

L2L™ Radial Head System

Surgical Technique



Table of Contents

Introduction	4
Pre-Operative Considerations	6
Surgical Technique Summary	7
Exposure	8
Bone Preparation	9
Implant Sizing	12
Trial Range of Motion	13
Implant Assembly	15
Implantation	16
Closure	17
Postoperative Care	17



Figure A
L2L Radial Head and Stem are designed to complement unique patient anatomy

Introduction

L2L Radial Head System is the simple solution for replacing the proximal radial head in patients with fractures. L2L Radial Head is designed with a smooth Stem to be implanted intentionally line-to-line. For example, a size 5 Stem will utilize a size 5 Reamer with the same diameter. In other words, not cemented and not press-fit. This allows the Implant to act as a metal spacer and complement unique patient anatomies. The L2L Radial Head's simple design is intended to provide fit and comfort for the patient, and ease of implantation for the surgeon.

Device Description

This device is a modular radial head prosthesis designed for use without bone cement. It is available in six Head sizes: 18, 20, 22, 24, 26, 28mm and eighteen Stem options: 5, 6, 7, 8, 9 and 10 mm diameters, each Stem with three height options: +0, +2 and +4 mm. The Heads are manufactured from Cobalt-Chrome and the Stems from Titanium alloy.

System Benefits

L2L Radial Head and Stem are designed to complement patient anatomy in order to minimize wear and maximize mobility.^{1,2} (Fig. A)

- Low profile distal edge of Head is designed to allow space for the annular ligament and proximal ulna promoting proper tracking with the humerus.
- Smooth Stem allows for radial head rotation with the capitellum and ulna during pronation and supination, thereby designed to minimize articular wear and optimize range of motion.
- Polished Cobalt-Chrome Head is designed to replicate natural radioulnar joint mechanics with no edge surfaces that can irritate the annular ligament or other soft tissues during pronation and supination.



Figure B
Stream-lined modular design



Figure C
Compact instrument case

Stream-lined modular design for ease of insertion and revision (Fig. B)

- Bullet-tip stem and inferior head contour is designed for ease of insertion.
- Smooth stem allows for a cement-free implantation for ease of insertion and revision.
- Modular implant assembled via taper connection and no moving parts is designed for simplicity.

Compact instrumentation intended to reduce costs and complexity (Fig. C)

- Compact single-layer instrument set is designed to optimize space utilization and minimize sterilization and cleaning costs in a hospital.
- Easy-to-use instruments are designed for operating room personnel to learn quickly and handle easily.



Figure D
Preoperative x-rays
(A/P, top image; M/L, bottom image)

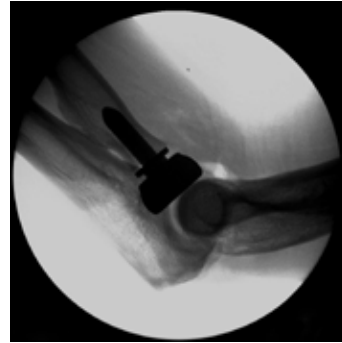


Figure E
Postoperative x-rays with L2L Radial Head
(A/P, top image; M/L, bottom image)

Preoperative Considerations

- A preoperative radiograph of the contralateral elbow can provide insight into the native radial head anatomy in cases where damage to radial head precludes measurement.
- Preoperative templating can be used to estimate the implant sizes prior to surgery.
- Head Trials are color coded to match the label on the Implant Head box. Stem Protectors are color coded to match the label on the Implant Stem box. Smallest sizes are purple and largest are brown.

Head Trials (color coding)



Stem Protectors (color coding)



X-Ray Template



Surgical Technique Summary

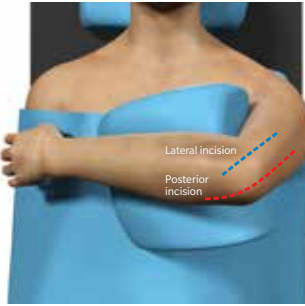


Figure 1.1
Initial skin incision

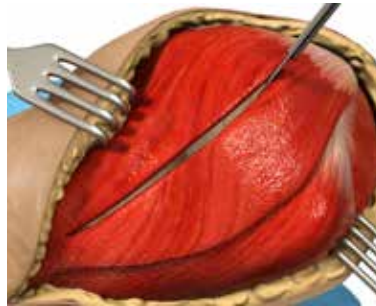


Figure 1.2
Common extensor split



Figure 2.1
Resect radial neck



Figure 2.4
Gently ream canal



Figure 2.5
Plane the resected surface



Figure 3.1
Rebuild fragments in Sizer Dish.



Figure 4.1
Snap trials together



Figure 4.4
Perform trial range of motion



Figure 5.2
Assemble Implant



Figure 6.1
Insert Implant



Figure 6.2
Final view

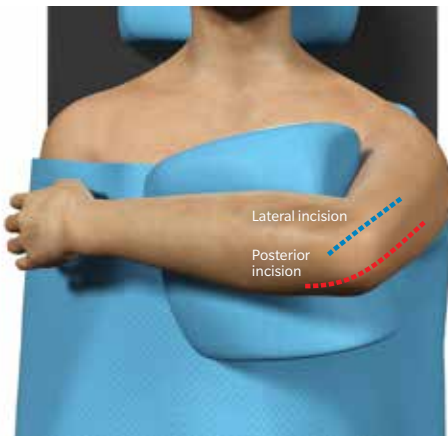


Figure 1.1
Initial skin incision

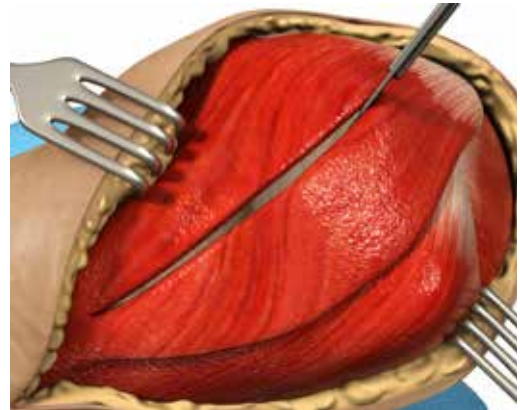


Figure 1.2
Common extensor split

Exposure

1.1 Positioning

- Place the patient in the supine position.
- Place the arm over the chest, with a bump under the ipsilateral scapula.

1.2 Surgical Approach

- Lateral approach.
 - Make initial incision (Figure 1.1).
 - Start at the supracondylar ridge and incise several centimeters distal to the mid portion of the radial head.
 - Common extensor split.
 - Longitudinally split the extensor digitorum communis tendon at the middle aspect of the radial head (Figure 1.2).
 - Incise the annular ligament and common extensor digitorum communis tendon.

ⓘ **Note:** If more visualization is required, extend the incision proximally with detachment of a portion of the extensor carpi radialis longus from the humerus.

- Kocher approach (optional).
 - Incise through the Kocher interval between the anconeus and the extensor carpi ulnaris.
 - Elevate the extensor carpi ulnaris anteriorly to gain access to the radial head.

Technique Tip: A variety of surgical approaches are acceptable to expose the radial head. A lateral approach exposes the radial head at its midline for excellent visualization, while a posterior incision can be advantageous if the surgeon needs access to the medial side.

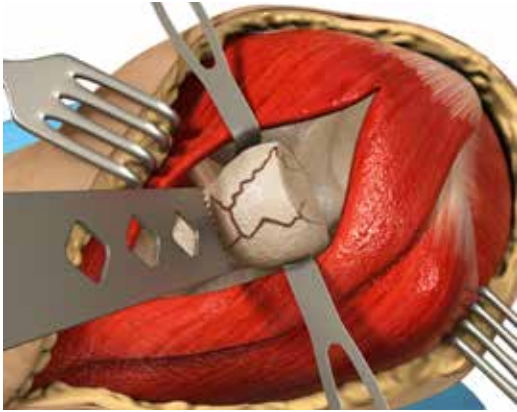


Figure 2.1
Resect radial neck

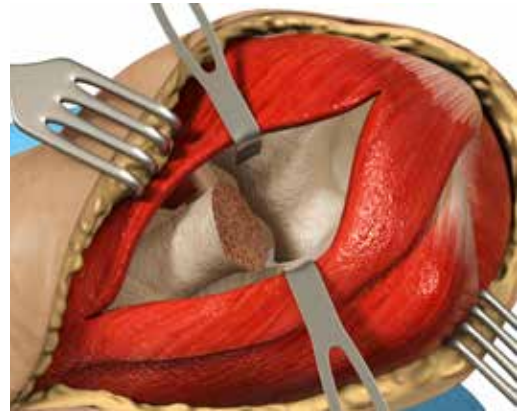


Figure 2.2
Resected surface

Bone Preparation

2.1 Remove Bone Fragments

- Carefully remove bone fragments and save for implant sizing in Section 3.

Technique Tip: Avoid removing excess bone. The shortest possible implant construct above the resection is 9mm and the largest is 18mm.

2.2 Resect Radial Neck

- Note:** For improved access, retract the radial shaft posteriolaterally.
- Create a smooth surface on which to place the Implant (Figure 2.1-2).
 - Use a microsagittal saw.
 - Resect at the level of the fracture.
 - Resect perpendicular to the radial neck.

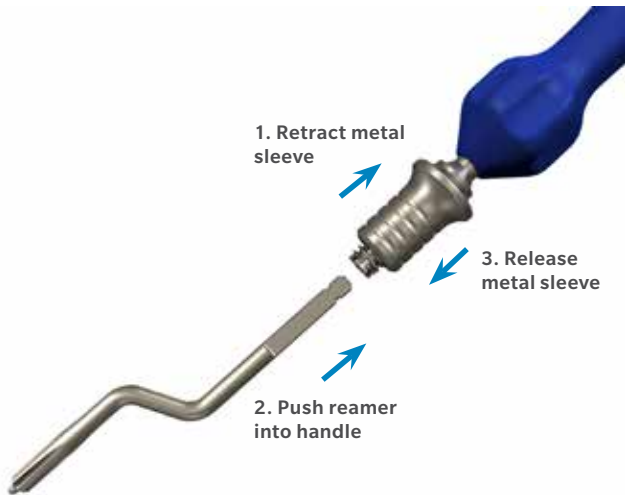


Figure 2.3
Attach Reamer to Handle

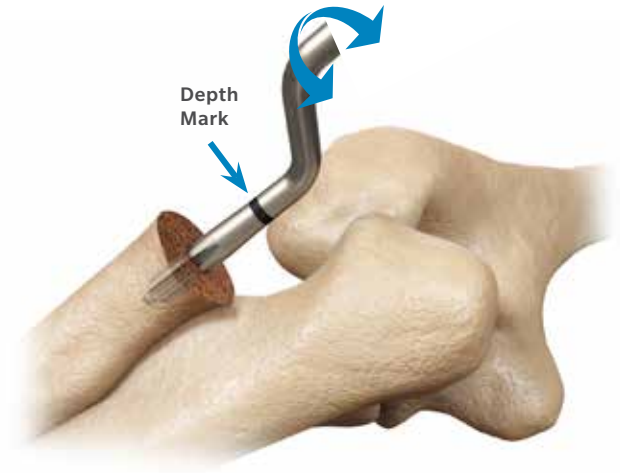


Figure 2.4
Gently ream the canal

2.3 Ream Radial Canal

- ⓘ **Note:** Be aware that it is possible to split the cortex if too large a reamer is used.
- ⓘ **Note:** Do not use Reamers on power; only use AO Handle for manual reaming.
- Attach the smallest Reamer (5 mm) to the AO Quick Connect Handle. (Figure 2.3).
- Insert Reamer into radial canal (Figure 2.4).
 - Apply gentle pressure while rotating the Handle back and forth.
 - Sink Reamer until depth mark reaches the resected plane.
 - Ream in-line with the axis of the radial neck.
- Determine Implant stem diameter.
 - Continue to ream with sequentially larger reamers until cortical chatter occurs for a fully inserted reamer.

- ⓘ **Note:** Implant stem diameter is the same dimension as the corresponding Reamer, thus the Implant will fit line to line in the canal meaning no press-fit, and no cement required.
- ⓘ **Note:** Selection of either the +2mm or +4mm Stem height should occur only after a passive range of motion with the standard Stem Trial (+0) has been assessed and a noticeable gap is present when the joint is manually reduced.

Technique Tip: Straight and Offset Radial Stem Reamers are available in each instrument set. Choice is dependent on surgeon preference. Offset Reamers will enable axial reaming in smaller exposure windows.

AO Quick Connect Handle



Reamers (Offset)



Reamers (Straight)



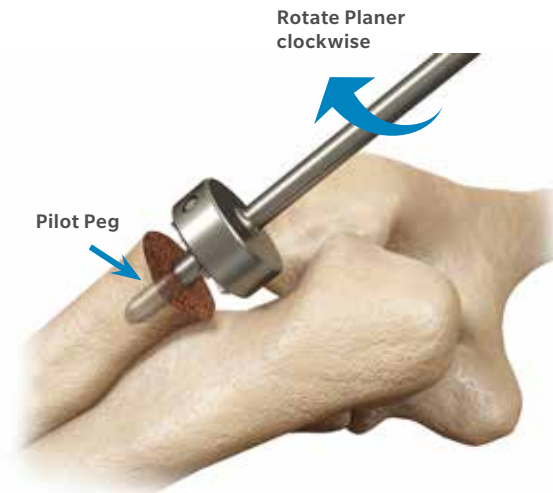


Figure 2.5
Plane the resected surface

2.4 Plane Radial Neck

- ⓘ **Note:** In some cases, an adjustment to the proximal neck may be necessary due to a jagged fracture or a resection which was not perpendicular to the radial neck axis. Use the Radial Neck Planer to create a smooth, flat surface oriented perpendicular to the canal in order to provide a surface for the Implant Head to rotate.
- ⓘ **Note:** To prevent non-perpendicular reaming to the radial axis, it is recommended to use the Small Radial Neck Planer after the 5 mm Reamer when reaming 5, 6 or 7 mm. It is recommended to use the Large Radial Neck Planer after the 8 mm Reamer when reaming 8, 9, 10 mm.
- ⓘ **Note:** The cutting surface of the Radial Neck Planer is not intended to cut when rotated counter-clockwise.
- ⓘ **Note:** Do not use Planer on power; only use AO Handle for manual planing.
 - Gently plane the resection to create a smooth surface for Implant Head to rest.
 - Attach the Radial Neck Planer to the AO Quick Connect Handle.
 - Place the Radial Neck Planer pilot peg into the radial canal.
 - Apply a gentle downward axial pressure while rotating the Handle clockwise (Figure 2.5).
 - Stop when resected surface is perpendicular to the axis of the radial neck.

AO Quick Connect Handle



Radial Neck Planer, Small/Large





Figure 3.1
Determine the Radial Head diameter

Implant Sizing

3.1 Determine Head diameter

- Reconstruct bone fragments in Radial Head Sizer Dish.
- Choose the opening diameter that most closely replicates natural radial head diameter.
- If between sizes, choose the smaller diameter.

Technique Tip: If +4mm Stem does not provide enough height restoration, increasing the head size will yield a 1mm height increase. For example, an 18mm head is 9mm tall, and a 20mm head is 10mm tall.





Figure 4.1
Snap Trials together on back-table

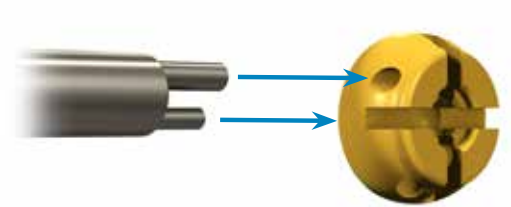


Figure 4.2
Attach Inserter/Remover into Trial Head.



Figure 4.3
Snap Trials together in situ (optional)

Trial Range of Motion

4.1 Assemble Trials

Note: Assembly of the Trials can be performed either on the back-table or in situ.

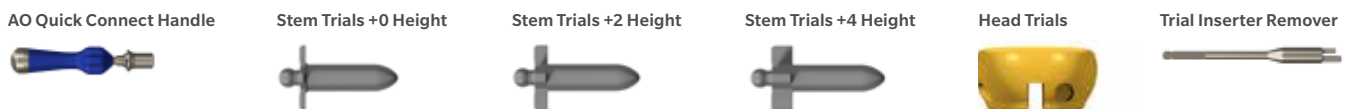
- Assemble Trials on back-table.
 - Align cruciform shape of the selected Stem Trial on the selected Head Trial (Figure 4.1).
 - Snap pieces together using finger pressure.

Note: The size of the Head Trials and Stem Trials are the same as the final components.

- Assemble Trials in-situ (optional)
 - Place Stem Trial into the radial canal.

Note: Stem Trial should fit and rotate freely in the radius. Downsizing is recommended if stem fits snugly.

- Carefully connect the AO Quick Connect Handle to the Trial Inserter Remover.
- Insert the two prongs of the Trial Inserter Remover into the hole and slot in the Trial Head (Figure 4.2).
- Place the Trial Head onto the Trial Stem, and snap pieces together using finger pressure (Figure 4.3).



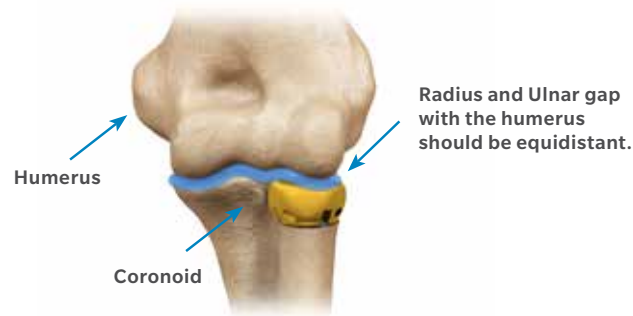


Figure 4.5
Head must not extend beyond coronoid



Figure 4.4
Perform trial range of motion



Figure 4.6
Lever off Trial Head

4.2 Perform Trial Range of Motion

ⓘ **Note:** Over-stuffing of the radial head space is a common clinical error due to apparent joint laxity when forearm is not under a valgus load.

- Move elbow through a full arc of flexion and forearm rotation (Figure 4.4).
 - Ensure Head Trial articulates with the capitellum smoothly.
 - Ensure the Head Trial does not extend proximally more than the coronoid of the ulna (Figure 4.5).
 - Check for normal distal ulnar and radial variance at the wrist using fluoroscopy if desired.
- If required, change Head and /or Stem Trial size.
 - Lever off Head Trial from the Stem Trial using the Trial Inserter Remover by rotating clockwise and upwards (Figure 4.6).

- If Stem Trial height needs to be adjusted, remove Stem Trial and replace with either a +2 or +4 mm height Stem Trial, keeping the same stem diameter.

AO Quick Connect Handle



Stem Trials +0 Height



Stem Trials +2 Height



Stem Trials +4 Height



Head Trials



Trial Inserter Remover



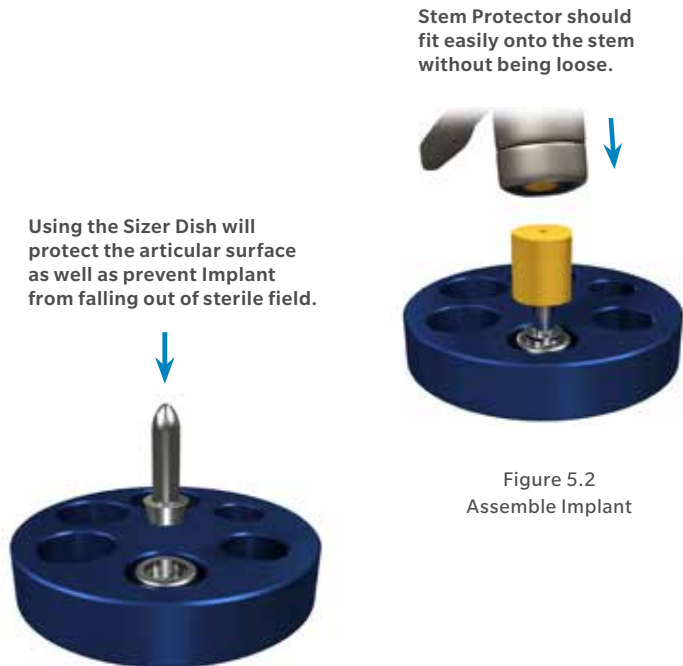


Figure 5.1
Assemble the construct

Figure 5.2
Assemble Implant

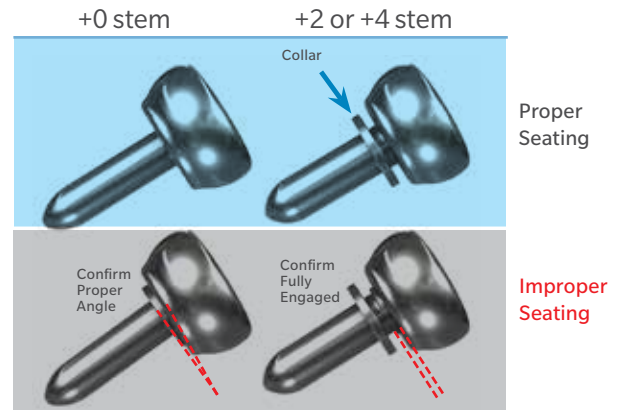


Figure 5.3
Verify connection

Implant Assembly

5.1 Assemble the Implants

- ⓘ **Note:** Before placing Radial Head Implant into Radial Head Sizer Dish, clear all debris and bone fragments.
- ⓘ **Note:** Assemble Implants on the back table.
- ⓘ **Note:** Prior to assembly, ensure both the Implant Head and Stem taper surfaces are free of debris and moisture.
- ⓘ **Note:** Once assembled, the taper is not intended to be disassembled and cannot be disassembled without significantly damaging the Implant's smooth surfaces.
- Place the Radial Head Implant into the size-matched opening hole in the Radial Head Sizer Dish; female taper is facing up, articulation surface facing down.
- Place the Radial Stem male taper into the Radial Head female taper (Figure 5.1)
- Protect the Stem by covering the exposed end with the appropriately-sized Radial Stem Protector.
- Connect the components by gently impacting the Stem into Head using a mallet (Figure 5.2).
- Verify the under-surface of the male taper is inserted flush to or deeper than the inferior edge of the Radial Head Implant (Figure 5.3).
- ⓘ **Note:** Fully seated +0 Stem will look different than a fully seated +2 or +4mm Stem, as there will be a visible gap between the collar of the +2 or +4mm Stem and the bottom of the Head (Figure 5.3).

Radial Stem Protector



Radial Head Sizer Dish





Figure 6.1
Insert Implant



Figure 6.2
Look of final Implant

Implantation

6.1 Position the final Implant

- Verify that the stem rotates freely in the canal.
- Place the assembled Implant into the proximal opening of the radial canal (Figure 6.1).
- Apply axial force using finger pressure to the proximal surface of the Implant assembly to fully seat it.

ⓘ **Note:** Lateralization of the radius may be necessary to completely insert the Implant assembly into the canal as the Radial Head Implant may contact the distal humerus during insertion.

ⓘ **Note:** The Radial Stem Implant will slide freely when the proper reamer size was used.

6.2 Assess fit of the final Implant

- Reduce the radiohumeral joint and put the elbow through the full range flexion, extension, pronation and supination.
- Verify the Implant articulates well against the capitellum (Figure 6.2).



Figure 7.1
Closure

Closure

7.1 Closure

- Perform wound closure by capsular repair.
 - Repair the annular ligament.
 - If the lateral collateral ligament complex was avulsed from its lateral epicondyle origin, repair it using non-absorbable No. 2 sutures or suture anchors through bone holes in the lateral epicondyle.
 - Repair the split in the extensor digitorum communis and close the wound.

Postoperative Care

8.1 Postoperative Care

Postoperative management will depend on the patient's associated bony and ligamentous injuries. Mobilize based on elbow stability.

References

1. J Bone Joint Surg Am. 2007 May;89(5):1075-80. Radial head arthroplasty with a modular metal spacer to treat acute traumatic elbow instability. Doornberg JN, Parisien R, van Duijn PJ, Ring D.
2. J Bone Joint Surg Am. 2016 Apr 6;98(7):527-35. doi: 10.2106/JBJS.15.00128. Radial Head Fractures Treated with Modular Metallic Radial Head Replacement: Outcomes at a Mean Follow-up of Eight Years. Marsh JP, Grewal R, Faber KJ, Drosdowech DS, Athwal GS, King GJ.

For complete product information, including indications, contraindications, warnings, precautions and potential adverse events, see package insert and www.zimmerbiomet.com

This publication and all content, is protected by copyright, trademarks and other intellectual property rights owned by or licensed to Zimmer Biomet or its affiliates unless otherwise indicated. It must not be used, copied or reproduced in whole or in part without the express written consent of Zimmer Biomet or its authorized representatives.

This material is intended for the physicians and the Zimmer Biomet sales force only. The distribution to any other recipient is prohibited.

©2016 Zimmer Biomet



ZIMMER BIOMET
Your progress. Our promise.™