported Clinical Outcomes in Hip Arthroplasty  | Reported clinical outcomes in hip arthroplasty procedures                           | Clinical studies report positive outcomes in hip arthroplasty procedures using the modular BioBall® Adapter System.<br><br><i>Ref: BioBall® Literature overview <a href="https://merete.de/wp-content/uploads/2024/05/BioBall_Literature_OT-013-H111-001-EN.pdf">https://merete.de/wp-content/uploads/2024/05/BioBall_Literature_OT-013-H111-001-EN.pdf</a></i> |
| Clinical                   | Long-Term Clinical Experience                   | Over two decades of documented clinical use                                         | The BioBall® Adapter System has been used in clinical practice for over two decades, providing accumulated clinical experience.                                                                                                                                                                                                                                 |
| Clinical                   | Documented Use in Revision Procedures           | Documented in more than 50 publications                                             | Documented in over 50 publications, the BioBall® Adapter System is described in the literature as a useful and supportive option in hip revision procedures.                                                                                                                                                                                                    |
| Economic / Hospital        | Support for Efficient Surgical Workflow         | Efficient intraoperative workflow through modular implant configuration             | The modular BioBall® Adapter System supports efficient intraoperative workflow by enabling flexible implant configuration.                                                                                                                                                                                                                                      |
| Economic / Hospital        | Potential Reduction of Procedure Time           | Potential reduction of procedure time by avoiding implant exchange                  | The BioBall® Adapter System may contribute to reduced procedure time in certain surgical scenarios by avoiding additional implant exchanges.                                                                                                                                                                                                                    |
| Economic / Hospital        | Support for Cost-Efficient Treatment Pathways   | Cost-efficient treatment through intraoperative adjustment without full replacement | The BioBall® Adapter System may contribute to cost efficiency by enabling intraoperative adjustment without full implant replacement.                                                                                                                                                                                                                           |
| Economic / Hospital        | Support for Flexible Surgical Decision-Making   | Flexible intraoperative response to unexpected surgical situations                  | The BioBall® Adapter System enables intraoperative adjustment options, supporting flexible responses to unexpected situations.                                                                                                                                                                                                                                  |
| Economic / Hospital        | Independence from Stem-Specific Instrumentation | Use without stem-specific instrumentation for flexible surgical planning            | The BioBall® Adapter System is designed for use without requiring instrumentation from the original stem manufacturer, supporting flexible surgical planning.                                                                                                                                                                                                   |
| Evidence / Registry Claims | Registry-Based Usage Data                       | Representation in national joint registry data (e.g. EPRD)                          | The use of the BioBall® Adapter System is reflected in national joint registry data (e.g., EPRD), depending on data availability and reporting scope.                                                                                                                                                                                                           |
| Market                     | Market Presence in Hip Revision                 | Significant share in the German hip revision market                                 | BioBall® holds a significant share of the German market for hip revision procedures<br><br><i>Ref: Versorgungen der strukturierten Qualitätsberichte der Krankenhäuser gemäß §136b SGB V, QB Analyzer, internal analyses</i>                                                                                                                                    |
| Market                     | German manufactured BioBall® implants           | Defined quality standards in German manufacturing.                                  | BioBall® implants are manufactured in Germany in accordance with defined quality standards.                                                                                                                                                                                                                                                                     |

| Category  | Title                                       | Advantage                                                                                  | Description                                                                                                                                                                        |
|-----------|---------------------------------------------|--------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Market    | Premium Quality Positioning                 | Positioned as a high-quality modular revision solution                                     | The BioBall® Adapter System is positioned as a high-quality solution based on material selection and manufacturing processes.                                                      |
| Market    | Multi-Source Component Availability         | Component sourcing from qualified manufacturing partners (e.g. CeramTec)                   | The BioBall® Adapter System includes components sourced from qualified manufacturing partners (e.g. CeramTec for Ceramic Heads) to support supply continuity.                      |
| Technical | Broad Range of Standard and Offset Adapters | Wide range of standard and offset adapters for different clinical requirements             | The BioBall® Adapter System offers a wide range of standard and offset adapter options to support different clinical requirements.                                                 |
| Technical | Intraoperative Adjustment Capability        | Intraoperative adjustment of neck length and offset for joint reconstruction               | The BioBall® Adapter System enables intraoperative adjustment of offset, neck length, lateralisation, anterversion/retroversion to support joint revision.                         |
| Technical | Compensation of Component Misalignment      | Support for compensation of positional misalignment between stem and acetabular components | The BioBall® Adapter System allows surgeons to intraoperatively compensate for misalignments between in situ femoral stems and acetabular cups                                     |
| Technical | Taper Identification Support                | Support for taper identification for correct adapter selection                             | Merete offers support for identification of taper configurations to assist in correct adapter selection.                                                                           |
| Technical | Modular System Concept                      | Modular system combining adapters with ceramic and metal heads                             | The BioBall® Adapter System is based on a modular concept combining adapters and compatible BioBall® Ceramic and BioBall® Metal Heads to support flexible intraoperative revision. |
| Technical | Instrument-Supported Surgical Workflow      | Dedicated instrumentation supporting structured intraoperative workflow                    | The BioBall® Adapter System includes dedicated instrumentation to support structured intraoperative workflow.                                                                      |

## 2. BioBall® Adapter Selector® - Claims

| Category  | Title                                             | Advantage                                                    | Description                                                                                                                                                                                     |
|-----------|---------------------------------------------------|--------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Clinical  | Documentation of the identified taper             | Documented intraoperative taper fit verification             | The BioBall® Adapter Selector® is used to document the intraoperative compatibility check between the stem taper and the inner taper of the BioBall® Adapters as part of the surgical records.. |
| Technical | Compatibility Assessment between Stem and Adapter | Intraoperative compatibility assessment                      | The BioBall® AdapterSelector® enables intraoperative assessment of compatibility between the stem taper and the inner taper of the BioBall® Adapter.                                            |
| Technical | Support for Taper Geometry Assessment             | Assessment of 11 taper geometries across multiple stem types | The BioBall® AdapterSelector® is an instrument for intraoperative inspection of taper geometry, enabling identification of 11 different taper geometries during surgery.                        |
| Technical | Integration into Instrument Trays                 | Integrated into instrument trays for intraoperative workflow | The BioBall® Adapter Selector® is included as part of BioBall® Instrument Trays to support intraoperative workflow.                                                                             |

### 3. BioBall® Head Separating Wedge - Claims

| Category  | Title                                         | Advantage                                                                | Description                                                                                                                                                                                                                  |
|-----------|-----------------------------------------------|--------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical | Controlled Head Removal with Taper Protection | Controlled removal of the femoral head with reduced risk of taper damage | The BioBall® Head Separating Wedge is used for removal of the existing head and features a dual-sided design, including a dedicated stem-facing side intended to reduce the risk of damage to the taper during head removal. |

### 4. BioBall® Offset PositionAssistant - Claims

| Category  | Title                                                       | Advantage                                                                          | Description                                                                                                                                                |
|-----------|-------------------------------------------------------------|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical | BioBall® Offset PositionAssistant for Visualization Support | Ex situ visualization of BioBall® Offset Adapter positioning prior to implantation | The BioBall® Offset PositionAssistant is designed to support visualization of the offset BioBall® Offset Adapter position (ex situ) prior to implantation. |

### 5. BioBall® Trial components - Claims

| Category  | Title                                                        | Advantage                                                     | Description                                                                                                                                                                                                                                  |
|-----------|--------------------------------------------------------------|---------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical | Radiopaque BioBall® Trial Components for trial repositioning | Support intraoperative visualization and assessment           | Radiopaque BioBall® Trial Components enable visualization during imaging and facilitate intraoperative assessment and adjustment of prosthetic fit, range of motion, soft tissue tension, and component seating prior to final implantation. |
| Technical | BioBall® Trial Adapters with secure fixation                 | Secure fixation on the stem taper without unintended movement | BioBall® Trial Adapters are intended to fit securely onto the stem taper during intraoperative use.                                                                                                                                          |

### 6. BioBall® Adapter Extractor & Extractor Sleeve - Claims

| Category  | Title                                               | Advantage                                                                                                     | Description                                                                                                                                                                                                                                                                                   |
|-----------|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical | Instrument-Assisted Separation of Head from Adapter | Controlled separation of the BioBall® Head from the BioBall® Adapter with size-specific instrument adaptation | If the BioBall® Head needs to be separated from the BioBall® Adapter, the BioBall® Adapter Extractor is used. For specific adapter sizes (e.g. 12/14, size S and 14/16, size M), the corresponding extractor sleeve is required to ensure proper engagement and controlled component removal. |

### 7. BioBall® Heads - Claims

| Category  | Title                    | Advantage                                                   | Description                                                                                                                                                                                                                |
|-----------|--------------------------|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical | Wide Range of Head Sizes | Multiple head sizes (Ø 28–48 mm) for anatomical variability | BioBall® Heads are available in multiple standard sizes to support anatomical variability.<br><br>BioBall® Ceramic Heads<br>Size, Ø 28, 32, 36, 40, 44, 48 mm<br>BioBall® Metal Heads<br>Size, Ø 28, 32, 33, 35, 36, 38 mm |

| Category  | Title                                     | Advantage                                              | Description                                                                                                           |
|-----------|-------------------------------------------|--------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| Technical | Manufactured to Defined Quality Standards | Manufactured according to defined quality requirements | BioBall® Heads are manufactured in accordance with defined quality requirements using qualified production processes. |

## 8. BioBall® Ceramic Heads - Claims

| Category  | Title                                                 | Advantage                                                                    | Description                                                                                                                                                                |
|-----------|-------------------------------------------------------|------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Clinical  | Low Biological Reactivity of BioBall® Ceramic Heads   | Low biological reactivity under physiological conditions                     | *BioBall® Ceramic Heads made of BIOLOX® delta ceramic are associated with low biological reactivity under physiological conditions.                                        |
| Technical | High Wear Resistance of BioBall® Ceramic Heads        | High wear resistance under physiological joint loading                       | *BioBall® Ceramic Heads made of BIOLOX® delta ceramic are designed to provide high wear resistance under physiological joint loading conditions.                           |
| Technical | Wettability Characteristics of BioBall® Ceramic Heads | Excellent wettability under physiological conditions                         | *BioBall® Ceramic Heads made of BIOLOX® delta ceramic exhibit excellent wettability under physiological conditions                                                         |
| Technical | Chemical Stability of BioBall® Ceramic Heads          | High chemical stability under physiological conditions                       | *BioBall® Ceramic Heads made of BIOLOX® delta ceramic demonstrate high chemical stability in physiological environments.                                                   |
| Clinical  | Surface Characteristics of BioBall® Ceramic Heads     | Reduced bacterial adhesion characteristics of BIOLOX® delta ceramic surfaces | *Studies indicate that BIOLOX® delta Ceramic surfaces used in BioBall® Ceramic Heads may exhibit different bacterial adhesion characteristics compared to other materials. |

\*Ref:

BIOLOXdelta-Quick-Reference-Guide.pdf. Retrieved from: <https://www.ceramtec-medical.com/en/biolox/implant-material> (accessed 2026-05-26).

## 9. BioBall® Metal Heads - Claims

| Category  | Title                                           | Advantage                                                                  | Description                                                                                                                                      |
|-----------|-------------------------------------------------|----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical | Metallic Material with High Mechanical Strength | Metallic materials with established mechanical properties for articulation | BioBall® Metal Heads are manufactured from metallic materials with established mechanical properties (ISO 5832-9) for use in joint articulation. |

### Use of claims / claim approval

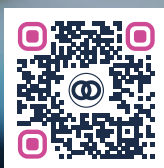
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## Merete GmbH

Alt-Lankwitz 102  
12247 Berlin  
Germany

Tel. +49 (0)30 77 99 80-0  
[service@merete.de](mailto:service@merete.de)  
[merete.de/en](https://merete.de/en)



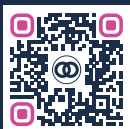
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