Integra®

Cranial Stabilization Pediatric Solution

Because we are committed to limiting uncertainty, we provide a specific design dedicated to Pediatric procedures.







Integra® Cranial Stabilization - Pediatric Solution

What can bring our Pediatric Solution?	4
MAYFIELD® Infinity System	5
MAYFIELD® Infinity Support System (A1112)	6
MAYFIELD® Infinity Coupler (419B1010)	6
MAYFIELD® Infinity Adult Horseshoe (419A1031)	7
MAYFIELD® Infinity Pediatric Horseshoe (419A1030)	7
MAYFIELD® Infinity General Purpose Headrest (419A1050)	7
MAYFIELD® Infinity Skull Clamp (A1114)	8
MAYFIELD® Child's Rocker Arm (419B12O5)	9
MAYFIELD® Standard Adult Rocker Arm (419B12O4)	9
MAYFIELD® Triad Rocker Arm (419B12O6)	9
MAYFIELD® Single Pin Accessory (419A1207)	9
MAYFIELD° Torque Screw (419A1209 & 419A1208)	9
MAYFIELD® Pediatric Skull Pins (A1114)	10
MAYFIELD® Child Disposable Skull Pins (A1119)	10
MAYFIELD® Child Reusable Skull Pins (A1122)	10
MAYFIELD® Child Disposable Skull Pins (A1084)	10
MAYFIELD® Child Reusable Skull Pins (A1048)	10
MAYFIELD® Retractor Systems	12
Budde [®] Halo Retractor System (A1040)	12
Integra® Brain Retractor System (A2012)	12

What can bring our Pediatric Solution?

Adjustable:

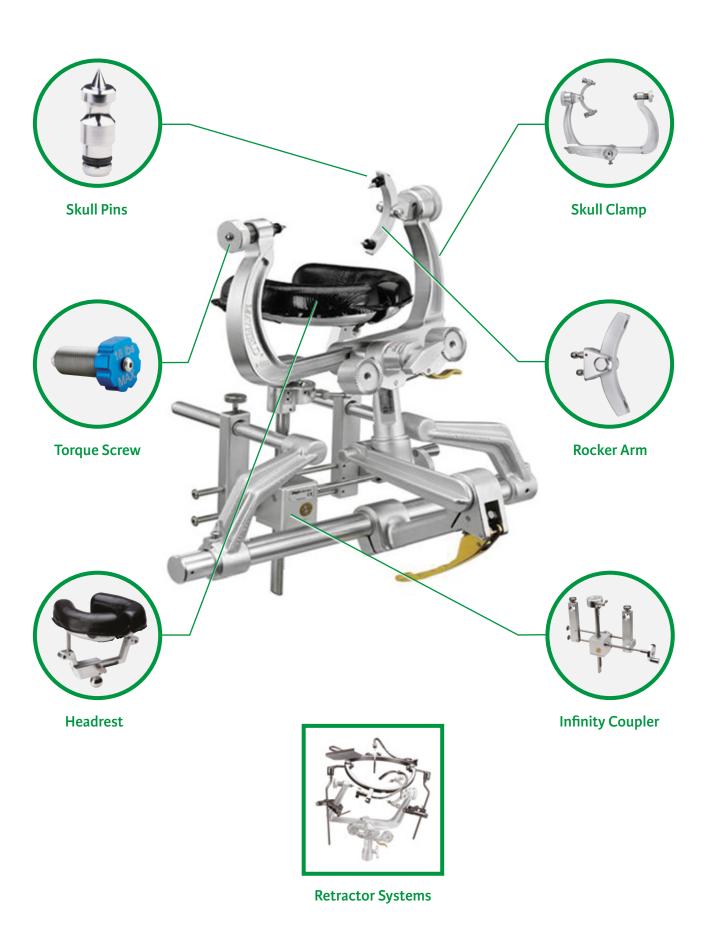
- Provides various positioning (prone and supine position).
- Accommodating with various head sizes in child positioning.
- Control of the pressure.

Mini invasive approach.

Large range of pins for pediatric surgery.

Non-invasive fixation opportunity.

System of retraction.



MAYFIELD® Infinity Support System - ref A1112

- Cranial support: prone or supine position.
- The MAYFIELD® Infinity attaches to any MAYFIELD® Base Unit, creates a method for simultaneous application of a head support (Adult, Pediatric or general purpose) and a skull clamp (patients ages 5†). This is especially important for patients who require a low clamping force to stabilize the position of the head, such as Pediatric patients (ages 5†) and trauma patients.

MAYFIELD® Infinity Coupler - ref 419B1010

- Easy mounting on any MAYFIELD® Base Unit.
- Head supports can be adjusted vertically & laterally for flexibility in patient positioning.
- Position of head support can be tilted on ball socket joint and locked in place, then securely locked in place.
- Positioning close to the operating room table allows surgery for patient with a short neck length.



MAYFIELD® Infinity Support System (A1112) includes*:

	, , , , , , , , , , , , , , , , , , , ,	
Catalog #	Component	Quantity
419B1010	Infinity Support Coupler	1
419A1030	Horseshoe - Pediatric	1
419A1031	Horseshoe - Adult	1
419A1050	Horseshoe - General Purpose	1
419A1048	Mini Gel Pad	2
419A1060	Storage Case (not pictured)	1

^{*}Any of the above components may be ordered separately.

MAYFIELD® Infinity Adult Horseshoe - ref 419A1031 MAYFIELD® Infinity Pediatric Horseshoe - ref 419A1030

- Cranial support: prone or supine position (419A1031 is recommended for adults and older children 419A1030 is recommended for infants and young children)
- Adjustable pad base (faceplates) accommodates with various head sizes.
- Vertical and lateral adjustments allow flexibility in patient positioning.
- Gel pads provided for comfort and reduction in the incidence of pressure necrosis.

MAYFIELD® Infinity General Purpose Headrest - ref 419A1050

- Cranial support: supine or semi-sitting position.
- Gel pads can be positioned in multiple receptacles and can be tilted on their hinges.

TRICK: during non-invasive procedures, the mini gel pads can be positioned in the pin carrier holes of all MAYFIELD® Skull Clamps.



Indications

The MAYFIELD® Infinity Support System (A1112) is a headrest support device that attaches to any MAYFIELD® Base Unit Support rods, creating a method for simultaneous application of a headrest (adult, pediatric, or general purpose) and a Skull Clamp (ages 5°).

Contraindications

Do not use the MAYFIELD® Infinity Support System (A1112) for other indications than those provided.

MAYFIELD® Infinity Skull Clamp - ref A1114

- Elongated arms to provide more room for clearance around the patient head.
- Multiple rocker arm options allowing it to adapt to specific cases.
- Two torque screw options to choose the desired amount of pressure for the patient and procedure.
- Compatible with the full line of MAYFIELD® products (except Swivel Adaptors A1115 & A1116).
- The rocker arm attachments snap in place no tools required.
- Length and curved contours of the skull clamp allow the clamp to better interface with the horseshoe headrest of the Infinity Support System (A1112) providing a lower profile fixation with the ability to tuck in beneath the headrests.
- Indicated for young Children from age 5⁺.





MAYFIELD® Infinity Skull Clamp (A1114) includes*:

,, ,						
Catalog #	Component	Quantity				
A1114	Infinity Skull Clamp	1				
419B12O4	Adult Rocker Arm	1				
419B12O5	Child Rocker Arm	1				
419B12O6	MAYFIELD® Triad Rocker Arm	1				
419A1207	Single Pin Accessory	1				
419A1208	Reduced Load 18 lbs Torque Screw	1				
419A1209	80 lbs Torque Screw	1				
41A1482	Adjustment Wrench (not pictured)	1				
419A1250	Storage Case (not pictured)	1				

Indications

The MAYFIELD® Infinity Skull Clamp is placed on the patient's skull to hold their head and neck in a particular position when rigid fixation is desired. The skull clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary. The accessories provided with the skull clamp also allow it to be used where stabilization is desired instead of complete fixation.

Contraindications

Do not use the MAYFIELD° Infinity Skull Clamp for other indications than those provided.

^{*}Any of the above components may be ordered separately.

MAYFIELD° Child's Rocker Arm - ref 419B1205

• Configured for smaller size patient skulls.



MAYFIELD° Standard Adult Rocker Arm - ref 419B12O4

 The same two-pin Rocker Arm as provided with the standard MAYFIELD® skull clamp.



MAYFIELD® Triad Rocker Arm - ref 419B1206

• Provides visual indication of clamping force of the two pins on the Rocker Arm.



MAYFIELD® Single Pin Accessory - ref 419A1207

- Provide a directly opposing point of stabilization.
- Can be used with mini gel pads.



MAYFIELD° Torque Screw - ref 419A1209 (80 lbs) and ref 419A1208 (18 lbs: reduced load)

- Two torque Screw options to assist in providing the desired amount of pressure for the patient and the procedure.
- Along with the standard MAYFIELD® 80 lbs (+/- 36kg) Torque Screw, a reduced load 18 lbs Torque Screw provided for procedures where lower, more controlled pressure and less penetration of the pins is needed.
- Maximal pressure: 18 lbs (+/- 8 kg). Graduated in 3 lbs increments, can deliver up to 18 lbs of impingement force.

NOTE: The reduced load Torque Screw should always be used in conjunction with a horseshoe headrest or other form of primary patient head support.





MAYFIELD® Reusable and Disposable Pediatric Skull Pins

A1119 - MAYFIELD° Child Disposable Skull Pins (Titanium)



Catalog #	Composition	Type of use	MRI Compatibility	Description	Packaging
A1119	Titanium	Disposable	Yes	 Pinpoint reduced to control penetration Designed and tested for use in MR Systems up to 3.0 Tesla (T)* Artifacts reduced Wings that improve fit into pin receptacles of skull clamps Finger grooves provide a sure grip for easy removal Vinyl pin covers are provided to help prevent cross-contamination and assist in the easy removal from the package prior to skull clamp application 	12 sets of 3 pins per carton, sterile

A1122 - MAYFIELD° Child Reusable Skull Pins (Titanium)

Catalog #	Composition	Type of use	MRI Compatibility	Description	Packaging
A1122	Titanium	Reusable	Yes	 Pinpoint reduced to control penetration Designed and tested for use in MR Systems up to 3.0 Tesla (T)* Artifacts reduced Black O-ring connotes reusable product 	Supplied individually and non sterile



A1084 - MAYFIELD® Child Disposable Skull Pins (Steel)

Catalog #	Composition	Type of use	MRI Compatibility	Description	Packaging
A1084	Steel	Disposable	No	Pinpoint reduced to control penetration Red O-ring connotes single use product	12 sets of 3 pins per carton, sterile





Catalog #	Composition	Type of use	MRI Compatibility	Description	Packaging
A1048	Steel	Reusable	No	 Pinpoint reduced to control penetration when used with a child. Black O-ring connotes reusable product, ensures a secure fit. 	Supplied individually and non sterile

^{*}These Skull pins are MR Conditional according to terminology specified in the American Society for testing and Materials (ASTM) International, Designation: F2503-05. See product instructions for Use for conditions

Integra®

Cranial Stabilization - Pediatric Solution - MAYFIELD® Pediatric Skull Pins Indications & Contraindications

MAYFIELD® Child Reusable Skull Pins (Steel) - ref A1048 Indications

The MAYFIELD® Reusable Adult (A1047) and Child (A1048) Skull Pins are used in conjunction with all generations of MAYFIELD® brand Skull Clamps (A1013, A1014, A1059, A1108, ou A2000), MAYFIELD® brand Radiolucent Skull Clamps (A1058 or A2002), and the improved GARDNER brand Skull (A1035) when rigid skeletal fixation is required. These pins are made of stainless steel and are removable for sterilization and reuse. MAYFIELD® Reusable Child skull pins (A1048) are recommended for young children over the age of 5 years, depending upon the size and age of the child. It is at the discretion of the surgeon when the MAYFIELD® reusable Adult skull pins may be used.

Contraindications

Do not use the MAYFIELD* Child reusable Skull pins - ref A1048 for other indications than those provided.

MAYFIELD° Child Reusable Titanium Skull Pins - ref A1122

Indications

The MAYFIELD® reusable Titanium Skull Pins (A1121 and A1122) are intended for use with a MAYFIELD® skull clamp that is placed on the patient's skull to hold their head and neck in a particular position during surgical procedures where rigid skeletal fixation is desired and intra-operative MR imaging is used. The MAYFIELD® Disposable Titanium Skull Pins (A1121 and A1122) are indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and when intra-operative MR imaging of the patient is used. The MAYFIELD® Disposable Titanium Skull Pins (A1119) are recommended for young children over the age of five years. It is at the discretion of the user, when the adult or child skull pins should be used.

Contraindications

Do not use the MAYFIELD $^{\circ}$ Child disposable Skull pins (A1119 and A1120) for other indications that those provided.

MAYFIELD® Child Disposable Titanium Skull Pin - ref A1119 Indications

The MAYFIELD® Disposable Titanium Skull Pins (A1119 and A1120) are intended for use with a MAYFIELD® skull clamp that is placed on the patient's skull to hold their head and neck in a particular position during surgical procedures where rigid skeletal fixation is desired and intra-operative MR imaging is used. The MAYFIELD® Disposable Titanium Skull Pins (A1119 and A1120) are indicated for use in open and percutaneous craniotomies and spinal surgeries when rigid skeletal fixation is necessary and when intra-operative MR imaging of the patient is used. The MAYFIELD® Disposable Titanium Skull Pins (A1119) are recommended for young children over the age of five years. It is at the discretion of the user, when the adult or child skull pins should be used.

Contraindications

Do not use the MAYFIELD $^{\circ}$ Child disposable Skull pins (A1119 and A1120) for other indications than provided.

MAYFIELD* Child Disposable Skull Pins (Steel) - ref A1084 Indications

The MAYFIELD® disposable skull pins, Adult – plastic base (A1072), adult – stainless Steel (A1083), or child Stainless steel (A1084) are used in conjunction with all generations of MAYFIELD® brand Skull Clamps (A1013, A1014, A1059, A1108, and A2000), MAYFIELD® brand radiolucent skull clamps (A1058, A2002, A2114), and the improved GARDNER brand skull clamp (A1035) when rigid skeletal fixation is required. The MAYFIELD® disposable skull pins, Adult – plastic base (A1072), adult – stainless Steel (A1083), or child Stainless steel (A1084) are recommended for young children over the age of 5 years, depending upon the size and age of the child. It is at the discretion of the surgeon when The MAYFIELD® disposable skull pins, Adult – plastic base (A1072), adult – stainless Steel (A1083), or child Stainless steel (A1084) pins

may be used. Contraindications

Do not use the MAYFIELD® Child reusable Skull pins – ref A1084 for other indications than those provided.

BUDDE° Halo Retractor System - ref A1040*

- Recommended for difficult procedures.
- Easy assembly on Skull Clamp and / or on the operating room



^{*}For more information refer to Retraction Solution brochure.

The Retraction Solution allows an open view of the brain in procedures where delicate tissue retraction is required.

INTEGRA® Brain Retractor System - ref A2012*



BUDDE® Halo System (A1040) includes:

Catalog #	Type of surgery	Quantity
438B1178	ContinuTrac™ Halo Ring	1
438A1011	9" (229 mm) Halo Flex Arm - SS	3
438B1010	BUDDE® Halo Support Bracket	2
438A1188	BUDDE® Halo Support Rod (5/16")	2
438A1037	BUDDE® Halo Pattie Tray	1
438A1140	BUDDE® Halo Mini Vise (Not Shown)	1
438A1077	BUDDE® Curved Retractor	2
438A1082	TEW [™] Micro Retractor Blades (Not Shown)	1
438A1083	TEW™ Micro Retractor Blades (Not Shown)	1
438A1024	BUDDE® Halo Adjustment Wrench (Not Shown)	2
438A1096	BUDDE® Halo Poly Vac Sterilization Case (Not Shown)	1

The BUDDE® Halo Neurosurgical Retractor System (A1040) was designed for use in all intercranial procedures where retraction of delicate brain tissue is required. The BUDDE Halo Retractor is used in conjunction with the MAYFIELD° skull clamps (A1013, A1014, A1059, A1108, A1114 and A2000) or the MAYFIELD® Radiolucent skull clamps (A1058, A2002 and A2114). The BUDDE® Halo Retractor attaches to the skull clamp after the sterile draping process has been completed. For those intracranial procedures in which a conventional skull clamp is not employed (i.e pediatric brain surgery), the BUDDE® Halo Retractor is used in conjunction with the BUDDE" Halo side rail support (A1067) to secure the system to the side rails of the operating room table.

Contraindications

Do not use the BUDDE® Halo Retractor System (A1040) for other indications than those provided.

INTEGRA® Brain Retractor System (ref A2012) includes:

Catalog #	Type of surgery	Quantity
417A1000	Primary Bars and Clamp Assembly	2
417A1001	Floating Secondary Bars Assembly	4
417A1002	Retractor Arms 9.5 inches in lenghts	4
417A1003	Handrest	1
417A1004	Pattie Tray	1
417A1005	Tapered Retractor Blade, 1/4" to 3/4" (6.4 mm to 19.1 mm)	1
417A1006	Tapered Retractor Blade, 5/32" to 5/8"(4.0 mm to 15.9 mm)	1
417A1007	Tapered Retractor Blade, 1/8" to 1/2"(3.2 mm to 12.7 mm)	1
417A1008	Tapered Retractor Blade, 3/32" to 3/8"(2.4 mm to 9.5 mm)	1
417A1009	Tapered Retractor Blade, 1/16" to 1/4"(1.6 mm to 6.4 mm)	1
417A1010	Sterilization Case	1

The Integra® Brain retractor System is indicated for retraction of brain tissue during neurosurgical procedures. The Integra® Brain Retractor may be used in conjunction with MAYFIELD° skull clamps (A1013, A1014, A1059, A1108, A1114 and A2000) or may attach to the side rails of the operating room table. The Integra Brain retractor System also serves to support and position various instruments and headrests.

Contraindications

Do not use the Integra® Brain retractor System for other indications than those provided.

Sales & Marketing EMEA

Sales & Marketing Limita.

Integra LifeSciences Services (France) SAS
Immeuble Séquoia 2 ª 97 allée Alexandre Borodine
Parc technologique de la Porte des Alpes
6980 Saint Priest: FRANCE
Phone: +33 (0) 43 74 75 900 ° Fax: +33 (0) 43 74 75 99
emea info@integralife.com "integralife.eu

Sales & Marketing LAPAC

Integra LifeSciences Corporation 311 Enterprise Drive Plainsboro, New Jersey 08536 USA Phone +800-654-2873 +609-750-4259 (fax) lapac_cs@integralife.com

Customer Services

Europe, Middle East and Africa: +33 (0)4 37 47 59 50 *+33 (0)4 37 47 59 25 (fax) *csemea@integralife.com

Latin America: +1-800-654-2873 or +1-609-936-5400 *+1-609-750-4259 (fax) *lapac_cs@integralife.com

Asia/ Pacific: +1-800-654-2873 *+1-609-750-4259 (fax) *lapac_cs@integralife.com

Australia: +61 (0) 3 8540 0400 *+61 (0) 3 9540 0004 (fax) *orders@integral-Is.com.au

New Zealand: +64 (0) 9 447 3460 *+64 (0) 9 447 3400 (fax) *customerservice@integral-Is.com.au

New Zealand: +63 (0) 9 447 3460 *+64 (0) 9 447 3400 (fax) *customerservice@integral-Is.com.au

New Zealand: +64 (0) 2 37 4130 *+32 (0) 2 253 2466 (fax) *customerservice@integral-Is.com

Canada: +1-800-265-6693 or +1-905-632-7888 *+1-905-632-7938 (fax) *custserv.canada@integralife.com

Caranay: +49 (0) 2102 5535 600 *+49 (0) 120 553 65 65 (fax) *custsvocgrama@integralife.com

United Kingdom: +44 (0) 1264 345 780 *+44 (0) 1 264 363 782 (fax) *custsvocs.uk@integralife.com

Switzerland: +41 (0) 2 27 21 23 30 *+41 (0) 27 21 23 99 (fax) *custsvocs.uk@integralife.com

Distributed by



Integra LifeSciences Corporation 4900 Charlemar Drive, Building A Cincinnati, Ohio 45227 - USA

INTEGRATED INTEGRATED NEUROSciences Ltd
Newbury Road
Andover, Hampshire, SP10 4DR - UK

Analouse, Hampsine, Shri Qave, Tespan to a provide member of the products might vary form a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region. Please read carefully the instructions for use. Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality. WARNINC: Applicable laws restrict these products to sale by or on the order of a physician. Budde, Integra and the logo Integra are a registered trademark of Integra LifeSciences Corporation in the United States and/or other countries. Mayfield is a registered trademark of SM USA, Inc. and is used by Integra LifeSciences Corporation under license. ContinuTriac is a trademark of Integra LifeSciences Corporation. Cardner and Tew are trademarks of their respective owners. Additional information for EMEA Customers only: Products mentioned in this document are CE class I, Ila devices. Please contact Integra customer service should you need any additional information on devices classification. All the medical devices mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices and its relatives, unless specifically identified as "NOT CE MARKED". Last revision date: 01/2014.