KLS martin GROUP

CranioXpand

Cranial springs for the treatment
of sagittal craniosynostoses

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Oral and maxillofacial surgery is our passion! Its further development, together with our customers, is our ambition. Every day we work on developing innovative products and services which meet the highest demands on quality, and which contribute to the wellbeing of the patient.

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Cranial springs for the minimally invasive treatment of sagittal craniosynostoses

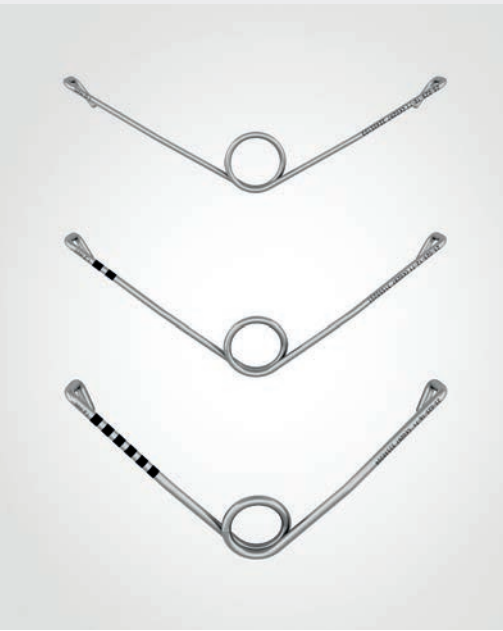
The therapy of craniosynostosis is a challenging task that requires an individual treatment plan tailored to the specific characteristics of each child.

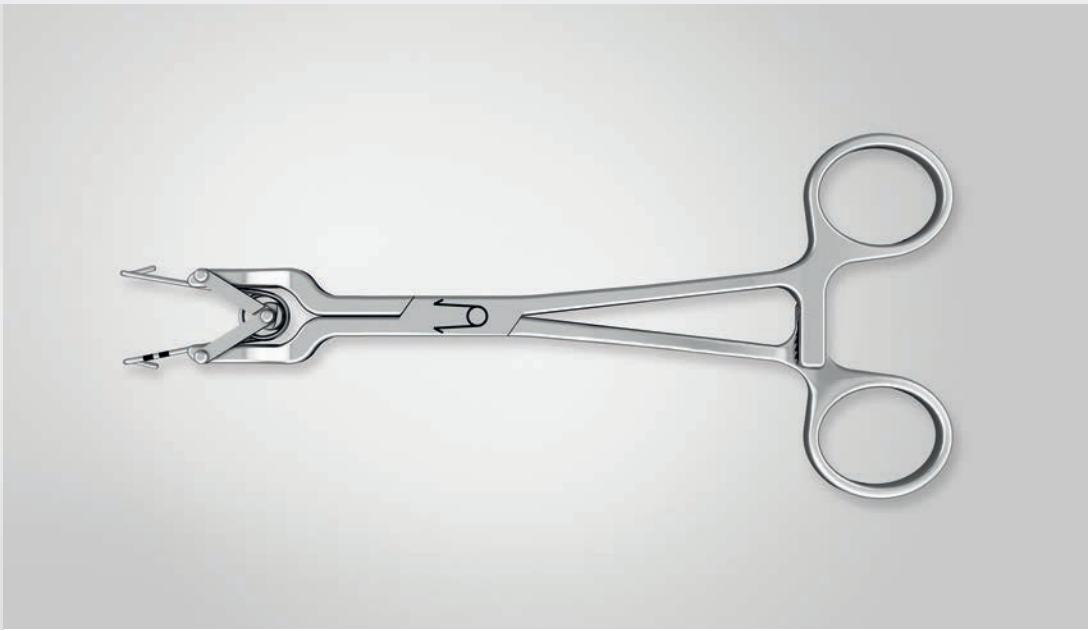
For this reason, various methods and procedures have become established in the past which can be used for surgical correction.

The use of cranial springs is considered to be a minimally invasive technique, which offers several advantages versus open treatment concepts, in particular significantly reduced blood loss as well as shorter times for surgery and thus also anesthesia. This significantly reduces stress on the young patient.

With CranioXpand - a holistic system based on the many years of experience of Dr. Noor ul Owase Jeelani - proven springs are available to support the surgeon in everyday clinical practice. In combination with a standardized surgical technique as well as instruments specifically designed for this purpose, best conditions for successful treatment are given.

Feature, Function and Benefit





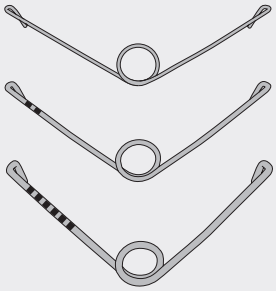
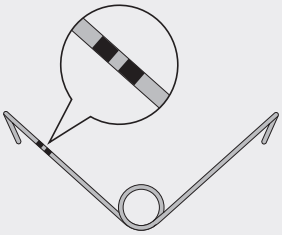
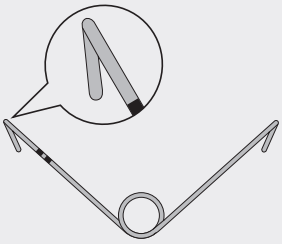
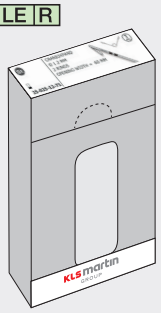
KLS Martin's aim is to offer a fully comprehensive portfolio of products for the surgical correction of cranial malformations to provide the user with the best possible care solution for the specific situation.

In addition to various cranial distractors and resorbable implants, cranial springs are now available for the minimally invasive treatment of craniosynostosis.

CranioXpand springs focus on the greatest possible protection. The rounded, atraumatic design results in optimal embedding in the soft tissue and the angled ends ensure best anchorage and a secure hold in the bone.

CranioXpand springs are available in different wire strengths or forces and are marked accordingly for easy identification.

CranioXpand – Implants

	Feature	Benefit
	■ Cranial springs in different wire thicknesses: ■ Wire thickness Ø 1.0 mm = 5 N ■ Wire thickness Ø 1.2 mm = 8 N ■ Wire thickness Ø 1.6 mm = 13 N	■ Maximum choice according to the malformation and expression to be treated ■ Reliable determination of the spring thickness with the selection instrument adapted to the surgical technique
	■ Identification of the springs according to the wire thickness: ■ Wire thickness Ø 1.0 mm = no ring ■ Wire thickness Ø 1.2 mm = 2 rings ■ Wire thickness Ø 1.6 mm = 6 rings	■ Unique identification and differentiation
	■ Angled, atraumatic ends	■ Enable firm anchorage in the bone ■ Secure hold and fit of the spring
St	■ Implants made of high-quality medical implant steel	■ Greatest possible stability ■ High biocompatibility
STERILE R 	■ All springs are available in individually sterile packaged versions ■ Including self-adhesive labels with all the relevant implant data	■ Direct, swift and application-oriented access ■ Maximum safety due to double sterile packaging (primary and secondary blister) ■ 100% batch retraceability and transparent, patient-related documentation

Feature, Function and Benefit

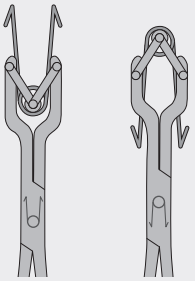
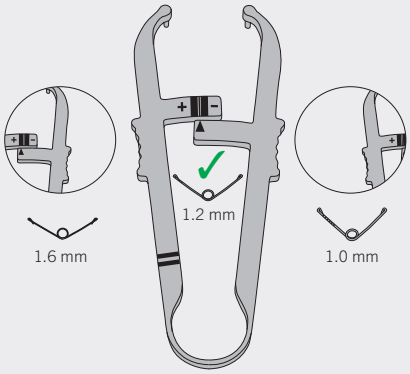
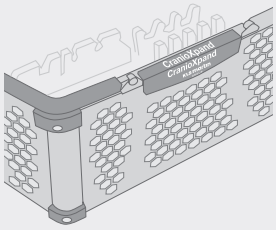
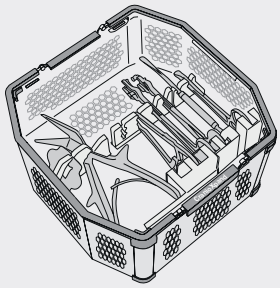
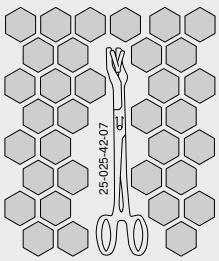
KLS Martin has set itself the goal of designing the system-specific instruments in terms of easy and efficient handling and thus as optimal as possible.

For this reason, the focus during development was not only on instruments perfectly matched to the surgical technique with good haptics, but also on intuitive, easy operability.

The special insertion instruments allow easy pick-up as well as adjustable compression of the spring, thus supporting the user in safe implantation.

In addition to providing direct access to the instruments, the design of the storage system also focused on the requirement for optimized reprocessability to equally serve the needs of all involved parties.

CranioXpand – Instruments and Storage

	Feature	Benefit
	■ Insertion instruments specifically matched to the springs	■ Easy pick-up of the spring ■ Adjustable compression and retention of the spring ■ Safe implantation, with the spring opening either anterior or posterior
	■ Instrument for the easy determination of the appropriate spring force ■ Adapted to the proven surgical technique and to an intra-operative opening of the gap of 15 mm	■ Facilitates selection of the correct spring force
	■ Stainless steel storage containers of honeycomb design combined with high-performance plastic.	■ High strength, light weight ■ Excellent rinsing capability due to large openings and reprocessing-optimized design
	■ In the storage container the instruments are arranged according to the sequence of use during surgery	■ Swift and intuitive supply of instruments during surgery ■ User-friendly and efficient passing of instruments to the surgeon ■ Transparent organization and arrangement
	■ Storage locations marked with laser images and article numbers of the instruments to be stored.	■ Facilitates sorting of the instruments into the storage container ■ Transparent organization and arrangement

Step by step to optimal care

Fields of Use

Minimally invasive treatment of scaphocephalus due to sagittal craniosynostosis in children aged three to six months.

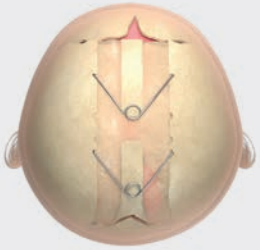
Scaphocephalus
Clinical picture

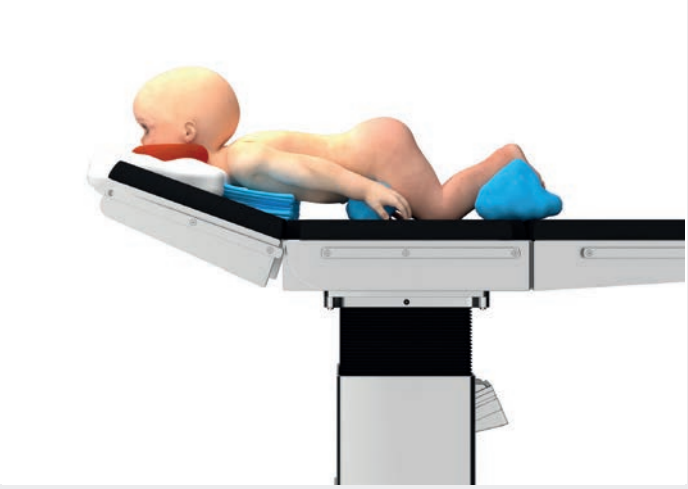
Surgical Technique

Scaphocephalus due to sagittal craniosynostosis

Treatment with two cranial springs, Ø 1.2 mm Pages 12 - 24

Dr. Noor ul Owase Jeelani





Preoperative planning

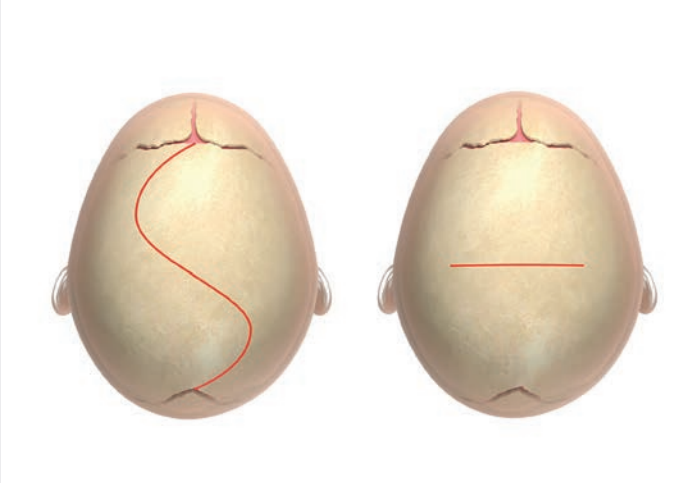
The diagnosis of sagittal craniosynostosis caused by the premature fusion of the sagittal suture is typically made on the basis of a clinical examination. The illustration on the right shows a patient with a clinical picture typical of scaphocephaly.

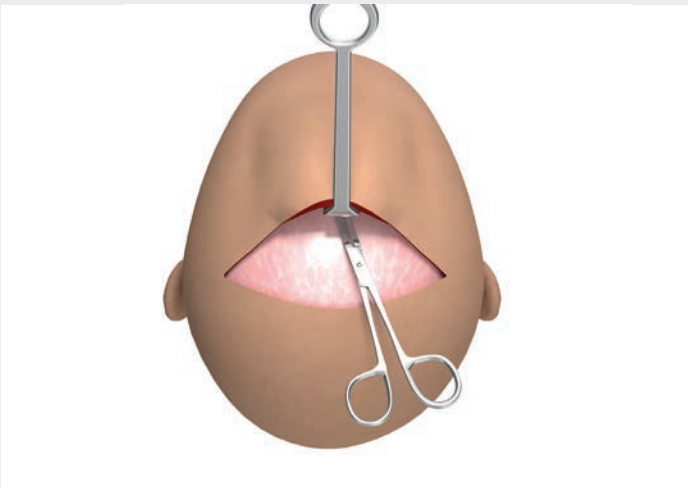
Positioning of the patient

The patient is placed face-down in the "sphinx"position on the operating table, whereby the neck is extended and the chin is placed on a horseshoe gel roll.

Support is provided at the chest and pelvis to ensure there is no abdominal compression which may impede venous return.

The head of the table is raised some 20 degrees until the top of the head is parallel with the operation room floor. Use a sandbag to ensure that the child does not slip down the table.





1. Approach

There are two options available for skin incision:

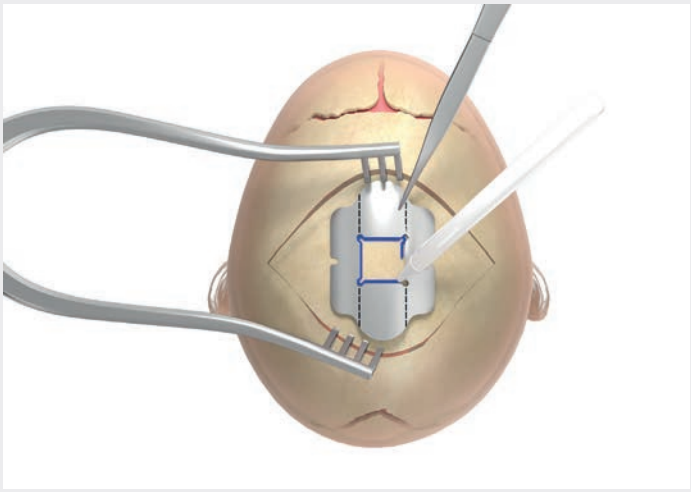
S-shaped incision
The opening can be made via an S-shaped incision over the sagittal suture. This provides exposure from the anterior fontanelle (which may be closed) to the confluence of the lambdoid sutures to provide excellent access to the cranium. This approach is recommended to gain initial experience with the technique. However, the advantage of a better view is countered by the disadvantage of a larger scar, as well as the problem that a section of the scar lies above the springs.

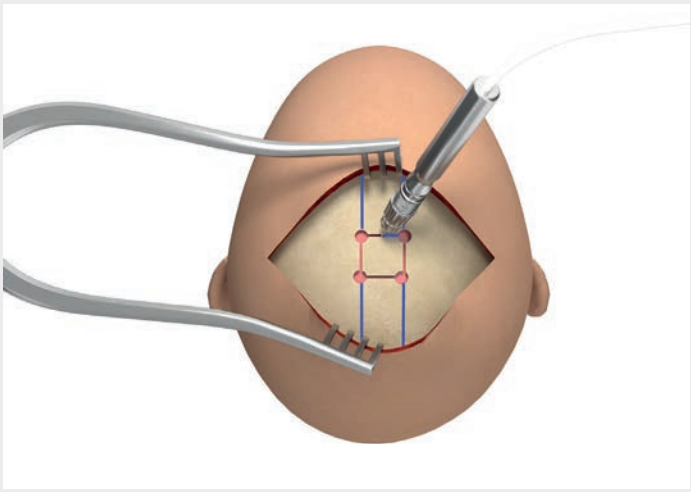
Perpendicular incision
Alternatively, an 8 cm incision can be made perpendicular to the sagittal suture. The anteroposterior location of the incision is approximately at the half way point between the anterior fontanelle and the confluence of the lambdoid sutures. The location may be adjusted depending on the expression of scaphocephaly. Two perpendicular incisions may be used for more severe cases or where the occipital protuberance may be a particular issue.

2. Exposure of the calvarium

After skin incision, the galea is transected to the subgaleal space. Blunt preparation with scissors and monopolar electrocautery follows in the relatively poorly perfused sub-galeal plane, exposing the calvarium from just anterior to the coronal sutures to past the lambdoid sutures. A “surgical corridor” approximately 4–5 cm wide is created in this plane.

Note:
As a precaution, approach and exposure should be performed separately. Any surgery employing a minimally invasive approach should allow switching to open surgery should the need arise. For the 8 cm perpendicular incision, the incision should be marked as a full bicoronal incision. The prep and drape are to be performed accordingly, so that should the need arise, the entire calvarium may be exposed. The other major advantage of prepping and draping the whole head is that it allows better orientation. With a minimal approach, internal landmarks may possibly not be easy to identify. Therefore, including the entire calvarium where the sutures are marked on the skin to begin with can prove most valuable in orienting the surgeon in the surgical field.





3. Marking the central craniectomy and parasagittal osteotomies

Open the soft tissue using wound retractors and then elevate.

To open the skull, a square piece of bone (15 mm^2) is removed from the center of the calvarium (craniectomy). The marking template is used to mark the outer contour of the square as well as the positions of the four burr holes in the corners.

The anteroposterior location of the square is roughly halfway between the anterior fontanelle and the confluence of the lambdoid sutures. This position may be altered to find the narrowest point of the skull.

After outlining the marks, the template is removed.

The two parasagittal osteotomies run in extension of the lateral edges of the square and are marked appropriately up to the frontal fontanelle as well as the confluence of the lambdoid sutures. Posteriorly, near the lambdoid sutures, the parasagittal incisions may fan out.

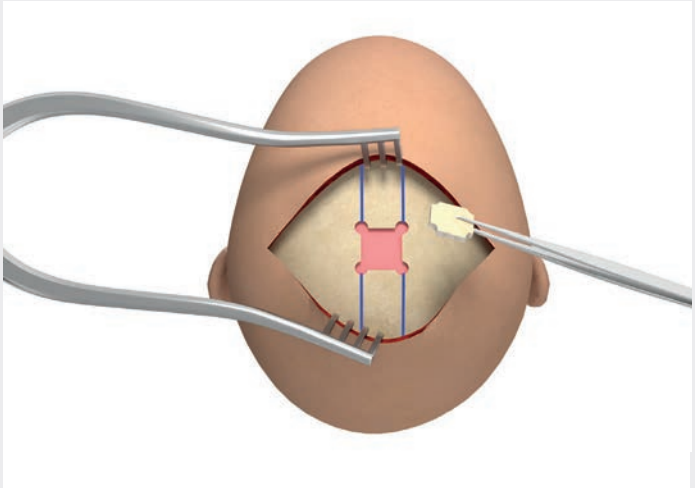
Template for marking

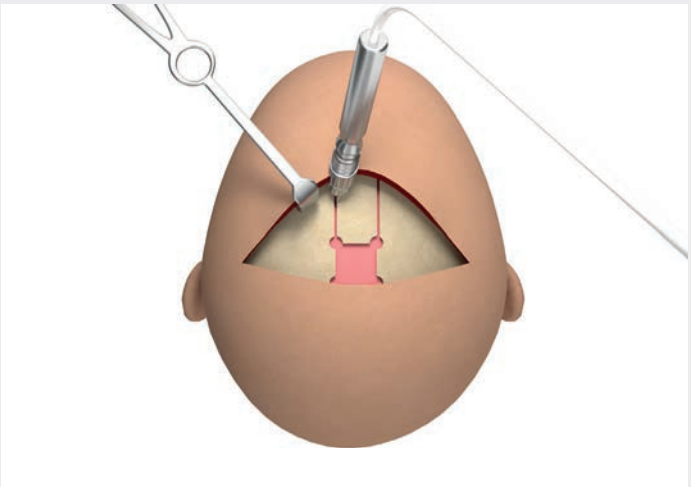
4. Opening of the calvarium

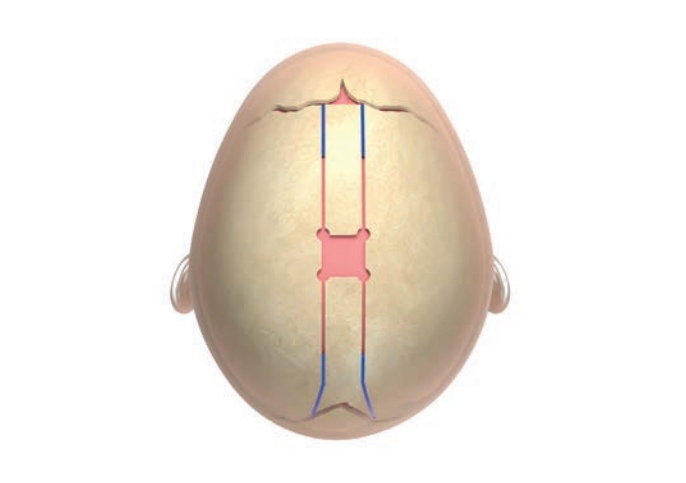
The drill holes are created via trepanation in the four corners of the marked square. Bone wax is filled into the holes to control bleeding, as necessary.

Once the dura is freed, the burr holes are joined using a craniotome with dura protector. The square piece of bone is then removed.

Note:
Great care must be taken as the sagittal sinus often indents the fused sagittal suture and rests in a U-shaped groove on the inside of the calvarium. The craniotomy bone cuts, as per standard neurosurgical practice, should come up to the middle but not cross it.



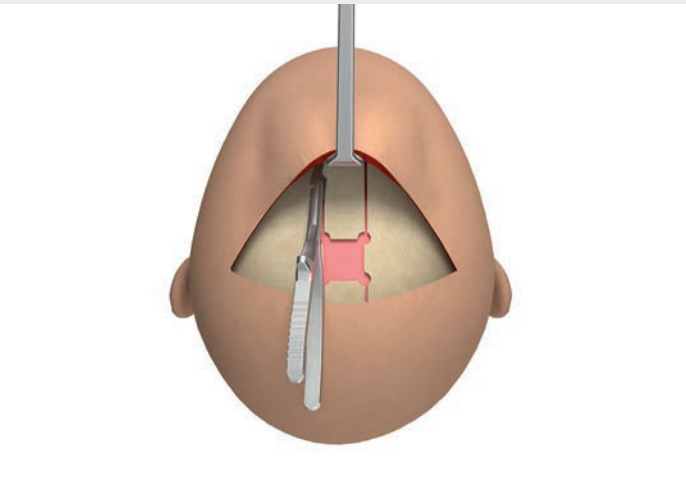


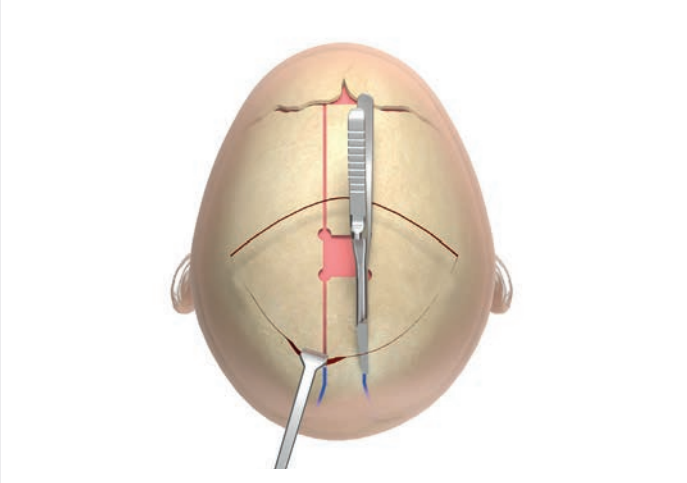


5. Performing the osteotomies

After removing the square of bone, the dura is stripped from the overlying calvarium under direct vision along the entire length of the planned parasaggital osteotomies. Starting from the lateral edges of the square, the two parallel osteotomies between the anterior and posterior fontanelles are performed with the craniotome and dura protector, whereby the sagittal suture lies in the middle.

Anteriorly, osteotomies may terminate in a free fontanelle or the coronal sutures. Posteriorly, the osteotomies diverge slightly in a fan shape when they bisect the lambdoid sutures. The primary aim is to keep them as far away from the sagittal suture as possible (approx. 10-15 mm). An additional bonus is that this results in the forces being more uniformly dissipated across the osteotomy-suture construct, resulting in less lambdoid ridging.

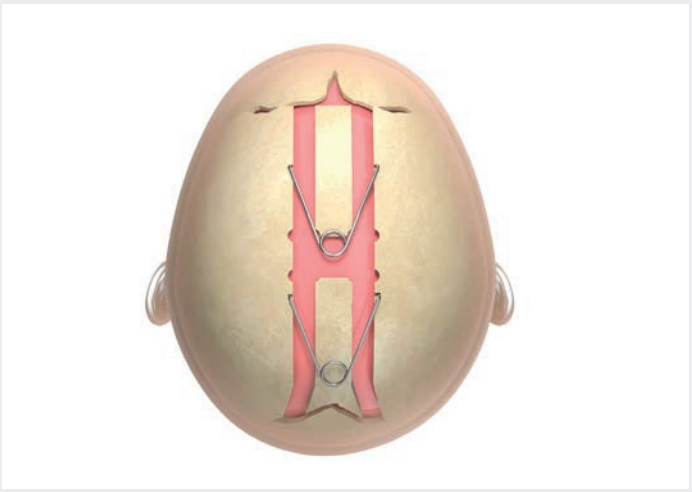


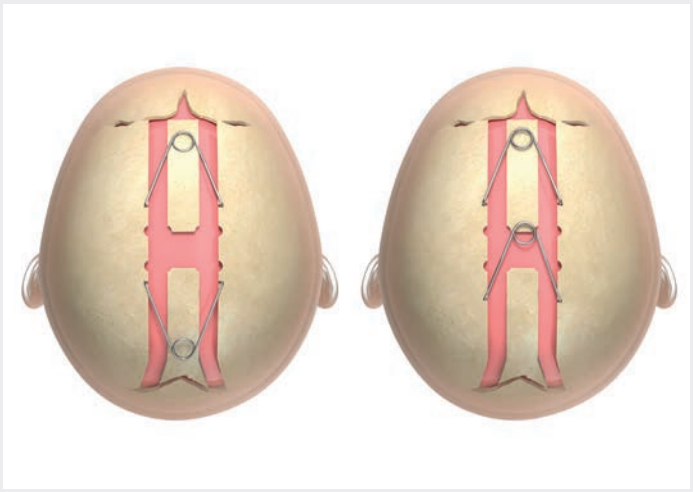


The most anterior and posterior parts of the osteotomies which are difficult to reach with the craniotome are finalized using the bone cutting forceps. In doing this, a midline strip is generated.

It is possible that diploid veins may be encountered in the middle line. These are coagulated using bipolar cautery under direct vision. At the end of this step, the anterior and posterior sagittal struts should be hinged quite freely on the coronal and lambdoid sutures. If this is not the case, the surgeon should ascertain that the parasagittal cuts are indeed complete and the dura stripped free.

Bone cutting forceps





6. Determining the position of the spring

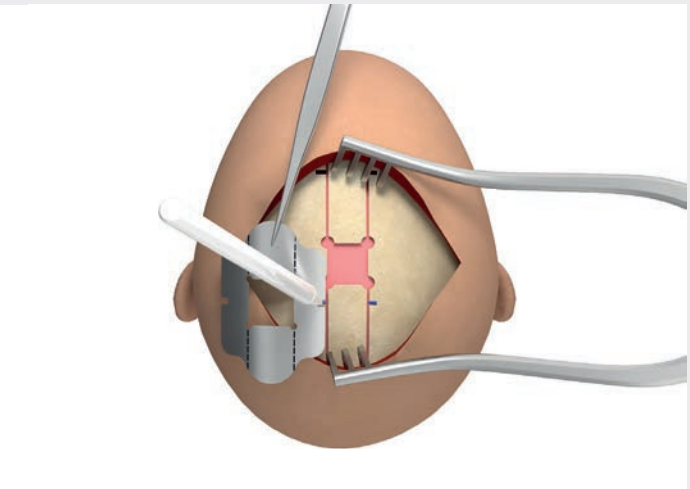
Typically, two springs are implanted.

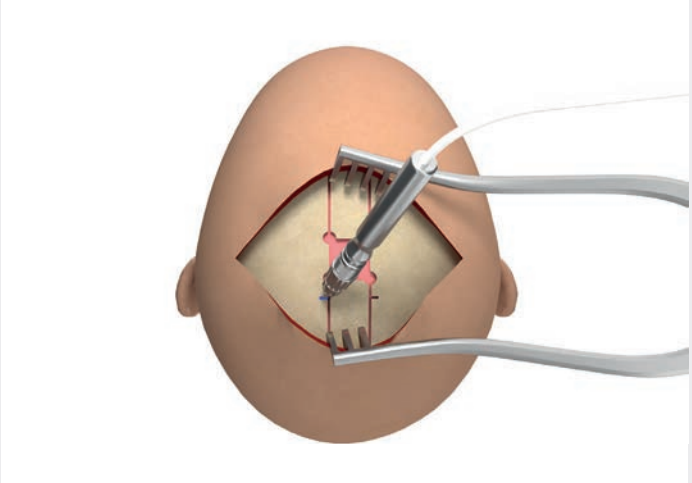
The position of the springs is dictated by the characteristics of the case and adjusted to where the widening effect is required the most.

With a symmetrical scaphocephaly, the springs are placed in a standard fashion. This is typically 1 cm from the anterior and posterior to the cut bone square.

In the case of a particularly pinched anterior/posterior section, the springs may be placed more posteriorly or more anteriorly, to provide maximum vectoral force at the point where maximal expansion is required.

Note:
For patient comfort, the placement of the posterior spring helix should avoid the occipital/resting area.





7. Preparation of implant bed/spring seat

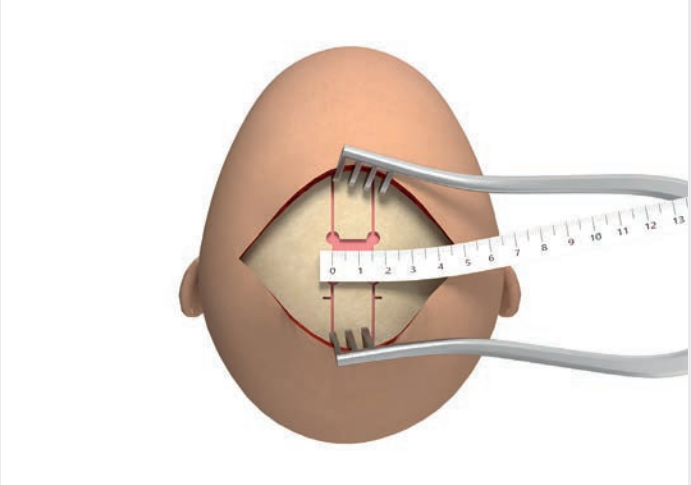
Once the spring position has been determined, 2 mm deep slots are marked on the parietal bones perpendicular to the sagittal suture at the corresponding positions.

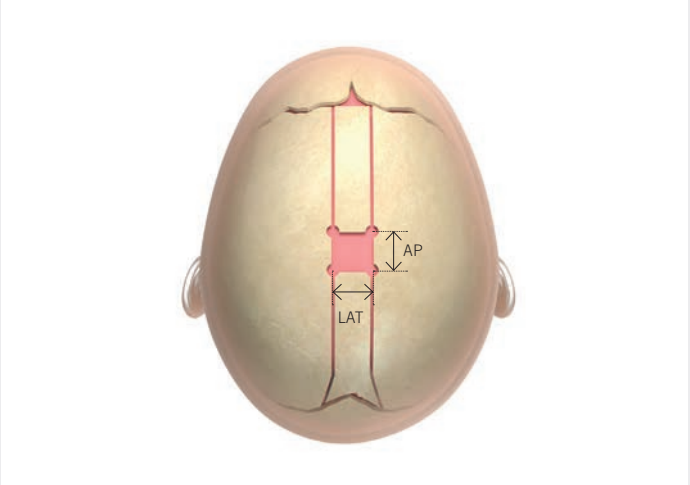
The springs have curved ends so that they sit firmly in these slots and ensure a secure hold.

Marking can be performed with the help of the marking template, which provides corresponding slots on the side.

The slots are created with the craniotome after marking.

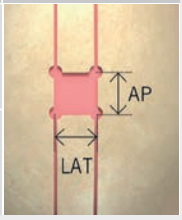
Template for marking

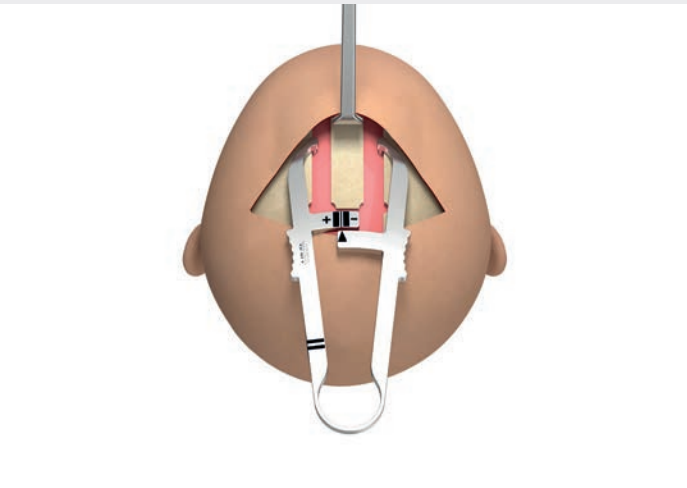


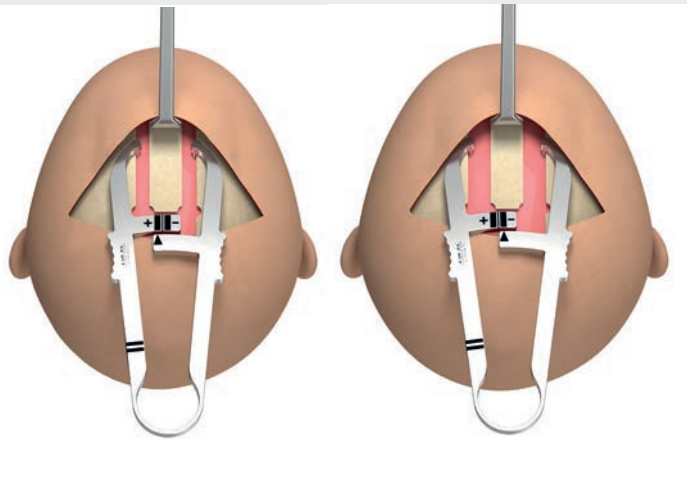


8. Measurements prior to spring insertion

Using a standard surgical ruler, the lateral edge-to-edge distance of the parietal bones (LAT) and the anterior-posterior distance (AP) of the craniotomy recess are measured before inserting the springs.

Measuring chart		
	Values after spring insertion	
Lateral distance (LAT) edge-to-edge distance of the parietal bones	_____ mm	
Anterior-posterior distance (AP) edge-to-edge distance of the craniotomy recess	_____ mm	





9. Selection of spring force (first spring)

The correct spring force is selected with the selection instrument. In terms of force, this is based on the medium, most commonly used spring with a spring thickness of Ø 1.2 mm and is designed for an intraoperative expansion of the calvarium of 15 mm.

For measurement purposes, the selection instrument is hooked with its pins into the prepared slots to simulate implantation of the Ø 1.2 mm spring.

If the arrow indicator is on the middle line, the spring with thickness 1.2 mm is the method of choice. If the arrow indicator lies to the right or to the left of the middle line, either a weaker (-) or a stronger (+) spring has to be chosen.

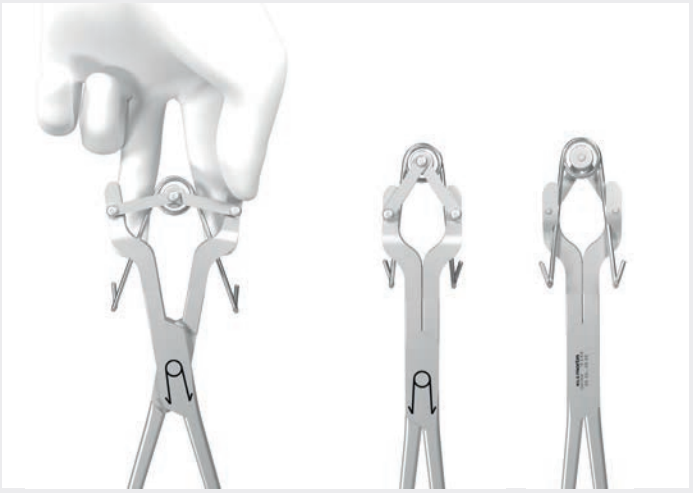
Finally, the overall opening from edge to edge of the parietal bones should be 30 mm (+/- 3 mm).

The arrow lies on the middle line:
Selection of Ø 1.2 mm spring

The arrow lies to the left of the marked area (+):
Selection of Ø 1.6 mm spring

The arrow lies to the right of the marked area (-):
Selection of Ø 1.0 mm spring

Selection instrument



10. Pick-up of the spring with the insertion instrument

After determining the spring size, the spring is picked up with the corresponding insertion instrument.

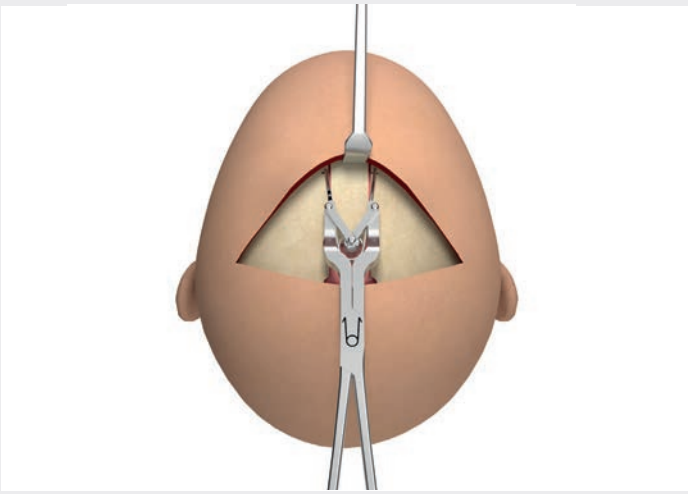
Depending on the desired direction of insertion there are two instruments available:

Spring opening to the front:
If the spring opening is to face to the front, the spring is picked up with insertion instrument 25-025-42-07. For this purpose, the spring helix is placed over the round coil of the instrument and the legs are inserted into the lateral guides when closing the instrument. This way, the spring ends are exposed and can be easily inserted into the prepared lateral slots.

Spring opening to the rear:
If the spring opening is to face to the rear, the spring is picked up with insertion instrument 25-025-43-07. For this purpose, the spring helix is placed over the round coil of the instrument. The legs are placed into the lateral guides.
By closing the instrument with the locking mechanism, the spring is increasingly compressed and can be held in the desired position to enable easy insertion.

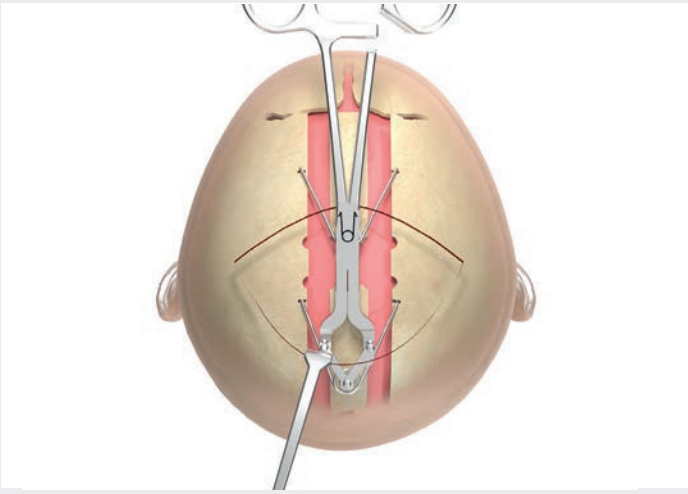
Insertion instrument

Insertion instrument



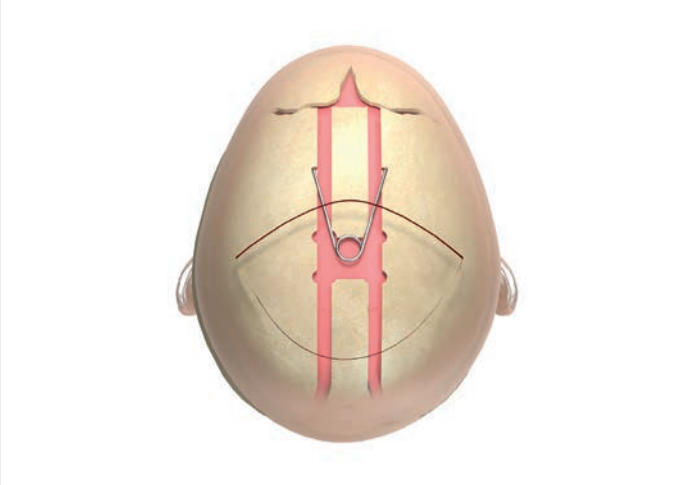
11. Insertion of the first spring

The spring is inserted in such a way that the curved ends hook into the vertical slots. Once the spring is firmly seated and has a secure hold, the insertion instrument can be opened and removed.



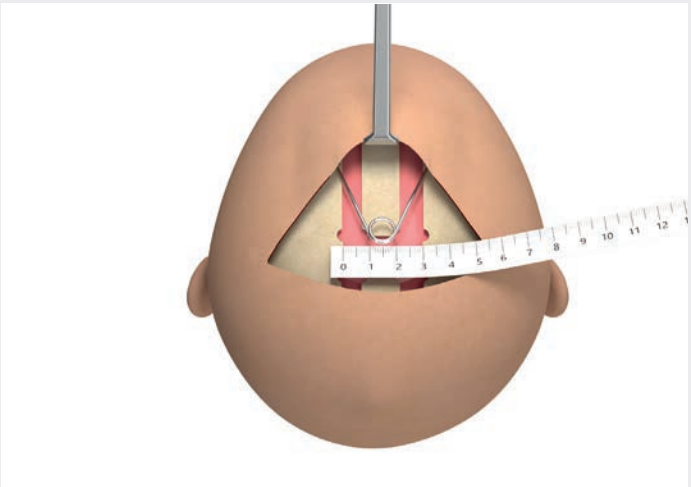
12. Selection of spring force and insertion of the second spring

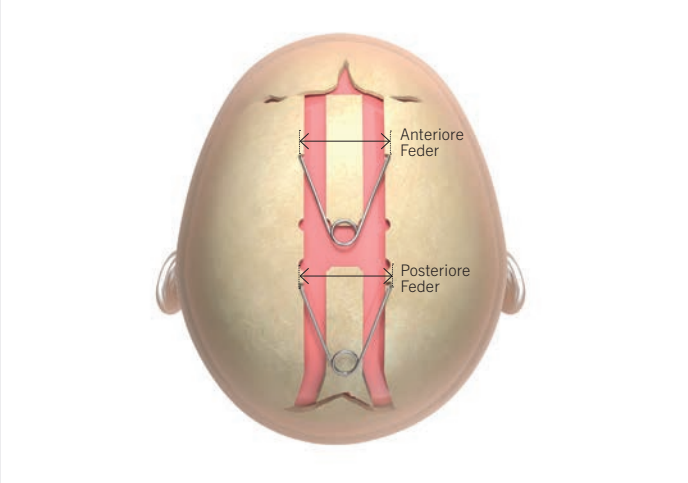
Selection of the spring thickness and insertion of the posterior spring is performed in the same manner as for the anterior spring. The procedure for this is described in steps 9 to 11.



Selection instrument

Insertion instrument



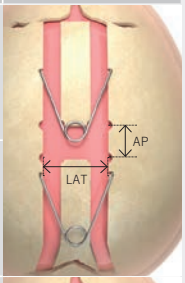
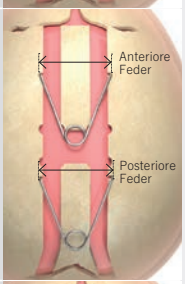
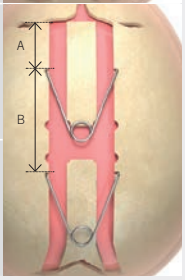


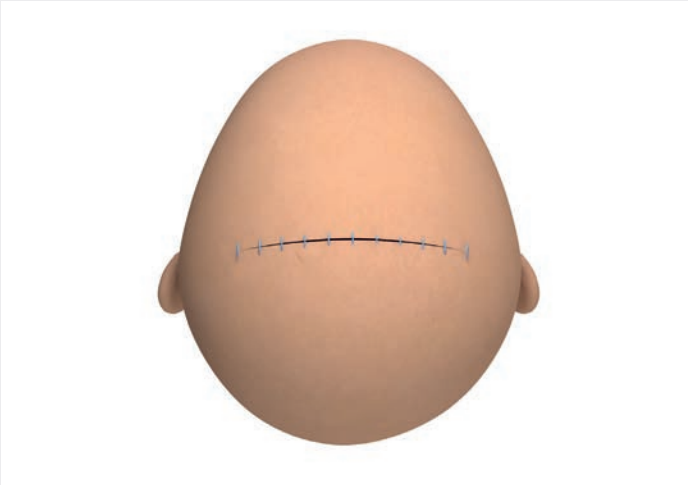
13. Measurements after spring insertion

After inserting the two springs, the edge-to-edge distance of the parietal bones (LAT) and the anterior-posterior distance (AP) of the craniotomy recess are measured.

Optionally, the overall opening of the legs at the curved ends can be measured for both springs.

To complete the dataset, we recommend measuring the distances between the two springs from each other (from the curved ends) as well as between the curved ends of the anterior spring and the coronal suture.

Measuring chart		
	Values after spring insertion	
Lateral distance (LAT) edge-to-edge distance of the parietal bones	_____ mm	
Anterior-posterior distance (AP) edge-to-edge distance of the craniotomy recess	_____ mm	
Overall opening of the legs from curved end to curved end	_____ mm	
Distance between the curved ends of the anterior spring and the coronal suture **(A)**	_____ mm	
Distance between the springs to each other **(B)** from curved end to curved end	_____ mm	



14. Wound closure and postoperative treatment

Hemostasis during the procedure may require the use of Floseal, surgical measures and bone wax with electrocautery under direct vision. Once hemostasis is confirmed, a Betadine wash is used. Next, a 20 ml Redon drain is placed in situ, and a two-layered scalp closure is performed, typically using a 3-0 Vicryl for the galea and 4-0 Monocryl for the dermis.

This is followed by the application of a head bandage.

Twenty-four hours of intravenous antibiotics are given. Restrictions are not required.

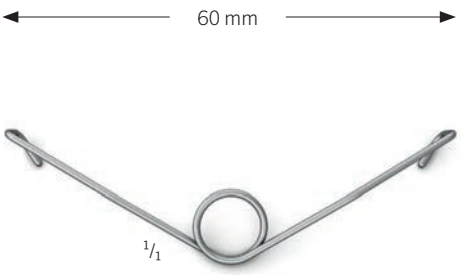
The following day, the drain and the bandage are removed and X-rays of the skull are taken. The child can then generally be discharged.

Hair should not be washed until five days after the procedure.

CranioXpand springs are generally left in situ for 3-6 months.

CranioXpand implants
Springs in different wire thicknesses

Cranial spring
Wire thickness Ø 1.0 mm

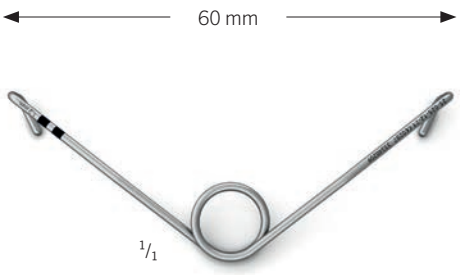


25-025-10-71

STERILE R

St 1

Cranial spring
Wire thickness Ø 1.2 mm



25-025-12-71

STERILE R

St 1

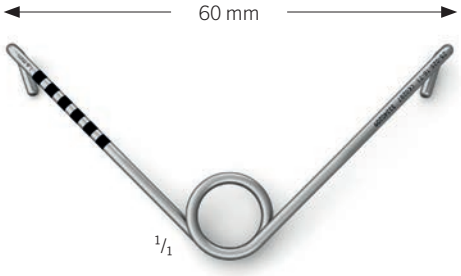
Explanation of icons

St Stainless steel

1 Packaging unit

STERILE R Sterile packaged implants

Cranial spring
Wire thickness Ø 1.6 mm



25-025-16-71

STERILE R

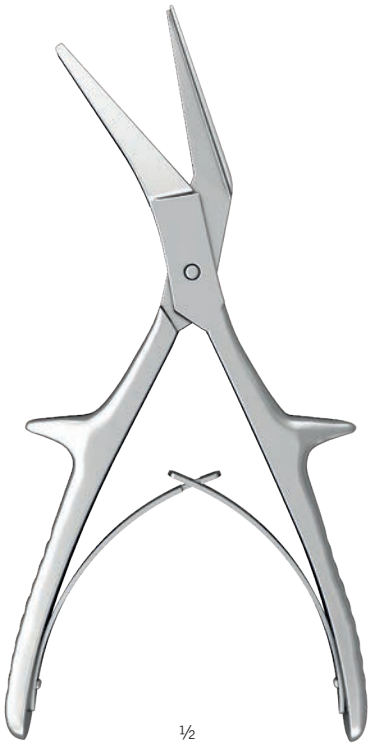
St 1

CranioXpand Instruments
Standard instrumentation

½

25-025-40-07
Template for marking

St 1



½

48-297-19-07
Bone cutting forceps

St 1

½

25-025-52-07
Selection instrument

St 1

Explanation of icons

St Stainless steel

1 Packaging unit

½

25-025-42-07

Insertion instrument

Spring opening to the front

St 1

½

25-025-43-07

Insertion instrument

Spring opening to the rear

St 1

½

25-025-45-07

Instrument for lifting springs

St 1

½

25-025-44-07

Instrument for removing springs

St 1

Storage **CranioXpand** for standard instrumentation

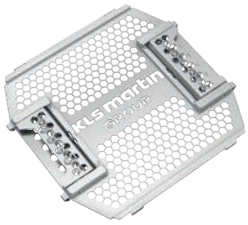
The storage system is not only simple and well-designed, for example with the instruments arranged according to their sequence of use during surgery, it also ensures optimum reprocessing due to large openings in the honeycomb design to equally serve the needs of all involved parties.

All the instruments required for an operation can be stored individually next to each other in the storage container.

The individual storage locations are marked with a laser on the base with an article number and illustration, making it easier to sort the instruments after cleaning.

55-925-10-04	CranioXpand Instrument storage container set, comprised of:
55-925-11-04	Instrument container
55-910-59-04	Lid

55-925-11-04
Instrument container



55-910-59-04
Lid

KLS Martin Group

KLS Martin Australia Pty Ltd.
Sydney · Australia
Tel. +61 2 9439 5316
australia@klsmartin.com

KLS Martin do Brasil Ltda.
São Paulo · Brazil
Tel. +55 11 3554 2299
brazil@klsmartin.com

KLS Martin Medical (Shanghai) International Trading Co., Ltd
Shanghai · China
Tel. +86 21 5820 6251
info@klsmartin.com

KLS Martin India Pvt Ltd.
Chennai · India
Tel. +91 44 66 442 300
india@klsmartin.com

KLS Martin Italia S.r.l.
Milan · Italy
Tel. +39 039 605 67 31
info@klsmartin.com

KLS Martin Japan K.K.
Tokyo · Japan
Tel. +81 3 3814 1431
info@klsmartin.com

KLS Martin SE Asia Sdn. Bhd.
Penang · Malaysia
Tel. +604 261 7060
malaysia@klsmartin.com

KLS Martin de México, S.A. de C.V.
Mexico City · Mexico
Tel. +52 55 7572 0944
mexico@klsmartin.com

KLS Martin Nederland B.V.
Huizen · Netherlands
Tel. +31 35 523 45 38
infonl@klsmartin.com

KLS Martin SE & Co. KG
Moscow · Russia
Tel. +7 499 792 76 19
russia@klsmartin.com

KLS Martin Taiwan Ltd.
Taipei · Taiwan
Tel. +886 2 2325 3169
taiwan@klsmartin.com

KLS Martin SE & Co. KG
Dubai · United Arab Emirates
Tel. +971 4 454 16 55
middleeast@klsmartin.com

KLS Martin UK Ltd.
Reading · United Kingdom
Tel. +44 118 467 1500
info.uk@klsmartin.com

KLS Martin LP
Jacksonville · Florida, USA
Tel. +1 904 641 77 46
usa@klsmartin.com

KLS Martin SE Asia Sdn. Bhd.
Hanoi · Vietnam
Tel. +49 7461 706-0
info@klsmartin.com

KLS Martin SE & Co. KG
A company of the KLS Martin Group
KLS Martin Platz 1 · 78532 Tuttlingen · Germany
PO Box 60 · 78501 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com

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