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Introduction

The Signature Orthopaedics Aria stem is a Ti6Al4V dual-tapered stem with a lateral shoulder and proximally plasma-spray coated to promote bone ongrowth. The Signature Orthopaedics Aria Instrument system is an instrument set for implantation of the Signature Orthopaedics Aria cementless hip stem. The Aria instrument set features a modular broach handle that quick-connects to several instrument attachments to reduce the overall number of instruments and reduce the size and weight of the instrument tray.

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 prosthetic replacement 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 (Excluding TSI stem)
- Traumatic injury involving the hip joint including traumatic arthritis or femoral head fracture
- Traumatic injury involving neck fracture (excluding TSI stem)

Signature Orthopaedics hip replacement components may be intended for cemented or cementless use. Please verify whether the particular component is intended for cemented or cementless use by checking the package label.

Signature Orthopaedic TSI stem is particularly indicated for individuals with demonstrably healthy bone stock, such as younger, more active individuals. It is an uncemented stem and thus must only be used when the treating physician is satisfied with the quality of the recipient's bone.

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.

Contraindications

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.
- Allergies to implanted materials, particularly metals (e.g. cobalt, chromium) as well as polyethylene and bone cement.
- · 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.
- The use of Signature Orthopaedics' constrained liners are contraindicated with skirted femoral heads.
- Signature Orthopaedics' TSI stem is contraindicated for treatment of inflammatory joint disease including rheumatoid arthritis, where bone stock may not be sufficient to support the device.
- Signature Orthopaedics' TSI stem is contraindicated for use with the Logical constrained liner due to restricted range of motion.
- Signature Orthopaedics' TSI stem is contraindicated for treatment of femoral head or neck fracture.
- Signature Orthopaedics' TSI stem is contraindicated for treatment of functional deformity including congenital hip dysplasia.



Aria Stem Features

Cementless Hip Stem

- Material and coating (Ti6Al4V with titanium plasma spray coating).
- Threaded proximal feature aids in positioning and removal.

1. Standard and High offset versions

2. 12/14 Taper

3. Low-profile lateral shoulder

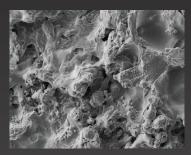
Enables insertion in reduced insertion techniques, including anterior approach.

4. Tapered geometry

Wedge-shaped stem initial fixation and proximal bone loading.

5. Titanium Plasma Spray Coating

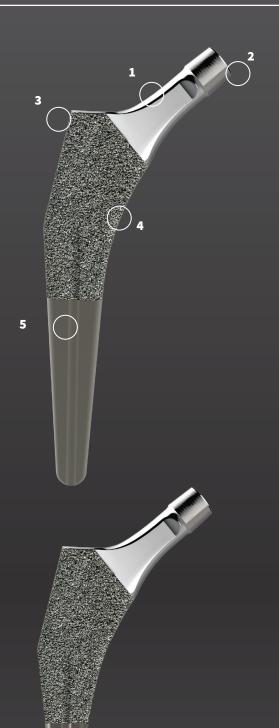
- Tensile Strength > 22MPa
- Shear Strength > 22MPa
- Coating Thickness 70-130 microns.



Aria coating x100

6. Reduced distal option*

- An option for cases where there are concerns over the distal loading of the femur.
- Provides surgical options to cater for a range of patients.

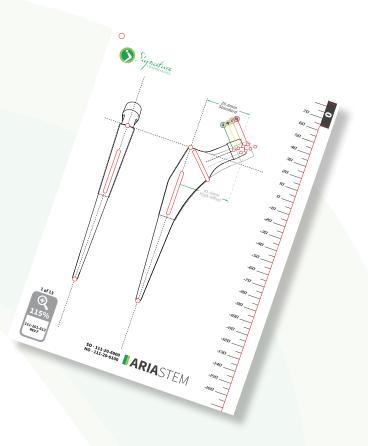


1

Preoperative Planning

Aria X-Ray templates can be used over anterior/posterior and lateral radiographs to help determine the correct size to restore the patient's anatomy.

Templates are 115% magnification.

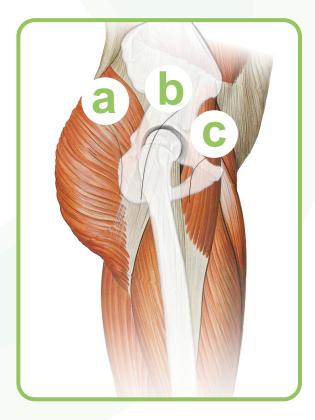


2

Preoperative Planning

The Aria stem can be used with any surgical approach that the surgeon selects.

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



Note:

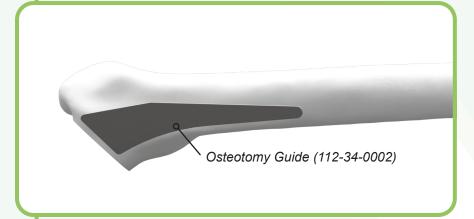
Prior to the following steps, complete all steps detailed in 111-12-0003 for the Logical acetabular cup implantation.





Femoral Neck Resection

The osteotomy guide should be used in conjunction with preoperative planning, to determine the level of the femoral neck resection. This can be performed in multiple steps, depending on surgeon preference.



Optional technique:

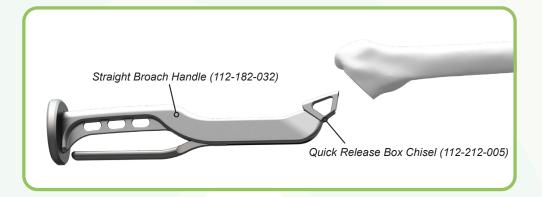
T-handle or under power to aid in the removal of the resected head, especially during an anterior approach technique.





Femoral Preparation

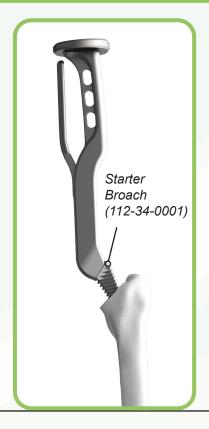
Enter the femoral canal as laterally as possible with the Box Osteotome to initiate access to the medullary canal. The Canal Reamer may be used as needed to open the natural axis of the femoral canal for broach preparation.



Optional technique:

While the Aria system is intended to be a broach-only system, the Aria instrument tray contains instruments for optional use to assist in proper axial alignment along the femoral canal and to induce lateral bias where needed:

- a. Starter broach induces lateral bias by rasping beneath the greater trochanter
- b.Canal reamer creates a guide hole for the distal end of the trochanteris reamer
- **c.**Trochanteric reamer removes trochanteric bone tissue laterally to assist neutral alignmen with the femoral axis during broaching



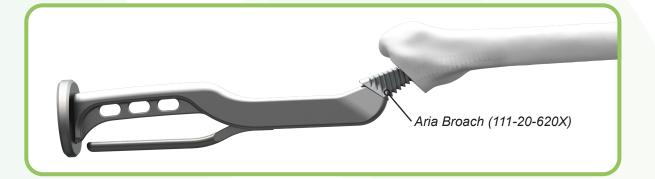






Broaching

The broach should run parallel to the posterior cortex following the natural anatomy of the femur. Begin with the smallest broach and increase the size of the broach sequentially until longitudinal and rotational stability is achieved: broaching should then be stopped. Careful preoperative planning is key to help selection of the final broach size. The version will be determined be the natural version of the femur.



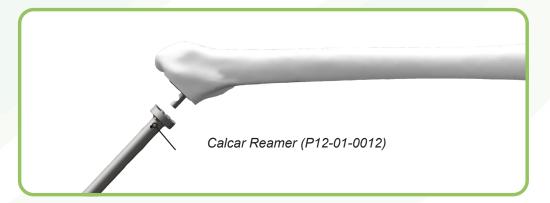
Note:

Refer to **Appendix:Broaching Techniques and Tips** for detail on the theory of compaction broaching, why this technique is used for Aria stems, and how to form a bed of compacted bone.



Calcar Reaming

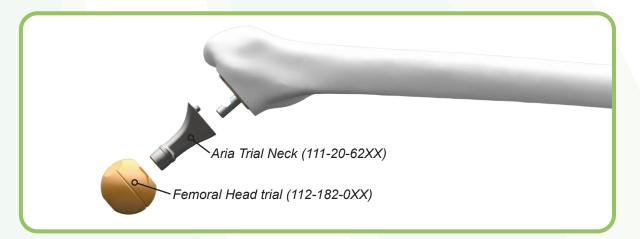
With the broach in situ, use the Calcar Reamer to achieve a flat resection surface. Slide the reamer over the broach quick connect fitting to maintain the resection angle. Carefully advance the reamer towards the broach face and into the resected edge of the femur until it bottoms out against the broach face.





Trial Reduction

With the final broach still in situ, attach the appropriate trial neck and trial head. Reduce the hip and assess what adjustments, if any, are required to provide stability through a full range of motion. Remove the trial head, trial neck and final broach. DO NOT irrigate or dry the femoral canal. This will help to preserve the compacted cancellous bone quality and may encourage biological fixation of the stem.





Instrument identification:

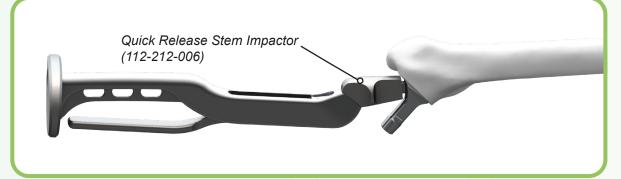
Trial heads are colour coded based on offset. Refer to Aria Implants Sizing Guide in this surgical technique for more details.



Femoral Component Insertion

When implanting the definitive stem (same size as final broach) in the femoral canal, ensure that it is directed in by hand. This will help avoid changing the version as a precautionary measure. There should be no more than 15-20mm between the resection line and the top of the porous coating on the stem. If the stem does not readily go down this far, the surgeon should broach again. Once the stem is placed, lightly tap the stem impactor to fully seat. DO NOT over-impact as this may lead to splitting of the femur.





Instrument operation:

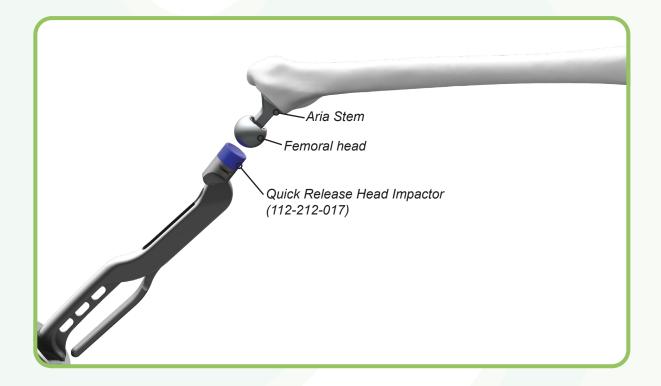
To connect the Aria stem to the stem positioner, first slide the inner shaft of the positioner through the outer shaft, spinning the strikeplate so the inner shaft threads in and falls through. Turn the threaded tip of the inner shaft into the female threads on the Aria stem until a snug hold is achieved to prevent damage to the threads.



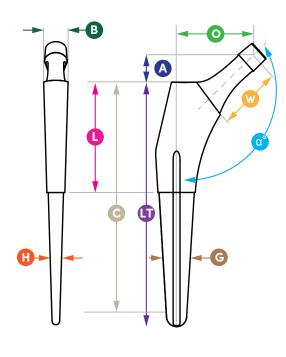


Femoral Head Impaction

A final trial reduction is carried out to confirm joint stability and range of motion. Clean and dry the stem taper to remove any particulate matter or debris. Place the femoral head onto the taper and lightly tap it using the head impactor. Ensure that bearing surfaces are clean and finally reduce the hip.



T	AILLE	OFFSET	LT	L	W	0	α°	G	Н	C	В	A
0	111-20-6000	Standard Offset	128	54	35.7	35.6	132	4.9	4.4	120	11.5	11.4
U	111-20-6100	High Offset	128	54	40.1	41.6	132	4.9	4.4	120	11.5	11.4
1	111-20-6001	Standard Offset	130	61	38.5	38.7	132	5.6	4.6	122	11.8	12.7
	111-20-6101	High Offset	130	61	43.0	44.7	132	5.6	4.6	122	11.8	12.7
2	111-20-6002 111-20-6102	Standard Offset High Offset	133 133	63 63	39.4 43.8	40.1 46.1	132 132	6.9 6.9	4.9 4.9	124 124	12.2 12.2	13.4 13.4
						40.1	132	0.9				15.4
3	111-20-6003 111-20-6103	Standard Offset High Offset	136 136	64 64	39.3 43.8	40.7 46.7	132 132	8.2 8.2	5.0 5.0	126 126	12.2 12.2	13.4 13.4
3		Standard Offset Reduced Distal	136	64	43.8	46.7	132	6.2	5.0	126	12.2	13.4
	111-20-6403	High Offset Reduced Distal	136	64	43.8	46.7	132	6.2	5.0	126	12.2	13.4
	111-20-6004 111-20-6104	Standard Offset High Offset	138 138	65 65	40.4 44.9	42.1 48.1	132 132	8.9 8.9	5.0 5.0	128	12.5 12.5	14.1 14.1
4	111-20-6104	Standard Offset Reduced Distal	138	65	44.9	40.1	132	6.9	5.0	128 128	12.5	14.1
	111-20-6404	High Offset Reduced Distal	138	65	44.9	48.1	132	6.9	5.0	128	12.5	14.1
	111-20-6005	Standard Offset	140	66	40.4	42.7	132	9.7	5.0	130	12.6	14.1
E	111-20-6105	High Offset	140	66	44.9	48.7	132	9.7	5.0	130	12.6	14.1
5	111-20-6305	Standard Offset Reduced Distal	140	66	40.4	42.7	132	7.7	5.0	130	12.6	14.1
	111-20-6405	High Offset Reduced Distal	140	66	44.9	48.7	132	7.7	5.0	130	12.6	14.1
	111-20-6006	Standard Offset	143	67	40.4	43.3	132	10.9	5.1	132	12.8	14.1
6	111-20-6106 111-20-6306	High Offset Standard Offset Reduced Distal	143 143	67 67	44.9 40.4	49.3 43.3	132 132	10.9 8.9	5.1 5.1	132 132	12.8 12.8	14.1 14.1
	111-20-6406	High Offset Reduced Distal	143	67	44.9	49.3	132	8.9	5.1	132	12.8	14.1
	111-20-6007	Standard Offset	145	68	40.4	43.9	132	11.7	5.2	134	12.9	14.1
7	111-20-6007	High Offset	145	68	45.0	49.9	132	11.7	5.2	134	12.9	14.1
		Standard Offset Reduced Distal	145	68	40.4	43.9	132	9.7	5.2	134	12.9	14.1
	111-20-6407	High Offset Reduced Distal	145	68	45.0	49.9	132	9.7	5.2	134	12.9	14.1
	111-20-6008	Standard Offset	148	70	43.4	46.8	132	13	5.2	136	13.2	16.1
8	111-20-6108 111-20-6308	High Offset Standard Offset Reduced Distal	148 148	70 70	47.9 43.4	52.8 46.8	132 132	13 11	5.2 5.2	136 136	13.2 13.2	16.1 16.1
	111-20-6308	High Offset Reduced Distal	148	70	43.4	52.8	132	11	5.2	136	13.2	16.1
	111-20-6009	Standard Offset	151	71	43.4	47.4	132	14.0	5.3	138	13.4	16.1
0	111-20-6109	High Offset	151	71	47.9	53.4	132	14.0	5.3	138	13.4	16.1
9	111-20-6309	Standard Offset Reduced Distal	151	71	43.4	47.4	132	12.0	5.3	138	13.4	16.1
	111-20-6409	High Offset Reduced Distal	151	71	47.9	53.4	132	12.0	5.3	138	13.4	16.1
		Standard Offset	153	72	43.4	48.0	132	13.4	5.3	140	15	16.1
10	111-20-6110 111-20-6310	High Offset Standard Offset Reduced Distal	153 153	72 72	47.9 43.4	54.0 48.0	132 132	13.4 11.4	5.3 5.3	140 140	15 15	16.1 16.1
	111-20-6410	High Offset Reduced Distal	153	72	47.9	54.0	132	11.4	5.3	140	15	16.1
	111-20-6011	Standard Offset	158	74	43.4	49.3	132	17.2	6.0	142	14.3	16.1
11	111-20-6111	High Offset	158	74	47.9	55.3	132	17.2	6.0	142	14.3	16.1
	111-20-6311	Standard Offset Reduced Distal	158 158	74 74	43.4	49.3 55.3	132 132	15.2	6.0 6.0	142	14.3 14.3	16.1
	111-20-6411	High Offset Reduced Distal	156	74	47.9	33.3	132	15.2	6.0	142	14.5	16.1
	111-20-6012	Standard Offset	163	76	43.6	50.5	132	19.7	6.3	144	14.6	16.1
12	111-20-6112 111-20-6312	High Offset Standard Offset Reduced Distal	163 163	76 76	48.0 43.6	56.5 50.5	132 132	19.7 17.7	6.3 6.3	144 144	14.6 14.6	16.1 16.1
	111-20-6412	High Offset Reduced Distal	163	76	48.0	56.5	132	17.7	6.3	144	14.6	16.1

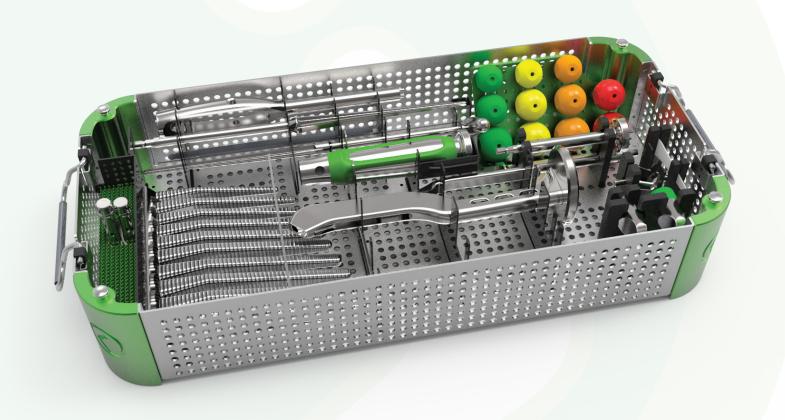


ARIA RDS (Reduced Distal) Only available in USA*

	Ø28	Ø32	Ø36	Ø40
Stainless Steel	-3.5 111-152-011 111-152-611 111-152-111	-4.0 111-152-021 111-152-621 111-152-121	-4.0 111-152-031 111-152-631 111-152-131	-4.0 111-152-041 111-152-641
CoCr Ceramic	+0.0 111-152-012 111-152-612	+0.0 111-152-022 111-152-622	+0.0 111-152-032 111-152-632	+0.0 111-152-042 111-152-642
Stainless Steel CoCr Ceramic	+3.5 111-152-112 +3.5 111-152-013 111-152-613	+4.0 111-152-122 +111-152-023 111-152-623	+4.0 111-152-033 111-152-633	+4.0 111-152-043 111-152-643
Stainless Steel CoCr Ceramic	111-152-113	+7.0 111-152-024 111-152-624	+8.0 111-152-034 111-152-634	+8.0 111-152-044 111-152-644
Stainless Steel	ı	111-152-124	111-152-134	111 132 044

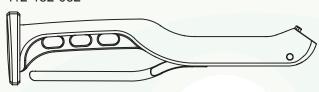
*Reduced distal is USA only





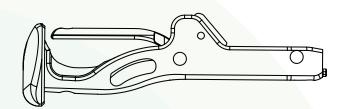
Straight Broach Handle

112-182-032



Short Broach Handle

112-25-0146



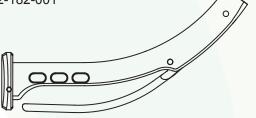
Calcar Reamer

P12-01-0012



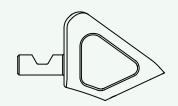
Curved Broach Handle

112-182-001



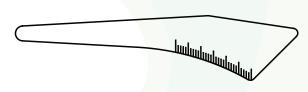
Quick Release Box Chisel

112-212-005



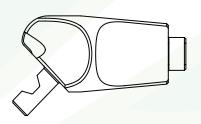
Osteotomy Guide

112-34-0002



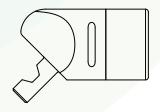
Quick Release Stem Impactor

112-212-006



Quick Release Head Impactor

112-212-017



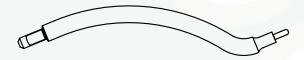
Stem Positioner

112-182-027 Outer 112-182-028 Inner



Modular Stem Impactor

112-25-0080 Curved 112-25-0092 Offset 112-25-0093 Bullet Tip



Trochanteric Canal Reamer

112-212-022

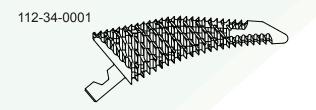


IM Drill

112-182-087



Starter Broach



Stem Positioner UniBody

112-212-026



Canal Reamer

112-212-023



Stepped Entry Reamer

112-162-001



Femoral Head Extractor

112-182-117



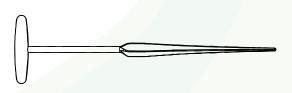
Small Tapered Pin Reamer

112-182-013



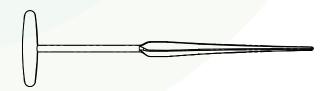
Large Tapered Pin Reamer

112-182-144



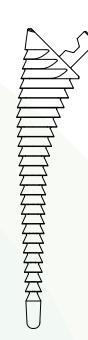
XL Tapered Pin Reamer

112-182-148



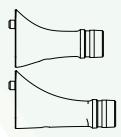


Aria Broaches		Distal Reduced A	Aria Broaches*
111-20-6200 111-20-6201 111-20-6202 111-20-6203 111-20-6204 111-20-6205 111-20-6206 111-20-6207 111-20-6208 111-20-6209 111-20-6210 111-20-6211 111-20-6212	Size 0 Size 1 Size 2 Size 3 Size 4 Size 5 Size 6 Size 7 Size 8 Size 9 Size 10 Size 11 Size 12	111-20-6903 111-20-6904 111-20-6905 111-20-6906 111-20-6908 111-20-6909 111-20-6910 111-20-6911 111-20-6912	Size 3 Size 4 Size 5 Size 6 Size 7 Size 8 Size 9 Size 10 Size 11 Size 12



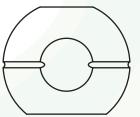
Aria Trial Necks

111-20-6250	Size 0 Standard Offset
111-20-6260	Size 0 High Offset
111-20-6251	Size 1 Standard Offset
111-20-6261	Size 1 High Offset
111-20-6252	Size 2-3 Standard Offset
111-20-6262	Size 2-3 High Offset
111-20-6253	Size 4-7 Standard Offset
111-20-6263	Size 4-7 High Offset
111-20-6254	Size 8-12 Standard Offset
111-20-6264	Size 8-12 High Offset



Trial Femoral Heads

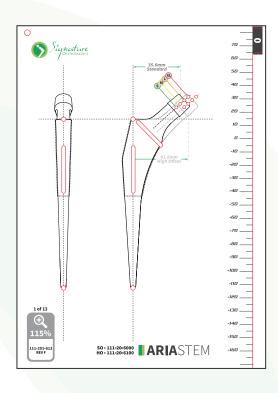
112-182-040	Ø28mm -3.5mm Green
112-182-041	Ø28mm 0.0mm Yellow
112-182-042	Ø28mm +3.5mm Orange
112-182-017	Ø32mm -4.0mm Green
112-182-018	Ø32mm 0.0mm Yellow
112-182-019	Ø32mm +4.0mm Orange
112-182-020	Ø32mm +8.0mm Red
112-182-021	Ø36mm -4.0mm Green
112-182-022	Ø36mm 0.0mm Yellow
112-182-023	Ø36mm +4.0mm Orange
112-182-024	Ø36mm +8.0mm Red
112-182-043	Ø40mm -4.0mm Green
112-182-044	Ø40mm 0.0mm Yellow
112-182-045	Ø40mm +4.0mm Orange
112-182-046	Ø40mm +8.0mm Red



Aria Preoperative Templates

111-201-613

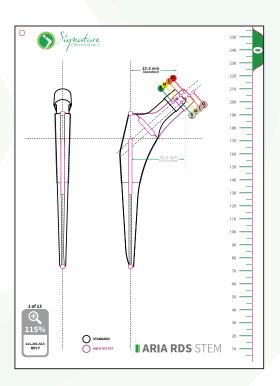
Size 0-12 Template



Aria RDS Preoperative Templates

111-201-513

Size 0-12 Template



Aria Implants

Aria Standard Offset Stem

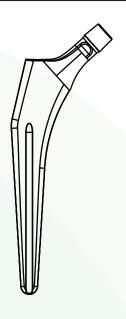
111-20-6000	Size 0
111-20-6001	Size 1
111-20-6002	Size 2
111-20-6003	Size 3
111-20-6004	Size 4
111-20-6005	Size 5
111-20-6006	Size 6
111-20-6007	Size 7
111-20-6008	Size 8
111-20-6009	Size 9
111-20-6010	Size 10
111-20-6011	Size 11
111-20-6012	Size 12

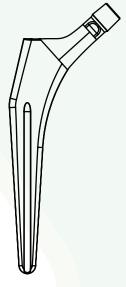
Aria High Offset Stem

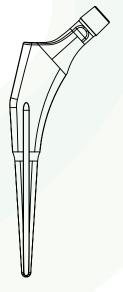
111-20-6100	Size 0
111-20-6101	Size 1
111-20-6102	Size 2
111-20-6103	Size 3
111-20-6104	Size 4
111-20-6105	Size 5
111-20-6106	Size 6
111-20-6107	Size 7
111-20-6108	Size 8
111-20-6109	Size 9
111-20-6110	Size 10
111-20-6111	Size 11
111-20-6112	Size 12

Aria Stem, Standard Offset – Reduced Distal*

111-20-6303	Size 3
111-20-6304	Size 4
111-20-6305	Size 5
111-20-6306	Size 6
111-20-6307	Size 7
111-20-6308	Size 8
111-20-6309	Size 9
111-20-6310	Size 10
111-20-6311	Size 11
111-20-6312	Size 12



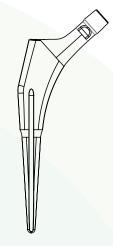




Aria Implants

Aria Stem, High Offset – Reduced Distal*

111-20-6403	Size 3
111-20-6404	Size 4
111-20-6405	Size 5
111-20-6406	Size 6
111-20-6407	Size 7
111-20-6408	Size 8
111-20-6409	Size 9
111-20-6410	Size 10
111-20-6411	Size 11
111-20-6412	Size 12



Signature Ceramic Femoral Head

111-152-611	Size 28mm S
111-152-612	Size 28mm M
111-152-613	Size 28mm L
111-152-621	Size 32mm S
111-152-622	Size 32mm M
111-152-623	Size 32mm L
111-152-624	Size 32mm XL
111-152-631	Size 36mm S
111-152-632	Size 36mm M
111-152-633	Size 36mm L
111-152-634	Size 36mm XL
111-152-641	Size 40mm S
111-152-642	Size 40mm M
111-152-643	Size 40mm L
111-152-644	Size 40mm XL
111-152-651	Size 44mm S
111-152-652	Size 44mm M
111-152-653	Size 44mm L
111-152-654	Size 44mm XL



Fusion Ceramic Femoral Head*

111-22-0511	Size 28mm
111-22-0512	Size 32mm
111-22-0513	Size 36mm



Aria Implants

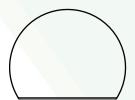
Signature SS Femoral Head

111-152-111	Size 28mm S
111-152-112	Size 28mm M
111-152-113	Size 28mm L
111-152-121	Size 32mm S
111-152-122	Size 32mm M
111-152-123	Size 32mm L
111-152-124	Size 32mm XL
111-152-131	Size 36mm S
111-152-132	Size 36mm M
111-152-133	Size 36mm L
111-152-134	Size 36mm XL



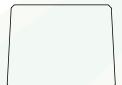
Signature CoCr Femoral Head

111-152-011	Size 28mm S
111-152-012	Size 28mm M
111-152-013	Size 28mm L
111-152-021	Size 32mm S
111-152-022	Size 32mm M
111-152-023	Size 32mm L
111-152-024	Size 32mm XL
111-152-031	Size 36mm S
111-152-032	Size 36mm M
111-152-033	Size 36mm L
111-152-034	Size 36mm XL
111-152-041	Size 40mm S
111-152-042	Size 40mm M
111-152-043	Size 40mm L
111-152-044	Size 40mm XL



Ti6Al4V Fusion Taper Sleeve*

111-37-0001	Fusion Taper Sleeve -4mm
111-37-0006	Fusion Taper Sleeve -2mm
111-37-0002	Fusion Taper Sleeve 0mm
111-37-0007	Fusion Taper Sleeve +2mm
111-37-0003	Fusion Taper Sleeve +4mm
111-37-0008	Fusion Taper Sleeve +6mm
111-37-0004	Fusion Taper Sleeve +8mm



Appendix: Broaching Techniques and Tips

It is advised to stop broaching when stability is achieved with a slightly countersunk broach than to attempt to force as oversized broach into the canal. The coating limit line on the implant stem will sit below the resection line but the stem should achieve stability. Consider a longer neck or higher head offset.

Managing Different Femoral Canal Geometries

The Dorr femur type system classifies femurs based on a ratio that relates to the geometry of the femoral canal:

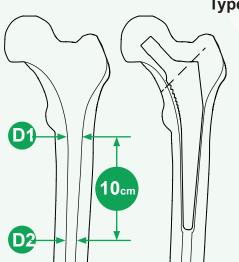
 $R = D_2/D_2$

see figures at the bottom left

An R-value less than ~0.5 implies a very fluted canal that will more likely bind distally if the canal is not over-reamed. Preoperative templating is especially important for this reason. Refer to the Aria Implant Sizing guide in this technique to help decide what size reamer to use. The three types are as follows.

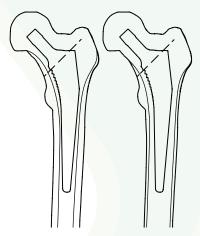
Type A
Type B
Type C

R < 0.5 R = 0.5 to 0.9 R > 0.9



Type A

Reaming the femoral canal to the distal tip of the definitive stem ensures compaction of the metaphyseal cancellous bone and reduced binding against the cortical wall, which can lead to stress shielding and an ill-seated stem



Types B & C

The Aria broaches preserve the natural anatomy of the femoral canal. Rotational and axial stability and a change in pitch indicate an appropriate amount of compaction broaching.

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