Acetabular Labral Repair or “Labral Refixation”

There are multiple reasons for acetabular labral tears, the most common being femoral acetabular impingement (FAI). Also, even if a tear is not present, in order to treat a pincer deformity, the surgeon usually must elevate the labrum off the acetabular rim, burr down the excessive bone underneath, and then refixate the labrum to the acetabulum. Regardless of the method of injury, the surgical goals are the same:

**Goals of Labral Refixation Procedure**
1. Re-attach the labrum to the acetabular rim
2. Restore the orientation of the labrum (or “version” of the labrum) so that it rests on the femoral head. This will restore the joint suction seal, which is a critical function of the acetabular labrum.

Failure to accomplish both goals could allow fluid to escape the joint and could possibly contribute to chondral damage and arthritis. Most implants on the market focus on the first goal, but don’t provide the surgeon with the control necessary to reliably and repeatably achieve the second. Achieving labrum orientation is often left to the surgeon’s ability to place a precise stitch and tie an arthroscopic knot effectively, or in the case of a knotless implant like Pushlock, guess how much suture to leave and hope it was the right amount. While dependably addressing the first goal of secure and stable fixation, the SpeedLock HIP system focuses on providing the control to make the second goal of labral positioning and orientation easier and more repeatable.

**SpeedLock HIP Positioning**

SpeedLock HIP is a PEEK knotless fixation implant which is indicated for use in fixation of soft tissue to bone in the hip. Examples of such procedures include:

- Hip capsule repair
- Acetabular labrum reattachment

With the combination of independent bone lock, suture lock, and incremental, reversible tissue tensioning, the SpeedLock HIP system gives surgeons maximum control of their hip labral repairs, allowing for consistently precise and anatomic placement of the labrum on the acetabular rim.
**Competitive Selling Guide**

**Control**
Independent bone lock, suture tensioning and suture lock allow for precise and repeatable placement of the anchor
- Placement of the anchor
- Tensioning of the suture and
- Fixation of the construct

Incremental and reversible tissue tensioning
- Enables the surgeon to consistently reduce the labrum to the acetabular rim and control the orientation or version of the labrum to maintain the suction seal

**Streamlined**
Streamlined technique
- Push-in anchor design for faster insertion
- Manage and tension sutures quickly by rotating knobs
- Knotless technology delivers repeatable suture lock with the twist of a dial

**Stability**
Suture-to-bone fixation
- Internal suture lock helps maintain final tension over time
- Implant design provides strong bone and suture lock
- High pullout strength (171N in 20lb bone foam—366N in 35lb bone foam)*

This guide is designed to summarize the competitive implants, but more importantly outline how to position SpeedLock HIP to help the surgeon accomplish their surgical goals given what they are currently using.

**Common Features and Topics in Hip Implants:**

**Implant Size**
Most of the focus for recent implants is anchor diameter, with companies driving to smaller and smaller implants. The reason most often given is that the bone available on the anterior acetabular rim is minimal. In reality, most labral tears occur on the superior aspect of the acetabulum (from the 10 to 2 o’clock position). Even if the tear travels anterior a surgeon could use SpeedLock HIP for the majority of the tear to control labrum orientation and add a few small anchors (if needed) anterior to supplement fixation.

Also, papers have shown that length of drill and implant is as important as diameter in terms of being able to place the implant without violating the articular surface of the acetabulum (Philippon et al., Am J Sports Med. 2011 Jul) Defining a safety margin for labral suture anchor insertion using the acetabular rim angle. SpeedLock HIP offers the shortest drill length compared to other systems.

**Implant Pullout**
Although the hip is a weight bearing joint, the labrum is not a primary stabilizer of the hip joint and so the hip labrum does not experience a lot of clinical force. Most implants on the market have sufficient pullout strength.

**Suture Tensioning**
Most options on the market are pre-loaded (knot tying) anchors. By using this method of fixation, the surgeon relies on their stitch and knot tying to properly orient the labrum. Prior to the introduction of SpeedLock HIP, there was concern about the inaccuracy of a knotless repair – specifically over-tightening the labrum, which can cause the labrum to invert and compromise the suction seal. This is because implants like PushLock don’t provide independent bone lock, suture tensioning, and suture lock.

Other reasons why knotless might be preferred to knot tying:
1. Knot stacks can migrate or irritate the capsule.
2. Tying knots takes longer and is less repeatable than suture lock with SpeedLock HIP

Manual vs. Incremental Tensioning

SpeedLock HIP offers both manual tensioning and incremental tensioning (with ratchet wheels) options. The decision on which method to use depends on the surgeon’s current technique and preferred stitch.

Surgeons might prefer manual tensioning if:
1. They like to “feel” the tension on the labrum in their hands
2. They place “luggage tag” or vertical mattress stitches in labrum
3. They want to be able to independently tension each suture limb
4. They currently use Pushlock

Surgeons might prefer incremental tensioning with ratchet wheels if:
1. They prefer a simple stitch or a cerclage stitch
2. They like the ease and accuracy of the ratchet
3. They are current user of SpeedLock and other “OPUS®” type implants

It is possible that a surgeon may switch back and forth between the two methods. Discuss your surgeon’s stitch preference to understand which tensioning method would be more effective for their repair. You may also want to encourage them to try both in a case to determine their preference.

Regardless of their tensioning preference, SpeedLock HIP still provides surgeons with maximum control of their repair; both methods allow for bi-directional tensioning of the labrum that is independent from bone lock and suture lock. With both options, once the desired tension is achieved they can lock the construct internally in a dependable, repeatable manner.

Main Stitch Types

<table>
<thead>
<tr>
<th>Stitch Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertical Mattress</td>
<td>Up and down orientation stitch that completely penetrates the labral tissue for each suture limb. Tensioning each limb can help control version of labrum. When placed at the labral chondral junction, it is referred to as the Labral Base Refixation Stitch.</td>
</tr>
<tr>
<td>Horizontal Mattress</td>
<td>Side to side orientation of stitch that completely penetrates the labral tissue. Can maximize tear coverage based on length of stitch.</td>
</tr>
<tr>
<td>Luggage Tag</td>
<td>Loop placed in labrum. Free suture limbs fed back through loop and pulled tight. Each suture limb is locked. Maximizes surface area of suture to labral tissue.</td>
</tr>
<tr>
<td>Simple Stitch</td>
<td>Typically placed mid substance of labrum. Helpful if there is enough tissue present. Allows for placement of stitch without contacting femoral head.</td>
</tr>
<tr>
<td>Cerclage Stitch</td>
<td>Loops around labrum. Requires violating labral chondral junction for placement.</td>
</tr>
</tbody>
</table>
## Competitive Dimensions

### HIP Implants

<table>
<thead>
<tr>
<th>(all dims in mm)</th>
<th>SpeedLock HIP Knotless</th>
<th>S&amp;N Bioraptor Knotless</th>
<th>Hip PushLock (2.9) Knotless</th>
<th>S&amp;N Bioraptor 2.3</th>
<th>Pivot NanoTak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant length</td>
<td>11.9</td>
<td>12</td>
<td>15.5</td>
<td>11.6</td>
<td>8</td>
</tr>
<tr>
<td>Implant diameter (nom)</td>
<td>3.0</td>
<td>3.1</td>
<td>2.9</td>
<td>2.6</td>
<td>1.4</td>
</tr>
<tr>
<td>Implant diameter (max)</td>
<td>3.4</td>
<td>3.7</td>
<td>3.65*</td>
<td>3.0</td>
<td>1.6</td>
</tr>
<tr>
<td>Drill diameter</td>
<td>3.0*</td>
<td>2.9-3.5 Tapered</td>
<td>2.85</td>
<td>2.6</td>
<td>1.4</td>
</tr>
<tr>
<td>Drill depth</td>
<td>16.6**</td>
<td>21</td>
<td>19.5</td>
<td>20</td>
<td>17</td>
</tr>
</tbody>
</table>

**Note**

- * drill has 3.4mm proximal countersink
- **drill depth allows for 2-3mm of extra room to tap implant down if desired
- All dimensions measured during predicate device testing
- *Add width of 2 suture strands (0.75mm) to implanted diameter
- Preloaded with #1 suture
Smith & Nephew created the market for hip arthroscopy and they have an extensive hip product line. This includes anchors, passers, Wands, distraction tables, access instruments, burrs, shavers, video, pumps, and ancillaries. They typically use their extensive product line to bundle products and leverage capital equipment for use of their implants.

**S&N Bioraptor 2.3**
Bioraptor 2.3 is a PEEK push in, knot tying anchor preloaded with #2 suture. Although they passively promote it as a 2.3mm anchor, the S&N Bioraptor is actually 3.0mm on the outer diameter. The surgeon drills a minimum 2.6mm or larger hole to place the implant.

**Strengths:**
- The Bioraptor 2.3 is the most widely used implant to date for hip labral repairs
- Reliable

**Weaknesses:**
- Smith & Nephew has been slow to innovate past their initial technologies. Surgeons are looking for something new
- Knot-tying implant (see Suture Tensioning Section)
- They have been passively misrepresenting the size of the implant to surgeons

**Selling against Smith & Nephew’s Bioraptor 2.3:**
S&N was first to market with hip products, but they have not kept up. ArthroCare has now introduced a number of new products and technologies for hip arthroscopy that bring unique value.

Our Coblation® Wands are market leading for a reason - you have multiple options available to address your surgeon’s needs. Additionally, SpeedStitch® can also be compelling to surgeons that like to close the capsule or prefer a mid substance stitch.

Given the Bioraptor 2.3 is a pre-loaded anchor, the surgeon has to depend on his knots to properly orient the labrum and create the appropriate seal with the femoral head. Once the knot is tied, the surgeon cannot re-adjust the labral position. SpeedLock HIP has bi-directional tensioning and allows the surgeon to adjust the labrum orientation in either direction as many times as needed to achieve a precise repair. Even after the suture is locked, SpeedLock HIP can be re-tensioned by driving the anchor further (i.e. when the other anchors have been placed and the suture of the first has loosened as a result).
S&N Bioraptor Knotless
Bioraptor Knotless is a PEEK knotless implant. While attempting to offer independent bone lock, suture tensioning, and suture lock, it fails in execution. SpeedLock HIP is superior in providing control for precise repairs.

**Strengths**
- Knotless
- Independent suture tensioning and suture lock

**Weaknesses**
- Very finicky, high fiddle factor - anchor prematurely detaches from inserter
- Poor suture lock
- Large implant promoted as a 2.9mm anchor, but outer diameter is 3.75mm
- If not implanted at correct depth, tensioning sutures is difficult

**Selling against Smith & Nephew’s Bioraptor Knotless**
While the bone lock on the Bioraptor Knotless is probably sufficient, the anchor falls short with suture lock. In a sawbone, we were able to hand pull the suture to failure. Bioraptor Knotless offers independent bone lock and suture tensioning, but poor anchor-to-inserter attachment and difficulty tensioning sutures when the anchor is not properly seated may frustrate surgeons.

Most surgeons who currently or previously used the Bioraptor Knotless will agree that SpeedLock HIP is a better implant that truly provides the control they are looking for in a knotless implant.
Pivot Medical

Pivot Medical is a hip arthroscopy startup that has recently introduced some innovative new devices to market. Leveraging a design and consulting team of well-known hip surgeons, they have been successful in targeting and winning business from high volume hip arthroscopists. They have focused on making their suture implants (NanoTak and now CinchLock) as small as possible, and have employed #1 suture in order to be able to shrink the anchor geometry. They have introduced suture passers (NanoPass and Injector) as well as a novel cannula system and a beaver blade. They are currently launching a knotless implant called CinchLock.

**Pivot Nanotak**

Nanotak is a PEEK push-in knot-tying anchor preloaded with #1 suture.

**Strengths**
- Very small implant – 1.4mm drill hole, 1.6mm OD implant
- Famous design surgeon team
- Simple delivery – press fit, with an expanding distal end
- Good for far anterior and posterior aspects of the acetabulum where the rim is narrow

**Weaknesses**
- Knot-tying implant (see suture tensioning section)
- Implant is flimsy
- Must implant 2x as many to achieve same stable repair
- Pivot is a very small company and has limited resources
- They do not have a Wand portfolio to offer surgeons
- While their size can be viewed as a strength outside the 10 o’clock to 2 o’clock region, it is not necessary inside this region

**Pivot CinchLock (In Launch)**

- PEEK Knotless push-in anchor with #1 suture

**Strengths**
- 2.4mm drill hole
- Independent bone lock, suture tensioning, suture lock

**Weaknesses**
- Attachment of implant to inserter is flimsy – it prematurely detaches easily
- Must implant more to get same fixation as SpeedLock HIP
- Pivot is a very small company and has limited resources
- They do not have a Wand portfolio to offer surgeons
- While their size can be viewed as a strength outside the 10 o’clock to 2 o’clock region, it is not necessary inside this region

**Selling against Pivot’s Nanotak and CinchLock**

Although the surgeon is gaining a small anchor, he is losing the precise control of properly orienting the hip labrum in a critical region of the repair. Additionally, the Nanotak and CinchLock use #1 suture, which is primarily how they are able to make the anchor smaller. However, this can raise concerns about cutting through deficient labrums. Surgeons also feel that they need to place more implants (nearly twice as many!) to accomplish the same function as SpeedLock HIP. This increases the distraction time and cost of the procedure. If your surgeon is concerned with size, encourage them to use SpeedLock HIP in the regions with more bone stock (superior aspect of the acetabular rim) to accurately fixate and orient the labrum. They can always supplement as needed.

Given that the Nanotak is a pre-loaded anchor, the surgeon has to depend on his knots to properly orient the labrum and create the appropriate seal. Once the knot is tied, the surgeon cannot re-adjust the labral position. SpeedLock HIP has bi-directional tensioning and allows the surgeon adjust the labrum orientation in either direction as many times as needed for a precise repair.

The Nanotak has been shown to work well in the hands of expert hip arthroscopists, but it is not a robust implant, and in the hands of a less experienced surgeon or one with less arthroscopic skill, it could be a difficult and frustrating device.

While CinchLock offers surgeons independent bone lock, suture tensioning and suture lock, flimsy attachment of the implant to the inserter can easily cause premature detachment in an already difficult procedure. Surgeons that have tried both prefer SpeedLock HIP.
Arthrex has duplicated their technologies from the shoulder for the hip. As in shoulder, their hip products strive to be quick and easy, but not precise. Like S&N, they have an extensive product line of ancillary products for hip procedures. They typically have many more reps than other companies covering a territory.

**Arthrex Hip Pushlock**

Pushlock is a knotless implant, offered in PEEK and biocomposite material, with a couple different sizes.

**Strengths**
- Knotless
- Fast, easy

**Weaknesses**
- Arthrex’s hip fixation implants are nothing new for the hip except size
- They still depend on the bone-to-anchor interface to lock the suture
- They combine bone lock, suture tensioning, and suture lock into one step. This leads to less precise, less repeatable repairs, and the potential to over or under tighten the repair.

**Selling against Arthrex’s PushLock Hip**

The same strategy that is used to sell against PushLock in the shoulder can be used in the hip. In particular, the combination of bone lock and suture lock can often overtension the hip labrum and leave a gap for fluid to escape. For this reason, surgeons that have used PushLock may have a negative impression of knotless anchors. PushLock is why many surgeons think that knotless = less control. Once implanted there is no ability to readjust tension. Take time to review the precision that SpeedLock HIP offers with bi-directional, independent, incremental tensioning.
Biomet has successfully created a market for all-suture anchors. Surgeons like the idea of a soft anchor in the joint in case of pullout or failure. Like Pivot, Juggerknot focuses on size as a primary advantage.

**Biomet Juggerknot**
Juggerknot is an all-suture anchor in a variety of sizes

**Strengths**
- Small
- All-suture

**Weaknesses**
- Pull out strength and security an issue
- Unpredictable deployment
- Knot-tying anchor (see Suture Tensioning section)

**Selling against Biomet’s Juggerknot**
There are still concerns with this implant about micromotion in the bone. Arthrex has targeted this issue and attacked Biomet’s design to bear this out. Deployment of the Juggerknot can also be unpredictable – the surgeon has to remove the implant shaft and count on the implant expanding before it leaves the bone hole. This can lead to anchors pulling out of the bone prior to deployment.

Focus on the reproducibility and accuracy of SpeedLock HIP. Specifically, be prepared to discuss how the implant deploys.

Given that the Juggerknot is a pre-loaded anchor, the surgeon has to depend on his knots to properly orient the labrum and create the appropriate seal. Once the knot is tied, the surgeon cannot re-adjust the labral position. SpeedLock HIP has bi-directional tensioning and allows the surgeon adjust the labrum orientation in either direction as many times as needed for a precise repair. Additionally, SpeedLock HIP can be advanced after implantation for additional tension.
We have a different perspective.

We don’t see the status quo; we see opportunities to improve.
We don’t see routine procedures; we see the opportunities for better outcomes.
ArthroCare looks at the big picture.
We see the connections between our patients, our physicians, and our solutions.
We always look for new ways to advance the standard of care.