

b-one
ORTHO



PRIMO[™]
ACETABULAR
SYSTEM



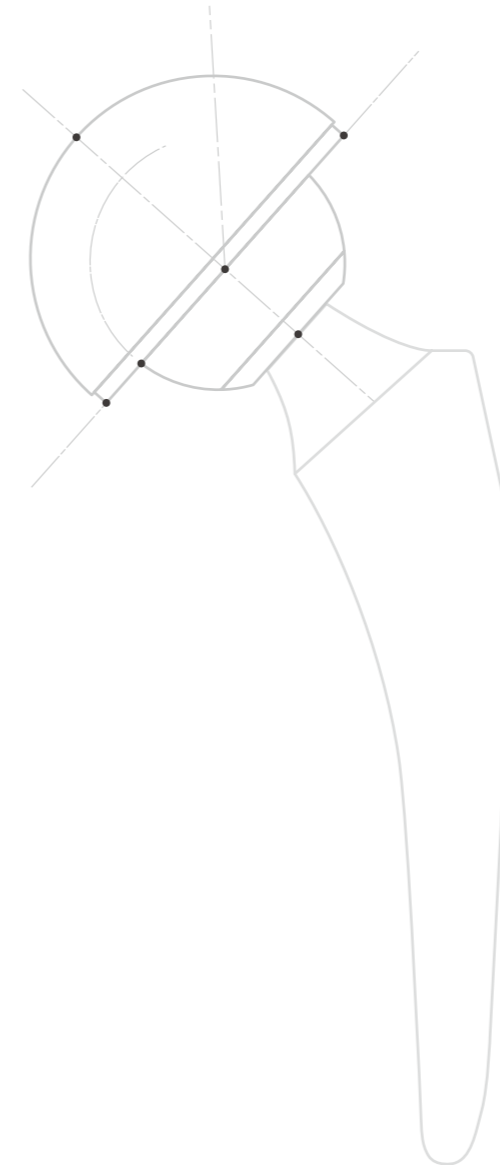
Richard H. Rothman
M.D., PH.D.

1936-2018

Founder of Rothman Institute

Special Thanks

Dr. Rothman has provided invaluable insights and experience in the development of **JUVENO®** and **PRIMO™** hip replacement systems. Total Hip System, shared years of clinical data and research from the Rothman Orthopaedic Institute, allowing the hip replacement systems to fully reflect the anatomical characteristics of patients worldwide.



System Introduction

PRIMO™ Acetabular System and **JUVENO®** Femoral Stem System is developed by b-ONE ORTHO, bringing together the experience of clinical opinion leaders from the United States, China, France, Canada and other countries. After years of extensive research and development, it was introduced to the world-wide audience in 2019.

The **PRIMO™** system integrates b-ONE's unique patented locking technology, in combination with advanced bearing options like Vitamin E liners to reduce wear over lengthened stem life in younger patients. Coating options include titanium porous plasma spray (PPS) and hydroxyapatite dual coating (PPS+HA).

Design Surgeons

Richard H. Rothman
Rothman Institute

Donald M. Kastenbaum
Mount Sinai Hospital

Michael H. Huo
UT Southwestern Medical Center

Sébastien Lustig
Lyon North University Hospital

Bassam A. Masri
Gordon and Leslie Diamond
Healthcare Centre

Antonia F. Chen
Brigham and Women's Hospital
Harvard Medical School

Philip O. Merrit
Adventist Health Glendale

BEST-IN-CLASS LOCKING MECHANISM

PRIMO™ Acetabular System

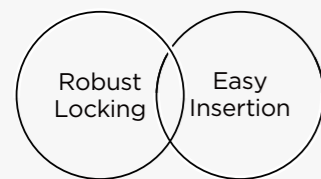


-  Patented Locking Mechanism
-  Excellent Wear Performance
-  Better Range of Motion
-  Advanced Coating Technology

> Patented Locking Mechanism

The patented locking mechanism of **PRIMO™** acetabular cup consists of **three** main parts: an external asymmetric anti-rotational tab that provides extra locking for the poly liner, an inner locking rim and multi-bearing guiding surface which provides firm lock and inter-changeability between different bearing options*.

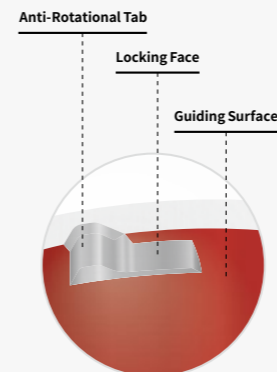
The goal of the locking mechanism is to simplify installation while reducing micromotion and backside wear by providing strong axial and rotational stability.



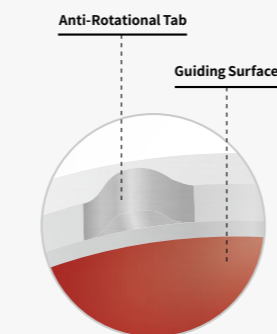
- 1 Asymmetric Anti-Rotational Tab
- 2 Multi-Bearing Guiding Surface
- 3 Inner Locking Rim



For the availability of different bearing options, please contact your local sales representative.



Asymmetric Anti-Rotational Tab
12:12 Matching



Symmetric Anti-Rotational Tab
12:6 or 12:12 Matching

1 Asymmetric Anti-Rotational Tab

There are **12** scallop-shaped asymmetric anti-rotation tabs featured on the **PRIMO™** acetabular cup. When a polyethylene liner is used, all 12 of the anti-rotation tabs mate with poly anti-rotation device and creates 12-12 match. Compared with the common symmetric type, the locking mechanism offers additional locking by featuring shallow locking face near anti-rotational device that mates with the corresponding structure on the liner. As a result, it improves the axial and rotational locking.

2 Inner Locking Rim

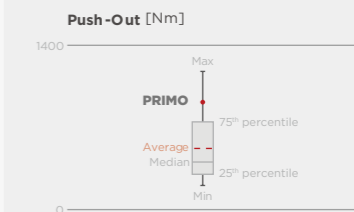
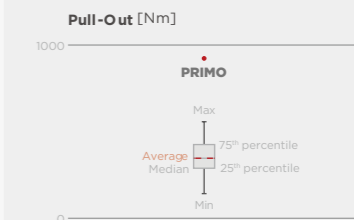
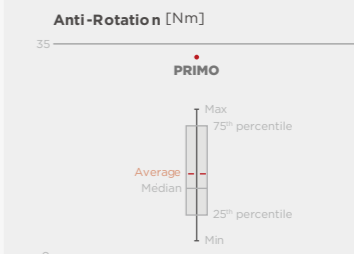
Similar to the traditional locking mechanisms, a locking rim is featured near the dome of the acetabular cup, which matches a ring on the polyethylene liner to provide basic poly locking.

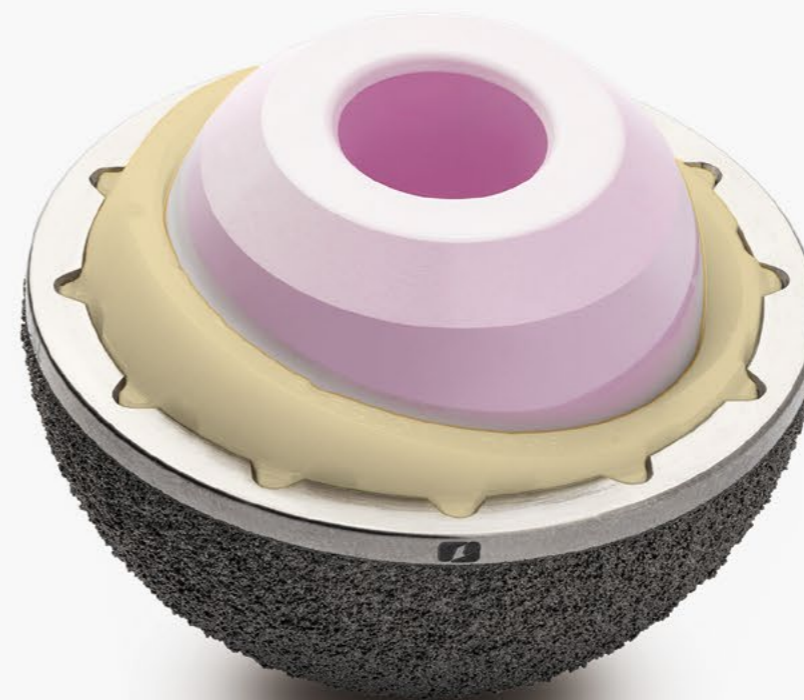
3 Multi-Bearing Guiding Surface

Multi-bearing guiding surface is designed to simplify installation and improve intra-operative experience.

Endolab® Test Results

Endolab® test results showed that the anti-rotation torque of **b-ONE** patented locking mechanism was 34.1NM, the liner priming torque was **45NM** (equivalent load of **962N**), and the liner pull-out output was **1075N**. The **three** test indexes were significantly higher than that of other brands measured by **Endolab®**¹ as shown below.





> Excellent Wear Performance

The **PRIMO™** acetabular system offers Vitamin E highly crosslinked polyethylene with **BIOLOX®** delta ceramic femoral head advanced bearing option.

Benefiting from the locking mechanism's excellent performance, **PRIMO™** acetabular system significantly reduces micromotion under load, resulting in reduced backside wear as shown in test results from Endolab®. The wear rates of **PRIMO™** under both clean and abrasive conditions are lower than that of similar products in the market¹.

Contact your local sales representative to determine availability of the products shown in your region.

Endolab® Test Results

A 36mm CoCr metal femoral head and a Vitamin E infused poly liner was used under two different test conditions.

Under clean condition, after 5 million cycles of wear testing, the average wear rate of **PRIMO™** hip system was **4.06mg/** million cycles, lower than the average of **4.91mg/** million cycles of other brands tested by Endolab®.

Under abrasive conditions, after 2 million cycles, the total wear rate of **PRIMO™** system was **297.83mg**, yielded **24%** lower wear rate than the Stryker **X3** System (**394.4 Mg**) under the same conditions as reported in the literature¹.

Clean wear, 5 million cycles (Mg/Million cycles)



Abrasive wear, 2 million cycles (Mg/Million cycles)



> Better Range of Motion

Clinically, the use of a larger femoral heads has shown to reduce the risk of postoperative dislocation. The larger diameter femoral head reduces the incidence of impingement between the femoral neck and the acetabular cup.

The **PRIMO™** system provides a variety of acetabular liners to allow surgeons to adjust to patient conditions.

Acetabular Cup	Poly Liners		
	Neutral	Hooded 10°	Lateral Offset 4mm
40	22	22	
42			
44	28	28	28
46			
48	32	32	32
50			
52	36	36	36
54			
56			
58			
60			
62			
64			
66			
68			

VE Induced Highly Cross-linked



Neutral >

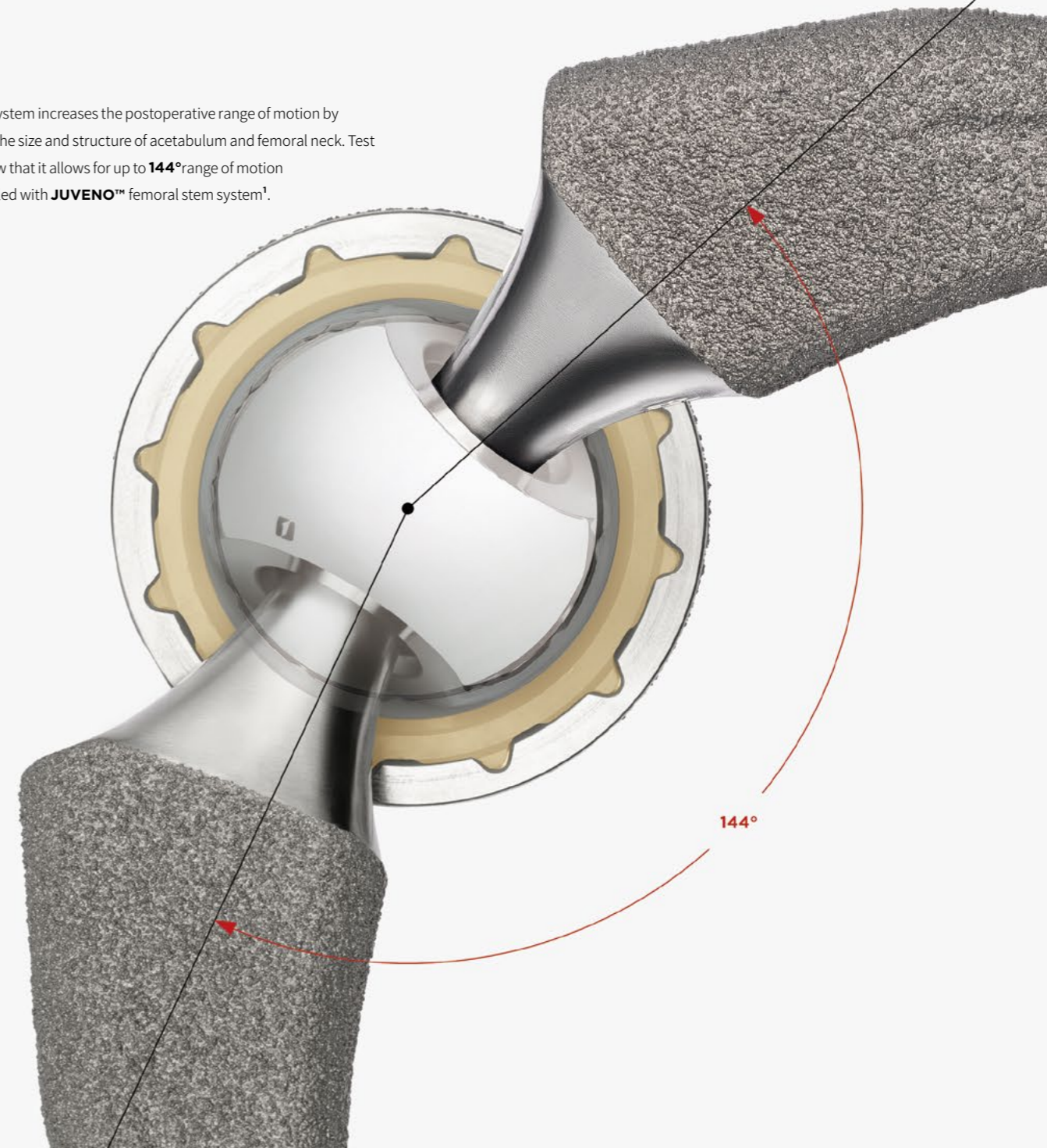


Hooded >



4mm lateral Offset >

PRIMO™ system increases the postoperative range of motion by improving the size and structure of acetabulum and femoral neck. Test results show that it allows for up to **144°** range of motion when coupled with **JUVENO™** femoral stem system¹.



> Implant Sizes

Femoral Heads >

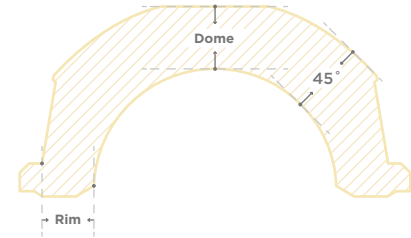
Size	S	M	L	XL
36mm	-4	0	4	8
32mm	-4	0	4	7
28mm	-3,5	0	3,5	7
22,2mm	0	2	4	N/A

Screws >

Length (mm)	20	25	30	35

Acetabular Cup and Liner >

Cup Sizes (mm)	Head Sizes (mm)	VE Liner Thickness (mm)		
		45°	Dome	Rim
44	28	5.9	4.6	3.6
46		6.6	5.3	4.6
48	32	5.3	4	3.6
50		6.6	5.2	4.6
52	36	5.3	4	3.6
54		6.1	5.2	4.6
56		6.8	6.5	5.6
58		7.5	7	6.5
60		8.2	8	7.5



> Reference

1. b-ONE internal test data
2. Chambers et al. "Hydroxyapatite-Coated Tapered Cementless Femoral Components in Total Hip Arthroplasty." The journal of Arthroplasty. Vol. 22 No. 4 Suppl. 1 2007.
3. Frayssinet, P. et al. (1995) "Natural History of Bone Response to Hydroxyapatite-Coated Hip Prostheses Implanted in Humans," Cells and Materials: Vol. 5 : No. 2, Article 2.
4. Herrera, A. et. Al. Clinical Study Cementless Hydroxyapatite Coated Hip Prosthesis, "Biomed Research International, vol 2015.

