ZIMMER BIOMET
Moving You Forward.™

Scheda Tecnica

TESTE FEMORALI ZB IN CoCr (12/14 e T1)

SC_N_3876Rev_25/01/2024 17:40:29

AVVERTENZA

Le informazioni contenute nella presente scheda tecnica, scritta dalla società di distribuzione in Italia, non sono istruzioni per l'uso e devono essere utilizzate solo per la valutazione del prodotto in fase di acquisizione

Distributore Italia	**Zimmer Biomet Italia S.r.l.**
Destinazione d'uso	Teste femorali metalliche di sistema totale per sostituzione articolare coxofemorale Freedom - Teste femorali metalliche (lega di CoCrMo) di sistema totale ritentivo per sostituzione articolare coxo-femorale.
Indicazioni	Tra le indicazioni d'uso delle teste femorali rientrano le seguenti: - Malattie degenerative non infiammatorie delle articolazioni comprese osteoartriti, necrosi avascolare e artrite post-traumatica - Artrite reumatoide - Correzione di deformità funzionale - Revisione di fallita ricostruzione articolare o trattamento dell'articolazione - Trattamento di fratture del collo femorale e trocanteriche del femore Il sistema acetabolare ritentivo Freedom® è indicato per l'utilizzo in una protesi totale d'anca, come primo impianto o revisione nei seguenti casi: In pazienti che hanno un alto rischio di dislocazione a causa di dislocazioni precedenti. Perdita ossea. Lassità tissutale o legamentosa. Malattie neuromuscolari. Instabilità intraoperatoria. Per tutti gli altri casi dove è consigliabile un inserto acetabolare ritentivo. Dolore all'articolazione e/o articolazione compromessa da artropatia.degenerativa non infiammatoria, comprese osteoartrite, artrite reumatoide, artrite traumatica e necrosi a-vascolare della testa femorale. Deformazione funzionale dell'anca. Revisione di artroplastica articolare parziale o totale pregressa fallita. Distacco e fratture del collo femorale e fratture trocanteriche del femore prossimale con coinvolgimento della testa, tali da non consentire l'applicazione di altre tecniche.

Controindicazioni	L'utilizzo delle teste femorali è controindicato nei pazienti che presentino: - Infezioni, sepsi, osteomielite - Pazienti che non collaborano o con disordini neurologici che li rendono incapaci di seguire le istruzioni - Osteoporosi - Disordini metabolici che possono alterare la formazione ossea - Osteomalacia - Infezione con focolaio locale e distante - Distruzione rapida delle articolazioni, perdita di osso marcata o riassorbimento dell'osso visibile da radiografia - Insufficienza vascolare, atrofia muscolare o malattie neuromuscolari. - Immaturità scheletrica - Obesità morbosa - Reazioni di sensibilità ai corpi estranei. Se si sospettano reazioni di sensibilità ai materiali, è necessario eseguire dei test prima dell'impianto - Tutte le condizioni che possono interferire con la sopravvivenza degli impianti come morbo di Paget, morbo di Charcot, anemia falciforme o trait falcemico, atrofia muscolare degli arti inferiori o malattie neuromuscolari Il sistema acetabolare ritentivo Freedom® è controindicato nei pazienti che presentino: Pazienti che non collaborano o con disordini neurologici che rifiutano o non sono in grado di seguire le istruzioni. Osteoporosi. Disordinimetabolici che possono alterare la funzione ossea.Osteomalacia. Focolai distanti di infezione che possonoestendersi fino alla sede dell'impianto. Reazioni di sensibilità aicorpi estranei. Se si sospettano reazioni di sensibilità aimateriali, è necessario eseguire dei test prima dell'impianto.Distruzione rapida delle giunture, perdita di osso marcata oriassorbimento dell'osso visibile da radiografia. Insufficienzavascolare, atrofia muscolare o malattie neuromuscolari.
Anno introduzione Mondo	N/D
Anno introduzione Italia	2022

Descrizione del Prodotto

- Le teste femorali metalliche sono sferiche e hanno un raggio di curvatura costante per articolare con la componente acetabolare.
- Il foro dalla caratteristica forma tronco-conica è disponibile nella versione 12/14 (base minore circa 12mm, base maggiore circa 14mm) e si accoppia tramite meccanismo di bloccaggio a Cono Morse con il collo femorale.
- Sono disponibili in diversi diametri e con una lunghezza del collo diversa (diverso offset), in modo da ricostruire al meglio i parametri anatomici.
- Sono realizzate in lega di cobalto-cromo-molibdeno, un materiale con proprietà meccaniche tali da poter essere utilizzato per accoppiamenti meccanici a scorrimento e/o rotolamento reciproco.
- La superficie è lucidata a specchio per limitare la formazione di detriti di usura nel movimento di

rotolamento reciproco tra testina e inserto articolare.

Le teste femorali ritentive Freedom® sono caratterizzate da una geometria appiatita a livello circonferenziale, con un grado di inclinazione di 15°. Questo permette ai chirurghi di introdurre più facilmente la testa, garantendo una maggiore resistenza alla dislocazione.
Il foro dalla caratteristica forma tronco-conica è disponibile nelle versioni 12/14 e T1.
Si accoppiano tramite meccanismo di bloccaggio a Cono Morse con il collo femorale.
Sono disponibili nel diametro di 36 mm e in lunghezze di collo diverse (diverso offset), in modo da ricostruire al meglio i parametri anatomici.
La testa da 36 mm, di grande diametro, è progettata per garantire una superiore stabilità articolare in situazioni in cui tale stabilità può essere a rischio, in quanto offre un maggiore range of motion con conseguente minor rischio di impingement e lussazione.
Sono realizzate in lega di cobalto-cromo-molibdeno (CoCrMo), un materiale con proprietà meccaniche tali da poter essere utilizzato per accoppiamenti meccanici a scorrimento e/o rotolamento reciproco. La superficie è lucidata a specchio per limitare la formazione di detriti di usura nel movimento di rotolamento reciproco tra testina e cotile.

Strumentario

E’ disponibile un set di strumenti chirurgici specificatamente disegnati per l’impianto delle teste femorali. Questi strumenti sono essenziali per il loro corretto inserimento. Gli strumenti sono fabbricati in acciaio inossidabile di grado appropriato, con manici ed altri componenti prodotti in materiali plastici. Sono disponibili inoltre degli strumenti che consentono di fissare la testa sullo stelo femorale o di rimuoverla se il diametro o la lunghezza del collo non risulta appropriato.

Misure Disponibili

Le teste femorali sono disponibili con diametro da 22.2 a 44 mm e offset variabile.

Le teste femorali ritentive Freedom® sono disponibili nei diametri da 32 e 36 mm e in lunghezze di collo che variano; per le testine da 32mm sono presenti le misure -3, 0, +3, +6 e per le testine da 36mm le misure -6, -3, 0, +3, +6, +9, con cono morse da 12/14 e T1.

Prodotti

Codice	Descrizione	CND	RDM	UDI
11-107016	FREEDOM TESTA RITENTIVA TAPER 1 36MM -6MM	P090804050202	688667 (MDD)	00880304203433
11-107017	FREEDOM TESTA RITENTIVA TAPER 1 36MM -3MM	P090804050202	688667 (MDD)	00880304203457
11-107018	FREEDOM TESTA RITENTIVA TAPER 1 STD	P090804050202	688667 (MDD)	00880304203464
11-107019	FREEDOM TESTA RITENTIVA TAPER 1 36MM +3MM	P090804050202	688667 (MDD)	00880304203471

Codice	Descrizione	CND	RDM	UDI
11-107020	FREEDOM TESTA RITENTIVA TAPER 1 36MM +6MM	P090804050202	688667 (MDD)	00880304203488
11-107021	FREEDOM TESTA RITENTIVA TAPER 1 36MM +9MM	P090804050202	688667 (MDD)	00880304203495
14-107016	FREEDOM TESTA RITENTIVA 12/14 -6MM	P090804050202	688667 (MDD)	00880304432505
14-107017	FREEDOM TESTA RITENTIVA12/14 -3MM	P090804050202	688667 (MDD)	00880304432604
14-107018	FREEDOM TESTA RITENTIVA 12/14 STD	P090804050202	688667 (MDD)	00880304432529
14-107019	FREEDOM TESTA RITENTIVA 12/14 +3MM	P090804050202	688667 (MDD)	00880304432536
14-107020	FREEDOM TESTA RITENTIVA 12/14 +6MM	P090804050202	688667 (MDD)	00880304432499
14-107021	FREEDOM TESTA RITENTIVA 12/14 +9MM	P090804050202	688667 (MDD)	00880304432512
802202805	ZB 12/14 COCR HD 28MM X +10.5	P090804050202	2002681 (MDD)	00889024498815
802202201	ZB 12/14 COCR HD 22.2MM X -2	P090804050202	2001501 (MDD)	00889024498747
802202202	ZB 12/14 COCR HD 22.2MM X +0	P090804050202	2001504 (MDD)	00889024498754
802202203	ZB 12/14 COCR HD 22.2MM X +3	P090804050202	2001505 (MDD)	00889024498761
802202801	ZB 12/14 COCR HD 28MM X -3.5	P090804050202	1901993 (MDD)	00889024498778
802202802	ZB 12/14 COCR HD 28MM X +0	P090804050202	1901993 (MDD)	00889024498785
802202803	ZB 12/14 COCR HD 28MM X +3.5	P090804050202	1901993 (MDD)	00889024498792
802202804	ZB 12/14 COCR HD 28MM X +7	P090804050202	1901993 (MDD)	00889024498808
802203201	ZB 12/14 COCR HD 32MM X -3.5	P090804050202	2001513 (MDD)	00889024498822
802203202	ZB 12/14 COCR HD 32MM X +0	P090804050202	2001517 (MDD)	00889024498839
802203203	ZB 12/14 COCR HD 32MM X +3.5	P090804050202	2001518 (MDD)	00889024498846
802203204	ZB 12/14 COCR HD 32MM X +7	P090804050202	2001520 (MDD)	00889024498853
802203205	ZB 12/14 COCR HD 32MM X +10.5	P090804050202	2002682 (MDD)	00889024498860
802203601	ZB 12/14 COCR HD 36MM X -3.5	P090804050202	2001525 (MDD)	00889024498877
802203602	ZB 12/14 COCR HD 36MM X +0	P090804050202	2001526 (MDD)	00889024498884
802203603	ZB 12/14 COCR HD 36MM X +3.5	P090804050202	2001527 (MDD)	00889024498891
802203604	ZB 12/14 COCR HD 36MM X +7	P090804050202	2001540 (MDD)	00889024498907
802203605	ZB 12/14 COCR HD 36MM X +10.5	P090804050202	2002683 (MDD)	00889024498914
802204001	ZB 12/14 COCR HD 40MM X -3.5	P090804050202	2002661 (MDD)	00889024498921

Codice	Descrizione	CND	RDM	UDI
802204002	ZB 12/14 COCR HD 40MM X +0	P090804050202	2002665 (MDD)	00889024498938
802204003	ZB 12/14 COCR HD 40MM X +3.5	P090804050202	2002666 (MDD)	00889024498945
802204004	ZB 12/14 COCR HD 40MM X +7	P090804050202	2002667 (MDD)	00889024498952
802204005	ZB 12/14 COCR HD 40MM X +10.5	P090804050202	2002686 (MDD)	00889024498969
802204401	ZB 12/14 COCR HD 44MM X -3.5	P090804050202	2002672 (MDD)	00889024498976
802204402	ZB 12/14 COCR HD 44MM X +0	P090804050202	2002675 (MDD)	00889024498983
802204403	ZB 12/14 COCR HD 44MM X +3.5	P090804050202	2002676 (MDD)	00889024498990
802204404	ZB 12/14 COCR HD 44MM X +7	P090804050202	2002678 (MDD)	00889024499003
802204405	ZB 12/14 COCR HD 44MM X +10.5	P090804050202	2002687 (MDD)	00889024499010
802403201	ZB 12/14 COCR FRDM 32MM X -3	P090804050202	2305987 (MDD)	00889024499027
802403202	ZB 12/14 COCR FRDM 32MM X +0	P090804050202	2305987 (MDD)	00889024499034
802403203	ZB 12/14 COCR FRDM 32MM X +3	P090804050202	2305987 (MDD)	00889024499041
802403204	ZB 12/14 COCR FRDM 32MM X +6	P090804050202	2305987 (MDD)	00889024499058
802403601	ZB 12/14 COCR FRDM 36MM X -6	P090804050202	2305987 (MDD)	00889024499065
802403602	ZB 12/14 COCR FRDM 36MM X -3	P090804050202	2305987 (MDD)	00889024499072
802403603	ZB 12/14 COCR FRDM 36MM X +0	P090804050202	2305987 (MDD)	00889024499089
802403604	ZB 12/14 COCR FRDM 36MM X +3	P090804050202	2305987 (MDD)	00889024499096
802403605	ZB 12/14 COCR FRDM 36MM X +6	P090804050202	2305987 (MDD)	00889024499102
802403606	ZB 12/14 COCR FRDM 36MM X +9	P090804050202	2305987 (MDD)	00889024499119
110025126	FRDM CNSTR HD 32MM T12/14 +3MM	P090804050202	1560837 (MDD) 2378012 (MDR)	00880304687455
110025127	FRDM CNSTR HD 32MM T12/14 +6MM	P090804050202	1560837 (MDD) 2378012 (MDR)	00880304687462
110025128	FRDM CNSTR HD 32MM T12/14 STD	P090804050202	1560837 (MDD) 2378012 (MDR)	00880304687479
110025129	FRDM CNSTR HD 32MM T12/14 -3MM	P090804050202	1560837 (MDD) 2378012 (MDR)	00880304687486
110025130	FREEDOM CONSTR HD 32MM T1 +3MM	P090804050202	1560837 (MDD) 2378012 (MDR)	00880304687493
110025131	FREEDOM CONSTR HD 32MM T1 STD	P090804050202	1560837 (MDD) 2378012 (MDR)	00880304687509
110025132	FREEDOM CONSTR HD 32MM T1 -3MM	P090804050202	1560837 (MDD) 2378012 (MDR)	00880304687516

Codice	Descrizione	CND	RDM	UDI
110025133	FREEDOM CONSTR HD 32MM T1 -6MM	P090804050202	1560837 (MDD)2378012 (MDR)	00880304687523
110025134	FREEDOM CONSTR HD 32MM T1 +6MM	P090804050202	1560837 (MDD) 2378012 (MDR)	00880304687530

Materiali

Le teste femorali metalliche sono realizzate in lega di cobalto-cromo-molibdeno (Protasul-20), utilizzata allo scopo di migliorare la resistenza agli sforzi di taglio e quindi minimizzare l'usura del polietilene. Le proprietà meccaniche (statiche e dinamiche) di questo materiale garantiscono l'affidabilità meccanica strutturale della protesi e la finitura superficiale (a specchio) rende questo materiale ideale per accoppiamenti meccanici a scorrimento e/o rotolamento reciproco.

Ref	Nome Materiale	Nome Commerciale	Standard	Composizione chimica	Nichel
1	CoCrMo	Lega di Cobalto-Cromo-Molibdeno	ASTM F1537	*C max 0.14%; Cr max 30.0% - min 26.0%; Mo max 7.0% - min 5.0%; Ni max 1.0%; Fe max 0.75%; S max 1.0%; Mn max 1.0%; N max 0.25%; Co per la restante %*	Sì

RDM

688667 (MDD)	
Fabbricante	Biomet Orthopedics Inc
Rappresentante EU	Biomet Global Supply Chain Center B.V.
Classe di rischio	III
CND	P090804050202
Sterile	Sì
Metodo Sterilizzazione	raggi gamma
Durata sterilità (mesi)	120
Confezione primaria	Doppio blister termoformato plastica-altro
Materiali	Ref: 1

525 (MDD), 2001526 (MDD), 2001527 (MDD), 2001540 (MDD), 2002683 (MDD), 2002661 (	
Fabbricante	Zimmer Inc
Rappresentante EU	Biomet Global Supply Chain Center B.V.

525 (MDD), 2001526 (MDD), 2001527 (MDD), 2001540 (MDD), 2002683 (MDD), 2002661 (	
Classe di rischio	III
CND	P090804050202
Sterile	Sì
Metodo Sterilizzazione	raggi gamma
Durata sterilità (mesi)	120
Confezione primaria	Doppio blister termoformato polietilene

1560837 (MDD) 2378012 (MDR)	
Fabbricante	Biomet Orthopedics Inc
Rappresentante EU	Biomet Global Supply Chain Center B.V.
Classe di rischio	III
CND	P090804050202
Sterile	Sì
Metodo Sterilizzazione	raggi gamma
Durata sterilità (mesi)	120
Confezione primaria	Doppio blister termoformato polietilene

Compatibilità

Le teste femorali in lega di cromo-cobalto sono progettate per essere utilizzate in accoppiamento a steli femorali Zimmer Biomet e a inserti in polietilene Poly Ringloc, AllPoly cementati, E1, Arcom XL, Vivacit-E e Longevity.

Le teste femorali ritentive Freedom® sono progettate per essere utilizzate in associazione a inserti ritentivi Freedom®.

Compatibilità RMN

Per avere le corrette informazioni riguardanti la compatibilità alla risonanza magnetica degli impianti di produzione ZIMMER BIOMET fare riferimento alle etichette-prodotto e ai relativi foglietti illustrativi. Se tali informazioni non fossero disponibili, significa che ZIMMER BIOMET non ha ancora valutato la sicurezza e la compatibilità del dispositivo con la Risonanza Magnetica (RM).

Certificazioni del Sistema di Qualità e Marcatura CE

Le società del gruppo ZIMMER BIOMET sono in possesso di un Sistema di Qualità che ha conseguito la certificazione ISO 13485:2016 (requisiti per dispositivi medici). I prodotti ZIMMER BIOMET dispongono del marchio CE in quanto conformi ai requisiti essenziali richiesti dalla direttiva 93/42/CEE e successivi aggiornamenti concernente i dispositivi medici.

Zimmer Biomet™ CoCr and Ceramic Femoral Heads

Surgical Technique

ZIMMER BIOMET

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Introduction

This document is intended to describe general surgical technique steps for Zimmer Biomet femoral heads made from cobalt-chromium alloy and ceramic. This surgical technique is applicable to part numbers included within ordering information '2307.X-GLBL-en-Ceramic Heads Ordering Information' and '1839.X-GLBL-en-CoCr Heads Ordering Information'.

For specific product compatibility, reference the following compatibility website: https://IFU.zimmer.com

CoCr Femoral Heads

Zimmer Biomet CoCr Femoral Heads and Freedom® Constrained Heads are made from cobalt-chromium molybdenum alloy. They are manufactured to include a 12/14 taper or Type I taper and are offered in a variety of head diameters and neck configurations. See the applicable Ordering Information document for detailed product descriptions.

CoCr femoral heads are intended for mating with titanium alloy, cobalt-chromium molybdenum alloy, cobalt-chromium-nickel-molybdenum alloy and stainless steel femoral stems.

Ceramic Femoral Heads

Zimmer Biomet offers ceramic heads that are made from an aluminum oxide matrix composite ceramic in accordance with ISO 6474-2.

Ceramic femoral heads are offered in non-sleeved and sleeved designs. Non-sleeved heads are manufactured to include a 12/14 taper or Type I taper. Sleeved options include taper adaptors compatible with 12/14, Type 1 and 6° femoral stem tapers. See the applicable Ordering Information document for detailed product descriptions.

Non-sleeved ceramic femoral heads should only be implanted on pristine/non-damaged stems. In revision cases, a sleeved ceramic femoral head with a taper adaptor should be implanted.

The Zimmer Biomet Ceramic Heads are intended for use as a component of a total hip or hemi-hip prosthesis in primary and revision patients. Refer to the Zimmer Biomet Ceramic Heads package insert for the indications for use.

Non-sleeved Zimmer Biomet Ceramic heads with a 12/14 taper (part numbers beginning with 8026) and Type 1 taper (part numbers beginning with 8028) are intended for mating with Ti-6Al-4V Alloy, Ti-6Al-7Nb Alloy, Cobalt-Chromium Molybdenum Alloy and Cobalt-Chromium-Nickel-Molybdenum Alloy femoral stems equipped with tapered necks.

Do not couple 22.2 mm ceramic head sizes with cobalt-chrome femoral stems. Generally, this material imposes higher stresses on the ceramic head.

Table of Contents

Preoperative Planning

Figure 1

Pre-operative Planning

The objectives of pre-operative planning are to define:

- Pre-operative leg length
- Acetabular component size and position
- Femoral component size
- Femoral offset and center of rotation

X-ray templates and digital templates, for some brands, are provided with acetabular and femoral systems.

When performing a revision of the acetabular component only, it is important to identify the stem which will remain in situ during the pre-operative planning. This will help select the appropriate CoCr femoral head type or the right taper adaptor for a ceramic head. The inner taper of the head adapter must fit the stem taper.

Spherical and Freedom Constrained CoCr Femoral Heads

Figure 2

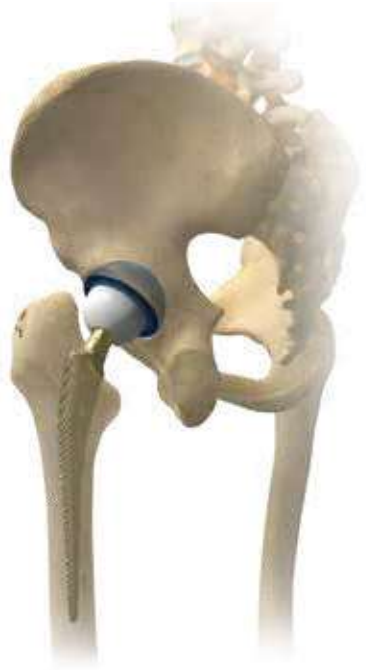

Figure 3

Femoral Head Trial

Select the correct provisional head that matches the stem taper (Figure 2). Visually inspect the trial heads for damage prior to use. Select the appropriate head diameter and offset to create equal leg length and needed lateralization.

Trial Reduction

Perform a trial to assess leg length, range of motion, stability and abductor tension (Figure 3). Repeat as necessary until optimal offset and leg length are established making any necessary adjustments to restore joint mechanics, range of motion and stability.

Make certain that prominent impinging bone and/or osteophytes are removed from the periphery of the acetabulum to maximize range of motion and stability.

Note for Freedom Constrained Heads: Only Freedom provisional heads are compatible for trialing with Freedom implant liners. Never mix the implant components and the provisional components to perform a trial reduction.

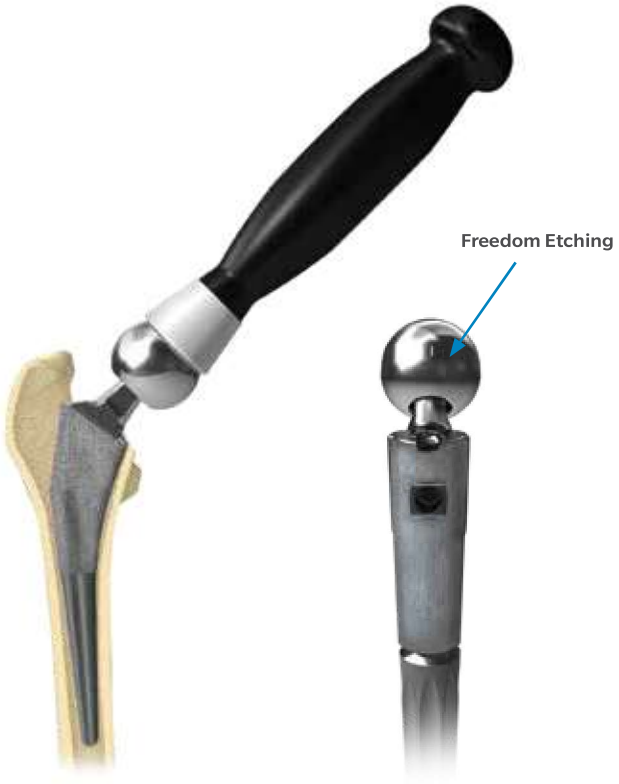

Figure 4

Figure 5

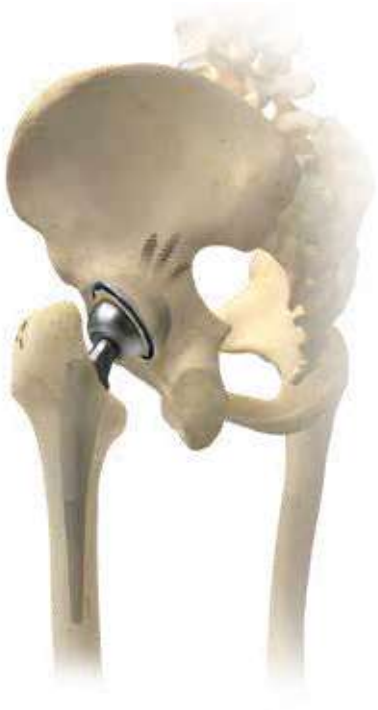

Figure 6

Femoral Head Impaction

Thoroughly clean and dry the implant trunnion taper. Assemble the appropriate mating CoCr femoral head onto the stem taper. Impact the femoral head with at least one hard mallet strike using the femoral head impactor axially aligned on the femoral head to the stem taper (Figure 4). Test the security of the head fixation by trying to remove it by hand.

Note for Freedom Constrained Heads: Make sure to position the Freedom head on the stem so that the etch marking on the head is located in the most superior position prior to impaction (Figure 5).

Final Reduction

Once all final implants have been placed, reduce the hip and assess leg length, range of motion, stability, and abductor tension (Figure 6).

Non-Sleeved Ceramic Femoral Head

Figure 7

Figure 8

Femoral Head Trial

Select the correct provisional that matches the stem taper (Figure 7). Visually inspect the provisional heads for damage prior to use. Select the appropriate head diameter and offset to create equal leg length and needed lateralization.

Trial Reduction

Perform a trial reduction to assess leg length, range of motion, stability, and abductor tension (Figure 8). Repeat as necessary until optimal offset and leg length are established making any necessary adjustments to restore joint mechanics, range of motion and stability.

Make certain that prominent impinging bone and/or osteophytes are removed from the periphery of the acetabulum to help maximize range of motion and stability.

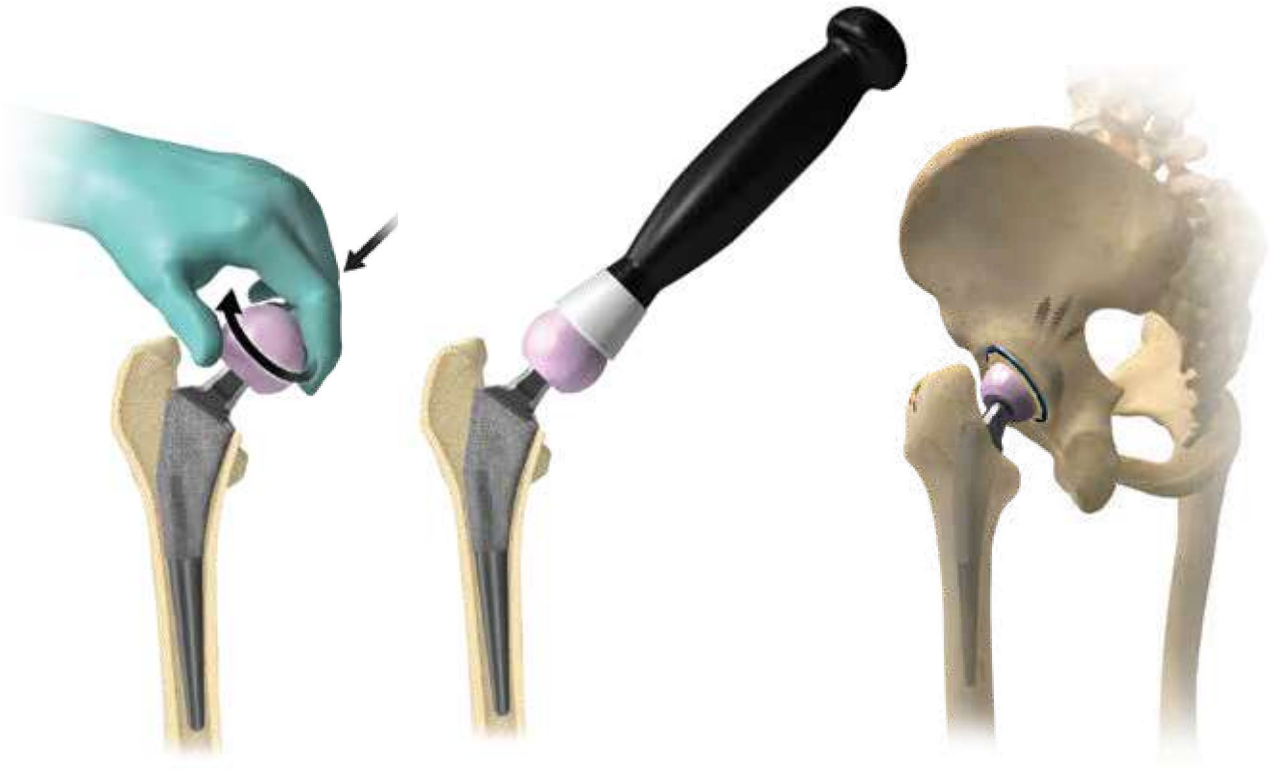

Figure 9

Figure 10

Figure 11

Femoral Head Impaction

Thoroughly clean and dry the implant trunnion taper.

Place the non-sleeved ceramic femoral head onto the stem taper by gently turning it (Figure 9). Impact the femoral head with at least one light mallet strike using the femoral head impactor axially aligned on the femoral head to the stem taper. Impact the head with a plastic femoral head impactor only (Figure 10). Test the security of the head fixation by trying to remove it by hand.

Do not couple 22.2 mm ceramic head sizes with cobalt-chrome femoral stems. Generally, this material imposes higher stresses on the ceramic head.

Note: The use of metal impactors or any other metallic objects may scratch or crack the modular head bearing surface, compromising the integrity of the component. If the modular ceramic head becomes scratched or cracked, the head and neck sleeve (if using a sleeved component) must be replaced.

Final Reduction

Once all final implants have been placed, reduce the hip and assess leg length, range of motion, stability, and abductor tension (Figure 11).

Sleeved Ceramic Femoral Head

Taper with broad truncation | Slanted taper | Crushed taper | Taper with scratch/defect at a height of 0.25 mm

Figure 12

Stem Trunnion Inspection - Acetabular/Head revision

The sleeved ceramic femoral head can be used on either a new/pristine stem or a previously implanted stem. If the ceramic femoral head is being used with a previously implanted stem, use the Goldberg[1] scale to determine if the condition of the trunnion is tolerable or intolerable.

Tolerable Condition

Used stem tapers displaying fine marks from head/stem disassembly and/or up to, and including a score of 3 as described by Goldberg:

- Taper surface discolored or dull
- <10% of taper surface containing black debris, pits, or etch marks

Intolerable Condition

Used stem tapers with a score of 4 as described by Goldberg:

- >10% of taper surface containing black debris, pits, or etch marks
- Several bands of fretting scars involving several adjacent machine lines, or flattened areas with nearby fretting scars
- A taper with a scratch/defect at a height of 0.25 mm, taper with a broad truncation, slanted taper or a crushed taper are all intolerable taper conditions.

Note: Sleeved ceramic femoral heads must not be used with tapers that exhibit these intolerable condition characteristics (Figure 12).

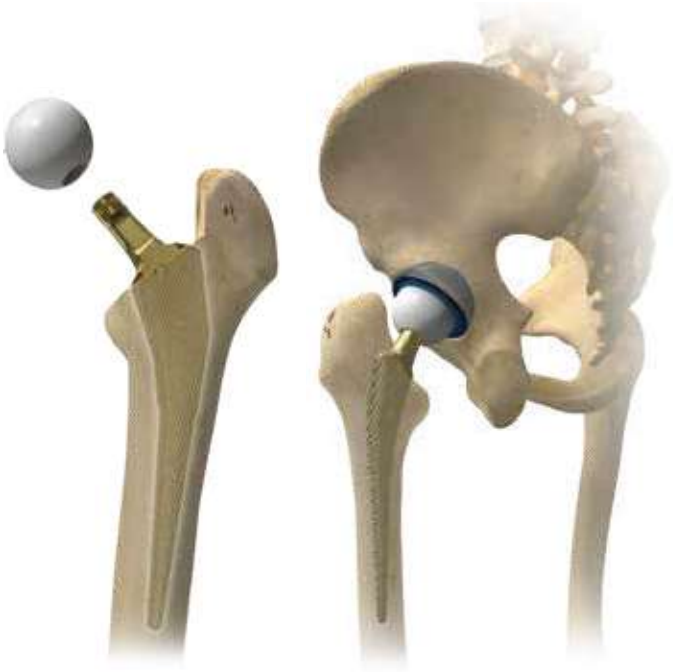

Figure 13

Figure 14

Figure 15

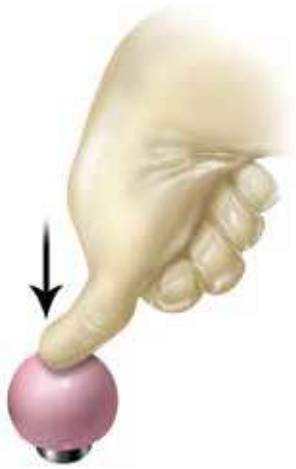

Figure 16

Femoral Head Trial

Verify the taper type on the existing stem if performing an acetabular only revision, or the stem to be inserted, and select the correct provisional that matches the stem taper (Figure 13).

Using the appropriate femoral head provisionals, perform a trial reduction as detailed in previous sections (Figure 14).

Assembly Instructions

Verify the correct selection of both the ceramic femoral head and the neck sleeve as predetermined during the trialing process.

Assemble the modular head components prior to positioning them onto the stem. Align the head onto the neck sleeve axially and apply pressure (Figure 15 and 16). A slight resistance will be felt once the taper is engaged.

Note: Heads and neck sleeves may be packaged either together or separately. See ordering information for detailed packaging notes.

Figure 17

Figure 18

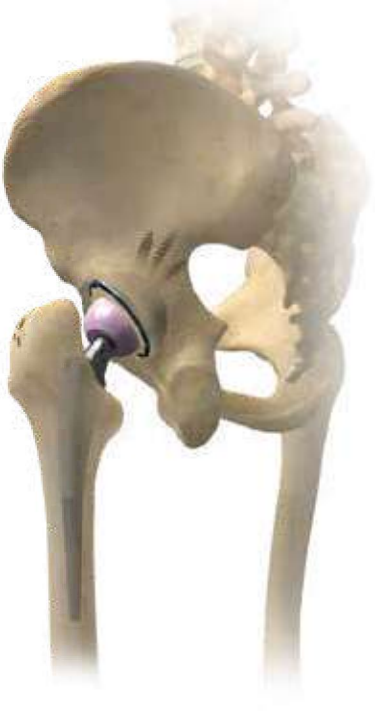

Figure 19

Femoral Head Impaction

Thoroughly clean and dry the implant trunnion taper. Place the ceramic femoral head with sleeve assembled onto the stem taper by gently turning it (Figure 17). Impact the femoral head with at least one firm mallet strike using the femoral head impactor axially aligned on the femoral head to the stem taper. Impact the head with a plastic femoral head impactor only (Figure 18). Test the security of the head fixation by trying to remove it by hand.

Note: The use of metal impactors or any other metallic objects may scratch or crack the modular head bearing surface, compromising the integrity of the component. If the modular ceramic head becomes scratched or cracked, the head and neck sleeve must be replaced.

Final Reduction

Once all final implants have been placed, reduce the hip and assess leg length, range of motion, stability, and abductor tension (Figure 19).

Notes

Notes

References

1. Goldberg, J. *et al.* A Multicentric retrieval study of the taper interfaces of a modular hip prosthesis. Clinical Orthopaedics & Related Research. 401. 149-61. 2002.

Zimmer Biomet Total Hip Implant Systems in the Magnetic Resonance (MR) Environment

Unless otherwise specified in the instructions for use, the risks associated with a passive implant in an MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.

Non-clinical testing has demonstrated that Zimmer Biomet Total Hip Implant Systems are MR Conditional. A patient with this device can be safely scanned in a MR system meeting the following conditions:

MR Information

Safety information for the use of MRI procedures (i.e. imaging, angiography, functional imaging, spectroscopy, etc.) pertains to shielded MRI systems under the following specifications:

- Static magnetic field of 1.5-Tesla (1.5 T) and 3.0-Tesla (3.0 T)
- Maximum spatial gradient field of 1300 Gauss/cm when used with a stainless steel hip component and 2500 Gauss/cm when used with a cobalt-chromium alloy or titanium alloy hip component.
- Maximum MR System reported, whole-body-averaged specific absorption rate (SAR) of:

2 W/kg for 15 minutes of scanning for patient landmarks above the umbilicus and

1 W/kg for 15 minutes of scanning for patient landmarks below the umbilicus.

- Quadrature Transmit Mode only.
- Padding for protection against Radio Frequency (RF) burns should be placed between the wall of the bore and extremities.
- Insulating padding between the knees to prevent legs from touching.
- Arms and hands of the patient should not touch each other or other bare skin.

The effects of MRI procedures using MR systems and conditions above these levels have not been determined. The health state of the patient or the presence of other implants may require a lowering of MR limits.

MR Heating

Under the scan conditions defined above, the implants are expected to produce a maximum temperature rise of less than 3°C after 15 minutes of continuous scanning.

Image Artifacts

In non-clinical testing, the image artifact caused by the device extends up to 100 mm from stainless steel implants and 80mm from titanium and cobalt chromium implants when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

Other

In non-clinical 3.0 T testing, the materials used in Zimmer Biomet implant systems did not produce any magnetically induced displacement force or torque that would result in migration of the devices in the spatial gradient and static fields identified above.

Products manufactured by Zimmer Biomet are not designed to be compatible with products from other manufacturers. There is no assurance that products from different companies may be safely used in combination with each other.

The product compatibility website was developed to address the potential compatibility of product families across Zimmer Biomet companies. In order to establish compatibility, testing and/or engineering evaluations are being completed to assure our global customers that paired products can safely be used in combination. www.zimmerbiomet.com

For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

Zimmer Biomet does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

This surgical technique is applicable to part numbers included within ordering information '2307.X-GLBL-en-Ceramic Heads Ordering Information' and '1839.X-GLBL-en-CoCr Heads Ordering Information'.

Check for country product clearances and reference product-specific instructions for use.

Not for distribution in France.

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Products with this system are under the design control of various manufacturers. Refer to the product labeling of each device for the legal manufacturer.

CE 2797

CE mark on a surgical technique is not valid unless there is a CE mark on the product label.

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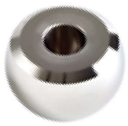
1705.1-OUS-en-REV0320 MC 217807/00 A4

CoCr Femoral Heads

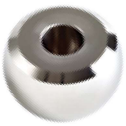
Ordering Information

Implants

Spherical CoCr Femoral Heads

Product	Description	Offset	Diameter	Part Number
	**Zimmer Biomet® 12/14 CoCr Heads**	-2 mm	22.2 mm	802202201
		0 mm		802202202
		+3 mm		802202203
		-3.5 mm	28 mm	802202801
		0 mm		802202802
		+3.5 mm		802202803
		+7 mm		802202804
		+10.5 mm		802202805
		-3.5 mm	32 mm	802203201
		0 mm		802203202
		+3.5 mm		802203203
		+7 mm		802203204
		+10.5 mm		802203205
		-3.5 mm	36 mm	802203601
		0 mm		802203602
		+3.5 mm		802203603
		+7 mm		802203604
		+10.5 mm		802203605
		-3.5 mm	40 mm	802204001
		0 mm		802204002
		+3.5 mm		802204003
		+7 mm		802204004
		+10.5 mm		802204005
		-3.5 mm	44 mm	802204401
		0 mm		802204402
		+3.5 mm		802204403
		+7 mm		802204404
		+10.5 mm		802204405

Implants (cont.)
Spherical CoCr Femoral Heads (cont.)

Product	Description	Offset	Diameter	Part Number
	**Zimmer Biomet Type 1 CoCr Heads**	-5 mm	22.2 mm	163652
		-3 mm		163653
		0 mm		163651
		-6 mm	28 mm	163660
		-3 mm		163661
		0 mm		163662
		+3 mm		163663
		+6 mm		163638
		+9 mm		163665
		+12 mm		163666
		-6 mm	32 mm	163667
		-3 mm		163668
		0 mm		163669
		+3 mm		163670
		+6 mm		163674
		+9 mm		163672
		+12 mm		163673
		-6 mm	36 mm	11-363660
		-3 mm		11-363661
		0 mm		11-363662
		+3 mm		11-363663
		+6 mm		11-363664
		+9 mm		11-363665
		+12 mm		11-363666
		-6 mm	40 mm	010001037
		-3 mm		010001036
		0 mm		010001035
		+3 mm		010001034
		+6 mm		010001033
		+9 mm		010001032
		+12 mm		010001031
		-6 mm	44 mm	010001044
		-3 mm		010001043
		0 mm		010001042
		+3 mm		010001041
		+6 mm		010001040
		+9 mm		010001039
		+12 mm		010001038

Implants (cont.)
Freedom® CoCr Femoral Heads

Product	Description	Offset	Diameter	Part Number
	**Zimmer Biomet 12/14 CoCr Freedom Heads**	-3 mm	32 mm	802403201
		0 mm		802403202
		+3 mm		802403203
		+6 mm		802403204
		-6 mm	36 mm	802403601
		-3 mm		802403602
		0 mm		802403603
		+3 mm		802403604
		+6 mm		802403605
		+9 mm		802403606
	**Zimmer Biomet Type 1 CoCr Freedom Heads**	-6 mm	32 mm	110025133
		-3 mm		110025132
		0 mm		110025131
		+3 mm		110025130
		+6 mm		110025134
		-6 mm	36 mm	11-107016
		-3 mm		11-107017
		0 mm		11-107018
		+3 mm		11-107019
		+6 mm		11-107020
		+9 mm		11-107021

Instruments
Provisional Femoral Heads

Product	Description	Part Number
	Zimmer Biomet 12/14 Spherical Heads Tray	110040312
	Zimmer Biomet 12/14 Trial Heads Lid	110040314

Product	Description	Offset	Diameter	Part Number
	**Zimmer Biomet 12/14 Provisional Heads**	-2 mm	22.2 mm	803302201
		0 mm		803302202
		+3 mm		803302203
		-3.5 mm	28 mm	803302801
		0 mm		803302802
		+3.5 mm		803302803
		+7 mm		803302804
		+10.5 mm		803302805
		-3.5 mm	32 mm	803303201
		0 mm		803303202
		+3.5 mm		803303203
		+7 mm		803303204
		+10.5 mm		803303205
		-3.5 mm	36 mm	803303601
		0 mm		803303602
		+3.5 mm		803303603
		+7 mm		803303604
		+10.5 mm		803303605
		-3.5 mm	40 mm	803304001
		0 mm		803304002
		+3.5 mm		803304003
		+7 mm		803304004
		+10.5 mm		803304005
		-3.5 mm	44 mm	803304401
		0 mm		803304402
		+3.5 mm		803304403
		+7 mm		803304404
		+10.5 mm		803304405

Instruments (cont.)
Provisional Femoral Heads (cont.)

Product	Description	Part Number
	Zimmer Biomet 12/14 Freedom Heads Tray	110040313
	Zimmer Biomet 12/14 Trial Heads Lid	110040314

Product	Description	Offset	Diameter	Part Number
	**Zimmer Biomet 12/14 Freedom Provisional Heads**	-3 mm	32 mm	802503201
		0 mm		802503202
		+3 mm		802503203
		+6 mm		802503204
		-6 mm	36 mm	802503601
		-3 mm		802503602
		0 mm		802503603
		+3 mm		802503604
		+6 mm		802503605
		+9 mm		802503606

Instruments (cont.)
Provisional Femoral Heads (cont.)

Product	Description	Part Number
	Head Provisional Type 1 Half Tray (Empty)	110002768

Product	Description	Offset	Diameter	Part Number
	**Zimmer Biomet Type 1 Provisional Heads**	-5 mm	22.2 mm	010002484
		-3 mm		010002483
		0 mm		010002482
		-6 mm	28 mm	010002491
		-3 mm		010002490
		0 mm		010002489
		+3 mm		010002488
		+6 mm		010002487
		+9 mm		010002486
		+12 mm		010002485
		-6 mm	32 mm	010002498
		-3 mm		010002497
		0 mm		010002496
		+3 mm		010002495
		+6 mm		010002494
		+9 mm		010002493
		+12 mm		010002492
		-6 mm	36 mm	010002505
		-3 mm		010002504
		0 mm		010002503
		+3 mm		010002502
		+6 mm		010002501
		+9 mm		010002500
		+12 mm		010002499
		-6 mm	40 mm	010002512
		-3 mm		010002511
		0 mm		010002510
		+3 mm		010002509
		+6 mm		010002508
		+9 mm		010002507
		+12 mm		010002506
		-6 mm	44 mm	010002519
		-3 mm		010002518
		0 mm		010002517
		+3 mm		010002516
		+6 mm		010002515
		+9 mm		010002514
		+12 mm		010002513

Instruments (cont.)
Provisional Femoral Heads (cont.)

Product	Description	Offset	Diameter	Part Number
	**Zimmer Biomet Type 1 Freedom Provisional Heads**	-6 mm	32 mm	110010728
		-3 mm		110010725
		0 mm		110010724
		+3 mm		110010727
		+6 mm		110010729
		-6 mm	36 mm	31-127016
		-3 mm		31-127017
		0 mm		31-127018
		+3 mm		31-127019
		+6 mm		31-127020
		+9 mm		31-127021

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