



smartflex

CRANIAL SPRING DISTRACTION SYSTEM



SURGICAL TECHNIQUE GUIDE



Rethinking Possibilities, Reshaping Lives

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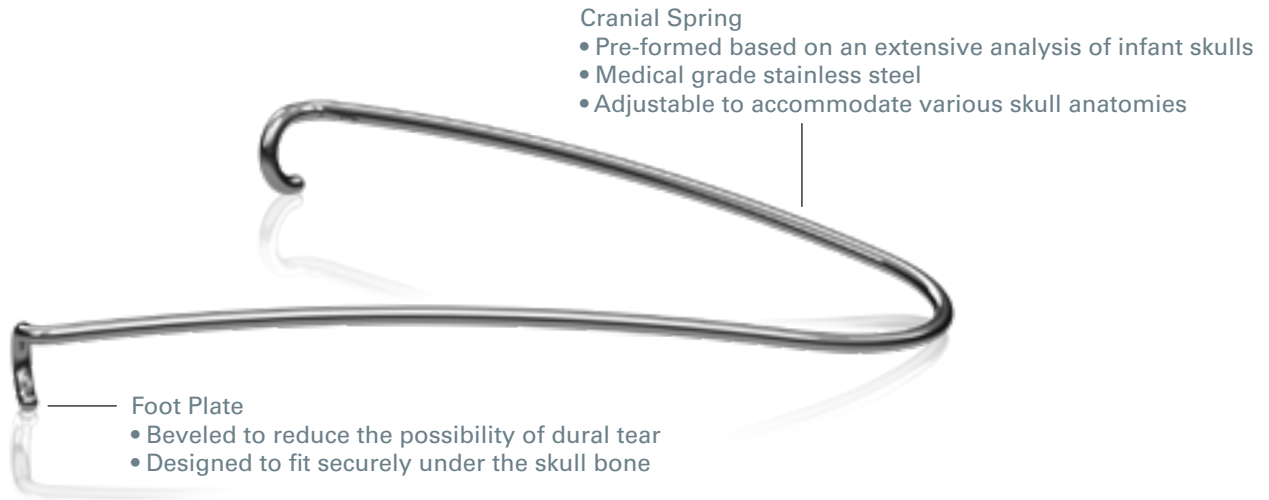


SPRING ASSISTED SURGERY FOR THE TREATMENT OF CRANIOSYNOSTOSIS

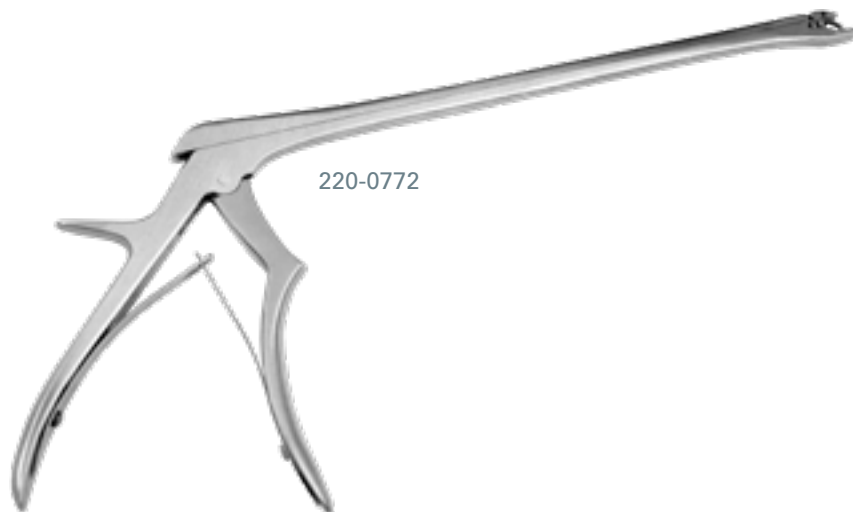
Introduction

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

SMARTFLEX CRANIAL SPRING



RONGEUR



SPRING CUTTER



Rx ONLY
FEDERAL LAW (U.S.A.)
RESTRICTS THE DEVICE TO
SALE BY OR ON THE ORDER OF
A PHYSICIAN

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.

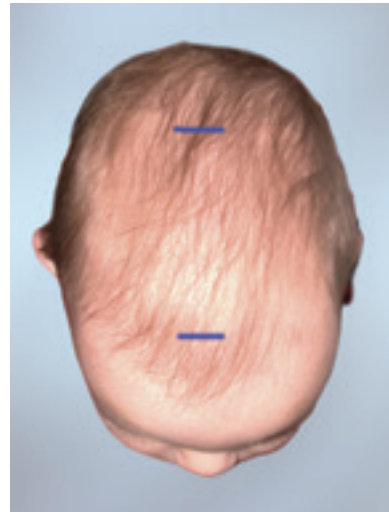
| ANTERIOR SPRING SELECTION | | | |
|---|---------------------|---------------------------|---------------------|
| Patient Age (Months) Type of Deformity | Bone Thickness <2mm | Bone Thickness 2mm to 5mm | Bone Thickness >5mm |
| 3 to 4 Mild | 6N | 6N | 6.5N |
| 3 to 4 Moderate | 6N | 6N | 6.5-7N |
| 3 to 4 Severe | 6.5N | 6.5N | 6.5-7N |
| 5 to 6 Mild | 6.5N | 6.5N | 7N |
| 5 to 6 Medium | 6.5N | 7N | 7.5N |
| 5 to 6 Severe | 6.5N | 7N | 7.5-8N |

| POSTERIOR SPRING SELECTION | | | |
|---|---------------------|---------------------------|---------------------|
| Patient Age (Months) Type of Deformity | Bone Thickness <2mm | Bone Thickness 2mm to 5mm | Bone Thickness >5mm |
| 3 to 4 Mild | 6.5N | 6.5N | 6.5N |
| 3 to 4 Medium | 6.5N | 6.5N | 6.5N |
| 3 to 4 Severe | 6.5N | 7N | 7N |
| 5 to 6 Mild | 7N | 7N | 7.5N |
| 5 to 6 Medium | 7N | 7.5N | 7.5-8N |
| 5 to 6 Severe | 7N | 7-8N | 8-8.5N |

MANUAL SPRING IMPLANTATION

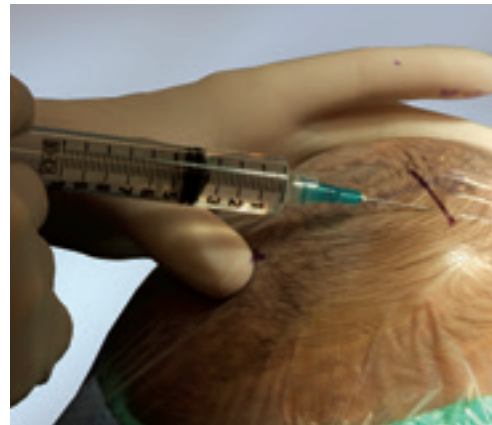
Step 1

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



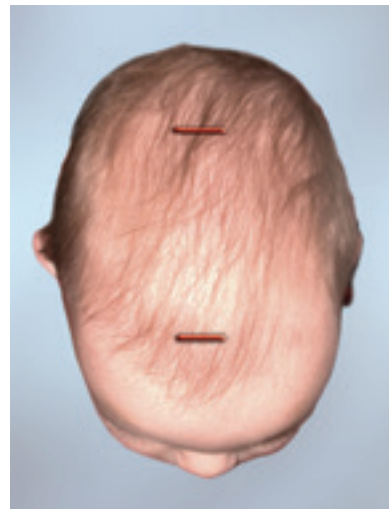
Step 2

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

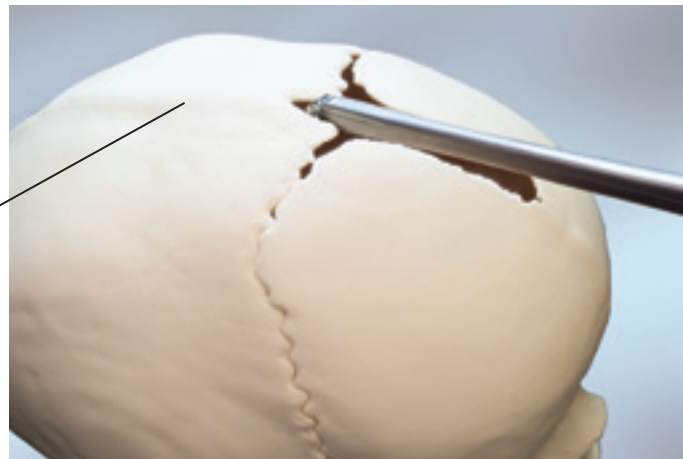
Lift the scalp in the subgaleal plane under direct vision from the incision to the anterior and posterior limit of the suture.



Step 5

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

FUSED SUTURE



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.

| ANTERIOR SPRING SELECTION | | | |
|---|---------------------|---------------------------|---------------------|
| Patient Age (Months) Type of Deformity | Bone Thickness <2mm | Bone Thickness 2mm to 5mm | Bone Thickness >5mm |
| | 3 to 4 Mild | 6N | 6N |
| 3 to 4 Moderate | 6N | 6N | 6.5-7N |
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| 5 to 6 Mild | 6.5N | 6.5N | 7N |
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| POSTERIOR SPRING SELECTION | | | |
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| 5 to 6 Medium | 7N | 7.5N | 7.5-8N |
| 5 to 6 Severe | 7N | 7-8N | 8-8.5N |

Step 8

Place the springs and confirm positioning.

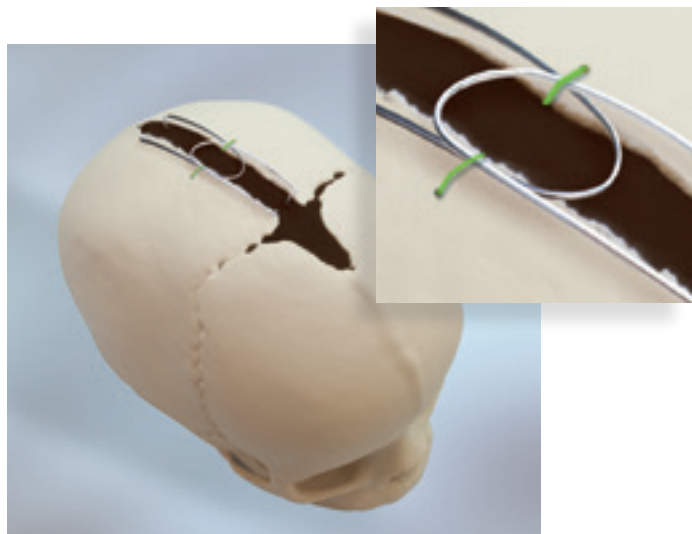
Note: Ensure foot plate hooks are positioned firmly on the cranial bone.

Note: To prevent spring migration, the spring 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)



Step 10

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



Step 11

Place a head wrap to protect the incisions.



SPRING REMOVAL GUIDE

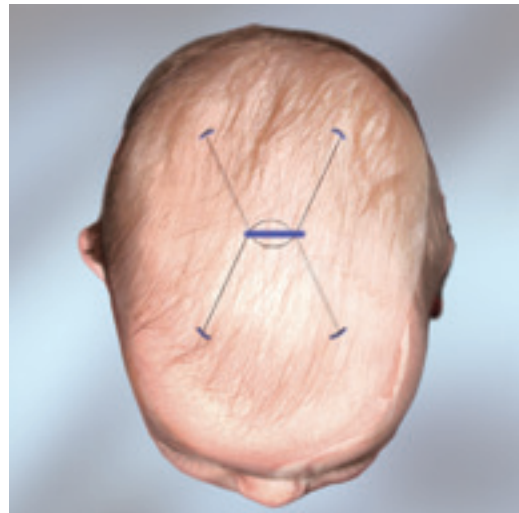
Step 1

Palpate the springs at their overlap and bony insertion points.



Step 2

Design a small incision over each of the 4 foot-plates and mark the portion of the previous incision that will be utilized.



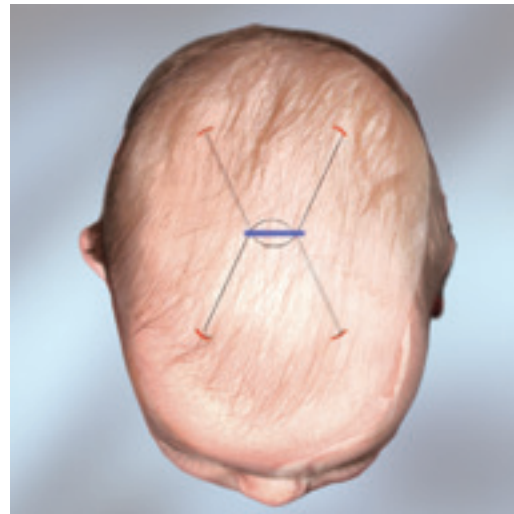
Step 3

Inject local into the 5 incisions.



Step 4

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



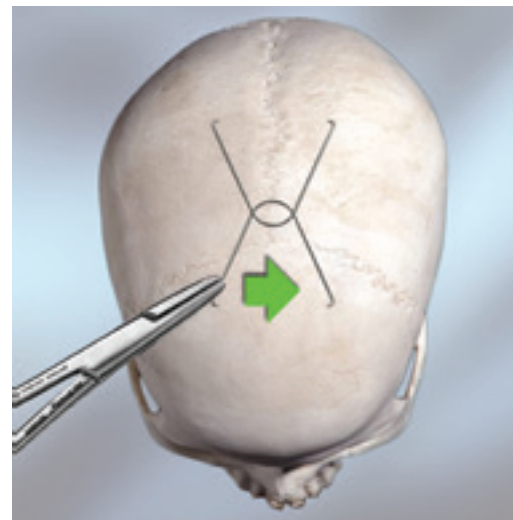
Step 5

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.



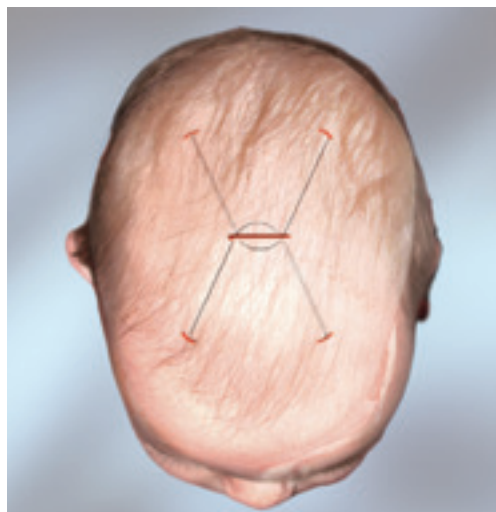
Step 7

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.



FREQUENTLY ASKED QUESTIONS

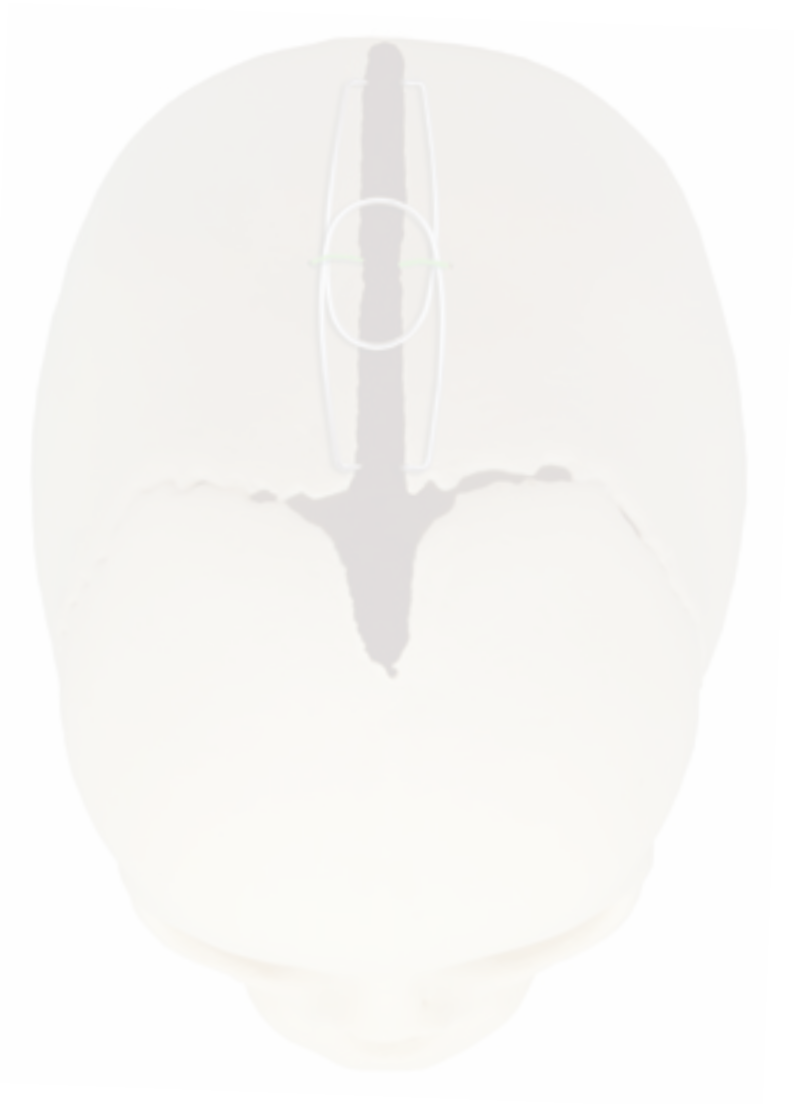
1. How is bleeding controlled around the bone edges after performing the craniectomy?

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 implant the springs by hand?

Yes.





Rethinking Possibilities, Reshaping Lives



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