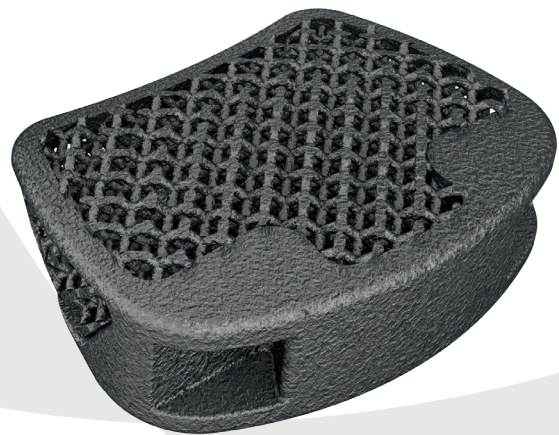


# CONDUIT™ Cervical System

## EIT™ Cellular Titanium

Surgical Technique



# Contents

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# Indications and Contraindications

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## **Intended use / Indications**

The EIT™ Cellular Titanium Cervical Cages are indicated for use in skeletally mature patients with degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by patient history and radiographic studies) and instabilities at one or more levels of the cervical spine with accompanying radicular symptoms, ruptured or herniated discs, and pseudarthrosis or failed spondylodesis. Patients should have at least six (6) weeks of non-operative treatment prior to surgery. EIT Cellular Titanium Cervical Cages are used to restore the intervertebral height and to facilitate intervertebral body fusion in the cervical spine (C2-T1) and are placed via an anterior approach. In cases of segmental instability, supplemental internal fixation using a cervical plating system should be considered.

## **Contraindications**

Do not use the EIT Cellular Titanium Cervical Cage in cases of:

- Any medical or surgical condition precluding the potential benefit of spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thus preclude the use of these or any other orthopedic implant
- Severe instabilities
- Vertebral body fractures
- Spinal tumors
- Systemic and metabolic diseases
- Conditions that may place excessive stress on bone and implants, such as severe obesity or degenerative diseases
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material

# Product Overview

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## CONDUIT™ Cervical Implant

### Lattice Structure Geometry

- ~ 80% porosity<sup>1</sup>
- ~700 µm diamond pore size<sup>2</sup>

### Dome shaped

Dome shaped to fit endplate anatomy<sup>3,4</sup>

### Rough surface

Rough elevated surface

### Grafting

Designed to allow for bone grafting

### Various sizes

2 footprint sizes for maximized endplate contact

- Small (S) = 12 x 16 mm
- Large (L) = 14 x 18 mm

### Various heights

7 heights in 1mm increments

- 4-10 mm

### Several angles

4° and 8° lordosis angle for spinal alignment and sagittal balance

### Lateral wedge

Lateral wedge design for maximal contact of the uncovertebral joint



#### References:

1. VAL2016-043 Strut diameter summary rev 0.
2. EIT Scaffold characteristics P773 Signed Report\_DM 20180417.
3. Panjabi M, Duranceau J, Goel V, et al. Cervical Human Vertebrae. Quantitative Three-dimensional anatomy of the middle and lower regions. Spine 1991; 16:861-869.
4. EIT Implant Sizing Guides.

# Implants

## CONDUIT Cervical Implants

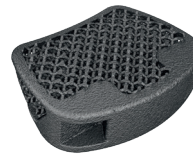


### 4° Angle

Height	Small	Large
4 mm	CHI4040S	CHI4040L
5 mm	CHI4050S	CHI4050L
6 mm	CHI4060S	CHI4060L
7 mm	CHI4070S	CHI4070L
8 mm	CHI4080S	CHI4080L
9 mm	CHI4090S	CHI4090L
10 mm	CHI4100S	CHI4100L

### 8° Angle

Height	Small	Large
4 mm	CHI8040S	CHI8040L
5 mm	CHI8050S	CHI8050L
6 mm	CHI8060S	CHI8060L
7 mm	CHI8070S	CHI8070L
8 mm	CHI8080S	CHI8080L
9 mm	CHI8090S	CHI8090L
10 mm	CHI8100S	CHI8100L

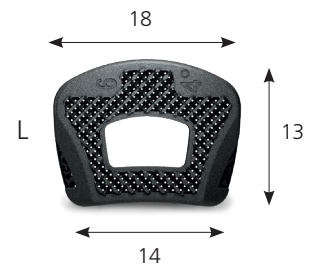
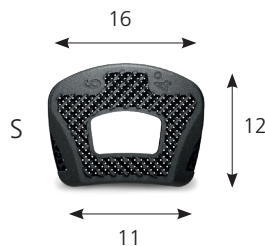


### 4° Angle

Height	Small	Large
4 mm	CEI4040S	CEI4040L
5 mm	CEI4050S	CEI4050L
6 mm	CEI4060S	CEI4060L
7 mm	CEI4070S	CEI4070L
8 mm	CEI4080S	CEI4080L
9 mm	CEI4090S	CEI4090L
10 mm	CEI4100S	CEI4100L

### 8° Angle

Height	Small	Large
4 mm	CEI8040S	CEI8040L
5 mm	CEI8050S	CEI8050L
6 mm	CEI8060S	CEI8060L
7 mm	CEI8070S	CEI8070L
8 mm	CEI8080S	CEI8080L
9 mm	CEI8090S	CEI8090L
10 mm	CEI8100S	CEI8100L



Note: Implant sizes are subject to market availability

# Instruments

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## Trials

### 4° Angle

Height	Small	Large
4 mm	CET2040S	CET2040L
5 mm	CET2050S	CET2050L
6 mm	CET2060S	CET2060L
7 mm	CET2070S	CET2070L
8 mm	CET2080S	CET2080L
9 mm	CET2090S	CET2090L
10 mm	CET2000S	CET2000L

### 8° Angle

Height	Small	Large
4 mm	CET2840S	CET2840L
5 mm	CET2850S	CET2850L
6 mm	CET2860S	CET2860L
7 mm	CET2870S	CET2870L
8 mm	CET2880S	CET2880L
9 mm	CET2890S	CET2890L
10 mm	CET2800S	CET2800L



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CET30101      Inserter



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CET30131      Slender Inserter



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Part A      Inserter Tube



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Part B      Gripper



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Part C      Stopper



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Part D      Tail wheel



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Part E      Tube wheel



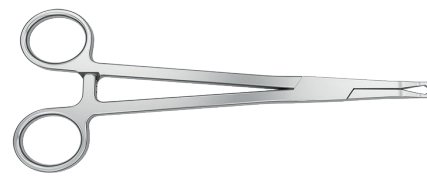
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CET30201      Impactor



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CET60100      Removal forceps



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CEC00101      Cervical Instrument Tray -  
fits 15 trials



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CEC00199      Cervical Tray Insert -  
fits 5 additional trials





# Surgical Technique

## Preparation and Approach

Place the patient in the supine position with slight extension to facilitate access to the anterior cervical spine. Locate the correct operative level and incision site with fluoroscopy. Use the medial anterior approach for C2-T1 and dissect the affected disc space per the standard operating procedure for an anterior cervical discectomy and fusion. (Figure 1)

## Discectomy and Endplate Preparation

Use a Caspar Distractor to distract the space. Perform microsurgical decompression to relieve all points of neural compression and prominent ventral spondylosis ridges, preserving the uncovertebral joints and subchondral bone as much as possible. Perform the discectomy using curettes, rongeurs, rasps, or high speed drills. The vertebral bony endplates need to stay intact and it is important to thoroughly remove the cartilaginous material from these surfaces. The implant is intended to laterally rest on the uncovertebral joints. Carefully prepare the disc space symmetrically to ensure an optimal width for an appropriate cage fit.

## Determination of Cage Size

Choose an appropriately sized trial. “Lollipop” Trials are available matching footprint, height, and angle of each implant. Ensure the side marked “TOP” is cranial and position the Trial in the intervertebral disc space. Evaluate the fit by tactile feedback and, if necessary, fluoroscopy. Repeat until a suitable match is found and then remove the Trial. (Figure 2)

**Note: Implants are slightly higher (0.25 mm) than the Trials due to the implant’s off-set dome shaped porous structure.**

Figure 1

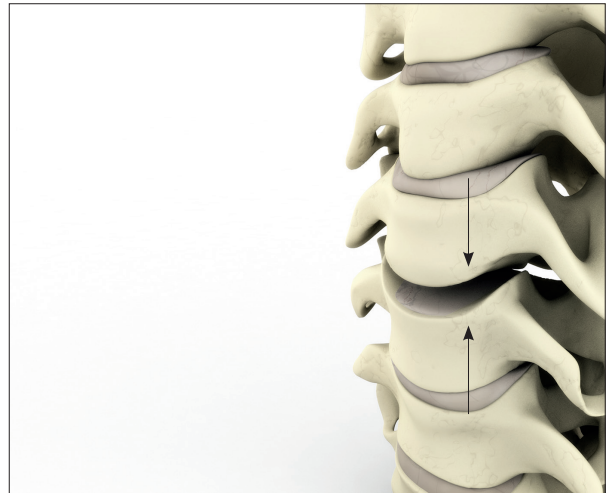


Figure 2



### Insertor options

1. Insertor: Insertor-Forceps, no assembly required. (Figure 3)
2. Slender Insertor: Pencil shaped insertor, assembly required. (Figure 4)

### Slender Insertor Assembly

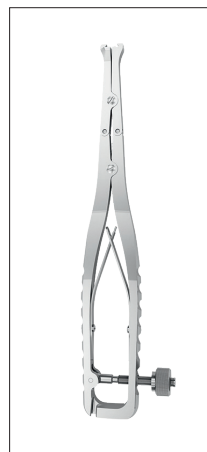
The Slender Insertor consists of five parts that must be assembled (Figure 5). Connect the Tube wheel (part E) to the Insertor Tube (part A). Slide the Gripper (part B) in the Insertor Tube (part A) and Tube Wheel (part E) to prevent the Tube Wheel from falling off of the Insertor Tube. Connect the Tail Wheel (part D) to the Tube Wheel (part E). Slide the Stopper (part C) into the Gripper and both wheels and turn the Tail Wheel clockwise to complete assembly. Ensure the wings at the front of the Stopper slide over the Gripper. Turn the Tail Wheel to change the position of the Stopper. Make sure the Gripper is in the open position by turning the Tube Wheel.

### Implant - Insertor connection

Upon selecting the appropriate Trial, remove the implant from its sterile packaging.

1. Attach the implant to the Insertor: (Figure 6)
  - Make sure the Insertor is in the open position (tips are apart).
  - Place the implant between the tips. Make sure the side marked 'TOP' on the implant is cranial.
  - Lock the implant with the grip notches between the tips by pressing the grips together and turning the wheel of the Insertor.
  - Confirm that the implant is securely connected to the Insertor.
2. Attach the implant to the Slender Insertor:
  - Make sure the Slender Insertor is in the open position (tips are apart), and the Stopper is located near the tube (turn Tail Wheel clockwise).
  - Place the implant between the tips. Make sure the side marked 'TOP' on the implant is cranial.
  - Lock the implant by rotating the Tube Wheel clockwise.
  - Set the preferred distance of the Stopper from the implant by turning the Tail Wheel.
  - Confirm that the implant is securely connected to the Insertor.

Figure 3



Insertor

Figure 4



Slender Insertor

Figure 5



A B C D E

Figure 6



### Implant Insertion

The implant can be packed with bone graft to facilitate the fusion process. Insert the implant into the intervertebral disc space. The implant should be positioned posteriorly to fit the concavity of the inferior endplate of the superior vertebral body. Confirm the position of the implant with fluoroscopy. The posterior edge of the implant should be at least 2 mm anterior to the dura. Detach the Inserter from the implant, by opening the Inserter Forceps (Figure 7) or turning the Tube Wheel counter clockwise to open up the tips of the Slender Inserter.

If repositioning is needed, the Impactor can be used to position the implant further into the vertebral disc space. The vertebral body stops of the Impactor allow the implant to be inserted up to 3 mm deep into the intervertebral space. The use of fluoroscopy is recommended during implantation to ensure proper positioning.

### Completion of Surgery / Postoperative Care

After implanting the cage and removing the Caspar Distractor, close the wound. The use of the CONDUIT cervical cage does not require any specific postoperative care and the patient should be treated according to hospital and medical standards.

### Implant Removal / Revision surgery

Removal with the Removal Forceps:

- Make sure the forceps are in the open position (tips are apart).
- Place the tips of the Removal Forceps into the implant and close the forceps. The tips should now grasp the implant inside the cavities.
- Remove the implant from the intervertebral disc space. (Figure 8)

**Warning: Do not use the Removal Forceps for implantation. The lack of a stop could result in an error of placing the device too deep into the disc space resulting in spinal cord injury.**

Figure 7



Figure 8



# Instructions for Use

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## Contents

The package contains one EIT Cellular Titanium Cervical Cage.

## Description

The EIT Cellular Titanium Cervical Cage is an implant made from a titanium alloy for the anterior stabilization of the cervical spinal column using an Anterior Cervical Discectomy and Fusion (ACDF) surgery. EIT Cellular Titanium Cervical Cages are offered in a variety of geometries and sizes to accommodate patient anatomy.

## Material

The EIT Cellular Titanium Cervical Cage is made from titanium 6-aluminum 4-vanadium alloy (ISO 5832-3). It is supplied sterile and is available in a variety of heights, footprints and lordosis angles.

## Intended use / Indications

The EIT Cellular Titanium Cervical Cages are indicated for use in skeletally mature patients with degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by patient history and radiographic studies) and instabilities at one or more levels of the cervical spine with accompanying radicular symptoms, ruptured or herniated discs, and pseudarthrosis or failed spondylodesis. Patients should have at least six (6) weeks of non-operative treatment prior to surgery. EIT Cellular Titanium Cervical Cages are used to restore the intervertebral height and to facilitate intervertebral body fusion in the cervical spine (C2-T1) and are placed via an anterior approach. In cases of segmental instability, supplemental internal fixation using a cervical plating system should be considered.

## Contraindications

Do not use the EIT Cellular Titanium Cervical Cage in cases of:

- Any medical or surgical condition precluding the potential benefit of spinal surgery
- Acute or chronic systemic, spinal or localized infections
- Severe osteoporosis or osteopenia which may prevent adequate fixation and thus preclude the use of these or any other orthopedic implant
- Severe instabilities
- Vertebral body fractures
- Spinal tumors
- Systemic and metabolic diseases
- Conditions that may place excessive stress on bone and implants, such as severe obesity or degenerative diseases
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- Prior fusion at the level(s) to be treated
- Demonstrated allergy or foreign body sensitivity to the implant material

## Adverse reactions

Adverse reactions may include:

- Clinical failure (i.e. pain or injury) due to bending, loosening, wear and tear, fracture, loss of fixation, dislocation and/or migration
- Pain, discomfort and/or abnormal sensations due to the presence of the implant
- Primary and/or secondary infections
- Allergic reactions to a foreign body, or implant material sensitivity

- Neurological injury due to surgical trauma or presence of the device, tethering of nerves in scar tissue, muscle weakness and paraesthesia
- Fracture of vertebrae or other bony structures
- Decrease in bone density due to stress shielding
- Degenerative changes or instability of segments adjacent to fused vertebral levels
- Dural tears experienced as a result of surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis
- Injury to vessels, nerves and organs; malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period
- If a pseudarthrosis occurs coupled with the implant, mechanical grinding may occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints. Wear debris can also cause other possible local or systemic adverse reactions.
- Reflex sympathetic dystrophy
- Hematoma and/or impaired wound healing; hemorrhage
- Venous thrombosis, lung embolism, and cardiac arrest
- Nonunion or delayed union
- Spinal cord impingement or damage
- Paralysis
- Bursitis
- Death

Note: This list may not include all complications caused by the surgical procedure itself

## Safety precautions

- Prior to use, thoroughly read these instructions for use and become familiar with the surgical technique.
- Keep the instructions for use accessible to all staff.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques. Proper surgical performance of the implantation is the responsibility of the operating surgeon.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrect operating techniques, the limitations of treatment methods or inadequate asepsis.
- Under no circumstances may modular implant components from different suppliers be combined.
- Each patient's record shall document the implant used (article number, description and lot number).
- During the postoperative phase, it is of particular importance that the physician keeps the patient well informed about post-surgical behavioral requirements.
- Damage to the weight-bearing structures can give rise to loosening, dislocation and migration, as well as other complications. To ensure the earliest possible detection of such catalysts of implant dysfunction, the implant must be checked periodically post-operative using appropriate techniques.

- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery
- Never reuse an implant. Although the implant may appear undamaged, previous stresses may have created nonvisible damage that could result in implant failure.
- Never use an implant if its packaging is damaged.
- An implant with damaged packaging might be damaged itself and thus may not be resterilized or used.
- Never use an implant that is past its expiration date.

### Storage, inspection and resterilization

#### Storage

The implant is individually packed in protective packaging that is labeled according to its contents. The implant is sterilized with gamma sterilization (25 kGy minimum).

- Always store the implant in the original protective packaging.
- Do not remove the implant from the packaging until immediately before use.
- Store the implant in a dry and dust-free place (standard hospital environment).

#### Disinfection/cleaning

The implant is not designed to be disinfected or cleaned by the user.

#### Resterilization

The implant is not designed to be resterilized by the user.

#### Magnetic Resonance (MR) compatibility

Non-clinical testing has demonstrated that the EIT Cellular Titanium Cervical Cage is MR Conditional and can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Spatial gradient field of up to:
  - 24,330 G/cm (243.30 T/m) for 1.5 T systems
  - 12,160 G/cm (121.60 T/m) for 3 T systems
- Maximum whole body averaged specific absorption rate (SAR) of:
  - 4.0 W/kg for 15 minutes of scanning in First Level Controlled Operating Mode at 1.5 T
  - 4.0 W/kg for 15 minutes of scanning in First Level Controlled Operating Mode at 3 T

#### 1.5 T RF heating

In non-clinical testing with body coil excitation, the EIT Cellular Titanium Cervical Cage produced a temperature rise of less than 0,5 °C at a maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 T Siemens Espree (MRC30732) MR scanner with SYNGO MR B19 software.

#### 3 T RF heating

In non-clinical testing, the EIT Cellular Titanium® Cervical Cage produced a temperature rise of less than 0,5 °C at a maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3 T Siemens Trio (MRC20587) MR scanner with SYNGO MR A35 4VA35A software.

Warning: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.

#### MR Artifact

In testing with gradient-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to 1.7 cm from the device.

#### Procedure

Only implant the EIT Cellular Titanium Cervical Cage with the applicable EIT cervical instruments.

Note: The EIT cervical instruments are available from the manufacturer at any time.

#### Preoperative

The operating surgeon draws up an operation plan specifying and documenting the following:

- Implant component(s) and their dimensions; correct selection of the proper implant size is imperative for best outcomes.
- Proper position of the implant component(s)
- Determination of intraoperative orientation points

The following conditions must be fulfilled prior to application:

- All required implant component(s) are available.
- Highly aseptic operating conditions are present.
- All requisite implantation instruments are available and in working order.

Warning: Never use or process damaged or defective instruments. Contact your local representative or dealer for repair or replacement.

Warning: The use of an instrument for tasks other than those for which they are intended may result in damaged/broken instruments or patient injury.

- The operating surgeon and operating room team are thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied. Complete information on these subjects is readily available at the workplace.
- The operating surgeon is especially trained in spinal surgery, biomechanical principles of the spine and the relevant operating techniques.

The operating procedure must be explained to the patient, and the patient's understanding of the following information must be documented:

- The patient is aware of the risks associated with neurosurgery, general surgery, orthopedic surgery and with general anesthesia.
- The patient has been informed about the advantages and disadvantages of the implant procedure and about possible alternative treatments.
- The implant can fail due to excessive load, wear and tear, or infection. Internal fixation devices are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the device. Notches, scratches, or bending of the implant during the course of surgery may also contribute to early failure.

- 
- The service life of the implant is determined by body weight and physical activity. The implant must not be subjected to overload through extreme strain, or through work-related or athletic activities.
  - Corrective surgery may be necessary if the implant fails.
  - The patient must have a physician carry out follow-up examinations of the implant at regular intervals.

#### **Intraoperative**

Prior to use, inform yourself in the product brochure about the operating technique, the related implants and the instruments.

Prior to use, verify the integrity of the sterile packaging and check the product expiration date.

Warning: Never use the implants if the packaging is damaged.

Warning: Never use implants that are past their expiration date.

The EIT Cellular Titanium Cervical Cage is implanted using a standard anterior approach to the cervical spine. Adequate cleaning and preparation of the endplates is necessary to allow for good bone contact of the device.

- Determine the appropriate implant size with the Trial.
- Place the implant into position using the Inserter.
- If necessary, slightly adjust the location of the implant using the impactor under X-ray control.

In cases of instability, consider supplemental internal fixation using a cervical plating system.

Warning: When performing cauterization around an implant, avoid contact with the implant.

#### **Postoperative**

- Reiterate preoperative instructions to the patient.
- Ensure that the patient is aware of physical activity restrictions and possible adverse reactions.

#### **Revision surgery / Implant removal**

The EIT Cellular Titanium Cervical Cage is intended for permanent implantation and is not intended for removal. However, removal may be advisable in the following situations:

- Implant breakage, migration or other clinical failure
- Pain due to the implant
- Infection

The Removal Forceps can be used to grasp and remove the implant if necessary.

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