Lineage®

Acetabular Cup System







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Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience and patient condition. Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions for Use Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

Package inserts can be found under: Prescribing on ortho.microport.com

Chapter 1



Ordering Information	Ordering Information				
X-Ray Template	3600XR15				
Surgical Technique	012032B				
Instruments	8000KIT4 Lineage® Core Instrument Kit				
	3100KIT2 Interseal® Stainless Steel Trial Shells Group 1-4				
	8400KIT1 Screw Instruments				
Implants	3644KITB Lineage® Acetabular Shell Quad shells Group 1-3				
	3644KITC Lineage® Acetabular Shell Group 4				
	364XKITA Lineage® A-CLASS® Polyethylene Liners				
	1808KITL Acetabular Screws				
	* Rim-Lock Ceramic Liners				
	* Lineage® Metal Heads				
	* Lineage®Ceramic Heads				
	* Lineage® non crosslinked polyethylene liners				
	* Lineage® Biolox® Forte Ceramic Liners				

* No kit codes, please see tables in chapter 6 for part numbers

For additional risk information, please consult the Instructions for Use package insert.

A-CLASS® Advanced

traditional Poly liner

Crosslinked and

Optimal ingrowth surface

Sintered Titanium beads 30% Porosity - avg. 114 µm pore size

Optimal outer geometry

- Hemi-spherical Single
- radius 152°
- Flattened dome
- Equatorial rim flare (14º)



Figure 1

Lineage® Cup accommodates 2 types of liners **Ceramic liner** Biolox[®] Forte Biolox[®] Delta • 0° and 15° lip options

* Biolox® Forte & Biolox® Delta Trademark of Ceramtec AG

Chapter 2

Preoperative Planning

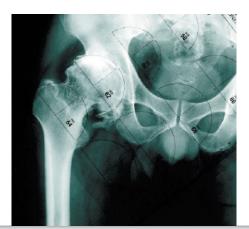


Figure 2

Preoperative assessment of the appropriate size and position of the acetabular component will provide intraoperative guidance for acetabular reaming.

An A/P X-ray (Figure 2) of the pelvis will aid in leg length and offset assessment. Accurate templating requires good quality standardized radiographs of the pelvis and operated hip. Leg length discrepancies should be determined preoperatively and addressed intraoperatively.

Radiographic overlays for the Lineage[®] Acetabular Cup System are available in 15 percent magnification (3600XR15).

CAUTION: Preoperative templating is intended for estimation purposes only.

NOTE: The use of a magnification marker will aid in determining the x-ray magnification.





Preparation of the Acetabulum

Osteophytes should be removed to enable assessment of the true acetabular rim. Reaming should be sequential and start with the smallest reamer that conforms to the acetabular cavity. Reaming to the edge of the reamer will mimic a full hemisphere. Gradually enlarge the acetabulum by reaming articular cartilage until a continuous surface of cancellous bone is exposed.

Ream to the size of the component to be implanted. This will provide a 2mm press-fit at the rim, and a 1mm press fit at the dome.

CAUTION: Care should be taken not to over ream the acetabulum. NOTE: Lineage® shells come in 2mm increments, ranging from 46-68mm. NOTE: Reamers are not included in the Lineage® instrument set.



Figure 4

Sizing the Acetabulum

Thread the trial shell (40002046-64, 41002050, 41002058) onto the shell impactor/extractor (8000Cl00) to check the size of the acetabulum.

The trial shells are a full hemisphere and are undersized by 1mm compared to the actual implant.





Trial Shell 40002046-64, 41002050, 41002058

Shell Impactor/Extractor 8000Cl00



Figure 5

Inserting the shell

Thread the appropriate size shell onto the cup positioner/ impactor (8400CP01 or 33330060). Laser markings on the rim of the shell corresponding to the location of the screw holes should be positioned between the plane of the anterior superior iliac spine and the anterior inferior iliac spine. (Figure 5).

An alignment guide (33330080) can be mounted to the impactor to aid in positioning the implant. The guide is set for 45° degrees of cup abduction and 15° degrees of flexion. Once in position, tighten the guide. Place the guide 90° to the midline of the patient. Rotate the guide until the appropriate marked cross bar points to the patients ipsilateral shoulder. This will position the implant at 15° of anteversion. The alignment guide should be tilted downward if less than 45 degrees of abduction is desired. Positions given are based on a posterior approach / affected side up.

Seat the shell with a series of firm mallet blows on the end of the impactor. Complete seating of the implant can be confirmed through the apical hole and screw holes. NOTE: The patient might have shifted during surgery and the alignment guide can therefore only be seen as an orientation guide.

CAUTION: When threading the implant shell onto the cup impactor, care should be taken to avoid damaging the threads of the implant or impactor. While holding the impactor vertical, rotate the shell counter-clockwise until a slight drop is felt, then rotate the shell clockwise until tight. Do not over tighten.

CAUTION: Avoid scratching or denting the rim or internal taper of the shell. Injury to the shell taper will create stress-risers at the shell-liner interface. If the locking mechanism is damaged during implantation, the shell should be replaced.



Shell Impactor 33330010



Cup Positioner / Impactor 8400CP01



Alignment Guide 33330080



Screw Placement

Determine the screw location and select a suitable length drill bit. Modular drill bits are provided in 3.2 and 4.5mm diameters, (8400FD04-8400FD06, 8400FD07-8400FD10). The modular drill bits have to be used by attaching them to the flexible drill bit shaft (8400FD12). The drill guide (8400DG01) is also available 3.2mm and 4.5mm diameters with fixed angle and adjustable options.

Position the drill guide into the shell ensuring that it is placed into one of the screw holes.

Insert the drill into the guide and carefully drill through the acetabular cortex. (Figure 6)

Use the screw depth gauge (8400SG02) to determine the appropriate length screw. (Figure 7)



Modular drill bits (8400FD04-8400FD06, 8400FD07-8400FD10)

Screw depth gauge (8400SG02) Cardan Screw Driver (8400SD03)

6.5mm Screw-Holding Forceps (4820SH0000)

Grasp the screw head with the screw-holding forceps (4820SH0000) and utilize the hex screwdriver (8400SD03 or 8400SD06 connected to the screw driver handle 8400SD11) to orient and fixate the screw (Figure 8). Release the screwholding forceps to allow for the countersinking of the screw head.

Ensure the screw head is completely seated and does not protrude into the shell space, as this may prevent the liner from seating.

CAUTION: Due to intrapelvic vascularity, screw placement in the medial aspect of the acetabulum must be carefully considered.

CAUTION: To ensure proper prosthetic liner seating in the shell, all screw heads must be seated below the inner surface of the shell. Full and unobstructed seating is crucial to implant fit and longevity.



Screw driver handle (8400SD11)

Solid screw driver bit (8400SD06)

Flexible drill bit shaft (8400FD12) Drill guide (8400DG01)

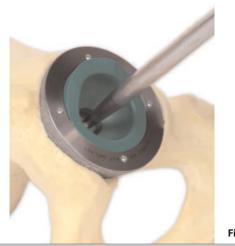


Figure 9



Figure 10

Trial Liner Placement

Trial liners (8015280*, 8*0028**, 8*0032**, 8015320*, 84003664) that match the prosthetic implant are available to evaluate the optimum position of the final implant.

Insert the trial liner into the shell. (Figure 9) Position the trial liner in the desired orientation and secure it in place with the captured screw using a 3.5mm hex screwdriver (18410135).

If a polyethylene lipped liner is to be used, take note of the position of the lip prior to removal of the trial for later reference. A reference mark can be made on the acetabulum to aid in proper reposition with the final liner implant.

NOTE: Care should be taken to avoid neck/liner impingement in all potential positions. The acetabular component should be repositioned as necessary to relieve impingement.

* For all part numbers, refer to the part number information in Chapter 6.

Apical Hole Plug Insertion

Do not insert the apical hole plug until after final trial reduction with the trail liners. After the trial reduction, seal the apical hole with the apical hole plug. The poly rod will break off at the plug once it is tightened into the apical hole. A final tightening of the hole plug should be performed using a 3.5mm hex screwdriver. (Figure 10).

NOTE: Apical hole plug is sold separately. Part Number 3818000200.





3.5mm Hex Screwdriver 18410135





Figure 11

Liner Placement

Clean out any soft tissue from the inner taper area before impacting and engaging the implant and liner.

Ceramic Liner

Insert the liner by hand ensuring that the face of the liner is parallel with the face of the shell. Ensure the liner is flush with the shell. (Figure 11). Assemble the modular impactor tip (80000020) to the insert impactor handle (80000010). Attach the appropriate femoral head trial (1805605*, 1805606* or 1805602*) that corresponds to the liner I.D. and place into the liner. Apply a series of mallet blows to fully seat the liner. (Figure 12).

NOTE: Lineage $^{\circ}$ Shells accept both BIOLOX $^{\circ}$ Forte and BIOLOX $^{\circ}$ Delta Liners. Table 1.

* For all part numbers, refer to the part number information in Chapter 6.

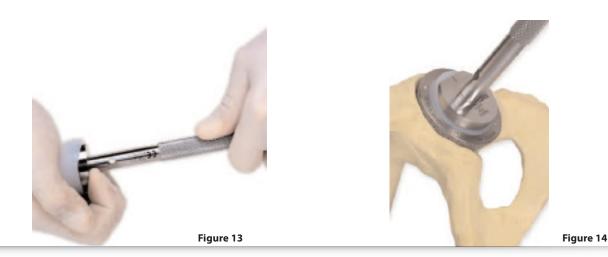
Shell Size (mm)	Biolox® Forte Liners PN	Lineage® Liners Group	Liner ID	Biolox® Delta Liners	Rim-lock™ Liner Group	Liner ID
46/48/50	71002846	1	28mm	PHA04504	В	28mm
52/54/56	72002852 / 72003252	2	28mm / 32mm	PHA04508	D	32mm
58/60/62	73002858 / 73003258	3	28mm / 32mm	PHA04512 PHA04516	F	36mm / 40mm
64/66/68	74002864 / 74003264	4	28mm / 32mm	PHA04514 PHA04518	G	36mm / 40mm



Insert Impactor Handle 80000010

Modular Impactor Tip 8000020 Trial Head 1805605*, 1805606*, 1805602*

Table 1



Polyethylene Liner

Assemble the 0° (80002800, 80003200, 80003600) or 15° (80002815, 80003215) liner impactor tip to the impactor handle (80000010). Attach the polyethylene liner to the appropriate liner impactor tip and tighten in a clockwise direction. Place the liner in the selected position. Apply a series of firm mallet blows to fully seat the liner. Remove the liner impactor by turning the liner impactor in a counter-clockwise direction.

A final inspection of the liner should be done to ensure the liner is firmly locked in place and flush with the shell face.

CAUTION: Improper position and impaction of the liner will damage the liner and shell.





0° Liner Impactor Tip 80002800, 80003200, 80003600





15° Liner Impactor Tip 80002815, 80003215, 800003615

Chapter 4

Implant Removal



Polyethylene Liner Removal

To remove a polyethylene liner, utilize the flexible drill bit (8400FD04-10) with an acetabular drill guide (8400DG01) and drill a hole slightly off-center from the liner apex.

Using a 3.5mm hex screwdriver, thread a 20mm cancellous screw (18080301) into the drilled hole.

Ceramic Liner Removal

To remove a ceramic liner, thread the appropriate liner extractor (8*00021) onto the shell impactor/extractor. Align the tabs on the extractor with the dimples on the shell face. Apply two mallet blows and inspect the liner for disengagement. Repeat if necessary until the liner is removed.

NOTE: If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

* For all part numbers, refer to the part number information in Chapter 6.



20mm Cancellous Screw 18080301



Liner Extractor 81000021, 82000021 83000021, 84000021



Modular drill bits (8400FD04-8400FD06, 8400FD07-8400FD10) Acetabular Drill Guide 8400DG01



Technique Overview



1. Preparation of the Acetabulum / Reaming



2. Sizing the Acetabulum





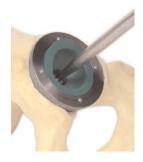
3. Inserting the shell



4. Screw Placement / Drilling



5. Screw Placement / Fixation



6. Trial Liner Placement



7. Apical Hole Plug Insertion



8. Liner Placement

- Liner Options: • Polyethylene
- Ceramic

Chapter 6 Ordering Information - Implants

Lineage[®] Acetabular Shell Quad Shells Group 1-3



Catalog No.	Description	Group	Head Diameter	Quantity
36430046	Porous Coated Quad Shell	Group 1	46mm	1 ea
36430048	Porous Coated Quad Shell	Group 1	48mm	1 ea
36430050	Porous Coated Quad Shell	Group 1	50mm	1 ea
36430052	Porous Coated Quad Shell	Group 2	52mm	1 ea
36430054	Porous Coated Quad Shell	Group 2	54mm	1 ea
36430056	Porous Coated Quad Shell	Group 2	56mm	1 ea
36430058	Porous Coated Quad Shell	Group 3	58mm	1 ea
36430060	Porous Coated Quad Shell	Group 3	60mm	1 ea
36430062	Porous Coated Quad Shell	Group 3	62mm	1 ea
3818000200	Apical Hole Plug			1 ea

3644KITB

Lineage® Acetabular System Porous Beaded Quadrant Shells Group 4

3644KITC

Catalog No.	Description	Group	Head Diameter	Quantity
36430064	Porous Coated Quad Shell	Group 4	64mm	1 ea
36430066	Porous Coated Quad Shell	Group 4	66mm	1 ea
36430068	Porous Coated Quad Shell	Group 4	68mm	1 ea
3818000200	Apical Hole Plug			1 ea

Lineage[®] / Dynasty[®] Acetabular Screws

1808KITL

Catalog No.	Description	Length
18080300	6.5 Cancellous Screw	15mm
18080301	6.5 Cancellous Screw	20mm
18080302	6.5 Cancellous Screw	25mm
18080303	6.5 Cancellous Screw	30mm
18080304	6.5 Cancellous Screw	35mm
18080305	6.5 Cancellous Screw	40mm
18080306	6.5 Cancellous Screw	45mm
18080307	6.5 Cancellous Screw	50mm



Ordering Information - Implants

Lineage® A-CLASS® Polyethylene Liners Groups 1-4

364XKITA



Catalog No.	Description	Group	Head Diameter	Quantity
364128X1	Lineage [®] A-CLASS [®] Acetabular Liner 0° Std	Group 1	28mm	2 ea
364128X2	Lineage® A-CLASS® Acetabular Liner 0° Std	Group 2	28mm	2 ea
364128X3	Lineage® A-CLASS® Acetabular Liner 0° Std	Group 3	28mm	2 ea
364128X4	Lineage [®] A-CLASS [®] Acetabular Liner 0° Std	Group 4	28mm	2 ea
364528X1	Lineage [®] A-CLASS [®] Acetabular Liner 15° Std	Group 1	28mm	2 ea
364528X2	Lineage® A-CLASS® Acetabular Liner 15° Std	Group 2	28mm	2 ea
364528X3	Lineage [®] A-CLASS [®] Acetabular Liner 15 [°] Std	Group 3	28mm	2 ea
364528X4	Lineage [®] A-CLASS [®] Acetabular Liner 15° Std	Group 4	28mm	2 ea
364132X2	Lineage [®] A-CLASS [®] Acetabular Liner 0° Std	Group 2	32mm	2 ea
364132X3	Lineage [®] A-CLASS [®] Acetabular Liner 0° Std	Group 3	32mm	2 ea
364132X4	Lineage® A-CLASS® Acetabular Liner 0° Std	Group 4	32mm	2 ea
364532X2	Lineage® A-CLASS® Acetabular Liner 15° Std	Group 2	32mm	2 ea
364532X3	Lineage [®] A-CLASS [®] Acetabular Liner 15° Std	Group 3	32mm	2 ea
364532X4	Lineage [®] A-CLASS [®] Acetabular Liner 15° Std	Group 4	32mm	2 ea
364136X3	Lineage [®] A-CLASS [®] Acetabular Liner 0° Std	Group 3	36mm	2 ea
364136X4	Lineage [®] A-CLASS [®] Acetabular Liner 0° Std	Group 4	36mm	2 ea
364536X3	Lineage [®] A-CLASS [®] Acetabular Liner 15 [°] Std	Group 3	36mm	2 ea
364536X4	Lineage [®] A-CLASS [®] Acetabular Liner 15 [°] Std	Group 4	36mm	2 ea

Lineage® non-crosslinked Polyethylene Liners

Catalog No.	Description	Group	Head Diameter
36412801	Lineage [®] Non-crosslinked Polyethylene Liners 0°	Group 1	28mm
36412802	Lineage [®] Non-crosslinked Polyethylene Liners 0°	Group 2	28mm
36412803	Lineage [®] Non-crosslinked Polyethylene Liners 0°	Group 3	28mm
36412804	Lineage [®] Non-crosslinked Polyethylene Liners 0°	Group 4	28mm
36413202	Lineage [®] Non-crosslinked Polyethylene Liners 0°	Group 2	32mm
36413203	Lineage [®] Non-crosslinked Polyethylene Liners 0°	Group 3	32mm
36413204	Lineage [®] Non-crosslinked Polyethylene Liners 0°	Group 4	32mm
36413603	Lineage [®] Non-crosslinked Polyethylene Liners 0°	Group 3	36mm
36413604	Lineage [®] Non-crosslinked Polyethylene Liners 0°	Group 4	36mm
36453202	Lineage [®] Non-crosslinked Polyethylene Liners 15°	Group 2	32mm
36453203	Lineage [®] Non-crosslinked Polyethylene Liners 15°	Group 3	32mm
36453204	Lineage [®] Non-crosslinked Polyethylene Liners 15°	Group 4	32mm
36453603	Lineage [®] Non-crosslinked Polyethylene Liners 15°	Group 3	36mm
36453604	Lineage [®] Non-crosslinked Polyethylene Liners 15°	Group 4	36mm

Ordering Information - Implants



Metal Heads

Catalog No.	Description	Diameter	Head Length
	Description	Diameter	(mm)
26012801	Lineage [®] Metal Heads	28mm	-3,5
26012802	Lineage® Metal Heads	28mm	0
26012803	Lineage® Metal Heads	28mm	+3,5
26012804	Lineage® Metal Heads	28mm	+7
26012805	Lineage® Metal Heads	28mm	+10,5
26010007	Lineage® Metal Heads	32mm	-3,5
26010008	Lineage® Metal Heads	32mm	0
26010009	Lineage® Metal Heads	32mm	+3,5
26010010	Lineage® Metal Heads	32mm	+7
26000025	Lineage® Metal Heads	36mm	-3,5
26000026	Lineage [®] Metal Heads	36mm	0
26000027	Lineage® Metal Heads	36mm	+3,5
26000028	Lineage® Metal Heads	36mm	+7

Biolox[®] Ceramic Heads

Catalog No.	Description	Diameter	Head Length (mm)
26000004	Biolox [®] Forte Ceramic Head	28mm	-3,5
26000005	Biolox [®] Forte Ceramic Head	28mm	0
26000006	Biolox [®] Forte Ceramic Head	28mm	+3,5
2600007	Biolox [®] Forte Ceramic Head	32mm	-3,5
2600008	Biolox [®] Forte Ceramic Head	32mm	0
26000009	Biolox [®] Forte Ceramic Head	32mm	+3,5
26000010	Biolox [®] Forte Ceramic Head	36mm	-5,5
26000011	Biolox [®] Forte Ceramic Head	36mm	-2,0
26000012	Biolox [®] Forte Ceramic Head	36mm	+1,5
PHA04402	Biolox [®] Delta Ceramic Head	28mm	-3,5
PHA04404	Biolox [®] Delta Ceramic Head	28mm	0
PHA04406	Biolox [®] Delta Ceramic Head	28mm	+3,5
PHA04408	Biolox [®] Delta Ceramic Head	32mm	-4,0
PHA04410	Biolox [®] Delta Ceramic Head	32mm	0
PHA04412	Biolox [®] Delta Ceramic Head	32mm	+4,0
PHA04414	Biolox [®] Delta Ceramic Head	36mm	-4,0
PHA04416	Biolox [®] Delta Ceramic Head	36mm	0
PHA04418	Biolox [®] Delta Ceramic Head	36mm	+4,0
PHA04420	Biolox [®] Delta Ceramic Head	40mm	-4,0
PHA04422	Biolox [®] Delta Ceramic Head	40mm	0
PHA04424	Biolox [®] Delta Ceramic Head	40mm	+4,0

* Biolox® Forte & Biolox® Delta Trademark of Ceramtec AG





Ordering Information - Implants

Biolox[®] Forte Ceramic Liners



Catalog No.	Description	Diameter	Shell Size	Group
71002846	Biolox [®] Forte Alumina Ceramic Liner	28mm	46-50mm	Group 1
72002852	Biolox [®] Forte Alumina Ceramic Liner	28mm	52-56mm	Group 2
72003252	Biolox [®] Forte Alumina Ceramic Liner	32mm	52-56mm	Group 2
73002858	Biolox [®] Forte Alumina Ceramic Liner	28mm	58-62mm	Group 3
73003258	Biolox [®] Forte Alumina Ceramic Liner	32mm	58-62mm	Group 3
74002864	Biolox [®] Forte Alumina Ceramic Liner	28mm	64-68mm	Group 4
74003264	Biolox [®] Forte Alumina Ceramic Liner	32mm	64-68mm	Group 4

* Biolox® Forte & Biolox® Delta Trademark of Ceramtec AG

Biolox[®] Delta Rim-Lock Ceramic Liners

Catalog No.	Description	Diameter	Shell Size	Group
PHA04504	Biolox [®] Delta Rim-Lock Ceramic Liner	28mm	46-50mm	В
PHA04508	Biolox [®] Delta Rim-Lock Ceramic Liner	32mm	52-56mm	D
PHA04512	Biolox [®] Delta Rim-Lock Ceramic Liner	36mm	58-62mm	F
PHA04514	Biolox [®] Delta Rim-Lock Ceramic Liner	36mm	64-68mm	G
PHA04516	Biolox [®] Delta Rim-Lock Ceramic Liner	40mm	58-62mm	F
PHA04518	Biolox [®] Delta Rim-Lock Ceramic Liner	40mm	64-68mm	G

* Biolox® Forte & Biolox® Delta Trademark of Ceramtec AG



Ordering Information - Instruments

Lineage[®] Core Instrument Set

8000KIT4





Catalog No.	Description	Quantity
80152801	Lineage [®] Trial Liner 28mm 15° Group 1	1 ea
80152802	Lineage [®] Trial Liner 28mm 15° Group 2	1 ea
80152803	Lineage [®] Trial Liner 28mm 15° Group 3	1 ea
80152804	Lineage [®] Trial Liner 28mm 15° Group 4	1 ea
81002846	Lineage [®] / Transcend [®] Trial Liner 28mm 0° Group 1	1 ea
82002852	Lineage [®] / Transcend [®] Trial Liner 28mm 0° Group 2	1 ea
83002858	Lineage [®] / Transcend [®] Trial Liner 28mm 0° Group 3	1 ea
84002864	Lineage [®] / Transcend [®] Trial Liner 28mm 0° Group 4	1 ea
82003252	Lineage [®] / Transcend [®] Trial Liner 32mm 0° Group 2	1 ea
83003258	Lineage [®] / Transcend [®] Trial Liner 32mm 0° Group 3	1 ea
84003264	Lineage [®] / Transcend [®] Trial Liner 32mm 0° Group 4	1 ea
80153202	Lineage [®] Trial Liner 32mm 15° Group 2	1 ea
80153203	Lineage® Trial Liner 32mm 15° Group 3	1 ea
80153204	Lineage® Trial Liner 32mm 15° Group 4	1 ea
84003664	Lineage [®] / Transcend [®] Trial Liner 36mm 0° Group 4	1 ea
80002815	Lineage® Liner Positioner / Impactor 28mm 15°	1 ea
80003215	Lineage® Liner Positioner / Impactor 32mm 15°	1 ea

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Ordering Information - Instruments

Lineage[®] Core Instrument Set

8000KIT4

Catalog No.	Description	Quantity
80002800	Lineage [®] / Transcend [®] 28mm 0° Liner / Positioner / Impactor	1 ea
80003200	Lineage [®] / Transcend [®] 32mm 0° Liner / Positioner / Impactor	1 ea
80003600	Lineage [®] / Transcend [®] 36mm 0° Liner / Positioner / I mpactor	1 ea
80000010	Lineage [®] / Transcend [®] Insert Impactor Handle	1 ea
80000020	Lineage [®] / Transcend [®] Modular Impactor Tip	1 ea
8000Cl00	Lineage [®] / Transcend [®] Shell Impactor / Extractor	1 ea
18080288	Infinity® Universal Joint Screwdriver	1 ea
18410135	Ortholoc [®] Tibial Screwdriver	1 ea
81000021	Lineage [®] Liner Extractor Group 1	1 ea
82000021	Lineage [®] Liner Extractor Group 2	1 ea
83000021	Lineage® Liner Extractor Group 3	1 ea
84000021	Lineage [®] Liner Extractor Group 4	1 ea
81000000	Lineage [®] / Transcend [®] Impactor / Extractor Tip Group 1	1 ea
82000000	Lineage [®] / Transcend [®] Impactor / Extractor Tip Group 2	1 ea
83000000	Lineage [®] / Transcend [®] Impactor / Extractor Tip Group 3	1 ea
84000000	Lineage [®] / Transcend [®] Impactor / Extractor Tip Group 4	1 ea
18056020	SLT Taper Fem Head Trial 36mm OD -3.5mm w/Flat Short Neck	1 ea
18056021	SLT Taper Fem Head Trial 36mm OD +0mm w/Flat Medium Neck	1 ea
18056022	SLT Taper Fem Head Trial 36mm OD +3.5mm w/Flat Long Neck	1 ea
18056023	SLT Taper Fem Head Trial 36mm OD +7mm w/Flat X-Long Neck	1 ea
18056060	SLT Taper Fem Head Trial 32mm OD -3.5mm w/Flat Short Neck	1 ea
18056061	SLT Taper Fem Head Trial 32mm OD +0mm w/Flat Medium Neck	1 ea
18056062	SLT Taper Fem Head Trial 32mm OD +3.5mm w/Flat Long Neck	1 ea
18056063	SLT Taper Fem Head Trial 32mm OD +7mm w/Flat X-Long Neck	1 ea
18056050	SLT Taper Fem Head Trial 28mm OD -3.5mm w/Flat Short Neck	1 ea
18056051	SLT Taper Fem Head Trial 28mm OD +0mm w/Flat Medium Neck	1 ea
18056052	SLT Taper Fem Head Trial 28mm OD +3.5mm w/Flat Long Neck	1 ea
18056053	SLT Taper Fem Head Trial 28mm OD +7mm w/Flat X-Long Neck	1 ea
18056054	SLT Taper Fem Head Trial 28mm OD w/Flat XX-Long Neck	1 ea
8400CP01or 33330060	Cup Positioner / Impactor	1 ea
84004000	Lineage® Cup Instrument Tray and Lid	1 ea

Ordering Information - Instruments

Interseal® Stainless Steel Trial Shells Group 1-4

3100KIT2

Catalog No.	Description	Group	Diameter
40002046	Interseal [®] Stainless Steel Trial Shell	Group 1	46mm
40002048	Interseal [®] Stainless Steel Trial Shell	Group 1	48mm
40002052	Interseal [®] Stainless Steel Trial Shell	Group 2	52mm
40002054	Interseal [®] Stainless Steel Trial Shell	Group 2	54mm
40002056	Interseal [®] Stainless Steel Trial Shell	Group 2	56mm
40002060	Interseal [®] Stainless Steel Trial Shell	Group 3	60mm
40002062	Interseal [®] Stainless Steel Trial Shell	Group 3	62mm
40002064	Interseal [®] Stainless Steel Trial Shell	Group 3	64mm
41002050	Interseal [®] Stainless Steel Trial Shell	Group 1	50mm
41002058	Interseal [®] Stainless Steel Trial Shell	Group 2	58mm

Screw Instruments

Catalog No.	Description
4820SH0000	Screw Holder
8400DG01	Fixed Angle Drill Guide 3.2mm / 4.5mm
8400DG03	Adjustable Drill Guide
8400FD04	Flex Drill Bit 3.2 x 15mm
8400FD05	Flex Drill Bit 3.2 x 25mm
8400FD06	Flex Drill Bit 3.2 x 35mm
8400FD07	Flex Drill Bit 4.5 x 15mm
8400FD08	Flex Drill Bit 4.5 x 25mm
8400FD09	Flex Drill Bit 4.5 x 35mm
8400FD10	Flex Drill Bit 4.5 x 45mm
8400SD02	Hex Head Screwdriver Bit Modular
8400SD03	Cardan 3.5mm Hex Driver Shaft
8400SD04	Ball & Socket 3.5mm Hex Driver Shaft Straight Solid
8400SD06	Hex Driver Shaft Straight Solid 3.5mm
8400SG02 OR 8400SG01	Flexible Screw Depth Gauge
8400ST01	Screw Tap Modular 6.5 x 15mm
8400ST02	Screw Tap Modular 6.5 x 25mm
8400ST03	Screw Tap Modular 6.5 x 35mm
84003000	Acetabular Screw Instrument Case
8400SD11 or 2002QCRH	Quick connect Rachet Handle
8400FD12 or 8400FD01	Flexible Drill Bit Shaft



Chapter 7

Indications and Warnings

Intended Use

MicroPort acetabular systems are intended for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

- Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
- 2. Inflammatory degenerative joint disease such as rheumatoid arthritis;
- 3. Correction of functional deformity; and,
- 4. Revision procedures where other treatments or devices have failed

LINEAGE[®] modular shells with porous metal bead coating may be used in either cemented or uncemented arthroplasty.

Contraindications

Patients should be warned of these contraindications.

Contraindications include:

- 1. Overt infection;
- Distant foci of infections (which may cause hematogenous spread to the implant site);
- Rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram;
- Skeletally immature patients (patient is less than 21 years of age at the time of surgery);

- Cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;
- 6. Neuropathic joints;
- 7. Hepatitis or HIV infection;
- 8. Neurological or musculoskeletal disease that may adversely affect gait or weightbearing.

Additional Contraindications

Patient selection should consider the following factors which could lead to increased risk of failure and can be critical to the eventual success of the procedure: the patient's weight, activity level, and occupation. The patient should not have unrealistic functional expectations for occupations or activities that include substantial walking, running, lifting, or muscle strain.

Product Specific Warnings and Precautions

The potential long-term biological effects of metal wear debris and metal ion production are not known. Questions regarding carcinogenicity have been raised in literature; no studies have conclusive evidence that metal wear debris or metal ions are carcinogenic.

Indications and Warnings

Acetabular Fixation Screws

Perforation of the pelvis with dome fixation screws or rim screws is to be completely avoided. Care is to be used when determining and selecting the proper length of screws to be used to prevent perforation of the pelvis.

Modular Acetabular Shell/Liner

• Fixation screws, when used, should be fully seated to ensure stable fixation of the shell, and avoid interference with the liner component. Before implanting, be certain the selected shell and liner are compatible. Prior to seating the liner component into the shell component, surgical debris must be cleaned from the interior of the shell and the shell must be thoroughly dried. Debris and fluid may inhibit the liner from locking into the shell component. Failure to properly seat the liner into the shell can lead to disassociation of the liner from the shell.

In order to prevent mismatch of tapers:

 Modular liners from MicroPort must be used only with shell components of the same system from MicroPort.

Other Modular Components

Scratching of femoral heads, modular necks and proximal and distal stem tapers should be avoided. Repeated assembly and disassembly of these components could compromise the locking action of the taper joint. Prior to assembly, surgical debris must be cleaned from the interior of the female seat of the proximal body to ensure proper locking. Ensure components are firmly seated to prevent disassociation. The femoral head, neck taper of the femoral component, modular neck tapers, body taper, female seat of the proximal body **must** be clean and dry before assembly. Do not resterilize femoral prostheses with ceramic femoral heads seated on the stem.

Please refer to the content below for specific warnings and precautions regarding ceramic femoral heads.

Stems and modular necks with the 12/14 SLT Taper should only be used in combination femoral heads with the 12/14 SLT Taper. Cobalt chrome femoral heads with the 12/14 SLT Taper are designed for use with cobalt-chrominum-molybdenum, titanium alloy and (ISO 5832-9) stainless steel femoral components with the 12/14 SLT Taper and to articulate with UHMWPE liners only. The superfinished cobalt chrome femoral heads are designed to articulate with UHMWPE liners.

The superfinished cobalt chrome femoral heads are designed to articulate with UHMWPE liners. Ceramic femoral heads should not be placed on scratched or previously assembled metal tapers as this may lead to a ceramic fracture.

CoCr Modular necks are not for use with the following devices:

- Alumina (Biolox[°] Forte) Ceramic Femoral Head size 28mm long
- Profemur[®] E Size 0 Hip Stem

Indications and Warnings

Ceramic/ceramic articulating combinations should only combine bearing components from a single manufacturer to ensure the two components possess compatible manufacturing tolerances.

The joint may not luxate during movement or subluxate through impingement of the implant components or of soft tissue.

Seat the acetabular shell at a 45° inclination with 15° anteversion for proper positioning to decrease the chance of dislocation. The inclination of the cup components should not significantly exceed or fall below a value of 40-45°.

The anteversion of the cup components should not significantly exceed or fall below a value of 10-20°.

Outside this range there are restrictions in movement which can lead to subluxations and/or dislocations of the femoral head from the ceramic insert.

For a cup position which lies outside the above-mentioned values, a ceramic insert must not be used. For acetabular shells in retroversion, a ceramic insert must not be used. Possible consequences are an increase in the surface pressure on the cup edge with grain break-out from the ceramic insert associated with increased ceramic debris. Excessive ceramic debris can lead to adverse tissue reactions, loosening of the prosthesis and in extreme cases ceramic breakage.

Ensure adequate joint tension is achieved on implantation, as luxation can also lead to the adverse results listed above.

Always ensure proper alignment and seating of the acetabular liner before impacting to prevent chipping or damage.

Do not disassemble and reassemble the liner component to the

acetabular shell because the locking joint and taper joint might become damaged.

Do not scratch modular shells and tapers to prevent damage to the locking joint.

Do not place ceramic components on scratched or previously assembled metal tapers as this may lead to a ceramic fracture.

The ceramic femoral head is placed on the stem taper by twisting lightly and using axial manual pressure until it sits firmly.

Place the plastic head impactor on the pole of the ceramic femoral head, and with a moderate tap of the hammer in an axial direction, firmly and definitively fix it on the stem taper. The surface structure of the metal taper becomes distorted plastically by the tapping of the impactor, causing an optimal distribution of pressure and a torsion-resistant fixation.

On rare occasions, in vivo fracturing of the ceramic components may occur. In order to minimize this risk, the components were individually examined before delivery. Extremely careful handling is required with ceramic devices, which must not be used if dropped, even in the absence of any apparent damage. Even small scratches or impact points can cause wear and tear or fracture and lead to complications. Cause of fracture can be an overload on the prosthesis, for example through incorrect placement of the ceramic head on the stem taper or a wrong or missing fit between the ceramic head and the stem taper. The use of prosthesis components which are not released by MicroPort for combination with a ceramic component can also lead to the fracture of the implant. The recommended position of the acetabular insert (inclination/ anteversion) must be observed. Only use a plastic tip to introduce the ceramic devices.

Indications and Warnings

Fracture of ceramic components is a serious complication. Patients should be advised to report unusual noise and/or sharp pain as both can be an indication of fracture. Decision to revise should not be postponed as ceramic fragments can cause severe damage to surrounding soft tissue and metal components. Revision outcomes after ceramic fractures can be compromised by the remaining ceramic debris present in the tissue even after careful debridement.

Damage has been reported in polyethylene and metal components used in revisions after ceramic fractures. Metal heads should not be used after a ceramic fracture. Surgeons are advised to carefully consider all available implant options on an individual basis. It must be noted that removal of all components including femoral stems and acetabular shells may not prevent accelerated wear due to ceramic debris in the tissue. Partial or complete synovectomy has been recommended by some authors.

The size 28mm Long Neck alumina (Biolox Forte) "Ceramic Femoral Heads" are indicated for use only with titanium alloy femoral stems. All other sizes of the alumina (Biolox Forte) "Ceramic Femoral Heads" and all sizes of the Alumina Matrix Composite Heads ("Biolox Delta Femoral Head") are indicated for use with titanium alloy, cobalt chrome, or MicroPort stainless steel (not available in the U.S. or Canada) femoral stems. IMPORTANT: Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions for Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

Lineage® Acetabular Cup System



Full Function, Faster®



MicroPort Orthopedics Inc. 5677 Airline Road Arlington, TN USA 38002 866.872.0211

EC REP

MicroPort Orthopedics BV Hoogoorddreef 5 1101 BA Amsterdam The Netherlands +31 20 545 01 00

ortho.microport.com

The CE-Marking of Conformity is applied per catalog number and appears on the outer package label, if applicable.

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