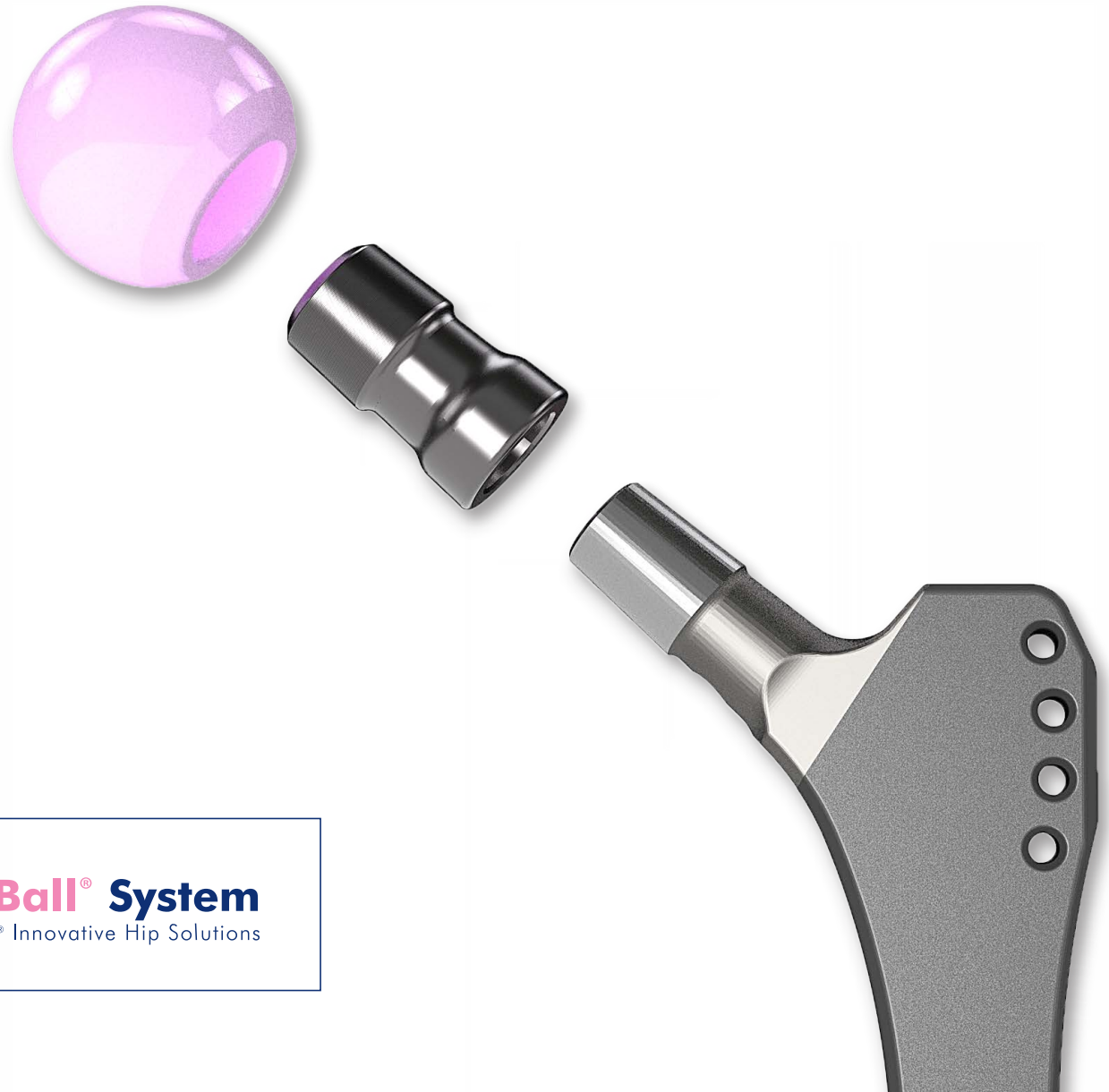
merete®

BioBall™ Adapter System

Surgical Instructions and Ordering Information



BioBall® System
Merete® Innovative Hip Solutions

Caution

The following product descriptions contain detailed information on the recommended procedure (and associated surgical techniques) for using Merete® implants and instruments. Training in the correct handling of implants and instruments by an authorised Merete representative is essential.

Table of Contents

1. Description

The BioBall™ Adapter System consists of the Standard and Offset Adapter components which may be optionally combined with the following joint head components:

- BioBall™ Metal Head
- BioBall DELTA™ Ceramic Head
- BioBall™ Bipolar Duo Head
- BioBall™ MaxiMotion™ Cup

This concept can be applied both in revision prosthetics of existing prosthetic stems and in primary care for intraoperative correction of already implanted shafts. Intraoperatively, standard femoral neck length corrections from S (-3.0 mm) to 5XL (+21 mm) can be performed with the BioBall™ Standard Adapters. In addition to neck length correction from M to 5XL, BioBall™ Offset Adapters allow medialisation or lateralisation as well as limited correction of retro- or antetorsion.

Adapters are available for prosthesis stems with standard tapers 12/14* and 14/16* (*stem tapers meeting the CeramTec BIOLOX® specification). Adapters for other tapers are available upon request. All adapters can only be combined with the BioBall™ Heads.

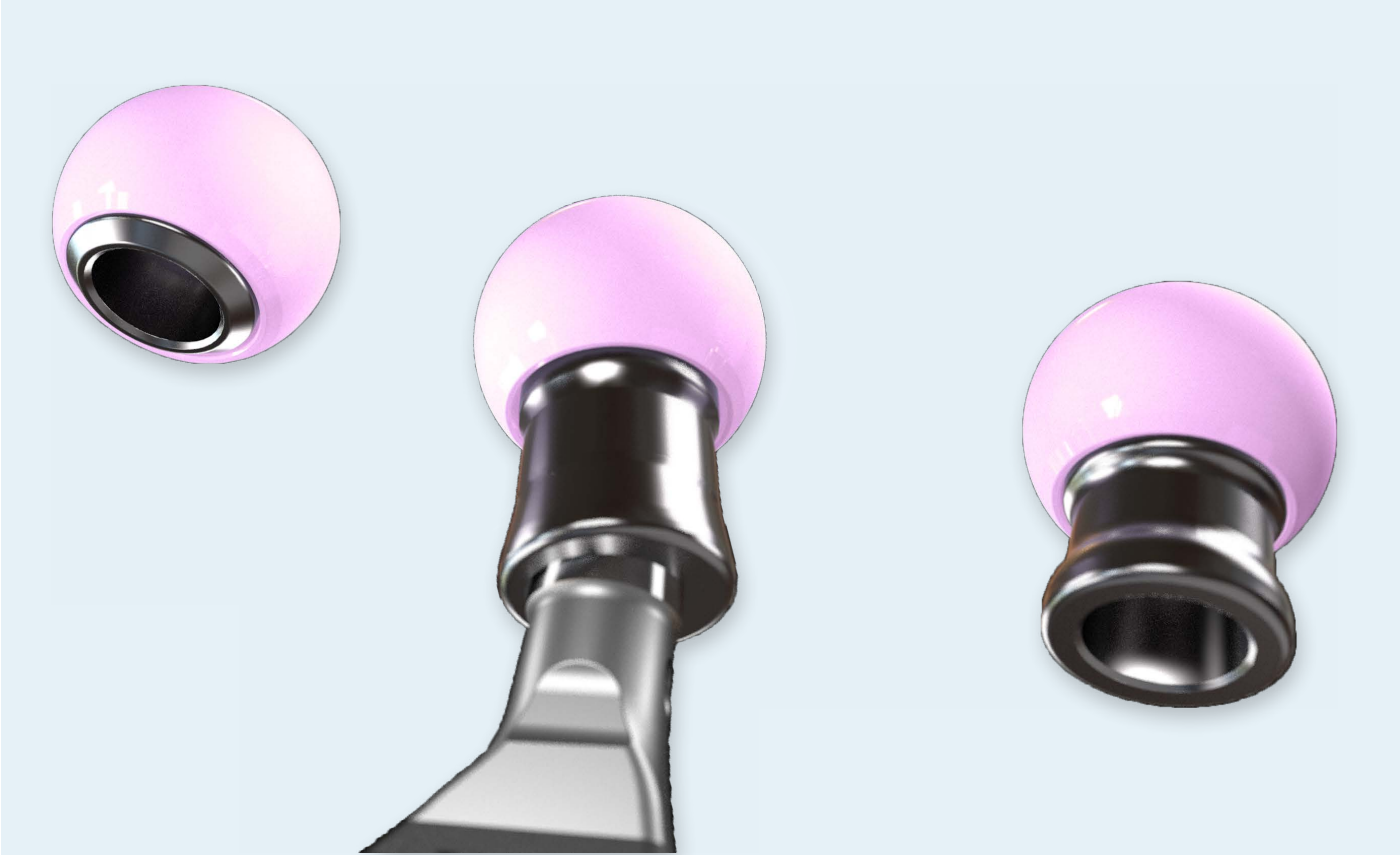


Figure 1 BioBall™ Adapter System

1.1 Intended Purpose

WARNING	**Use of implants contrary to intended purpose** • Risk of injury due to implant fracture! ➲ Implantat must only be used in accordance with intended purpose.

BioBall™ Adapters 12/14, 14/16, MS 8/10, MS 10/12, MSZI, MSV4, MST1, MSBG, MSPC, MSSR and MSSY are for use as a replacement part in hip revision operations in combination with a BioBall™ Head. They serve 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

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

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

Figure 2 Functional principle of BioBall™ Adapter System

1.4 MRI Safety Information

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 TiAl6V4 ELI (ISO 5832-3), Vivium® (ISO 5832-9), CoCrMo (ISO 5832-4/5832-12), BIOLOX® delta ceramic (ISO 6474-2), PE/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.

2. General Information

GENERAL INFORMATION

WARNING

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.

WARNING

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 fracture!
- Risk of Sepsis!

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

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

- Risk of injury due to implant fracture!

➲ 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.

WARNING

Resterilisation of implants

- Risk of injury due to premature implant fracture 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.

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".

3. System Compatibility

 WARNING	**Combination of BioBall™ Adapters with hip stems with neck insertion system** • Risk of injury due to premature implant fracture! ➲ BioBall™ Adapters must not be combined with hip stems that use a neck insertion system.

 WARNING	**Combination with over-long heads** • Risk of injury due to implant fracture! ➲ Impaired component safety due to higher lever forces.

NOTE	BioBall™ DELTA™ Ceramic Heads must not be used with BioBall™ Special Adapters (MS 8/10, MSV4 Offset 2XL and 3XL, MST1, MSBG, MSPC, MSZI, MSSR and MSSY).

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. In primary surgery, BioBall™ Adapter 12/14 is only intended for use together with the Merete-brand hip stems approved for that purpose.

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 (for possible combinations, see page 10). 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, it must adhere to the applicable CeramTec BIOLOX® 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 prosthesis taper. 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.

BioBall™ adapters may be used with stems whose tapers are made of the following materials:

- TiAl6V4 ELI (DIN EN ISO 5832-3)
- TiAl6Nb7 (DIN ISO 5832-11)
- CoCr alloys (DIN ISO 5832-4/-12)
- Stainless steel (DIN ISO 5832-9)

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

- BioBall™ metal heads may only be combined with UHMWPE inlays or cups.
- BioBall DELTA™ heads may only be combined with BIOLOX® delta[1] inlays, or with UHMWPE inlays or cups.

Possible sliding pairs

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

Combination BioBall™ Adapter and BioBall™ heads

BioBall™ Adapter	Standard	Offset	BioBall™ Head
12/14	S-5XL	M-5XL	Ceramic or Metal
14/16	M-5XL	2XL-5XL	
MS 10/12	S-3XL	M-3XL	
MSV4	M-3XL	M-XL	
MS 8/10	S-2XL	M-2XL	Metal only
MSZI	S-3XL	-	
MST1	M-3XL	M-3XL	
MSV4	-	2XL-3XL	
MSBG	M-2XL	-	
MSPC	M-L	-	
MSSR	M-XL	-	
MSSY	S-XL	-	

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

Implant Materials

BioBall™Adapters are made of the following material

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

Heads may be made of the following materials

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

Acceptable combinations may be made with cups or inlays made of the following materials

- BIOLOX® delta[2] (Mixed Ceramic ISO 6474-2)
- UHMWPE (DIN ISO 5834-2)

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

NOTE
With ceramic heads, a slight risk of fracture can never be ruled out entirely.
The risk is higher in the case of obesity and pre-obesity. The patient must be informed about such risks.

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

4. Surgical Technique

4.1 Pre-Operative Planning

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 fracture 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

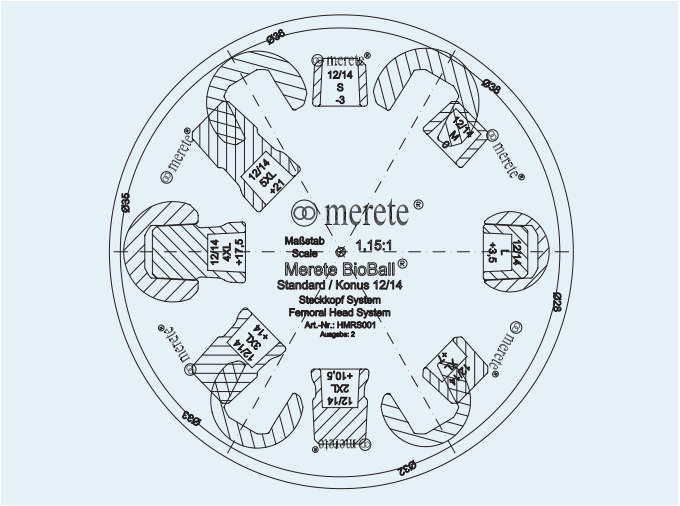
- Risk of injury due to implant fracture!

➲ Thoroughly clean any foreign bodies from implant components.

For pre-operative planning with X-rays, the BioBall™ Adapter System X-ray templates should be used. They are available for the standard tapers 12/14 and 14/16 and for the offset version 12/14 and 14/16 (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 passport together with the BioBall™ manufacturer's specifications.

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



Instructions for Digital Planning

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

4.2. Use of the BioBall™ Adapter Head System

WARNING	**Breaking of ceramic components** • Risk of injury due to implant fracture! ➲ When performing revision surgery following breakage of a ceramic component, do not use metal heads. ➲ Replacement components must also be a ceramic head.

The following mounting 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, etc.) are completely removed.
- Before positioning BioBall™ components, check all components as well as the stem taper for damage, deformation, wear or contamination.

Implant handling

During implantation and repositioning, care must be taken that the implant surface is not damaged. Dents and scratches have a significant effect on the lifespan of the implant and the system components combined with it.

4.3 Removal of the Existing Head

To do so, the appropriate separating wedge (Ref. HM10007 – Ref. HM10009) is screwed in the universal handle (Ref. HM10005). The wedge is then positioned between the head and the stem and the head is levered off the stem taper with a light pressure (Fig. 3). In so doing, the wording "Head side" on the wedge must face the head. Size indications S, M, L on the wedge refer to the intraoperative stem neck length. (Compare page 27, "Use of Separating Wedge and Separating Instruments").

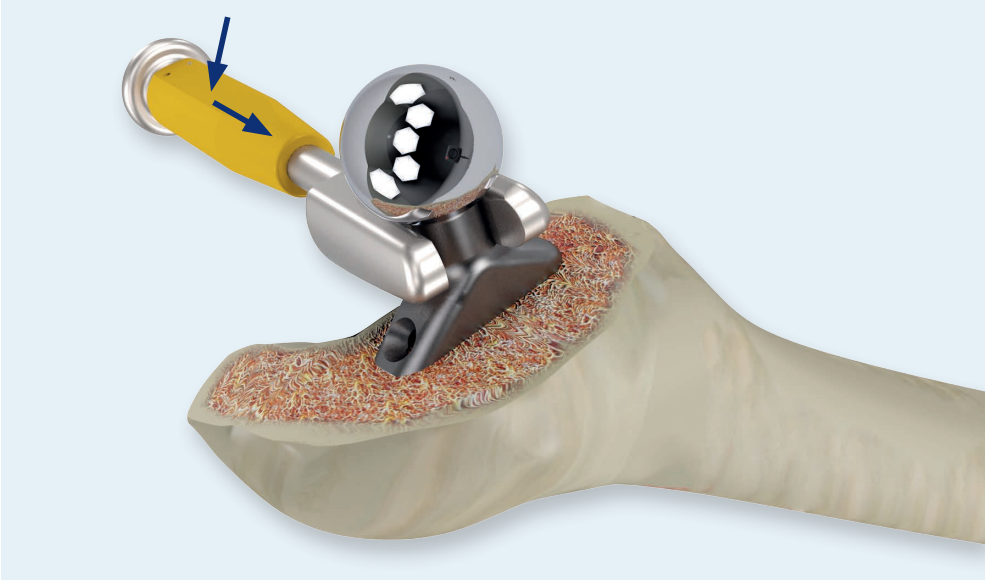


Figure 3 Withdrawal of the head with suitable separating wedge

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 secure anchored hip prosthesis stem. Prior to use of the instrument, all information about the stem taper should be collected and evaluated. The BioBall™ AdapterSelector™ is labelled with the taper designation corresponding to the taper and also the taper diameter and angle. This enables a suitable BioBall™ Adapter to be assigned.

Step 1: Assessment of the stem taper

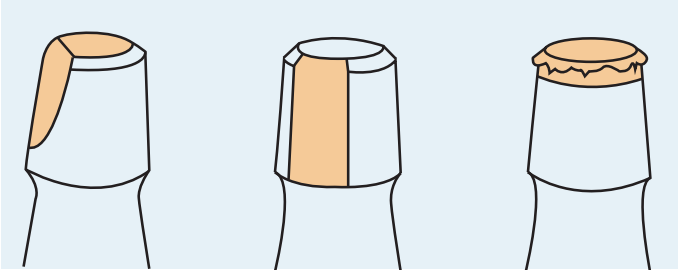


Figure 4 Damaged tapers

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 stem surface, the BioBall™ System cannot be used (Fig. 4).

Step 2: Testing the taper front face

If the stem taper shows no signs of shape-altering damage, the BioBall™ AdapterSelector™ is fitted to the taper. An assessment is made of the flat face visible in the opening of the BioBall™ AdapterSelector™. If the front face of the taper is between the marks shown by the arrows (Fig. 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.

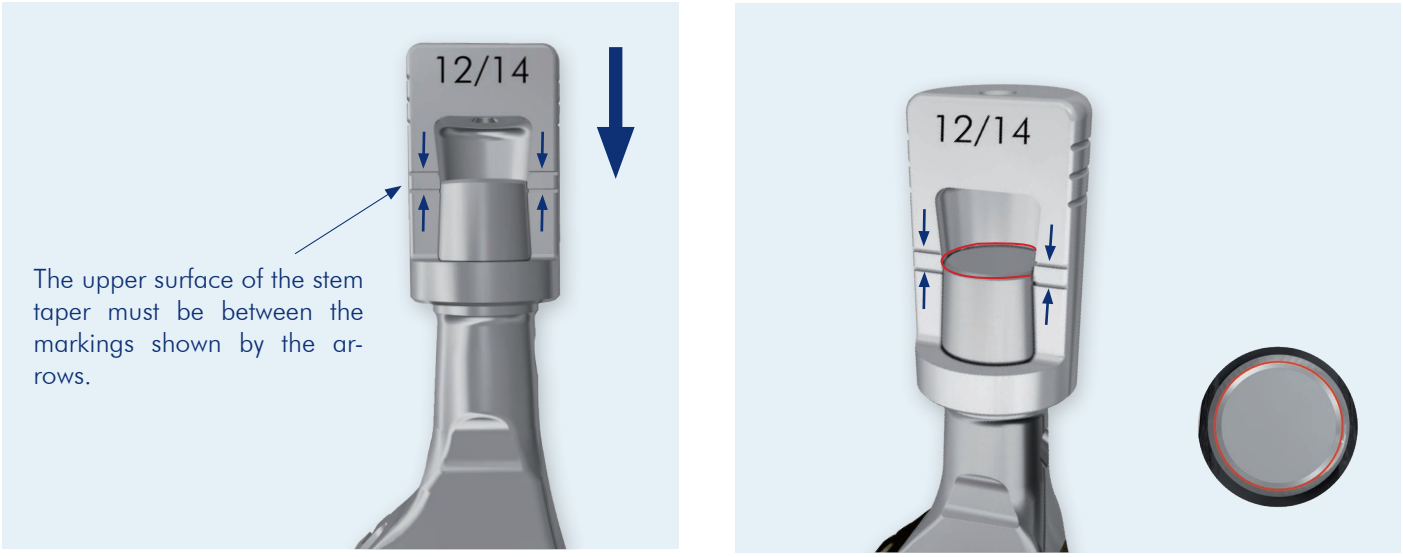


Figure 5 Testing the taper front face

Step 3: Fit check

The seating of the BioBall™ AdapterSelector™ on the stem taper is tested. To do this, the clamp connection is tested with the BioBall™ AdapterSelector™ by a vigorous tilting movement (Fig. 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 (Fig. 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 Sleeve may be implanted. In this way, unnecessary major revisions can be avoided.

Figure 6 Testing the clamp connection with a vigorous tilting movement

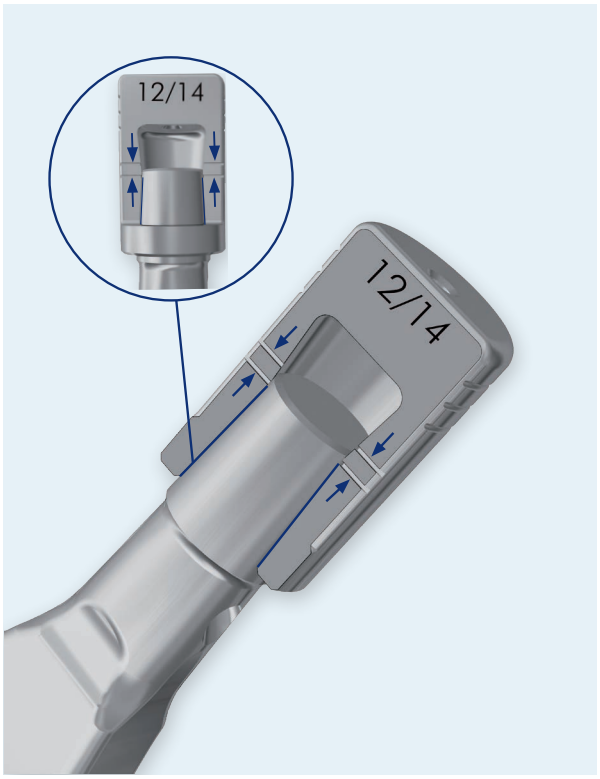


Figure 7 Gap-free seating in BioBall™ AdapterSelector™

4.5 BioBall™ System with Standard Adapter

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 light hammer blows in an axial direction on the plastic impactor.

Breaking of ceramic components

- Risk of injury due to implant fracture!

➲ 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 fracture 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 trial adapter for the desired shortening or lengthening and assembly it on the previously determined prosthesis taper. The trial head is then inserted on the adapter up to the stop (Fig. 8). To check neck length, Rage of Motion and soft tissue tension, the joint is repositioned, with following function test (Fig. 9).

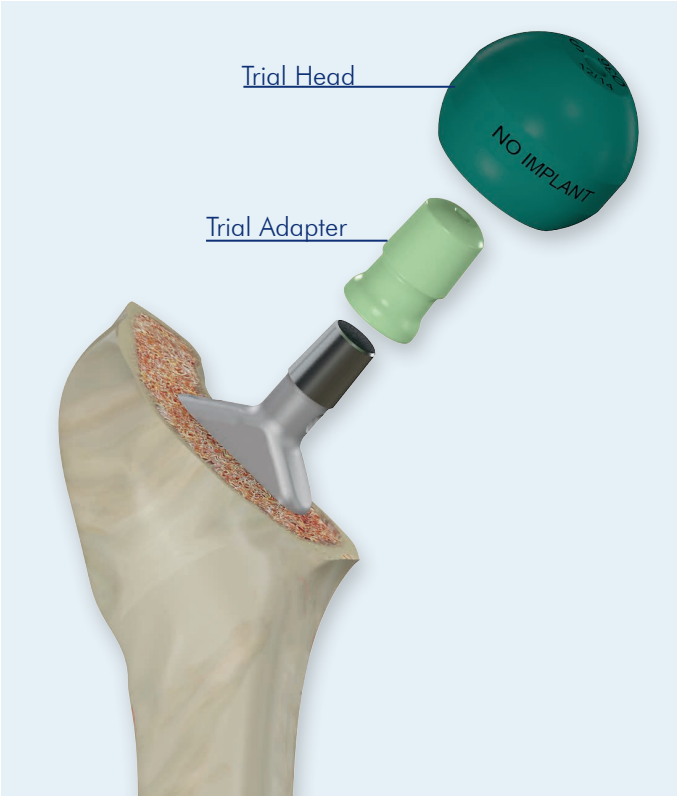


Figure 8 Mounting of trial adapter head system

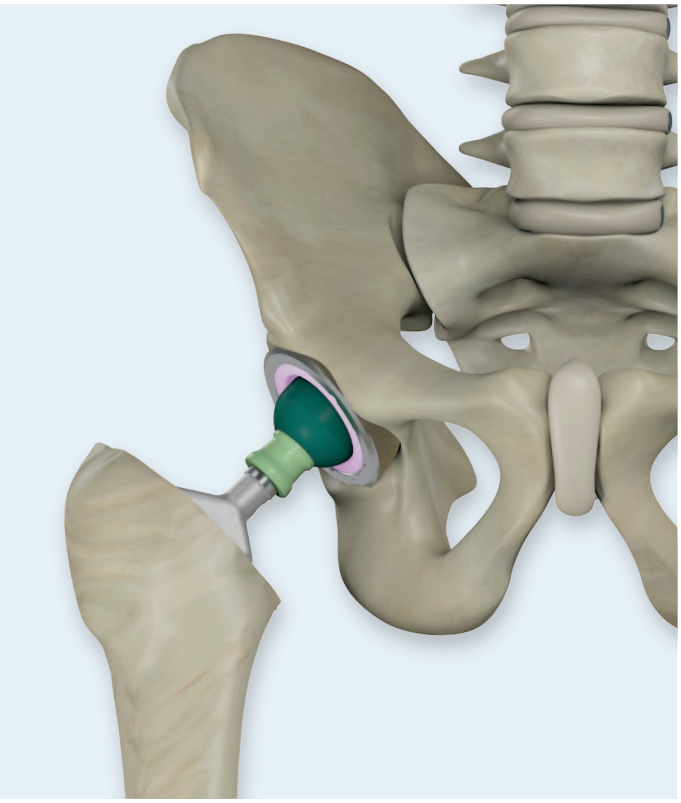


Figure 9 System repositioned

NOTE

The trial components grip the taper and can be released again by an anti-clockwise rotation. If the grip is too strong, the separating wedge (Ref. HM10007, Ref. HM10008, Ref. HM10009) can be used. The trial head is inserted on the adapter up to the stop. All trial components are made of X-ray opaque materials, allowing X-ray control of the correct seating.

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

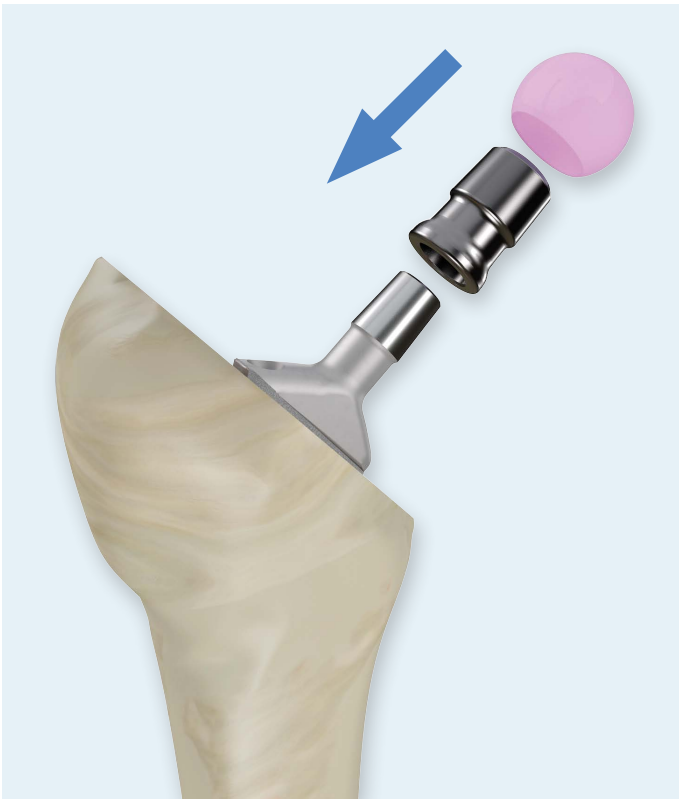


Figure 10 Attaching the implants

The following assemble instructions should be observed

- The BioBall™ Adapter is applied onto the prepared stem taper with slight axial pressure in combination with a right turn.
- Next, place the head on the BioBall™ Adapter and, as with the adapter, press it firmly in an axial direction with a clockwise turn (Fig. 10).
- Finally, check the correct seating of the head and adapter.
- Fixing of the head with a light hammer blow in axial direction using the plastic head inserter (head impactor, Fig. 11).
- **NOTE:** Never strike the adapter or the head with a hammer directly!

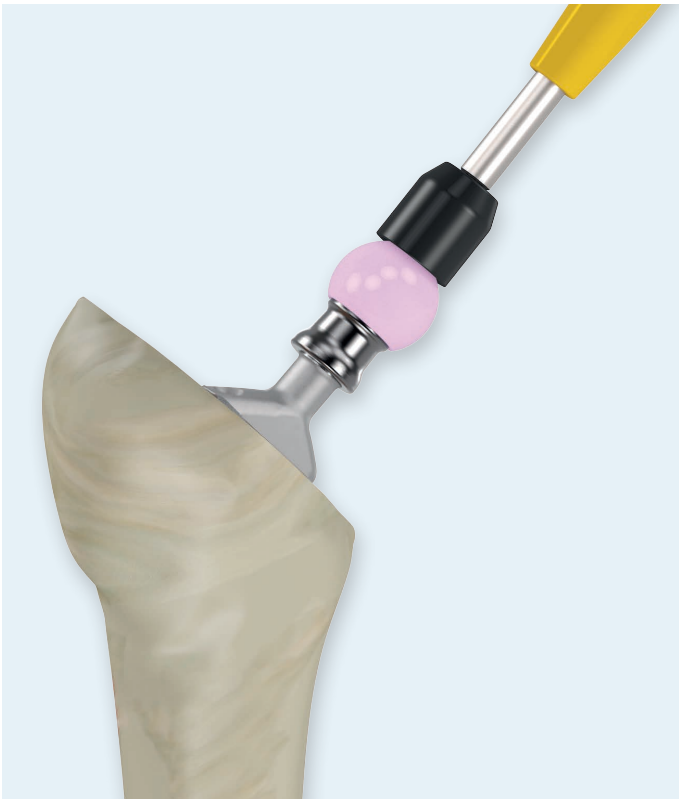


Figure 11 Light tapping of the head with the head impactor

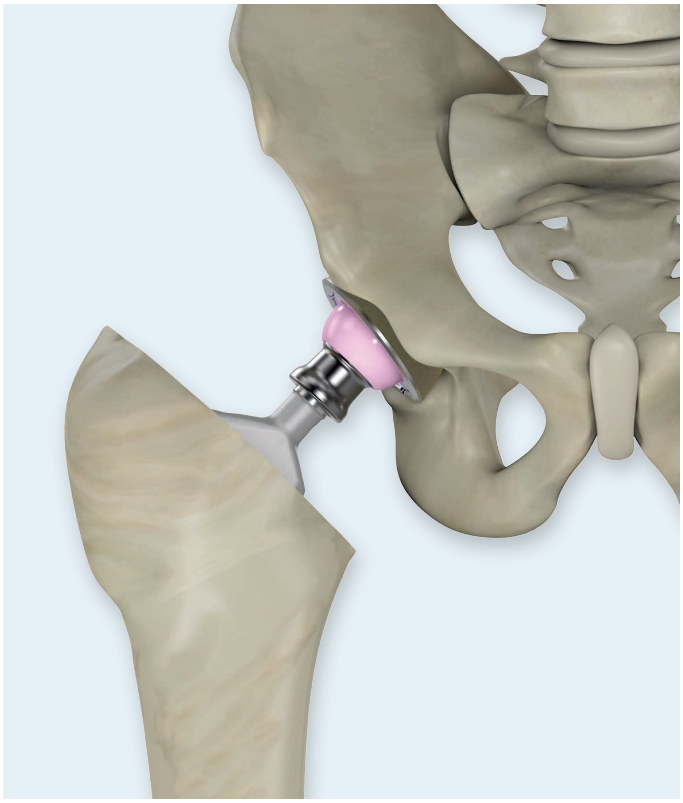


Figure 12 Implants repositioned

4.6 BioBall™ System with Offset Adapter

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 light hammer blows in an axial direction on the plastic impactor.

Breaking of ceramic components

- Risk of injury due to implant fracture!

➲ 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 fracture 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 on the BioBall™ Offset PositionAssistant

By using the head extractor with a suitable separating wedge (see pages 16 and 27), the existing head can be carefully removed with a levering movement.

Testing the stem taper with the BioBall™ AdapterSelector™ (see pages 16 ff.).

Selection of the desired offset trial adapter for the desired lengthening. Mounting of the corresponding BioBall™ Offset PositionAssistant (Fig. 13).

The BioBall™ Offset PositionAssistant serves for better visualisation of the adjustment of the BioBall™ Offset Adapter. It is a non-in-situ stem with corresponding taper on which the necessary adjustments (lateralisation, antetorsion, retrotorsion) can be tested with the offset trial adapter (Fig. 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 (Fig. 14).

Next the trial adapter is positioned on the in-situ stem, and the identified settings of the trial adapter (3, 6, 9 or 12 o'clock) can be noted.

Examples of offset settings

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

Figure 15 Antetorsion on right femur

Figure 16 Retrotorsion on right femur

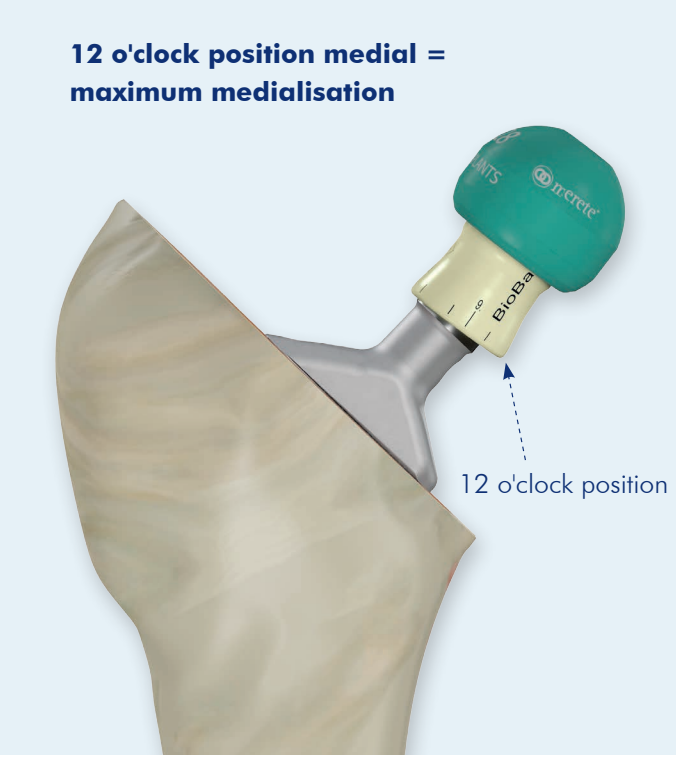


Figure 17 Medialisation

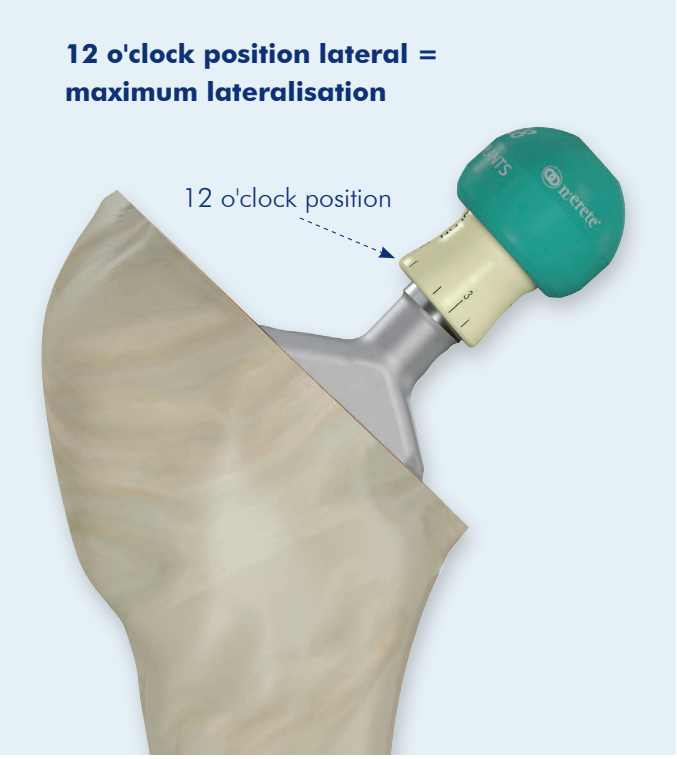


Figure 18 Lateralisation

A mark may be transferred to the prosthesis neck with a sterile marker pen, e.g. Merete SteriPen™ (Ref. EP13403). This mark serves to orient the alignment of the BioBall™ Offset Adapter (Fig. 19).

Figure 19 Alignment of trial adapter on the prosthesis neck

Figure 20 Mounted trial components

After all necessary adjustments have been identified, the trial head with appropriate diameter is selected and mounted on the trial adapter (Fig. 20). To check neck length, offset, Rage 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 trial adapter anti-clockwise (arrow mark on outer surface of trial components). If the desired final position has been achieved, the position of the trial adapter 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 (Figs. 22-24).

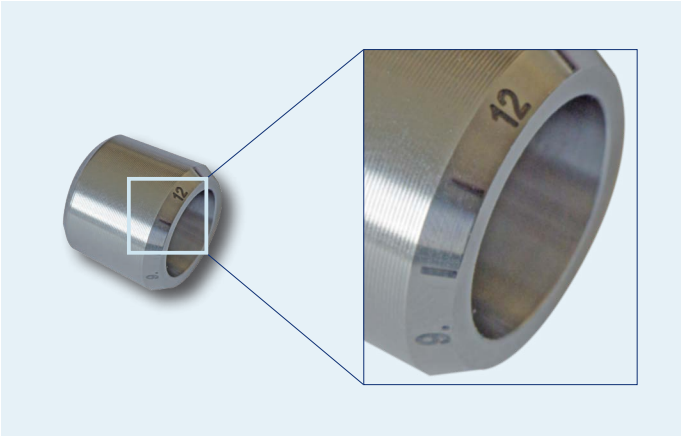


Figure 21

NOTE

In order to determine the correct position of the implant, rotate it anti-clockwise. Be guided by the numbers on the base of the implant when bringing it into agreement with the predetermined position of the trial implant (see Figs. 15-18).

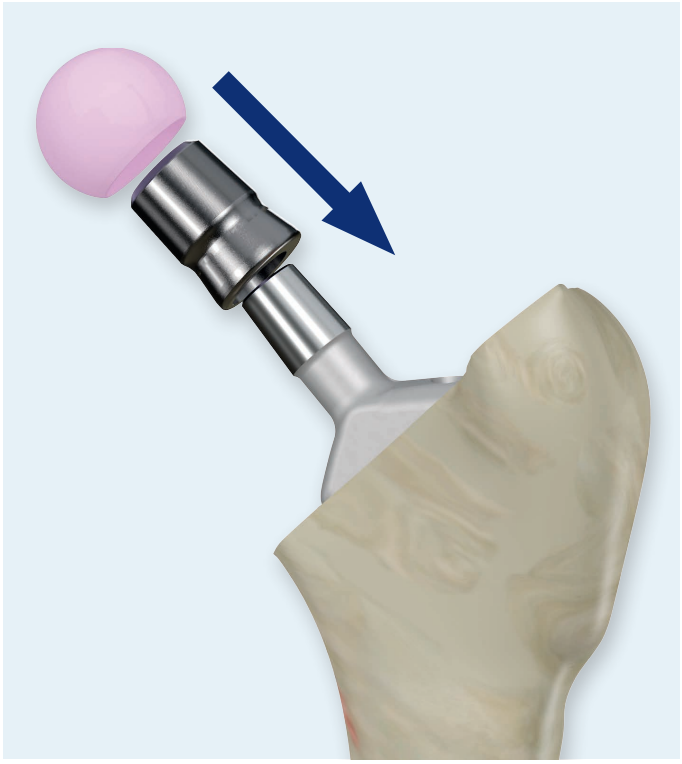


Figure 22 Attaching the implants

The following attaching instructions should be observed

- Apply BioBall™ Offset Adapter to the stem taper with axial pressure in the selected angle (CCD or antetorsion).
- Then mount the head on the BioBall™ Adapter with axial pressure.
- Finally, check the correct seating of the head and adapter.
- Fixing the head with a light hammer blow in axial direction using the plastic head inserter (head impactor, Fig. 23).
- **NOTE:** Never strike the adapter or the head with a hammer directly!

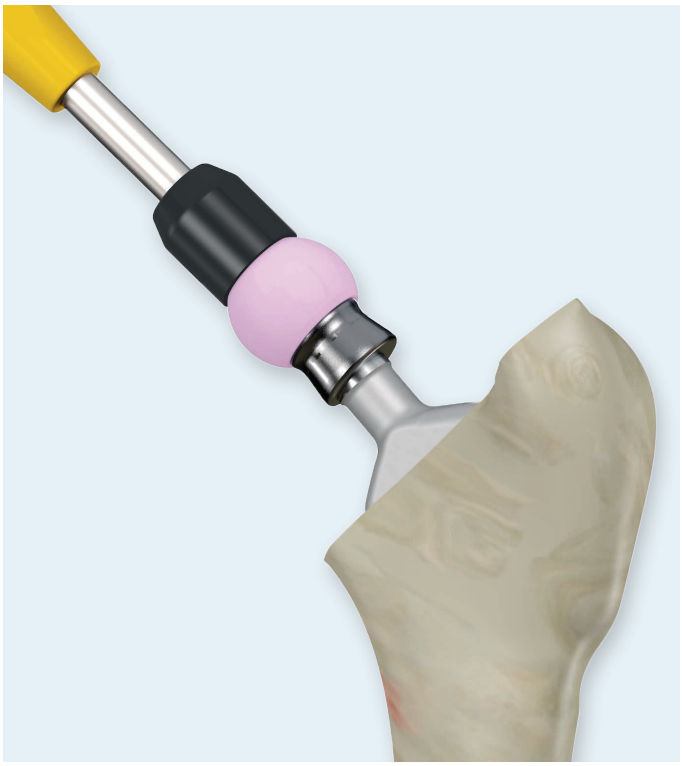


Figure 23 Light tapping of the head with the head impactor

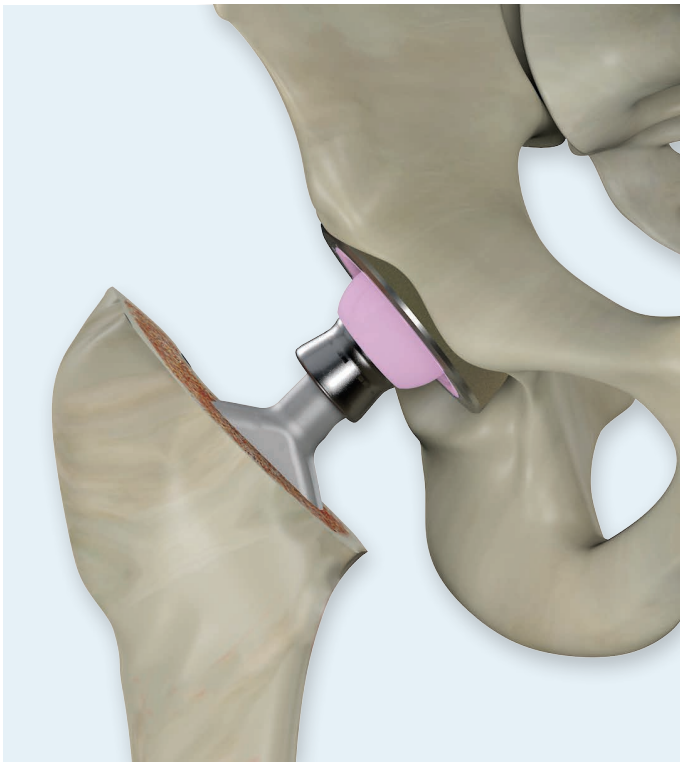


Figure 24 Implants repositioned

NOTE

Depending on the design, short offset adapters (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 Use of Separating Wedge and Separating Instruments

If it should become apparent during surgery that the adapter is not correctly positioned and that the adapter has a conical clamp on the taper, the connection can be undone with the separating wedge. To do so, the appropriate separating wedge (Ref. HM10007 – Ref. HM10009) is screwed in the universal handle (Ref. HM10005). The wedge is then positioned between the head and the stem and the adapter is levered off the stem taper with a light pressure (Fig. 25). In so doing, the wording "Head side" on the wedge must face the head.

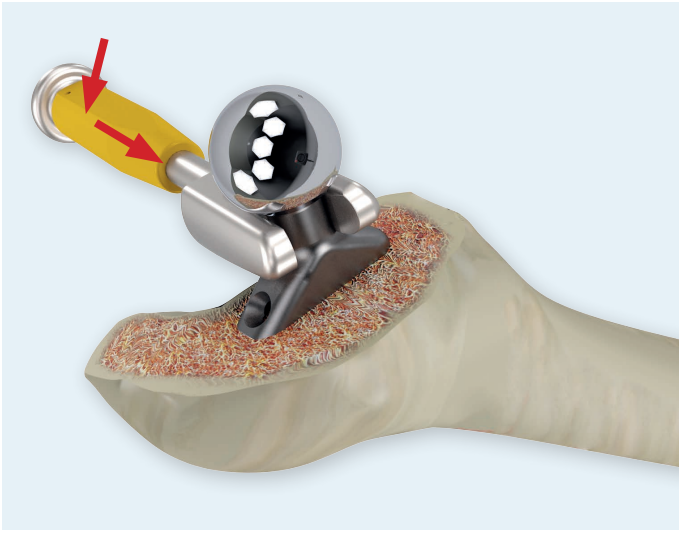


Figure 25 Use of separating wedge

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

- Screw out the handle to the ring mark (Fig. 26).
- To separate the implant components, push the BioBall™ Adapter with head over the separating sleeve until the lip engages behind the adapter (Fig. 27).
- Rotate the handle clockwise until the head has been released from the adapter (Fig. 28)
- Rotate the handle anti-clockwise until the ring mark is visible again.
- The BioBall™ Adapter can be removed from the separating instrument.
- To separate the trial components, the marked side of the handle can be used (Fig. 31).

Figure 26 Use of Adapter Extractor

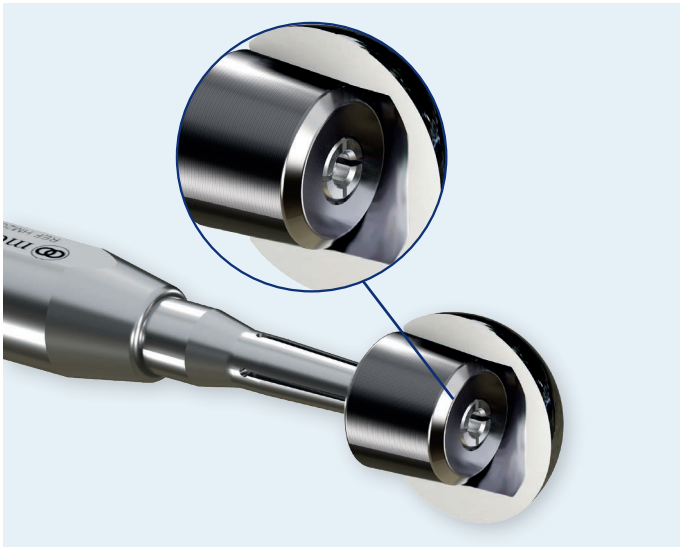


Figure 27 Close-up of lip

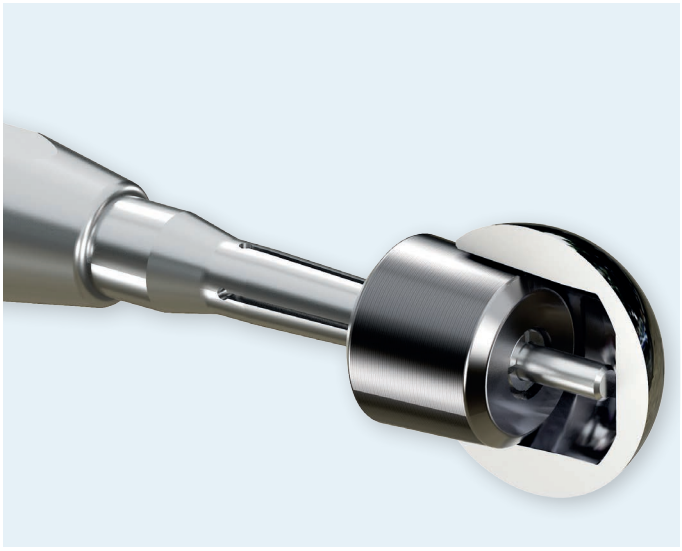


Figure 28 Pushing off the head

Separation of adapter and head (Adapter 12/14 S or Adapter 14/16 M)

If a BioBall™ Adapter 12/14 of size S Standard or a BioBall™ Adapter 14/16 of size M Standard is used, then separating the BioBall™ Head will additionally require the adapter sleeve (Ref. HM20002, Ref. HM20003) to be fitted to the separating instrument (Fig. 29). The separating instrument can then be used as described in the steps on page 27 (Fig. 30).

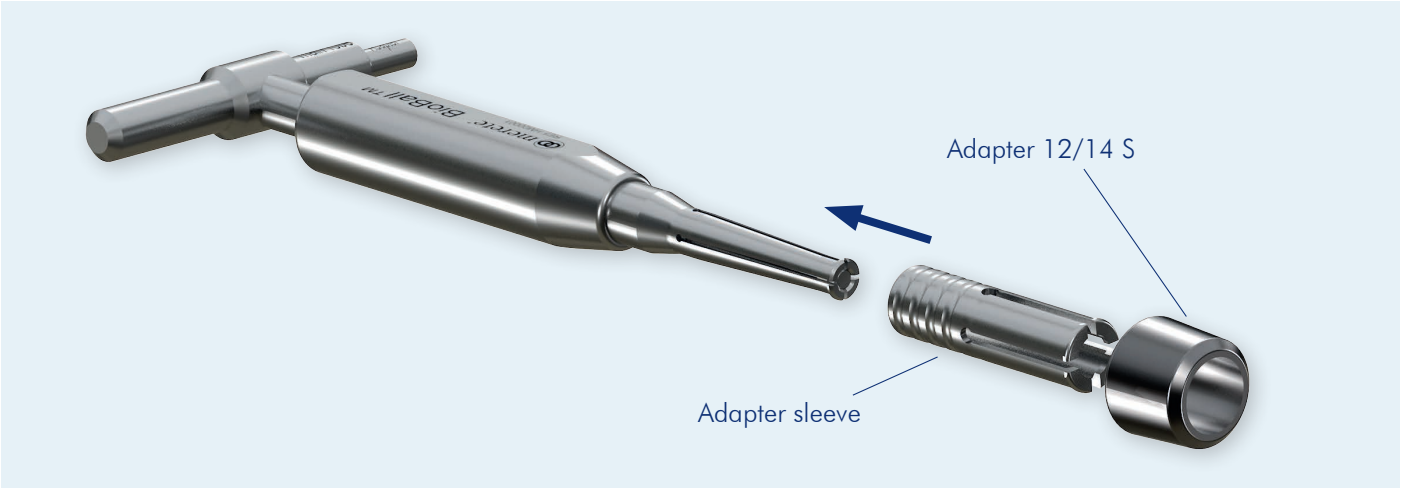


Figure 29 Assambling the adapter sleeve on the separating instrument

Figure 30 Use of separating instrument with adapter sleeve

Figure 31 Separation of the trial components

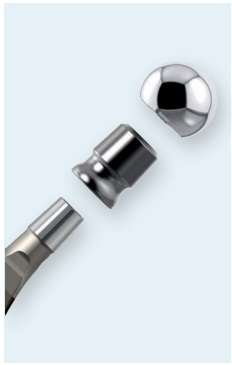
NOTE

To separate the trial adapter connected to the trial head from 40 mm, twist the handle out of the separating instrument and use it to perform the separation.

5. Ordering Information

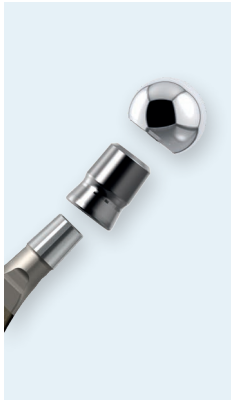
5.1 BioBall™ Adapter

NOTE
Die BioBall™ Adapter may only be combined with BioBall™ Heads



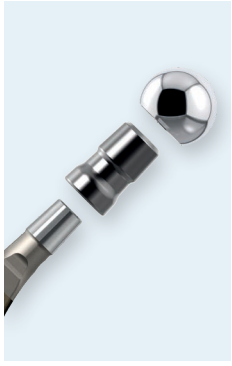
Standard 12/14

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



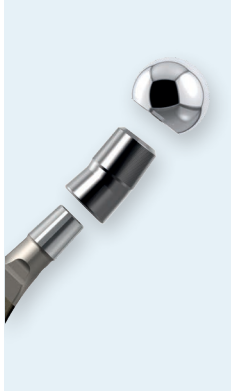
Offset 12/14

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



Standard 14/16

BioBall™ Adapter System Standard 14/16 steril							
Neck length	M (0)	L (+3,5)	XL (+7,0)	2XL (+10,5)	3XL (+14,0)	4XL (+17,5)	5XL (+21,0)
Ref.	HM30142	HM30143	HM30144	HM30145	HM30146	HM30147	HM30148



Offset 14/16

BioBall™ Adapter System Offset 14/16 steril				
Neck length	2XL (+10,5)	3XL (+14,0)	4XL (+17,5)	5XL (+21,0)
Offset (mm)	1,4	1,5	2,0	2,5
Ref.	HM30445	HM30446	HM30447	HM30448

NOTE
Special adapters for other taper are available on request.

Material: TiAl6V4 ELI

5.2 BioBall™ Heads

NOTE
BioBall™ heads may only be combined with BioBall™ Adapters.

BioBall™ Metal Head, steril

Material: Vivium®[1]

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).

BioBall DELTA™ Ceramic Head, steril

Material:
BIOLOX® delta[2] Ceramic

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

NOTE
Implant only in combination with polyethylene cups and inlays (UHMWPE) or with BIOLOX® delta[2] inlays from CeramTec GmbH.

BioBall DELTA™ Ceramic Head may only be used with the12/14 und 14/16 BioBall™ Adapters and with the BioBall™ Adapter for special tapers MS 10/12 and MSV4 (Standard size M-3XL/Offset size M-XL).

BioBall™ Duo Head with pre-assembled BioBall™ Metal Head, steril

Material: Vivium®[1], UHMWPE

Ref.	Ø
HM30342	42 mm
HM30343	43 mm
HM30344	44 mm
HM30345	45 mm
HM30346	46 mm
HM30347	47 mm

Ref.	Ø
HM30348	48 mm
HM30349	49 mm
HM30350	50 mm
HM30351	51 mm
HM30352	52 mm
HM30353	53 mm

Ref.	Ø
HM30354	54 mm
HM30355	55 mm
HM30356	56 mm
HM30357	57 mm
HM30358	58 mm

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

5.3 BioBall™ Adapter System Instruments

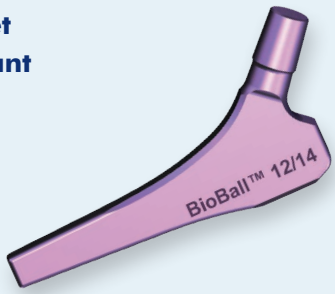
BioBall™ AdapterSelector™

Ref.	Description
HI39006	AdapterSelector™ 12/14

Ref.	Description
HI39007	AdapterSelector™ 14/16

Further types for special adapters on request.

BioBall™ Offset PositionAssistant



Ref.	Description
HM39106	Offset PositionAssistant 12/14
HM39107	Offset PositionAssistant 14/16

Further types for special adapters on request.

BioBall™ Trial Adapter

Length	Ref. Standard 12/14	Ref. Offset 12/14	Ref. Standard 14/16	Ref. Offset 14/16
S (-3,0)	HM40121	-	-	-
M (0)	HM40122	HM40222	HM40142	-
L (+3,5)	HM40123	HM40223	HM40143	-
XL (+7,0)	HM40124	HM40224	HM40144	-
2XL (+10,5)	HM40125	HM40225	HM40145	HM40445
3XL (+14,0)	HM40126	HM40226	HM40146	HM40446
4XL (+17,5)	HM40127	HM40227	HM40147	HM40447
5XL (+21,0)	HM40128	HM40228	HM40148	HM40448

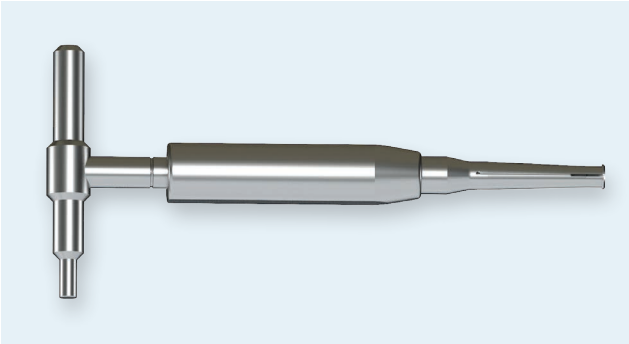
BioBall™ Trial Heads

Ref.	Ø
HM40028	28
HM40132	32
HM40033	33
HM40035	35
HM40036	36
HM40038	38
HM40040	40
HM40342	42

Ref.	Ø
HM40343	43
HM40344	44
HM40345	45
HM40346	46
HM40347	47
HM40348	48
HM40349	49
HM40350	50

Ref.	Ø
HM40351	51
HM40352	52
HM40353	53
HM40354	54
HM40355	55
HM40356	56
HM40357	57
HM40358	58

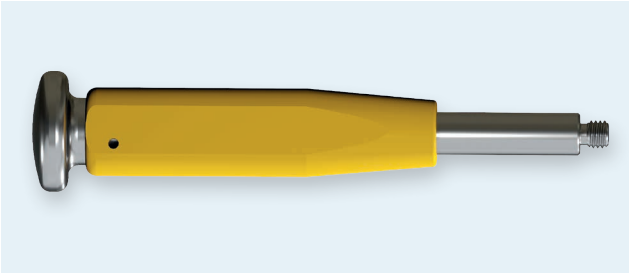
Adapter Extractor	
Ref.	HM20001

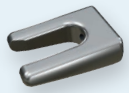
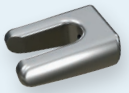
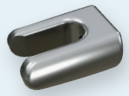


Extractor Sleeve for Adapter 12/14 S	
	Ref.
	HM20002

Extractor Sleeve for Adapter 14/16 M	
	Ref.
	HM20003

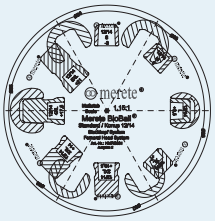
Handle	
Ref.	HM10005



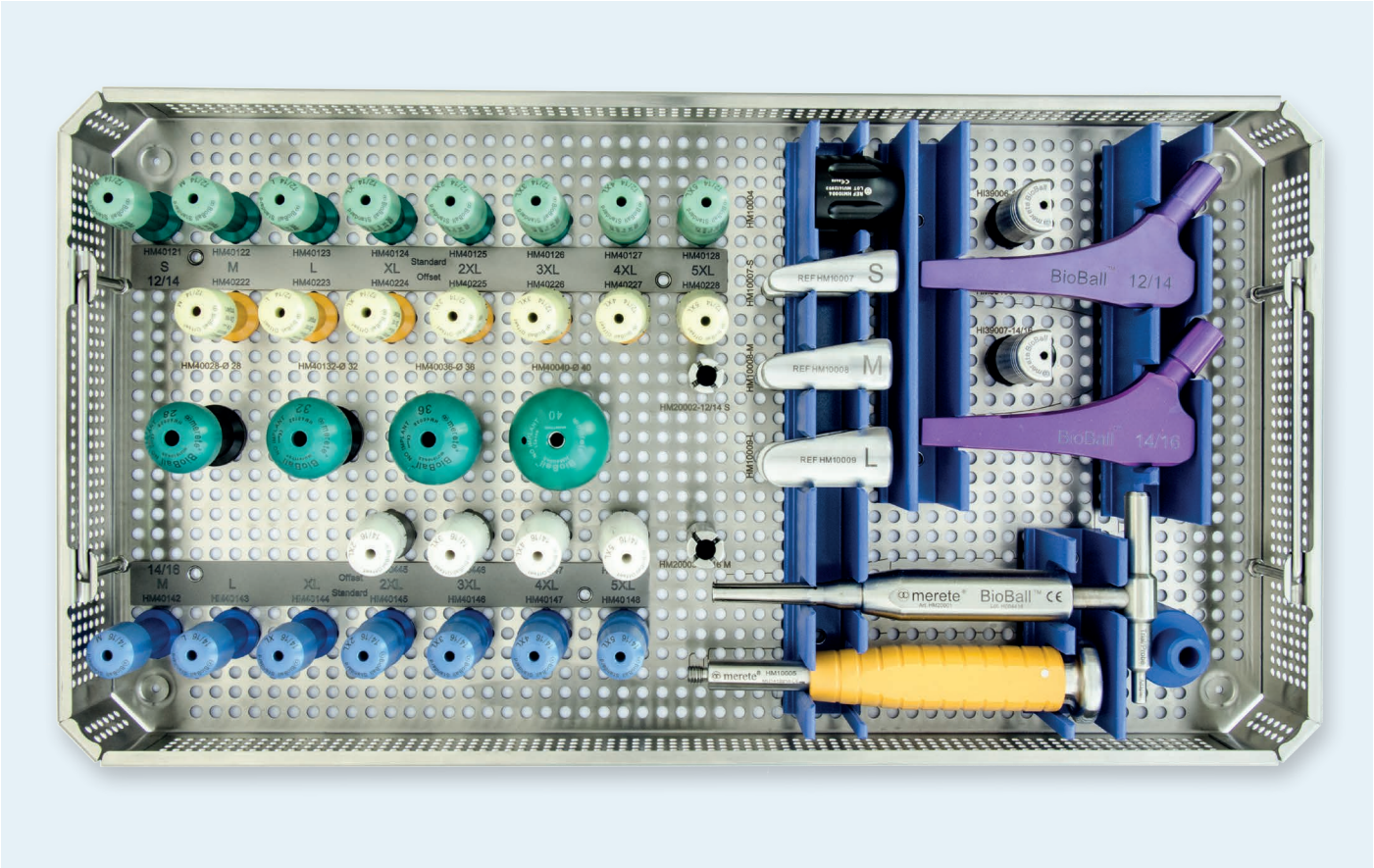
Separating Wedge	Size	Ref.
	S	HM10007
	M	HM10008
	L	HM10009

Head-Impactor		
	Ref.	HM10004

SteriPen™ SteriMarker™		VE (Slice)
Ref.	EP13403	50

Pre-Operative Planning: X-Ray templates	Ref.	Typ
	HMRS001	12/14 Standard
	HMRS005	12/14 Offset
	HMRS002	14/16 Standard
	HMRS006	14/16 Offset

BioBall™ Tray Standard



Ref.	Bezeichnung
HM30770	BioBall™ Instrument tray 12/14 und 14/16 Standard

Tray contents are described on pages 34 -35.

5.4. BioBall™ Literature

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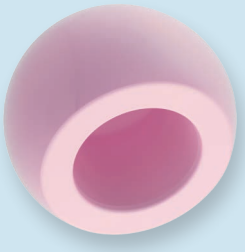
6. Overview of the BioBall® System

BioBall™
Metal Head

BioBall DELTA™
Ceramic* Head



BioBall™ Duokopf Bipolar
with pre-assembled Metal Head

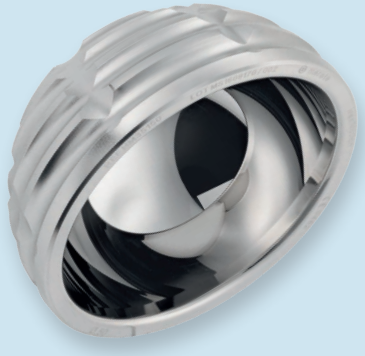
BioBall™ AdapterSelector™
Testing instrument for intraoperative
Inspection of the taper geometry

BioBall™ Adapter
Standard 12/14

BioBall™ Adapter
Standard 14/16

BioBall® System
Merete® Innovative Hip Solutions

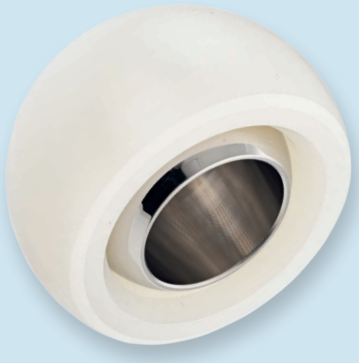
BioBall™ MaxiMotion™ Cup cemented



BioBall™ MaxiMotion™ Cup TPS-Coating and BONIT® non-cemented

BioBall™ MaxiMotion™ XPE Inlay

with pre-assembled Metal Head

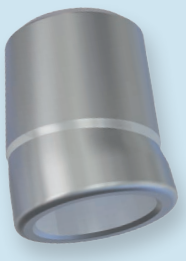


BioBall™ MaxiMotion™ XPE Inlay

with pre-assembled BioBall DELTA™-Ceramic* Head

BioBall™ Adapter Offset 12/14

BioBall™ Adapter Offset 14/16



Other adapter sizes (tapers/ angles) available on request.

*BIOLOX® delta Ceramic is a registered tradeark of CeramTec GmbH

merete®

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