

The image shows the cover of a surgical technique guide for the Oracle system. The background is black. At the top, there is a close-up of a surgical instrument with a mesh plate attached, with the number '20' visible on the handle. In the center, a white rectangular box contains the title 'oracle' in a large, bold, sans-serif font, with 'SURGICAL TECHNIQUE GUIDE' in a smaller, bold, sans-serif font below it. At the bottom, there is a larger image of a surgical instrument with a mesh plate attached, with the numbers '217-1215' and '15' visible on the handle. The overall design is clean and professional, emphasizing the medical nature of the product.

# *oracle*

## SURGICAL TECHNIQUE GUIDE



Rethinking Possibilities, Reshaping Lives

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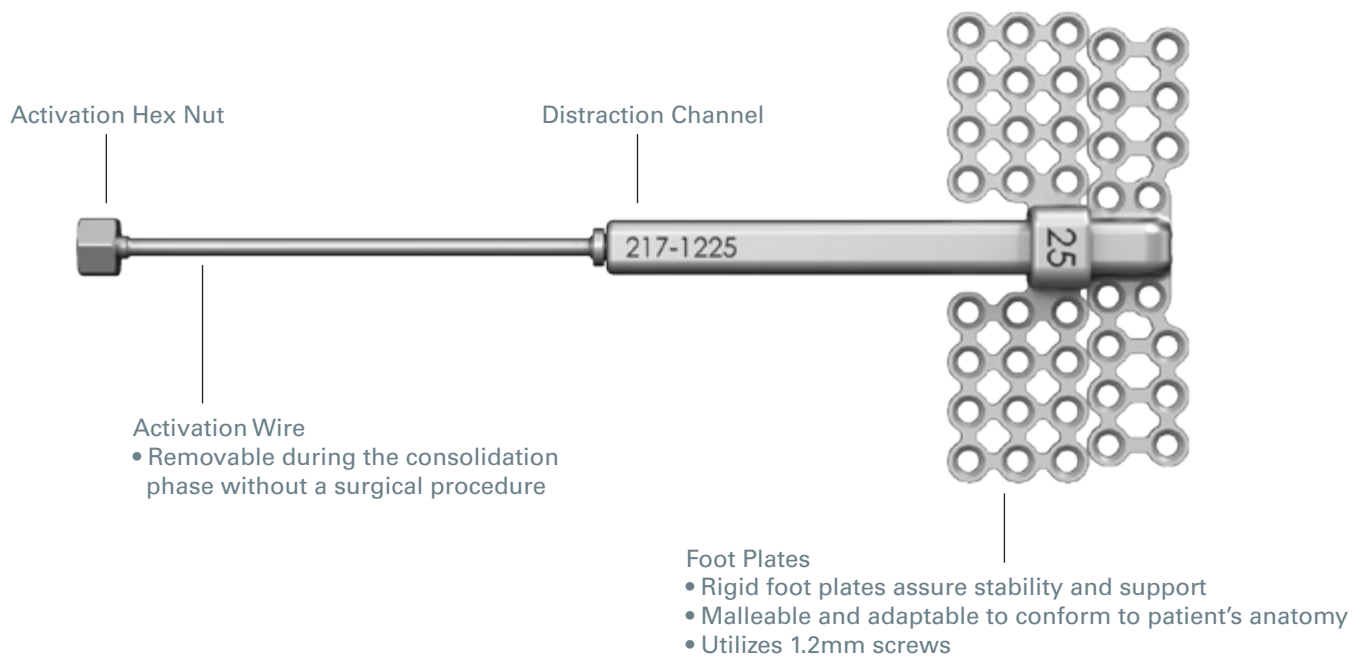
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# INTERNAL CRANIAL DISTRACTION SYSTEM FOR THE PURPOSE OF EXPANDING THE CRANIAL VAULT

## Introduction

The OsteoMed Oracle Cranial Distraction System is a distraction osteogenesis system consisting of low profile, internal distractors, specifically designed to expand the cranial vault.



## Indications

The OsteoMed Oracle Cranial Distraction System is indicated for use in the treatment of cranial conditions such as syndromic craniosynostosis and congenital deficiencies in which osteotomies and gradual bone distraction are indicated.

## Contraindications

- Use of the OsteoMed Oracle Cranial Distraction System is contraindicated in cases of active or suspected infection, in patients previously sensitized to titanium; in patients with certain metabolic diseases, or patients who are immune compromised.
- It is further contraindicated in patients exhibiting disorders which would cause the patient to ignore the limitations of distraction osteogenesis.
- The OsteoMed Oracle Cranial Distraction System is also contraindicated in those cases where there is an inadequate volume or quality of bone to place the distractor securely.

# PREOPERATIVE PLANNING

Correct placement and orientation of the devices and osteotomies is critical to a successful treatment.

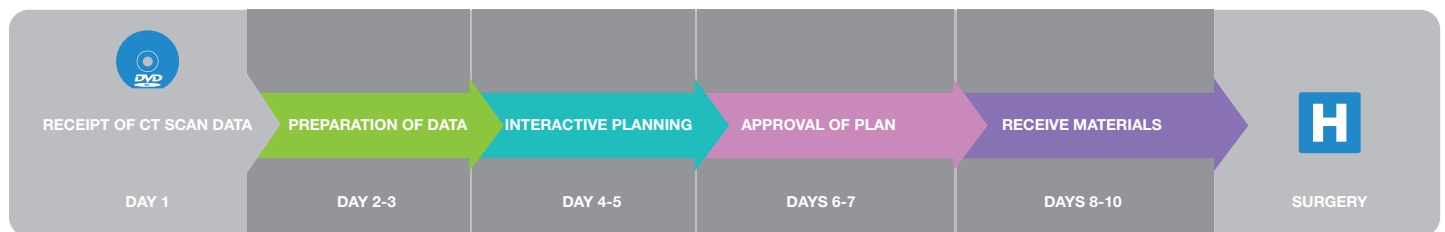
OsteoMed's Digital Surgical Planning (DSP) service and patient specific models are great tools to assist in determining post-distraction anatomical objectives.

## Digital Surgical Planning

- Simulate entire procedure using the patient's CT/CBCT
- Identify osteotomies and bony movements prior to surgery
- Identify potential bone interferences
- Transfer the surgical plan to surgery using patient specific guides and spacers

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## Digital Surgical Planning Timeline

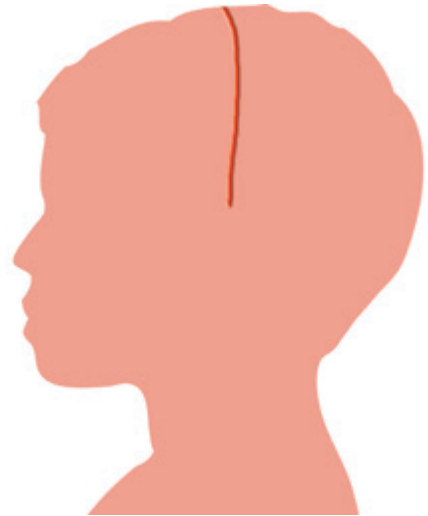


# DISTRACTOR IMPLANTATION

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## Step 1

Make a coronal incision and bring down the scalp to expose the cranial bone.



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## Step 2

Outline a cranial bone flap as indicated for the particular case.

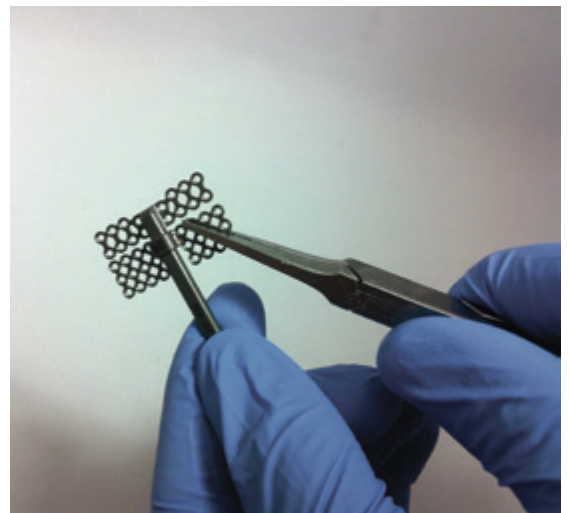


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## Step 3

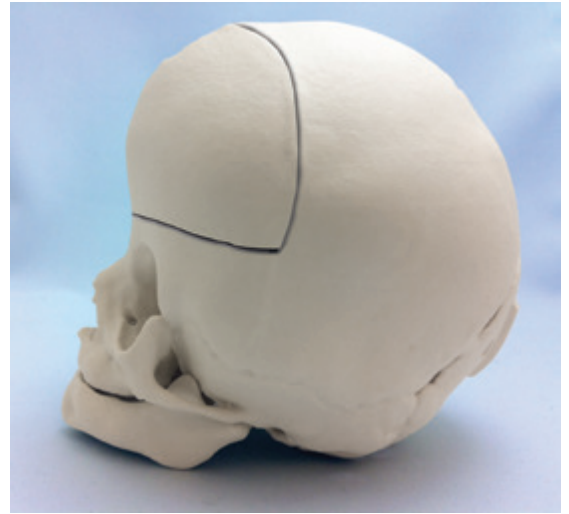
Locate a flat surface of bone and mark the placement of the distractor devices. Adjust the distractor foot plates as necessary to conform to patient's anatomy.

*Note: It is important that the axis of the distractors lie parallel to one another and that their vectors coincide with the direction of the desired expansion.*



## Step 4

Using a craniotome, cut the bone previously marked in Step 2 leaving the bone attached to the dura.



## Step 5

Secure the distractors to the cranial bone with 1.2mm screws. (Pilot drilling may be necessary, depending on the use of standard or self drilling screws). There are two areas of the distractor that must be fixated to the cranial bone: (see note) 1) the stationary plate 2) the moving plate.

When fixating the stationary plates, place one screw in each mesh plate. Then place screws in remaining plate holes.

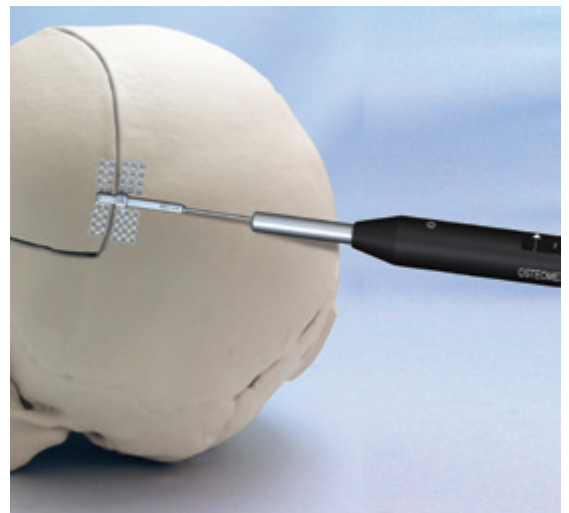
*Note: If necessary, secure the spacers to the distractor prior to securing the distractor to the cranial bone. Place a minimum of three screws in each arms of the distractor.*



## Step 6

Using the distractor tool (217-1210), rotate it clockwise to advance the distractor.

*Note: 3 turns = 1mm of distraction.*



## DISTRACTOR IMPLANTATION

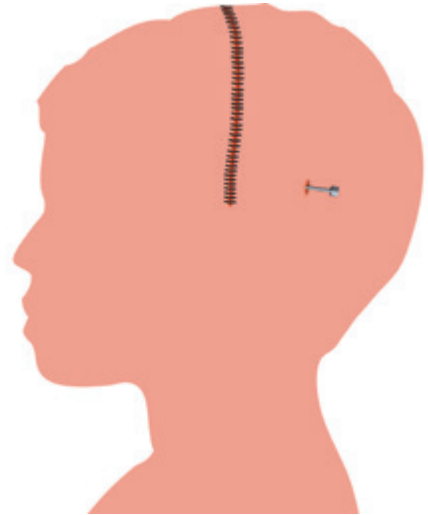
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### Step 7

Place the scalp flap back over the cranial bone covering the distractors. The distractor arm is brought through punctures in the scalp unless the arm is near an incision line, in which case it is allowed to exit through the incision.

Suture the incision closed. Meticulous hemostasis and wound closure are necessary to minimize hemotoma and infection.

*Note: Wound care should be routinely done where the activation wire exits the skin.*



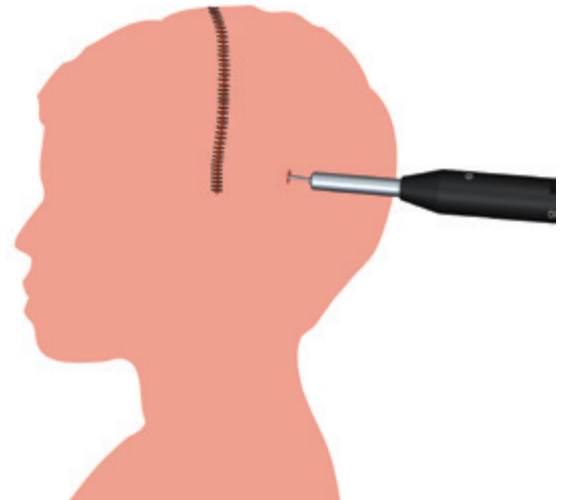
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### Step 8

Distraction is recommended to begin at the conclusion of the latency period and continue at a rate as determined by the surgeon until the desired distraction is achieved.

If the patient's guardian will be performing the distraction, provide them with the Instructions for Use worksheet and distraction tool (217-1210).

*Note: 3 turns = 1mm of distraction. The patient guardian should make sure that the turns are made in the direction of the arrow indicated on the flat end of the distraction tool. If excessive resistance is felt, STOP distracting and contact the surgeon.*

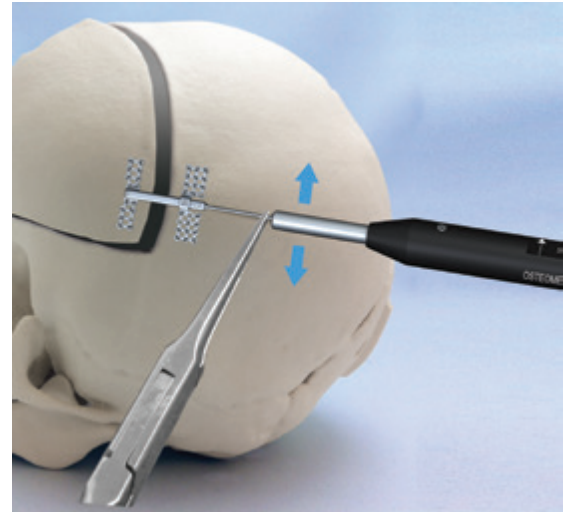


# ACTIVATION WIRE REMOVAL

After the distraction period is complete, the activation wire may be removed prior to the consolidation period using the Activation Wire Removal Tool (216-0103).

## Step 1

Hold the activation wire with grasping forceps near the hex nut. Using the distraction tool (217-1210) move the hex nut horizontally until it breaks off.



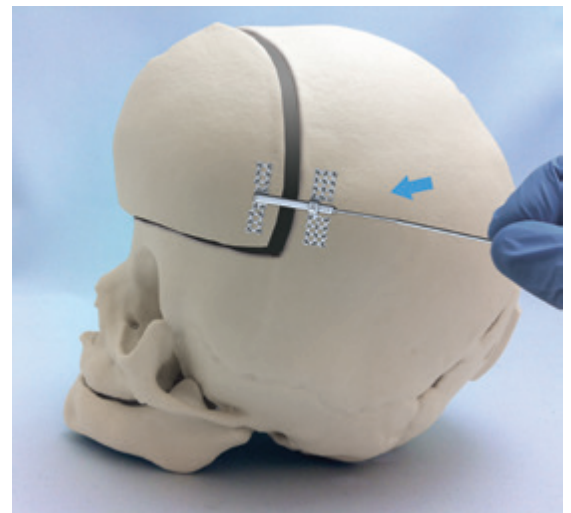
## Step 2

Slide the Activation Wire Removal Tool (216-0103) all the way until it reaches the distractor body.

Move the wire horizontally until it breaks off. Do not move the wire up and down, this may cause stress on the device.

Discard the removed activation wire and Activation Wire Removal tool in accordance with standard biohazard waste disposal procedures.

The distractor should remain implanted for the consolidation period determined by the surgeon.



# DISTRACTOR REMOVAL

Remove the distractor after consolidation period has been achieved.

## Step 1

Make the cranial incision and expose the distractor.

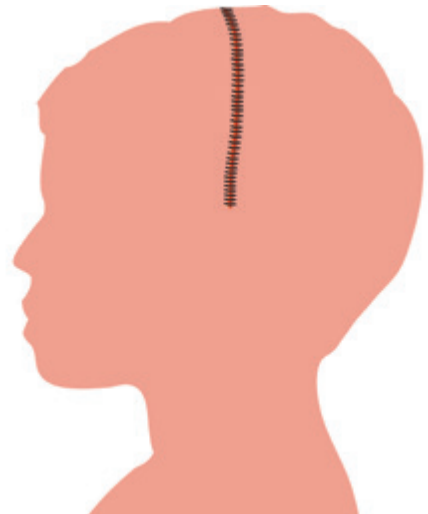
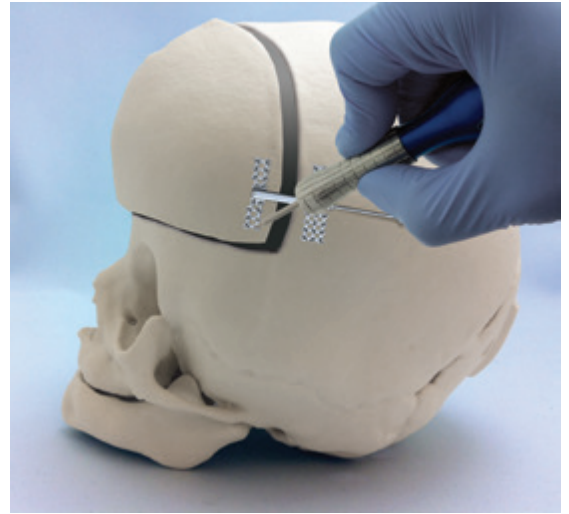
Remove the screws fixating the distractor to the cranium.

Remove the distractor from the cranium.

Remove the spacers from the cranium, if used.

Discard all devices according to standard biohazard disposal procedures.

Suture the distraction site closed.



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**Technique Tip:**

After removal of the distractors, OsteoVation Bone Void filler can be used to fill and contour any remaining defects.

**OsteoVation Impact**

390-2103	OsteoVation 3cc, Impact Formula
390-2105	OsteoVation 5cc, Impact Formula
390-2110	OsteoVation 10cc, Impact Formula

**OsteoVation Inject**

390-2005	OsteoVation 5cc, Inject Formula
390-2010	OsteoVation 10cc, Inject Formula
390-3000	OsteoVation Inject Delivery Kit



# INSTRUMENTS



220-0262 Blue Metal Screwdriver Body



217-1210 Distraction Tool, Short



220-0027 Small Grasping Forceps



220-0049 Plate Bending Forceps



220-0028 Plate Cutter



220-0022 1.2mm Screwdriver Shaft, Manual



450-0610 0.9mm Pilot-Drill, 4mm Stop, OsteoDriver™



450-0611 0.9mm Pilot-Drill, 5mm Stop, OsteoDriver™



450-0618 1.2mm Screwdriver Shaft, OsteoDriver™



220-1250 1.2mm AutoDrive Visidisk  
220-1251 1.2mm Standard Visidisk



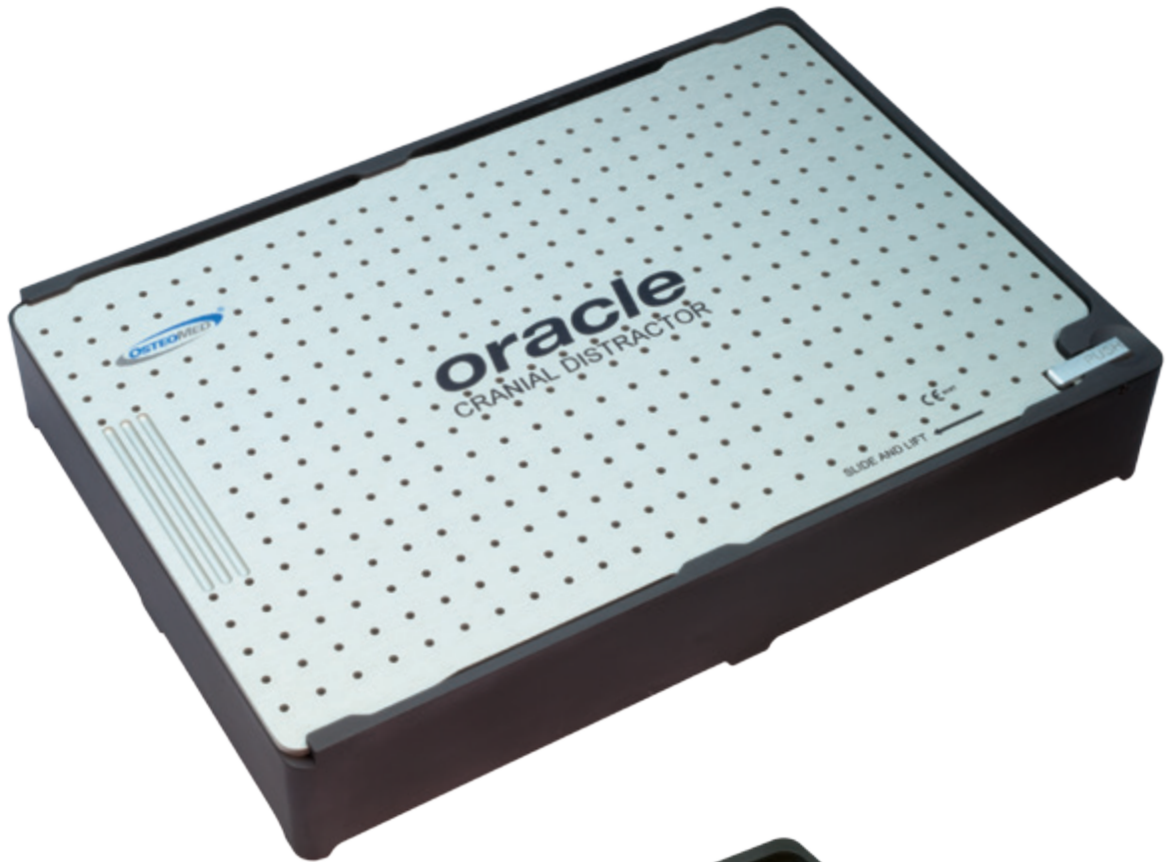
450-0600 OsteoDriver™ Disposable AutoDriver™



217-1230 Oracle 1.5mm Spacer

# ORGANIZER BLOCK

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217-1260 Oracle Distraction System

# DISTRACTION PROTOCOL

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## Step 1

Engage the hex nut of the activation wire with the internal hex of the distraction tool.

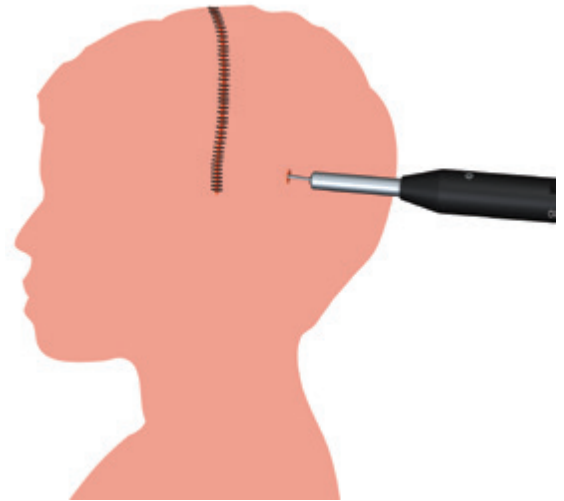
Rotate the distraction tool in the direction of the arrow on the distraction tool. Three (3) rotations advances the distractor 1mm.

### Precautions to the patient's guardian:

Your doctor has fitted your child with a distraction device to aid in the lengthening of his/her cranium. This process requires you to be familiar with the instructions for daily use of this distractor. Patient progress should be tracked on the "Patient Progress Chart" inside this pamphlet. Your compliance with your physician's instructions will help ensure positive outcome. If you have any questions or concerns, contact the physician. If excessive resistance is felt, STOP distracting and call physician immediately

### Precautions to the physician:

Please be sure the patient's guardian has read and understands this pamphlet before patient returns home after surgery. The patient guardian should track progress on the progress chart. Please instruct patient's guardian on the appropriate diet and activity level for the patient. Please instruct patient's guardian on proper techniques for routine wound care.



# CRANIAL DISTRACTOR PATIENT PROGRESS CHART

Patient Name: \_\_\_\_\_ First Distraction Date: \_\_\_\_\_

Physician Name: \_\_\_\_\_ Last Distraction Date: \_\_\_\_\_

Physician Phone: \_\_\_\_\_ Distraction Plan: Turns AM: \_\_\_\_\_  
 Turns Noon: \_\_\_\_\_  
 Turns PM: \_\_\_\_\_

- The patient's guardian should track the patient progress from the beginning of distraction to the end as instructed by the physician.
- A copy of this progress report should be given to the physician once the distraction has been completed.
- If you have any questions or concerns, please contact your physician.
- If excessive resistance is felt, STOP distracting and contact the surgeon.
- Place distractor tool over hex nut and turn clockwise. **Note: 3 turns is 1mm of distraction.**

Rotations

Day	Date	AM	NOON	PM
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Rotations

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