freedom™

CONSTRAINED LINER

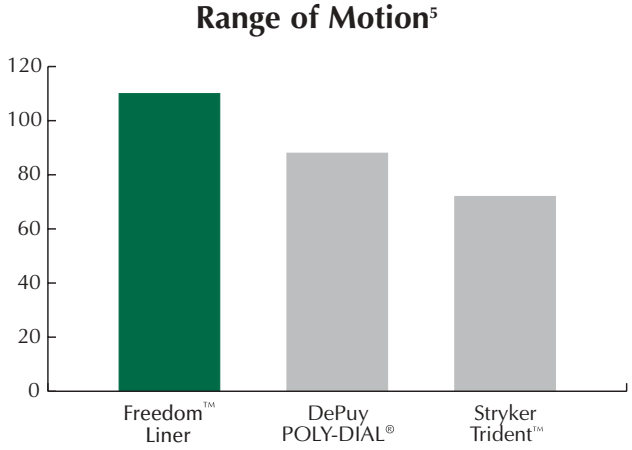
innovation ● performance ● results ● innovation ● performance ● results ● innov

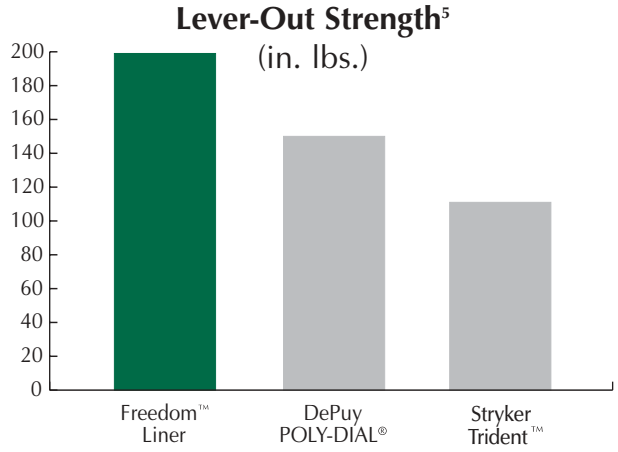
BIOMET ORTHOPEDICS, INC.

Patients presenting with hip instability have traditionally been forced to accept severely limited range of motion in order to maintain a stable joint.

The advent of Biomet's new constrained liner has ushered in a new era of unparalleled surgical latitude, where range of motion and stability come in one package:

The Freedom™ Constrained Liner System.





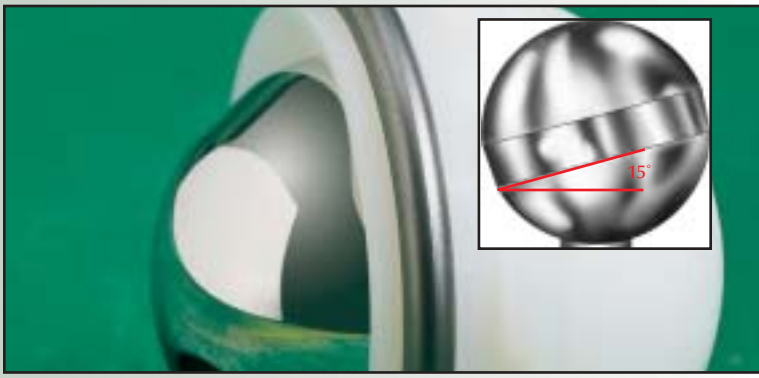
The Freedom™ Constrained Liner System offers simple instrumentation and five distinct liner options with one goal in mind: to provide the surgeon a versatile implant system tailored to meet patients' needs.

The first generation of constrained liners relied almost exclusively on a metal constraining ring to provide stability and prevent dislocation. Biomet's Freedom™ Constrained Liner System takes this design two steps further to a new level of tri-mode stabilization in order to improve performance and enhance functional range of motion.

Tri-Mode Constraint Provides Superior Stability and Range of Motion

MODE ONE: MODULAR HEAD EQUATORIAL FLATS

Circumferential flats along the Freedom™ Liner's 36mm head permit easier reduction and provide an extremely strong construct that actively counters the distractive forces that can lead to hip dislocation.

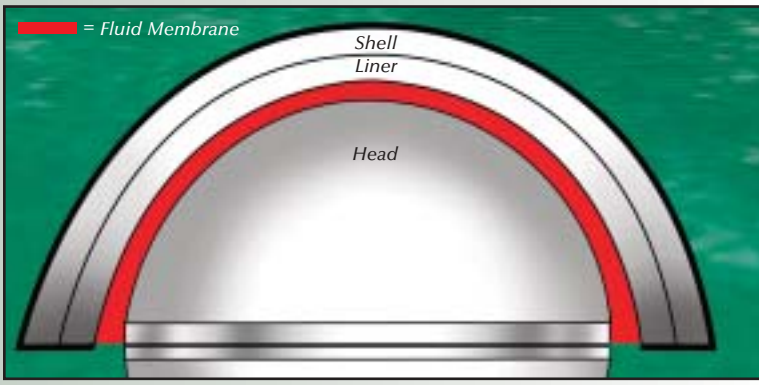


MODE TWO: TITANIUM CONSTRAINT RING

This traditional titanium constraint ring supplements the Freedom™ Liner's inherent stability by increasing resistance to lever-out under high demand conditions.

MODE THREE: HYDRAULIC STABILIZATION

Tightly controlled manufacturing tolerances on the Freedom™ Liner recreate a natural fluid membrane between the head and liner, resulting in a "suction effect" that further minimizes the possibility of joint dislocation.[1]



Average Lever-out Force: 198 in. lbs.

Range of Motion: 110°

The breadth and scope of Biomet's revision hip product line defines the state of the industry. Shells pictured, from left to right: Par 5™ Protrusio Cup, Mallory-Head® Protrusio Cage, Healey™ Flanged Cup, Recovery® Protrusio Cage, MARS® Reconstructive System, and the Max-Ti™ Protrusio Cage.

Designed to Constrain the Patient's Hip, Not Your Intraoperative Options

For maximum intraoperative flexibility, the Freedom™ Liner can be used in any Biomet RingLoc® shell and is available in +5, 10-degree, and low-profile designs—there is even an all-poly option available for cemented applications.

With a full selection of six non-skirted neck lengths (including +9), soft tissue laxity and leg length discrepancies can be addressed easily and permanently.

And Biomet's ArCom® isostatically molded polyethylene offers the strongest clinical history of any poly on the market.[2–4]

Revision hip arthroplasty may at times present unique technical challenges, but the Freedom™ Constrained Liner System and Biomet's wide range of revision shells offer a compelling answer for treating the unstable hip.

This brochure is presented to demonstrate the technique utilized by Mark A. Klaassen, M.D. Biomet, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each individual patient. Biomet is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

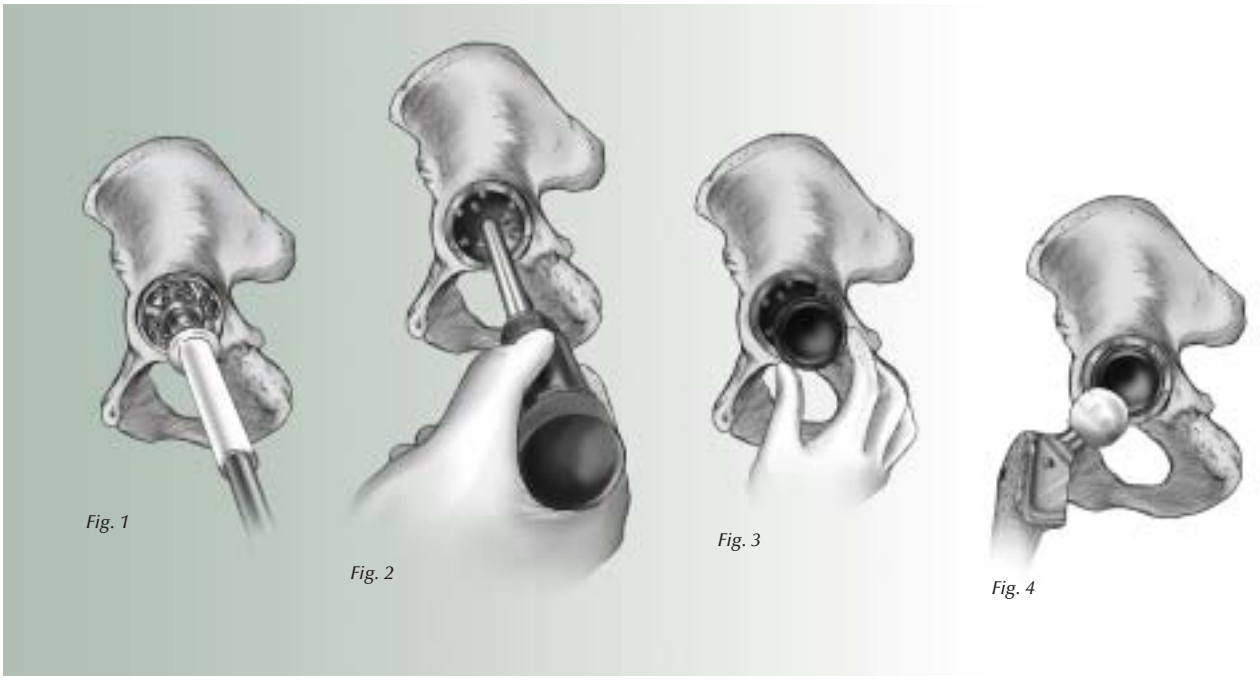


Fig. 1

Fig. 2

Fig. 3

Fig. 4

STEP 1: REAMING AND SIZING

Carefully ream the acetabulum to prepare for placement of the Biomet RingLoc® shell or Biomet® protrusio cage (Figure 1).

STEP 2: SHELL INSERTION

Thread the RingLoc® shell inserter onto the chosen cup implant and place into the acetabulum (Figure 2). Impact the shell, taking care to continuously check for proper anatomic positioning (placing the cup at 35–40 degrees of abduction and 20–25 degrees of anteversion will provide optimal range of motion).

STEP 3: FREEDOM™ TRIAL LINER INSERTION

Place the selected Freedom™ trial liner into the shell, as shown in Figure 3 (keeping in mind that standard face, 10 degree and +5 options are available).* The trial will fit loosely around the rim tabs and will loosely engage the locking ring.**

STEP 4: TRIALING WITH FREEDOM™ TRIAL HEADS

Determine the desired neck length (-6, -3, Std., +3, +6, +9mm) and select the appropriate trial head. Now, locate the small line etch on the head; position this line marking in the most superior position (please refer to Figure 6). Reduce the joint by aligning the flat aspect of the head with the liner's mouth and place the joint through a full range of motion to ensure stability, checking that there is no early impingement (Figure 4).

IMPORTANT SURGICAL NOTE:

Never mix the implant components and the trial components to perform a trial reduction! Trials may become attached to the implant, and the process of forcing these components apart can irreparably damage the implant(s).

* Low-profile shells (i.e. Rx90™ shell) will accept **only** the +5 Low-Profile Freedom™ liner.

** For the cemented Freedom™ liner, determine the appropriate size by subtracting 4mm from the cage size (Mallory-Head® and Recovery™ Cage) or 8mm (Max-Ti™ Cage).

Fig. 5

Fig. 6

Fig. 7

STEP 5: FREEDOM™ IMPLANT INSERTION

Select the liner size and type (standard face, +5, 10-degree, low-profile, or all-poly) to be used and have this implant opened and brought into the sterile field. Remove the black plug covering the mouth of the liner using the plug remover tool; discard this plug. Now place the Freedom™ Liner implant into the cup or cage (Figure 5). When satisfied with placement, use the Freedom™ Liner impactor to seat the implant into the shell.

STEP 6: FREEDOM™ 36MM HEAD PLACEMENT

Clean the femoral implant trunion with a dry sponge. Bring the selected 36mm Freedom™ head into the sterile field and position so that the small line etched on the head is located in the most superior position (Figure 6). Press the head onto the stem and double-check that the etch is still in the most superior position. Fully seat the head on the neck with at least three firm mallet blows.

STEP 7: REDUCTION

Mobilize the leg so that the Freedom™ head is placed at the mouth of the Freedom™ Liner. Flex and abduct the leg until the circumferential flat aspect of the Freedom™ head aligns with the liner mouth. Apply firm pressure straight into the liner until the head snaps into place. There will often be an audible "snap" when the head is fully reduced.

STEP 8: ENSURE FULL STABILITY

Before wound closure, re-check that the joint remains stable and will move throughout the anticipated range of motion without early impingement (Figure 7).

ORDERING INFORMATION

Freedom™ 36mm Modular Heads		
Part Number	**Trial Number**	**Size**
11-107016	31-107016	-6mm
11-107017	31-107017	-3mm
11-107018	31-107018	Std.
11-107019	31-107019	+3mm
11-107020	31-107020	+6mm
11-107021	31-107021	+9mm

Freedom™ Standard Face Constrained Liner		
Part Number	**Trial Number**	**Size**
11-107323	31-107323	24
11-107324	31-107324	25
11-107325	31-107325	26
11-107326	31-107326	27
11-107327	31-107327	28

Freedom™ 10 Degree Constrained Liner		
Part Number	**Trial Number**	**Size**
11-107423	31-107423	24
11-107424	31-107424	25
11-107425	31-107425	26
11-107426	31-107426	27
11-107427	31-107427	28

Freedom™ +5mm Standard Face Constrained Liner		
Part Number	**Trial Number**	**Size**
11-107022	31-107022	23
11-107023	31-107023	24
11-107024	31-107024	25
11-107025	31-107025	26
11-107026	31-107026	27
11-107027	31-107027	28

Freedom™ +5mm Std. Face Low-Profile Constrained Liner		
Part Number	**Trial Number**	**Size**
11-107222	31-107222	43
11-107223	31-107223	44
11-107224	31-107224	45
11-107225	31-107225	46
11-107226	31-107226	47
11-107227	31-107227	48

Freedom™ All-Poly Standard Face Constrained Liner		
Part Number	**Trial Number**	**Size**
11-107122	–	50
11-107123	31-107123	52
11-107124	–	54
11-107125	31-107125	56
11-107126	–	58
11-107127	31-107127	60
11-107128	–	62

Freedom™ Liner Sizing Matrix (No Rim Screws)					
Shell Size	**Standard**	**10 Degree**	**+5**	**Low-Profile**	**All-Poly**
50/52mm	–	–	23	43	–
54/56mm	24	24	24	44	–
58/60mm	25	25	25	45	52mm
62/64mm	26	26	26	46	56mm
66/68mm	27	27	27	47	60mm
70/80mm	28	28	28	48	–

Freedom™ Liner Sizing Matrix (with Rim Screws)					
Shell Size	**Standard**	**10 Degree**	**+5**	**Low-Profile**	**All-Poly**
50/52mm	–	–	23	43	–
54/56mm	24	24	24	44	–
58/60mm	23	23	23	43	52mm
62/64mm	24	24	24	44	56mm
66/68mm	25	25	25	45	60mm
70/72mm	26	26	26	46	–
74/76mm	27	27	27	47	–
78/80mm	28	28	28	48	–

References

1. Konistek, R., *et al*.: "In-Vivo Comparison of Hip Separation After Metal-on-Metal or Metal-on-Polyethylene Total Hip Arthroplasty." *JBJS*, 84: 1836–1841, 2002.
2. Head, W.C., Emerson, R.H., Hillyard, J.M., Higgins, L., Finlinson, M.S.: "Comparison of Polyethylene Wear in Machined Versus Molded Polyethylene Liners in RingLoc Acetabular Cups." 11th Annual Winter Total Joint and Sports Medicine Symposium. Steamboat Springs, CO, January 11–14, 2001.
3. Bankston, A.B., Keating, E.M., Ranawat, C., Faris, P.M., Ritter, M.A.: "The Comparison of Polyethylene Wear in Machined Versus Molded Polyethylene." *CORR*, No. 317, pp. 37–43, August 1995.
4. Ranawat, C., *et al*.: "Polyethylene Wear: Ram Extruded Versus Isostatic Molded Machined Liners—A Matched Pair Analysis." Annual Meeting of AAHKS, Dallas, Texas, November 3–5, 2000.
5. Data on file at Biomet, Inc.

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