EXACTECH | HIP

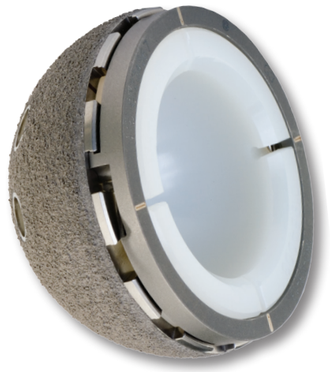
Operative Technique

NOVATION®

Crown Cup®
Constrained Liner

RENEWING INNOVATIONS.
ENDURING SOLUTIONS.

Exactech®



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NOVATION CROWN CUP DESIGN TEAM:

Wael K. Barsoum, MD
Cleveland Clinic Foundation

Raymond P. Robinson, MD
Virginia Mason Medical Center

Charles N. Cornell, MD
Hospital for Special Surgery

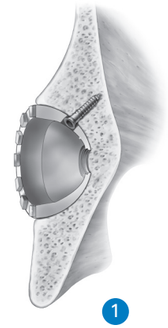
Jerome D. Wiedel, MD
University of Colorado

INTRODUCTION

The Novation® Crown Cup® Constrained Liner assists surgeons in meeting the challenges of recurrent dislocation of the hip following total hip arthroplasty. It is designed to capture the femoral head within the liner assembly, preventing the disassociation of the implant construct. The Crown Cup Constrained Liner is indicated for use in primary or revision procedures in which the patient is at high risk of hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease or intra-operative instability.

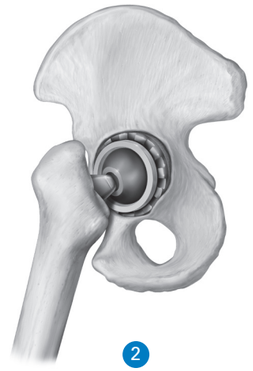
The Crown Cup Constrained Liner offers great flexibility through a comprehensive offering of implants that features 28mm, 32mm and 36mm ID acetabular liners that fit Crown Cup Acetabular Shells from 48-68mm and retaining rings in sizes 48-68mm.

OPERATIVE TECHNIQUE OVERVIEW



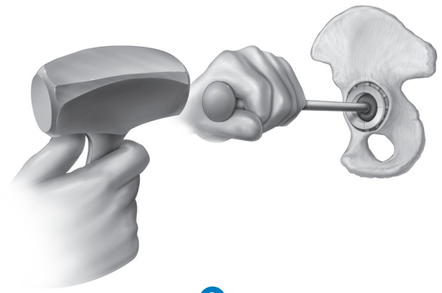
1

Fixed Acetabular Shell (From Primary Implantation or Removal of Existing In Vivo Liner)



2

Trial Reduction



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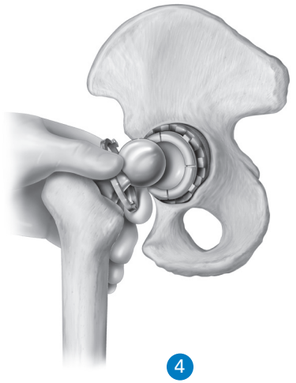
Liner Insertion



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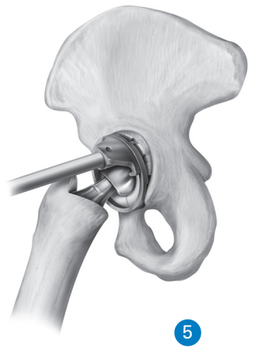
Placing the Constraining Ring and Reducing the Hip



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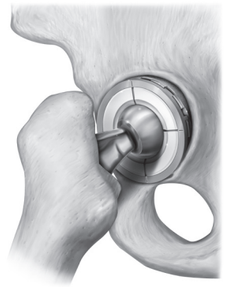
Ring Impaction



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Impacted Constraining Ring

DETAILED OPERATIVE TECHNIQUE

In revision procedures where the shell will not be replaced, refer to patient records and note the size of the existing *in vivo* liner. In order to ensure shell/liner compatibility, select a Crown Cup Constrained Liner of identical size to the existing *in vivo* liner (i.e., Group 1, 2, 3, 4 or 5).

TECHNIQUE FOR IMPLANTATION

For use with Novation Crown Cup Acetabular Shells, sizes 48-68mm (excluding no-hole shells).

Primary

Step 1: Implant the Novation Crown Cup Acetabular Shell (excluding no-hole shells) according to the Novation Crown Cup Operative Technique (#711-65-30), from the Approach and Exposure step through the Acetabular Shell Implantation and Adjunctive Fixation steps. Continue to the Trial Reduction on the following page.

Revision

Step 1: Begin by assembling the **Poly Removal Tool** to the **Ratcheting T-Handle** by pulling the release on the Ratcheting T-Handle and sliding the non-sharp end of the Poly Removal Tool into the Ratcheting T-Handle. Next, remove the existing liner by engaging the screw tip into the liner until the locking mechanism is disengaged and the liner can be pulled out. Next, verify that the Acetabular Shell is well fixed or could be well fixed with additional bone screw fixation. If fixation with the in vivo Acetabular Shell appears to be inadequate, even with additional screw fixation, the shell should be removed and the acetabulum should be prepared for a new Acetabular Shell.

IMPORTANT: *If the Acetabular Shell does not permit bone screw fixation, do not use a Constrained Liner.*

Note: *The Novation Crown Cup Constrained Liner Instrument Case does not include drill instrumentation. If adjunctive fixation is required, the Novation General Acetabular Instrument Case must be included.*

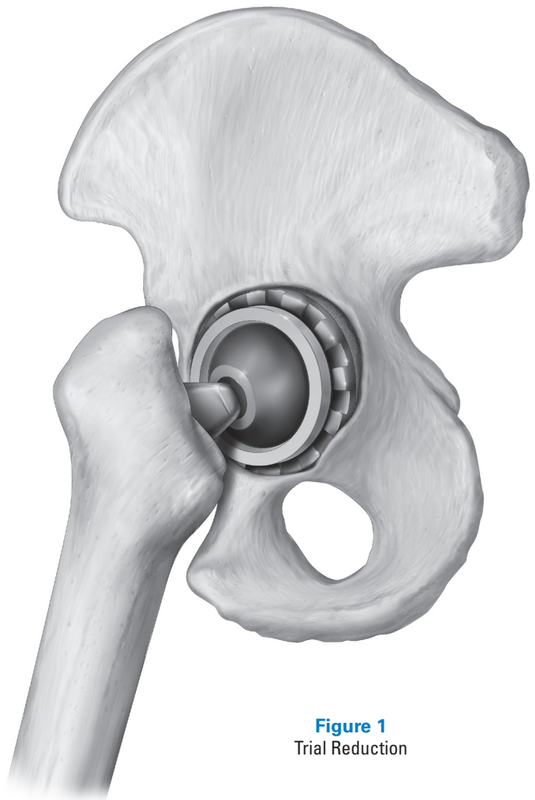


Figure 1
Trial Reduction

Table 1: Liner ID availability

Shell Size (mm)	Acetabular Shell Groups		Constrained Liner Options	
	Cluster-Hole Shell	Multi-Hole Shell	Liner Grouping	Constrained Liner ID (mm)
48	Group 1	Group 1	Group 1	28
50				
52	Group 2	Group 2	Group 2	32
54				
56	Group 3		Group 3	36
58				
60	Group 4	Group 3	Group 4	36
62				
64	Group 5	Group 4	Group 5	36
66				
68				

Note: *Constrained Liner system only compatible with sizes 48-68mm Crown Cup shells.*

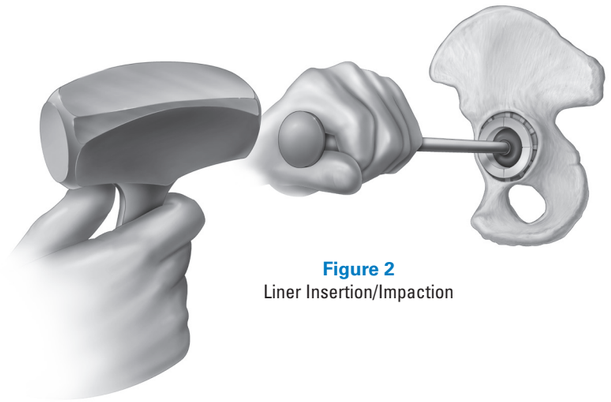


Figure 2
Liner Insertion/Impaction

TRIAL REDUCTION

Step 1: After removing the existing liner from the implanted cup, verify the size of the shell/liner. In order to ensure shell/liner compatibility, select a Constrained Liner of identical size to the explanted liner (i.e., Group 1, 2, 3, 4 or 5). It is important to assess that the shell locking mechanism has not been damaged during the removal of the previous liner and that the shell remains securely fixed in the acetabulum.

Step 2: Use of a **Crown Cup Constrained Liner Trial** is recommended prior to the insertion of the definitive liner into the Acetabular Shell. Select the appropriately sized Liner Trial according to the Acetabular Shell in place *(Table 1)*. Ensuring that the mating surfaces of the shell and liner are clear from soft tissue or debris, insert the Liner Trial by hand into the shell. The Liner Trial provides a gentle press fit that should be achieved by hand pressure when inserting. Perform trial reduction *(Figure 1)*.

Note: *The Liner Trial does not provide constraint of the femoral head, but approximates offset and range-of-motion. Crown Cup Constrained Liner Trials can be used with either a trial femoral head or the implant femoral head.*

LINER INSERTION

Step 1: Remove the Liner Trial using the **Liner Trial Removal T-Handle**. Place the T-Handle into the central slot of the Liner Trial, rotate approximately 90 degrees and then pull on the T-Handle to remove the Liner Trial. Ensure the internal taper of the Acetabular Shell is clear from soft tissue and debris.

Step 2: Insert the appropriate Novation Crown Cup Constrained Liner by hand, taking care to ensure that the tabs of the Constrained Liner enter the gaps between the crowns on the rim of the Acetabular Shell. Also, note that the ID of the Constrained Liner is dictated by the size of the Acetabular Shell *(Table 1)*; the femoral head must then match.

Step 3: Assemble the appropriate diameter **Novation Liner Driver Head** on the end of the **Keyed Liner Driver Handle**. With a mallet, strike the driving platform of the Liner Driver with one sharp blow *(Figure 2)*. Once seated, the top surface of the liner will rest slightly above the level of the Acetabular Shell crowns and at a uniform height around the circumference of the implant construct.

PLACING THE CONSTRAINING RING AND REDUCING THE HIP

Step 1: With the femoral head securely fixed to the trunnion, place the Novation Crown Cup Constraining Ring that corresponds to the acetabular cup (i.e., Group 1, 2, 3, 4 or 5) around the trunnion with the tab features facing the acetabulum *(Figure 3)*.

Step 2: Reduce the femoral head into the Constrained Liner. Place the Constraining Ring onto the shell and around the Constrained Liner. Align the four marks on the ring with slots on the Constrained Liner's constraining petals.

RING IMPACTION

Step 1: Assemble the **Crown Cup Constraining Ring Inserter** (that corresponds to the Constraining Ring to be implanted) to either the **Crown Cup Constraining Ring Inserter Keyed 40-Degree Adapter**, the **Crown Cup Constraining Ring Inserter Keyed "C" Adapter**, or directly to the Keyed Liner Driver Handle. If either of the adapters is used, it also must then be attached to the Keyed Liner Driver Handle.

Step 2: Place the Constraining Ring Inserter onto the face of the Constraining Ring so that the tabs align with the line markings on the Constraining Ring *(Figure 4a)*. Impact the first side of the Constraining Ring, then move the Constraining Ring Inserter to the opposite side for subsequent impaction *(Figure 4b)*. It is recommended to impact all four locations on the Constraining Ring.

Note: *For orientation, tangs on the underside of the Constraining Ring Inserter mate with 'slots' in the Constrained Liner while the Constraining Ring Inserter rests on the Constraining Ring.*

Step 3: Inspect the Constraining Ring to ensure that the Constraining Ring is properly seated against the Acetabular Shell. The Constraining Ring is fully seated when the face of the Constraining Ring is parallel and sits slightly below the top of the Constrained Liner surface *(Figure 5)*.

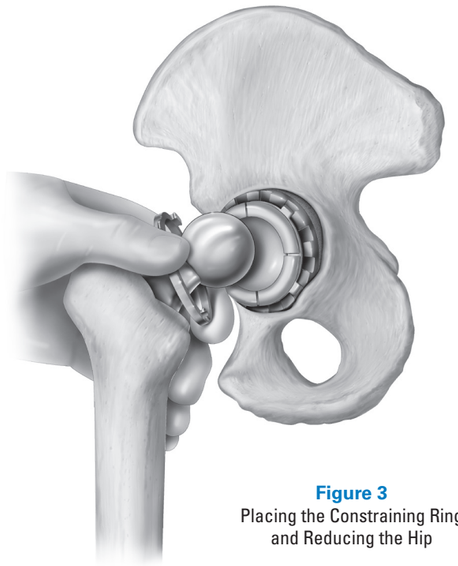


Figure 3
Placing the Constraining Ring and Reducing the Hip

IMPACTOR OPTIONS

Straight Impaction
Keyed Liner Driver Handle and Crown Cup Constraining Ring Inserter

Angled Impaction
Keyed Liner Driver Handle, Crown Cup Constraining Ring Inserter
Keyed 40-Degree Adapter and Crown Cup Constraining Ring Inserter

Offset Impaction
Keyed Liner Driver Handle, Crown Cup Constraining Ring Inserter
Keyed "C" Adapter and Crown Cup Constraining Ring Inserter

Figure 4a
Ring Impaction

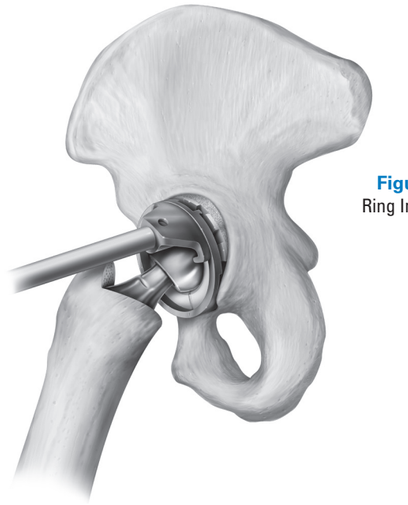
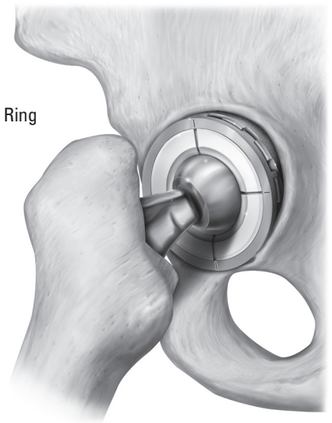


Figure 4b
Ring Impaction

Figure 5
Impacted Constraining Ring



OPTIONAL TECHNIQUE

Step 1: Insert Liner - Insert the appropriate Novation Crown Cup Constrained Liner by hand, taking care to ensure that the tabs of the Constrained Liner enter the gaps between the crowns on the rim of the Acetabular Shell. Assemble the appropriate diameter Novation Liner Driver Head on the end of the Keyed Liner Driver Handle. With a mallet, strike the driving platform of the Liner Driver with one sharp blow.

Step 2: Insert Femoral Head - Select the appropriately sized femoral head and insert into the Constrained Liner. Insert by applying force through the femoral head taper with a Femoral Head Impactor or Liner Driver Handle.

Step 3: Insert/Impact the Constraining Ring - Select the appropriate size Constraining Ring. Place the Constraining Ring onto the Acetabular Shell and around the Constrained Liner. Align the four marks on the Constraining Ring with the 'slots' on the Constrained Liner's constraining petals. Select the appropriate Constraining Ring Inserter (assembled to the Liner Driver Handle) and place onto the face of the Constraining Ring so that the tabs align with the line markings on the Constraining Ring and the slots of the Constrained Liner; impact. Move to all four positions around the Acetabular Shell. (For images and details of ring impaction, see *Figures 4a and 4b.*)

Step 4: Reduce Stem into Head - Position the femoral head such that the female taper is directed to accept the trunnion of the femoral stem. Reduce the trunnion of the femoral stem into the femoral head.

RING REMOVAL

Step 1: If the Constraining Ring must be removed for any reason, the **Crown Cup Constraining Ring Removal Tool** is designed to be inserted in between the crowns on the Acetabular Shell and the Constraining Ring. There are four locations that must be disengaged. They are positioned at 90-degree increments, each approximately 5mm counterclockwise to the line markings on the Constraining Ring. Once inserted, the Constraining Ring Removal Tool functions as a 'pry-bar' and is levered with the handle moving from inside the shell circumference to outside. This will disengage the locking mechanism for that section of the Constraining Ring. Continue around the Constraining Ring until all sections have been disengaged.

IMPORTANT: *The Constraining Ring should only be assembled to the metal shell once to avoid damaging the components.*

SYSTEM SPECIFICATIONS

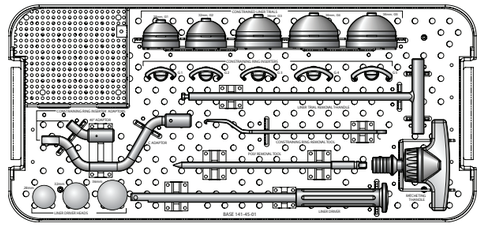
Shell Size (mm)	Acetabular Shell Groups		Constrained Liner Specifications				
	Cluster-Hole Shell	Multi-Hole Shell	Liner Grouping	Constrained Liner ID (mm)	Poly Thickness (mm)	Range of Motion (degrees)	Lever Out Value (in/lbs)
48	Group 1	Group 1	Group 1	28	6.9	120	240
50							
52	Group 2	Group 2	Group 2	32	6.4	130	240
54							
56	Group 3		Group 3	36	6.4	137	240
58							
60	Group 4	Group 3	Group 4	36	8.4	137	240
62							
64	Group 5	Group 4	Group 5	36	10.4	137	240
66							
68							

Note: *Constrained Liner system only compatible with sizes 48-68mm Crown Cup shells.*

Acetabular Shell Groups	Constrained Liner	Constraining Ring
Group 1	134-28-41	180-03-11
Group 2	134-32-42	180-03-12
Group 3	134-36-43	180-03-13
Group 4	134-36-44	180-03-14
Group 5	134-36-45	180-03-15

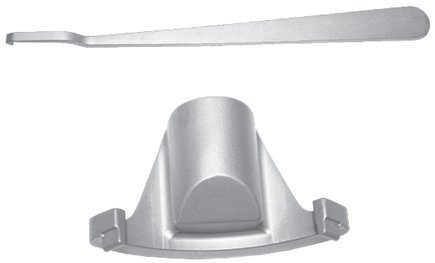
INSTRUMENT LISTING

Catolog Number	Part Description
141-45-00	Novation Crown Cup Constrained Liner Instrument Case
101-16-00	Poly Removal Tool
101-31-06	Ratcheting T-Handle
131-01-02	Liner Trial Removal T-Handle
135-28-11	Crown Cup Constrained Liner Trial, Group 1, 28mm ID
135-32-12	Crown Cup Constrained Liner Trial, Group 2, 32mm ID
135-36-13	Crown Cup Constrained Liner Trial, Group 3, 36mm ID
135-36-14	Crown Cup Constrained Liner Trial, Group 4, 36mm ID
135-36-15	Crown Cup Constrained Liner Trial, Group 5, 36mm ID
141-01-28	Novation Liner Driver Head, 28mm
141-01-32	Novation Liner Driver Head, 32mm
141-01-36	Novation Liner Driver Head, 36mm



INSTRUMENT LISTING

Catolog Number	Part Description
181-03-00	Keyed Liner Driver Handle
181-03-01	Crown Cup Constraining Ring Inserter Keyed 40-Degree Adapter
181-03-02	Crown Cup Constraining Ring Inserter Keyed “C” Adapter
181-03-03	Crown Cup Constraining Ring Removal Tool
181-03-11	Crown Cup Constraining Ring Inserter, Group 1
181-03-12	Crown Cup Constraining Ring Inserter, Group 2
181-03-13	Crown Cup Constraining Ring Inserter, Group 3
181-03-14	Crown Cup Constraining Ring Inserter, Group 4
181-03-15	Crown Cup Constraining Ring Inserter, Group 5



Note: *If necessary, ancillary instrumentation (Novation Acetabular Reamer Case and/or Novation General Acetabular Instrument Case) must be ordered in addition to this kit.*

NOTES

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For additional device information, refer to the Exactech Novation® Hip System– Instructions for Use for a device description, indications, contraindications, precautions and warnings. • For further product information, please contact Customer Service, Exactech, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

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