Anterior Cervical
Intervertebral Locking Cage System
Warning
This publication describes the recommended procedures for using Double Engine devices and instruments. It offers guidance that you should pay attention to. But as with any such technical guide, the guide alone does not provide sufficient background for direct use of the instrument set, each surgeon should also consider the particular needs of each patient and make appropriate adjustments when required. Instruction by experienced surgeon is still highly recommended.

All non-sterile devices must be cleaned and sterilized before use. Multi-component instruments must be disassembled for cleaning. Please follow the instructions provided in our Reprocessing, Care and Maintenance Guide (RCMG-2012).

Please refer to Package Insert for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Caution
The implants are designed for temporary fixation of fractured bone fragments until the bone heals. Therefore, if bone does not heal or bone consolidation is delayed or not sufficient, the system may break. Post-operative care under the guidance of the surgeon is also very important and it must be done to ensure the promotion of bone consolidation.
Surgical Technique

Indications
For cervical spine (C2–C7)
- Degenerative disc disease (DDD, defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spinal stenosis
- Failed previous fusions
- Pseudoarthrosis

Contraindications
- Spinal fracture
- Spinal tumor
- Severe osteoporosis
- Spinal infection

Preoperative Plan
Prior to surgery:
- Determine the desired surgical approach
- Determine the appropriate screw length
- Estimate the appropriate Implant size.

An initial estimate of the size can be made by comparing the x-ray template for implant with the adjacent intervertebral discs on a lateral radiograph. Definitive information on the appropriate size should be obtained by measuring the distracted disc space during the operation using the trial spacers.

Notes:
- It is recommended to select the maximum implant size in order to optimize the stability of the segment through tension in the annulus fibrosus and longitudinal ligaments.
- Template images are 115% of actual implant size to correspond to typical radiographic magnification.

Patient Position
Position the patient in a supine position on a radiolucent operating table. Ensure that the neck of the patient is in a sagitally neutral position and supported by a cushion.

Note: When treating C6–C7 make sure that the shoulders do not limit the x-ray monitoring. For all cases, both vertebrae should be completely visible.

STEP 1
DETERMINE IMPLANT

1.1 Approach
Locate the correct operative level under radiographic control and make an incision. Expose the intervertebral disc and the adjacent vertebral bodies through a standard anterior approach to the cervical spine.

1.2 Distraction
Perform segmental distraction.

Note: Distraction of the segment is essential for restoring disc height and for providing good access to the inter-vertebral space.

1.3 Determine Implant

Select a trial implant of the appropriate height and depth according to the height and depth of the intervertebral space, the preoperative plan and the patient’s anatomy.

Position the trial implant in the correct cranial/caudal alignment and carefully insert it into the disc space. If necessary, the mallet can be used to help insert and/or remove the trial implant.

Notes:
- The trial implants do not have a depth limiter; an image intensifier should be used to check the position during insertion. With the segment fully distracted, the trial implant must fit tightly and accurately between the end plates.
- The height of the trial implant is 0.8 mm less than that of the corresponding implant to account for penetration of the teeth into the vertebral end plate.
- To minimize potentially increased risk to the patient, it is recommended to use shorter height trial implants before using taller height trial implants.
STEP 4
FIX SCREW

According to different clinical situations and surgeon’s preference, we provide 5 ways to achieve screw fixation. For all of the following options, please note:
- All the following steps should be carried out under X-ray image intensifier.
- It is recommended that the first hole be created for a caudally pointing screw.
- Lateral screws should always point medially.
- Determine the entry point and trajectory for the screw. The correct angulations for the screws are 40° in the caudal or cranial direction. The medial screws point 2.5° laterally and the lateral screws point 2.5° medially.

Option A: Aiming Device

Aiming device allows one screw to be inserted with the instrument attached to the implant. This helps to keep the implant in place while the other screw holes are prepared and screws inserted.

A1. Drill first pilot hole

- 111671800    Aiming Device
- 111672500    Drill Bit φ2.0, 12 mm
- 111672600    Drill Bit φ2.0, 14 mm
- 111672900    Drill Bit φ2.0, 16 mm
- 111314800    Handle with Quick Coupling

Select a drill bit of appropriate length. Insert the drill bit into the screw hole of the aiming device and drill until the stop on the drill bit contacts the guide. Remove drill bit.

Note: When using the drill bit in combination with the aiming device, take care to apply only axial forces to the drill bit. Bending forces applied when the tip of the drill bit is engaged in the aiming device can lead to the drill bit breaking.

A2. Insert first screw

- 111671100    Screwdriver Shaft, T8, self-holding
- 111672600    Torque Limiter with Quick Coupling, 1.2 Nm
- 111314800    Handle with Quick Coupling
- 111671000    Holding Sleeve for Screws

Select the appropriate screw length according to the preoperative planning and intraoperative findings. Assemble the torque limiter to the screwdriver shaft.

Note:
- It is recommended to use the torque limiter. If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.
- Retract the sleeve when inserting the first screw through the aiming device.

Using the aiming device

Attach the aiming device to the implant. Once the implant is securely attached, carefully insert the implant into the distracted segment. If necessary, tap the top of the aiming device with the mallet to advance the implant into the disc space. If distraction has been applied, release the distraction while leaving the aiming device attached to the implant.

Using the implant holder

Use the implant holder to insert the implant, once the implant is partially introduced into the disc space it can be advanced to the correct posterior depth using the flat and/or impactor with ball tip.

Note: Verify final implant position relative to the vertebral bodies in the AP and lateral direction with the help of an intraoperative x-ray.
A3. Drill remaining pilot holes
- 111671800 Aiming Device
- 111671300 Drill Bit φ2.0, 12 mm
- 111671400 Drill Bit φ2.0, 14 mm
- 111671500 Drill Bit φ2.0, 16 mm
- 111314800 Handle with Quick Coupling

Repeat step A1 to drill remaining pilot holes.

A4. Insert remaining screws
- 111671000 Screwdriver Shaft, T8, self-holding
- 111673000 Torque Limiter with Quick Coupling, 1.2 Nm
- 111314800 Handle with Quick Coupling
- 111671000 Holding Sleeve for Screws

Remove the aiming device from the implant. Repeat step A2 to insert remaining pilot holes.

Note: If the aiming device is difficult to remove, verify that the screw is advanced far enough so that the aiming device is not contacting the screw during removal.

A5. Tighten screws
- 111672600 Torque Limiter with Quick Coupling, 1.2 Nm
- 111671100 Screwdriver Shaft, T8, self-holding

To lock the screw head in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

Notes:
- If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.
- The screws should be tightened only after all screws have been inserted.

Option B: Drill Guide with Handle

B1. Drill first pilot hole
- 111671500 Drill Guide with Handle
- 111673000 Drill Bit φ2.0, 12 mm
- 111671400 Drill Bit φ2.0, 14 mm
- 111671500 Drill Bit φ2.0, 16 mm
- 111314800 Handle with Quick Coupling

Insert the drill guide into the screw hole at the appropriate angle. The tip of the drill guide is designed to fit inside the screw hole of the plate and provide a “feel” for the correct angle. Select a drill bit of appropriate length, insert it into the guide and drill until the stop on the drill bit contacts the guide. Remove the drill bit and guide.

B2. Insert first screw
- 111671100 Screwdriver Shaft, T8, self-holding
- 111672600 Torque Limiter with Quick Coupling, 1.2 Nm
- 111314800 Handle with Quick Coupling
- 111671000 Holding Sleeve for Screws

Select the appropriate screw length according to the preoperative planning and intraoperative findings. Assemble the torque limiter to the screwdriver shaft.

B3. Insert remaining screws
- 111671100 Screwdriver Shaft, T8, self-holding
- 111672600 Torque Limiter with Quick Coupling, 1.2 Nm
- 111314800 Handle with Quick Coupling

Repeat steps B1 and B2 for the remaining screws.

Note: It is recommended to use the torque limiter. If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.
B4. Tighten screws

111672600  Torque Limiter with Quick Coupling, 1.2 Nm
111671100  Screwdriver Shaft, T8, self-holding

To lock the screw head in the plate, always use the torque limiter with the screwdriver to tighten each screw to the 1.2 Nm torque.

Notes:
- If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.
- The screws should be tightened only after all screws have been inserted.

C4. Tighten screws

111672600  Torque Limiter with Quick Coupling, 1.2 Nm
111671100  Screwdriver Shaft, T8, self-holding

To lock the screw head in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

Notes:
- If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

C2. Insert first screw

111671100  Screwdriver Shaft, T8, self-holding
111672600  Torque Limiter with Quick Coupling, 1.2 Nm
111314800  Handle with Quick Coupling
111671000  Holding Sleeve for Screws

Select the appropriate screw length according to the preoperative planning and intraoperative findings. Assemble the torque limiter to the screwdriver shaft.

C3. Insert remaining screws

Repeat steps C1 and C2 for the remaining screws.

C1. Drill first pilot hole

111671600  Drill Guide with threaded tip
111671300  Drill Bit φ2.0, 12 mm
111671400  Drill Bit φ2.0, 14 mm
111671500  Drill Bit φ2.0, 16 mm
111314800  Handle with Quick Coupling

Attach the screw onto the self-retaining screwdriver with torque limiter. The screw will self-retain to the screwdriver, however, for increased screw retention the holding sleeve may be used. Advance the screw until the head of the screw contacts the plate.

Note: It is recommended to use the torque limiter. If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

C1. Drill first pilot hole

111671600  Drill Guide with threaded tip
111671300  Drill Bit φ2.0, 12 mm
111671400  Drill Bit φ2.0, 14 mm
111671500  Drill Bit φ2.0, 16 mm
111314800  Handle with Quick Coupling

Note: It is recommended to use the torque limiter. If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

C3. Insert remaining screws

Repeat steps C1 and C2 for the remaining screws.

C2. Insert first screw

111671100  Screwdriver Shaft, T8, self-holding
111672600  Torque Limiter with Quick Coupling, 1.2 Nm
111671000  Handle with Quick Coupling
111314800  Holding Sleeve for Screws

Attach the screw onto the self-retaining screwdriver with torque limiter. The screw will self-retain to the screwdriver, however, for increased screw retention the holding sleeve may be used. Advance the screw until the head of the screw contacts the plate.

Note: It is recommended to use the torque limiter. If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

C3. Insert remaining screws

Repeat steps C1 and C2 for the remaining screws.
Notes:
- The tip of the awl is designed to fit inside the screw hole of the plate and provide a “feel” for the correct angle.
- Take care that the awl does not move the implant relative to the vertebral body. For particularly hard bone, drilling is recommended to minimize implant movement.

D2. Insert first screw
11167100 Screwdriver Shaft, T8, self-holding
111672600 Torque Limiter with Quick Coupling, 1.2 Nm
111314800 Handle with Quick Coupling
111671000 Holding Sleeve for Screws

Select the appropriate screw length according to the preoperative planning and intraoperative findings. Assemble the torque limiter to the screwdriver shaft.

D3. Insert remaining screws
Repeat step D1 and D2 for the remaining screws.

D4. Tighten screws
111672600 Torque Limiter with Quick Coupling, 1.2 Nm
111671100 Screwdriver Shaft, T8, self-holding

To lock the screw head in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

Notes:
- If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.
- The screws should be tightened only after all screws have been inserted.

Option E: Angled Awl

For screws that are difficult to drill or insert because of interfering anatomy, the angled awl and angled screwdriver may be used.

E1. Awl first pilot hole
111672400 Awl, angled, φ2.0
111671700 Mallet

Insert the awl at the appropriate angle into the screw hole of the plate and tap with the mallet until the awl is seated. Remove the awl, maintaining alignment of the hole and plate.
E2. Insert first screw
111670900 Screwdriver with Sleeve, T8, self-holding, angled
Select the appropriate screw length according to the preoperative planning and intraoperative findings. Attach a screw onto the angled screwdriver. Advance the screw until the head of the screw contacts the plate.

E3. Insert remaining screws
Repeat steps E1 and E2 for the remaining screws.

E4. Tighten screws
111670900 Screwdriver with Sleeve, T8, self-holding, angled
111672600 Torque Limiter with Quick Coupling, 1.2 Nm
111671100 Screwdriver Shaft, T8, self-holding
To lock the screw head in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

Note: If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

Notes:
- If multiple screws need to be removed, it is recommended to first loosen all screws before removing any of the screws from the implant. It ensures the implant will be properly secured during removal.
- Torque limiting attachment should not be used with driver to remove screws.

Extract implant
111671800 Aiming Device
Once all screws are removed, the implant may be removed using the aiming device. Attach the aiming device to the implant by aligning the screw holes of the implant with the retention features on the aiming device and then expanding the aiming device. After the implant is securely attached, carefully remove the implant.

Note: Use of distraction at the disc space is recommended to facilitate removal.

STEP 5
REMOVE IMPLANT
If an implant must be removed, the following technique is recommended.

Remove screw
111671100 Screwdriver Shaft, T8, self-holding
111314800 Handle with Quick Coupling
Attach the handle to the screwdriver shaft, and then engage the assembled driver into the drive recess of the screw to be removed. Rotate the driver counterclockwise to first loosen the screw from the implant. Continue to rotate the driver counterclockwise to remove the loosened screw from the implant.
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