

unique

custom made femoral prosthesis

FEMORAL BALL HEADS AND ACETABULAR COMPONENTS

VERSION 6.1

This document describes the options available for femoral head and acetabular components in combination with the Unique® femoral stem for THA.




Due to the risk of serious prosthesis malfunction, including possible fracture of femoral head or acetabular cup, the Unique® femoral stem should only be used in combination with components approved and certified by SCP.

1 INTRODUCTION

The individually manufactured Unique® femoral stem can be used in combination with a large number of femoral ball heads and acetabular components from various vendors. This flexibility allows the orthopaedic surgeon a freedom to choose a caput and acetabular component which best meets the requirements of each individual patient.

But in order to ensure that the chosen components will continue to function well for years to come, with minimal risk of failure, it is important that all components chosen are fully compatible. This document describes the risks involved, and provides a list of available caput and acetabular components recommended by SCP.

2 IMPORTANT INFORMATION

	<ul style="list-style-type: none"> • Use ONLY components approved and certified by SCP. • NEVER use a ceramic ball head on a used stem taper. • Ensure the taper is rinsed and then dried and free of foreign bodies before fitting the ball head to the stem taper. • Always make sure the femoral ball head is fitted to the stem using the utmost care. • NEVER use a metal hammer to fix the head to the stem taper. • Incorrect fixation of a ceramic ball head on the taper may cause overloading of the prosthesis. • Always observe the warnings and guidelines when handling non-SCP components.
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3 FEMORAL BALL HEADS

3.1 General recommendations

3.1.1 Femoral Ball Head Material

In combination with an individually manufactured Unique® femoral stem,

SCP recommends the use of femoral ball heads manufactured in

- **Alumina ceramic**
- **Cobalt chromium (CoCr)** (option planned size and length is not available in ceramic)

3.1.2 Femoral Ball Head Size

SCP recommends the use of a 28 mm or 32 mm femoral ball head.

Alternatively, SCP recommends the use of a 22.225 mm femoral ball head only when the acetabular component is too small to encompass sufficient material wear thickness in combination with a larger femoral ball head.

3.1.3 Femoral Ball Head Taper

The Unique® stem is manufactured with a tapered neck that securely fixates a compatible ball head. When ordering the stem, it is possible to specify a number of neck dimensions to suit a range of femoral ball heads. To ensure a lasting connection with minimal risk of excessive wear or fracture to stem or ball head, it is necessary that the stem and ball head is manufactured to the same standard.

SCP recommends the use of

- **12/14-EURO taper for femoral ball heads of 28 mm or 32 mm. If necessary due to the size of the acetabular component 22.225mm ball heads can be used.**

3.2 Femoral ball heads provided by SCP

SCP recommends and provides the femoral ball heads listed in Table 1 for use in combination with the Unique® femoral stem.

Table 1 : Recommended Femoral Ball Heads

Femoral Ball Head	Manufacturer	Recommended Sizes	Stem Taper
Bilox Forte Alumina 28 mm	CeramTec	S, M, L	12/14
Bilox Forte Alumina 32 mm	CeramTec	S, M, L	12/14

3.3 Alternative femoral ball heads provided by SCP

3.3.1 22.2mm for 12/14 taper

As an alternative, SCP provides an Articul/eze (CoCr) 22.225 mm femoral ball head from DePuy with a 12/14 taper. Due to reduction in head-neck-ratio, this solution will give a reduced range of motion.

3.3.2 28mm XL, XL


In cases of need for additional lengthening, XL and XXL heads may be provided in CoCr for 28mm (DePuy Articul/EZE).

Other femoral ball heads may be used in combination with a Unique® femoral stem, but only after SCP has investigated the head's dimensions and certified its use.

Table 2 show the complete range of femoral ball heads provided by SCP.

Table 2 : Summary of head systems and sizes provided by SCP.

Taper	Ball Head	Femoral Ball Head Diameter											
		22.225 mm			28.0 mm					32.0 mm			
		S	M	L	S	M	L	XL	XXL	S	M	L	
12/14	Bilox Forte ceramic				●	●	●				●	●	●
12/14	DePuy Articul/EZE CoCr	●		●				●	●				

	<ul style="list-style-type: none"> • A Unique® femoral stem must not be used in combination with a femoral ball head other than those approved and certified by SCP for use in combination with each individual stem. • Unless a different taper is specified before an order is approved by the customer, the Unique® stem is manufactured with a 12/14-EURO taper for use with a BioloX Forte ceramic ball head.
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3.4 Additional information

3.4.1 Default femoral ball head offset in preop. planning

The table below shows the length that forms the basis for the pre-operative planning of the Unique(R) custom stem for the different head systems.

Table 3 : Default Femoral Head Length

Femoral ball head	Length forming the basis for pre operative planning.
28 mm (BioloX Forte)	M (+0)
32 mm (BioloX Forte)	M (+0)
22.225 mm - Taper 12/14 (Articul/EZE)	S (+5)

3.4.2 Femoral ball head product codes

Table 4 below lists the manufacturer's product code for all femoral ball heads provided by SCP. All products are usually shipped within 5 working days. Please contact SCP for prices and availability.

Table 4 : Femoral Ball Heads available from SCP

Product Code	Name	Diameter	Taper	Length	Marked Offset	Real Offset
38.49.7172.005.50	BioloX Forte	28mm	12/14	S	-3.5 mm	-3.5 mm
38.49.7172.015.50	BioloX Forte	28mm	12/14	M	+0.0 mm	+0 mm
38.49.7172.025.50	BioloX Forte	28mm	12/14	L	+3.5 mm	+3.5 mm
136514000	Articul/EZE	28mm	12/14	XL	+12.0 mm	+7.0 mm
136515000	Articul/EZE	28mm	12/14	XXL	+15.5 mm	+10.5 mm
38.49.7172.045.27	BioloX Forte	32mm	12/14	S	-4.0 mm	-4.0 mm
38.49.7172.055.20	BioloX Forte	32mm	12/14	M	+0 mm	+0 mm
38.49.7172.065.24	BioloX Forte	32mm	12/14	L	+4.0 mm	+4.0 mm
9113-112	Articul/EZE	22.225 mm	12/14	S	+5.0 mm	+0 mm
9113-113	Articul/EZE	22.225 mm	12/14	L	+9.0 mm	+4.0 mm

3.4.3 Femoral ball head labeling

Femoral Ball Heads provided by SCP have been provided with a second label stating the conformance with the Unique® femoral stem, as shown in Figure 1.

Figure 1 : Femoral ball head packaging labels

	<p>Original label for the BioloX Forte femoral ball head stating size, length and sterility date..</p>
	<p>Original label for Articul/eze femoral ball heads stating size, length and sterility date.</p>
	<p>Additional SCP label stating size, length and conformance with SCP taper.</p>

4 ACETABULAR COMPONENTS

4.1 Acetabular component materials

The Unique® femoral stem may be used in combination with most acetabular components.

4.2 Cemented / uncemented acetabular cups

SCP approves the use of the Unique® femoral stem in combination with both cemented and uncemented acetabular cups.

4.3 Liner / insert

BioloX Forte Alumina ceramic ball head provided by SCP may be used in combination with acetabular cups with BioloX Forte Alumina ceramic insert.

The Unique® stem with recommended femoral ball heads may be used in combination with most polyethylene liners and cups.

4.4 Acetabular components

Most acetabular components can be used in combination with the Unique® femoral stem. Contact SCP for approval and certification of your preferred components.

	<ul style="list-style-type: none"> A Unique® femoral stem must not be used in combination with acetabular components other than those specifically approved and certified by SCP for use with each individual stem.
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5 RESTERILISATION OF FEMORAL BALL HEADS

Both alumina (Bilox Forte) and CoCr (Articul/EZE) can be re-sterilized using steam sterilization (autoclave) without damaging the material. SCP do however not take responsibility for re-sterilized ball heads. All ball heads supplied by SCP are delivered sterile.

6 SURGICAL PROCEDURE - TRIAL REDUCTION

The surgical procedure of the Unique concept includes trial reduction with trial necks mounted on the custom rasp (broach) and trial heads. Refer to the "Surgical Technique Manual] for more information.

7 HOW TO ORDER

When ordering femoral ball heads, please include the following information:

- Type of ball head (brand)
- Diameter
- Length/Offset or Product Code
- Quantity

- Address
- Your order number

8 MORE INFORMATION

Do not hesitate to contact us for further information !

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