LOGICAL

Digitally signed by Chicu Natalia
Date: 2022.06.30 15:33:23 EEST
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Location: Moldova

Signature ORTHOPAEDICS

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Introduction

The Signature Orthopaedics Logical Instrument system is an optimised instrument set for implantation of the Signature Orthopaedics Logical Cementless Acetabular Cup and Liner. The Logical instrument set is comprised of two trays for a s*treamlined* and efficient instrument set.
The primary tray contains all of the common base instruments needed for every procedure.
The secondary tray serves as an ancillary case that is required only for very small and large statured patients.

Indications

Signature Orthopaedics' hip replacement range are intended to replace a hip joint where bone stock is sufficient to support the implant. When a surgeon has selected prostheticreplacement as the preferred treatment, the devices are indicated for:

- Non-inflammatory degenerative joint disease including osteoarthritis or avascular necrosis
- Inflammatory joint disease including rheumatoid arthritis (excluding TSI stem)
- Correction of functional deformity including congenital hip dysplasia
- Traumatic injury involving the hip joint including traumatic arthritis or femoral head or neck fracture
- Failed previous hip surgery including internal fixation or joint fusion, reconstruction, hemiarthroplasty, surface replacement, or total replacement.

Signature Orthopaedics' constrained liner components are indicated particularly for patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

Contradictions

In general, prosthetic components require adequate bone support for correct fit and function. The use of prosthetic components is therefore contraindicated where any pathological condition may reduce the quantity and or strength of the bone which is supporting the prosthesis. Some contraindications are relative to the extent and severity of conditions and the benefits of prosthetic arthroplasty should be considered based on the patient's overall evaluation and the possibility of alternative treatment. Examples of such conditions include; osteoporosis, osteomalacia, osteogenesis imperfecta, or hypophosphatemia.
Other contraindications include:

- Conditions limiting blood supply to the bone or joint.
- Systemic or local infection.
- Previous high dose radiotherapy.
- Psychological or neurological conditions which would restrict the patient's ability or compliance in restricting physical activity.
- Skeletal immaturity
- Conditions or activity which may place excessive load on the components such as; obesity, muscle, tendon & ligament deficiencies, multiple joint disabilities, and Charcot joints.
- Signature Orthopaedics' constrained liners are contraindicated particularly for active patients.

Logical Acetabular Cup and Liner Features

Ceramic Liner (not available in the U.S.A)

- Clinically proven geometry and material (BIOLOX® delta)
- Excellent biological behaviour
- Significantly low taper corrosion
- No metal ion release

Polymer Liner

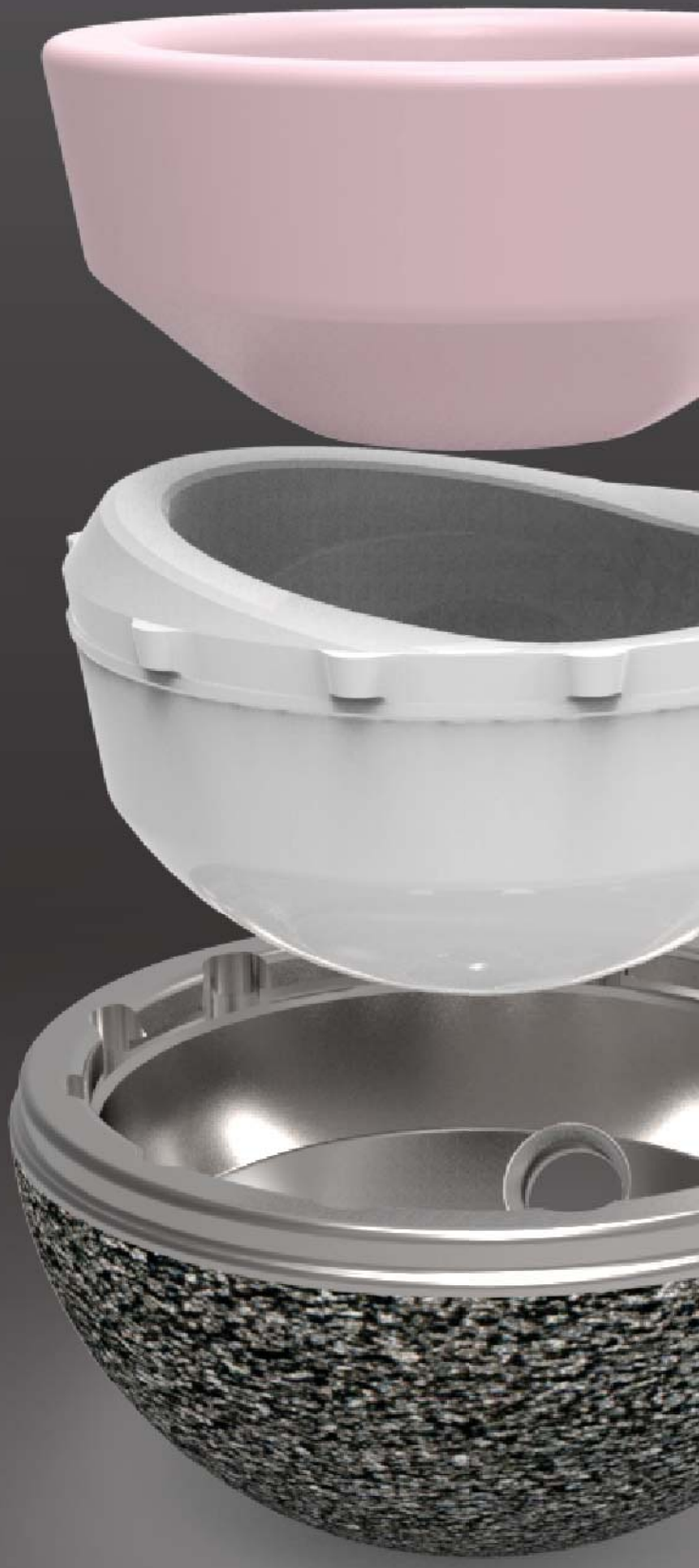
- Clinically proven geometry, material (UHMWPE)
- Base resin: GUR1020
- Stock Forming: Compression molded
- Cross Linking: Gamma irradiation at 7.5 MRads
- Thermal Stabilisation: Remelting
- Sterilisation: ETO
- Available in both neutral, 10° hooded, constrained and +4mm lateralised variations

Acetabular Cup

- Clinically proven geometry, material (Ti6Al4V) and porous coating.
- Available in 3-Hole, multi-hole and no hole options.

Sintered Titanium Coating (G-Series)

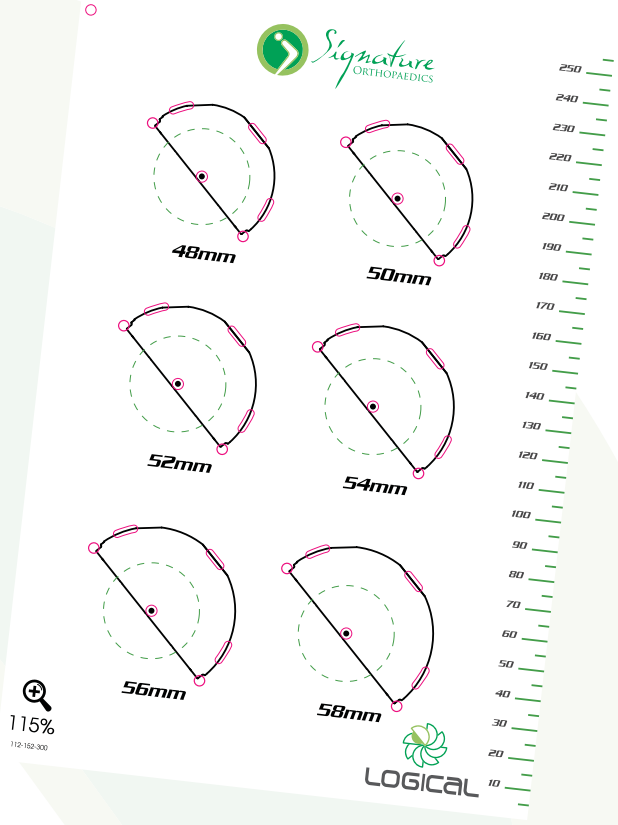
- Tensile Strength > 35MPa
- Shear Strength > 25MPa
- Porosity 45-65% and pore size 100-300 microns.



1

Preoperative Planning

Preoperative assessment of the appropriate size and position of the acetabular component will provide intraoperative guidance for acetabular reaming. To determine the acetabular cup size and position, hold the template at approximately 45° of abduction and place the center of rotation over the anatomic center of the acetabular image. Final component size and position should be determined intraoperatively. Templates are 115% magnification.

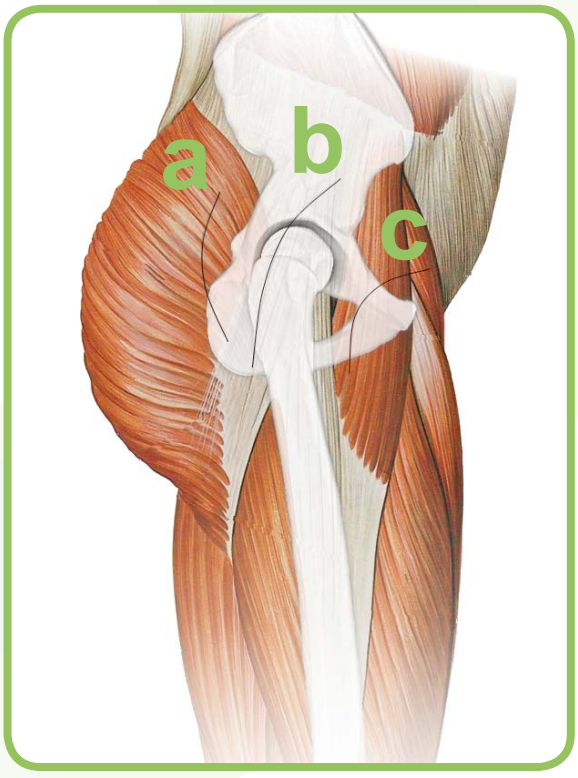


2

Preoperative Planning

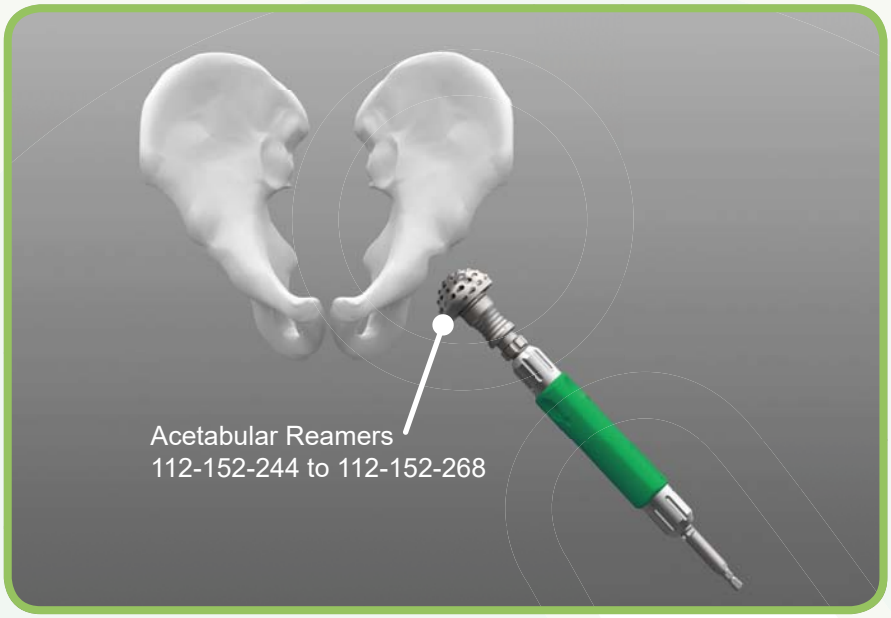
The Logical cup can be used with any surgical approach that the surgeon selects.

a. Posterior approach
b. Posterolateral/anterolateral approach
c. Anterior approach

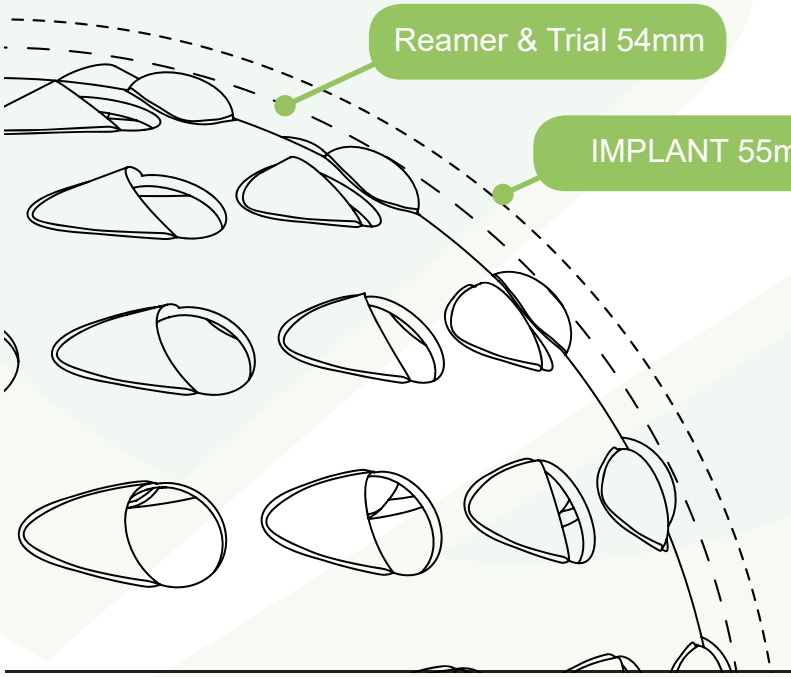


3 Acetabular Preparation

Osteophytes should be removed to gain 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 circumferential line on the reamer will mimic a full hemisphere. Gradually enlarge the acetabulum by reaming articular cartilage until a continuous surface of cancellous bone is exposed.



Note:
A 54mm reamer will ream a hemispherical cavity 54mm in diameter, and a 54mm trial cup is Ø54mm.
A 54mm Logical cup is 54mm + 1mm of porous coating. This coating thickness of 1mm will give a press fit.



Reamer Handles available in both large (112-152-018) and slim verisons (112-152-342)

4 Acetabular Preparation

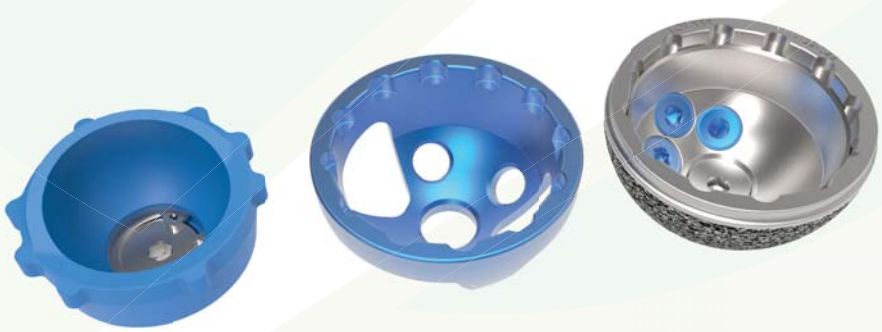
Osteophytes should be removed to gain assessment of the true acetabular rim. Reaming should be sequential and start with the smallest reamer that conforms to the acetabular cavity. Reaming to the circumferential line on the reamer will mimic a full hemisphere. Gradually enlarge the acetabulum by reaming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

Trial Acetabular Cups

Part Number	Diameter
112-152-191	44mm
112-152-192	46mm
112-152-193	48mm
112-152-194	50mm
112-152-195	52mm
112-152-196	54mm
112-152-197	56mm
112-152-198	58mm
112-152-199	60mm
112-152-200	62mm
112-152-201	64mm
112-152-202	66mm
112-152-203	68mm

Instrument Identification:
Trial acetabular cups are identified by the size marked on the top rim. They are also colour-coded to match with compatible trial liners. Each trial cup size corresponds to a Logical cup implant size. Refer to the Logical Implants Sizing Chart in this technique for more details (pg13).

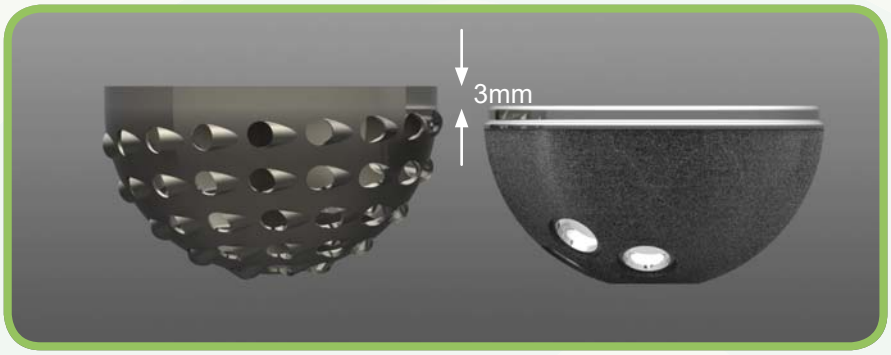
Example below:
Connection type B shown, the blue trial liner matches the blue trial shell, which matches the blue colouring on the box label and the hole covers on the implant.

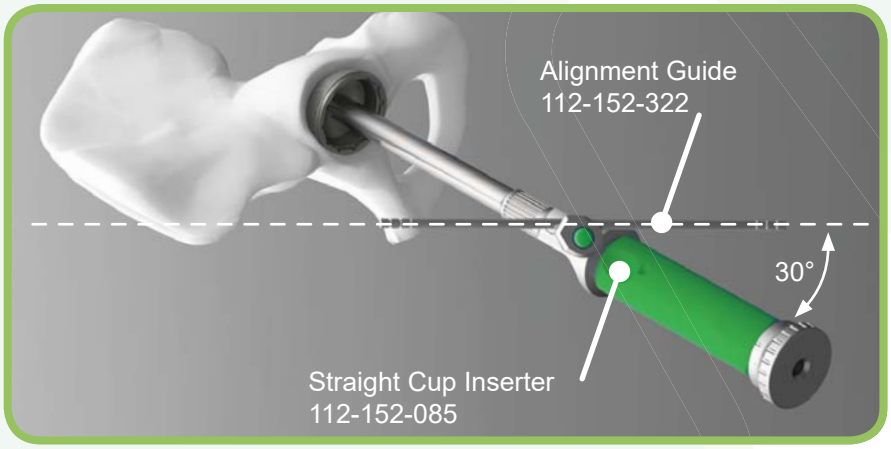


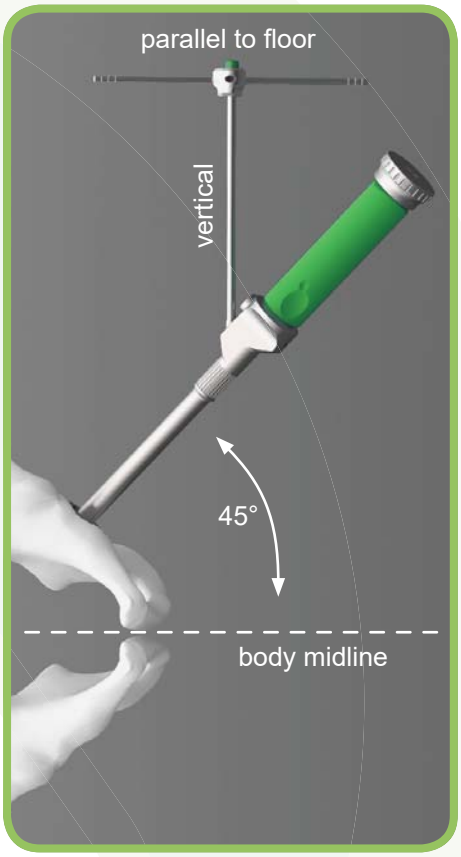
5

Implant Acetabular Cup Insertion

Thread the appropriate size prosthetic cup onto the impactor (same size as the final reamer). The cup rotation can be adjusted with regards to the impactor by pressing the button and rotating the strikeplate, in increments of 15°. The alignment guide can be attached to the impactor to help with anteversion and abduction angles. Seat the cup with a series of firm mallet blows to the end of the impactor. Screw placement can begin once the cup component is securely positioned and the impactor is removed.





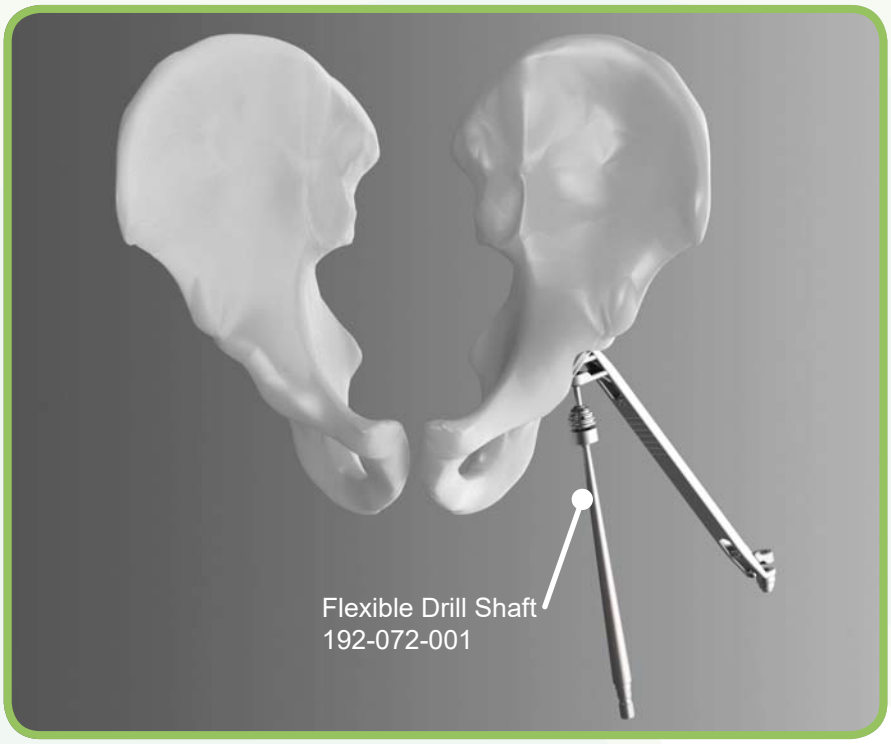


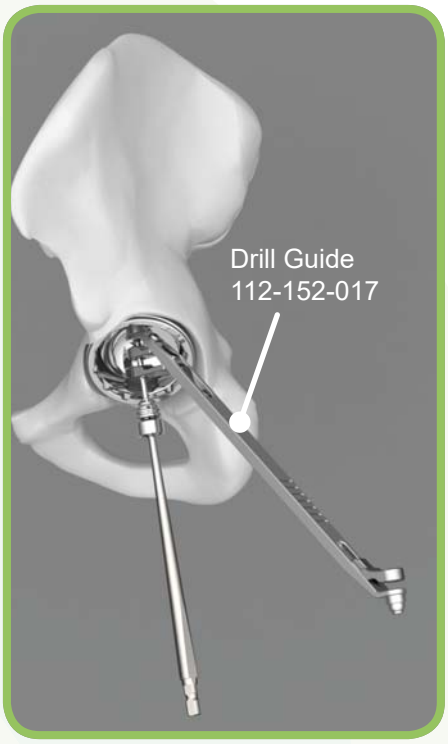
Note:
The alignment guide indicates 30° of operative anteversion, which equates to 20° of radiographic anteversion. Operative anteversion differs from radiographic anteversion due to the projection of angles on a radiograph.

Optional:
A curved cup inserter option is also available, please inquire for additional instructions for use.

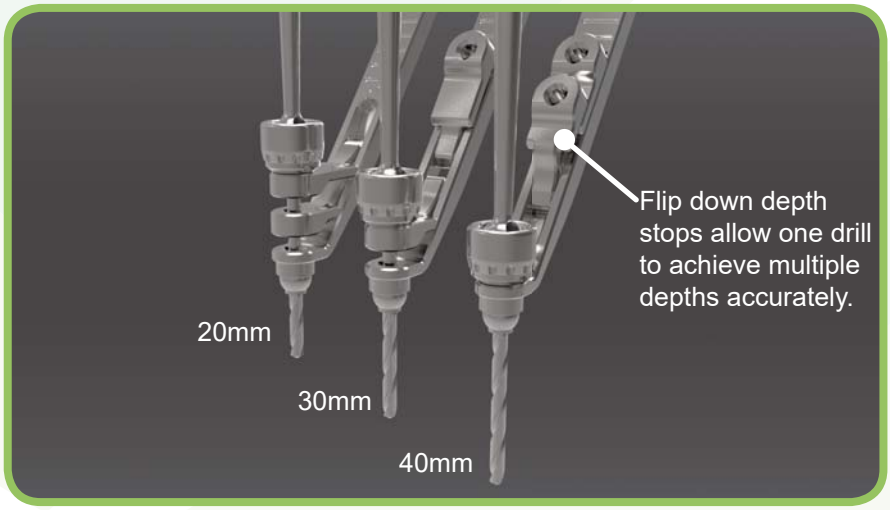
6 Determine Screw Location and Drill Depth

Determine screw location and select a suitable drill depth (see figure below). The flexible drill allows a wide range of drilling angles while still being able to apply pressure to the drill.



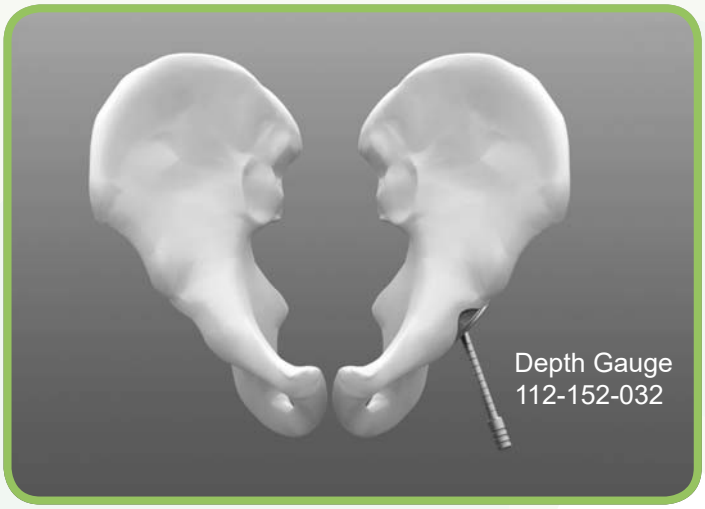


Instrument operation:
The drill guide has flip-down depth stops at each end. One end has 10mm steps, which allows a 50mm drill to drill a hole at 40, 30 and 20mm deep.
While the other end has steps of 5mm, which allows holes to be drilled at 25 and 35mm.



7 Determine Screw Length

Use the screw depth gauge to determine the appropriate length screw. Due to intrapelvic vascularity, screw placement in the medial aspect of the acetabulum must be carefully considered.



8 Insert Screws

Screws snap into the screw inserter, allowing them to rotate freely without falling out at any angle. Pull inserter off screw to allow for countersinking of the screw head. Full seating can be confirmed with the use of a trial liner prior to impacting the prosthetic liner, or by manually examining the inner surface. To ensure proper prosthetic liner seating in the cup, screw heads must be seated below the inner surface of the cup. Hex driver available in both tapered and parallel versions.

Solid end provides stability to flexible driver.

9 Trial Liner Evaluation

Trial liners that match the prosthetic implant are available to evaluate the optimum position of the final implant. Position the trial liner in the desired orientation and secure it in place with the captured screw using one of the 3.5mm hex screwdriver shafts. Apical Screw insertion should not take place until a reduction with the trial liner is completed.

Neutral	10° Hooded	Head Ø(mm)	Cup Ø(mm)
112-152-156	112-152-061	28	44-46
112-152-157	112-152-062	28	48-50
112-152-158	112-152-063	28	52-54
112-152-159	112-152-064	32	48-50
112-152-160	112-152-065	32	52-54
112-152-161	112-152-066	32	56-58
112-152-162	112-152-067	32	60-70
112-152-163	112-152-068	36	52-54
112-152-164	112-152-069	36	56-58
112-152-165	112-152-070	36	60-70
112-152-166	112-152-142	40	56-58
112-152-167	112-152-143	40	60-70

10 Liner Placement

Prior to inserting the prosthetic liner, thoroughly irrigate and clean the cup. Insert the prosthetic liner by hand (or using the ceramic liner inserter (112-152-230) if ceramic is chosen), making sure the face of the liner is parallel with the face of the acetabular cup. The anti-rotation tabs should be lined up with the slots in the cup. Use the liner impactor on the cup impactor to apply a series of firm mallet blows to fully seat the liner.

A final inspection of the liner should be done to ensure the liner is firmly locked in place. Neutral and ceramic liners should be flush with the cup face along the entire rim. Only the lower half of the rim of lipped liners should be flush with the cup face.

10

Ceramic Liner Placement

The ceramic liner inserter (112-152-230), has a series of snap rings that are coloured per the connection type. The example below is yellow (C type connection).
4 different Impactor heads are available (28/32/26/40mm - 112-152-21X).
The snap ring is loaded onto the inserter first, followed by the impactor head. This will grip the ceramic liner firmly, in any position desired.
Once the ceramic liner is loaded into the shell, a firm tap on the end of the inserter will see the snap ring let go of the ceramic liner, and the ceramic liner seat into the shell. Further impaction may be done using the straight cup inserter coupled with the ceramic liner impact adapter, as shown below.

An alternative to the liner impactor for the ceramic liners, is to use the “Ceramic Liner Impact Adapter” (112-152-305) with an appropriate sized trial head. This combination can also be used on the polyethylene liners.

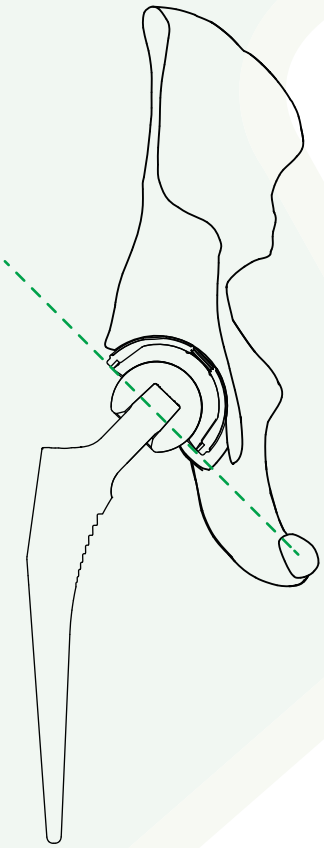
11

Positioning

Current studies* have highlighted that correct acetabular component positioning is a key element to success with all types of bearings used in hip replacement surgery. As well as subluxation, impingement, fixation and range of motion, optimum femoral head coverage and mechanical loading of the bearing must also be considered when positioning the acetabular component. Incorrect acetabular component positioning can lead to edge loading and undesirable effects across all bearings, such as dislocation, increased wear, and polyethylene fractures.

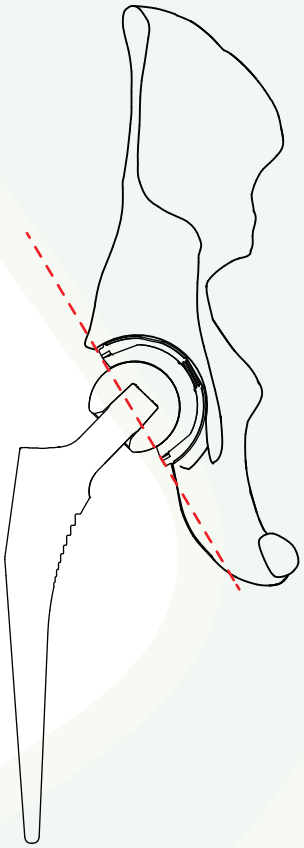
CORRECT

Inclination 40-45°
Anteversion 15-20°



INCORRECT

Inclination >45°
Anteversion >20°



*Data on file

12

Polyethylene Liner removal

Upon removal of any Liner, inspect the taper and polyethylene locking mechanisms for damage.
Special care should be taken not to lever against the Shell during Liner removal.

• Locate a 3.5mm drill bit included in the Kit.

• Drill a pilot hole into the dome of the Liner between the pole and the taper region of the Shell.

• Drive the screw into the pilot hole by hand until the Liner is lifted out of the Shell.

• Special care should be taken not to damage the Shell taper or locking mechanism during removal of the Liner.

Logical Implant Sizing Guide

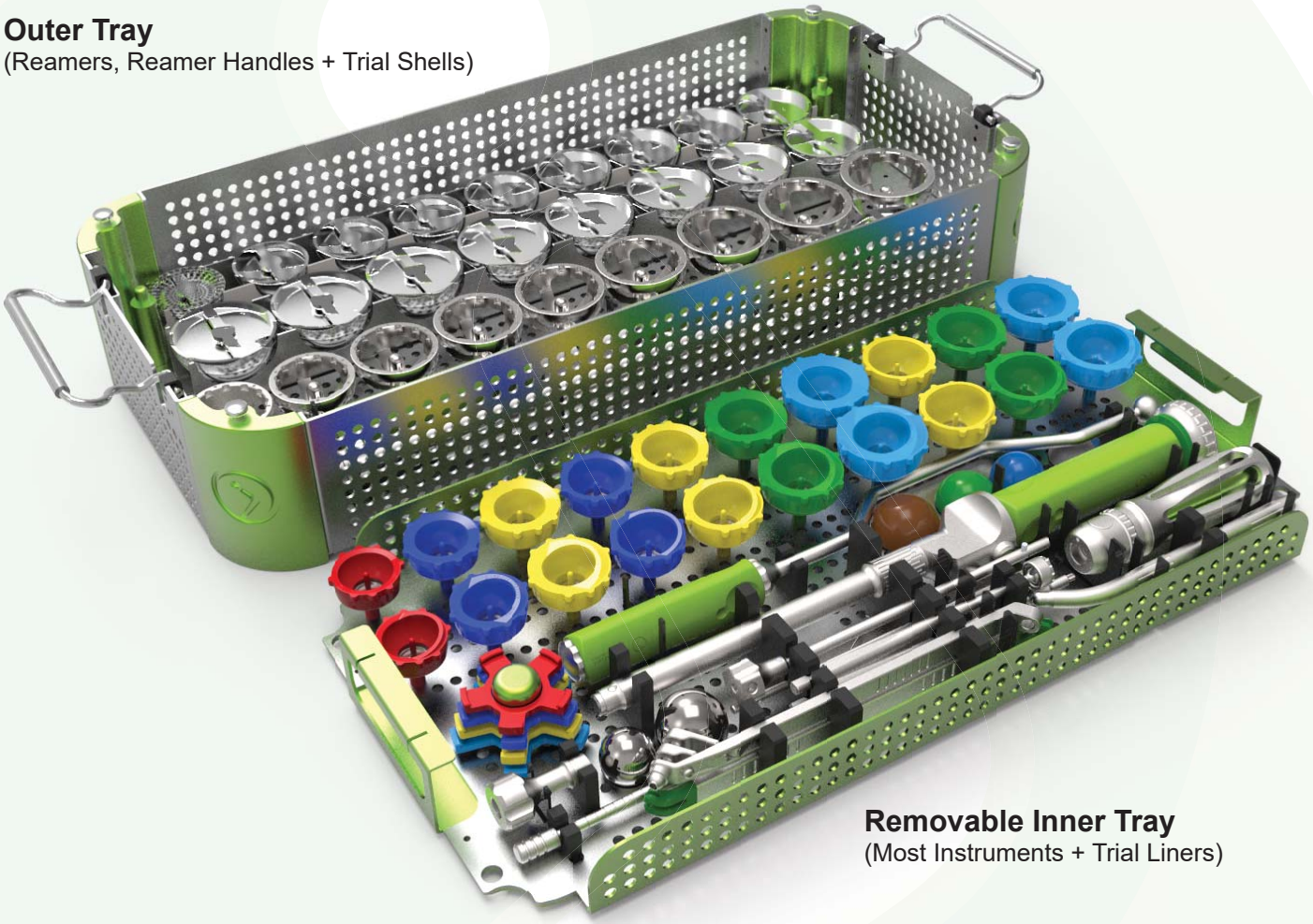
Acetabular Cups, ceramic and UHMWPE Liners

	28	32	36	40
111-12-3344 44 111-12-3346 46  A	Neutral 111-12-5844 Hooded 111-12-6844 Ceramic 111-22-1002 Constrained 111-12-9211 Lateralised 111-12-7844			
111-12-3348 48 111-12-3350 50  B	Neutral 111-12-5850 Hooded 111-12-6850 Ceramic 111-22-1003 Lateralised 111-12-7850	Neutral 111-12-5250 Hooded 111-12-6250 Ceramic 111-22-1005 Constrained 111-12-9212 Lateralised 111-12-7250		
111-12-3352 52 111-12-3354 54  C	Neutral 111-12-5852 Hooded 111-12-6852 Ceramic 111-22-1004 Lateralised 111-12-7852	Neutral 111-12-5252 Hooded 111-12-6252 Ceramic 111-22-1006 Lateralised 111-12-7252	Neutral 111-12-5652 Hooded 111-12-6652 Ceramic 111-22-1009 Constrained 111-12-9213 Lateralised 111-12-7652	
111-12-3356 56 111-12-3358 58  D	Neutral 111-12-5856 Hooded 111-12-6856	Neutral 111-12-5256 Hooded 111-12-6256 Ceramic 111-22-1007 Lateralised 111-12-7256	Neutral 111-12-5656 Hooded 111-12-6656 Ceramic 111-22-1010 Lateralised 111-12-7656	Neutral 111-12-5456 Hooded 111-12-6456 Ceramic 111-22-1012 Constrained 111-12-9214 Lateralised 111-12-7456
111-12-3360 60 111-12-3362 62 111-12-3364 64 111-12-3366 66 111-12-3368 68 111-12-3370 70  E	Neutral 111-12-5860 Hooded 111-12-6860	Neutral 111-12-5260 Hooded 111-12-6260 Ceramic 111-22-1008 Lateralised 111-12-7260	Neutral 111-12-5660 Hooded 111-12-6660 Ceramic 111-22-1011 Lateralised 111-12-7660	Neutral 111-12-5460 Hooded 111-12-6460 Ceramic 111-22-1013 Lateralised 111-12-7460

Logical Instrument Trays

Primary Logical Instrument Tray

Outer Tray
(Reamers, Reamer Handles + Trial Shells)



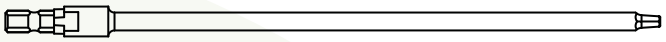
Removable Inner Tray
(Most Instruments + Trial Liners)

The secondary tray that is required only for very small and large statured patients not shown.

Logical Instruments

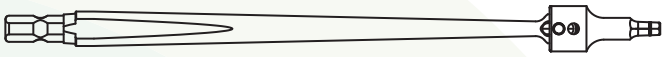
Hi Torque Screwdriver 3.5mm Hex

112-152-306



Flexible Screwdriver

112-152-026



Drill Guide

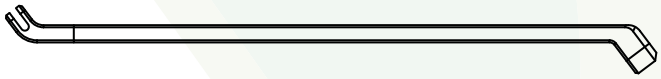
112-152-017

Depth Gauge

112-152-032

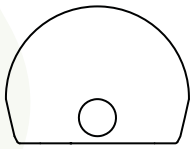
Screw Inserter

112-152-038



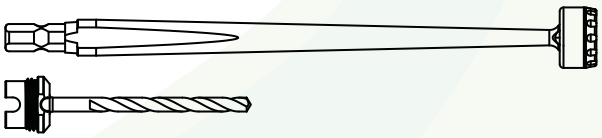
Liner Impactors

112-152-002 - 28mm
112-152-334 - 32mm
112-152-121 - 36mm
112-152-003 - 40mm



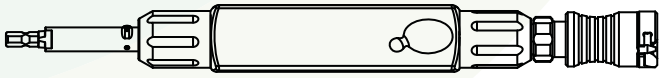
Optimus Drill (Flexible Drill)

192-072-001 (Drill bits 192-072-002)



Reamer Shaft Assembly

112-152-018 (Large Reamer Grip 112-152-316



Logical Instruments

Straight Cup Inserter

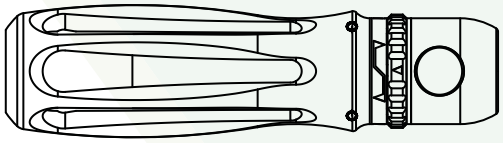
112-152-085 (Cup alignment can be set in increments of 15°)

Alignment Guide (Two parts in tray)

112-152-322 (Button release)

Ratcheting Screwdriver

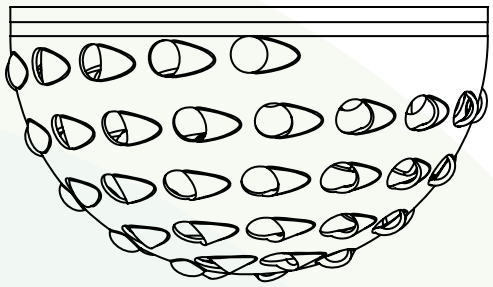
192-062-001



Logical Instruments

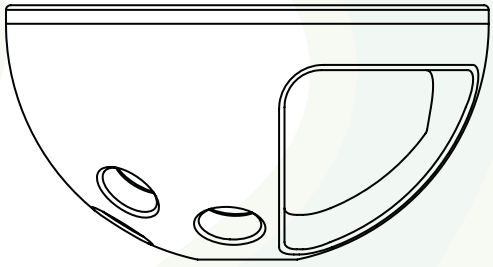
Acetabular Reamers

112-152-244	44mm
112-152-245	45mm
112-152-246	46mm
112-152-247	47mm
112-152-248	48mm
112-152-249	49mm
112-152-250	50mm
112-152-251	51mm
112-152-252	52mm
112-152-253	53mm
112-152-254	54mm
112-152-255	55mm
112-152-256	56mm
112-152-257	57mm
112-152-258	58mm
112-152-259	59mm
112-152-260	60mm
112-152-261	61mm
112-152-262	62mm
112-152-263	63mm
112-152-264	64mm
112-152-265	65mm
112-152-266	66mm
112-152-267	67mm
112-152-268	68mm
112-152-269	69mm
112-152-270	70mm



Trial Acetabular Cups

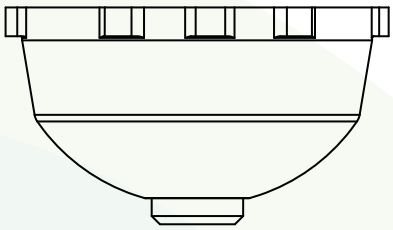
112-152-191	44mm
112-152-192	46mm
112-152-193	48mm
112-152-194	50mm
112-152-195	52mm
112-152-196	54mm
112-152-197	56mm
112-152-198	58mm
112-152-199	60mm
112-152-200	62mm
112-152-201	64mm
112-152-202	66mm
112-152-203	68mm
112-152-206	70mm



Logical Instruments

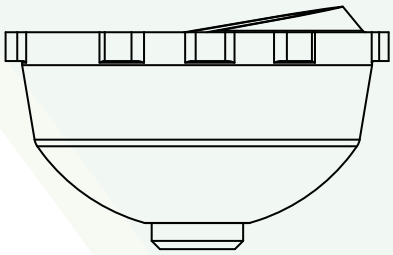
Logical Trial Liner Neutral

112-152-156	28/44-46mm	A
112-152-157	28/48-50mm	B
112-152-158	28/52-54mm	C
112-152-159	32/48-50mm	B
112-152-160	32/52-54mm	C
112-152-161	32/56-58mm	D
112-152-162	32/60-70mm	E
112-152-163	36/52-54mm	C
112-152-164	36/56-58mm	D
112-152-165	36/60-70mm	E
112-152-166	40/56-58mm	D
112-152-167	40/60-70mm	E



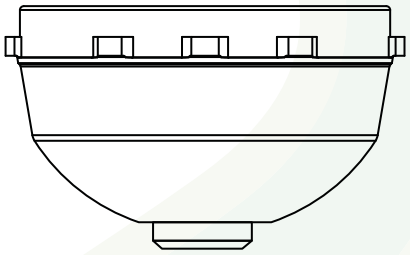
Logical Trial Liner 10° Hooded

112-152-061	28/44-46mm	A
112-152-062	28/48-50mm	B
112-152-063	28/52-54mm	C
112-152-064	32/48-50mm	B
112-152-065	32/52-54mm	C
112-152-066	32/56-58mm	D
112-152-067	32/60-70mm	E
112-152-068	36/52-54mm	C
112-152-069	36/56-58mm	D
112-152-070	36/60-70mm	E
112-152-142	40/56-58mm	D
112-152-143	40/60-70mm	E



Logical Lateralised Trial Liner Neutral

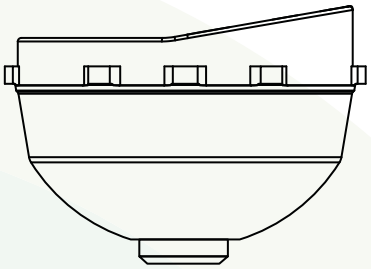
112-15-7244	28/44-46mm	A
112-15-7850	28/48-50mm	B
112-15-7852	28/52-54mm	C
112-15-7250	32/48-50mm	B
112-15-7252	32/52-54mm	C
112-15-7256	32/56-58mm	D
112-15-7260	32/60-70mm	E
112-15-7652	36/52-54mm	C
112-15-7656	36/56-58mm	D
112-15-7660	36/60-70mm	E
112-15-7456	40/56-58mm	D
112-15-7460	40/60-70mm	E



Logical Instruments

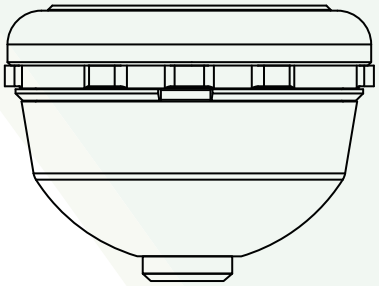
Logical Lateralised Trial Liner 10° Hooded

112-15-8244	28/44-46mm	A
112-15-8850	28/48-50mm	B
112-15-8852	28/52-54mm	C
112-15-8250	32/48-50mm	B
112-15-8252	32/52-54mm	C
112-15-8256	32/56-58mm	D
112-15-8260	32/60-70mm	E
112-15-8652	36/52-54mm	C
112-15-8656	36/56-58mm	D
112-15-8660	36/60-70mm	E
112-15-8456	40/56-58mm	D
112-15-8460	40/60-70mm	E



Logical Constrained Trial Liner

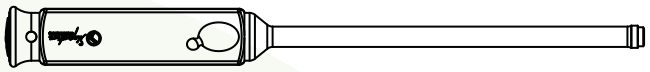
112-152-359	28/44-46mm	A
112-152-360	32/48-50mm	B
112-152-361	36/52-54mm	C
112-152-362	40/56-58mm	D
112-152-363	40/60-70mm	E



Logical Optional Instruments

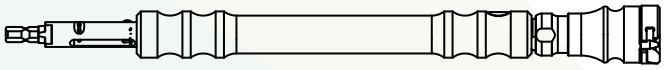
Simple Cup Inserter

112-152-310 (No moving parts)



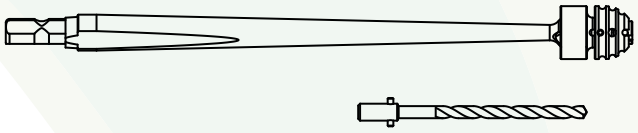
Slim Reamer Shaft Assembly

112-152-342 (Slim grip 112-152-022)



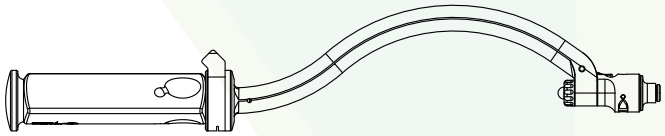
Optimus Q Drill (Flexible Drill)

192-072-020 (Drill bits 192-072-013)



Curved Cup Inserter

112-172-001

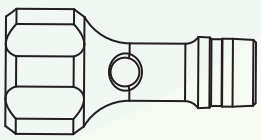


Alignment Guide (Two parts in tray)

112-172-022 (Spring fit)

Ceramic Liner Inserter

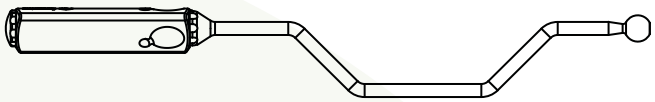
112-152-305



Logical Optional Instruments

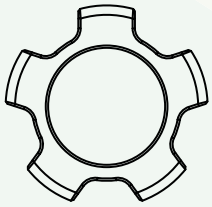
Ceramic Liner Inserter

112-152-230



Ceramic Liner Snap Rings

Part Number	Shell Size	Connection Type
112-152-214	44-46mm	A
112-152-215	48-50mm	B
112-152-216	52-54mm	C
112-152-217	56-58mm	D
112-152-218	60-70mm	E



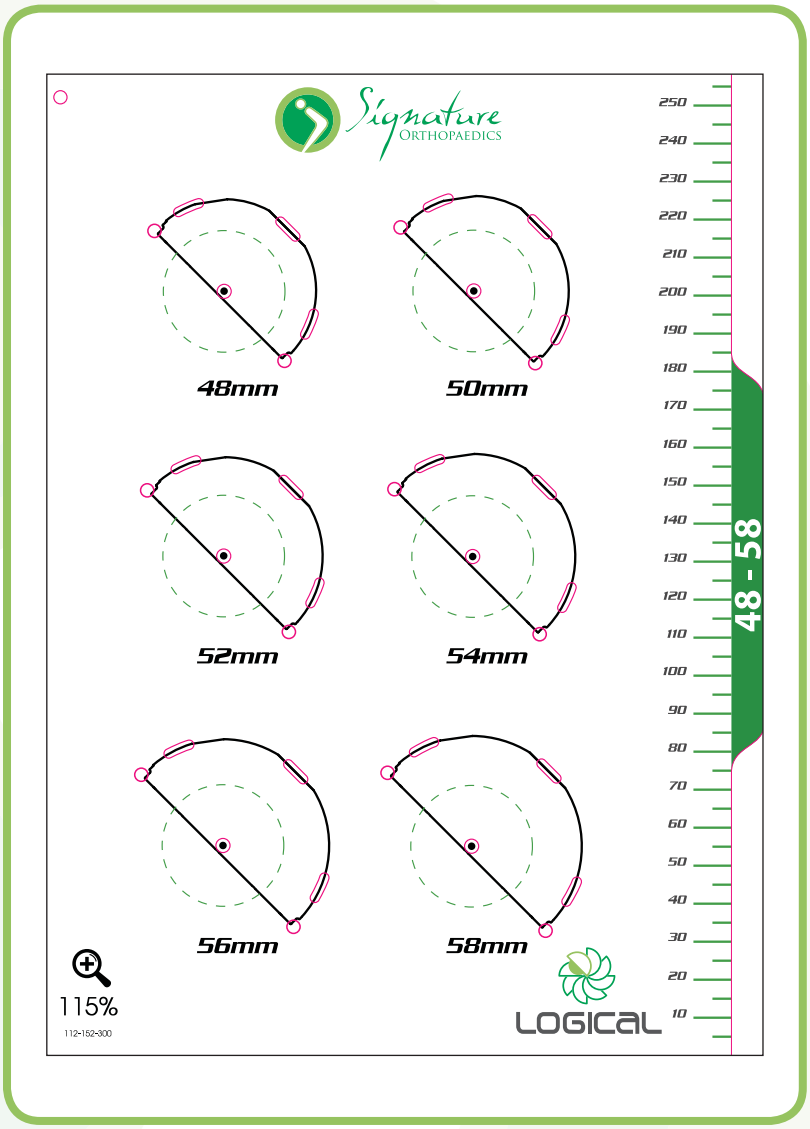
Ceramic Liner Snap Rings

112-152-210	Ø28mm
112-152-211	Ø32mm
112-152-212	Ø36mm
112-152-213	Ø40mm

Logical Preoperative Templates

Logical Templates

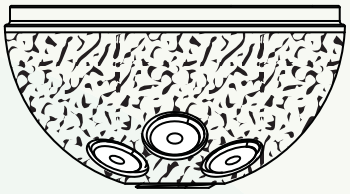
112-152-304	38-46mm
112-152-300	48-58mm
112-152-301	60-70mm



Logical Implants

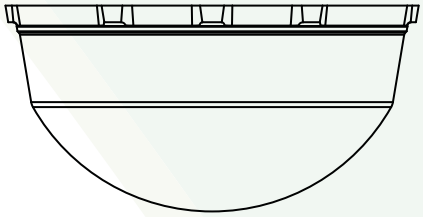
Logical G Series Acetabular Cups, 3 Hole

111-12-3344	44mm
111-12-3346	46mm
111-12-3348	48mm
111-12-3350	50mm
111-12-3352	52mm
111-12-3354	54mm
111-12-3356	56mm
111-12-3358	58mm
111-12-3360	60mm
111-12-3362	62mm
111-12-3364	64mm
111-12-3366	66mm
111-12-3368	68mm



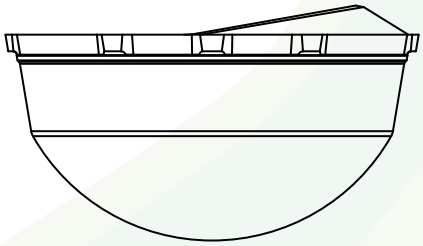
Logical UHMWPE Liner Neutral

111-12-5844	28/44-46mm	A
111-12-5850	28/48-50mm	B
111-12-5852	28/52-54mm	C
111-12-5250	32/48-50mm	B
111-12-5252	32/52-54mm	C
111-12-5256	32/56-58mm	D
111-12-5260	32/60-70mm	E
111-12-5652	36/52-54mm	C
111-12-5656	36/56-58mm	D
111-12-5660	36/60-70mm	E
111-12-5456	40/56-58mm	D
111-12-5460	40/60-70mm	E



Logical UHMWPE Liner 10° Hooded

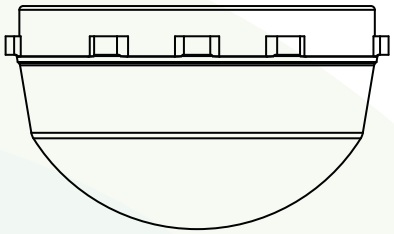
111-12-6844	28/44-46mm	A
111-12-6850	28/48-50mm	B
111-12-6852	28/52-54mm	C
111-12-6250	32/48-50mm	B
111-12-6252	32/52-54mm	C
111-12-6256	32/56-58mm	D
111-12-6260	32/60-70mm	E
111-12-6652	36/52-54mm	C
111-12-6656	36/56-58mm	D
111-12-6660	36/60-70mm	E
111-12-6456	40/56-58mm	D
111-12-6460	40/60-70mm	E



Logical Implants

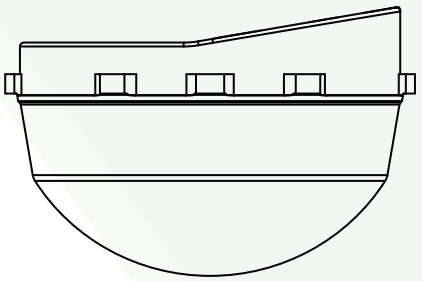
Logical UHMWPE Liner Neutral Lateralised

111-12-7844	28/44-46mm	A
111-12-7850	28/48-50mm	B
111-12-7852	28/52-54mm	C
111-12-7250	32/48-50mm	B
111-12-7252	32/52-54mm	C
111-12-7256	32/56-58mm	D
111-12-7260	32/60-70mm	E
111-12-7652	36/52-54mm	C
111-12-7656	36/56-58mm	D
111-12-7660	36/60-70mm	E
111-12-7456	40/56-58mm	D
111-12-7460	40/60-70mm	E



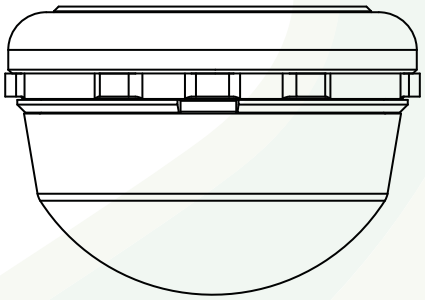
Logical UHMWPE Liner 10° Hooded Lateralised

111-12-8844	28/44-46mm	A
111-12-8850	28/48-50mm	B
111-12-8852	28/52-54mm	C
111-12-8250	32/48-50mm	B
111-12-8252	32/52-54mm	C
111-12-8256	32/56-58mm	D
111-12-8260	32/60-70mm	E
111-12-8652	36/52-54mm	C
111-12-8656	36/56-58mm	D
111-12-8660	36/60-70mm	E
111-12-8456	40/56-58mm	D
111-12-8460	40/60-70mm	E



Logical UHMWPE Liner Constrained

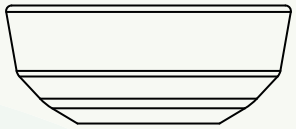
111-12-9200	22/44-46mm	A
111-12-9201	28/48-50mm	B
111-12-9202	32/52-54mm	C
111-12-9203	36/48-50mm	D
111-12-9204	40/60-70mm	E



Logical Implants

Logical Ceramic Liner Neutral

111-12-1002	28/44-46mm	A
111-12-1003	28/48-50mm	B
111-12-1004	28/52-54mm	C
111-12-1005	32/48-50mm	B
111-12-1006	32/52-54mm	C
111-12-1007	32/56-58mm	D
111-12-1008	32/60-70mm	E
111-12-1009	36/52-54mm	C
111-12-1010	36/56-58mm	D
111-12-1011	36/60-70mm	E
111-12-1012	40/56-58mm	D
111-12-1013	40/60-70mm	E

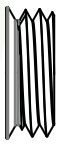


Acetabular Fixation Screws, Ø6.5mm

111-12-9115	15mm
111-12-9120	20mm
111-12-9125	25mm
111-12-9130	30mm
111-12-9135	35mm
111-12-9140	40mm
111-12-9145	45mm
111-12-9150	50mm
111-12-9155	55mm
111-12-9160	60mm
111-12-9165	65mm
111-12-9170	70mm

Apical Screw

111-12-9001



AUSTRALIAN MADE

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Signature ORTHOPAEDICS

CE 0086