merete®

BioBall by merete

Instructions for Use

BioBall® Adapter and Head

ENGLISH


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BioBall by merete

Content

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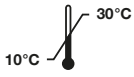
1. Explanations to Used Symbols

CE 0482	CE marking of conformity followed by the identification number of the notified body
	Manufacturer
	Date of manufacture
	Use-by date
LOT	Batch code
REF	Catalogue number
STERILE R	Sterilized using irradiation
	Do not resterilise
	Do not use if package is damaged
	Keep dry
	Storage temperature limits
	Do not re-use
	Consult instructions for use
	Caution
QTY 1	Quantity
	Keep away from sunlight
	MR Conditional
UDI	Unique device identifier (UDI)
UDI-DI	UDI-DI code (HRI – Human readable interpretation)
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside
MD	Medical Device/Device Name
CH REP	Indicates the authorized representative in Switzerland (if applicable)
	Name of the patient or patient ID
	Date of implantation
	Name and address of the healthcare institution/provider

2. Product Description

2.1 Intended Purpose

WARNING

Use of implants contrary to intended purpose

- Risk of injury due to implant failure!
- ➲ Implants must only be used in accordance with intended purpose.

The BioBall® Adapters are for use as a spare part in hip revision operations in combination with a BioBall® Head. The BioBall® System (Adapters & Heads) serves to preserve the existing anchored hip stem or total hip endoprosthesis (Hip TEP). The BioBall® Adapter 12/14 can also be used during the primary operation for correcting positioning with only the approved stems of the Merete GmbH.

2.2 Indications, User Specification and Patient Group

Indications

- Bearing couple revisions
- Intraoperative correction of offset, neck length, lateralisation and anteversion/retroversion with anchored prosthesis stem
- BioBall® Adapter 12/14: intraoperative correction of offset, neck length, lateralisation and anteversion/retroversion during primary operation as well

Intended user

- The products may only be used by qualified surgeons in the field of orthopedics, trauma or reconstructive surgery or surgeons with equal qualification and experience. To ensure the success of the operation, it is essential that the surgeon is familiar with the surgical technique recommended for this system and applies this technique with great care.

Intended patient population

- Age: when the bone growth is completed
- Body weight: obesity or pre-obesity can interfere with the success of the implant
- Activity: observe aftercare, physical activities associated with strong shocks which could result in the implant being exposed to impacts and/or excessive loads (e.g. hard physical labour, certain types of sport) can interfere the success of the implant

User environment

- The implants are to be used in a sterile operating room.

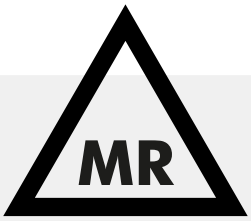
2.3 Contraindications

- Acute or chronic infections in the hip joint or the immediate vicinity
- Patients with joint diseases that may be successfully treated with another, joint salvage treatment
- Any comorbidities that could pose a risk to the function or success of the implant, especially severe muscular, nervous or vascular disorders with specific effects on the limb to be operated upon
- Severely damaged in-situ stem tapers (visible changes in shape, or palpable defects, such as localised wear, abrasion/material loss, or scratches/ridges) or implants which cannot be clearly identified
- Allergies to any of the materials used

2.4 Factors Interfering with Success

- Obesity or pre-obesity
- Local bone tumours
- Osteoporosis or osteomalacia
- Malformations, congenital hip dislocation, severe axial displacement of the knee
- Systemic or metabolic disorders
- Smoking, Alcohol or drug abuse
- Physical activities associated with strong shocks which could result in the implant being exposed to impacts and/or excessive loads (e.g. hard physical labour, certain types of sport)
- Patients with pathological mental or neurological conditions, or patients who are not capable of following the necessary post-operative care instructions

2.5 Possible Negative Side Effects (incl. MRI-Parameters)



MRI Safety Information/Indications for Use

Non-clinical testing has demonstrated that the Merete® Hip Implant System (consisting of cemented or non-cemented hip stem, taper adapter, metal or ceramic head ball, inlay and cup from the materials unalloyed Titanium (ISO 5832-2), TiAl6V4 ELI (ISO 5832-3), Vivium®[1] (ISO 5832-9), CoCrMo (ISO 5832-4/5832-12), BIOLOX®[2] delta ceramic (ISO 6474-2), UHMWPE/XPE (ISO 5834-2)) is MR conditional. A patient with the entire assembled Merete® Hip Implant System can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla.
- Maximum spatial gradient field of 3,000 Gauss/cm (30 T/m).
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) at 1.5 Tesla or 3.0 Tesla of 1 W/kg for 15 minutes of scanning. Under the scan conditions defined above, the Merete® Hip Implant System is expected to produce a maximum temperature rise of less than 6 °C after 15 minutes of continuous scanning.
- In non-clinical testing, the image artifact caused by the Merete® Hip Implant System extends at least 1 cm and up to approximately 8 cm from the device and exhibits geometric distortion in the image when imaged with a gradient echo pulse sequence or a fast-spin echo pulse sequence and a 1.5 Tesla MRI system or a 3.0 Tesla MRI system.

[1] Vivium® (High Nitrogen Stainless Steel) according to ISO 5832-9 is a registered trademark of Merete GmbH.
[2] BIOLOX® delta is a registered trademark of CeramTec GmbH.

The side effects listed below are among the most common adverse effects of implantation procedures:

- Early or late onset infections
- Dislocation, subluxation, insufficient range of motion, undesired shortening or lengthening of the affected extremities as a result of suboptimal implant positioning
- Bone fractures due to unilateral overuse or weakened bone substance
- Reduced bone density due to stress shielding or bone resorption as a tissue response to abrasion particles
- Tissue reactions, osteolysis and loosening of the implant due to metal corrosion or accumulation of abrasive particles or loose cement
- Corrosion with local tissue reactions or pain
- Aseptic loosening
- Noise development (“squeaking”)
- Corrosion and fretting
- Local tissue reactions and hypersensitivity
- Dissociation of modular components
- Temporary or permanent nerve damage due to pressure or haematoma
- Wound haematoma and delayed wound healing
- Vascular disorders, including vein thrombosis, pulmonary embolism and heart failure
- Heterotopic ossification
- Nerve damage as a result of surgical trauma

NOTE With ceramic components, a risk of fracture can never be ruled out entirely.
The following factors can increase this risk:

- Obesity or pre-obesity
- Alcohol or drug abuse
- Physical activities associated with strong shocks which could result in the implant being exposed to impacts and/or excessive loads (e.g. hard physical labour, certain types of sport)

The patient must be informed about such risks.

2.6 System Compatibility

WARNING

Combination of BioBall® Adapters with hip stems with neck insertion system

- Risk of injury due to premature implant failure!
- ➲ BioBall® Adapters must not be combined with hip stems that use a neck insertion system.

Combination of implant components of different sizes

- Damage to implant components!
- ➲ Combine only components of the same size.

2.6.1 Primary Surgery

Insofar as the BioBall® Adapter label does not indicate otherwise, BioBall® Adapters may be used in combination with either Metal or Ceramic BioBall® Heads (possible combination see ▶ Chapter 2.6.3 "BioBall® Product Combinations"). In primary surgery, BioBall® Adapter 12/14 is only intended for use together with the Merete®-brand hip stems approved for that purpose.

2.6.2 Revision Surgery

Insofar as the BioBall® Adapter label does not indicate otherwise, BioBall® Adapters may be used in combination with either Metal or Ceramic BioBall® Heads (possible combination see ▶ Chapter 2.6.3 "BioBall® Product Combinations")! Surgeons wishing to perform revisions using BioBall® Adapters with hip stems from other manufacturers must check taper (adapter-stem) compatibility prior to the operation. If using a 12/14 taper in such cases, this must adhere to the applicable CeramTec BIOLOX®[2] specification. The taper may not display any kind of shape-altering damage, severe abrasion/material loss, or deep scratches/burrs or similar surface defects. Use the BioBall® AdapterSelector® to check the taper geometry. If desired, Merete® can provide information regarding suitable tapers. No biomechanical testing information is available on the use of BioBall® Adapters, with hip stems from other manufacturers. Consequently, only manufacturer-approved extensions may be used.

NOTE BioBall® Ceramic Heads must not be used with BioBall® special adapters (MS 8/10, MSV4 Offset 2XL and 3XL, MST1, MSBG, MSPC and MSSR).

[2] BIOLOX® delta is a registered trademark of CeramTec GmbH.

2.6.3 BioBall® Product Combinations

Combination: BioBall® Adapter – BioBall® Head

BioBall® Adapter	Stem-taper-geometry	Size range & max. extension	BioBall® Head combination
12/14 Standard	12/14 - 5°42′	S (-3.0 mm) - 5XL (+21.0 mm)	Metal and Ceramic
12/14 Offset	12/14 - 5°42′	M (0 mm) - 5XL (+21.0 mm)	Metal and Ceramic
14/16 Standard	14/16 - 5°42′	M (0 mm) - 5XL (+21.0 mm)	Metal and Ceramic
14/16 Offset	14/16 - 5°42′	2XL (+10.5 mm) - 5XL (+21.0 mm)	Metal and Ceramic
MS 8/10 Standard	8/10 - 5°42′	S (-3.0 mm) - 2XL (+10.5 mm)	Metal
MS 8/10 Offset	8/10 - 5°42′	M (0 mm) - 2XL (+10.5 mm)	Metal
MS 10/12 Standard	10/12 - 5°42′	S (-3.0 mm) - 3XL (+14.0 mm)	Metal and Ceramic
MS 10/12 Offset	10/12 - 5°42′	M (0 mm) - 3XL (+14.0 mm)	Metal and Ceramic
MSBG (14/16) Standard	14/16 - 6°0′	M (0 mm) - 2XL (+10.5 mm)	Metal
MSPC (13/14) Standard	13/14 - 2°52′	M (0 mm) - L (+3.5 mm)	Metal
MSSR (11/13) Standard	11/13 - 6°2′	M (0 mm) - XL (+7.0 mm)	Metal
MSSY (10/12) Standard	10/12 - 6°0′	S (-3.0 mm) - XL (+7.0 mm)	Metal and Ceramic
MST1 (11/13) Standard	11/13 - 4°3′	M (0 mm) - 3XL (+14.0 mm)	Metal
MST1 (11/13) Offset	11/13 - 4°3′	M (0 mm) - 3XL (+14.0 mm)	Metal
MSV4 (11/12) Standard	11/12 - 5°39′	M (0 mm) - 3XL (+14.0 mm)	Metal and Ceramic
MSV4 (11/12) Offset	11/12 - 5°39′	M (0 mm) - 3XL (+14.0 mm)	Metal and Ceramic (M, L, XL)
MSZI (10/12) Standard	10/12 - 6°0′	S (-3.0 mm) - 3XL (+14.0 mm)	Metal and Ceramic

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Combination: BioBall® Adapter – Stem Taper Material

BioBall® Adapters may be used with stems whose tapers are made of the following materials:

BioBall® Adapter	Stem taper material			
	TiAl6V4	TiAl6Nb7	CoCr Alloys	Stainless steel
12/14	✓	✓	✓	✓
14/16	✓	✓	✓	✓
MS 8/10	✓	✓	✓	✓
MS 10/12	✓	✓	✓	✓
MSBG (14/16)	✓	✓	✓	✓
MSPC (13/14)	✓	✓	✓	✓
MSSR (11/13)	✓	✓	–	–
MSSY (10/12)	✓	✓	✓	✓
MST1 (11/13)	✓	✓	✓	✓
MSV4 (11/12)	✓	✓	✓	✓
MSZI (10/12)	✓	✓	✓	✓

Combination: Stems – Heads – Inlays – Cups

Note the following system-specific requirements for product combination:

Stems	Heads		Inlay	Cups		Cup & Inlay – combined *To be inserted in the natural acetabulum*
	HipBall® Premium Metal Head **Material:** CoCrMo alloy **Taper:** 12/14	**BIOLOX®2 delta ceramic Head** **Material:** BIOLOX®2 delta ceramic **Taper:** 12/14	**MaxiMotion® Inlay** without pre-assembled Head **Material:** UHMWPE	**BioBall® MaxiMotion® Cup** non-cemented **Material:** · Vivium®1 with TPS3 and BONIT®4 · Vivium®1 with TPS3 · Vivium®1	**BioBall® MaxiMotion® Cup** cemented **Material:** · Vivium®1 with TPS3 and BONIT®4 · Vivium®1 with TPS3 · Vivium®1	**Bipolar TwinSet® Cup** incl. Inlay and locking ring **Material:** Vivium®1, UHMWPE
may only be combined with the ***BioBall® System components*** *or with* ***Heads with taper 12/14*** *that fulfil Merete® specifications. The 12/14 taper according to Merete® specifications, is compatible to BIOLOX®2* *may only be combined with* ***Heads*** *made of:* · ***Vivium®1*** · ***CoCrMo alloy*** · ***BIOLOX®2 delta ceramic***	*may only be combined with* ***PE/XPE Inlays*** *and* ***PE-Cups***	*may only be combined with* ***BIOLOX®2 delta ceramic Inlays, PE/XPE Inlays*** *and* ***PE-Cups***	*may only be combined with a* ***Ø 28 mm Head*** *of following systems, if used* ***without*** ***BioBall® Adapter: HipBall® Premium Metal Head, BIOLOX®2 delta ceramic Head***	*may only be combined with* ***BioBall® MaxiMotion® XPE Inlays*** *and* ***MaxiMotion® XPE Inlays***		*may only be combined with a* ***Ø 28 mm Head*** *of following systems:* ***HipBall® Premium Metal Head, BIOLOX®2 delta ceramic Head***
Combination: Stem – Head – Inlay – Cup *The Heads, Inlays and Cups marked with ✓ may be combined with the listed Merete® Stems.*						
IntraBlock® TwinStem® **Material: cemented** Vivium®1 **Material: non-cemented** · TiAl6V4 ELI alloy, TPS3 and BONIT®4 · TiAl6V4 ELI alloy, TPS3 **Taper:** 12/14	✓	✓	✓	✓	✓	✓
Merete®: Müller Straight Stem (Geradschaft) **Material:** Vivium®1 **Taper:** 12/14	✓	✓	✓	✓	✓	✓

[1] Vivium® (High Nitrogen Stainless Steel) according to ISO 5832-9 is a registered trademark of Merete GmbH.
[2] BIOLOX® delta is a registered trademark of CeramTec GmbH.
[3] TPS titanium plasma spray (Titanium plasma spray coating).
[4] BONIT® is a registered trademark of DOT GmbH.

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Combination: Stems – BioBall® Adapters – Heads – Inlays – Cup

Note the following system-specific requirements for product combination:

Stems			BioBall® Adapters			BioBall® Heads		
Stems whose tapers are made of the following materials may be used with the BioBall® Adapters: • **Titanium alloys (TiAl6V4/ TiAl6Nb7)** • **CoCr alloys** • **Stainless Steel**	**IntraBlock® TwinStem®** **Material: cemented** Vivium®[1] **Material: non-cemented** · TiAl6V4 ELI alloy, TPS[3] and BONIT®[4] · TiAl6V4 ELI alloy, TPS[3] **Taper:** 12/14	**Merete®: Müller Straight Stem (Geradschaft)** **Material:** Vivium®[1] **Taper:** 12/14	**Material:** TiAl6V4 ELI			**BioBall® Metal Head** **Material:** Vivium®[1]	**BioBall® Ceramic Head** **Material:** BIOLOX®[2] delta ceramic	
	may only be combined with ***Heads*** *made of:* · ***Vivium®[1]*** · ***CoCrMo alloy*** · ***BIOLOX®[2] delta ceramic***		*may only be combined with* ***BioBall® Heads***			*may only be combined with* ***UHMWPE/XPE Inlays*** *or* ***Cups***	*may only be combined with* ***BIOLOX®[2] delta ceramic Inlays****, or with UHMWPE/* ***XPE Inlays*** *or* ***Cups***	
NOTE: Use the BioBall® Adapter only after verifying the taper size using the Merete® BioBall® AdapterSelector® according to surgical technique.								
Combination: Stem – Adapter *The BioBall® Adapter may be combined with following Stems, marked with ✓.*			**BioBall® Adapter**	**Stem taper geometry**	**Size range & max. extension**	**Combination: Adapter – Head** *The BioBall® Adapter may be combined with Heads, marked with ✓.*		
✓	✓	✓	**12/14** Standard	12/14 - 5°42´	S (-3.0 mm) - 5XL (+21.0 mm)	✓	✓	
✓	✓	✓	**12/14** Offset	12/14 - 5°42´	M (0 mm) - 5XL (+21.0 mm)	✓	✓	
✓			**14/16** Standard	14/16 - 5°42´	M (0 mm) - 5XL (+21.0 mm)	✓	✓	
✓			**14/16** Offset	14/16 - 5°42´	2XL (+10.5 mm) - 5XL (+21.0 mm)	✓	✓	
✓			**MS 10/12** Standard	10/12 - 5°42´	S (-3.0 mm) - 3XL (+14.0 mm)	✓	✓	
✓			**MS 10/12** Offset	10/12 - 5°42´	M (0 mm) - 3XL (+14.0 mm)	✓	✓	
✓			**MSSY (10/12)** Standard	10/12 - 6°0´	S (-3.0 mm) - XL (+7.0 mm)	✓	✓	

[1] Vivium® (High Nitrogen Stainless Steel) according to ISO 5832-9 is a registered trademark of Merete GmbH.
[2] BIOLOX® delta is a registered trademark of CeramTec GmbH.
[3] TPS titanium plasma spray (Titanium plasma spray coating).
[4] BONIT® is a registered trademark of DOT GmbH.

	BioBall® MaxiMotion® Inlays with pre-assembled Heads		BioBall® MaxiMotion® Cups		Inlay	Cups & Inlays – combined *To be inserted in the natural acetabulum*	
	BioBall® MaxiMotion® Inlay with pre-assembled BioBall® Metal Head **Material:** Vivium®1, UHMWPE	**BioBall® MaxiMotion® Inlay** with pre-assembled BioBall® Ceramic Head **Material:** BIOLOX®2 delta ceramic, UHMWPE	**BioBall® MaxiMotion® Cup** non-cemented **Material:** · Vivium®1 with TPS3 and BONIT®4 · Vivium®1 with TPS3 · Vivium®1	**BioBall® MaxiMotion® Cup** cemented **Material:** · Vivium®1 with TPS3 and BONIT®4 · Vivium®1 with TPS3 · Vivium®1	**MaxiMotion® Inlay** without pre-assembled Head **Material:** UHMWPE **(+ BioBall® Metal Head/ Ceramic Head + BioBall® MaxiMotion® Cups)**	**BioBall® Duo Head** with pre-assembled BioBall® Metal Head **Material:** Vivium®1, UHMWPE	**Bipolar TwinSet® Cup** incl. Inlay and locking ring **Material:** Vivium®1, UHMWPE **(+ BioBall® Metal Head or BioBall® Ceramic Head)**
	*may only be combined with **BioBall® MaxiMotion® Cups***		*may only be combined with **BioBall® MaxiMotion® XPE Inlays** and **MaxiMotion® XPE Inlays***		*may only be combined with **Ø 28 mm Head** of following systems if used **with** **BioBall® Adapter System: BioBall® Ceramic Head, BioBall® Metal Head***	*may **only** be used with the **BioBall® Adapter System***	*may only be combined with a **Ø 28 mm Head** of following systems: **BIOLOX®2 delta ceramic Head, BioBall® Metal Head***
	Combination: Adapter – Inlay *The BioBall® Adapter may be combined with Inlays, marked with ✓.*		**Combination: Adapter – Cup** *The BioBall® Adapter may be combined with Cups, marked with ✓.*		**Combination: Adapter (-Head) – Inlay (-Cup)** *The BioBall® Adapter may be combined with Inlays, marked with ✓.*	**Combination: Adapter – Cup (with Inlay)** *The BioBall® Adapter may be combined with Cups, marked with ✓.*	
	✓	✓	✓	✓	✓	✓	✓
	✓	✓	✓	✓	✓	✓	✓
	✓	✓	✓	✓	✓	✓	✓
	✓	✓	✓	✓	✓	✓	✓
	✓	✓	✓	✓	✓	✓	✓
	✓	✓	✓	✓	✓	✓	✓
	✓	✓	✓	✓	✓	✓	✓

Continued ▶

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Combination: Stems – BioBall® Adapters – Heads – Inlays – Cup (continued – 1)

Note the following system-specific requirements for product combination:

Stems			BioBall® Adapters			BioBall® Heads		
Stems whose tapers are made of the following materials may be used with the BioBall® Adapters: • **Titanium alloys (TiAl6V4/ TiAl6Nb7)** • **CoCr alloys** • **Stainless Steel**	**IntraBlock® TwinStem®** **Material: cemented** Vivium®[1] **Material: non-cemented** · TiAl6V4 ELI alloy, TPS[3] and BONIT®[4] · TiAl6V4 ELI alloy, TPS[3] **Taper:** 12/14	**Merete®: Müller Straight Stem (Geradschaft)** **Material:** Vivium®[1] **Taper:** 12/14	**Material:** TiAl6V4 ELI			**BioBall® Metal Head** **Material:** Vivium®[1]	**BioBall® Ceramic Head** **Material:** BIOLOX®[2] delta ceramic	
	*may only be combined with **Heads** made of:* · ***Vivium®[1]*** · ***CoCrMo alloy*** · ***BIOLOX®[2] delta ceramic***		*may only be combined with **BioBall® Heads***			*may only be combined with **UHMWPE/XPE Inlays** or **Cups***	*may only be combined with **BIOLOX®[2] delta ceramic Inlays**, or with UHMWPE/ **XPE Inlays** or **Cups***	
NOTE: Use the BioBall® Adapter only after verifying the taper size using the Merete® BioBall® AdapterSelector® according to surgical technique.								
Combination: Stem – Adapter *The BioBall® Adapter may be combined with following Stems, marked with ✓.*			**BioBall® Adapter**	**Stem taper geometry**	**Size range & max. extension**	**Combination: Adapter – Head** *The BioBall® Adapter may be combined with Heads, marked with ✓.*		
✓			**MSV4 (11/12)** Standard	11/12 - 5°39′	M (0 mm) - 3XL (+14.0 mm)	✓	✓	
✓			**MSV4 (11/12)** Offset	11/12 - 5°39′	M (0 mm) - 3XL (+14.0 mm)	✓	M, L, XL	
✓			**MSZI (10/12)** Standard	10/12 - 6°0′	S (-3.0 mm) - 3XL (+14.0 mm)	✓	✓	
✓			**MS 8/10** Standard	8/10 - 5°42′	S (-3.0 mm) - 2XL (+10.5 mm)	✓	*No combination with BioBall® Ceramic Heads*	
✓			**MS 8/10** Offset	8/10 - 5°42′	M (0 mm) - 2XL (+10.5 mm)	✓		
✓			**MSBG (14/16)** Standard	14/16 - 6°0′	M (0 mm) - 2XL (+10.5 mm)	✓		

[1] Vivium® (High Nitrogen Stainless Steel) according to ISO 5832-9 is a registered trademark of Merete GmbH.
[2] BIOLOX® delta is a registered trademark of CeramTec GmbH.
[3] TPS titanium plasma spray (Titanium plasma spray coating).
[4] BONIT® is a registered trademark of DOT GmbH.

	BioBall® MaxiMotion® Inlays with pre-assembled Heads		BioBall® MaxiMotion® Cups		Inlay	Cups & Inlays – combined *To be inserted in the natural acetabulum*	
	BioBall® MaxiMotion® Inlay with pre-assembled BioBall® Metal Head **Material:** Vivium®1, UHMWPE	**BioBall® MaxiMotion® Inlay** with pre-assembled BioBall® Ceramic Head **Material:** BIOLOX®2 delta ceramic, UHMWPE	**BioBall® MaxiMotion® Cup** non-cemented **Material:** · Vivium®1 with TPS3 and BONIT®4 · Vivium®1 with TPS3 · Vivium®1	**BioBall® MaxiMotion® Cup** cemented **Material:** · Vivium®1 with TPS3 and BONIT®4 · Vivium®1 with TPS3 · Vivium®1	**MaxiMotion® Inlay** without pre-assembled Head **Material:** UHMWPE **(+ BioBall® Metal Head/ Ceramic Head + BioBall® MaxiMotion® Cups)**	**BioBall® Duo Head** with pre-assembled BioBall® Metal Head **Material:** Vivium®1, UHMWPE	**Bipolar TwinSet® Cup** incl. Inlay and locking ring **Material:** Vivium®1, UHMWPE **(+ BioBall® Metal Head or BioBall® Ceramic Head)**
	*may only be combined with **BioBall® MaxiMotion® Cups***		*may only be combined with **BioBall® MaxiMotion® XPE Inlays** and **MaxiMotion® XPE Inlays***		*may only be combined with **Ø 28 mm Head** of following systems if used **with** **BioBall® Adapter System: BioBall® Ceramic Head, BioBall® Metal Head***	*may **only** be used with the **BioBall® Adapter System***	*may only be combined with a **Ø 28 mm Head** of following systems: **BIOLOX®2 delta ceramic Head, BioBall® Metal Head***
	Combination: Adapter – Inlay *The BioBall® Adapter may be combined with Inlays, marked with ✓.*		**Combination: Adapter – Cup** *The BioBall® Adapter may be combined with Cups, marked with ✓.*		**Combination: Adapter (-Head) – Inlay (-Cup)** *The BioBall® Adapter may be combined with Inlays, marked with ✓.*	**Combination: Adapter – Cup (with Inlay)** *The BioBall® Adapter may be combined with Cups, marked with ✓.*	
	✓	✓	✓	✓	✓	✓	✓
	✓	M, L, XL	✓	✓	✓	✓	✓
	✓	✓	✓	✓	✓	✓	✓
	✓	*No combination with BioBall® Ceramic Heads*	✓	✓	✓	✓	✓
	✓		✓	✓	✓	✓	✓
	✓		✓	✓	✓	✓	✓

Continued ▶

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Combination: Stems – BioBall® Adapters – Heads – Inlays – Cup (continued – 2)

Note the following system-specific requirements for product combination:

Stems			BioBall® Adapters			BioBall® Heads		
Stems whose tapers are made of the following materials may be used with the BioBall® Adapters: • **Titanium alloys (TiAl6V4/ TiAl6Nb7)** • **CoCr alloys** • **Stainless Steel**	**IntraBlock® TwinStem®** **Material: cemented** Vivium®[1] **Material: non-cemented** · TiAl6V4 ELI alloy, TPS[3] and BONIT®[4] · TiAl6V4 ELI alloy, TPS[3] **Taper:** 12/14	**Merete®: Müller Straight Stem (Geradschaft)** **Material:** Vivium®[1] **Taper:** 12/14	**Material:** TiAl6V4 ELI			**BioBall® Metal Head** **Material:** Vivium®[1]	**BioBall® Ceramic Head** **Material:** BIOLOX®[2] delta ceramic	
	*may only be combined with **Heads** made of:* · ***Vivium®[1]*** · ***CoCrMo alloy*** · ***BIOLOX®[2] delta ceramic***		*may only be combined with **BioBall® Heads***			*may only be combined with **UHMWPE/XPE Inlays** or **Cups***	*may only be combined with **BIOLOX®[2] delta ceramic Inlays**, or with UHMWPE/ **XPE Inlays** or **Cups***	
NOTE: Use the BioBall® Adapter only after verifying the taper size using the Merete® BioBall® AdapterSelector® according to surgical technique.								
Combination: Stem – Adapter *The BioBall® Adapter may be combined with following Stems, marked with ✓.*			**BioBall® Adapter**	**Stem taper geometry**	**Size range & max. extension**	**Combination: Adapter – Head** *The BioBall® Adapter may be combined with Heads, marked with ✓.*		
✓			**MSPC (13/14)** Standard	13/14 - 2°52´	M (0 mm) - L (+3.5 mm)	✓	*No combination with BioBall® Ceramic Heads*	
✓			**MSSR (11/13)** Standard	11/13 - 6°2´	M (0 mm) - XL (+7.0 mm)	✓		
✓			**MST1 (11/13)** Standard	11/13 - 4°3´	M (0 mm) - 3XL (+14.0 mm)	✓		
✓			**MST1 (11/13)** Offset	11/13 - 4°3´	M (0 mm) - 3XL (+14.0 mm)	✓		

[1] Vivium® (High Nitrogen Stainless Steel) according to ISO 5832-9 is a registered trademark of Merete GmbH.
[2] BIOLOX® delta is a registered trademark of CeramTec GmbH.
[3] TPS titanium plasma spray (Titanium plasma spray coating).
[4] BONIT® is a registered trademark of DOT GmbH.

	BioBall® MaxiMotion® Inlays with pre-assembled Heads		BioBall® MaxiMotion® Cups		Inlay	Cups & Inlays – combined *To be inserted in the natural acetabulum*	
	BioBall® MaxiMotion® Inlay with pre-assembled BioBall® Metal Head **Material:** Vivium®1, UHMWPE	**BioBall® MaxiMotion® Inlay** with pre-assembled BioBall® Ceramic Head **Material:** BIOLOX®2 delta ceramic, UHMWPE	**BioBall® MaxiMotion® Cup** non-cemented **Material:** · Vivium®1 with TPS3 and BONIT®4 · Vivium®1 with TPS3 · Vivium®1	**BioBall® MaxiMotion® Cup** cemented **Material:** · Vivium®1 with TPS3 and BONIT®4 · Vivium®1 with TPS3 · Vivium®1	**MaxiMotion® Inlay** without pre-assembled Head **Material:** UHMWPE **(+ BioBall® Metal Head/ Ceramic Head + BioBall® MaxiMotion® Cups)**	**BioBall® Duo Head** with pre-assembled BioBall® Metal Head **Material:** Vivium®1, UHMWPE	**Bipolar TwinSet® Cup** incl. Inlay and locking ring **Material:** Vivium®1, UHMWPE **(+ BioBall® Metal Head or BioBall® Ceramic Head)**
	*may only be combined with **BioBall® MaxiMotion® Cups***		*may only be combined with **BioBall® MaxiMotion® XPE Inlays** and **MaxiMotion® XPE Inlays***		*may only be combined with **Ø 28 mm Head** of following systems if used **with** **BioBall® Adapter System: BioBall® Ceramic Head, BioBall® Metal Head***	*may **only** be used with the **BioBall® Adapter System***	*may only be combined with a **Ø 28 mm Head** of following systems: **BIOLOX®2 delta ceramic Head, BioBall® Metal Head***
	Combination: Adapter – Inlay *The BioBall® Adapter may be combined with Inlays, marked with ✓.*		**Combination: Adapter – Cup** *The BioBall® Adapter may be combined with Cups, marked with ✓.*		**Combination: Adapter (-Head) – Inlay (-Cup)** *The BioBall® Adapter may be combined with Inlays, marked with ✓.*	**Combination: Adapter – Cup (with Inlay)** *The BioBall® Adapter may be combined with Cups, marked with ✓.*	
	✓	*No combination with BioBall® Ceramic Heads*	✓	✓	✓	✓	✓
	✓		✓	✓	✓	✓	✓
	✓		✓	✓	✓	✓	✓
	✓		✓	✓	✓	✓	✓

Based on their dimensions, sliding pairs may be formed using only the following combinations of materials:

BioBall® Heads	Inlays	Cups
Vivium®[1] (DIN ISO 5832-9)	UHWMPE (DIN ISO 5834-2)	Vivium®[1] (DIN ISO 5832-9)
BIOLOX®[2] delta ceramic (ISO 6474-2)	UHWMPE (DIN ISO 5834-2)	Vivium®[1] (DIN ISO 5832-9)
Vivium®[1] (DIN ISO 5832-9)	XPE (DIN ISO 5834-2)	Vivium®[1] (DIN ISO 5832-9)
BIOLOX®[2] delta ceramic (ISO 6474-2)	XPE (DIN ISO 5834-2)	Vivium®[1] (DIN ISO 5832-9)
BIOLOX®[2] delta ceramic (ISO 6474-2)	BIOLOX®[2] delta ceramic (ISO 6474-2)	

2.6.4 Implant Materials

Materials used in implants are indicated on the label.

BioBall® Heads are made of the following materials:

- Metal Head: Vivium®[1] (High Nitrogen Stainless Steel) according to ISO 5832-9
- Ceramic Head: BIOLOX®[2] delta ceramic according to ISO 6474-2

BioBall® Adapters are made of:

- TiAl6V4 ELI alloy according to ISO 5832-3

Chemical composition TiAl6V4 ELI according to ISO 5832-3:

%	AL	V	Fe	O	C	N	H
Min.	5.5	3.5	–	–	–	–	–
Max.	6.5	4.5	0.25	0.13	0.08	0.05	0.012

Chemical composition Vivium®[1] according to ISO 5832-9:

%	C	Si	Mn	P	S	N	Cr	Mo	Ni	Nb	Cu
Min.	–	–	2.00	–	–	0.25	19.50	2.00	9.00	0.25	–
Max.	0.08	0.75	4.25	0.025	0.01	0.50	22.00	3.00	11.00	0.08	0.25

[1] Vivium® (High Nitrogen Stainless Steel) according to ISO 5832-9 is a registered trademark of Merete GmbH.
[2] BIOLOX® delta is a registered trademark of CeramTec GmbH.

Chemical composition BIOLOX®[2] delta according to ISO 6474-2:

	Unit	Value
Aluminium oxide, Al_2O_3	wt%	72 – 76
Zirconium oxide, ZrO_2 + HfO_2	wt%	24.0 – 25.5
Percentage of HfO_2 in ZrO_2	wt%	≤ 5
Percentage Additives	wt%	1.51 – 1.87
Max. percentage of impurities	wt%	≤ 0.2
Gamma activity zirconium oxide	Bq/kg	≤ 200

2.7 Further Product Information

Implantation in Children:

- Complete bone growth is a prerequisite for the application of the BioBall® System.
- Use the BioBall® System for children in exceptional cases. The decision is up to the user.
- Adjust the size and type of the implant as best as possible to the age, height, weight and bone development of the child.
- Due to growth, a subsequent operation for removal and/or revision is more likely in children.
- Perform follow-up checks at shorter intervals.
- Training in the correct handling of implants and instruments by an authorised Merete® representative is essential.

Delivery conditions:

The BioBall® System components are only permitted for single use and is supplied in a sterile condition (gamma sterilization).

Intended lifetime:

The expected lifetime of the BioBall® System is 15 years. However, the lifetime in situ is influenced by the physical activity of the patient and his physiology too.

[1] Vivium® (High Nitrogen Stainless Steel) according to ISO 5832-9 is a registered trademark of Merete GmbH.
[2] BIOLOX® delta is a registered trademark of CeramTec GmbH.

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3. Instructions for Use

3.1 General Information

MRI Safety Information/Indications for Use

Non-clinical testing has demonstrated that the Merete® Hip Implant System (consisting of cemented or non-cemented hip stem, taper adapter, metal or ceramic head ball, inlay and cup from the materials unalloyed Titanium (ISO 5832-2), TiAl6V4 ELI (ISO 5832-3), Vivium®[1] (ISO 5832-9), CoCrMo (ISO 5832-4/5832-12), BIOLOX®[2] delta ceramic (ISO 6474-2), UHMWPE/XPE (ISO 5834-2)) is MR conditional. A patient with the entire assembled Merete® Hip Implant System can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla.
- Maximum spatial gradient field of 3,000 Gauss/cm (30 T/m).
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) at 1.5 Tesla or 3.0 Tesla of 1 W/kg for 15 minutes of scanning. Under the scan conditions defined above, the Merete® Hip Implant System is expected to produce a maximum temperature rise of less than 6 °C after 15 minutes of continuous scanning.
- In non-clinical testing, the image artifact caused by the Merete® Hip Implant System extends at least 1 cm and up to approximately 8 cm from the device and exhibits geometric distortion in the image when imaged with a gradient echo pulse sequence or a fast-spin echo pulse sequence and a 1.5 Tesla MRI system or a 3.0 Tesla MRI system.

Damage to taper connection

- Risk of implant failure!
- ➲ Ensure careful implantation.
- ➲ Do not use damaged implants.

Combination of implant components of different sizes

- Damage to implant components!
- ➲ Combine only components of the same size.

Combination with products from other manufacturers

- Risk of injury due to implant failure (e.g. implant loosening, fretting or corrosion)!
- ➲ BioBall® Adapters may only be combined with stem tapers after taper specifications have been clearly identified and matched.

Foreign bodies (e.g. cement residues, tissue, bones) between implant components

- Risk of injury due to failure of implant!
- ➲ Thoroughly clean any foreign bodies from implant components.

[1] Vivium® (High Nitrogen Stainless Steel) according to ISO 5832-9 is a registered trademark of Merete GmbH.
[2] BIOLOX® delta is a registered trademark of CeramTec GmbH.

Breaking of ceramic components

- Risk of injury due to implant failure!
- ➲ When performing revision surgery following breakage of a ceramic component, do not use metal heads.
- ➲ Replacement component must also be a ceramic head.

Use of damaged or defective implants

- Risk of injury due to premature implant failure!
- ➲ Implants with identifiable damage may not be used.
- ➲ Avoid notches, scratches or bending of the implant in order to preserve its stability.

Use of implant/instrument contrary to intended use

- Damage to/destruction of instrument/implant and injury to patient!
- ➲ Ensure correct handling of implant/instrument. Do not misuse.

Use of implants which have been previously used

- Risk of injury due to premature failure of implant!
- Risk of sepsis!
- ➲ Implants are only approved for single use, not repeated use.

Use of implants contrary to intended purpose

- Risk of injury due to implant failure!
- ➲ Implants must only be used in accordance with intended purpose.

Prior to using Merete® products, surgeons and assisting staff must study in detail the safety information in this product information sheet as well as the product-specific guidelines listed in the surgical technique. The relevant documentation is available from Merete® on request. Surgeons must also be aware of any remaining risks associated with the products he or she intends to use and must inform patients of such risks in advance. Implant operations must only be performed by surgeons who are not only qualified to carry out such operations, but also have extensive verified knowledge and experience in this field. The surgeon bears all responsibility for adverse effects or complications arising from misdiagnosis, improper surgical technique, incorrect implant selection or handling, or failure to observe the safety instructions provided in this Instructions for Use. Neither the manufacturers nor authorized Merete® product representatives may be held liable in such cases. Before operating, study the techniques outlined in the surgical technique carefully. Training in the correct handling of implants and instruments by an authorized Merete® representative is essential. For training in the correct handling of implants and instruments please contact your local Merete® sales representative or contact us under ▶ service@merete.de.

The implantation of a joint endoprosthesis should only be considered if, after careful evaluation, this represents the best solution compared with other possible nonsurgical or joint salvage alternatives. The substitution of a severely altered, diseased joint through prosthesis can reduce pain and allow a good mobility and weight bearing. An implanted artificial joint prosthesis can never reach the full operability of a natural, healthy joint. Various factors may, in the longer term, lead to the loosening or wear of the even stably implanted artificial joint. The revision surgery may therefore be required, however, it is associated with significant health risk. Severe morphological changes in the supporting bone structure can affect implant performance, as can wear and tear on the mobile components. In extremely rare cases, especially if there is trauma or overuse, such changes may cause a component to fail. Patients should always be made aware of these potential risks so that they can take appropriate precautions to reduce overuse and mechanical stress on the implant.

Features BioBall® System

The BioBall® System is made up of a titanium BioBall® Adapter which may only be used with a BioBall® Head. The primary indication is the revision of existing prosthetic stems. The BioBall® Adapter 12/14 can also be used during the primary operation for purposes of intraoperative correction with approved stems of the Merete GmbH. In general, it is possible to vary offset, neck length, lateralisation and anteversion. BioBall® Adapters change hip stem offset, thereby changing the biomechanics of the joint. As a result of these biomechanical alterations, excessive strain on the implant may cause it to loosen, break, or wear down, thus shortening its lifespan. BioBall® Heads may only be combined with BioBall® Adapters. Implants must be inserted with the appropriate Merete® instruments. Under no circumstances may BioBall® implants be reused. When performing revision surgery following breakage of a ceramic component, do not use BioBall® Metal Heads – replacement component must also be a BioBall® Ceramic Head. The individual components of the implant system are assembled with secure taper connections. Only an exact match of the taper dimensions makes this possible. Taper sizes are indicated on product labels – and, where possible, on the implants themselves – in the form of two numbers and an angle (e.g., 12/14 – 5°42′ or 14/16 – 6°0′). BioBall® Heads may only be attached to new, unused BioBall® Adapter tapers. BioBall® Adapters may only be combined with stem tapers after taper specifications have been clearly identified and matched (see ▶ Chapter 2.6 "System Compatibility"). It is particularly important to keep contact surfaces clean and dry during assembly (see ▶ Chapter 3.4 "Information on Handling Implants")! Only combinations using Merete®-approved bearing couples (see ▶ Chapter 2.6 "System Compatibility") are permitted. Using large heads may produce larger quantities of abrasion particles, depending on the materials and sizes of the mating components used. This can negatively impact implant durability. For best results, it is important to choose mating component materials and head sizes with care, tailoring the selection to the individual patient's profile.

Additional information (surgical technique) is available from Merete® on request. There are no known interactions with any medications.

3.2 Preoperative Planning

WARNINGS

Combination with products from other manufacturers

- Risk of injury due to implant failure (e.g. implant loosening, fretting or corrosion)!

➲ BioBall® Adapters may only be combined with stem tapers after taper specifications have been clearly identified and matched.

Combination of implant components of different sizes

- Damage to implant components!

➲ Combine only components of the same size.

Operation planning should be done on the basis of in-depth evaluations of patient X-rays, which provide the information necessary for determining the appropriate prosthesis type, size, and possible combinations. If desired, X-ray templates for pre-operative planning are available from Merete®. It is also important to carry out pre-operative tests on the patient to rule out allergic reaction to the implant materials. Use trial components during the operation in order to check correct implant size and positioning. The components planned for implantation must be on hand in all available sizes. It is absolutely essential to check the implant label (type, item number, material and size) against the information on the package before insertion. Use the additional enclosed patient labels for documentation in surgery reports, implant card and for re-ordering. Check that all implant surfaces are free of soiling.

Important: Always check the sterilization expiration date!

When combining with other Merete® components, observe the instructions in the relevant user instructions, instrumentation guides and surgery videos, if any. In case of doubt, contact Merete GmbH.

3.3 Patient Information

Prior to use BioBall® System components it is required to inform the patient about the procedure that will be performed. This shall include at least a general description of the surgical procedure as well as risks of the procedure. The information shall also include preoperative and postoperative instructions on patient behavior.

Instructions on Patient Information

Surgeons must make their patients aware of information mentioned in ▶ Chapter 2, i.e. any factors that could hinder the success of the operation as well as potential complications that may occur as a result of specific indications. There is a risk of the implant failing prematurely, for example due to implant luxation, dislocation, or loosening caused by changes in load bearing behavior, fatigue or fracture of the cement bed, and/or tissue reactions to the implant and its abrasion particles; see also ▶ Chapter 2.5. Further risks exist in connection with the general surgical procedures to be performed, as well as risks of an operation under anesthesia. With ceramic components, a risk of fracture can never be ruled out entirely. This risk must be explained to the patient. Patients also need to be informed of any measures they can take to help prevent potential consequences of these factors. Furthermore, the patient has to be informed about alternative methods of treatment and other systems with adequate intended uses. The operating surgeon should keep a written record of all information given to the patient.

A separate patient information and implant card is provided by Merete® and shall be made available to the patient prior and/or after the implantation by the surgeon. The patient information is available at ▶ labeling.merete.de and the implant card is included with each implant package. If you cannot access these documents, please contact your local Merete® sales representative under +49 (0)30 77 99 80-0, or ▶ service@merete.de.

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3.4 Information on Handling Implants

3.4.1 General Instructions

WARNINGS

Use of implants contrary to intended purpose

- Risk of injury due to implant failure!

➲ Implants must only be used in accordance with intended purpose.

Use of implants which have been previously used

- Risk of injury due to premature failure of implant!
- Risk of sepsis!

➲ Implants are only permitted for single use, not for repeated use.

Combination of implant components of different sizes

- Damage to implant components!

➲ Combine only components of the same size.

Combination with over-long heads

- Risk of injury due to implant failure!

➲ Impaired component safety due to higher lever forces.

Use of damaged or defective implants

- Risk of injury due to premature implant failure!

➲ Implants with identifiable damage may not be used.

➲ Avoid notches, scratches or bending of the implant in order to preserve its stability.

Damage to head

- Risk of implant failure!

➲ Never strike the head or the adapter directly with a hammer.

➲ It is advisable to secure the head in place with a light hammer blow in an axial direction on the head impactor.

Damage to taper connection

- Risk of implant failure!

➲ Ensure careful implantation.

➲ Do not use damaged implants.

Foreign bodies in the taper connection

- Risk of implant failure!
- ➲ Thoroughly clean all foreign bodies from the taper connection.

Foreign bodies (e.g. cement residues, tissue, bones) between implant components

- Risk of injury due to implant failure!
- ➲ Thoroughly clean any foreign bodies from implant components.

Breaking of ceramic components

- Risk of injury due to implant failure!
- ➲ When performing revision surgery following breakage of a ceramic component, do not use metal heads.
- ➲ Replacement component must also be a ceramic head.

Use of instruments with electrical energy

- Risk of injury due to implant failure!
- ➲ Do not damage the surfaces of the implants under any circumstances.

The surgical steps are described and illustrated in the surgical technique. Implants must be inserted with the appropriate Merete® instruments. The use of Merete® instruments for any other purpose is not permitted.

Do not reuse an implant that has been removed under any circumstances. Do not use any components that have been damaged during handling under any circumstances. When inserting and repositioning implants, the operating surgeon must ensure that implant surfaces have not been scratched or dented in any way. Even a tiny scratch can significantly reduce the life of an implant. All components must be checked intraoperatively for function. Do not use stems with damaged or deformed taper regions, and do not use stems/acetabular components with non-standard configuration or geometry. In revision surgeries, BioBall® Heads must only be used in combination with unused BioBall® Adapters. Adhere to the instructions in ▶ 3.2 “Preoperative Planning”, and ▶ 2.6 “System Compatibility”, when working with previously used tapers. Use the BioBall® AdapterSelector® to check the prosthesis taper and the compatibility to the BioBall® Adapter. The wound must be thoroughly cleaned before closure. In particular, cement residue and bone splinters can significantly impair the bearing performance and thus lead to premature wear of the bearing surfaces.

Please observe the following when implanting BioBall® components:

- Rinse and dry the stem taper to ensure that all foreign bodies (including bone fragments, soft tissues, bone cement and other substances) are completely removed
- Before positioning BioBall® components, check all components as well as the stem taper for damage, deformation, wear or contamination
- Apply the BioBall® Adapter to the prepared stem taper using axial pressure while simultaneously turning it slightly towards the right. Apply axial pressure only at the selected angle (CCD or anteversion). Then place the BioBall® Head under axial pressure on the BioBall® Adapter. After that, check both Head and Adapter to ensure that they are set correctly into place.

- The intended purpose of the product may lead to limitations in technical range of motion (ROM) arising from the following factors:
  - Distance from stem shoulder to centre of head
  - Exterior contour of the stem neck (with S through XL adapters)
  - CCD angle of stem in situ (medialisation and lateralisation limit ROM)
  - Cup unfavourably skewed in acetabulum and/or usage of luxation-reducing cup systems
  - Cup geometry
- Never use a BioBall® Ceramic Head which has fallen onto a hard surface or otherwise been damaged.
- When performing revision surgery following breakage of a ceramic component, do not use BioBall® Metal Heads – replacement components must also be made of ceramic.
- For a detailed description of the procedure to implant the BioBall® System refer to the surgical technique of the BioBall® System.

3.4.2 Information to Revisions Surgeries and Associated Warnings

WARNING

Breaking of ceramic components

- Risk of injury due to implant failure!

➲ When performing revision surgery following breakage of a ceramic component, do not use metal heads.

➲ Replacement component must also be a ceramic head.

If all components of the artificial joint replacement are replaced during a revision operation, the same conditions apply to the treatment of the implants as for a first implantation. A partial change of implants leads to the mixing of old, pre-damaged components and new implants. In these cases, special conditions must be observed:

- Both bearing surfaces of an artificial joint should always be replaced.
- Under no circumstances should a ceramic head be placed on an already used stem taper.
- If it is necessary to change the head on an already used stem taper, this may only be done with a metal head or with the use of the BioBall® System. In the event of severe damage to the stem taper, the prosthesis stem must be revised.
- When performing revision surgery following breakage of a ceramic component, do not use metal heads. Replacement component must also be made of ceramic.
- Training in the correct handling of implants and instruments by an authorised Merete® representative is essential.

3.4.3 Sterile Implants

WARNING

Risk of infection due to non-sterile implants!

- ➲ Do not use implants whose packaging is damaged.
- ➲ Do not use implants whose expiry date has passed.

Use of soiled implants

- • Risk of sepsis!
- ➲ Use only implants without identifiable soiling.
- ➲ Handle implants only with sterile surgical gloves.

Use of damaged or defective implants

- • Risk of injury due to premature implant failure!
- ➲ Implants with identifiable damage may not be used.
- ➲ Avoid notches, scratches or bending of the implant in order to preserve its stability.

NOTE: Observe symbol on packaging: "Do not re-use". 

Implants which are delivered sterile are clearly labelled "STERILE". Sterile implants have been sterilised with 25 to 42 kGy (2.5 to 4.2 Mrad) gamma rays. All sterile implants should be stored in their unopened original packaging at a storage temperature between 10–30 °C in a clean and dry environment until they are to be used. Before using any implants, check the sterilisation expiration date on the product label, and check the protective packaging for damage. The red sterilization dot on the package serves as an indicator that the product is sterile. Do not use products in damaged packaging. Observe the rules of asepsis when removing products from their protective packaging.

Packaging system BioBall® Adapters:

Title	Material
Sterile barrier system	PA/PE
Protective packaging	PA/PE
Folding box	Carton
Dust protection	FP QSL/polyolefin

Packaging system BioBall® Heads:

Title	Material
Sterile barrier system	PA/PE
Protective packaging	PA/PE
Foam	PE foam
Outer packaging (Sleeve)	Carton
Outer packaging (Drawer)	Carton
Dust protection	FP QSL/polyolefin

3.4.4 Resterilisation of Implants

WARNING

Resterilisation of implants

- Risk of injury due to premature implant failure caused by adverse material changes!
- ➲ Implants delivered sterile by Merete GmbH must not be resterilised and/or repacked.
- ➲ Products whose expiry date has passed may be returned to Merete GmbH.

Merete GmbH wishes to provide patients with products that are state of the art at all times. Therefore, we do not offer resterilisation for our products.

3.4.5 Handling and Storage of Implants

WARNING

Risk of infection due to non-sterile implants!

- ➲ Do not use implants whose packaging is damaged.
- ➲ Do not use implants whose expiry date has passed.

Use of soiled implants

- Risk of sepsis!
- ➲ Use only implants without identifiable soiling.
- ➲ Handle implants only with sterile surgical gloves.

Use of damaged or defective implants

- Risk of injury due to premature implant failure!
- ➲ Implants with identifiable damage may not be used.
- ➲ Avoid notches, scratches or bending of the implant in order to preserve its stability.

Store implants in their unopened original packaging at a storage temperature between 10°–30°C in a clean and dry environment. Check the sterilisation expiration date on the product label and ensure that the protective packaging is intact before using any implants. Do not use products in damaged packaging. Observe the rules of asepsis when removing products from their protective packaging. Implants must be handled with the greatest of care. Even the slightest surface defects increase wear and tear, which could lead to complications. Therefore, do not alter the prosthesis surfaces in any way and avoid touching them with metallic or hard objects (e.g. instruments). Any mechanical manipulation or alteration of implants negates their approval for use and is not permitted. Do not implant any components of the prosthesis that have been handled incorrectly or show signs of damage (e.g. scratches – see also ▶ Chapter 3.4.3 “Sterile Implants”).

4. Explantation

For explantation purposes, always request instrument sets from Merete GmbH. There are no special requirements for explantation of components. The explantation technique is decided by the surgeon.

5. Disposal

Disposal of implants according to standard hospital procedures.

6. Updates of Information

The electronic Instructions for Use (eIFU) are available at ▶ labeling.merete.de. A printed version can be provided free of charge upon request. Please ensure that you have read and understood the most current version of the eIFU before using the product.

The Summary of Safety and Clinical Performance (SSCP) for the BioBall® System is available in the European Database on Medical Devices (EUDAMED) [▶ URL: ec.europa.eu/tools/eudamed]. The SSCP for the BioBall® System is linked to the device via the Basic UDI-DI [01404826600000000000001XX] in EUDAMED. If the website is not available, please contact your local Merete® Sales representative, or ▶ service@merete.de.

If you have further questions or in case, you need further information in regard to the BioBall® System please contact your local Merete® Sales representative or visit our website ▶ merete.de/en.

We want to advise, that it is required to inform Merete® and the competent authority of your Member State about any serious incident resulting from the use of BioBall® System. In case of such events please contact your local Merete® Sales representative, under +49 (0)30 77 99 80-0, or ▶ service@merete.de.

Subject to technical change without notice. Further information available from Merete GmbH or your authorized Merete® representative. New clinical experience may result in changes to certain procedures. Merete GmbH recommends regular attendance at refresher courses.

merete®

Merete GmbH
Alt-Lankwitz 102
12247 Berlin
Germany

Tel. +49 (0)30 77 99 80-0
service@merete.de
merete.de/en

CE 0482

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