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SPRING ASSISTED SURGERY FOR THE TREATMENT OF CRANIOSYNOSTOSIS

Introduction
SmartFlex offers early minimally invasive surgical intervention to decrease the morbidity associated with an extensive decompression operation.

SMARTFLEX CRANIAL SPRING

Cranial Spring
- Pre-formed based on an extensive analysis of infant skulls
- Medical grade stainless steel
- Adjustable to accommodate various skull anatomies

Foot Plate
- Beveled to reduce the possibility of dural tear
- Designed to fit securely under the skull bone

SMARTFLEX SPRING CLIP

Spring Clip
- Low profile, ergonomic design to a minimally invasive surgical approach.

SmartFlex Cranial Spring
- Pre-formed to match curvature of infant skull
- Medical grade stainless steel

Push-Button Attachment
- Secures the spring clip to the spring inserter instrument.

Spring Sleeve
- Secures the springs during implantation.

Foot Plate
- Beveled to reduce the possibility of dural tear
- Designed to fit securely under the skull bone
SMARTFLEX INSERTER

Push-Button Feature
Secures the spring clip to the spring inserter instrument.

Spring Loaded Trigger

Ergonomic Handle
For comfort and ease of use.
PREOPERATIVE PLANNING

Evaluate Initial 3-D CT scan

- Determine characteristics of skull shape.
- Rule out intracranial abnormalities.

Utilize the 3D model or CT scan to plan spring placement.
- Identify type of scaphocephaly, bone thickness and assess underlying pathology.
- Contour the springs to accommodate the skull anatomy.

Note: Excessive contouring may compromise the force of the spring.

Utilize the table below to determine spring force. Force is based on age, bone thickness, and severity of the deformity.

*Note: The 4N and 4.5N cranial springs are available for rare malformations such as a cloverleaf skull deformity.*

### ANTERIOR SPRING SELECTION

<table>
<thead>
<tr>
<th>Patient Age (Months)</th>
<th>Type of Deformity</th>
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MANUAL SPRING IMPLANTATION

Step 1
Design incisions on the anterior and posterior fontanel approximately 4 cm in width.

Step 2
Inject local (.25% marcaine with epinephrine) at incision site and over the area of the fused suture.

Step 3
Make the incision with a 15 blade in the direction of the hair follicles to preserve them.
Step 4

Lift the scalp in the subgaleal plane under direct vision from the incision to the anterior and posterior limit of the suture.

Step 5

Remove 1 cm of the fused suture throughout entire length with the help of the endoscope and bone cutters.

Step 6

Obtain hemostasis at the bone margin and the dura.
DISTRACTOR IMPLANTATION

Step 7

Select the spring force based on guide that considers age, bone thickness, and severity of the deformity.

If necessary, bend the spring using the supplied bending instrument to accommodate patient’s anatomy.

Note: Off plane bending and excessive bending may compromise the spring force.

Step 8

Place the springs and confirm positioning.

Note: Ensure foot plate hooks are positioned firmly on the cranial bone.

Note: To prevent spring migration, the spring leap shall be placed parallel to the suture line.

Step 9

Secure the springs to the bone where they overlap with a 4-0 vicryl suture by drilling a hole in the bone lateral to where the springs overlap. (Should be done on both sides)

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Step 10

Close the incisions with a 2 layer subcutaneous and a subcuticular closure of absorbable sutures.

Step 11

Place a head wrap to protect the incisions.
**INSERTER SPRING IMPLANTATION**

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**Step 1**

Design a “W” shape incision in between the anterior and posterior fontanel approximately 4 cm in width.

---

**Step 2**

Inject local (.25% marcaine with epinephrine) at incision site and over the area of the fused suture.

---

**Step 3**

Make the incision with a 15 blade in the direction of the hair follicles to preserve them.
Step 4

Lift the scalp in the subgaleal plane under direct vision from the incision to the anterior and posterior limit of the suture.

Step 5

Using a Neuro Rongeur, remove 1 cm of the fused suture throughout entire length with the help of the endoscope.
Step 7
Select the spring force based on guide that considers age, bone thickness, and severity of the deformity.

Refer to page 5.

Note: The 4N and 4.5N cranial springs are available for rare malformations such as a cloverleaf skull deformity.
Step 8

Remove the spring clip assembly from the packaging. If necessary, bend the spring using the supplied bending instrument PN: 220-0024 to accommodate patient's anatomy.

Note: Off-plane bending and excessive bending may compromise the spring force.

a. Place the spring inside the clip.

Step 9

Assemble the smartflex Spring PN: 218-30XX-SP to the smartflex Spring Inserter Instrument PN: 220-0771-SP.

Assembly Instructions

a. Insert the spring (218-30XX-SP) into the inserter until the blue tab locks into place.

b. Compress the trigger until you hear an audible click, then release the trigger.

c. Remove the security clip located on the underside of the spring clip assembly.

d. Pull the shaft of the inserter forward, retracting the arms into the spring clip assembly.

e. Make sure the spring is in the closed position.
DISTRACTOR IMPLANTATION

Step 10

Insert the assembled inserter instrument under the incision. Completely compress the trigger to release the spring in desired location.

*Note: Ensure foot plates are positioned firmly on the cranial bone.*

*Note: To prevent spring migration, the spring legs shall be placed parallel to the suture line.*

Step 11

Secure the springs to the bone where they overlap with a 4-0 vicryl suture by drilling a hole in the bone lateral to where the springs overlap. (Should be done on both sides)

Step 12

Close the incisions with a 2 layer subcutaneous and a subcuticular closure of absorbable sutures.

Place a head wrap to protect the incisions. Wound care should be routinely done.
SPRING REMOVAL GUIDE

Step 1
Palpate the springs at their overlap and bony insertion points.

Step 2
Design a small incision over each of the 4 footplates and mark the portion of the previous incision that will be utilized.

Step 3
Inject local into the 5 incisions.
SPRING REMOVAL GUIDE

Step 4
Make each of the footplate incisions and expose the spring footplate.

Step 5
Use a Dingman elevator to free the soft tissue around the footplates and separate it from the bone.

Step 6
Use a needle driver to rotate the footplate away from the bone in the direction opposite of the initial osteotomy.
Step 7
Repeat 5 and 6 for each of the 4 footplate sites.

Step 8
Open the portion of the previous incisions to expose where the springs overlap in the midline.

Step 9
Cut the wire at the apex of the spring on each side.
Step 10
Pull the segments of spring out of their respective incisions.

Step 11
Close the incisions with a buried and subcuticular layer of absorbable suture.

Step 12
Apply antibiotic ointment to each of the incisions, no head wrap is required.
Discard all devices according to standard biohazard disposal procedures.
1. How is bleeding controlled around the bone edges after performing the craniectomy?

The bleeding may be controlled through a combination of methods:
- Utilize a bovie and protect the brain tissue with insulated malleable.
- Hemosorb and/or bone wax.
- Injection of Floseal in osteotomy site.

2. Can we reuse the inserter instrument on other procedures?

No. Cleaning and autoclaving may compromise the integrity of the instrument. To assure efficacy, the instrument was designed to be used in a single procedure.

3. Can we remove the springs from the clip and implant them by hand?

Yes.