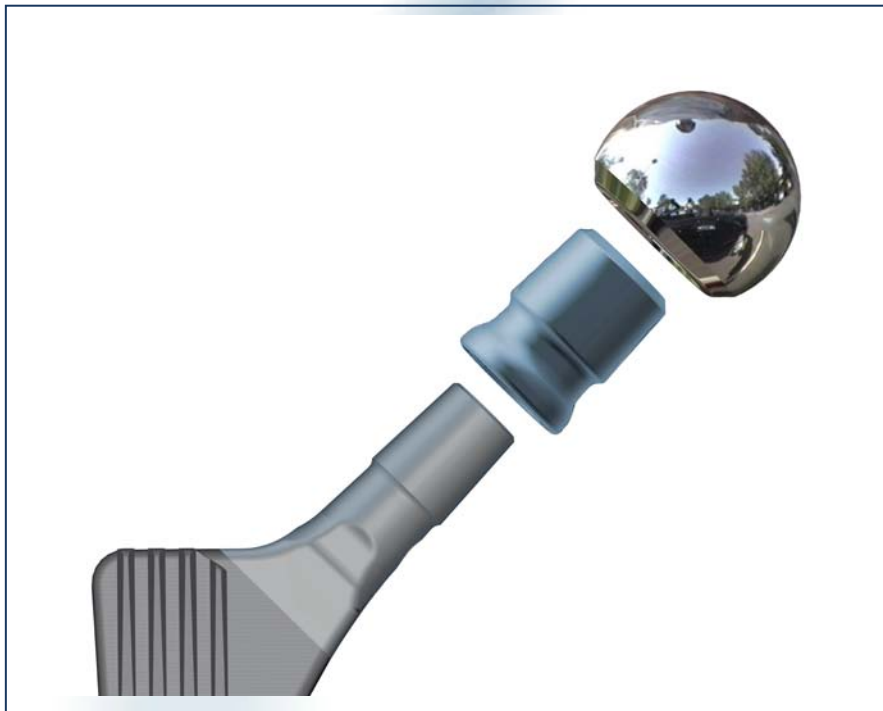




Manual

BioBall[®] Adapter System



Surgical Technique and Ordering Information

Merete Medical GmbH
Alt-Lankwitz 102
12247 Berlin, Germany
Tel.: +49 (0)30 77 99 80-0
Fax: +49 (0)30 76 68 03 61
E-Mail: service@merete.de
www.merete-medical.com

Contents

Topic	Page
1. Generalities.....	3
2. Indications.....	3
3. Contraindications	3
4. Factors Interfering with Success.....	3
5. System compatibility	4
5.1. Implant materials.....	5
6. Pre-operative planning	5
7. Use of the BioBall® Adapter System	6
7.2 BioBall® Adapter System Standard	7
7.3 BioBall® Adapter System Offset.....	8
8. Use of head extractor and separating.....	10
9. Ordering Information.....	12
BioBall® Adapter System	12

1. Generalities

The BioBall® Adapter System consists of a titanium adapter, which is combined with a fitting head. The main indication is the revision with well fitted prosthesis stems. The system may also be used for primary interventions in order to make intra operative corrections. The possibility to vary the offset, the neck length, the lateralization and the ante torsion is basically given.

The BioBall® adapter system is combined as desired with the following components:

- BioBall® Metal Head
- BioBall DELTA® Ceramic Head
- BioBall® Duo Head
- BioBall® Mono Head

For the improvement of the patient-specific optimal physiological joint reconstruction, the BioBall® Offset Adapter may also be used.

2. Indications

- For revision of the cup and the prosthesis stem in situ
- Revision of the articulating components
- Intra-Operative correction of offset, neck length, lateralization and antetorsion and/or retrotorsion

3. Contraindications

- Acute or chronic infections, local or systemic
- Severe muscle, nerve or vascular diseases, which would endanger the affected extremities
- Stem taper situated in situ shows evidence of severe damage (noticeable damage as erosion, abrasion/loss of material, scratches/ridges or similar injuries or visible deformation) or cannot be clearly identified
- All accompanying diseases which could endanger the functioning and the success of the implant
- Patients with mental or neurological disease conditions or patients who are not capable

4. Factors Interfering with Success

- Allergy to the implanted material, especially metal (e.g. chrome, nickel, etc.) but also polyethylene
- Adiposity or overweight of the patient
- Local bone tumors
- Osteoporosis or osteomalacia

- Malformations, congenital hip luxations, significant axial malposition in the knee area
- Systemic diseases or metabolic disturbances
- Alcohol or drug abuse
- Physical activity associated with strong shocks, in which the implant is exposed to blows and/or excessive strain (e.g. hard physical work, certain kinds of sports, etc.).

5. System compatibility

If the label does not give any other information BioBall® - Adapters can be used with BioBall® - Metal Heads or with BioBall® - Ceramic Heads.

BioBall® - Adapter are only intended to be used in combination with therefore approved Merete stems. If the surgeon wants to use a BioBall® - Adapter with a stem of another manufacturer he has to make sure that stem and adapter taper are compatible.

The use of BioBall® - Adapter with stems of other manufacturer has not been tested biomechanically. Under the condition that the correct dimensions have been chosen, a combination of the following materials is allowed:

- BioBall® - Metal Heads have to be combined exclusively with inlays or cups made of PE (UHMWPE).
- BioBall® - BIOLOX® DELTA¹ Heads have to be combined exclusively with inlays or cups made of BIOLOX® forte¹ / delta1 or with inlays or cups made of PE (UHMWPE).

Attention:

The use of BioBall® - adapters in combination with hip stems with a modular neck system is prohibited.

¹ BIOLOX® forte and BIOLOX® DELTA are trademarks of CeramTec AG

5.1. Implant materials

Heads can be made out of the following materials:

- a) BIOLOX® DELTA¹ (mixed ceramics)
- b) Vivium® (High Nitrogen Stainless Steel - ISO 5832-9)

Attention! The use of ceramic heads always contains a very small risk of breaking. The patient has to be informed of this risk.

Adapters are made out of the following material:

- a) TiAl6V4-ELI (ISO 5832-3)

The inlays or cups that can be combined considering point 5 can be made out of:

- a) BIOLOX® DELTA¹ (mixed ceramics)
- b) BIOLOX® forte¹ (Al₂O₃ ceramic ISO 6474)
- c) UHMWPE (ISO 5834-2)

Further information about the chemical composition and the mechanical characteristics of the used materials can be provided by Merete upon request.

6. Pre-operative planning

The BioBall® Adapter System allows a lengthening of existing, implanted hip stems on the basis of conical clamping. The operating surgeon is intra-operatively responsible for the compatibility of the stem taper with the BioBall® adapter. Therefore, the operating surgeon has to be certain of the compatibility before implantation. This planning must take place on the basis of detailed evaluations of the patient's x-rays, information from the implant pass combined with BioBall® manufacturers' specifications.

The taper specifications are marked on the product label and – as far as possible – on the implant with two numbers (e.g. 12/14 or 14/16).

In order to be able to react adequately to the intra-operative situations, it is advisable to have enough BioBall® components on stock.

For the pre-operative planning with x-rays, x-ray templates of the BioBall® Adapter System should be used. These are available for the standard tapers 12/14 and 14/16 as well as the offset version 12/14 (REF HMRS001, REF HMRS002, REF HMRS005, REF HMRS006).

Attention:

The BioBall® Adapter System may narrow the ROM of the *in situ* stem.

¹ BIOLOX® forte and BIOLOX® DELTA are trademarks of CeramTec AG

7. Use of the BioBall® Adapter System

After pre-selection of the components (head diameter, type and neck length), as well as observing the stem taper, a verification of the pre-selection by trial components, takes place.

Attention:

The reuse of BioBall® components is not allowed in any case. In case of revision after breakage of a ceramic head, the use of a metal head is not permitted. If the BioBall® Adapter is damaged or deformed in the taper zones, or the stem or the cup components show a different configuration or geometry, their use is forbidden. With an already used stem taper, the operating surgeon has to make sure, that the taper has no changes in its form, due to damage, such as severe wash-out areas, severe abrasion/material loss and/or deep scratches/ridges or similar defects. If the implant should be damaged as described prior, it is not allowed to be implanted.

7.1 Storage and Handling of Implants

The implants must be stored in the original packaging in a dry, clean place and at a temperature ranging from room temperature to cool but above freezing. Prior to using the implant, the sterilization expiration date on the product label has to be checked and the protective packaging inspected for any damage. If the packaging is damaged the implants should not be used. When removing the implant from the protective packaging, the rules of asepsis have to be followed. Joint endoprotheses must be handled with extreme care, since even the least damage to the surfaces can lead to increased wear and fatigue damage. Therefore even the subsequent marking of prostheses surfaces or touching them with metal or other hard objects (e.g. instruments) must be avoided. The mechanical processing and modification of medical components leads to a loss of authorization and is not allowed. Implants that were handled in an improper way or exhibit damage (e.g. scratches) may not be implanted.

Attention:

Never hit the BioBall® head or the adapter directly with a hammer!

Check the according use instructions when using a BioBall® DELTA® ceramic head!

7.2 BioBall® Adapter System Standard

- Careful removal of the existing head from the hip stem using the head extractor with appropriate separating wedge (fig. 1)
- Selection of the appropriate trial adapter for the desired shortening or extension and attachment on the prosthesis taper
- Selection of the trial head with the desired diameter and attachment on the trial adapter (fig. 2)
- Repositioning of the joint (fig. 3)
- Intra-operative verification of the Range of Movement to verify the neck length and ROM

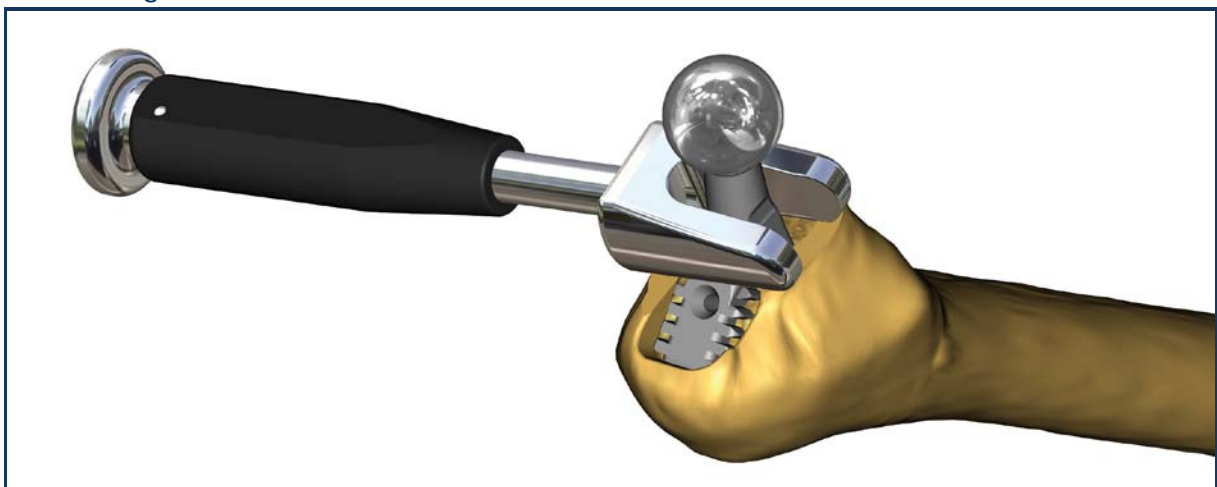


fig. 1: Use of the head extractor with an appropriate separating wedge

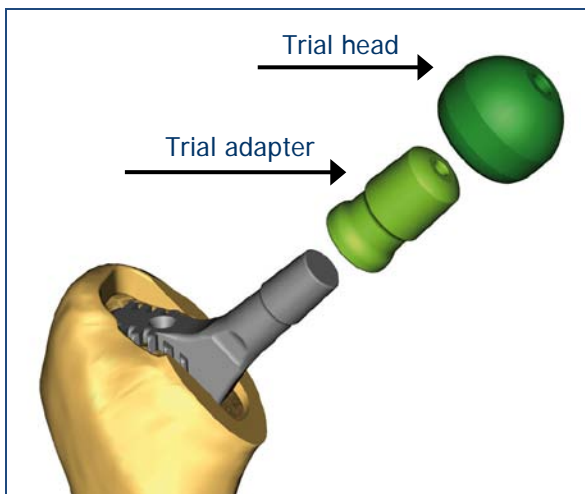


fig. 2: Mounting Trial Adapter System

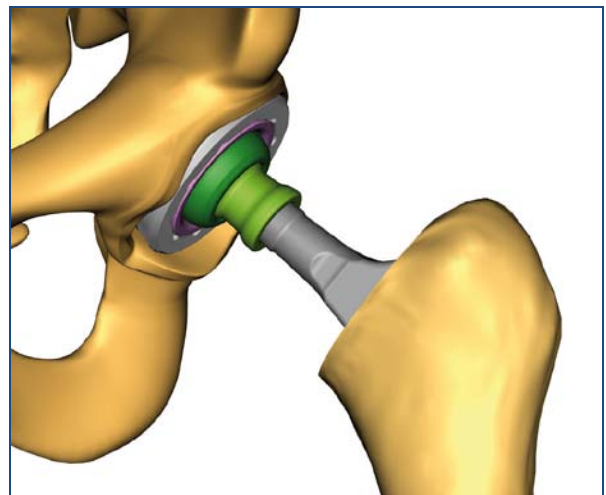


fig. 3: Trial System in reposition

Attention:

Trial head and trial adapter fit without press fit on the respective taper!

After a successful test run, replacement of the trial components by the corresponding implants (fig. 4 and 5)

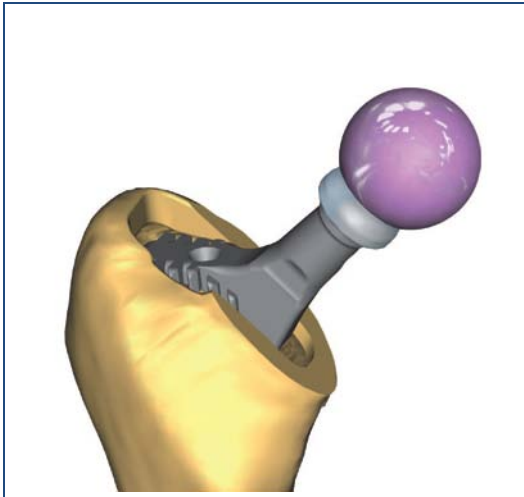


fig. 4: Attachment of the implant

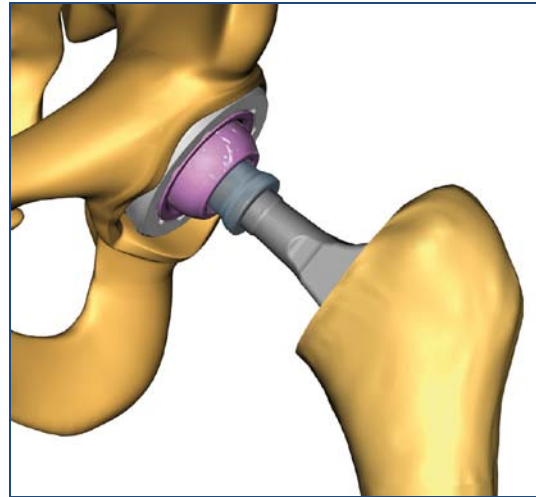


fig. 5: Implants in Reposition

7.3 BioBall® Adapter System Offset

- Careful removal of the existing head from the hip stem using the head extractor with appropriate separating wedge
- Selection of the desired offset trial adapter (regarding the desired neck length correction / offset adjustment) and attachment on the prosthesis taper

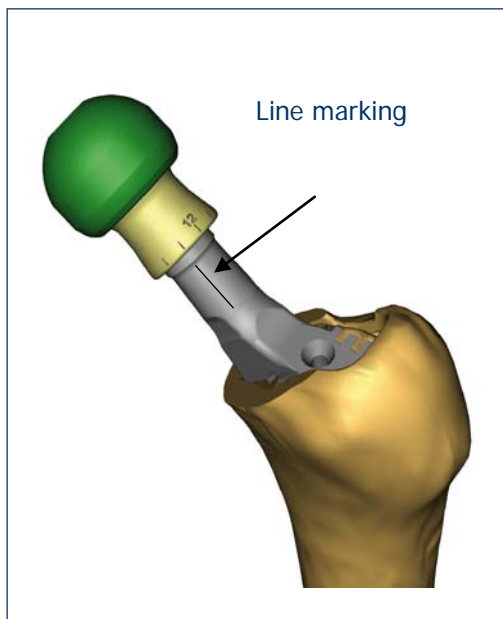


fig. 6: Alignment of the trial adapter

- To facilitate orientation, the offset implant and the offset trial components are marked with a scale. Using a sterile marker pen, e.g. Merete SteriPen™ (REF. EP13402) apply a marking line at an easily accessible place on the prosthesis neck. The marking serves for orientation during the directional positioning of the offset adapter (fig. 6)
- Alternatively, the orientation can be achieved using the arrow on the front surface of the trial adapter and the implant (fig. 7).



fig. 7: Additional orientation aid
(arrow marking displays the 12 O'clock position)

- Selection of the trial head with the desired diameter and attachment on the trial adapter
- Repositioning of the joint
- Perform intra-operative test run to check neck length, offset and ROM
- By turning the trial adapter counter clockwise, the CCD angle and retro- or antetorsion can be adjusted. When the desired position is reached, read the position of the trial adapter on the line marking and record.
- After a successful test run, the trial components are replaced by the corresponding implants.

Figures 8 - 10 show the possibilities of a change in position of the head epicenter by the offset adapter.

Examples of offset adjustment

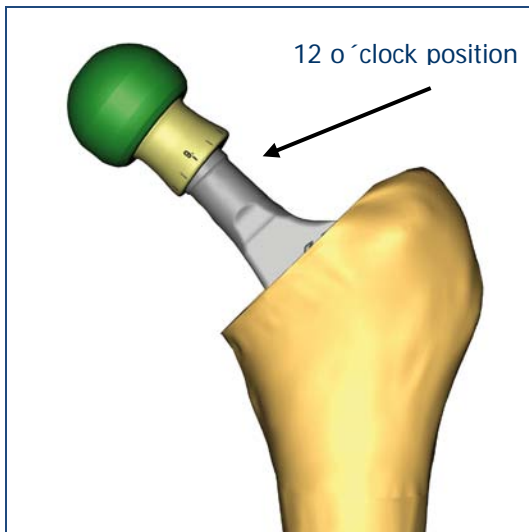


fig. 8: Lateralization of the stem

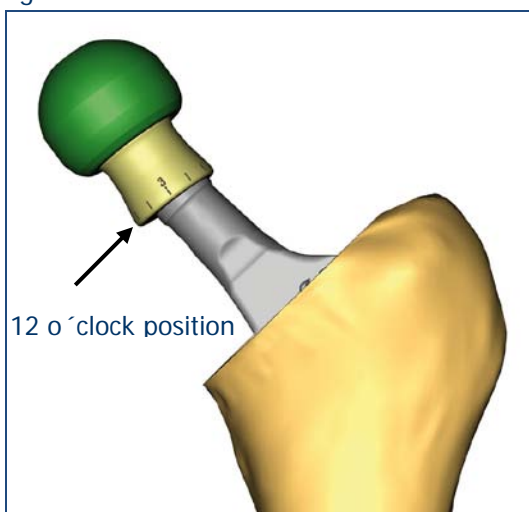


fig. 9: Medialization of the stem

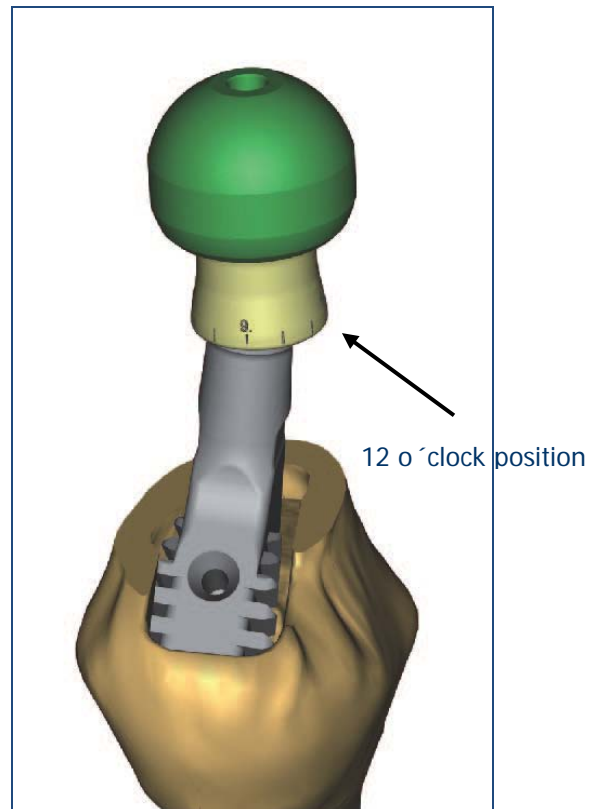


fig. 10: Antetorsion or retrotorsion

Attention: Offset trial adapter fits on the stem taper press fit!

8. Use of head extractor and separating

Should the case arise that intra-operatively the adapter is not in the correct position and the adapter has already achieved a conical clamping, the separating wedge can be used to release the connection. For this, the appropriate head extractor (REF HM10007 – REF HM10009) is threaded onto the separating wedge (REF HM10005). After this, the head extractor is positioned between adapter and stem and by slight pressure the adapter is released from the stem taper (fig. 11).

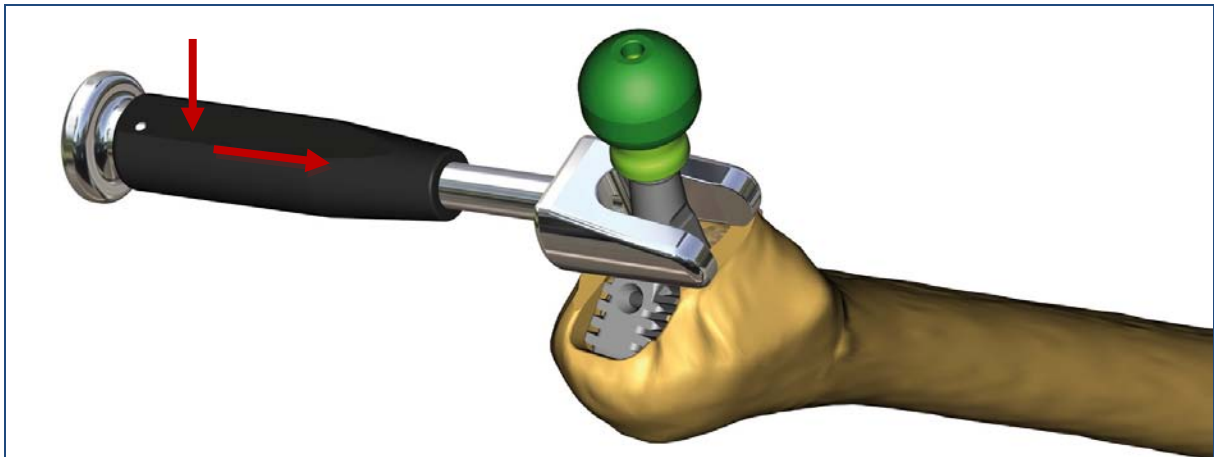


fig. 11: Use of the head extractor with an appropriate separating wedge

In the case where the BioBall® head has to be separated from the BioBall® Adapter, the adapter extractor (REF HM20001) should be used as follows:

- Loosen by unscrewing the clamp handle up to the ring marking (fig. 12).
- Push the BioBall® Adapter with the head over the separating sheath until the adapter engages behind the lip (fig. 13).
- Turn the clamp handle clockwise until the head is detached from the adapter (fig. 14).
- Turn the clamp handle counterclockwise until the ring becomes visible again.
- The BioBall® Adapter can be removed from the adapter extractor



fig. 12: Use of the adapter extractor

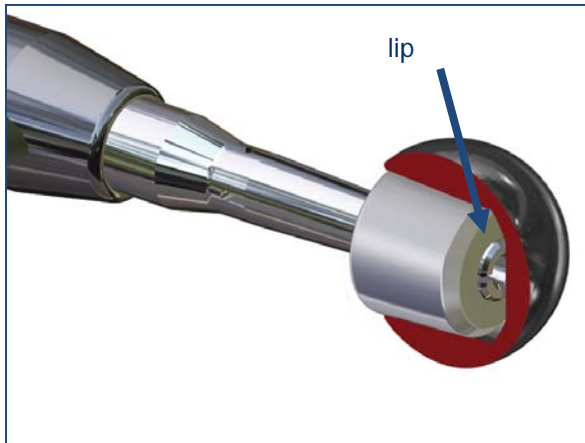


fig. 13: Representation of the Lip

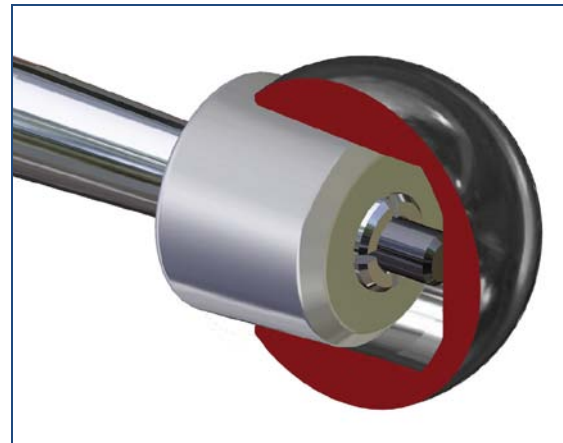


fig. 14: Pushing off the head

Separation of the Adapter and the Head (Adapter 12/14 S or 14/16 M)

Please note: If a BioBall® Adapter 12/14 of size S or a BioBall® Adapter 14/16 of size M was used, the extractor sleeve (REF HM20002/REF HM20003) must be attached to the adapter extractor in addition for separation of the BioBall® Head (fig. 15). Then the adapter extractor can be used as described in the step on page 10 (fig. 16).

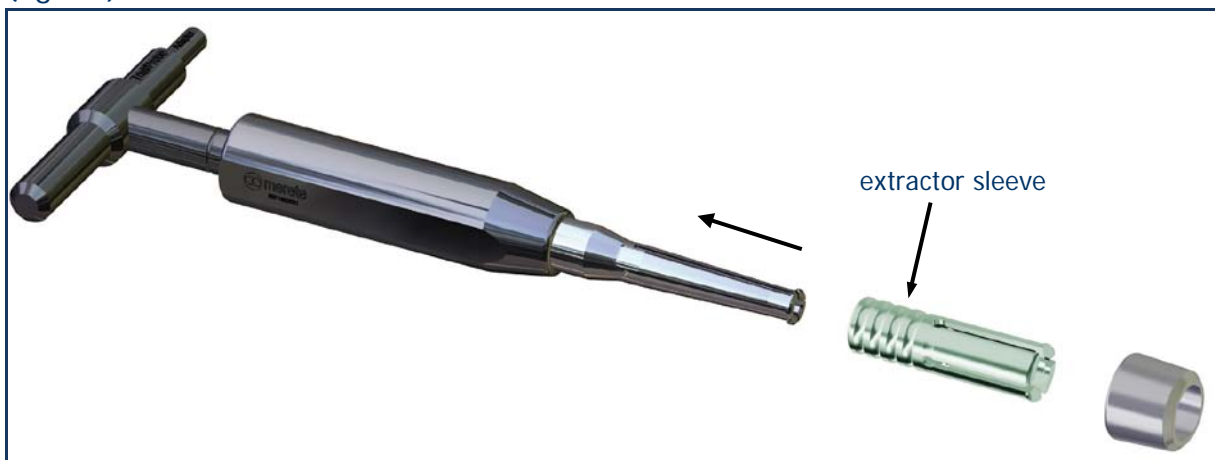


fig. 15: Attachment of the extractor sleeve to the adapter extractor




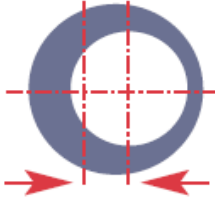


fig. 16: Use of the adapter extractor with extractor sleeve

9. Ordering Information

BioBall® Adapter System



Material: TiAl6V4 ELI (ISO 5832-3)

				
Neck Length	REF Standard	REF Standard	REF Offset 7,5°	REF Offset 7,5°
	12/14 sterile	14/16 sterile	12/14 sterile	14/16 sterile
S (-3,0)	HM30121	-	-	-
M (0)	HM30122	HM30142	HM30222	-
L (+3.5)	HM30123	HM30143	HM30223	-
XL (+7.0)	HM30124	HM30144	HM30224	-
2XL (+10.5)	HM30125	HM30145	HM30225	HM30445*
3XL (+14.0)	HM30126	HM30146	HM30226	HM30446*
4XL (+17.5)	HM30127	HM30147	HM30227	HM30447*
5XL (+21.0)	HM30128	HM30148	HM30228	HM30448*

*Use 14/16 Offset Adapter only with metal head

Adapters for more taper specifications are available upon request.

BioBall® Modular Heads (without BioBall® Adapter)

BioBall® Metal Head Material: Vivium® (ISO 5832-9)		BioBall DELTA® ceramic head Material: BIOLOX® DELTA ceramic	
			
REF. sterile	Ø	REF. sterile	Ø
HM30028	28 mm	HM50028	28 mm
HM30032	32 mm	HM50032	32 mm
HM30033	33 mm	HM50036	36 mm
HM30035	35 mm	HM50040	40 mm
HM30036	36 mm	HM50044	44 mm
HM30038	38 mm	HM50048	48 mm

Special sizes upon request.

Attention: see system compatibility (Point 5)!

Additional BioBall® Heads

BioBall® Duo Head Bipolar* Material: Vivium (ISO 5832-9), UHMWPE (ISO 5834-2)		BioBall® Mono head Material: Vivium® (ISO 5832-9)	
			
REF. sterile	Ø	REF. sterile	Ø
HM30342	42 mm	HM30242	42 mm
HM30343	43 mm	HM30243	43 mm
HM30344	44 mm	HM30244	44 mm
HM30345	45 mm	HM30245	45 mm
HM30346	46 mm	HM30246	46 mm
HM30347	47 mm	HM30247	47 mm
HM30348	48 mm	HM30248	48 mm
HM30349	49 mm	HM30249	49 mm
HM30350	50 mm	HM30250	50 mm
HM30351	51 mm	HM30251	51 mm
HM30352	52 mm	HM30252	52 mm
HM30353	53 mm	HM30253	53 mm
HM30354	54 mm	HM30254	54 mm
HM30355	55 mm	HM30255	55 mm
HM30356	56 mm	HM30256	56 mm
HM30357	57 mm	HM30257	57 mm
HM30358	58 mm	HM30258	58 mm


* Outer and inner head pre-mounted.
Economic and safe solution.

BioBall® Trial Adapters



Neck Length	REF Standard	REF Standard	REF Offset 7,5°	REF Offset 7,5°
	12/14	14/16	12/14	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	REF	Ø	REF	Ø
	HM40028	28	HM40343	43	HM40351	51
	HM40132	32	HM40344	44	HM40352	52
	HM40033	33	HM40345	45	HM40353	53
	HM40035	35	HM40346	46	HM40354	54
	HM40036	36	HM40347	47	HM40355	55
	HM40038	38	HM40348	48	HM40356	56
	HM40040	40	HM40349	49	HM40357	57
	HM40342	42	HM40350	50	HM40358	58

Handle for Duo and Mono Trial Heads

	REF
	HM10006

Adapter extractor

Extractor sleeve

					
				REF	HM20001
				12/14 S	HM20002
				14/16 M	HM20003

Universal Handle

Head Impactor

			
REF	HM10005	REF	HM10004

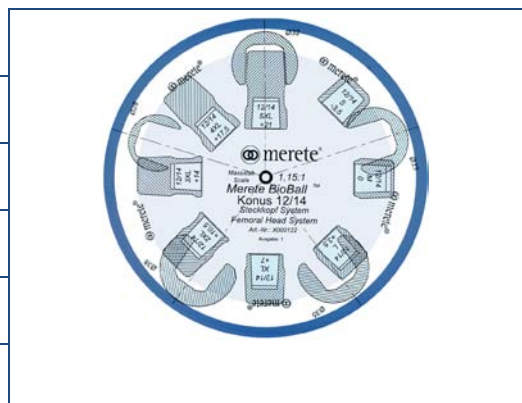
Separating Wedge

REF	Size
HM10007	S
HM10008	M
HM10009	L



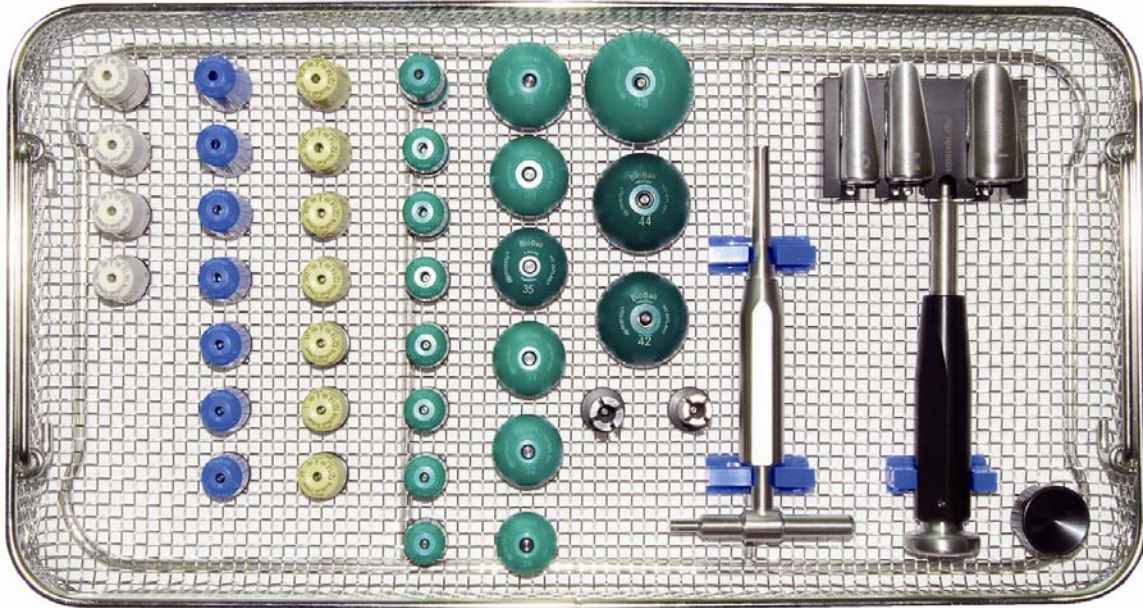
X-Ray Templates

REF	Type
HMRS001	12/14 Standard
HMRS005	12/14 Offset
HMRS002	14/16 Standard
HMRS006	14/16 Offset



BioBall® Sterilization tray Standard

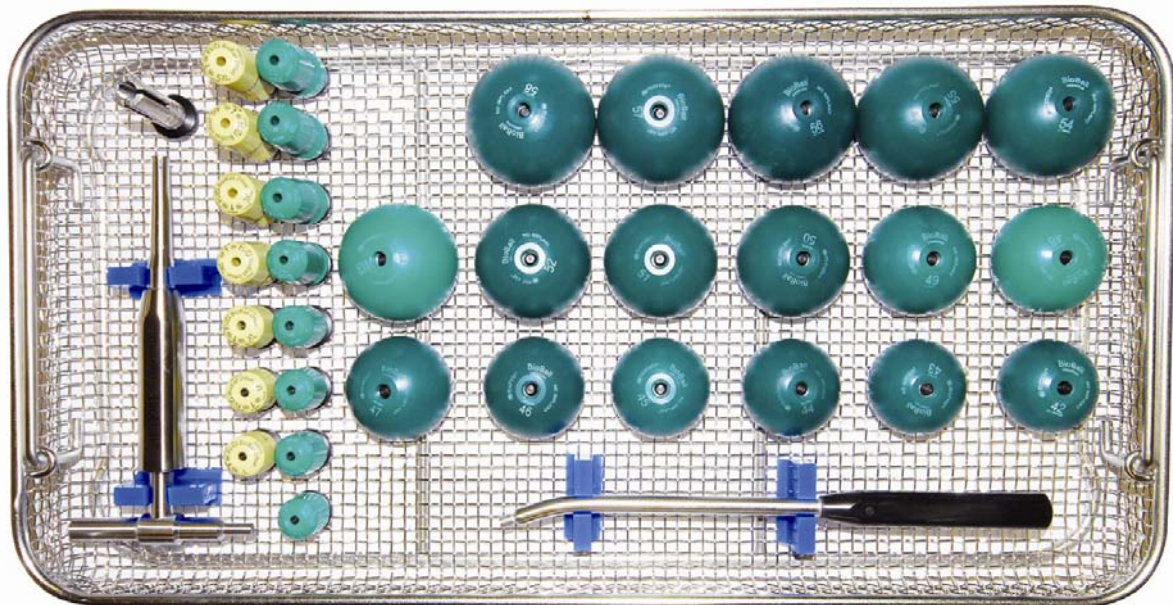
With 1 Instrument each, Trial heads and trial adapters



REF	HM30600
-----	---------

BioBall® Duo/Mono Sterilization Tray

Trial heads, separating wedge, standard trial adapters, handle



REF	HM50500
-----	---------