Surgical Technique

LCP Condylar Plate 4.5/5.0. Part of the LCP Periarticular Plating System.
This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

**Processing, Reprocessing, Care and Maintenance**
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
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## Surgical Technique

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## MRI Information

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The Synthes LCP Condylar Plate 4.5/5.0 is part of the LCP Periarticular Plating System, which merges locking screw technology with conventional plating techniques.

LCP Periarticular Plating System
The LCP Periarticular Plating System is capable of addressing:
- complex fractures of the distal femur with the LCP Condylar Plate 4.5/5.0.
- complex fractures of the proximal femur with the LCP Proximal Femoral Plate 4.5/5.0 or the LCP Proximal Femoral Hook Plate 4.5/5.0.
- complex fractures of the proximal tibia with the LCP Proximal Tibia Plate 4.5/5.0 or the LCP Medial Proximal Tibia Plate 4.5/5.0.

Locking Compression Plate
The Locking Compression Plate (LCP) has combi-holes in the plate shaft that combine a dynamic compression unit (DCU) hole with a locking screw hole. The combi-hole provides the flexibility of axial compression and locking capability throughout the length of the plate shaft.

Note: More detailed information on conventional and locked plating principles can be found in the Synthes Locking Compression Plate (LCP) Technique Guide (Art. No. 036.000.019/DSEM/TRM/0115/0278).
LCP Condylar Plate System
The LCP Condylar Plate System has many similarities to traditional plate fixation methods, with a few important improvements. The technical innovation of locking screws provides the ability to create a fixed-angle construct while using familiar AO plating techniques. Locking capability is important for a fixed-angle construct in osteopenic bone or multifragment fractures where screw purchase is compromised. These screws do not rely on plate-to-bone compression to resist patient load, but function similarly to multiple, small angled blade plates.

- Locking screws engaged in the plate create a fixed-angle construct that improves fixation in osteopenic bone and multifragmentary fractures.
- Multiple screw fixation in the femoral condyles allows improved fixation of many distal fractures (including all C3 fractures).
- Low-profile, anatomically shaped plates designed for left or right femur.
- 316L stainless steel implants

Plate head
- Anatomically shaped head is contoured to match the distal femur, eliminating intraoperative plate contouring.
- Six threaded screw holes accept locking screws.

Plate shaft
- Combi-holes combine a dynamic compression unit (DCU) hole with a locking screw hole, providing the flexibility of axial compression and locking capability throughout the length of the plate.
- Straight plates available with 6 or 8 combi-holes in plate shaft.
- Curved plates available with 10, 12, 14, 16, 18, 20 or 22 combi-holes in plate shaft to accommodate fracture patterns that include shaft fractures in conjunction with articular fragments.
- Curved plates are precontoured to mimic the anterior bow (1.1 m radius) from the lateral aspect of the femur.
- Plate shaft design permits use of a minimally invasive surgical technique.
- Limited-contact design

Note: For information on fixation principles using conventional and locked plating techniques, please refer to the Synthes Large Fragment Locking compression Plate (LCP) surgical technique.
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.

**Anatomic reduction**
Fracture reduction and fixation to restore anatomical relationships.

**Early, active mobilization**
Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

**Stable fixation**
Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.

**Preservation of blood supply**
Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

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Indications and Contraindications

**Indications**
- Buttressing of multifragmentary distal femur fractures
- Supracondylar fractures
- Intra-articular and extra-articular condylar fractures
- Malunions and nonunions of the distal femur
- Periprosthetic fractures
- Fractures in normal or osteopenic bone

**Contraindications**
No specific contraindications.
1 Preparation

Required sets

- LCP Condylar Plate Set 4.5/5.0 (stainless steel)
- Periarticular LCP Plating System Instrument Set
- Cannulated Locking and Cannulated Conical Screw Ø 5.0 and 7.3 mm Set
- LCP Large Fragment Instrument Set
- LCP Large Fragment Screw Set

Complete preoperative radiographic assessment and prepare the preoperative plan. Position the patient supine on a radiolucent operating table. Viewing the distal femur under fluoroscopy in both the lateral and AP views is necessary.

When using a LCP Condylar Plate Set with the Periarticular LCP Plating System Instrument Set and the Cannulated Locking and Cannulated Conical Screw Ø 5.0 and 7.3 mm Set, the following sets are also required: the LCP Large Fragment Instrument Set and LCP Large Fragment Screw Set.

Note: For information on percutaneous, submuscular insertion of the plate using the LCP Periarticular aiming instruments, please refer to the Periarticular Aiming Arm Instruments for LCP Condylar Plate 4.5/5.0 (DSEM/TRM/0815/0460)

Precautions:
- The incision can be extended if necessary to improve visualization of the articular surface or lateral metaphysis and diaphysis. It may not always be appropriate to use limited incisions and closed reduction techniques.
- Plate bending is not recommended as this may weaken the plate and the plate-screw interface and can compromise the targeting function of an aiming arm, if in use. However, there may be cases in which plate bending is clinically necessary. In such cases, the plate should only be bent to fit proximal femur anatomy and only bend the plate incrementally and between screw holes using the plate bending press (329.300), and never bend back-and-forth. Insert at least one screw distal to the bend.
Reduce articular surface

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>324.170</td>
<td>Guide for LCP Condylar Plate, right</td>
</tr>
<tr>
<td>324.171</td>
<td>Guide for LCP Condylar Plate, left</td>
</tr>
</tbody>
</table>

Reduce and temporarily secure the articular fragments with pointed reduction forceps and/or Kirschner wires. If a posterior Hoffa fragment is present, it must be reduced and provisionally stabilized with Kirschner wires inserted from anterior to posterior.

Secure the condyles with appropriately placed 6.5 mm cancellous bone screws or 6.5 mm / 7.3 mm cannulated screws. A plate guide, right or left, or the plate itself, may be held laterally on the condyle to select an area where the screw(s) will not interfere with plate placement.

For fixation of a posterior articular fragment (Hoffa fracture), place 3.5 mm cortex screws or 4.0 mm cancellous bone screws* from anterior to posterior and countersink the screw heads so they lie below the level of the articular cartilage. It may occasionally be necessary to reposition one of these screws to avoid impingement on a plate screw(s) considered essential for fixation.

* Most lengths are located in the Small Fragment Instrument and Implant Set; longer lengths may be required.
3 Determine plate position

<table>
<thead>
<tr>
<th>Instruments</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>324.175 Wire Guide 7.3, for Guide Wire Ø 2.5 mm</td>
<td></td>
</tr>
<tr>
<td>324.174 Wire Guide 5.0, for Guide Wire Ø 2.5 mm</td>
<td></td>
</tr>
<tr>
<td>310.243 Guide Wire Ø 2.5 mm, with drill tip, length 200 mm, Stainless Steel</td>
<td></td>
</tr>
</tbody>
</table>

Place a Kirschner wire across the femoral condyles at the level of the knee to indicate the joint axis. (Figure A)

Place a second Kirschner wire across the patellofemoral joint on the trochlear surface. (Figure B)

Attach the wire guide 7.3 to the central hole in the plate head.*

Prior to placing the plate against the bone, thread at least two wire guides 5.0 into the holes in the head of the plate. Use the wire guides to help position the plate on the bone.

Using anatomic landmarks and C-Arm imaging, mount the plate on the intact or reconstructed condyle without attempting to reduce the proximal portion of the fracture.

Insert a guide wire through the wire guide 7.3, parallel to the joint axis and parallel to the patellofemoral joint. (Figures A and B)

**Notes:**
- It is easier to thread the wire guides into the plate prior to placing the plate on the bone.
- Use of the wire guide is mandatory for locking the screws to the plate properly. Before proceeding, confirm plate head placement.

* As an alternative, guide wires may be placed using wire guides with the Guide for LCP Condylar Plate instead of with the plate.
Readjust plate position, if necessary, and place a second guide wire to prevent rotation of the plate. The second guide wire secures provisional fixation of the plate to the femoral condyle.

**Note:** Although any hole in the head of the plate can be used, the recommended placement for the second guide wire is in the most distal anterior hole.

The wire must be inserted through the wire guide 5.0.

**Prior to proceeding, confirm plate head placement.**

- Use clinical examination and C-Arm imaging to confirm:
  - that the guide wire inserted through the 7.3 mm central hole is parallel to both the distal femoral joint axis and the patellofemoral joint.
  - that the guide wires inserted through any of the four most distal 5.0 mm screw holes in the head of the plate are parallel to the femoral joint axis.
  - that the plate is properly oriented on the condyle under lateral C-Arm image. Because the shaft of the femur is frequently out of alignment with the distal fragment, proper plate placement can be determined by orienting the distal plate shape to that of the condyle. Placement of the plate on the condyle at this point will determine final flexion/extension reduction.

**Precaution:** Take into consideration that the most posterior distal 5.0 mm screw hole may be positioned distal to Blumensaat's line, requiring a unicondylar screw.
4

Insert screws (7.3 mm and 5.0 mm)

Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>319.701</td>
<td>Measuring Device for Cannulated Locking Screws and Cannulated Conical Screws Ø 5.0 and 7.3 mm</td>
</tr>
<tr>
<td>314.050</td>
<td>Screwdriver, hexagonal, cannulated, for Cannulated Screws Ø 6.5 and 7.3 mm</td>
</tr>
</tbody>
</table>

For predrilling in dense bone

<table>
<thead>
<tr>
<th>Code</th>
<th>Drill Bit Ø 5.0 mm, cannulated, length 200 mm, with Quick Coupling</th>
</tr>
</thead>
<tbody>
<tr>
<td>310.632</td>
<td></td>
</tr>
<tr>
<td>310.634</td>
<td>Drill Bit Ø 4.3 mm, cannulated, length 200 mm, with Quick Coupling</td>
</tr>
</tbody>
</table>

Secure the plate position on the lateral femoral condyle with at least 3 guide wires prior to inserting the first screw. Although screws may be inserted in any order, it is usually advantageous to start with the central 7.3 mm screw.

Advance the guide wire until it reaches the medial wall of the femoral condyle. Measure for screw length using the measuring device. For proper screw length measurement, the measuring device must contact the end of the wire guide. This will place the tip of the screw at the tip of the guide wire.

Note: The self-drilling, self-tapping flutes of the 7.3 mm and 5.0 mm screws make predrilling and pretapping unnecessary in most cases. In dense bone, the lateral cortex can be pre-drilled, if necessary.

- Use the 5.0 mm drill bit for 7.3 mm screws.
- Use the 4.3 mm drill bit for 5.0 mm screws.
Remove the wire guide and insert the appropriate length screw over the guide wire and into the bone using the screwdriver. Locking screws may be inserted using power equipment. However, do not use power to seat these screws since this may cause screws to cross-thread in the plate holes.

Securely tighten all locking screws to lock them to the plate.

Notes:

- If required, lag screw reduction of a fragment must be accomplished prior to inserting locking screws into the fragment.
- If the plate shifts during screw insertion, the guide wires must be removed and reinserted for the screws to lock to the plate properly.
- To compress the plate to the lateral femoral condyle, it is necessary to utilize a conical screw prior to any locking screws. Conical screws may be replaced with locking screws after reduction is complete.

Note: Some threads of the 7.3 mm cannulated locking screw will remain above the plate surface when fully seated.
5

Use the 5.0 mm screw nut for interfragmentary compression

Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>222.578</td>
<td>Screw Nut Ø 5.0 mm, Stainless Steel</td>
</tr>
<tr>
<td>319.701</td>
<td>Measuring Device for Cannulated Locking Screws and Cannulated Conical Screws Ø 5.0 and 7.3 mm</td>
</tr>
<tr>
<td>314.050</td>
<td>Screwdriver, hexagonal, cannulated, for Cannulated Screws Ø 6.5 and 7.3 mm</td>
</tr>
</tbody>
</table>

A screw nut may be used to achieve interfragmentary compression. The screw nut may only be used with the 5.0 mm cannulated conical screws.

Insert a guide wire through the bone until the tip is flush with the medial cortex. Measure for screw length using the measuring device. The measuring device must contact the end of the wire guide to provide accurate screw measurement. Select the proper length 5.0 mm cannulated conical screw by subtracting 15 mm from the measurement taken with the measuring device and then round up to the nearest screw length.

Insert the 5.0 mm cannulated conical screw. Once the screw has been positioned, advance the guide wire through the medial femoral cortex and surrounding soft tissue. The length of guide wire extending beyond the soft tissue should be sufficient to provide coaxial alignment for the screw nut and the 5.0 mm cannulated conical screw.

Make a small skin incision at the guide wire tip to insert the screw nut. Insert the screw nut over the tip of the guide wire. Using a cannulated hexagonal screwdriver, apply axial pressure while turning to advance the screw nut onto the 5.0 mm cannulated conical screw. Prevent rotation of the screw using a second cannulated hexagonal screwdriver. Advance the screw nut until it is fully seated on the screw or until the desired compression has been achieved. If the bone is osteopenic, take care to avoid overinsertion of the screw nut.

Note: Additional compression can be achieved by replacing the 5.0 mm cannulated conical screw with the next shorter screw length.
6
Reduce condyles to shaft

**Instrument**

| 321.120 | Tension Device, articulated, span 20 mm |

Reduce the plate to the proximal femoral shaft. Confirm rotation of the extremity by clinical examination and the anatomy of the fracture pattern.

Temporarily secure the plate to the bone with plate holding forceps.

Once reduction is satisfactory, and if it is appropriate based on the fracture morphology, the plate may be loaded in tension using the tension device.

**Note:** With multifragment fractures, it may not always be possible or desirable to achieve an anatomic reduction of the fracture. However, in simple fracture patterns, using the tension device may facilitate anatomic reduction of the fracture fragments. This device generates either compression or distraction.
In addition to having threaded locking holes, the plate functions similarly to DCP plates which offer the ability to self-compress fracture fragments. Therefore, a combination of lag screws and locking screws may be used.

**Note**: If a combination of cortex (1) and locking screws (2) is used, a cortex screw should be inserted first to pull the plate to the bone.

![Correct](image1.png)

![Incorrect](image2.png)

If locking screws (1) have been used to fix the plate to a fragment, subsequent insertion of a standard screw (2) in the same fragment without loosening and retightening the locking screws is not recommended.
7

Insert the 4.5 mm cortex screws

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>323.460</td>
<td>Universal Drill Guide 4.5/3.2, for neutral and load position</td>
</tr>
<tr>
<td>310.310</td>
<td>Drill Bit Ø 3.2 mm, length 145/120 mm, 2-flute, for Quick Coupling</td>
</tr>
<tr>
<td>319.100</td>
<td>Depth Gauge for Screws Ø 4.5 to 6.5 mm, measuring range up to 110 mm</td>
</tr>
<tr>
<td>314.270</td>
<td>Screwdriver, hexagonal, large, Ø 3.5 mm, with Groove, length 245 mm</td>
</tr>
</tbody>
</table>

Insert as many standard 4.5 mm cortex screws as necessary into the proximal portion of the plate.

**Precaution:** All of the 4.5 mm cortex screws must be inserted prior to insertion of locking screws.

Use the universal drill guide to predrill for 4.5 mm cortex screws, drilling through both cortices with the drill bit.

For the neutral position, press the drill guide down in the non-threaded hole. To obtain compression, place the drill guide at the end of the non-threaded hole away from the fracture. Do not apply downward pressure on the drill guide’s spring-loaded tip.

**Note:** The DCP or LC-DCP Drill Guides (322.440 or 323.450) are not compatible with the LCP plates.
Measure for screw length using the depth gauge. Select and insert the appropriate length 4.5 mm cortex screw using the hexagonal screwdriver.

**Note:** For detailed instructions please consult the Synthes Locking Compression Plate (LCP) Technique Guide (Art. No. 036.000.019/DSEM/TRM/0115/0278).
## Insert the 5.0 mm locking screws

### Instruments

<table>
<thead>
<tr>
<th>Item Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>323.042</td>
<td>LCP Drill Sleeve 5.0, for Drill Bits Ø 4.3 mm</td>
</tr>
<tr>
<td>310.430</td>
<td>LCP Drill Bit Ø 4.3 mm with Stop, length 221 mm, 2-flute, for Quick Coupling</td>
</tr>
<tr>
<td>319.100</td>
<td>Depth Gauge for Screws Ø 4.5 to 6.5 mm, measuring range up to 110 mm</td>
</tr>
<tr>
<td>511.771</td>
<td>Torque Limiter, 4.0 Nm, for Compact Air Drive and Power Drive</td>
</tr>
<tr>
<td>314.119</td>
<td>Screwdriver Shaft Stardrive 4.5/5.0, T25, self-holding, for AO/ASIF Quick Coupling</td>
</tr>
<tr>
<td>314.150</td>
<td>Screwdriver Shaft, hexagonal</td>
</tr>
<tr>
<td>314.152</td>
<td>Screwdriver Shaft 3.5, hexagonal, self-holding</td>
</tr>
<tr>
<td>324.052</td>
<td>Torque-indicating Screwdriver 3.5, self-holding, for Locking Screws Ø 5.0 mm</td>
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<tr>
<td>397.705</td>
<td>Handle for Torque Limiter Nos. 511.770 and 511.771</td>
</tr>
<tr>
<td>311.431</td>
<td>Handle with Quick Coupling</td>
</tr>
</tbody>
</table>

Attach the drill sleeve to the threaded portion of a hole in the plate shaft.

Carefully drill the screw hole using the drill bit. Read the drilled depth directly from the laser mark on the drill bit or determine the screw length with the depth gauge.

Insert the appropriate length 5.0 mm locking screw with a power tool and the torque limiter or manually with a handle and the torque limiter. The screw has to be tightened manually. After one click, the optimum torque is reached.

Repeat as necessary to insert additional locking screws.

**Warning:** If the torque limiter is unavailable, do not tighten the screws to the plate under power. Perform final tightening by hand.
**Note:** Use of the drill guide is mandatory for screws to lock to the plate properly.

Examine the limb clinically and radiographically. It is important that the femoral condyles are oriented properly to the femoral shaft.

- Securely tighten all distal locking screws again prior to closing.
### Cleaning Instruction

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Description</th>
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<tbody>
<tr>
<td>319.461</td>
<td>Cleaning Stylet Ø 2.5 mm, for Cannulated Instruments</td>
</tr>
</tbody>
</table>

Cleaning the cannulation in each instrument is imperative for proper function. Instruments should be cleared intraoperatorively using the cleaning stylet to prevent accumulation of debris in the cannulation and potential binding of the instruments about the guide wire.
### LCP Condylar Plates 4.5/5.0

<table>
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<th>Stainless steel</th>
<th>Holes</th>
<th>Length (mm)</th>
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<td>02.001.320</td>
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<td>02.001.322</td>
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<td>02.001.324</td>
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<td>02.001.308</td>
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All plates are available sterile packed.
For sterile implants add suffix S to article number.

### Additionally available
only sterile packed

<table>
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<th>Stainless steel</th>
<th>Holes</th>
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<tbody>
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<td>422</td>
<td>left</td>
</tr>
<tr>
<td>02.001.312S</td>
<td>22</td>
<td>458</td>
<td>left</td>
</tr>
</tbody>
</table>
Cannulated Locking Screw Ø 7.3 mm (02.207.020–02.207.145)
Creates a locked, fixed-angle screw-plate construct
- Threaded conical head
- Fully threaded shaft
- Self-drilling, self-tapping tip

Cannulated Conical Screw Ø 7.3 mm (02.207.250–02.207.295)
Compresses the plate to the lateral femoral condyle
- Smooth conical head
- Fully threaded shaft
- Self-drilling, self-tapping tip

Cannulated Conical Screw Ø 7.3 mm, short thread (02.207.450–02.207.545)
Compresses the plate to the lateral femoral condyle and provides interfragmentary compression
- Smooth conical head
- Partially threaded shaft
- Self-drilling, self-tapping tip

Cannulated Locking Screw Ø 5.0 mm (02.205.025–02.205.145)
Creates a locked, fixed-angle screw-plate construct
- Threaded conical head
- Fully threaded shaft
- Self-drilling, self-tapping tip
Screws

Cannulated Conical Screw Ø 5.0 mm (02.205.240–02.205.295)
Compresses the plate to the lateral femoral condyle and provides interfragmentary compression
- Smooth conical head
- Partially threaded shaft
- Self-drilling, self-tapping tip

Screw Nut Ø 5.0 mm (222.578)
Offers additional fixation and compression options for complex fractures
- Self-cutting, serrated tip
- Inserted from the medial aspect of the distal femur
- Internal threads mate with the 5.0 mm cannulated conical screws

Locking Screw Ø 5.0 mm (213.314–213.390 / 212.201–212.227)
Creates a locked, fixed-angle screw-plate construct
- Threaded conical head
- Fully threaded shaft
- Self-tapping tip

Cortex Screw Ø 4.5 mm (214.814–214.940)
- May be used in the DCU portion of the combi-holes in the plate shaft
- Compresses the plate to the bone or creates axial compression
### Drill and Wire Guides

<table>
<thead>
<tr>
<th>Part No.</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>323.042</td>
<td>LCP Drill Sleeve 5.0, for Drill Bits ø 4.3 mm</td>
<td>Fits the combi-holes in the plate shaft</td>
</tr>
<tr>
<td>324.174</td>
<td>Wire Guide 5.0, for Guide Wire ø 2.5 mm</td>
<td>Fits the five surrounding screw holes in the plate head</td>
</tr>
<tr>
<td>324.175</td>
<td>Wire Guide 7.3, for Guide Wire ø 2.5 mm</td>
<td>Fits the central screw hole in the plate head</td>
</tr>
</tbody>
</table>
Drill and Wire Guides

The hexagonal Screwdriver (313.930) and the cannulated hexagonal Screwdriver (314.050) for cannulated screws Ø 6.5 and 7.3 mm can be used to facilitate insertion and removal of wire and drill guides.
# Sets

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>01.120.021</td>
<td>Periarticular Instruments</td>
</tr>
<tr>
<td>68.120.447</td>
<td>Vario Case</td>
</tr>
<tr>
<td>68.120.445</td>
<td>Insert</td>
</tr>
</tbody>
</table>

**Additionally required**
- LCP Large Fragment Instrument Set
- LCP Large Fragment Screw Set

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>01.120.024</td>
<td>LCP Condylar Plates 4.5/5.0 (stainless steel)</td>
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<tr>
<td>68.120.448</td>
<td>Insert short plates</td>
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<tr>
<td>68.120.449</td>
<td>Insert long plates</td>
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MRI Information

Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07
Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a
Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils [whole body averaged specific absorption rate (SAR) of 2 W/kg for 6 minutes (1.5 T) and for 15 minutes (3 T)].

Precautions: The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:
- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermo regulation or temperature sensation should be excluded from MR scanning procedures.
- Generally it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.
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This publication is not intended for distribution in the USA.

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