UMEX™

UNIVERSAL MINI EXTERNAL FIXATOR

The
Inspired
Innovation

ADLER®

The Universal Mini External Fixator system derives its inspiration from the pinnacles of creativity and achievement in human endeavour. It aspires to provide the means to immaculately restore form and function with elegance and grace.

A mangled hand. A crushed foot. Talipes Equino Varus. These and myriad other afflictions of the hands and feet have posed complex challenges to surgeons the world over.

While external fixation has made rapid advancements in the management of open injuries and correction of deformities of the long bones, there has been a perceptible void in the development of mini fixator systems which contribute to the comprehensive management of trauma and deformities of the hands and feet.

CONCEPT AND PHILOSOPHY

Most of the commonly known mini-fixator systems are widely recognised to be miniature versions of conventional external fixator systems originally designed for use in the long bones. However, these miniaturised versions of large fixator systems fail to take into account the complex interplay of small bones and soft tissues, characteristic of the hands and feet. The following points serve to clearly illustrate the need for a completely new design philosophy and rationale to tackle these problems;

* The short long bones present a chain of skeletal elements interspersed by joints and spanned by common and segmental mobile units

* Complex multi-axial, multi-planar movements obligate stability of the immobilized segments while allowing functional mobilization of the unaffected segments.

* Close proximity of vital neurovascular structures impose severe constraints on placement of the anchoring devices used.

UMEX™, the Universal Mini External Fixator, a comprehensive, modular system, proven to successfully address a wide range of indications related to instability and deformity, has evolved over eight patient years of research, clinical application and constant refinement by a dedicated team of Indian orthopaedic surgeons and engineers. The UMEX™ system uses the K-wire as the anchoring device of choice. Schanz screws or threaded pins have a propensity to wind up soft tissues. Any attempt to unwind these tissues is accompanied by the inevitable backing out of the schanz screw. Further, dense cortical bone encountered in the diaphyseal areas of small bones necessitates pre-drilling for threaded anchoring devices.

THE SYSTEM

The Universal Mini External Fixator provides a stable skeletal hold using smooth, thin diameter K- wires (0.8mm - 2.5mm). This hold is utilized to construct a frame which stabilizes fractures and positions intervening joints in the functional attitude.

The ability to allow comfortable interdigital placement of the clamping elements is a critical design attribute of the UMEX™ system. This demanding requirement has led to the creation of small dimension, low profile clamping elements, ACTUAL SIZE  the smallest of which is only 8mm high.

The small dimensions complement a unique clamp design which allows the clamping action (of the connecting rod and K-wire) to be completed, simply, with the clockwise tightening of a single insert screw. 

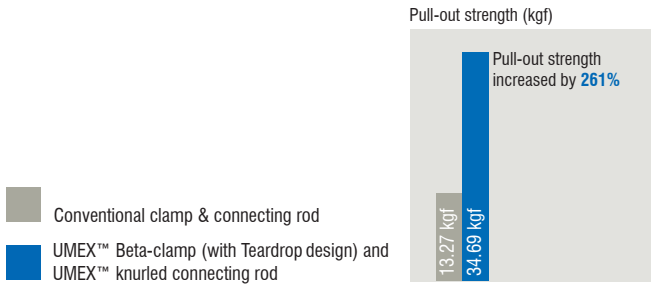
MECHANICAL PROPERTIES

Integrity of the bone-pin interface is widely accepted to be one of the most important factors in the maintenance of any external fixator construct. The Universal Mini External Fixator recognises the need for specially designed clamping elements to create a stable construct to enhance the integrity of the bone-pin interface.

UMEX™ clamps and the clamping elements in UMEX™ distractors are built with a patented Teardrop design which ensures three-point fixation of the K-wires. The design also lends itself to versatility of application by allowing optimal clamping of a range of wire diameters.

UMEX™ connecting rods are manufactured with specially knurled surfaces to improve the quality of the frictional interface between the insert screw, the connecting rod and the K- wire. 

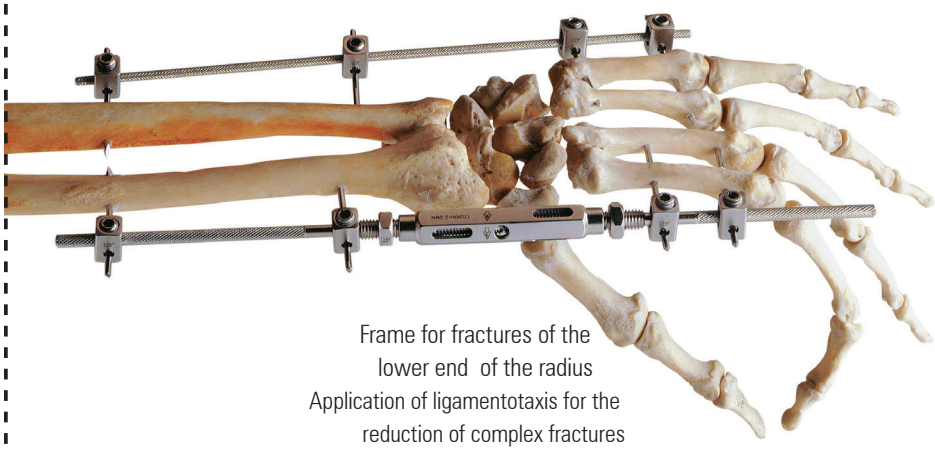
These design characteristics combine to provide a high pull-out strength (of K-wires in the clamped assembly) of upto 34.69 kgf as compared with an average of 13.27 kgf for conventional clamp and rod designs.



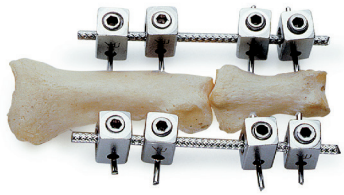
Pull-out strengths tested on an Instron 5586 using a dedicated fixture to hold the clamp assembly (Clamp, K-wire, connecting rod). Torque wrench used to standardise tightening torque of the insert screw.

APPLICATIONS - THE HAND

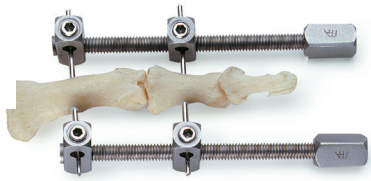
Innovatively designed low-profile clamping elements allow the operating surgeon to effectively manage most clinically unstable situations in the hand . The following examples serve to highlight the versatility of the UMEX™ system.



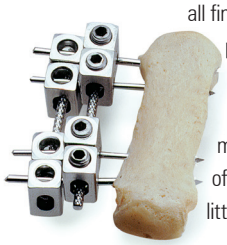
Frame for fractures of the lower end of the radius
Application of ligamentotaxis for the reduction of complex fractures of the distal end of the radius (may need to be supplemented by percutaneous K-wire fixation and bone grafting in selected cases).
Intra-operative distraction after osteotomies for malunited fractures of the distal radius.



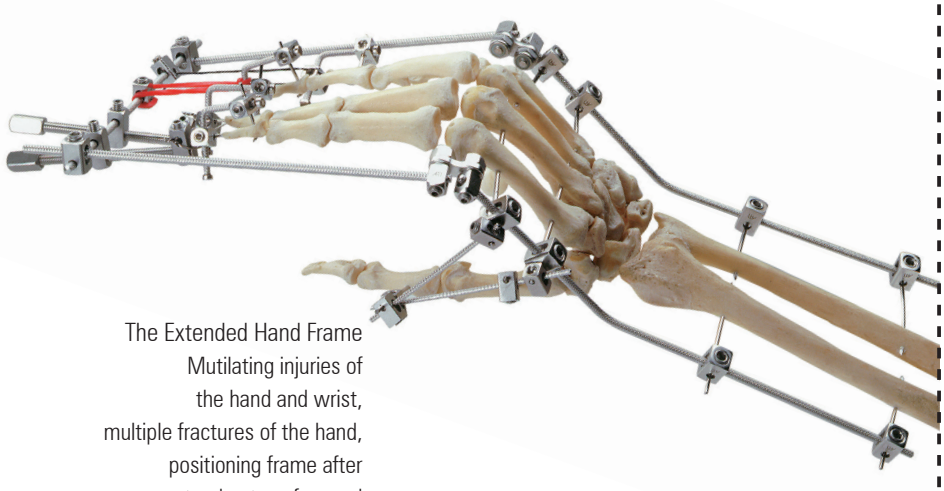
The Coplanar Frame
All fractures of the thumb and juxta-articular and intra-articular fractures of the fingers.



The Distraction Frame
Correction and maintenance of complex deformities of the hand and wrist, functional distraction-lengthening of amputated stumps.

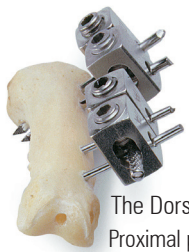


The Unilateral frame
Diaphyseal fractures of the middle phalanges of all fingers and proximal phalanges of the the index and little fingers; Isolated metacarpal fractures of the index and little fingers.



The Extended Hand Frame
Mutilating injuries of the hand and wrist, multiple fractures of the hand, positioning frame after tendon transfers and reconstructive surgery including microsurgery.

The Joint Spanning Frame
Juxta-articular and intra-articular fractures of the metacarpophalangeal joints of the index and little fingers.



The Dorso-lateral Frame
Proximal phalangeal fractures and isolated metacarpal fractures of the middle and ring fingers.

APPLICATIONS - THE FOOT

Percutaneous or open surgical correction of talipes equino varus has been widely reported to be associated with extensive scarring resulting in the weakening of crucial muscle groups, vital for locomotion.*

The UMEX™ club foot frame is capable of addressing complex three dimensional multi-axial deformities by fractional differential distraction to achieve progressive sequential correction. It has been noted that the correction achieved is maintained with growth and associated with remodelling of the skeletal elements.
The same frame erected by replacing distractors with static connecting rods is capable of stabilising fractures and dislocations of the foot and ankle in the anatomical position.

THE CLUBFOOT FRAME
Supple feet, no scarring. Fewer and milder relapses.
Computerised pedobarography
(Dr. Anil Bhave, MarylandCenter for limb lengthening and reconst., Baltimore, 1996)
*86% of the power of the gastrosoleus retained
*Heel in neutral position
*No calcaneal gait
*Proper stance phase timing (Data on file)

CONVENTIONAL CLUBFOOT SURGERY
13-50% unsatisfactory results
(W.B Lehman et. al., Revision surgery in club foot.
"The Clubfoot", Ed. George Simons. 1994, Springer Verlag)
Weakening of crucial muscle groups
(Ken N. Kuo et. al., Second International Congress on Clubfeet, Amsterdam, 1996)

UMEX™ COMPONENTS

DISTRACTORS

CODE NO	DESCRIPTION
F0301.0405	M4 Single hole -50mm (for finger)
F0301.0407	M4 Single hole -75mm
F0302.0407	M4 Double hole -75mm
F0302.0410	M4 Double hole -100mm
F0302.0415	M4 Double hole -150mm
F0302.0615	M6 Double hole -150mm
F0302.0620	M6 Double hole -200mm
F0302.0625	M6 Double hole -250mm
F0302.0630	M6 Double hole -300mm
F0304.0410	M4 Fishmouth -100mm
F0304.0415	M4 Fishmouth -150mm
F0304.0615	M6 Fishmouth -150mm
F0304.0620	M6 Fishmouth -200mm
F0304.0625	M6 Fishmouth -250mm
F0304.0630	M6 Fishmouth -300mm
F0305.0410	M4 Swivel -100mm
F0305.0415	M4 Swivel -150mm
F0305.0615	M6 Swivel -150mm
F0305.0620	M6 Swivel -200mm
F0305.0625	M6 Swivel -250mm
F0305.0630	M6 Swivel -300mm

DISTRACTION- COMPRESSION RODS (D-C)

CODE NO	DESCRIPTION
F0308.0475	M4 PIP Hinge Distractor -75mm
F0308.0410	M4 PIP Hinge Distractor -100mm
F0306.25	D-C Assembly -for 25mm Distraction
F0306.36	D-C Assembly -for 36mm Distraction
F0306.50	D-C Assembly -for 50mm Distraction
F0307.0625	Central sleeve -for 25mm D-C Assy.
F0307.0636	Central sleeve -for 36mm D-C Assy.
F0307.0650	Central sleeve -for 50mm D-C Assy.
F0407.0406	Rod 4mm; left threaded length 60mm
F0407.0408	Rod 4mm; left threaded length 80mm
F0407.0410	Rod 4mm; left threaded length 100mm
F0407.0415	Rod 4mm; left threaded length 150mm
F0406.0406	Rod 4mm; right threaded length 60mm
F0406.0408	Rod 4mm; right threaded length 80mm
F0406.0410	Rod 4mm; right threaded length 100mm
F0406.0415	Rod 4mm; right threaded length 150mm
F0308.0407	Three-block Distractor for deformity correction

UMEX™ COMPONENTS

CLAMPS

CODE NO	DESCRIPTION
F0101.2030	Alpha Clamp (Upto 2mm wire, 3mm rod)

Minimum pack size - 5pcs. / pack

F0101.3040	Beta Clamp (Upto 3mm wire, 4mm rod)

Minimum pack size - 5pcs. / pack

F0102.3040	Beta Clamp Add on (Upto 3mm wire, 4mm rod)

Minimum pack size - 2pcs. / pack

F0101.4040	Beta Clamp- 4 x 4 (Upto 4mm wires/rods)

HINGES

F0202.40	Bi-axial Uniplanar hinge joint

Minimum pack size - 1pc. / pack

STRAIGHT RODS - KNURLED

F0401.2007	Straight Rod 2mm x 75mm
F0401.2010	Straight Rod 2mm x 100mm

F0401.2507	Straight Rod 2.5mm x 75mm
F0401.2510	Straight Rod 2.5mm x 100mm
F0401.2515	Straight Rod 2.5mm x 150mm
F0401.2520	Straight Rod 2.5mm x 200mm

STRAIGHT RODS - KNURLED - contd.

CODE NO	DESCRIPTION
F0401.3007	Straight Rod 3mm x 75mm
F0401.3010	Straight Rod 3mm x 100mm
F0401.3015	Straight Rod 3mm x 150mm
F0401.3020	Straight Rod 3mm x 200mm
F0401.3025	Straight Rod 3mm x 250mm
F0401.3030	Straight Rod 3mm x 300mm

F0401.4010	Straight Rod 4mm x 100mm
F0401.4015	Straight Rod 4mm x 150mm
F0401.4020	Straight Rod 4mm x 200mm
F0401.4025	Straight Rod 4mm x 250mm
F0401.4035	Straight Rod 4mm x 350mm
F0401.4045	Straight Rod 4mm x 450mm

Minimum pack size - 2pcs. / pack

BENT RODS - KNURLED

F0402.2501	Small 'L' Rod -2.5mm
F0402. 3001	Small 'L' Rod -3.0mm
F0402. 4001	Small 'L' Rod -4.0mm

F0402.2502	Large 'L' Rod -2.5mm
F0402.3002	Large 'L' Rod -3.0 mm
F0402. 4002	Large 'L' Rod -4.0mm

F0403. 2503	'Z' Rod -2.5mm
F0403. 3003	'Z' Rod -3.0mm
F0403. 4003	'Z' Rod -4.0mm

Minimum pack size - 2pcs. / pack

UMEX™ COMPONENTS

TRACTION DEVICES - STIRRUPS

	CODE NO	DESCRIPTION
	F0601. 01	Mini Traction bow (Full Stirrup)
	F0601. 02	Mini Traction bow (Half Stirrup)

Minimum pack size - 1pc. / pack

INSTRUMENTS

	F0703. 01	Bender Tube, pair
	F0701. 0608	Spanner 6mm/8mm
	F0701. 1011	Spanner 10mm/11mm
	F0702. 00	Quick lock handle for Allen Keys
	F0702. 0120	Allen Key 2.0mm A/F, disposable
	F0702. 0130	Allen Key 3.0mm A/F, disposable
	F0705. 01	Clamp forceps
	F0705. 02	Rod and wire gauge

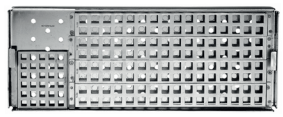
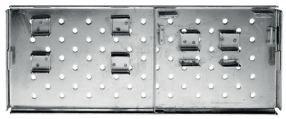
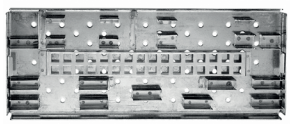
Minimum pack size - 1pc. / pack

IMPLANTS & MISC. COMPONENTS

CODE NO	DESCRIPTION
B1105. 1015	'K' wire ADLER™ 1.0mm x 150.mm
B1105. 1215	'K' wire ADLER™ 1.2mm x 150.mm
B1105. 1515	'K' wire ADLER™ 1.5mm x 150.mm
B1105. 1815	'K' wire ADLER™ 1.8mm x 150.mm
B1105. 2015	'K' wire ADLER™ 2.0mm x 150.mm
B1105. 2515	'K' wire ADLER™ 2.5mm x 150.mm

Minimum pack size - 5pcs. / pack

S.S. STERILISATION CASES AND TRAYS

	D0101. 0201	S.S. Case for UMEX™ Comprehensive set
	D0102. 0301	S.S. Tray 1 for Clamps
	D0102. 0302	S.S. Tray 2 for Instruments / K-wires
	D0102. 0303	S.S. Tray 3 for Bent Rods
	D0102. 0304	S.S. Tray 4 for Distractors
	D0102. 0305	S.S. Tray 5 for Rods /Special clamps

UMEX™ SETS

E0701.011* DIGITAL FRACTURES' SET

CODE NO	DESCRIPTION	QUANTITY
	CLAMPS	
F0101.2030	Alpha Clamp (Upto 2mm wire, 3mm rod)	10
F0101.3040	Beta Clamp (Upto 3mm wire, 4mm rod)	10
	STRAIGHT RODS - KNURLED	
F0401.2007	Straight Rod 2mm x 75mm	2
F0401.2010	Straight Rod 2mm x 100mm	2
F0401.3010	Straight Rod 3mm x 100mm	2
	INSTRUMENTS	
F0702.0120	Allen Key 2.0mm A/F, disposable	1
F0702.0130	Allen Key 3.0mm A/F, disposable	1
	K-WIRES - ADLER™	
B1105.1215	K-wire 1.2mm x 150mm	5
B1105.1515	K-wire 1.5mm x 150mm	5

Also available

*E0701.01 Digital Fractures' set without K-wires

E0701.021* LOWER END RADIUS SET

CODE NO	DESCRIPTION	QUANTITY
	DISTRACTION-COMPRESSION RODS	
F0306.25	Distraction-Compression (D-C) assembly for 25mm distraction	1
	CLAMPS	
F0101.3040	Beta Clamp (upto 3mm wire, 4mm rod)	15
	STRAIGHT RODS - KNURLED	
F0401.3025	Straight rod 3mm x 250mm	2
	INSTRUMENTS	
F0701.1011	Spanner 10mm / 11mm	1
F0702.0120	Allen Key 2.0mm A/F, disposable	1
F0702.0130	Allen Key 3.0mm A/F, disposable	1
	K-WIRES ADLER™	
B1105.2015	K-wire 2.0mm x 150mm	10

Also available

*E0701.02 Lower End Radius set without K-wires

E0701.031* BASIC HAND SET

CODE NO	DESCRIPTION	QUANTITY
	DISTRACTORS	
F0302.0407	M4 Double Hole - 75mm	2
	CLAMPS	
F0101.2030	Alpha Clamp (upto 2mm wire, 3mm rod)	10
F0101.3040	Beta Clamp (upto 3mm wire, 4mm rod)	20
F0102.3040	Beta Clamp Add-on (upto 3mm wire, 4mm rod)	2
	STRAIGHT RODS - KNURLED	
F0401.3010	Straight rod 3mm x 100mm	4
F0401.3015	Straight rod 3mm x 150mm	2
F0401.3020	Straight rod 3mm x 200mm	2
F0401.3025	Straight rod 3mm x 250mm	2

E0701.031* BASIC HAND SET - contd.

	DESCRIPTION	QUANTITY
	INSTRUMENTS	
F0702.0120	Allen Key 2.0mm A/F, disposable	1
F0702.0130	Allen Key 3.0mm A/F, disposable	1
	K-WIRES ADLER™	
B1105.1515	K-wire 1.5mm x 150mm	5
B1105.1815	K-wire 1.8mm x 150mm	10

Also available

*E0701.03 Basic Hand set without K-wires

E0701.041* EXTENDED HAND FRAME SET

CODE NO	DESCRIPTION	QUANTITY
	DISTRACTORS	
F0302.0410	M4 Double Hole - 100mm	2
	CLAMPS	
F0101.2030	Alpha Clamp (upto 2mm wire, 3mm rod)	10
F0101.3040	Beta Clamp (upto 3mm wire, 4mm rod)	20
F0102.3040	Beta Clamp Add-on (upto 3mm wire, 4mm rod)	6
F0101.4040	Beta Clamp - 4 x 4 (upto 4mm wires / rods)	4
	HINGES	
F0202.40	Bi-axial uniplanar hinge joint	2
	STRAIGHT RODS - KNURLED	
F0401.2010	Straight rod 2mm x 100mm	2
F0401.3010	Straight rod 3mm x 100mm	2
F0401.3020	Straight rod 3mm x 200mm	2
F0401.3025	Straight rod 3mm x 250mm	2
	TRACTION DEVICES - STIRRUPS	
F0601.02	Mini Traction Bow (Half-stirrup)	4
	INSTRUMENTS	
F0702.0120	Allen Key 2.0mm A/F, disposable	1
F0702.0130	Allen Key 3.0mm A/F, disposable	1
F0701.0608	Spanner 6mm/8mm	2
	K-WIRES ADLER™	
B1105.1515	K-wire 1.5mm x 150mm	10
B1105.2015	K-wire 2.0mm x 150mm	10

Also available

*E0701.04 Extended Hand Frame Set without K-wires

E0701.051* HAND FRAME for deformity correction

CODE NO	DESCRIPTION	QUANTITY
	DISTRACTORS	
F0301.0407	M4 Single Hole Distractor 75mm	1
F0308.0407	Three-Block Distractor for deformity correction	5
	CLAMPS	
F0101.2030	Alpha Clamp (Upto 2mm Wire, 3mm rod)	10
F0101.3040	Beta Clamp (Upto 3mm wire, 4mm rod)	20
F0102.3040	Beta Clamp - Add on (Upto 3mm wire, 4mm rod)	2
F0101.4040	Beta Clamp - 4 x 4	4
	HINGES	
F0202.40	Bi-axial Uniplanar hinge joint (Upto 4mm wires / rods)	2

UMEX™ SETS

E0701.051 * HAND FRAME for deformity correction contd.

CODE NO	DESCRIPTION	QUANTITY
	STRAIGHT RODS - knurled	
F0401.2010	Straight Rod 2mm x 100mm	2
F0401.3010	Straight Rod 3.0mm x 100mm	2
F0401.3020	Straight Rod 3.0mm x 200mm	2
F0401.3025	Straight Rod 3.0mm x 250mm	2
	TRACTION DEVICES - STIRRUPS	
F0601.02	Mini Traction bow (Half Stirrup)	5
	INSTRUMENTS	
F0701.0608	Spanner 6mm/8mm	2
F0702.0120	Allen Key 2.0mm A/F disposable	1
F0702.0130	Allen Key 3.0mm A/F disposable	1

IMPLANTS & MISC. COMPONENTS

	K-WIRES- 'ADLER'	
B1105.1215	'K' wires, 1.2mm x 150mm	5
B1105.1515	'K' wires, 1.5mm x 150mm	5
B1105.2015	'K' wires, 2.0mm x 150mm	5
B1105.2515	'K' wires, 2.5mm x 150mm	5

Also available

*E0701.05 Hand Frame for deformity correction without K-wires

E0702.011* SMALL CTEV SET

CODE NO	DESCRIPTION	QUANTITY
	DISTRACTORS	
F0302.0410	M4 Double Hole - 100mm	2
F0304.0415	M4 Fish Mouth - 150mm	2
	CLAMPS	
F0101.3040	Beta Clamp (upto 3mm wire, 4mm rod)	25
F0102.3040	Beta Clamp Add-on (upto 3mm wire, 4mm rod)	6
	STRAIGHT RODS - KNURLED	
F0401.3010	Straight rod 3mm x 100mm	4
F0401.3015	Straight rod 3mm x 150mm	2
F0401.3020	Straight rod 3mm x 200mm	2
	BENT RODS - KNURLED	
F0402.2501	Small 'L' rod - 2.5mm	2
F0402.2502	Large 'L' rod - 2.5mm	2
F0403.2503	'Z' rod - 2.5mm	2
	INSTRUMENTS	
F0702.0120	Allen Key 2.0mm A/F, disposable	1
F0702.0130	Allen Key 3.0mm A/F, disposable	1
	K-WIRES ADLER™	
B1105.1515	K-wire 1.5mm x 150mm	5
B1105.1815	K-wire 1.8mm x 150mm	5

Also available

*E0702.01 Small CTEV set without K-wires

E0702.012 SMALL CTEV SET with swivel distractors same content as E0702.011except
F0305.0410 M4 Swivel, 100mm replaces F0302.0410
F0305.0415 M4 Swivel, 150mm replaces F0304.0415.

E0702.021* MEDIUM CTEV SET

CODE NO	DESCRIPTION	QUANTITY
	DISTRACTORS	
F0302.0615	M6 Double Hole - 150mm	2
F0304.0620	M6 Fish Mouth - 200mm	2
	CLAMPS	
F0101.3040	Beta Clamp (upto 3mm wire, 4mm rod)	25
F0102.3040	Beta Clamp Add-on (upto 3mm wire, 4mm rod)	6
	STRAIGHT RODS - KNURLED	
F0401.3010	Straight rod 3mm x 100mm	2
F0401.3015	Straight rod 3mm x 150mm	6
F0401.3020	Straight rod 3mm x 200mm	2
	BENT RODS - KNURLED	
F0402.3001	Small 'L' rod - 3.0mm	2
F0402.3002	Large 'L' rod - 3.0mm	2
F0403.3003	'Z' rod - 3.0mm	2
	INSTRUMENTS	
F0702.0120	Allen Key 2.0mm A/F, disposable	1
F0702.0130	Allen Key 3.0mm A/F, disposable	1
	K-WIRES ADLER™	
B1105.1815	K-wire 1.8mm x 150mm	5
B1105.2015	K-wire 2.0mm x 150mm	5

Also available

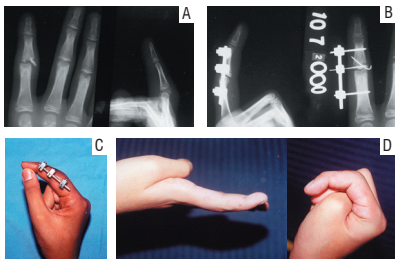
*E0702.02 Medium CTEV set without K-wires

E0702.022 MEDIUM CTEV SET with swivel distractors
same content as E0702.021except
F0305.0615 M6 Swivel, 150mm replaces F0302.0615,
F0305.0620 M6 Swivel, 200mm replaces F0304.0620

E0702.031* LARGE CTEV SET

CODE NO	DESCRIPTION	QUANTITY
	DISTRACTORS	
F0302.0620	M6 Double Hole - 200mm	2
F0304.0630	M6 Fish Mouth - 300mm	2
	CLAMPS	
F0101.3040	Beta Clamp (upto 3mm wire, 4mm rod)	15
F0102.3040	Beta Clamp Add-on (upto 3mm wire, 4mm rod)	6
F0101.4040	Beta Clamp - 4 X 4 (upto 4mm wires / rods)	20
	STRAIGHT RODS - KNURLED	
F0401.4010	Straight rod 4mm x 100mm	2
F0401.4015	Straight rod 4mm x 150mm	6
F0401.4045	Straight rod 4mm x 450mm	2
	BENT RODS - KNURLED	
F0402.4001	Small 'L' rod - 4.0mm	2
F0402.4002	Large 'L' rod - 4.0mm	2
F0403.4003	'Z' rod - 4.0mm	2
	INSTRUMENTS	
F0701.0608	Spanner 6mm / 8mm	1
F0701.1011	Spanner 10mm / 11mm	1
F0702.0120	Allen Key 2.0mm A/F, disposable	1
F0702.0130	Allen Key 3.0mm A/F, disposable	1

CLINICAL CASES

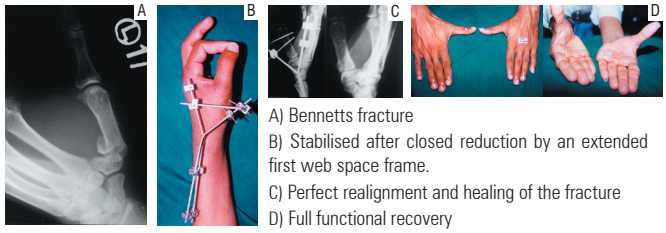


A) Two week old Salter Harris Type III intraarticular fracture of the middle phalanx of the right index finger.

B) Open reduction and articular reconstruction done maintaining the central slip of the extensor.

C) Neutralisation frame adding stability to the fixation by involving the physeal wire.

D) Function at the end of two months.

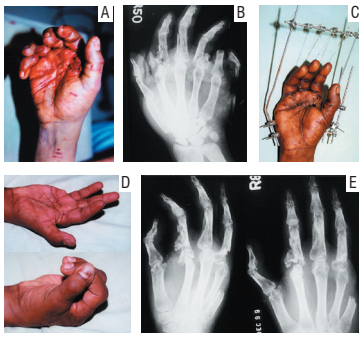


A) Bennetts fracture

B) Stabilised after closed reduction by an extended first web space frame.

C) Perfect realignment and healing of the fracture

D) Full functional recovery



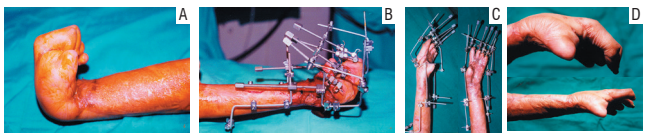
A) A typical burst injury of the hand

B) Shattered phalanges with jeopardised vascularity of the fingers

C) Simple hand frame applied keeping the fingers aligned and the first web space stretched

D) Excellent functional recovery

E) X-rays showing the quality of the healing in 12 weeks

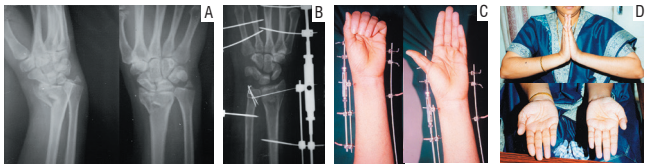


A) Devastation following thermal burns in a 9 year old boy.

B) Deformity correction frame applied after negligible benefit from an open release

C) Gradual, sequential distraction correction of all deformities

D) Correction of deformities of the thumb, wrist and the fingers, maintained over 3 months. Awaiting further reconstruction.

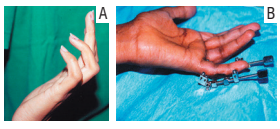


A) Frykman VIII injury of the distal radius

B) Closed reconstruction of the distal radius articular surface and DRUJ using the UMEX DC assembly with open reduction and fixation of the ulnar styloid

C) Good function of the hand during treatment

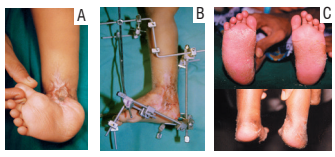
D) Full clinical functional recovery



A) Uncorrectable flexion contractures of the ring and little fingers following Zone II flexor tendon injuries

B) Use of the hinged distractors to correct the deformities gradually in two weeks.

C) Complete correction



A) Failed attempted open release with severe scarring and accentuation of the deformity

B) Fractional distraction over four weeks with the UMEX CTEV frame realigns the foot and ankle with composite tissue expansion and stretching of the scarred area by over 250%

C) Forefoot deformities are fully corrected with excellent correction of the heels

IMPORTANT MEDICAL INFORMATION
Warning and Precautions
THE UNIVERSAL MINI EXTERNAL FIXATOR SYSTEM

Note: The Universal Mini External Fixator system is for use only by a registered medical practitioner or by a hospital.

A Patient selection

1. Immunological Intolerance: Some patients may have immunological intolerance to implanted materials and foreign body sensitivity tests should be performed to rule out sensitivity in such cases.

2. Mental Illness: Patients suffering from mental illnesses may ignore limitations and precautions related to the use of this device, which may lead to failure or associated complications.

3. Alcohol / Drug addiction: Complications may arise in patients addicted to alcohol and or drugs who may ignore necessary precautions following the use of this device.

B. Indications and Contraindications

Indications suggested in this document serve only as guidelines. While using this device, the operating surgeon should ensure that the line of treatment followed is that which addresses the specific needs of the patient in any given situation.

The use of this device may be contraindicated in the following situations:

1. Active infection at the site of passage of the anchoring devices (K-wires)

2. This device should be used with caution in patients suffering from diabetes mellitus, hypertension and other medical conditions which may pose problems in the postoperative period. Appropriate medical treatment should be instituted prior to undertaking surgery in such patients.

C. Training

Surgeons intending to use this device must be familiar with the anatomy, physiology, pathology and natural history of the conditions being treated.

It is further recommended that the operating surgeon should attend specific training courses/ workshops / fellowships pertaining to the application of this device.

D. Patient education and compliance

The success of this device, as with any fixation system, is greatly dependent on patient compliance, especially during the course of the treatment. It is thus imperative that the patient / parents are informed about the procedure, the aftercare and the expected outcome.

When dealing with deformities, distraction lengthening and similar applications, it must be explicitly explained that the procedure would be a gradual one and that the frame would remain on the patient for periods varying from three weeks to three months generally depending on the specific clinical situation. The possible need for additional minor procedures and readjustments must be communicated to the patients / parents prior to commencement of the procedure.

E. Postoperative management

1. The Pin tracks: Regular care of the pin tracks and good general hygiene are mandatory.

2. The fixator: As with any external fixator system, it is advisable to periodically check the integrity of the clamping elements. Modulation or change in the configuration of the frame may be necessary as the treatment (correction in case of deformity) progresses. Occasionally, incorporation of splints may be necessary to assist mobilisation.

F. Compatibility / Reuse of fixator components

1. Compatibility: Components of the UMEX™ system are specially designed and manufactured with pre-defined dimensional relationships between components used as parts of assemblies. This device is not designed to be compatible with any other external fixation system.

2. Reuse of components: Used components, particularly those with threaded / knurled parts, which appear undamaged, may have internal and external defects with accumulated stresses, which may not be revealed, even by a thorough individual stress analysis of each component. Reuse of components is likely to compromise the stability of a construct which may ultimately lead to failure of the procedure.

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AHPL.IX.2023.15.a