ePAK™ Single-Use Delivery System
featuring DVR® Crosslock

Surgical Technique

Peel the Seal
and You’re Ready to Go!
Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it’s meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally invasive surgical technique, advanced biomaterials or a patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.
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The ePAK™ Single-Use Delivery System is a pre-sterilized, single use procedure pack. This system has been engineered to add value by addressing the productivity needs of the operating room in one complete package. This specific procedure pack addresses distal radius fractures, and features the advanced DVR® Crosslock implant and instruments.

**DVR® innovation milestones:**

- The first implant system with divergent pegs to capture dorsally displaced fractures from a volar approach.

- A low profile implant designed to mimic the volar aspect of the bone and be used as a reduction template.

- Fixed angle K-wires to confirm implant placement prior to final implantation.

- F.A.S.T. Guide® technology to simplify and speed up surgery.

- Cobalt Chrome multi-directional screws to provide the surgeon the flexibility to adjust screw trajectories while still creating a strong, stable construct.

**DVR® Crosslock enhancements over the DVR® Anatomic:**

- Cross-locking oblique screw options provide additional three-dimensional fixation in comminuted or osteoporotic bone.

- Locking screws are engineered with tapered heads and triple lead threads to create a stiff construct and to enhance insertion or removal characteristics.

- 2.7 mm screws create greater procedural efficiency by utilizing only one drill bit and one driver for all the implant screws while maintaining construct strength.

- Narrower shaft increases the ease of fitting the plate to the bone while still providing more fixation options than the current DVR® Anatomic.

- Length offering includes: mini (new), standard, medium, long.
**Implant Features**

Oblong screw hole
allows for fine tuning of the plate position.

Cross-locking
oblique screw options provide additional three-dimensional fixation in comminuted or osteoporotic bone.

Volar tilt
can aid in anatomic reduction, restoration of volar tilt, and is particularly useful for corrective osteotomies.

The distal shape of the plate
is contoured to match the watershed line to provide a visual guide for optimal placement and its low profile blends into the bone to mitigate risk of tendon irritation.

Make 2.7mm locking screws with tapered heads and triple lead threads create a stiff construct, which can enhance insertion or removal characteristics.

F.A.S.T. Guide® Insert
technology allows for easy drilling of fixed angle locking screws and visually distinguishes left and right plates.

Fixed Angle K-wire holes reference screw trajectory, and aid in optimal plate positioning.

Intersecting proximal and distal pegs
form a proprietary three dimensional scaffold, providing support of the articulating surface.

Multi-directional screws
Offer up to 20 degree cone off the fixed angle trajectory.

**Screws**
Screws are designed to work in the locking, non-locking, and oblong holes.

<table>
<thead>
<tr>
<th>Screws</th>
<th>Available Lengths</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.7 mm Cortical Screws (Locking)</td>
<td>10 mm to 30 mm in increments of 2 mm</td>
</tr>
<tr>
<td>2.7 mm Multi-Directional Screws (Locking)</td>
<td>10 mm to 30 mm in increments of 2 mm</td>
</tr>
</tbody>
</table>

Screws are individually packed

Available plate sizes and lengths listed on page 19
ePAK™ Single-Use Delivery System

ePAK™ Kit Features

Depth gauge: Hook effectively grasps the far cortex to provide accurate readings.

Screw length gauge: Is conveniently built into the tray to verify screw selection.

Screws: Are designed to function in the locking, non-locking and oblong holes. Screw distribution for each plate size has been determined based on comprehensive review of historical usage and anatomic data.¹

Soft Tissue Guide: Features a built-in scale so a direct reading can be taken off the drill bit.

Screwdriver: Has a unique tapered design to pick up all screw types and sizes.


K-wires and drill bit: Are new and sharp each time.

Single drill bit and driver: Minimize the need to interchange instruments.

Advanced DVR® Crosslock Plating Technology

ePAK™ Storage Case: Conveniently organizes the ePAK™ kits with graphics and part number information for ease of use.

¹References are not provided in the text.
With the ePAK™ Single-Use Delivery System healthcare professionals now benefit from Biomet’s product offering to reduce cost, improve efficiency and ultimately increase productivity.

The icons help to categorize the benefits of ePAK™ compared to a standard sterilization tray. These are value added solutions that are offered to the healthcare professional.

Reduced Case Disruptions

- Instruments have never been used, and are stocked and ready to go for every surgery.
- The pack is stocked, sterile and ready to reduce the risk of case disruption. Just peel the seal and go.
- Drop something? Instead of waiting for reprocessing, just grab an individually packed box from the storage case.

Time Savings

- Reduced time spent preparing instruments and implants for surgery.
- Rapid setup and turnover time between cases.
- Reduced delays caused by punctured blue wrap.

Efficient System Design

- The tray is less than 1 lb. and ergonomically designed.
- One part code per procedure.
- Streamlined system is easy to use and reduces complexity for the OR team.

Pre-Sterilized

- Pre-sterilized with protective packaging against contamination when in the hospital prior to use.
- Implants and instruments will not be exposed to previous surgeries.

Improved Productivity and Reduced Costs

- Reduced steps in managing orthopedic instruments could improve hospital staff productivity.
- Immediate availability of sterile pack could result in time efficiency and the potential for more cases.
- Transportation and sterilization costs are eliminated since packs are pre-sterilized.
Flexor Carpi Radialis (FCR) Approach

Incision
Make an incision over the course of the FCR tendon.

A zigzag incision is made across the wrist flexion crease to allow better access and visualization (Figure 1).

Release the FCR Tendon Sheath
Expose and open the sheath of the FCR tendon (Figure 2).
Dissect the FCR tendon distally to the level of the superficial radial artery.
Crossing the Deep Fascia
Retract the FCR tendon toward the ulna while protecting the median nerve (Figure 3).
Incise through the floor of the FCR sheath to gain access to the deeper levels.
Split the sheath of the FCR tendon distally up to the tuberosity of the scaphoid.

Mid-Level Dissection
Develop the plane between the flexor pollicis longus (FPL) and the radial septum to reach the surface of the radius (Figure 4).
Develop widely the subtendinous space of parona and expose the pronator quadratus muscle (PQ).
Flexor Carpi Radialis (FCR) Approach (Cont.)

Identifying the Watershed Line
Palpate the radius distally to identify the volar rim of the lunate fossa. This establishes the location of the watershed line (Figure 5).

The transitional fibrous zone (TFZ) is a band of fibrous tissue located between the watershed line and the PQ that must be elevated to properly visualize the fracture.

Release the PQ by sharply incising over the watershed line and proximally on the lateral edge of the radius (Figure 5).

Elevating the Pronator Quadratus
Use a periosteal elevator to elevate the PQ to expose the volar surface of the radius (Figure 6).

The fracture line on the volar cortex is usually simple, which facilitates reduction.

The origin of the FPL muscle can be partially released for added exposure.

Caution: During implantation, pronator quadratus is frequently ruptured. Please refer to Warnings and Precautions Section on the back cover.
Flexor Carpi Radialis (FCR) Approach (Cont.)

Release of the Distal Fragment

Release the insertion of the brachioradialis which is found on the floor of the first compartment in a step cut fashion (Figure 7).

**Note:** The brachioradialis is the prime deforming force of the distal fragment.

Identify and retract the abductor pollicis longus (APL) and extensor pollicis brevis (EPB) tendons.

**Important:** Care should be taken to protect the radial artery.

Extended FCR Approach

Pronation of the proximal fragment out of the way provides exposure to the dorsal aspect of the fracture, allowing fracture debridement and reduction.

**Intra-Focal Exposure**

Intra-focal exposure is obtained by pronating the proximal fragment out of the way. A bone clamp facilitates this maneuver (Figure 8).

Preserve the soft tissue attachments to the medial aspect of the proximal fragment.

**Note:** This is where the anterior interosseous vessels that feed the radial shaft are located.
Provisional Fracture Reduction
After fracture debridement, supinate the proximal radius back into place and restore radial length by reducing the volar cortex (Figure 9).

Plate Sizing
The plate size should be determined prior to opening the ePAK™ procedure pack. Use the plate sizing template set to determine the head width and plate length that will most closely match the patient’s anatomy. Flip the template over to change from right-side to left-side orientation (Figure 10).

Note: In situations where the comminution of the fracture makes it difficult to assess the appropriate size, use the opposite hand to establish the appropriate size to use.
Removing Plate from the Kit
A plastic clip holds the plate in position within the kit. While holding the kit with one hand, use your index finger and thumb from your other hand to gently lift up one side of the clip while pushing down the other side (Figure 11).

Proximal Plate Positioning
Determine the correct position for the plate by judging how the plate conforms to the watershed line and the volar surface of the radius (Figure 12).
Distal Row Plate Fixation

**Recommended Order for Inserting Screws**

The size distribution of screws for each plate size has been determined based on comprehensive review of historical usage and theoretical anatomic data. The surgeon should decide the priority of screws for each construct on an individual basis. The screws in the distal row of the head of the plate only need to cross the intersecting row of proximal screws and do not need to reach the dorsal cortex. Therefore, to ensure the screws available are used most effectively, the most distal row of screws should be installed last (Figure 13).

**Recommended Order**
1. Oblong hole in shaft of plate
2. Proximal row in head of plate
3. Remaining shaft holes
4. Distal row in head of plate

**Note:** Additional sterile-packed screws are available if required.

**Drilling for Non-Threaded Positions**

The soft tissue guide is pre-loaded onto the drill bit. The soft tissue guide should be used when drilling through the non-threaded and oblong screw holes (Figure 14).

Using the 2.2 mm drill bit with the soft tissue guide, drill through the center of the proximal oblong hole of the plate, which will allow for plate adjustments (Figure 14).

**Note:** The soft tissue guide should not be used when drilling through the F.A.S.T. Guide® insert.
Measuring for Non-Threaded Positions

When using the soft tissue guide to determine screw length, read the measurement where the marking on the drill bit aligns with the line on the soft tissue guide (Figure 15a).

The depth gauge can be used to verify the screw length required. The depth gauge scale will provide a direct measurement. When selecting a screw for the oblong hole or any other non-threaded screw hole in the shaft, round up measurement to the nearest 1 or 2 mm. Whereas, when selecting screws in the metaphysis or any other threaded hole, choosing a screw 1 or 2 mm less than the reading may reduce the risk of tissue irritation (Figure 15b).

**Note:** If using the depth gauge through the F.A.S.T. Guide® insert, read the measurement from the FG mark on the depth gauge.

Insert the appropriate length 2.7mm locking screw using the driver.

**Note:** The locking screws are designed to work in threaded, non-threaded, and oblong holes.

Distal Plate Fixation

Final Fracture Reduction

Final reduction is obtained by indirect means using the DVR® Crosslock plate as a template, then applying traction, ligamentotaxis, and direct pressure over the dorsal aspect (Figure 16).

**Note:** A properly applied bolster helps to maintain the reduction.
Drilling the Proximal Row

Using the 2.2 mm drill bit, drill through the proximal single-use F.A.S.T. Guide® inserts starting on the ulnar side in order to stabilize the lunate fossa (Figure 19).

**Distal Plate Fixation**

First, secure the distal fragment to the plate by inserting a K-wire through the most ulnar K-wire hole in the proximal row (Figure 17 and 18).

Proper plate positioning can be confirmed using fluoroscopy by obtaining a 20-30 degree lateral image.

The K-wire should be 2-3 mm subchondral to the joint line on this view.

**Note:** Bend the K-wire out of the way to facilitate drilling.

**Note:** K-wires installed in the proximal row aid in reduction of the distal fragments and allow proper assessment of screw placement prior to drilling.
Measuring Through the F.A.S.T. Guide® Insert

Measure the drilled hole with the depth gauge by taking a direct reading from the FG line (Figure 20).

The depth gauge calibration will provide a direct measurement. When selecting screws in the metaphysis, choosing a screw 1 mm or 2 mm less than the reading may reduce the risk of tissue irritation.

**Note:** If the F.A.S.T. Guide® insert is removed before measuring the screw length, use the line closest to the edge of the depth gauge.

Removing the F.A.S.T. Guide® Inserts

Remove each F.A.S.T. Guide® insert with the square driver after checking the drilled depth (Figure 21).

A F.A.S.T. Guide® collector has been built into the side of the ePAK™ tray for ease-of-use in keeping count of each F.A.S.T. Guide® insert removed from the plate. Each F.A.S.T. Guide® insert should be accounted for before and after the plate is installed to ensure that none are left in the surgical site.
Inserting Locking Screws in Proximal Row
Using the same driver, fill the holes in the head of the plate with the appropriate length locking screws (Figure 22).

Inserting a Multi-Directional Screw (MDS)
An MD screw option is provided separately in a sterile pack for locked fixation within a 20 degree cone of angulation off the fixed angle trajectory.

Remove the F.A.S.T. Guide® inserts using the square driver. Place the 2.2 mm end of the soft tissue guide into the screw hole.

Place the 2.2 mm drill bit through the soft tissue guide until it comes in contact with the bone. Determine the trajectory of the drill bit by varying the angle of the soft tissue guide and drill.

**Note:** A MDS screw can be used in any threaded locking hole.

**Note:** Fluoroscopy should be used to avoid placing a MDS screw in the intra-articular joint space.
Final Plate Fixation

**Inserting the Remaining Shaft Screws**

After inserting the proximal row of locking screws, go back to the shaft of the plate and fill the non-threaded holes first, using the same technique that was used for the oblong hole. The locking screws will act as a non-locking screw in the non-threaded holes.

Next, fill the crosslocking holes in the shaft, which are angled locking screw holes with F.A.S.T. Guide® inserts. Use the same technique as applying locking screws in the distal end of the plate.

**Inserting the Distal Row Screws**

The distal row is filled last, using the remaining screw lengths in the ePAK™. Since the distal row of the head of the plate converges on the proximal row between 14 mm and 18 mm, typically a 16mm length screw is all that is needed in the distal row.

Remove all F.A.S.T. Guide® inserts, even if the screw hole is not used.

**Note:** The proximal row provides support to the dorsal aspect of the articular surface. The distal row provides support to the central and volar aspects of the subchondral plate.
**Final Radiographs**

A 20-30 degree elevated lateral fluoroscopic view allows visualization of the articular surface, evaluation of the volar tilt, and confirmation of proper screw placement 2-3 mm proximal to the subchondral plate (Figure 26).

To confirm that the length of each individual screw is correct, pronate and supinate the wrist under fluoroscopy.

**Final Appearance**

A properly applied plate should be just proximal to the watershed line and not project above or beyond it in order to avoid contact with the flexor tendons (Figure 27).

**Note:** Ensure all F.A.S.T. Guide® inserts are removed prior to closing.

**Wound Closure**

Repair the TFZ in order to cover the distal edge of the plate. Repair the brachioradialis. Suture the PQ to the TFZ and the repaired brachioradialis.
ePAK™ Single-Use Distal Radius Fracture Implants & Instruments

Left
 xxxx-2x-xxx

Right
 xxxx-1x-xxx

ePAK™ Procedure Packs Available in these Size Options

<table>
<thead>
<tr>
<th>Mini (24 mm X 43 mm)</th>
<th>Standard (24 mm X 51 mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8118-22-040 (Left)</td>
<td>8118-22-050 (Left)</td>
</tr>
<tr>
<td>8118-12-040 (Right)</td>
<td>8118-12-050 (Right)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Narrow Mini (22 mm X 41 mm)</th>
<th>Wide (28 mm X 56 mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8118-21-040 (Left)</td>
<td>8118-23-050 (Left)</td>
</tr>
<tr>
<td>8118-11-040 (Right)</td>
<td>8118-13-050 (Right)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Narrow (22 mm X 51 mm)</th>
<th>Medium (24 mm X 62 mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8118-21-050 (Left)</td>
<td>8118-22-060 (Left)</td>
</tr>
<tr>
<td>8118-11-050 (Right)</td>
<td>8118-12-060 (Right)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Long (24 mm X 85 mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8118-22-090 (Left)</td>
</tr>
<tr>
<td>8118-12-090 (Right)</td>
</tr>
</tbody>
</table>

Note: Left plates are pictured.

Each ePAK™ kit contains one plate, 2.7 mm locking screws and necessary instrumentation. The plate sizing templates are available separately.
ePAK™ Single-Use Delivery System

Individually Packed Sterile Instruments: Available to prevent delays in case of dropped instruments from the ePAK™ kit

2120-00-002  Screwdriver
2120-00-003  Depth Gauge
2120-00-222  Soft Tissue Guide 2.2 mm
2120-00-008  1.6 mm K-Wire, Trochar Tip
2120-00-022  2.2 mm Drill Bit
2120-00-122  2.2 mm Long Drill Guide
2120-00-010  Plate Sizing Template Set

Individually Packed Sterile Screws: Available in case additional screws are required for a procedure

1318-27-3XX  2.7 mm Multi-Directional Screws
              (10-30 mm in 2 mm incr.)
1318-27-1XX  2.7 mm Locking Screws
              (10-30 mm in 2 mm incr.)
Individually Packed Sterile Instruments:
Available to prevent delays in case of dropped instruments from the ePAK™ kit

- 2120-00-002 Screwdriver
- 2120-00-003 Depth Gauge
- 2120-00-222 Soft Tissue Guide 2.2 mm
- 2120-00-008 1.6 mm K-Wire, Trochar Tip
- 2120-00-022 2.2 mm Drill Bit
- 2120-00-122 2.2 mm Long Drill Guide

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Available in case additional screws are required for a procedure

- 1318-27-3XX 2.7 mm Multi-Directional Screws
  (10-30 mm in 2 mm incr.)
- 1318-27-1XX 2.7 mm Locking Screws
  (10-30 mm in 2 mm incr.)
IMPORTANT: This Essential Product Information does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INDICATIONS: The use of metallic surgical appliances provides the orthopaedic surgeon with a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are intended as a guide to normal healing, and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or nonunions in the presence of load bearing or weight bearing might eventually cause the implant to break due to metal fatigue. All metal surgical implants are subjected to repeated stress in use, which can result in metal fatigue.

THE SYSTEM IS INTENDED FOR FIXATION OF FRACTURES, MALUNIONS AND OSTEOTOMIES INVOLVING THE DISTAL RADIUS.

CONTRAINDICATIONS: Screws, plates, intramedullary nails, compression hip screws, pins and wires are contraindicated in: active infection, conditions which tend to retard healing such as blood supply limitations, previous infections, insufficient quantity or quality of bone to permit stabilization of the fracture complex and/or fusion of the joints, conditions that restrict the patient’s ability or willingness to follow postoperative instructions during the healing process, foreign body sensitivity, and cases where the implant(s) would cross open epiphyseal plates in skeletally immature patients.

ADDITIONAL CONTRAINDICATION FOR ORTHOPAEDIC SCREWS AND PLATES ONLY: Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless supplemental fixation or stabilization methods are utilized.

WARNINGS AND PRECAUTIONS: In using partial weight-bearing or nonweight-bearing appliances (orthopaedic devices other than prostheses), a surgeon should be aware that no partial weight-bearing or nonweight-bearing device can be expected to withstand the unsupported stresses of full weight bearing.

• Do NOT open the volar wrist capsule. Doing so may cause devascularization of the fracture fragments and destabilization of the volar wrist ligaments.

• If necessary, contour the plate in small increments. Excessive contouring may weaken or fracture the plate.

• Do NOT use screw lengths that will excessively protrude through the far cortex. Protrusion through the far cortex may result in soft tissue irritation.

• Do NOT permanently implant K-wires through the holes of the plate as they may back out and cause tissue damage. Use of the K-wires allows you to provisionally secure the plates to the anatomy.

ADVERSE EVENTS: The following are the most frequent adverse events after fixation with orthopaedic screws, plates, intramedullary nails, compression hip screws, pins and wires: loosening, bending, cracking or fracture of the components or loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures; loss of anatomic position with nonunion or malunion with rotation or angulation; infection, both deep and superficial; and allergies and other adverse reactions to the device material.

NOTE: It is NOT required to remove F.A.S.T. Guide® inserts to sterilize the plate.

References

1. DVA-106221-DVAR