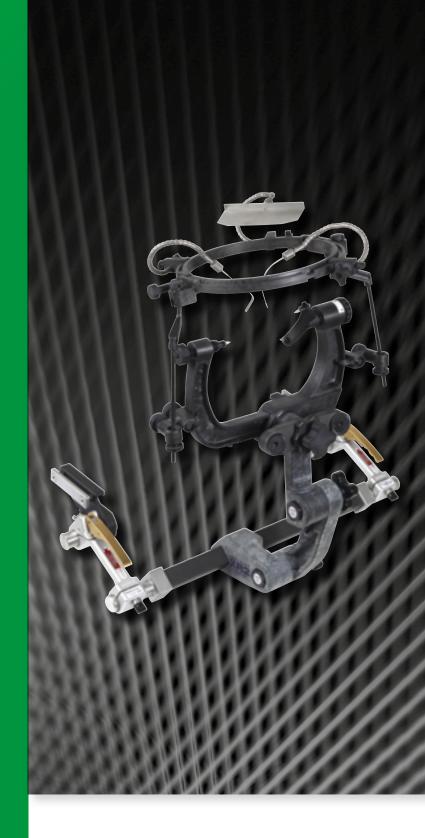
# **MAYFIELD**®

Radiolucent Solutions

Limit uncertainty by providing versatility in product configurations to meet positioning requirements during intraoperative imaging.





## Meeting Intraoperative Imaging Needs in the Neurosurgical operating room



Note about Compatibility of Radiolucent Products to operating room Tables

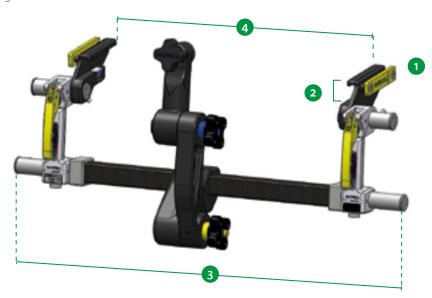
Radiolucent products are available for many intraoperative imaging configurations for CT, Angiography and MRI. New OR and imaging table products are developed routinely and compatibility must be determined in collaboration with all product suppliers. In many cases, adapting products to these OR and imaging tables can be accomplished with readily available off-the-shelf products. A pre-planning phase is recommended to assess overall product compatibility and function to achieve the desired imaging outcomes. If the standard Infinity XR2 Radiolucent Base Unit ("NEW" A2079, A2079E) does not attach to the operating table, please contact Integra for product support and also contact the OR table supplier.

## Step 1: Determine operating room (OR) table attachment

(If required for specific table or patient position)

## MAYFIELD° Infinity XR2 Radiolucent Base Units ("NEW" A2079 & A2079E)

- Provide rigid support between surgical table and skull clamp or headrest for patient positioning\*
- Suitable for Digital Subtraction Angiography (DSA), Fluoroscopy and CT imaging modalities\*
- Set-up and positioning is easy with the simplified linkage components that are secured by color-coded dual-action knobs, saving operating time
- Ultra-style double-cam locking handles for easier opening
- No wrench is required for adjustment of the locking handle
- Horizontal bar provides a wide imaging window full sideto-side lateral positioning



## For both "NEW" A2079 and A2079E:

- 1 New units are identifiable by gold auxiliary side rails
- 2 Rail channel is now 1.26 in (3,2 cm) high to accommodate wider table rails while still suitable for all tables that it originally fit

## Only for "NEW" A2079:

- 3 Total width 28.35 In (72cm)
  Shorter base posts stick out less side-to-side to better accommodate intraoperative imaging equipment allowing additional clearance around the table
- 4 Rail to Rail width: 19.5 In to 24 In (49,6 cm to 61 cm)

## Only for A2079E:

- 3 Total width 32.45 In (82,4 cm)
  This extended XR2 base unit is wider to accommodate wider
  OR tables commonly used in international markets
- 4 Rail to Rail width: 22 In to 28 In (55,9 cm to 71,1 cm)

## MAYFIELD° Infinity XR2 Radiolucent Base Unit includes

Catalog #	Component	Quantity
"NEW" A2079 or A2079E	MAYFIELD® Base Unit	1
437A2400	Swivel Assembly Standard	1

## **Optional Accessories**

Catalog #	Component	Quantity
A2111	MAYFIELD® XR2 Tri-Star Swivel Adaptor	1
437A2224	5 inch (12.7 cm) Link Arm Extension	1
437A2225	7 inch (17.8 cm) Link Arm Extension	1

<sup>\*</sup> Refer to A2079/A2079E IFU - publication number 451A2079 Rev B

## MAYFIELD® Infinity XR2 System Optional Accessories

## **MAYFIELD®** Infinity XR2 Link Arm Extensions





437A2224 (5 In -12.7 cm) Link Arm Extension

437A2225 (7 In -17.8 cm) Link Arm Extension

- Provide additional reach to allow the non-Radiolucent components of the XR2 Base Unit to be positioned further outside the imaging window
- Meet the same functional performance and strength requirements as other XR2 components
- Color coding system enables easy assembly
- Design prevents user from linking multiple Extensions in single set-up

Note: Link Arm Extensions do not fit in the Base Unit storage case

## Portable CT Set-Up with Link Arm Extensions



# MAYFIELD® Infinity XR2 Tri-Star Swivel Adaptor (A2111)

- Provides two additional strabursts for Image Guided surgery (IGS Procedure)
- Easy assembly thanks to colour code (blue and yellow)



## MAYFIELD° Spine Table Adaptor (A2600R)\*

The Spine Table Adaptor connects A2114 MAYFIELD\* Skull Clamp and Radiolucent Horseshoe Headrests to specialty spine

- Easy attachment to the rails thanks to lock knobs
- Double-cam locking handle ensures quick and secure fixation
- Connects to standard rail brackets of Spine Tables

\* Also available for standart MAYFIELD° Systems - ref A2600M





## **Step 2: Select Skull Clamps and Headrests**

## MAYFIELD® Infinity XR2 Skull Clamp (A2114)

- Provides rigid 3-point skeletal fixation for cranial and cervical procedures involving Digital Subtraction Angiography (DSA), Fluoroscopy, CT imaging, and MR imaging modalities\*
- Carbon fiber provides reduced artifact
- Swivel Rocker Arm rotates 360-degrees under full pressure, is easily locked or unlocked with a simple 1/4 turn of the knob, and can be removed without tools, for cleaning
- Ratchet extension is guided and fixed in place by a double-pawl feature to allow better control of the extension, requiring less force to apply the clamp to the patient
- Easy assembly and disassembly of the Rocker arms: no tool is needed





DSA Image with MAYFIELD° Radiolucent Skull Clamp in use

## NEW!\*

Indication update: Magnetic Resonance Compatibility up to 3 Tesla with the standard torque screw but using the metal-free conversion accessory versus the standard torque Screw, will avoid image distortion or artifact.

## MAYFIELD® Infinity XR2 Skull Clamp Optional Accessories:

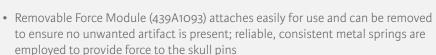


Removable Force Module (439A1093)



Metal-Free Conversion Accessory





- Metal-Free Conversion Accessory (Skull Clamp Ratchet Arm) allows for the use of the Removable Force Module to further limit artifact during the x-ray imaging process; exchange of one ratchet extension for another is quick and easy
- Child's Rocker Arm is available as an accessory



Child's Rocker Arm (439A1091)

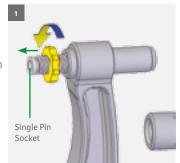
## Metal-Free Conversion Accessory - ref 439A1092 Force Module - ref 439A1093

- A special Rachet Extension allows the skull clamp to be free of any metal during imaging
- This removable Force Applicator can develop up to 80 lbs (36.28kg) of force; graduated in 20 lbs (9.08kg)

#### How it works

# Starting Position (stop wheel rotation)

Rotate the Stop Wheel to position it close to the single-pin socket.



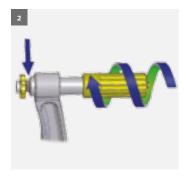
# Force Applicator Adjustment

Adjust the force on the pins by turning the Force Applicator until the desired force is indicated at the Force Applicator shaft.



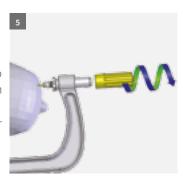
# Force Applicator Mounting

Mount the Force Applicator and advance it until a gap on the carrier shaft becomes visible between the Stop Wheel and the face of the ratchet.



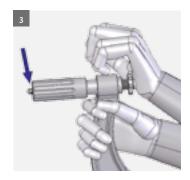
## Force Applicator Removal

Prior to scanning, the Force Applicator may be removed to reduce potential artifact. With the Stop Wheel engaged, the clamp will maintain the measured load when the Force Applicator is removed.



# Clamp Application and Removal Check

Press the Stop Wheel toward the Force Applicator until it registers.



## Warning

Skull Clamp removal: Refer to MAYFIELD\* Infinity XR2 Skull Clamp Instructions for Use.

## MAYFIELD° Infinity XR2 Skull Clamp includes:

Catalog #	Component	Quantity
A2114	MAYFIELD° Infinity XR2 Skull Clamp	1
439A1094	Removable Adult Rocker Arm	1

## **Optional Accessories:**

Catalog #		Quantity
439A1091	Removable Child Rocker Arm	1
439A1092	Metal-Free Conversion Accessory	1
439A1093	Force Module	1





Catalog #	Composition	Type of use	MRI Compatibility	Description	Packaging
A2020	Sapphire	Single use	Yes	<ul> <li>Engineered from synthetic Sapphire material to limit artifact during CT and MR imaging.*</li> <li>Wings improve fit into pin receptacles of skull clamps.</li> <li>Finger grooves provide a sure grip for easy removal.</li> <li>Designed and tested for use in MR Systems up to 3.0 Tesla (T).</li> </ul>	3 sterile pins per boxes

## MAYFIELD° Adult Disposable Titanium Skull Pin (A1120)



Catalog #	Composition	Type of use	MRI Compatibility	Description	Packaging
A1120	Titanium	Single use	Yes	<ul> <li>Designed and tested for use in MR Systems up to 3.0 Tesla (T)*.</li> <li>"Wings" design of the pin body improves the fit into receptacle holes of all MAYFIELD* Skull Clamps.</li> <li>Finger grooves molded into the pin body facilitate sure grip and easy removal from pin holders.</li> </ul>	12 sets of 3 sterile pins per boxes

## MAYFIELD° Child Disposable Titanium Skull Pin (A1119)



Catalog #	Composition	Type of use	MRI Compatibility	Description	Packaging
A1119	Titanium	Single use	Yes	<ul> <li>Pinpoint reduced to control penetration when used with a child.</li> <li>Designed and tested for use in MR Systems up to 3.0 Tesla (T)*.</li> <li>"Wings" design of the pin body improves the fit into receptacle holes of all MAYFIELD* Skull Clamps.</li> <li>Finger grooves molded into the pin body facilitate sure grip and easy removal from pin holders.</li> </ul>	12 sets of 3 sterile pins per boxes.

## MAYFIELD° Adult Reusable Titanium Skull Pin (A1121)



Catalog #	Composition	Type of use	MRI Compatibility	Description	Packaging
A1121	Titanium	Reusable	Yes	<ul> <li>Designed and tested for use in MR Systems up to 3.0 Tesla (T)*.</li> <li>Black o'Ring connotes a reusable product, ensures a secure fit and non sterile.</li> </ul>	Supplied individually and non sterile.

## MAYFIELD° Child Reusable Titanium Skull Pin (A1122)



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

<sup>\*</sup>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



## MAYFIELD<sup>®</sup> Adult Radiolucent Horseshoe Headrest (A2010) MAYFIELD<sup>®</sup> Pediatric Radiolucent Horseshoe Headrest (A2011)

- Radiolucent material construction provides strength and durability with minimal artifact
- Provide cranial support for adults, older children (A2010) and infants, young children (A2011) in either prone and supine positions
- Vertical and lateral adjustments allow for flexibility in patient positioning
- Adjustable pad base (faceplates) accommodates various head sizes
- Includes easily detached pulley rod for skeletal traction
- Supple fluid resistant gel pads provide comfort and reduction in the incidence of pressure necrosis
- Not MRI Compatible



MAYFIELD° Pediatric Radiolucent Horseshoe Headrest (A2011)



MAYFIELD° Adult Radiolucent Horseshoe Headrest (A2010)

### MAYFIELD® Radiolucent Horseshoe Headrests\*:

Catalog #	Component	Quantity
A2010	MAYFIELD® Adult radiolucent Horseshoe Headrest	1
A2011	MAYFIELD® Pediatric radiolucent Horseshoe Headrest	1

\*The above components are sold separately.

## MAYFIELD° replacement parts:

Catalog #	Component
41C1444	Gel Pad, Left, Adult
41C1445	Gel Pad, Right, Adult
440C1011	Gel Pad, Left, Pediatric
440C1012	Gel Pad, Right, Pediatric

## BUDDE<sup>®</sup> Halo Radiolucent Retractor System - ref A1096\*

- Compatible with the MAYFIELD° Radiolucent Headrest System (A2114)
- Designed to reduce or limit artifact during intracranial procedures
- Ring can be quickly changed to a half ring set up for improved access
- Blades can be micro-manipulated without flex arm extension readjustment
- Imaging compatible titanium retractor arms can remain in place during scanning



## **BUDDE**° Halo Radiolucent Retractor System:

Catalog #	Component	Quantity
443A1000	Halo Ring	1 Each
443A1070A	9" (229 mm) Halo Flex Arm	3 Each
443A1060	Rod Support Clamp Assembly	2 Each
443B1052	Radiolucent Support Rod	2 Each
438A1037	BUDDE <sup>®</sup> Halo Pattie Tray	1 Each
438A1140	BUDDE <sup>®</sup> Halo Mini Vise (not shown)	1 Each
443A1004	BUDDE® Halo Adjustment Wrench (not shown)	1 Each
443A1082	Retractor Arm Support	3 Each
443A1005	Halo Poly Vac Sterilization Case	1
438A1077	BUDDE® Curved Retractor Blades	2 Each
438A1082	TEW™ Micro Retractor Blades	1 Each
438A1083	TEW™ Micro Retractor Blades	1 Each
MFL438 A1200A	SAMY Vascular Retractors Short (3, 5, 7 mm)	1 set of 3
MFL438 A1200B	SAMY Vascular Retractors Long (3, 5, 7 mm)	1 set of 3

## **Optional Accessories:**

•	
Catalog #	Component
443A1070B	12" (300 mm) Halo Flex Arm
443A1070C	6" (150 mm) Halo Flex Arm
438A1151	TEW <sup>™</sup> Hooked Micro Retractor Blades (2 mm)
438A1152	TEW™ Hooked Micro Retractor Blades (4 mm)
438A1154	BUDDE® Tapered Retractor Blades
438A1155	TEW <sup>™</sup> Serrated Micro Retractor Blades (2 mm)
438A1157	TEW <sup>™</sup> Serrated Micro Retractor Blades (4 mm)

<sup>\*</sup>For more information, refer to our retraction Solution catalogue

## BUDDE: Halo Radiolucent Retractor System - ref A1096

The BUDDE' Halo Radiolucent Retractor System (REF A-1096) is designed to reduce or limit artifact during intracranial procedures where retraction of delicate brain tissue is required. The BUDDE' Halo Radiolucent Retractor is used in conjunction with the MAYFIELD' Skull Clamp (typically the MAYFIELD' Radiolucent Skull Clamp REF A-2002). The BUDDE' Halo Radiolucent Retractor attaches to the skull clamp after the sterile draping process is complete.

#### Contraindications

Do not use the MAYFIELD BUDDE Halo Radiolucent retractor System (A1096) for other indications than those provided.

## MAYFIELD\* Adult Radiolucent Disposable Skull Pins - A2020

The MAYFIELD' Radiolucent Disposable Skull Pins (A2020) are intended for use with a skull clamp that is placed on the patient's skull to hold the head and neck in a particular position during surgical procedures where rigid skeletal fixation is desired and intraoperative CT or MR imaging is used.

#### Contraindications

Do not use the MAYFIELD' Radiolucent Disposable Skull Pins (A2020) for other indications than those provided.

## MAYFIELD® Base Unit - ref A2079 / A2079E

#### Indications

The MAYFIELD' Base Unit Infinity XR2 (New A2079 / A2079E) is intended to be used to support a patient during diagnostic examination and/or surgical procedures when a rigid support between surgical table and headrest, or skull clamp is necessary, positional freedom is required and where X-ray imaging modalities will be used.

#### Contraindications

Do not use the MAYFIELD\* Base Unit Infinity XR2 (A2079) for other indications than those provided.

#### MAYFIELD° XR2 Tri-Star Swivel Adaptor - ref A2111 Indications

The MAYFIELD Infinity XR2 Tri-Star Swivel Adaptor (A2111) is designed to provide flexibility in positioning the patient's head by allowing rotation in 360 degrees. The MAYFIELD' Infinity XR2 Tri-Star Swivel Adaptor provides two extra starburst attachments for ancillary equipment, when needed.

#### Contraindications

Do not use the MAYFIELD' Infinity XR2 Tri-Star Swivel Adaptor – ref A2111 for other indications than those provided.

## MAYFIELD' Adult and Child Disposable Skull Pins - Adult: ref A1120 and Pediatric: ref

#### 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.

These skull pins are not recommended for use on children under five years of age and extreme caution should be exercised in pediatric cases because of the thin skull. The MAYFIELD' Disposable Titanium Skull Pins (Arity) 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' Child disposable Skull pins (A1119 and A1120) for other indications that those provided. Do not use the skull pins with the original GARDNER brand skull clamp.

#### MAYFIELD® Adult and Child Reusable Skull Pins - Adult: ref A1121 and Pediatric: ref A1122

#### Indications

The MAYFIELD\* Reusable Titanium Skull Pins (ref 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.

#### Contraindications

Do not use the MAYFIELD\* Reusable Titanium Skull Pins (ref A1121 and A1122) for other indications than those provided.

#### MAYFIELD® Spine Table Adaptor - ref A2600R

#### Indications

The MAYFIELD' Spine Table Adaptor is intended to be used to support a patient during diagnostic examination and/or surgical procedures where a rigid support between the carbon composite parallel rails style of surgery table and the skull clamp or headrest is necessary and positional freedom is required. (Item number A2600R is indicated for use when X-ray imaging modalities are required)

#### Contraindications

Do not use the MAYFIELD' Spine Table Adaptor (A2600R) for other indications than those provided

## MAYFIELD° Infinity XR2 Skull Clamp (A2114)

#### Indications

The MAYFIELD' Infinity XR2 Skull Clamp is placed on the patient's skull to hold their head and neck securely 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. In addition, the clamp is indicated for use durin utilization of imaging modalities such as intra-operative CT imaging, C-Arm X-Ray, and digital subtraction techniques.

#### Contraindications

Do not use the MAYFIELD' Skull Clamp Infinity XR2 (A2114) for other indications than those provided.

## MAYFIELD® Adult Radiolucent Horseshoe Headrests - ref A2010

#### Indications

The MAYFIELD Adult Radiolucent Horseshoe Headrest is intended to be used to support a patient's head in both the prone and supine positions during diagnostic examination o surgical procedures where support and stabilization of the head is desired but complete fixation of the head is not required.

#### Contraindications

Do not use the MAYFIELD' Adult Radiolucent Horseshoe Headrest for other indications than those provided.

## MAYFIELD® Pediatric Radiolucent Horseshoe Headrests - ref A2011

The MAYFIELD® Pediatric Radiolucent Horseshoe Headrest is intended to be used to support a patient's head in both the prone and supine positions during diagnostic examination or surgical procedures where support and stabilization of the head is desired but complete fixation of the head is not required.

#### Contraindications

Do not use the MAYFIELD' Pediatric Radiolucent Horseshoe Headrest for other indications than those provided.

## MAYFIELD® Infinity XR2 Radiolucent Base Units ("NEW" A2079, A2079E & Spine Table Adaptor A2600R)

### MAYFIELD° Infinity XR2 Radiolucent Base Unit includes:

Catalog #	Component	Quantity
"NEW" A2079 or A2079E	MAYFIELD® Base Unit	1
437A2400	Swivel Assembly Standard	1

## MAYFIELD° Spine Table Adaptor (A2600R) includes:

Catalog #	Component	Quantity
A2600R	Spine Table Adaptor	1
449A1030	XR2 Link Arm Adaptor	1
437A2400	XR2 Swivel adaptor	1

### **Optional Accessories:**

Catalog #		Quantity
A2111	MAYFIELD® XR2 Tri-Star Swivel Adaptor	1
437A2224	5 inch (12.7 cm) Link Arm Extension	1
437A2225	7 inch (17.8 cm) Link Arm Extension	1

## MAYFIELD® Infinity XR2 Skull Clamp (A2114)

### MAYFIELD® Infinity XR2 Skull Clamp includes:

Catalog #	Component	Quantity
A2114	MAYFIELD° Infinity XR2 Skull Clamp	1
439A1094	Removable Adult Rocker Arm	1

### **Optional Accessories:**

Catalog #		Quantity
439A1091	Removable Child Rocker Arm	1
439A1092	Metal-Free Conversion Accessory	1
439A1093	Force Module	1

## MAYFIELD® Infinity XR2 Horseshoe Headrests (A2010 & A2011)

### MAYFIELD Radiolucent Horseshoe Headrests\*:

Catalog #	Component	Quantity
A2010	MAYFIELD® Adult radiolucent Horseshoe Headrest	1
A2011	MAYFIELD® Pediatric radiolucent Horseshoe Headrest	1

## MAYFIELD° replacement parts:

Catalog #	Component
41C1444	Gel Pad, Left, Adult
41C1445	Gel Pad, Right, Adult
440C1011	Gel Pad, Left, Pediatric
440C1012	Gel Pad, Right, Pediatric

MAYFIELD® Skull Pins: For more information refer p. 8.

BUDDE® Halo Radiolucent Retractor System (A1096): For more information refer p. 10.

\*The above components are sold separately.

## Integra Contact - Sales & Marketing **EUROPE, MIDDLE-EAST and AFRICA**

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