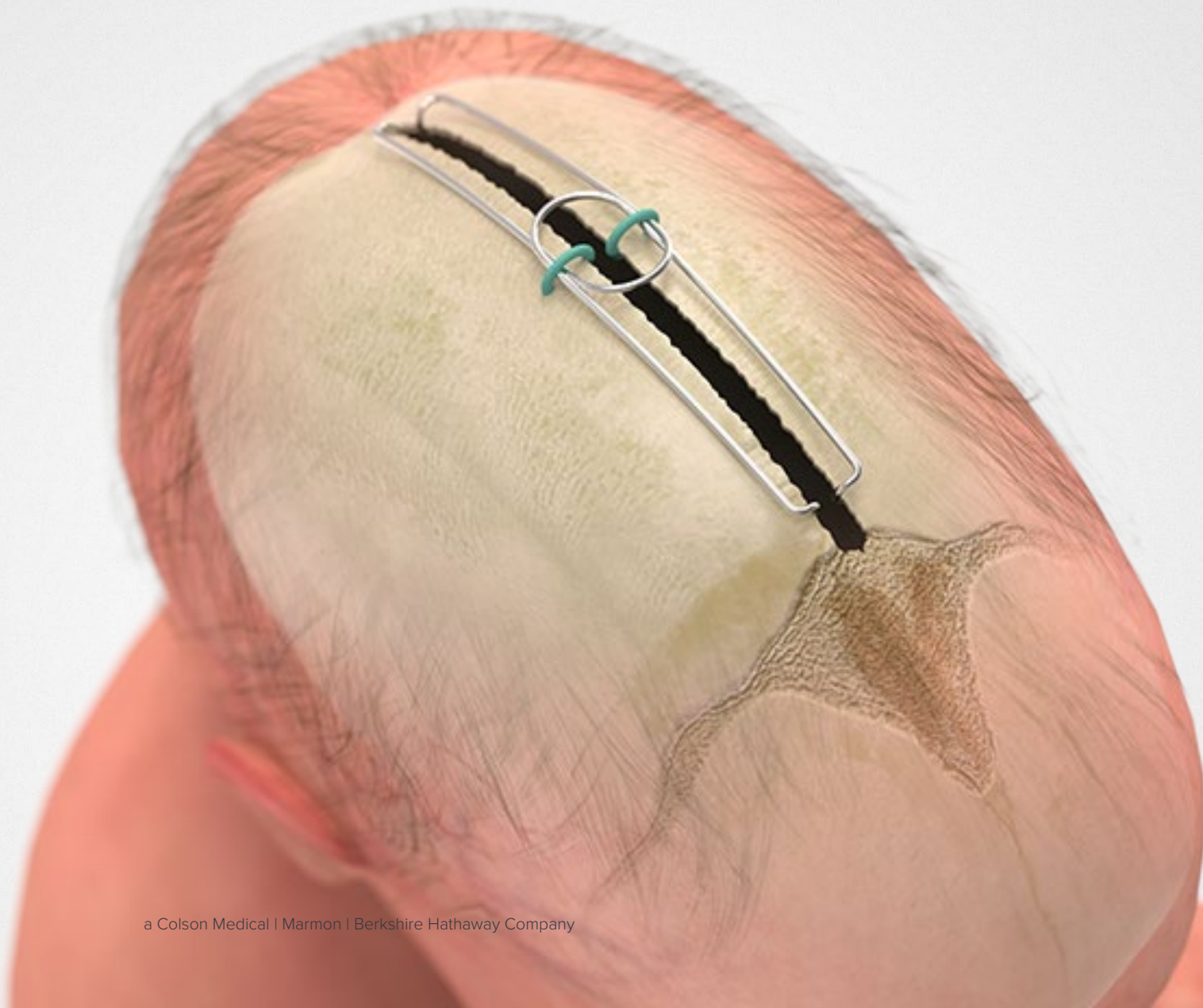


Surgical Technique



Acumed® is a global leader of innovative orthopaedic and medical solutions.



We are dedicated to developing products, service methods, and approaches that improve patient care.



SmartFlex™ Pediatric Cranial Spring Distraction System

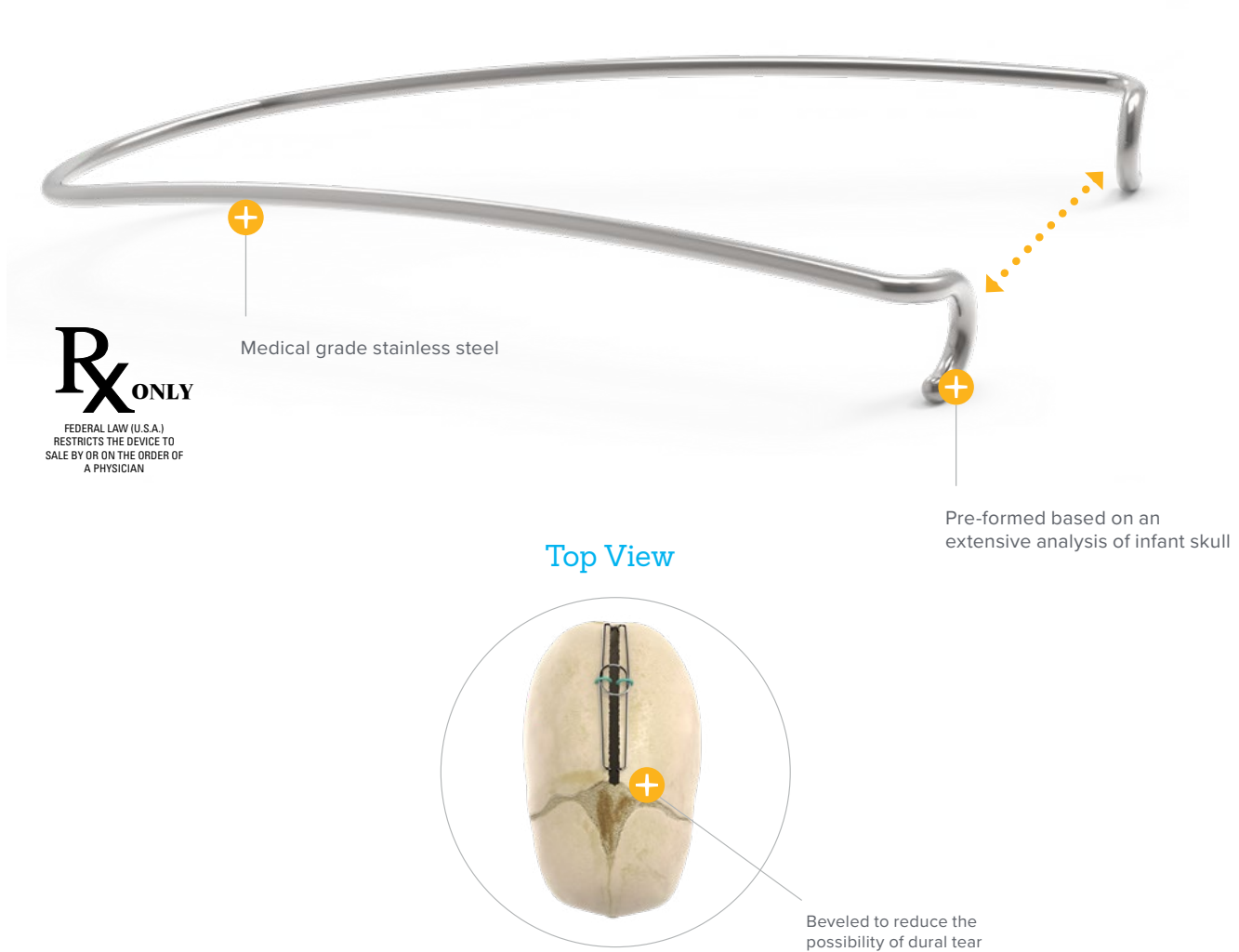
SmartFlex offers early minimally invasive surgical intervention to decrease the morbidity associated with an extensive decompression operation.

	Definition
Warning	Indicates critical information about a potential serious outcome to the patient or the user.
Caution	Indicates instructions that must be followed in order to ensure the proper use of the device.
Note	Indicates information requiring special attention.

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System Features



Frequently Asked Questions

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

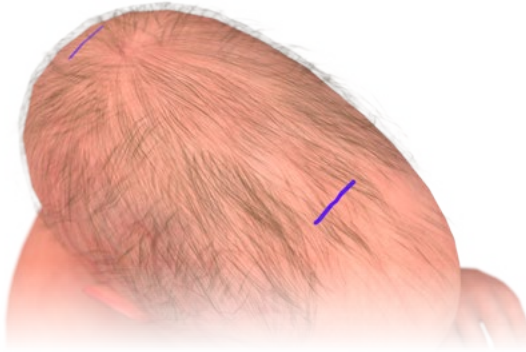
The bleeding may be controlled through a combination of methods:

- ▶ 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.

Preoperative Planning



1 Evaluate Initial 3-D CT Scan

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

2 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 4 N and 4.5 N cranial springs are available for rare malformations such as a cloverleaf skull deformity.

Note: Spring sizes range from 4 N - 9.5 N. The table below is a recommendation of common sizes and the final choice of the spring selections is at the discretion of the surgeon.

Anterior Spring Selection

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

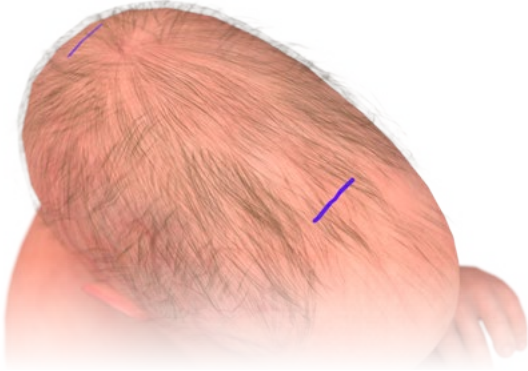
Posterior Spring Selection

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

Manual Spring Implantation Surgical Technique

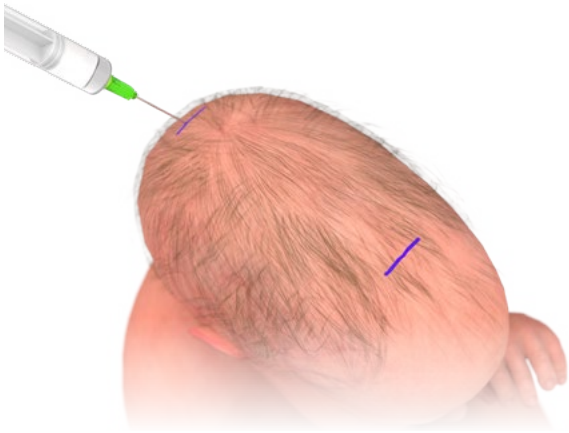
3 Incision

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



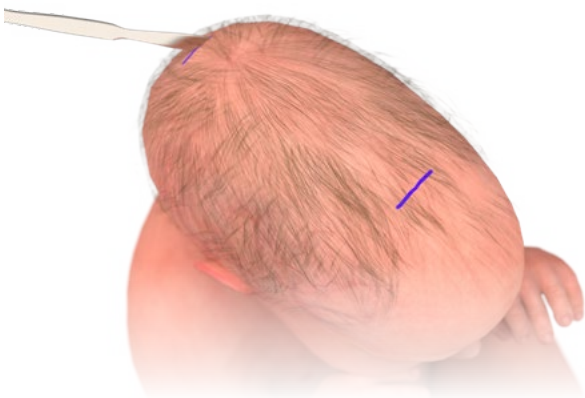
4 Inject Local

Inject local (0.25% marcaine with epinephrine) at incision site and over the area of the fused suture.

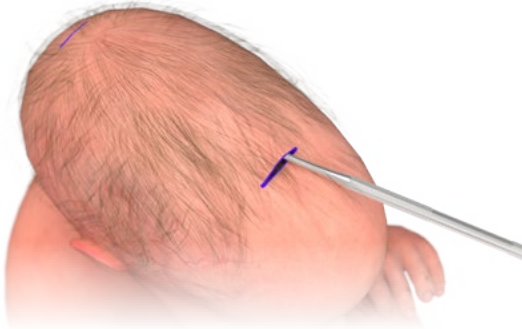


5 Make Incision

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

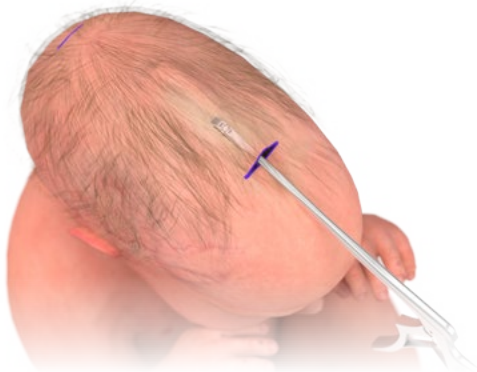


Manual Spring Implantation Surgical Technique [continued]



6 Lift the Scalp

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



7 Fused Suture

Remove 1 cm of the fused suture throughout entire length with the help of the endoscope and bone cutters. Obtain hemostasis at the bone margin and the dura.

Manual Spring Implantation Surgical Technique [continued]

8 Select the Spring

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.

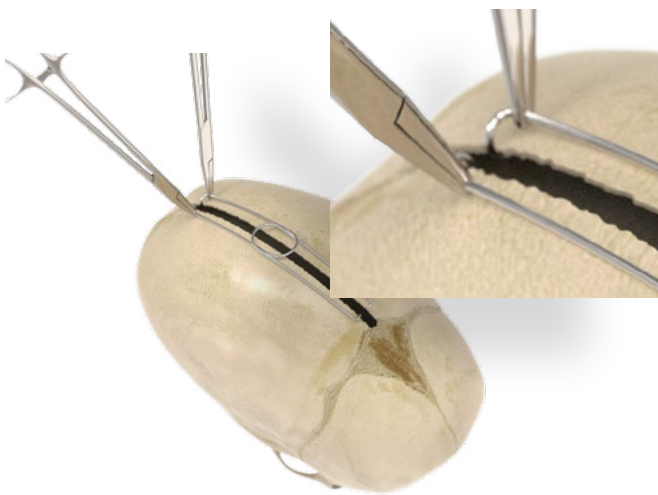
Note: Off plane bending and excessive bending may compromise the spring force.

Anterior Spring Selection

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

Posterior Spring Selection

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



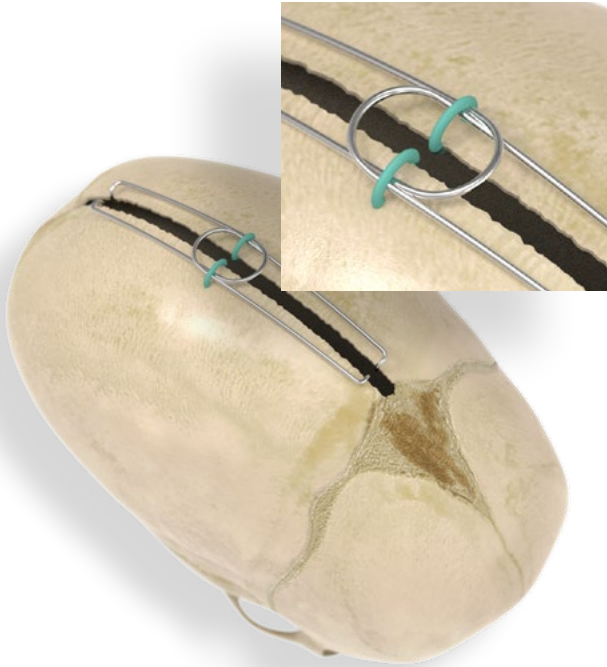
9 Place the Spring

Place the springs and confirm positioning.

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

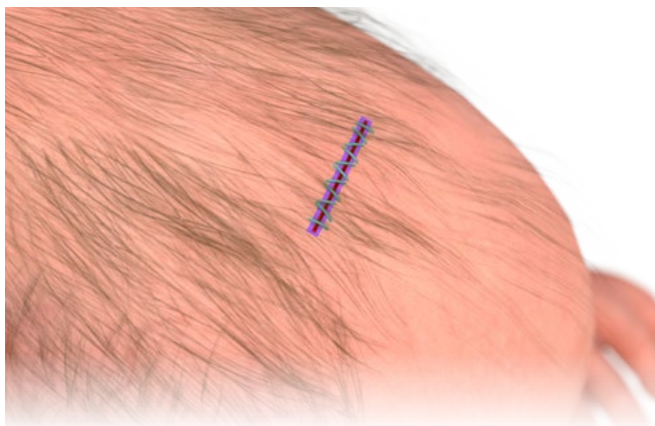
Note: To prevent spring migration, the spring shall be placed parallel to the suture line.

Manual Spring Implantation Surgical Technique [continued]



10 Secure the Spring

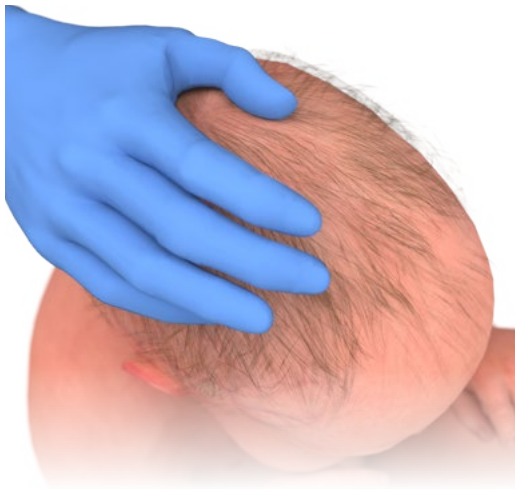
Secure the springs to the bone where they overlap with a 4-0 vicryl suture by drilling a hole in the bone lateral to where the springs overlap. (Should be done on both sides)



11 Close the Incisions

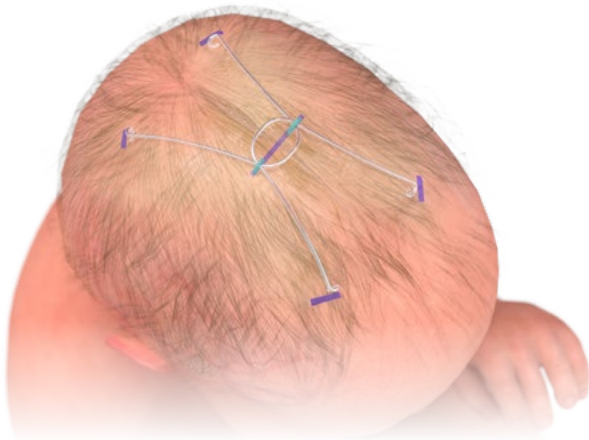
Close the incisions with a 2 layer subcutaneous and a subcuticular closure with absorbable sutures. Place a head wrap to protect the incisions.

Spring Removal Guide



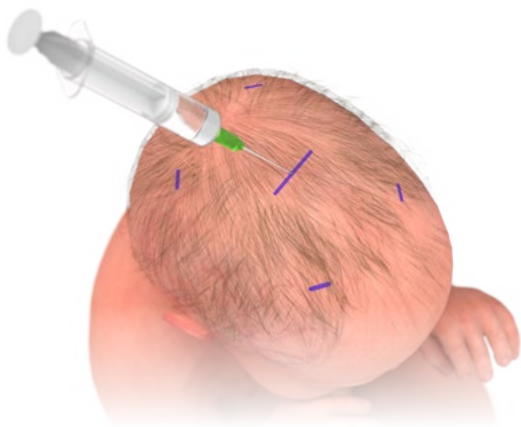
1 Palpate the Springs

Palpate the springs at their overlap and bony insertion points.



2 Plan Incision

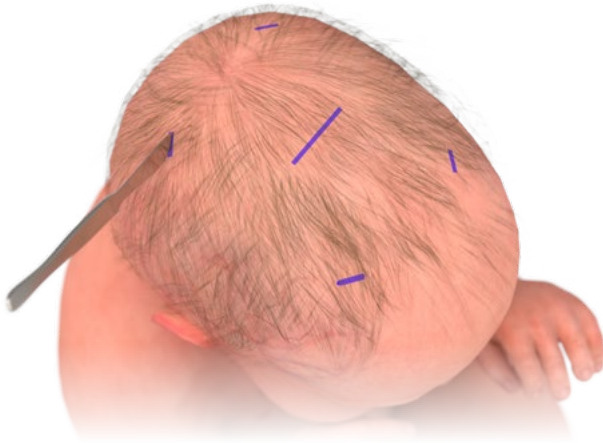
Design a small incision over each of the 4 footplates and mark the portion of the previous incision that will be utilized.



3 Inject Local

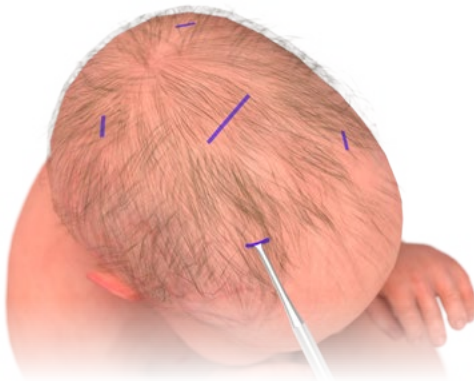
Inject local into the 5 incisions.

Spring Removal Guide [Continued]



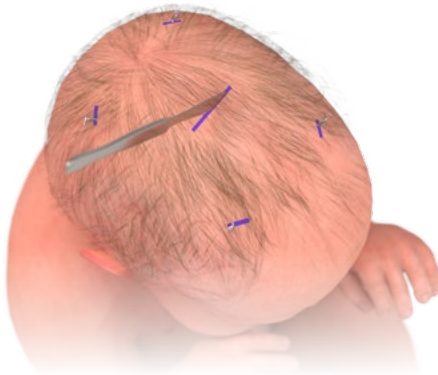
4 Make Incision

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



5 Free Soft Tissue

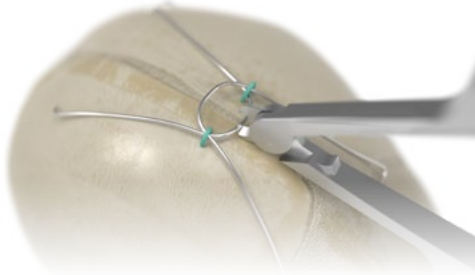
Use a Dingman elevator to free the soft tissue around the footplates and separate it from the bone.



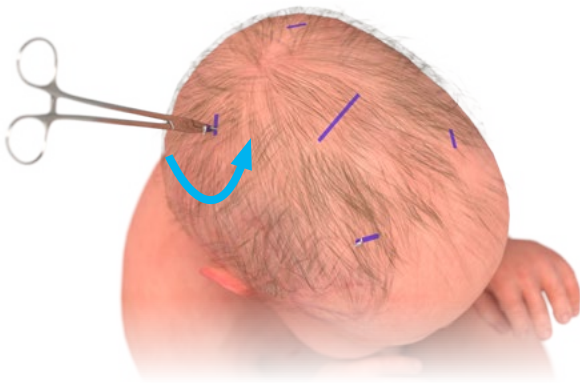
6 Portion

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

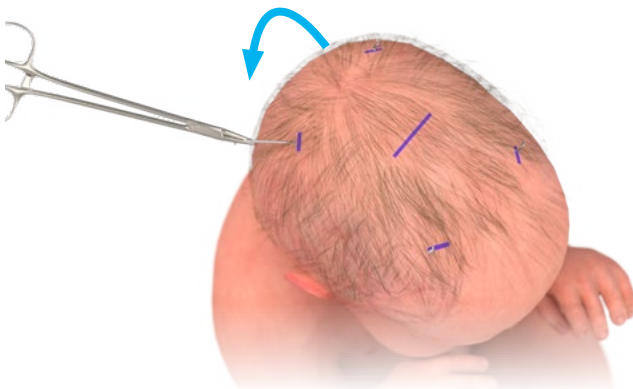
Spring Removal Guide [Continued]



- 7** **Cut**
Cut the wire at the apex of the spring on each side.



- 8** **Rotate the Footplates**
Use a needle driver to rotate the footplates away from the bone in the direction opposite of the initial osteotomy.



- 9** **Remove Spring**
Pull the segments of spring out of their respective incisions.
Close the incisions with a buried and subcuticular layer of absorbable suture.
Apply antibiotic ointment to each of the incisions, no head wrap is required.
Discard all devices according to standard biohazard disposal procedures.

Ordering Information



Instruments & Accessories

SmartFlex Sterilization Tray	220-0770
1 SmartFlex 5mm Rongeur	220-0772
2 SmartFlex Cutter	220-0773

Cranial Springs

SmartFlex SPRING NC - 4 N	218-3140-SP
SmartFlex SPRING NC - 4.5 N	218-3145-SP
SmartFlex SPRING NC - 5 N	218-3150-SP
SmartFlex SPRING NC - 5.5 N	218-3155-SP
SmartFlex SPRING NC - 6 N	218-3160-SP
SmartFlex SPRING NC - 6.5 N	218-3165-SP
SmartFlex SPRING NC - 7 N	218-3170-SP
SmartFlex SPRING NC - 7.5 N	218-3175-SP
SmartFlex SPRING NC - 8 N	218-3180-SP
SmartFlex SPRING NC - 8.5 N	218-3185-SP
SmartFlex SPRING NC - 9 N	218-3190-SP
SmartFlex SPRING NC - 9.5 N	218-3195-SP



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