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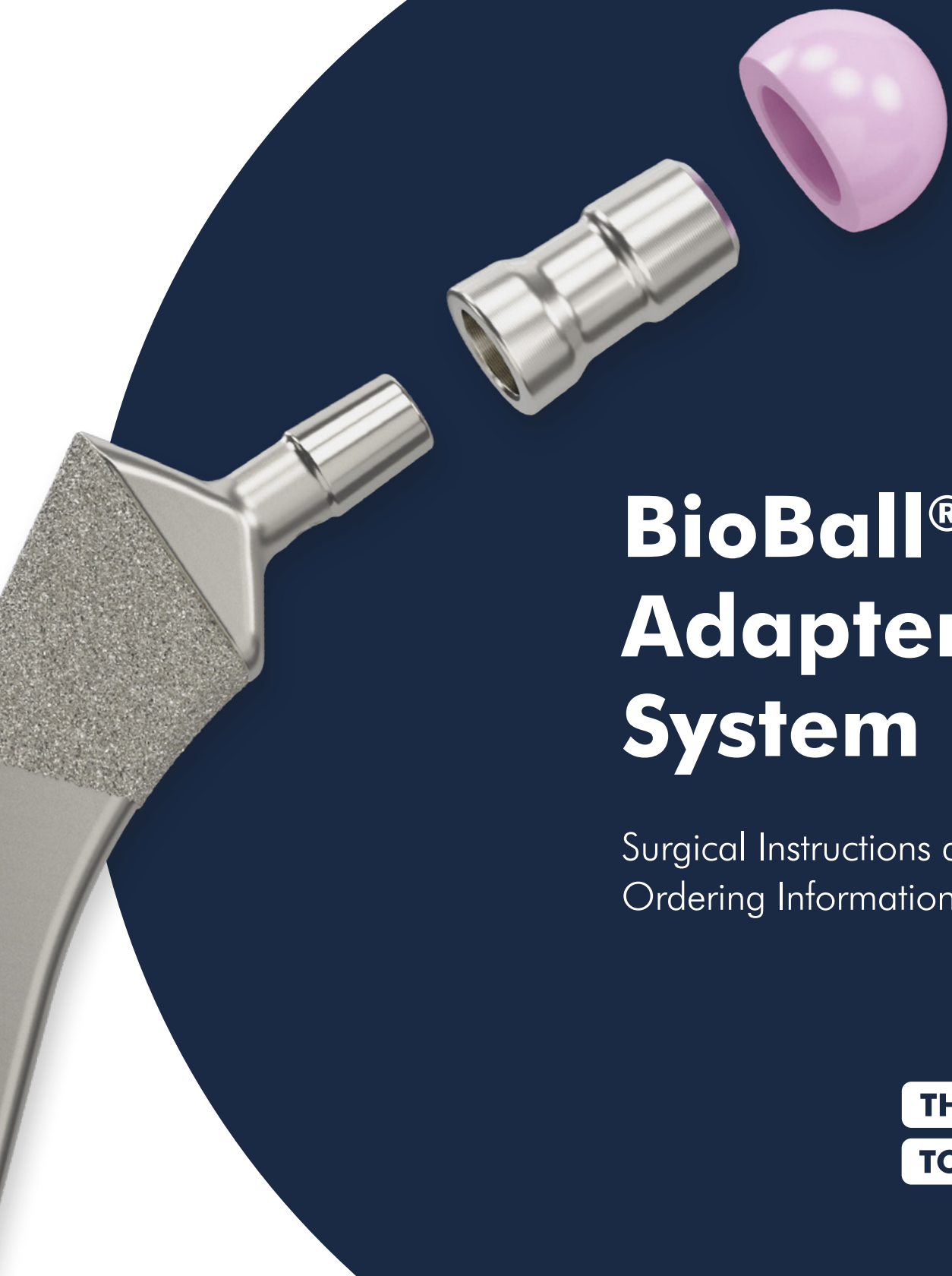

BioBall® Adapter System

Surgical Instructions and Ordering Information

THE POWER TO ADAPT

Download PDF with BioBall® Literature

Merete® Learning Center

THE POWER TO ADAPT

CAUTION The following product descriptions contain detailed information on the recommended procedure (and associated surgical techniques) for using Merete® implants and instruments. These descriptions are sufficient to allow immediate use of the products, but they are not a substitute for the comprehensive product training by a qualified Merete® employee or authorized Merete® representative.

Table of Contents

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1. Product Description

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1. Product Description

The BioBall® System is a modular system for the surgical care of patients in revision or primary hip surgery with different neck lengths and angle adjustments.

The BioBall® Adapter System consists of a titanium alloy BioBall® Adapter which is combined with a fitting BioBall® Metal Head or BioBall® Ceramic Head. The main indication is the revision with well fitted prosthesis hip stems. The system may also be used for primary interventions in order to make intra-operative corrections. Different adapter geometries and head materials can be used to deal with the individual fitting situation in the case of a revision without having to remove implants that are still firmly embedded. The BioBall® Adapter allows intra-operative correction of neck length as well as antetorsion/retrotorsion and lateralisation/medialisation on *in situ* stems. Depending on the specific model, BioBall® Adapters are available in sizes ranging from S (-3.0 mm) to 5XL (+21.0 mm) as Standard version and from M (0 mm) to 5XL (+21.0 mm) as Offset version. BioBall® Metal Heads are available in diameters 28, 32, 33, 35, 36, 38 mm. BioBall® Ceramic Heads are available in diameters 28, 32, 36, 40, 44, 48 mm.

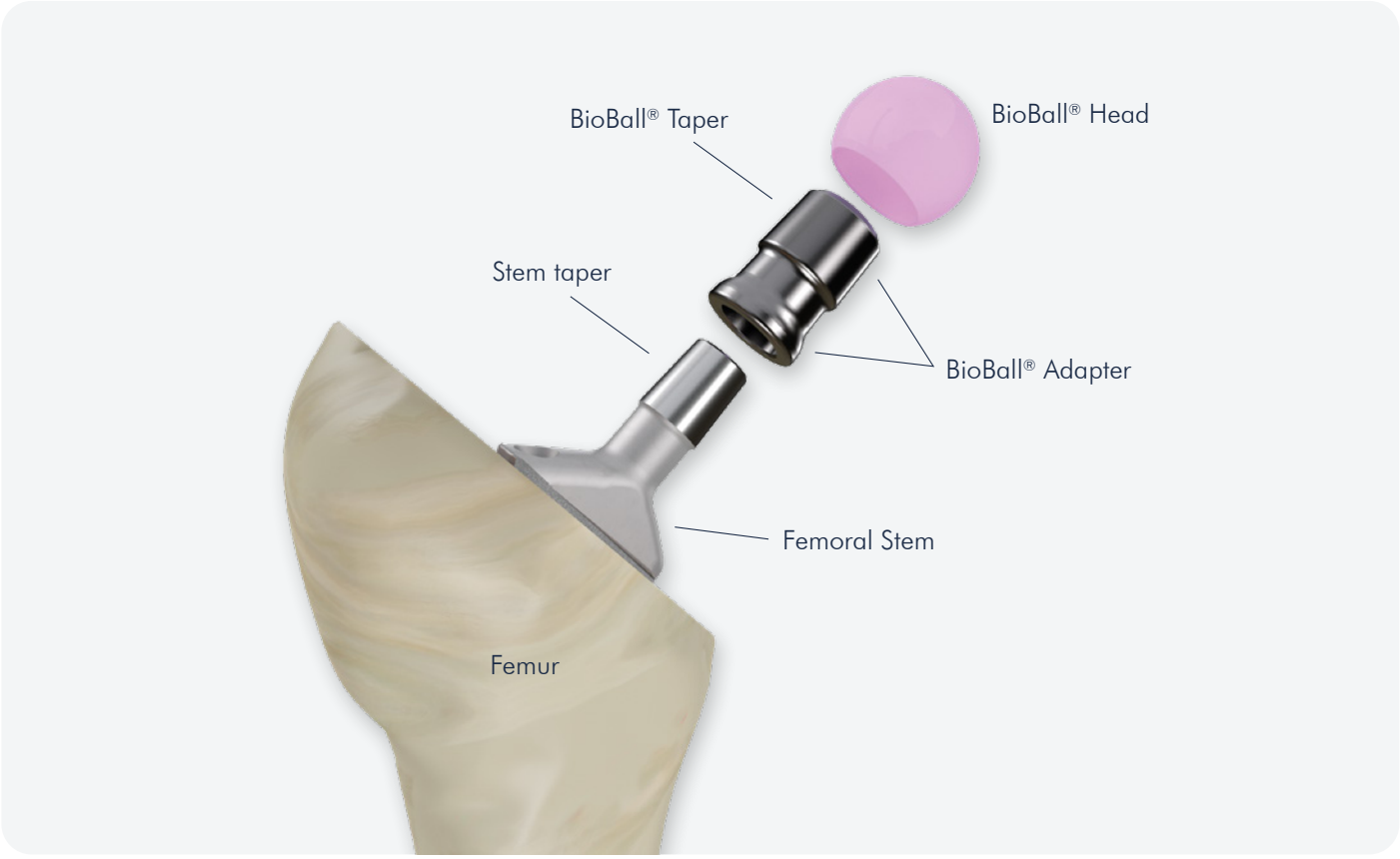

Figure 1 BioBall® Adapter System is shown in an exploded view of a femoral stem, BioBall® Adapter and BioBall® Ceramic Head

1.1 Intended Purpose of the Product

WARNING

Use of implants contrary to intended purpose

- Risk of injury due to implant failure!
- ➲ Implant 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 (Adapter & 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.

1.2 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 orthopaedics, 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.

1.3 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

1.4 MRI Safety Information / MRI Parameters

MR Conditional

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® (ISO 5832-9), CoCrMo (ISO 5832-4/5832-12), BIOLOX®[1] 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 1cm 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] BIOLOX® delta is a registered trademark of CeramTec GmbH.
[2] Vivium® is a registered trademark of Merete GmbH (High Nitrogen Stainless Steel DIN ISO 5832-9).

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2. General Information

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2. General Information

WARNINGS

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 damaged or defective instruments

- Risk of injury due to premature implant failure!
- ➲ Instruments with identifiable damage may not be used.

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.

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.

Use of implants which have been previously used

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

WARNINGS

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.

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.

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.

Use of instruments with electrical energy

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

NOTE **Sterilisation of instruments supplied non-sterile**

If Merete products are sterilised by the user, this must be noted in the surgical report.
All relevant labels and user instructions must be retained.

- ➲ Observe current RKI guidelines.
- ➲ Observe the standard preparation instructions provided.

NOTE Observe symbol on packaging: “Do not reuse!”

NOTE **Electronic Instructions for Use (eIFU)**

For all safety-related information and detailed instructions on the use of this product, please consult the electronic Instructions for Use (eIFU), 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.

Electronic Instructions for Use (eIFU)
labeling.merete.de

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3. System Compatibility, Implant Material

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3. System Compatibility, Implant Material

WARNINGS

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 with over-long heads

- Risk of injury due to implant failure!

➲ Impaired component safety due to higher lever forces.

NOTE BioBall® Ceramic Heads must not be used with BioBall® Special Adapters MS 8/10, MSBG, MSPC, MSSR, MST1 and MSV4 Offset 2XL and 3XL (see also ▶ Chapter 3.3 and ▶ Chapter 3.6)

3.1 Primary Surgery

Insofar as the BioBall® Adapter label does not indicate otherwise, BioBall® Adapters may be used in combination with either BioBall® Metal or BioBall® Ceramic Heads (possible combination see ▶ Chapter 3.3). In primary surgery, BioBall® Adapter 12/14 is only intended for use together with the Merete®-brand hip stems approved for that purpose.

3.2 Revision Surgery

Insofar as the BioBall® Adapter label does not indicate otherwise, BioBall® Adapters may be used in combination with either BioBall® Metal Heads or BioBall® Ceramic Heads (for possible combinations, see ▶ Chapter 3.3). Surgeon 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, it must be adhered to the applicable CeramTec BIOLOX®[1] specifications. 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 prothesis taper. If desired, Merete GmbH 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.

3.3 Combination BioBall® Adapters and BioBall® Heads

BioBall® Adapter	Stem-taper-geometry	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

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

3.4 Combination BioBall® Adapters and Stem Taper Materials

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)	✓	✓	✓	✓

3.5 Possible Sliding Pairs

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

- BioBall® Metal Heads may only be combined with UHMWPE/XPE inlays or cups
- BioBall® Ceramic Heads may only be combined with BIOLOX®[1] delta ceramic inlays, or with UHMWPE/XPE inlays or cups

Cup/Inlay	BIOLOX®[1] delta ceramic	UHMWPE/PE	UHMWPE/XPE
Head	BIOLOX®[1] delta ceramic	BIOLOX®[1] delta ceramic	Metal Head
Material Combination			

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

3.6 BioBall® Material Combination Matrix

BioBall® Adapter	Stem-taper-geometry	Max. extension	Stem-taper combination according to ▶ Chapter 3.4			BioBall® Head combination according to ▶ Chapter 3.3	
			Titanium alloys (TiAl6V4/ TiAl6Nb7)	**CoCr alloys**	**Stainless Steel**	**Metal Head** only be combined with UHMWPE/ XPE inlays or cups	**Ceramic Head** only be combined with BIOLOX®[1] delta ceramic inlays, or with UHMWPE/ XPE inlays or cups
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 8/10 Standard	8/10 - 5°42′	S (-3.0 mm) - 2XL (+10.5 mm)	✓	✓	✓	✓	-
MS 8/10 Offset	8/10 - 5°42′	M (0 mm) - 2XL (+10.5 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)	✓	✓	✓	✓	✓
MSBG (14/16) Standard	14/16 - 6°0′	M (0 mm) - 2XL (+10.5 mm)	✓	✓	✓	✓	-
MSPC (13/14) Standard	13/14 - 2°52′	M (0 mm) - L (+3.5 mm)	✓	✓	✓	✓	-
MSSR (11/13) Standard	11/13 - 6°2′	M (0 mm) - XL (+7.0 mm)	✓	-	-	✓	-
MSSY (10/12) Standard	10/12 - 6°0′	S (-3.0 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)	✓	✓	✓	✓	-
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)	✓	✓	✓	✓	✓

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

3.7 Implant Materials

BioBall® Adapters are made of the following material

- TiAl6V4 ELI alloy (DIN EN ISO 5832-3)

BioBall® Heads may be made of the following materials

- BIOLOX®[1] delta ceramic (Mixed ceramic ISO 6474-2)
- Vivium®[2] (DIN ISO 5832-9)

Additional information on the chemical composition and mechanical properties of the materials used is available from Merete GmbH on request.

NOTE With ceramic heads, a slight risk of failure 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.

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

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4. Surgical Technique

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4.1 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.

Implantation of trial implants

- Risk of injury due to failure of trial implant!
- ➲ Only use trial implants in order to select a suitable permanent implant.
- ➲ Trial implants are not suitable for permanent implantation.

Damage to taper connection

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

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

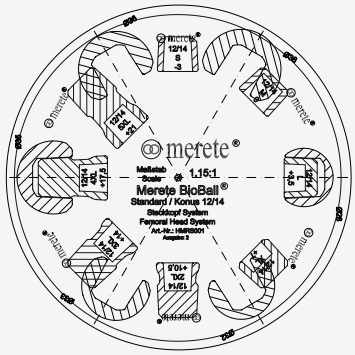
- Risk of injury due to implant failure!
- ➲ Thoroughly clean any foreign bodies from implant components.

For preoperative planning with X-ray images, the BioBall® System X-ray Templates (Figure 2) should be used. These are available for the tapers 12/14 and 14/16 in Standard and Offset version (Ref. HMRS001, Ref. HMRS002, Ref. HMRS005, Ref. HMRS006).

Intraoperative responsibility for the compatibility of the stem taper with the BioBall® Adapter lies with the surgeon, in that he or she must check the compatibility before beginning the implantation. This can and should be done by using the X-rays and the data from the patient's implant card together with the BioBall® manufacturer's specifications.

The identified taper size can be confirmed intraoperatively by using the BioBall® AdapterSelector®.

NOTE An alternative fallback has to be prepared in case of incompatibility of stem taper and BioBall® Adapter.



Ref.	X-ray template for adapter
HMRS001	12/14 Standard
HMRS005	12/14 Offset
HMRS002	14/16 Standard
HMRS006	14/16 Offset

Figure 2 BioBall® System X-ray Templates

Instructions for Digital Planning

Merete® products are included in the databases of several digital surgical planning tools.
Contact Merete GmbH for more information on these supporting systems.

4.2 Information on Handling Implants

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 components must also be a ceramic head.

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. 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
- 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.

4.3 Removal of the Existing Head

For removal of the existing head, the appropriate BioBall® Head Separating Wedge (Ref. HM10007 – Ref. HM10009) is firstly screwed onto the BioBall® Universal Handle (Ref. HM10005). Size indications – S, M, L – on the BioBall® Head Separating Wedge correspond to the intraoperative stem neck length. The wedge is then carefully positioned between the stem and the head. It is important that the marking "Head side" on the BioBall® Head Separating Wedge faces towards the head. A light hammer blow is applied to the wedge in a horizontal direction, which facilitates the separation of the head (Figure 3) from the stem.

Figure 3 Removal of the head (e.g. metal head) with suitable BioBall® Head Separating Wedge and BioBall® Universal Handle

NOTE Handle with care and do not damage the taper and stem with the BioBall® Head Separating Wedge.

4.4 Use of BioBall® AdapterSelector®

The BioBall® AdapterSelector® supports compatibility checks between the stem taper and the BioBall® Adapter in case of a revision surgery with firmly anchored hip prothesis stem. Before using the instrument, all available information about the stem taper should be collected and evaluated. The BioBall® AdapterSelector® is labelled with the taper designation corresponding to the taper, the taper diameter and angle. This enables a suitable BioBall® Adapter to be assigned.

Step 1: Assessment of the stem taper

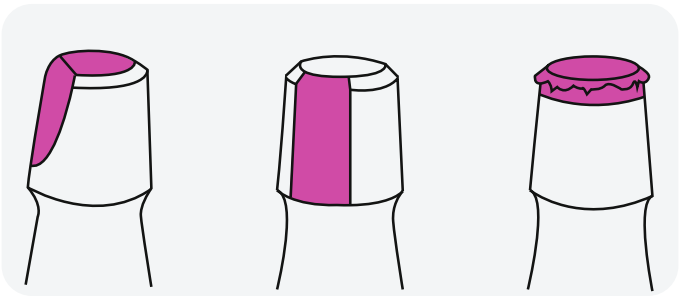


Figure 4 Damaged tapers

After the head is removed, the whole taper surface is then examined. A visual check of the prosthesis taper for intactness is a vital precondition for use of the BioBall® Adapter.

The taper may not display any kind of shape-altering damage such as wear, severe abrasion/material loss, or deep scratches/ burrs or similar surface defects. In case of strong discoloration or darkening of the stem taper or black deposits covering more than 10% of the taper surface, the BioBall® System cannot be used (Figure 4).

Step 2: Testing the taper front face

If the stem taper shows no signs of shape-altering damage, the BioBall® AdapterSelector® is placed on the stem taper until it fits tightly. An assessment is made of the upper surface of the taper visible in the opening of the BioBall® AdapterSelector®. If the upper surface of the taper is between the marks shown by the arrows (Figure 5), the lateral fit is then checked. If it is clearly positioned above or below these markings on the BioBall® AdapterSelector®, the stem taper is not the same as the taper indicated on the instrument.

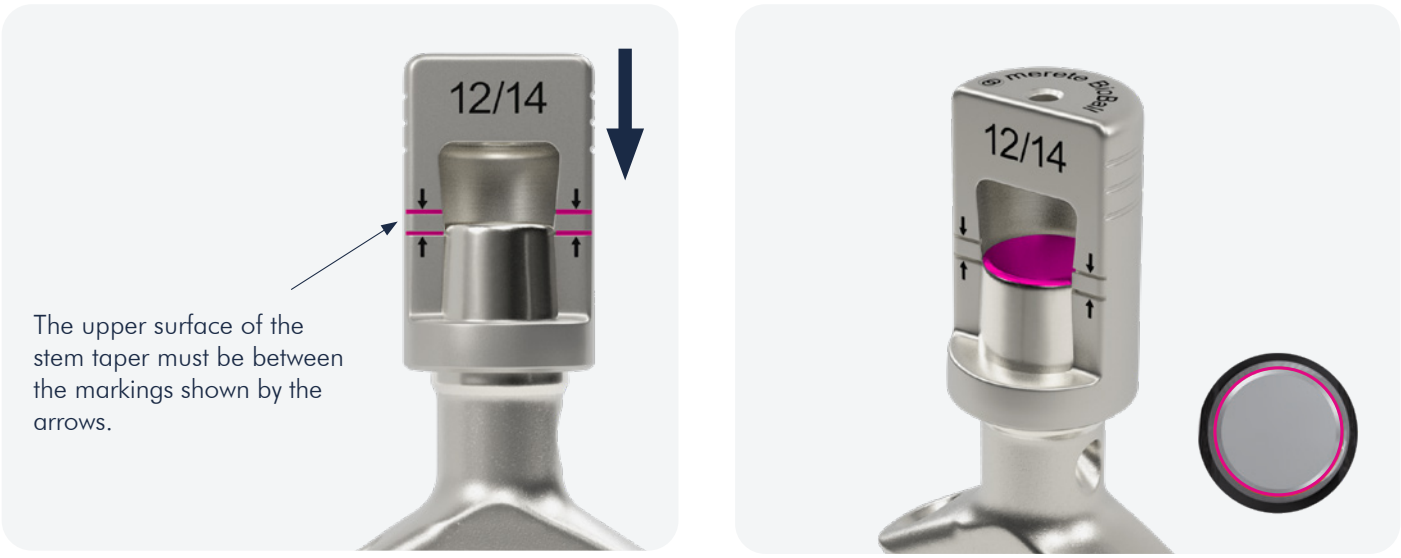


Figure 5 Testing the taper front face

Step 3: Lateral fit check

The seating of the BioBall® AdapterSelector® on the stem taper is inspected. The clamping connection of the AdapterSelector® can be tested by a vigorous tilting movement (Figure 6). If a gap is visible or rattling occurs, the stem taper is not the same as the taper indicated on the instrument.

This is followed by a visual inspection of the lateral accuracy of fit (Figure 7). To do so, check whether there is a gap in the upper or lower taper region between the stem taper and the BioBall® AdapterSelector®. If there is no visible or palpable gap in the upper or lower region, a suitable BioBall® Adapter may be inserted.

If the stem taper is tested with the BioBall® AdapterSelector® and it displays no shape-altering damage, a suitable BioBall® Adapter may be implanted. In this way, unnecessary major revisions can be avoided.

Figure 6 Testing the clamp connection

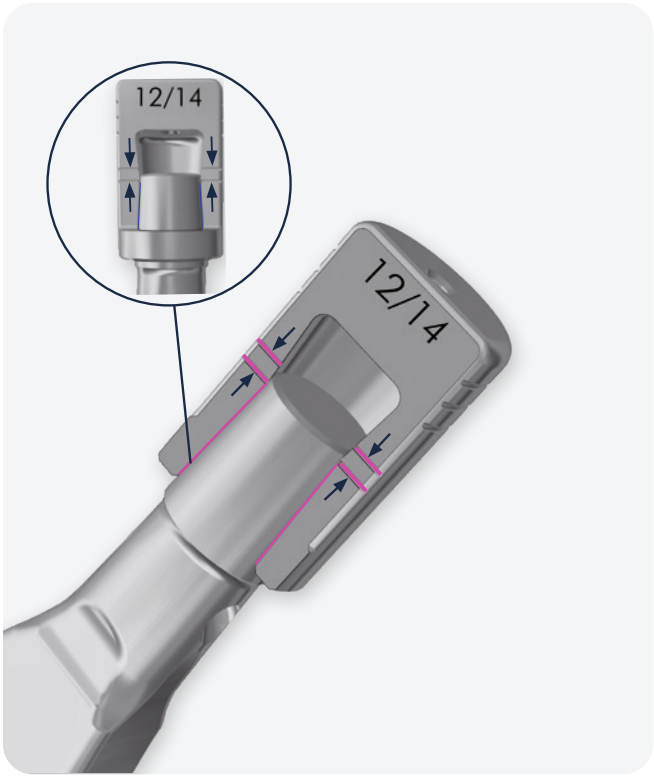


Figure 7 Gap free position of the BioBall® AdapterSelector®

4.5 BioBall® System with Adapter Standard

WARNINGS

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.

Breaking of ceramic components

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

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.

Implantation of trial implants

- Risk of injury due to failure of trial implant!
- ➲ Only use trial implants in order to select a suitable permanent implant.
- ➲ Trial implants are not suitable for permanent implantation.

Select a BioBall® Trial Adapter for the desired shortening or lengthening and assembly it on the previously determined prosthesis taper. The BioBall® Trial Head is then mounted on the BioBall® Trial Adapter up to the stop (Figure 8). To check neck length, Range of Motion and soft tissue tension, the joint is repositioned (Figure 9).

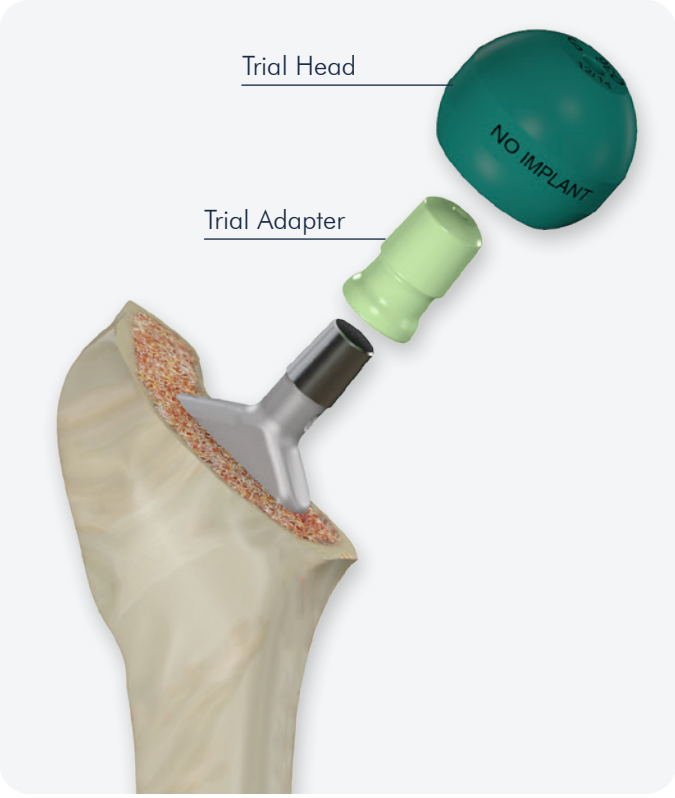


Figure 8 Mounting of Trial Adapter and Trial Head

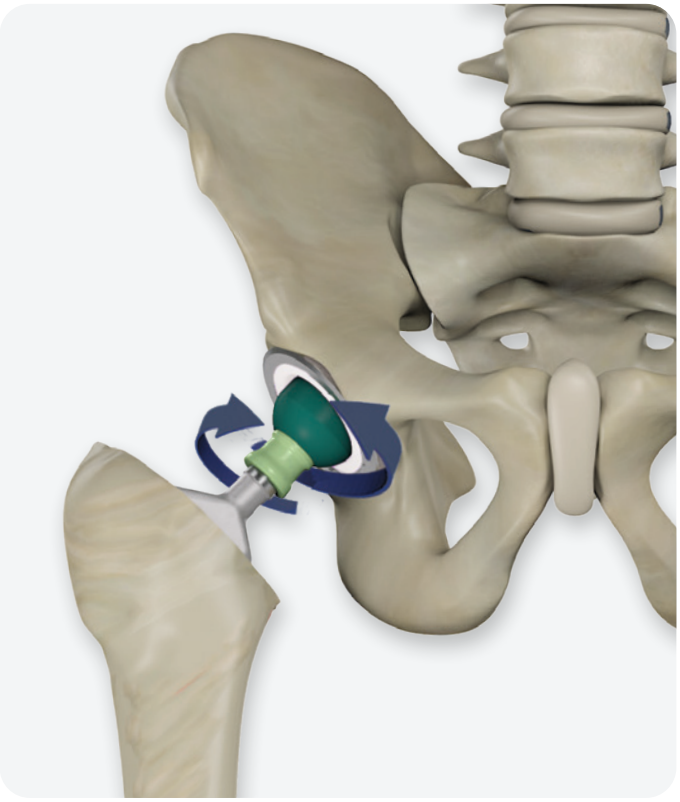


Figure 9 Trial components repositioned

NOTE The BioBall® Trial Adapter clamps on the stem taper and can be released again by an anti-clockwise rotation. If the clamp is too strong, the BioBall® Head Separating Wedge with the BioBall® Universal Handle (Ref. HM10007, Ref. HM10008, Ref. HM10009, Ref. HM10005) can be used (see also ▶ Chapter 5). The BioBall® Trial Head and BioBall® Trial Adapter also clamp and can be released by hand. If the clamp is too strong, the BioBall® Head Separating Wedge with universal handle can be used. All trial components are made of X-ray opaque materials, allowing X-ray control of the correct position.

After a successful trial run, the trial components are replaced by implants (Figure 10 to Figure 12).

Figure 10 Attaching the implants on stem taper

The following assemble instructions should be observed

- 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.
- The BioBall® Adapter is applied onto the prepared stem taper with slight axial pressure in combination with a right turn.
- Next, place the BioBall® Head on the BioBall® Adapter and press it firmly in an axial direction with a clockwise turn (Figure 10).
- Finally, check the correct position and the tight fit of the BioBall® Head and BioBall® Adapter.
- Fixing of the BioBall® Head with a light hammer blow in axial direction using the BioBall® Head impactor with the BioBall® universal handle (Ref. HM10004, Ref. HM10005) (Figure 11).

NOTE Never strike the adapter or the head with a hammer directly!

Figure 11 Fixing the implant with a light hammer blow

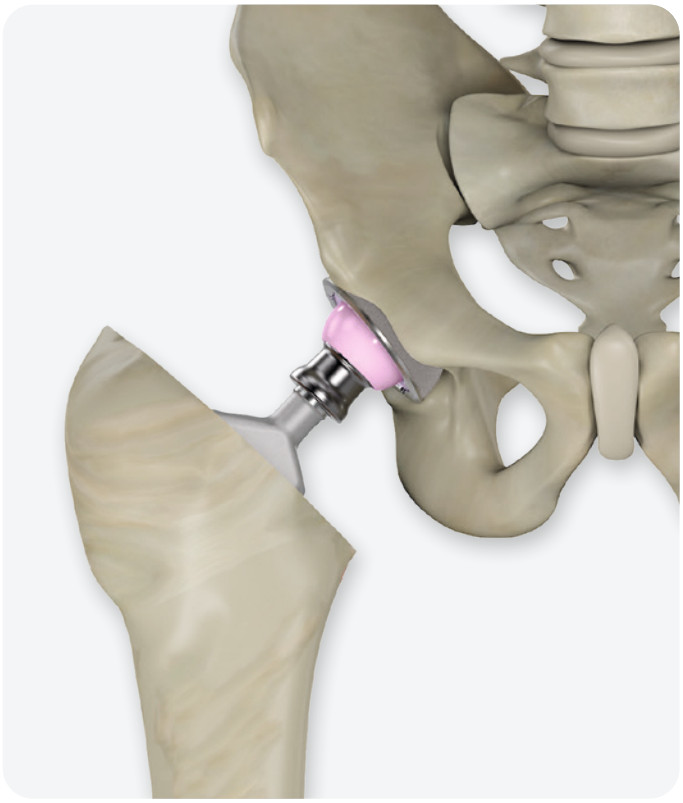


Figure 12 Implants repositioned

4.6 BioBall® System with Adapter Offset

WARNINGS

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.

Breaking of ceramic components

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

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.

Implantation of trial implants

- Risk of injury due to failure of trial implant!
- ➲ Only use trial implants in order to select a suitable permanent implant.
- ➲ Trial implants are not suitable for permanent implantation.

Figure 13 Alignment of Trial Adapter and Trial Head on the BioBall® Offset PositionAssistant

Select a BioBall® Offset Trial Adapter for the desired shortening or lengthening and assemble it on the corresponding BioBall® Offset PositionAssistant (Figure 13). The BioBall® Offset PositionAssistant serves for better visualisation of the adjustment of the BioBall® Adapter Offset. It is a non-implantable stem with corresponding taper on which the required settings of the BioBall® Offset Trial Adapter (lateralisation, medialisation, anteversion, retroversion) can be tested (Figure 13).

Figure 14 Additional orientation assistance (arrow corresponds to 12 o'clock marking)

The Offset implant and Offset trial components are marked with a scale for orientation purposes.

Alternatively, the arrow on the front face of the Trial Adapter and the implant can be used for orientation (Figure 14).

After testing with the BioBall® Offset PositionAssistant, the BioBall® Offset Trial Adapter is positioned on the *in situ* stem and the identified settings of the BioBall® Trial Adapter (3, 6, 9 or 12 o'clock) can be noted.

Examples of Offset settings

Right femur

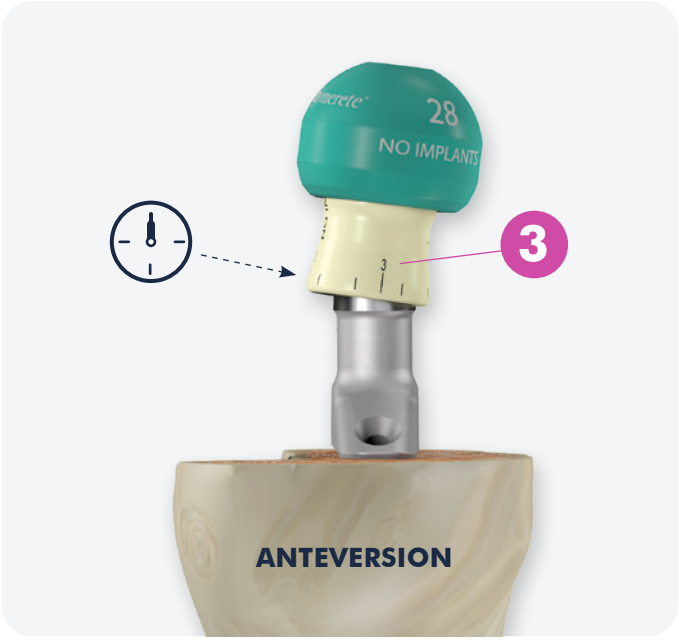


Figure 15 Anteversion on right femur (3 facing towards trochanter major)

Left femur

Figure 16 Anteversion on left femur (9 facing towards trochanter major)

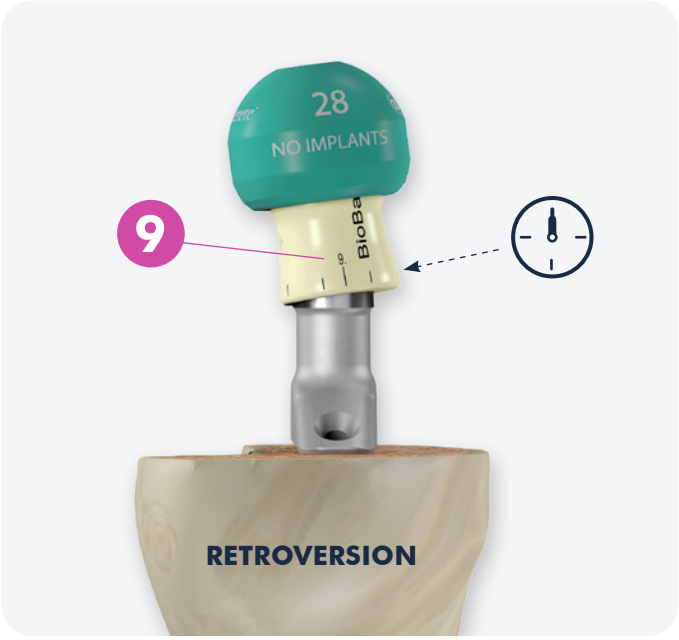


Figure 17 Retroversion on right femur (9 facing towards trochanter major)

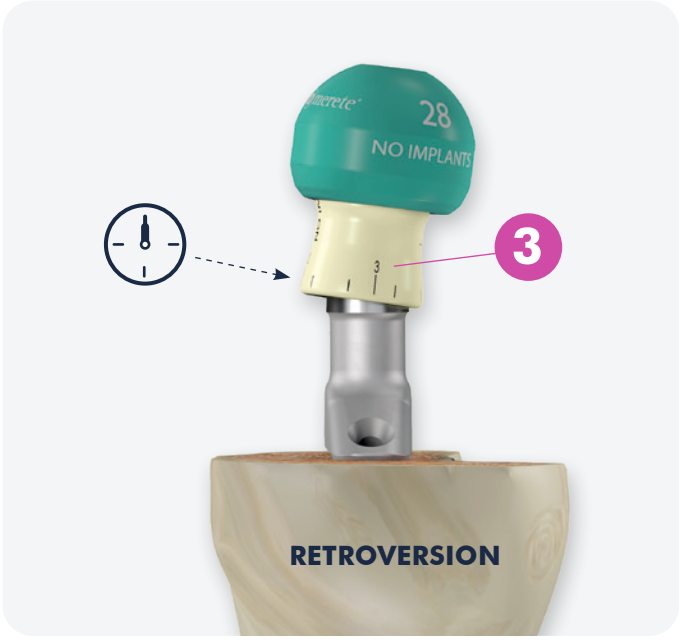


Figure 18 Retroversion on left femur (3 facing towards trochanter major)

12 o'clock position

Right femur

For each adapter size, the 12 o'clock position shows the maximum achievable Offset setting.

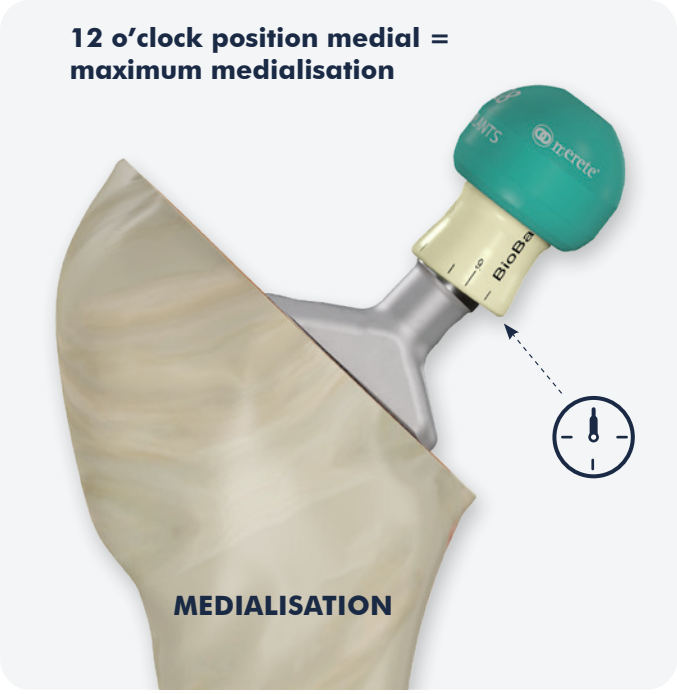


Figure 19 Medialisation of the right femur

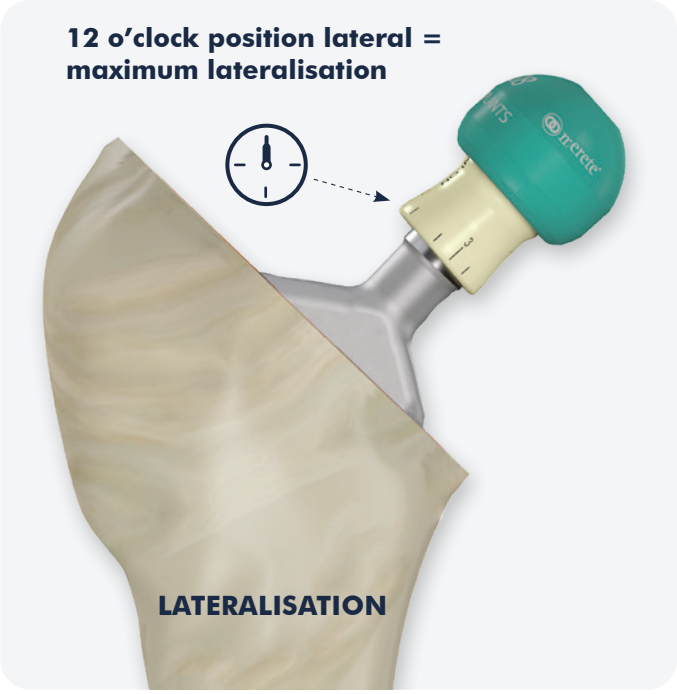


Figure 20 Lateralisation of the right femur

A mark may be transferred to the prothesis neck with a sterile permanent marker (e.g. Ref. AS-2750). This mark serves to orient the alignment of the BioBall® Adapter Offset (Figure 21).

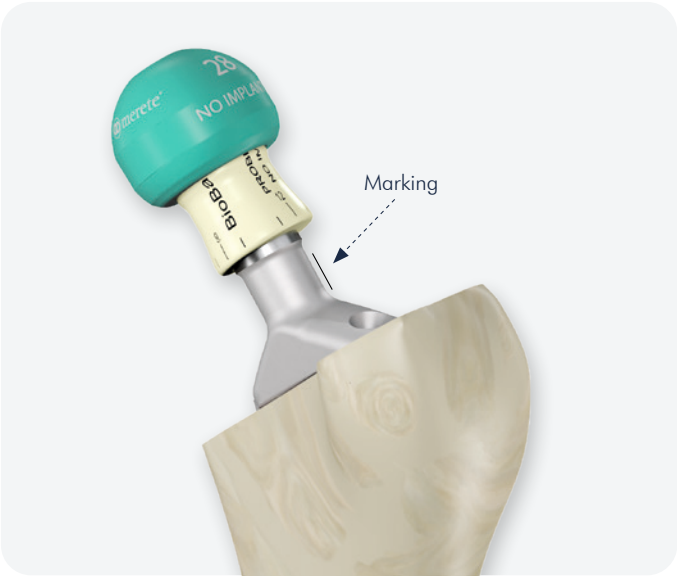


Figure 21 Alignment of BioBall® Trial Adapter Offset

Figure 22 Mounted trial components on the prosthesis neck

After all necessary adjustments have been identified, the BioBall® Trial Head with appropriate diameter is selected and mounted on the BioBall® Trial Adapter Offset (Figure 22). To check neck length, Offset, Range of Motion and soft tissue tension, the joint is now repositioned, followed by a function test. If the function test shows that the settings need to be corrected, the CCD angle and the retro- or antetorsion can be adjusted by rotating the BioBall® Trial Adapter Offset anti-clockwise (horizontal arrow mark on outer surface of trial adapters). If the desired final position has been achieved, the position of the BioBall® Trial Adapter Offset in relation to the line marking can be read off and noted. After a successful trial run, the trial components are replaced by the appropriate implants in the previously determined alignment.

12 o'clock position

NOTE In order to determine the correct position of the implant, rotate it anti-clockwise. Be guided by the scale on the bottom of the implant (Figure 23) when bringing it into agreement with the predetermined position of the trial implant (▶ Figure 15 to Figure 20).

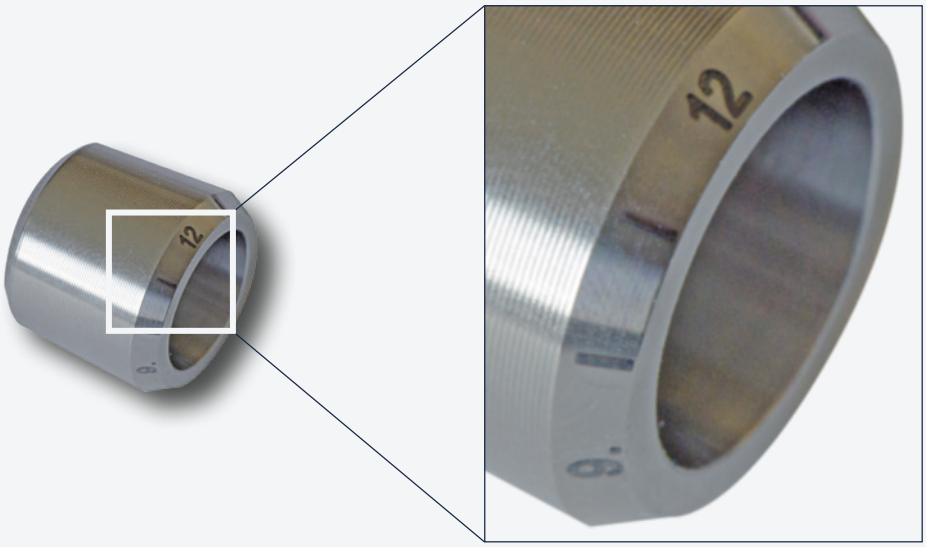


Figure 23 Scale for orientation on the bottom of the implant

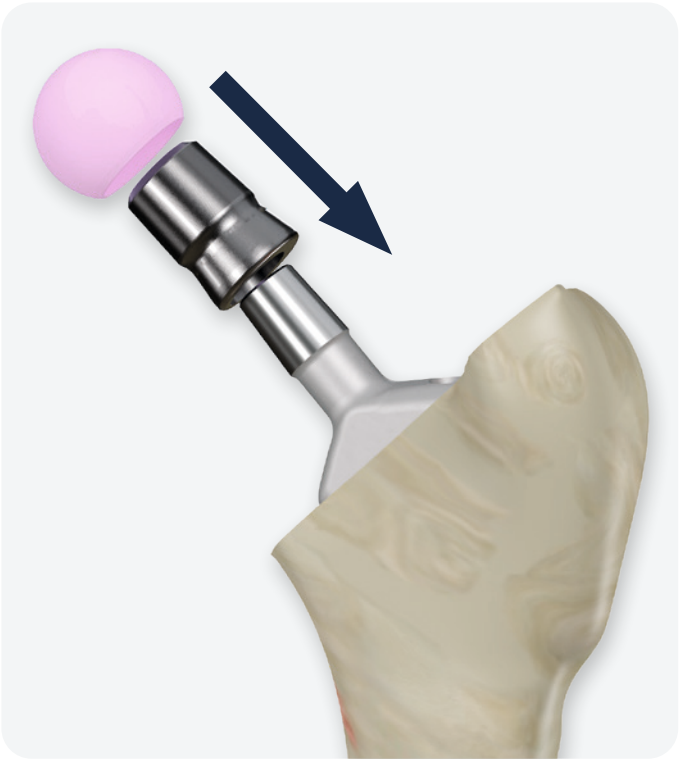


Figure 24 Placing the implants on stem taper

The following attaching instructions should be observed

- 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.
- The BioBall® Adapter Offset is applied onto the prepared stem taper with slight axial pressure in the selected angle (CCD or antetorsion).
- Next, place the BioBall® Head on the BioBall® Adapter Offset and press it firmly in an axial direction (Figure 24).
- Finally, check the correct position and the tight fit of the BioBall® Head and BioBall® Adapter.
- Fixing of the BioBall® Head with a light hammer blow in axial direction using the head impactor with universal handle (Ref. HM10004, Ref. HM10005) (▶ Figure 25).

NOTE Never strike the adapter or the head with a hammer directly!

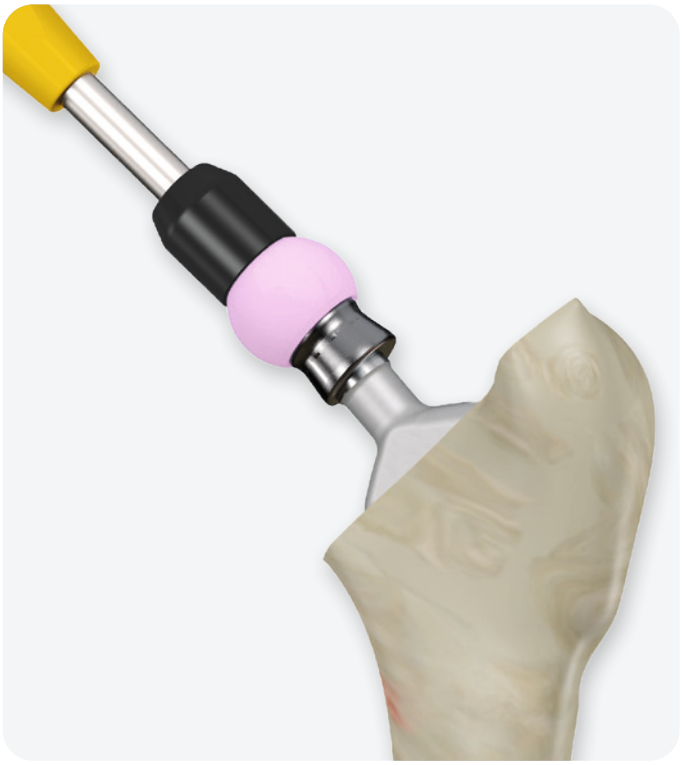


Figure 25 Fixing the implants with a light hammer blow

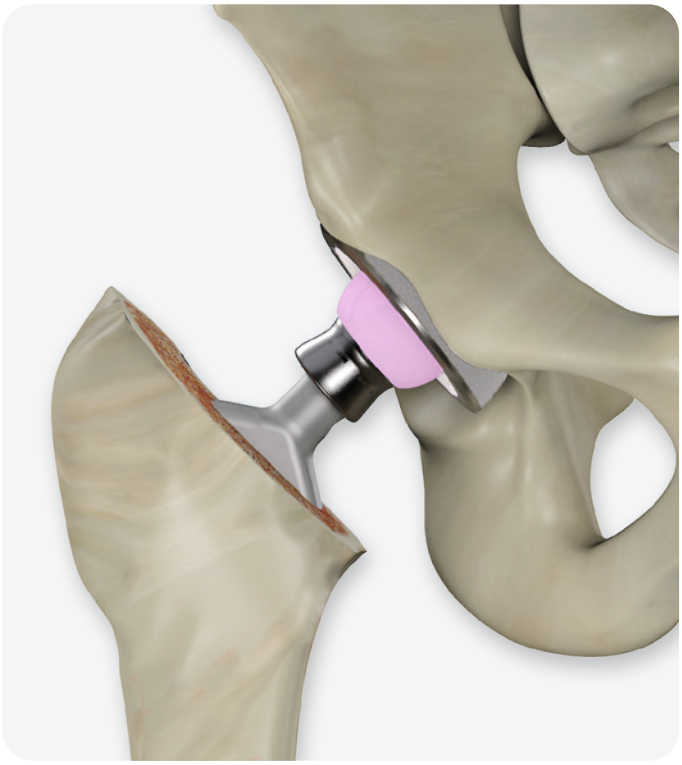


Figure 26 Implants in reposition

NOTE Depending on the design, short BioBall® Adapters Offset (size M-XL) may give the optical impression that they have been mounted the wrong way round. As this is the case, be sure to follow the scale only. This will reliably show the correct adapter orientation.

4.7 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.

To remove the BioBall® Head or BioBall® Adapter from stem taper, please refer to ▶ Chapter 5 "Use of BioBall® Head Separating Wedge and BioBall® Universal Handle".

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5. Technical Principles of Function

THE POWER
TO ADAPT

5.1 Technical Principles of Function

Use of BioBall® Head Separating Wedge and BioBall® Universal Handle

If it should become apparent during surgery that the BioBall® Adapter is not correctly positioned and that the BioBall® Adapter has a conical clamp on the taper and cannot be released by hand, the connection can be released with the BioBall® Head Separating Wedge.

To remove the BioBall® Head or BioBall® Adapter from the stem taper, the appropriate BioBall® Head Separating Wedge (Ref. HM10007 – Ref. HM10009) is first screwed onto the BioBall® Universal Handle (Ref. HM10005). The size indications – S, M, L – on the BioBall® Head Separating Wedge correspond to the intraoperative stem neck length. The wedge is then carefully positioned between the stem and the head (Figure 27) or the BioBall® Trial Adapter (Figure 28). It is important that the marking "Head side" on the BioBall® Head Separating Wedge faces towards the head. Light hammer blows are applied to the wedge in a horizontal direction, which facilitates the separation of the head or adapter from the stem.

Figure 27 Removal of the head (e.g. metal head) with suitable BioBall® Head Separating Wedge and BioBall® Universal Handle

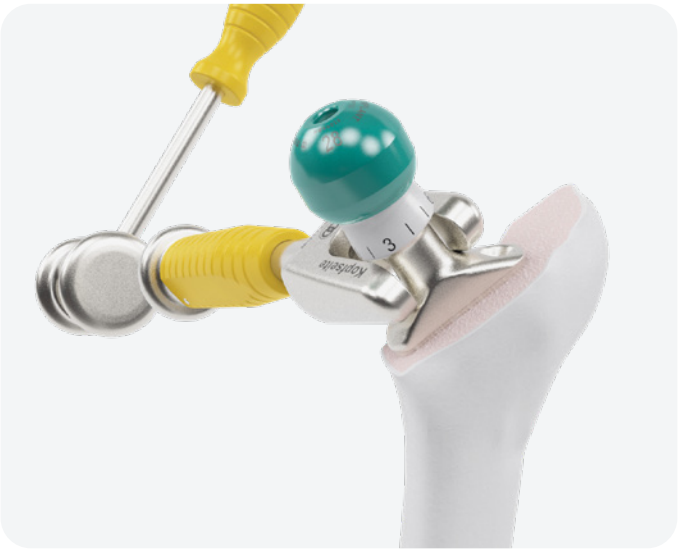

Figure 28 Removal of BioBall® Trial Adapter with suitable BioBall® Head Separating Wedge and BioBall® Universal Handle

NOTE Handle with care and do not damage the taper and stem with the BioBall® Head Separating Wedge.

Use of BioBall® Adapter Extractor

In the case that the BioBall® Head needs to be separated from the BioBall® Adapter, the BioBall® Adapter Extractor (Ref. HM20001) is used as follows:

- Screw out the handle until the ring mark on the handle is visible (Figure 29).
- To separate the implant components, push the BioBall® Adapter with BioBall® Head over the separating sleeve until the lip engages behind the BioBall® Adapter (Figure 30).
- Rotate the handle clockwise until the BioBall® Head has been released from the BioBall® Adapter (Figure 31).
- Rotate the handle anti-clockwise until the ring mark is visible again.
- The BioBall® Adapter can be removed from the separating sleeve.
- To separate the trial components, the marked side of the handle can be used (Figure 32).

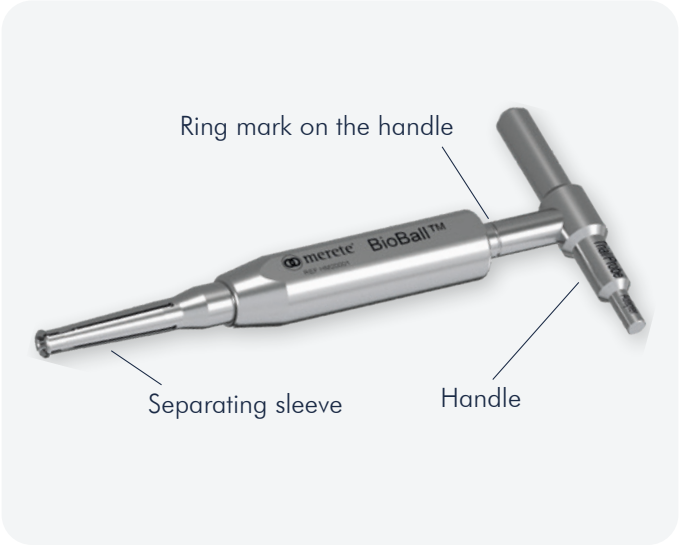

Figure 29 BioBall® Adapter Extractor

Figure 30 Lip engages behind the BioBall® Adapter

Figure 31 Pushing off the BioBall® Head

Figure 32 Separation of the BioBall® trial components

NOTE To separate the BioBall® Trial Adapter from the 40 mm BioBall® Trial Head, remove the handle from the BioBall® Adapter Extractor and use it as shown in Figure 33.

Figure 33 Separation of BioBall® Trial Adapter from the 40 mm BioBall® Trial Head

Use of the BioBall® Adapter Extractor with BioBall® Adapter Extractor Sleeve

If a BioBall® Adapter without an upper top surface is used then separating the BioBall® Head will additionally require an BioBall® Adapter Extractor Sleeve (see table below).

Ref.	Extractor Sleeve
HM20002	BioBall® Adapter Extractor Sleeve for Adapter 12/14 S and MSPC M/L
HM20003	BioBall® Adapter Extractor Sleeve for Adapter 14/16 M and MSBG M
HM20004	BioBall® Adapter Extractor Sleeve for Adapter MSV4 M and MSSR M/L
HM20005	BioBall® Adapter Extractor Sleeve for Adapter MS 10/12 S and MSSY S/M
HM20006	BioBall® Adapter Extractor Sleeve for Adapter MSZI S/M

The BioBall® Adapter Extractor in combination with the BioBall® Adapter Extractor Sleeve is used as follows:

- Screw out the handle until the ring mark on the handle is visible.
- Push the BioBall® Adapter Extractor Sleeve over the Separating Sleeve of the BioBall® Adapter Extractor (Figure 34).
- Push the BioBall® Adapter with BioBall® Head over the BioBall® Adapter Extractor Sleeve until the lip engages behind the BioBall® Adapter (Figure 35).
- Rotate the handle clockwise until the BioBall® Head has been released from the BioBall® Adapter.
- Rotate the handle anti-clockwise until the ring mark is visible again.
- The BioBall® Adapter and the BioBall® Adapter Extractor Sleeve can be removed from the Separating Sleeve.

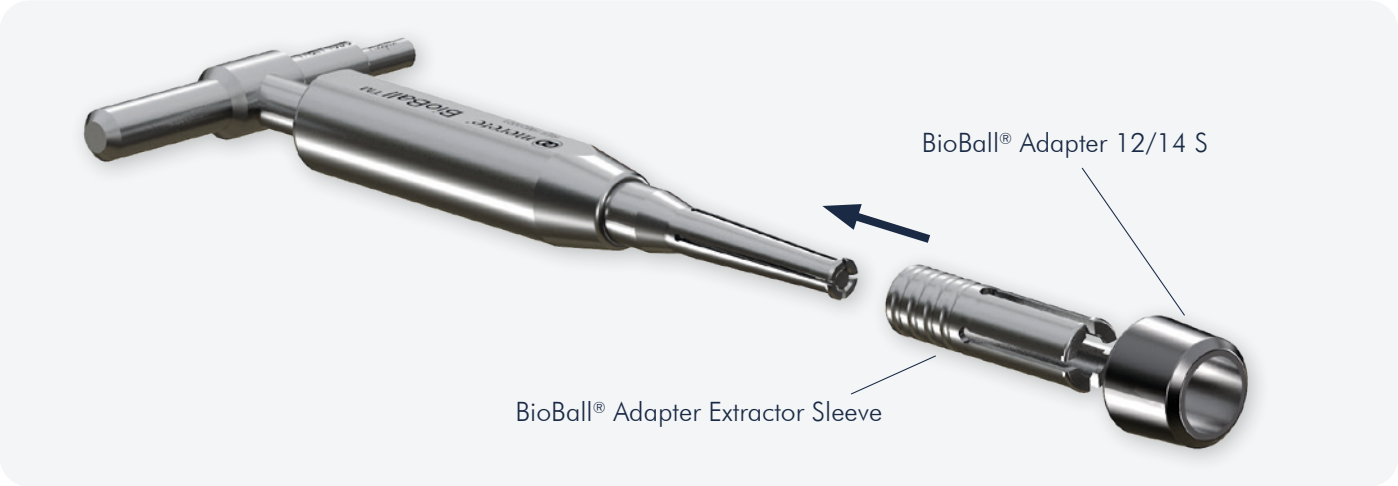

Figure 34 Assembling the BioBall® Adapter Extractor Sleeve on the Separating Sleeve of the BioBall® Adapter Extractor

Figure 35 Use of the BioBall® Adapter Extractor with BioBall® Adapter Extractor Sleeve

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6. Ordering Information

THE POWER
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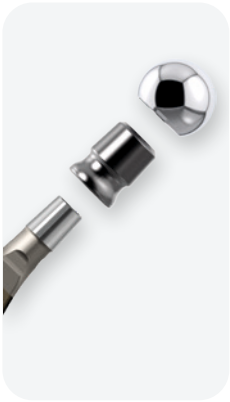
6.1 BioBall® Adapters

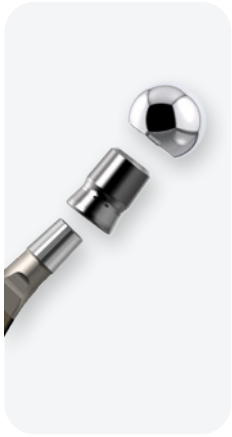
NOTE The BioBall® Adapters may only be combined with BioBall® Heads.

12/14 Standard, sterile



BioBall® Adapters 12/14, Standard, sterile								
Neck length	S (-3,0 mm)	M (0 mm)	L (+3,5 mm)	XL (+7,0 mm)	2XL (+10,5 mm)	3XL (+14,0 mm)	4XL (+17,5 mm)	5XL (+21,0 mm)
Ref.	HM30121	HM30122	HM30123	HM30124	HM30125	HM30126	HM30127	HM30128

12/14 Offset, sterile



BioBall® Adapters 12/14, Offset, sterile							
Neck length	M (0 mm)	L (+3,5 mm)	XL (+7,0 mm)	2XL (+10,5 mm)	3XL (+14,0 mm)	4XL (+17,5 mm)	5XL (+21,0 mm)
Offset (mm)	1,1	1,2	1,3	1,5	2,0	2,5	3,0
Ref.	HM30222	HM30223	HM30224	HM30225	HM30226	HM30227	HM30228

BioBall® Adapters for Special Tapers

Available on request.

Standard, sterile

BioBall® Adapter	14/16	MS 8/10 (8/10)	MS 10/12 (10/12)	MSBG (14/16)	MSPC (13/14)	MSSR (11/13)	MSSY (10/12)	MST1 (11/13)	MSV4 (11/12)	MSZI (10/12)
Neck length	**Ref.**									
S (-3,0 mm)	–	HM32121	HM30101	–	–	–	HM37121	–	–	HM33121
M (0 mm)	HM30142	HM32122	HM30102	HM31142	HM31132	HM31152	HM37122	HM36002	HM34122	HM33122
L (+3,5 mm)	HM30143	HM32123	HM30103	HM31143	HM31133	HM31153	HM37123	HM36003	HM34123	HM33123
XL (+7,0 mm)	HM30144	HM32124	HM30104	HM31144	–	HM31154	HM37124	HM36004	HM34124	HM33124
2XL (+10,5 mm)	HM30145	HM32125	HM30105	HM31145	–	–	–	HM36005	HM34125	HM33125
3XL (+14,0 mm)	HM30146	–	HM30106	–	–	–	–	HM36006	HM34126	HM33126
4XL (+17,5 mm)	HM30147	–	–	–	–	–	–	–	–	–
5XL (+21,0 mm)	HM30148	–	–	–	–	–	–	–	–	–

Offset, sterile

BioBall® Adapter	14/16	MS 8/10 (8/10)	MS 10/12 (10/12)	MST1 (11/13)	MSV4 (11/12)
Neck length	**Ref.**				
M (0 mm)	–	HM32222	HM30202	HM36022	HM34222
L (+3,5 mm)	–	HM32223	HM30203	HM36023	HM34223
XL (+7,0 mm)	–	HM32224	HM30204	HM36024	HM34224
2XL (+10,5 mm)	HM30445	HM32225	HM30205	HM36025	HM34225
3XL (+14,0 mm)	HM30446	–	HM30206	HM36026	HM34226
4XL (+17,5 mm)	HM30447	–	–	–	–
5XL (+21,0 mm)	HM30448	–	–	–	–

6.2 BioBall® Heads

NOTE BioBall® Heads may only be combined with BioBall® Adapters.

BioBall® Ceramic Heads, sterile

Material:
BIOLOX®[1] delta ceramic

Ref.	Ø
HM50028	28 mm
HM50032	32 mm
HM50036	36 mm
HM50040	40 mm
HM50044	44 mm
HM50048	48 mm

NOTE Implant may only be used in combination with polyethylene cups and inlays (UHMWPE) or with BIOLOX®[1] delta ceramic inlays from CeramTec GmbH.
BioBall® Ceramic Heads may only be used with the BioBall® Adapters 12/14 and with the BioBall® Adapter for special tapers 14/16, MS 10/12, MSV4 (Standard size M-3XL/Offset size M-XL), MSSY and MSZI.

BioBall® Metal Heads, sterile

Material:
Vivium®[2]

Ref.	Ø
HM30028	28 mm
HM30032	32 mm
HM30033	33 mm
HM30035	35 mm
HM30036	36 mm
HM30038	38 mm

NOTE Not to be used in combination with metallic acetabular reinforcements (metal-metal sliding pairs).

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

6.3 BioBall® System Instruments, non-sterile

BioBall® AdapterSelector®

Ref.	Size
HI39006	12/14

BioBall® AdapterSelector® for Special Tapers

Available on request.

Ref.	Size
HI39007	14/16
HI39005	MS 8/10
HI39003	MS 10/12
HI39008	MSBG
HI39009	MSPC

Ref.	Size
HI39010	MSSR
HI39001	MST1
HI39002	MSV4
HI39012	MSSY
HI39004	MSZI

BioBall® Offset PositionAssistant

Ref.	Size
HM39106	12/14
HM39107*	14/16

* Available on request.

BioBall® Trial Adapters

Length	12/14 Standard	12/14 Offset
	Ref.	
S (-3,0 mm)	HM40121	–
M (0 mm)	HM40122	HM40222
L (+3,5 mm)	HM40123	HM40223
XL (+7,0 mm)	HM40124	HM40224
2XL (+10,5 mm)	HM40125	HM40225
3XL (+14,0 mm)	HM40126	HM40226
4XL (+17,5 mm)	HM40127	HM40227
5XL (+21,0 mm)	HM40128	HM40228

merete®

BioBall® Trial Adapters for Special Tapers Available on request.

	14/16		MS 8/10		MS 10/12		MSBG	MSPC	MSSR
Length	**Standard**	**Offset**	**Standard**	**Offset**	**Standard**	**Offset**	**Standard**	**Standard**	**Standard**
	Ref.								
S (-3,0 mm)	–	–	HM39121	–	HM40101	–	–	–	–
M (0 mm)	HM40142	–	HM39122	HM39222	HM40102	HM40202	HM39142	HM39132	HM39152
L (+3,5 mm)	HM40143	–	HM39123	HM39223	HM40103	HM40203	HM39143	HM39133	HM39153
XL (+7,0 mm)	HM40144	–	HM39124	HM39224	HM40104	HM40204	HM39144	–	HM39154
2XL (+10,5 mm)	HM40145	HM40445	HM39125	HM39225	HM40105	HM40205	HM39145	–	–
3XL (+14,0 mm)	HM40146	HM40446	–	–	HM40106	HM40206	–	–	–
4XL (+17,5 mm)	HM40147	HM40447	–	–	–	–	–	–	–
5XL (+21,0 mm)	HM40148	HM40448	–	–	–	–	–	–	–

	MSSY	MST1		MSV4		MSZI
Length	**Standard**	**Standard**	**Offset**	**Standard**	**Offset**	**Standard**
	Ref.					
S (-3,0 mm)	HM39621	–	–	–	–	HM39421
M (0 mm)	HM39622	HM39002	HM39522	HM39322	HM39022	HM39422
L (+3,5 mm)	HM39623	HM39003	HM39523	HM39323	HM39023	HM39423
XL (+7,0 mm)	HM39624	HM39004	HM39524	HM39324	HM39024	HM39424
2XL (+10,5 mm)	–	HM39005	HM39525	HM39325	HM39025	HM39425
3XL (+14,0 mm)	–	HM39006	HM39526	HM39326	HM39026	HM39426
4XL (+17,5 mm)	–	–	–	–	–	–
5XL (+21,0 mm)	–	–	–	–	–	–

BioBall® Trial Heads

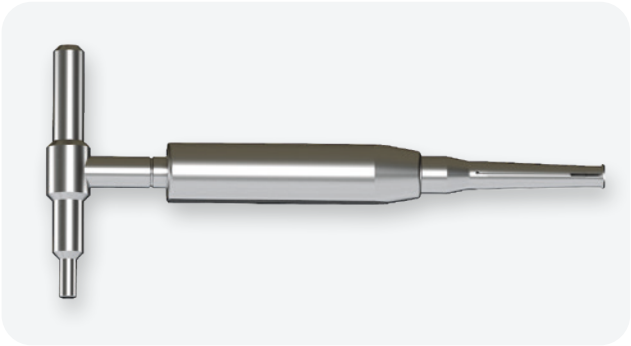
Ref.	Ø
HM40028	28 mm
HM40132	32 mm
HM40036	36 mm
HM40040	40 mm

Additional sizes are available on request:

Ref.	Ø
HM40033	33 mm
HM40035	35 mm
HM40038	38 mm
HM40342	42 mm
HM40344	44 mm
HM40346	46 mm
HM40348	48 mm

BioBall® Adapter Extractor

BioBall® Adapter Extractor	
Ref.	HM20001



BioBall® Adapter Extractor Sleeve 12/14 S

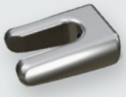
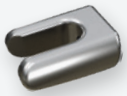
Ref.
HM20002

BioBall® Adapter Extractor Sleeves for Special Tapers

Available on request.

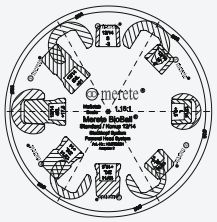
Ref.	BioBall® Adapter Extractor Sleeves
HM20002	MSPC M/L (also 12/14 S)
HM20003	14/16 M and MSBG M
HM20004	MSV4 M and MSSR M/L
HM20005	MS 10/12 S and MSSY S/M
HM20006	MSZI S/M

BioBall® Universal Handle	
Ref.	HM10005

BioBall® Head Separating Wedge	Size	Ref.
	S	HM10007
	M	HM10008
	L	HM10009

BioBall® Head Impactor	Ref.
	HM10004

Preoperative Planning

X-ray templates	Ref.	Type
	HMRS001	12/14 Standard
	HMRS005	12/14 Offset
	HMRS002	14/16 Standard
	HMRS006	14/16 Offset

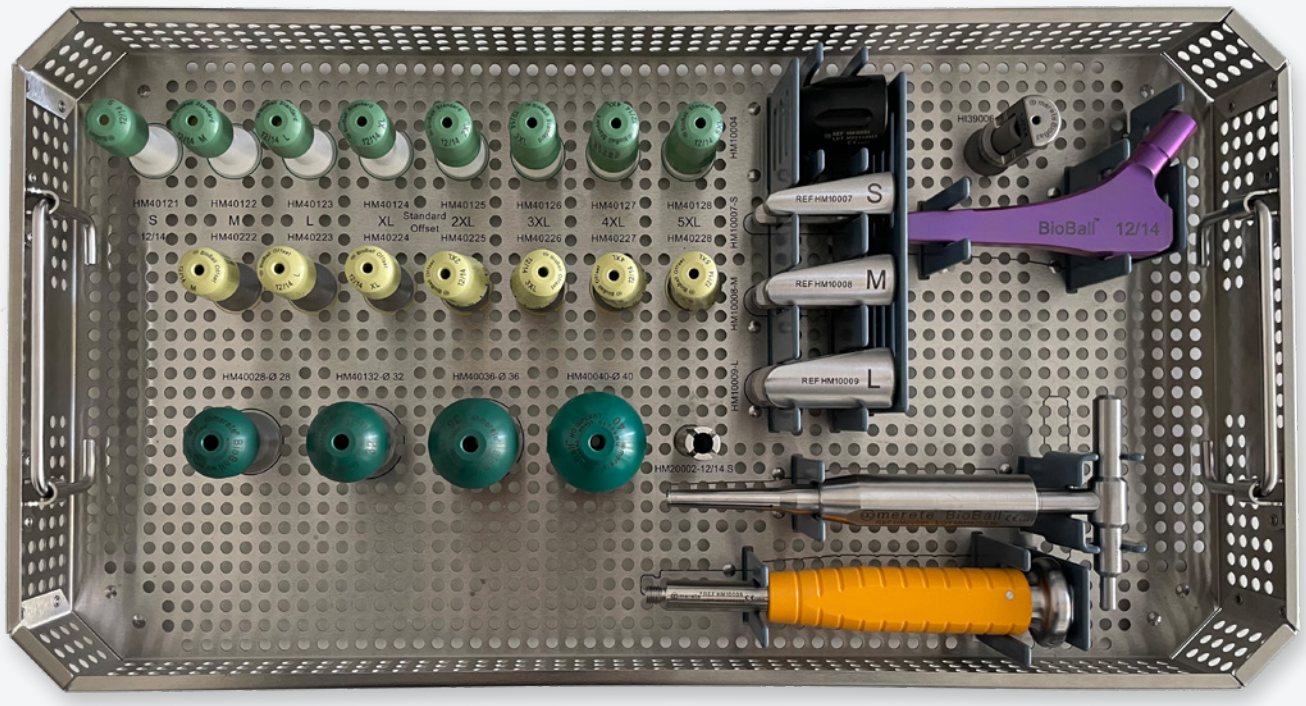
Merete® products are included in the databases of several digital surgical planning tools. Contact Merete GmbH for more information on these supporting systems.

Steri Permanent Marker

Available on request.

Ref.	Product Description	QTY / Pack
AS-2750	Steri permanent marker, single packed sterile	50

BioBall® Instrument Tray 12/14



Order Ref.	Product Description
HM30776	BioBall® Instrument Tray 12/14, complete, non-sterile

Included in instrument tray:

Ref.	Product Description	QTY
HM30776-1	BioBall® Instrument Tray 12/14, base, non-sterile	1
HM30776-2	BioBall® Instrument Tray 12/14, lid, non-sterile	1
HI39006	BioBall® AdapterSelector® 12/14, non-sterile	1
HM10004	BioBall® Head Impactor, non-sterile	1
HM10005	BioBall® Universal Handle, non-sterile	1
HM10007	BioBall® Head Separating Wedge S, non-sterile	1
HM10008	BioBall® Head Separating Wedge M, non-sterile	1
HM10009	BioBall® Head Separating Wedge L, non-sterile	1
HM20001	BioBall® Adapter Extractor, non-sterile	1
HM20002	BioBall® Adapter Extractor Sleeve, for Adapter 12/14 S and MSPC M-L, non-sterile	1
HM39106	BioBall® Offset PositionAssistant, 12/14, non-sterile	1

Ref.	Product Description	QTY
HM40028	BioBall® Trial Head Ø 28 mm, non-sterile	1
HM40132	BioBall® Trial Head Ø 32 mm, non-sterile	1
HM40036	BioBall® Trial Head Ø 36 mm, non-sterile	1
HM40040	BioBall® Trial Head Ø 40 mm, non-sterile	1
HM40121	BioBall® Trial Adapter 12/14, Standard, S (-3.0 mm), 12/14 (5°42´), non-sterile	1
HM40122	BioBall® Trial Adapter 12/14, Standard, M (0.0 mm), 12/14 (5°42´), non-sterile	1
HM40123	BioBall® Trial Adapter 12/14, Standard, L (+3.5 mm), 12/14 (5°42´), non-sterile	1
HM40124	BioBall® Trial Adapter 12/14, Standard, XL (+7.0 mm), 12/14 (5°42´), non-sterile	1
HM40125	BioBall® Trial Adapter 12/14, Standard, 2XL (+10.5 mm), 12/14 (5°42´), non-sterile	1
HM40126	BioBall® Trial Adapter 12/14, Standard, 3XL (+14.0 mm), 12/14 (5°42´), non-sterile	1
HM40127	BioBall® Trial Adapter 12/14, Standard, 4XL (+17.5 mm), 12/14 (5°42´), non-sterile	1
HM40128	BioBall® Trial Adapter 12/14, Standard, 5XL (+21.0 mm), 12/14 (5°42´), non-sterile	1
HM40222	BioBall® Trial Adapter 12/14, Offset, M (0.0 mm), 12/14 (5°42´), non-sterile	1
HM40223	BioBall® Trial Adapter 12/14, Offset, L (+3.5 mm), 12/14 (5°42´), non-sterile	1
HM40224	BioBall® Trial Adapter 12/14, Offset, XL (+7.0 mm), 12/14 (5°42´), non-sterile	1
HM40225	BioBall® Trial Adapter 12/14, Offset, 2XL (+10.5 mm), 12/14 (5°42´), non-sterile	1
HM40226	BioBall® Trial Adapter 12/14, Offset, 3XL (+14.0 mm), 12/14 (5°42´), non-sterile	1
HM40227	BioBall® Trial Adapter 12/14, Offset, 4XL (+17.5 mm), 12/14 (5°42´), non-sterile	1
HM40228	BioBall® Trial Adapter 12/14, Offset, 5XL (+21.0 mm), 12/14 (5°42´), non-sterile	1

Instrument Trays and Instruments for Special Adapters

Available on request.

Ref.	Product Description
HM30770	BioBall® Instrument Tray 12/14 and 14/16, complete with instruments
HM30740	BioBall® Instrument Tray MSBG /MSPC / MSSR, complete with instruments
HM30730	BioBall® Instrument Tray MST1, complete with instruments
HM30750	BioBall® Instrument Tray MSV4, complete with instruments
HM30785	BioBall® Instrument Tray with General Instruments
On request	BioBall® Instruments 14/16
On request	BioBall® Instruments MS 8/10
On request	BioBall® Instruments MS 10/12
On request	BioBall® Instruments MSZI
On request	BioBall® Instruments MSSY

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7. Information on Implant Card

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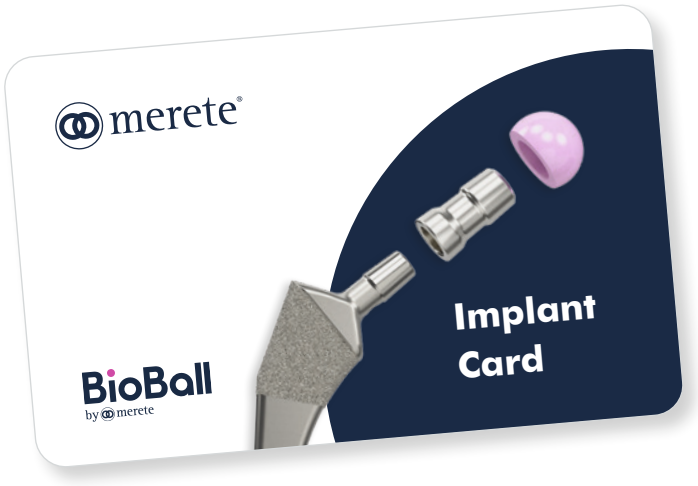
7. Information on Implant Card

The implant card is a document included with each implant package, providing essential information for both patients and healthcare providers. It is designed to help track and identify the implant throughout the patient's life, ensuring that critical information is readily available for any future needs. The card includes important details such as the implant type, unique identifiers, and contact information facilitating efficient communication and traceability.

7.1 Instructions for Implant Card (for Healthcare Providers)

How to fill out the implant card?
After each surgery, the implant card should be accurately filled out by the healthcare provider and handed to the patient. Healthcare providers should carefully complete the implant card by recording the following information in the fields next to each corresponding symbol:

Symbol	Record the following details in the empty field
	Name of the patient (full name) or patient ID
	Date of implantation (DD/MM/YYYY e.g. 20/12/2024)
	Name and address of the healthcare institution/provider
	Patient Label (Affix the patient label provided in the implant package into this space)



BioBall® Literature

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