Part No. **030-1782**
Rev. **A**

OSTEOMED *smartflex*
Pediatric Cranial Expander
Cranial Distraction System
Product Information and Indications for Use

Description
The *OSTEOMED smartflex Pediatric Cranial Expander (Cranial Distraction System) is a distraction osteogenesis system* consisting of spring distractors in various sizes. The distractor is anchored to the cranium by the distractor foot plate. The distractor gradually distracts the bone segments by applying a continuous force to the bones of the skull facilitating remodeling to expand the prematurely closed suture. The distractor can distract up to 55mm and stops distracting when there is no opposing force.

Material
The implantable smartflex spring distractor is made from medical grade stainless steel per ASTM-F-138. The clip and inserter tool are made from Radel. Other instrumentation is made from various grades of stainless steel and anodized aluminum.

Clinical Indications
The *OSTEOMED smartflex Cranial Spring Distraction System* is intended for use in the treatment of cranial conditions such as syndromic craniosynostosis and congenital deficiencies in which osteotomies and gradual bone distraction are indicated. This device is intended to provide temporary stabilization and gradual lengthening of the cranial bones. This device is intended to be removed after consolidation.

The *OSTEOMED smartflex Cranial Spring Distraction System* is intended for single patient use only.

Target Population
Pediatrics; Sub-population – Infant greater than 1 month to 2 years of age

Contraindications
- Use of the *OSTEOMED smartflex Cranial Spring Distractor* is contraindicated in cases of active or suspected infection, in patients previously sensitized to stainless steel; 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/guardian to ignore the limitations of distraction osteogenesis.
- The *OSTEOMED smartflex Cranial Distractor* is also contraindicated in those cases where there is an inadequate volume or quality of bone to place the distractor securely.

Warnings
1. Distractors or other appliances of dissimilar metals should not be used together in or near the implant site.
2. Multiple device bending may weaken the device and could result in implant fracture and failure.
3. Do not remove distractor before the consolidation period has been completed.
4. Distractor must be anchored properly on each side of the craniectomy.
5. Patient's activities must be governed according to the limitations of the device.
6. During distraction and consolidation period, the soft-tissue portal must remain clean.
7. Failure to follow Planning instructions may contribute to patient harm.
8. Failure to follow Implantation instructions may cause patient harm or device damage.
9. The devices can break or be damaged due to excessive activity or trauma. This could lead to failure of the distractor, which could require additional surgery and device removal.
10. It is recommended to remove any fractured implants from patients during surgery. If unable to remove, notify patient/guardian.
11. Magnetic Resonance (MR) Unsafe.
12. The *OSTEOMED smartflex Cranial Spring Distraction System* implants have not been tested for safety and compatibility in the MR environment, nor have they been tested for heating or migration in the MR environment.

Precautions
1. The patient/guardian is to be warned that the device can break or loosen as a result of stress, excessive activity or inappropriate diet.
2. The patient/guardian is to be made aware of the surgical risks and possible adverse effects prior to surgery, and warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.
3. Surgeon should limit patient activity while device is implanted.

Maintaining Device Effectiveness
1. The surgeon should have specific training, experience, and thorough familiarity with the use of cranial distraction products and techniques.
2. The surgeon must exercise reasonable judgment when deciding which size distractor to use for specific indications.
3. The *OSTEOMED smartflex Cranial Spring Distraction System* is not intended to endure excessive abnormal functional stresses.
4. The *OSTEOMED smartflex Cranial Spring Distraction System* is intended for temporary fixation once intended distraction is achieved and osteogenesis occurs.
5. Carefully inspect the OsteoMed implants prior to use. Inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty, damaged, or suspect should not be used.
6. OsteoMed recommends the use of OsteoMed products in a sterile environment.
7. Care must be taken not to damage distractor during implantation.

Instructions for Placing the OsteoMed *smartflex* Cranial Spring Distractor:
OsteoMed recommends that prior to performing a cranial distraction using the *OSTEOMED smartflex Cranial Spring Distraction* device, that pre-op planning is done by matching the device to a 3D Model (preferred) or x-rays/CT scans of the patient.

Instructions for Use: Planning
The *OSTEOMED smartflex Cranial Spring Distractor* can distract up to 55 mm. The distractor is chosen based on the desired cranial movement. During pre-op planning, x-rays/CT scans taken of the distraction site are needed in order to select the appropriate distractor and plan the necessary distraction. When selecting the appropriate distractor for distraction, it is important to consider the following:
- Location of osteotomy (Anterior and Posterior)
- Direction of distraction
- Age
- Cranial bone thickness
- Deformity Severity of Deformity

Note: Excessive contouring may compromise the force of the spring

OSTEOMED smartflex Cranial Spring Distractor
Size Selection Chart

Patient Age (Months) Type of Deformity	*Anterior Spring*			*Posterior Spring*		
	Bone Thickness (mm)			*Bone Thickness (mm)*		
	<2	*2-5*	*>5*	*<2*	*2-5*	*>5*
3-4 (Mild)	*5N*	*5N*	*5.5N*	*5.5N*	*5.5N*	*6N*
3-4 (Medium)	*5.5N*	*5.5N*	*6N*	*6N*	*6N*	*6.5N*
3-4 (Severe)	*5.5N*	*6N*	*6N*	*6N*	*6.5N*	*6.5N*
5-6 (Mild)	*6N*	*6N*	*6.5N*	*6.5N*	*6.5N*	*7N*
5-6 (Medium)	*6N*	*6.5N*	*7N*	*6.5N*	*7N*	*7.5N*
5-6 (Severe)	*6N*	*6.5N*	*7.5N*	*6.5N*	*7N*	*8N*

NOTE: The 4N and 4.5N *smartflex* cranial spring distractors are available for rare malformations such as a cloverleaf skull deformity.

Instructions for Use: Implantation (placing distractor can be done manually or with use of spring inserter instrument)

Note: *OSTEOMED smartflex Pediatric Cranial Expander (Cranial Distraction System)* Surgical Technique Guide can be used for further guidance 030-1781 and can be obtained from OsteoMed at no charge.

Manual Implantation
1. Design incisions on the anterior and posterior fontanel approximately 4cm in width.
2. Inject local anesthesia (.25% marcaine with epinephrine) at incision site and over the area of the fused suture.
3. Make the incision with a 15 blade in the direction of the hair follicles to preserve them.
4. Lift the scalp in the subgaleal plane under direct vision from the incision to the anterior and posterior limit of the suture.
5. Using a Neuro Rongeur, remove 1 cm of the fused suture throughout its' entire length with the help of the endoscope and bone cutters.
6. Obtain hemostasis at the bone margin and the dura.
7. Select the spring force based on guide that considers age, bone thickness, and severity of the deformity. Refer to Size Selection Chart.
   Note: The 4N and 4.5N smartflex cranial springs are available for rare malformations such as cloverleaf skull deformity.
8. Use, needle nose pliers to 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 legs shall be placed parallel to the suture line.
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)
10. Close the incisions with a 2 layer subcutaneous and a subcuticular closure of absorbable sutures.
11. Place a head wrap to protect the incisions. Wound care should be routinely done.

Inserter Spring Implantation
1. Design a "W" shape incisions in between the anterior and posterior fontanel approximately 4cm in width.
2. Inject local (.25% marcaine with epinephrine) anesthesia at incision site and over the area of the fused suture.
3. Make the incision with a 15 blade in the direction of the hair follicles to preserve them.
4. Lift the scalp in the subgaleal plane under direct vision from the incision to the anterior and posterior limit of the suture.
5. Using a Neuro Rongeur, remove 1 cm of the fused suture throughout its' entire length with the help of the endoscope.
6. Obtain hemostasis at the bone margin and the dura.
7. Select the spring force based on guide that considers age, bone thickness, and severity of the deformity. Refer to Size Selection Chart.

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

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. Place the spring inside the clip.
   Note: Off-plane bending and excessive bending may compromise the spring force.
9. Assemble the smartflex spring PN: 218-30XX-SP to the smartflex Inserter Instrument PN: 220-0771-SP.
   a. Assembly Instructions. Insert the spring 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.
10. Insert the assembled inserter instrument under the incision. Completely compress the trigger to release the spring in desired location.
    Note: Ensure foot plate hooks are positioned firmly on the cranial bone
    Note: To prevent spring migration, the spring legs shall be placed parallel to the suture line.
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)
12. Close the incisions with a 2 layer subcutaneous and a subcuticular closure of absorbable sutures.
13. Place a head wrap to protect the incisions. Wound care should be routinely done.

Instructions for use: Distraction
1. Distraction continues until the desired N force reaches equilibrium. After the desired distraction has been achieved, the distractor should remain implanted for the consolidation period determined by the surgeon.

Instructions for use: Distractors Removal:
1. Palpate the springs at their overlap and bony insertion points.
2. Design a small incision over each of the 4 footplates and mark the portion of the previous incisions that will be utilized.
3. Inject local anesthesia into the 5 incisions.
4. Make each of the footplate incisions and expose the spring footplate.
5. Use the dingman to free the soft tissue around the footplates and separate it from the bone.
6. Use a needle driver to rotate the footplate away from the bone in the direction opposite of the initial osteotomy.
7. Repeat 5 and 6 for each of the 4 footplate sites.
8. Open the portion of the previous incisions to expose where the springs overlap in the midline.
9. Cut the wire at the crotch of the spring on each side.
10. Pull the segments of spring out of their respective incisions.
11. Close the incisions with a buried and subcuticular layer of absorbable suture.
12. Apply antibiotic ointment to each of the incisions, no head wrap is required.
13. Discard all devices according to standard biohazard disposal procedures.

Sterility
- Implants are provided sterile (Gamma Sterilization). DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- The user facility must clean and disinfect instruments prior to sterilization per standard hospital procedures.

Caution
- Federal (United States) law restricts this device for sale by or on the order of a medical practitioner licensed to do so.
- Do not attempt a surgical procedure with faulty, damaged, or suspect OsteoMed instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.

OsteoMed
3885 Arapaho Road
Addison, Texas 75001 USA
Customer Service: 800/456-7779
Outside USA: 972/677-4600

EC REP
Shotwell & Carr
25 Barker Close,
Fishbourne, Chichester
West Sussex, UK P018 8BJ
Tel: +44 (0) 1243 779 550

CE 0086

Symbols and Definitions

	Single Use Only	REF	Catalogue Number
LOT	Batch Code (Lot Number)		Consult Instructions for Use
	Date of Manufacture		Manufacturer
	Attention, See Instructions for Use Caution, Consult Accompanying Documents	EC REP	Authorized Representative in the European Community
STERILE R	Sterile, Method of Sterilization Using Irradiation		Do not use if sterile package is damaged
Rx ONLY	Federal Law (U.S.A) Restricts this device to sale by or on the order of a physician.		

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