# **Pega** Medical

### FASSIER — DUVAL TELESCOPIC IM SYSTEM™



For the treatment of osteogenesis imperfecta, tibial pseudoarthrosis and other bone deformities

#### SURGICAL TECHNIQUE

# FASSIER - DUVAL TELESCOPIC IM SYSTEM

#### FASSIER – DUVAL TELESCOPIC IM SYSTEM™

Developed in collaboration with:

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Pierre Duval, MD, FRCS(C Quebec, Canada The Fassier-Duval Telescopic Intramedullary System is a new rod designed for patients suffering from Osteogenesis Imperfecta (OI), skeletal dysplasia and other bone deformities. Created to prevent or stabilize fractures, or correct deformity of the long bones whilst growth occurs. It is indicated for children 18 months and older suffering from Ol, also pseudoarthrosis and can be used concomitantly with external fixators in older children or short statured adults with limb length discrepancy. The Fassier-Duval rod has been designed for the femur, tibia and humerus.

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#### **PRELIMINARIES FEMORAL NAIL**

#### Choice of the technique

The standard technique usually employed is the open osteotomy technique. For patients with large bones and thin cortices, the use of the per cutaneous technique is recommended.

#### Choice of nail size

Estimate the length  $(\ell)$  of the rectified bone after osteotomy(ies).  $\ell$  is the distance between the Greater Trochanter and the distal growth plate. The maximum length of the uncut nail of the chosen size should be long enough to reach the distal epiphysis. The length of the female hollow component is cut pre-operatively to a length of  $\ell$ -7 mm. The length of the male solid nail is cut intraoperatively after both components are implanted, leaving 10 to 15 mm protruding from the proximal end to accommodate for future growth. The choice of L (long), S (short) or LON series, which defines the length of the distal thread or non-threaded fixation, should be based on the height of the distal epiphysis as measured from A-P x-ray film (see page 17).



**Antero-posterior view** 

#### **OPEN OSTEOTOMY TECHNIQUE**

#### Step 1

Through a classic postero-lateral approach, the femur is exposed subperiosteally. Subsequently the first osteotomy is executed under C-arm guidance.

#### Step 2

Reaming of the proximal fragment is done with a cannulated reamer or drill up to the Greater Trochanter over a small diameter guide wire (G-wire 016 or G-wire 020). The diameter of the reamer provided with the instrument set (DR132, DR140, DR148, DR156 and DR164) are 0.25 to 0.35 mm larger than the diameter of the correspondent Fassier-Duval Nail implant size chosen. The distal fragment is prepared in the same fashion. If the guide-wire does not reach the distal epiphysis, a second osteotomy should be performed after reaming the intermediate fragment.



**First osteotomy** 

rger ail he same hysis, the K-wire

Male driver

Male driver

K-wire (Male size)

Lock position

Spongy bone

Unlock position

Male driver

#### STEP 3

A male-size K-wire (not supplied) is inserted on the retrograde direction from the osteotomy through the proximal fragment (in case for a need of a second osteotomy, the male nail is inserted from the distal osteotomy). A second incision will be done at the buttock to allow the extremity of the K-wire to exit proximally.

The male driver (MDr132-L, MDr140-L, MDr148-L, MDr156-L or MDr164-L) is introduced over the male-size K-wire.

#### STEP 4

Male nail

The K-wire is removed and the male solid nail is placed in the male driver, making sure that the wings of the male solid nail are fitted into the male driver slot.

The male drivers have the possibility to lock the male component to facilitate maneuvering the nail upon insertion. To lock the male implant component after it is inserted inside the male driver, simply rotate the eccentric ring to the LOCK position.

#### Step 5

The male solid nail is pushed distally after reduction of the osteotomy(ies) and screwed into the distal epiphysis. Verify under fluoroscope that the distal thread is positioned beyond the growth plate (otherwise normal growth may be affected.) Optimal position of the male solid nail on the distal femoral epiphysis is achieved by centering the distal tip on both the antero-posterior and the lateral views. For Short thread and LON components see "Specifics on distal fixation" on page 17.

Once the male implant component has been screwed into the distal epiphysis, unlock the male by rotating the eccentric ring to the UNLOCK position before removing the male driver.

### WARNING: Failure to unlock the male driver from the male, may result in the male implant component being pulled out of the epiphysis and consequently lack of secure fixation.

**Epiphysis** 

The male driver is designed only to screw the male component. Do not use the male driver to reduce the fracture. Align the bone segments before advancing the driver into the canal. Incorrect use of the male driver could result in instrument damage.



**Physis** 

**Male nail** 

Sт	ΈP	6

Removal of the male driver (unlock position) is done with the assistance of the pushrod (PSR100) to reduce stressing of the nail fixation while the driver is pulled back.

#### Step 7

The female hollow nail is screwed into the Greater Trochanter using the female driver (FDr100 or FDr101).

The threaded portion of the female head should be inserted in bone (at least one to two threads), whereas the non-threaded part of the female head should be left within the non-ossified part of the Greater Trochanter.

Push rod

(Counter pressure)

Malpositioning of the implant may result in abnormal loading conditions, which may be conducive to premature implant failure.

#### STEP 8

The female driver is then removed and the male solid nail is cut with the Male Cutter (MC200) for a closer resection of the free end of the male component after the female component is implanted in place. Through a 2.5 cm incision, the size-specific exchangeable cutting tubes can cut the male component leaving a stub 10 to 15 mm above the female head for future growth.

#### STEP 9

The smoothness of the cut end of the male is checked with the probe (PRO132-140, PRO148-156 or PRO164) of appropriate size. Then, incisions are finally closed.





Male Cutter

Male driver pulled back

End of the nail

Male driver



end checked with the probe

Male Rod cut

Ж

#### PER CUTANEOUS TECHNIQUE



See the Open osteotomy technique (steps 4 to 9)

#### FEMORAL IMPLANT SPECIFICATIONS

Catalog #	Size Ø x Length [mm]	PROXIMAL FIXATION [MM]	DISTAL FIXATION [MM]		
Standard femoral implants (long threaded distal fixation)					
FD-032(L)-SS	Ø3.2 x 202	67	40 # gl3.2		
FD-040(L)-SS	Ø4.0 x 338	16.5	÷ .		
FD-048(L)-SS	Ø4.8 x 410	(110 16.5	12 12 14.0		
FD-056(L)-SS	Ø5.6 x 410	g10.75	135		
FD-064(L)-SS	Ø6.4 x 412	911.5 16.5	15		
Smi	all femoral or tib	ial implants (short threaded dist	al fixation)		
FD-032(S)-SS	Ø3.2 x 197	67			
FD-040(S)-SS	Ø4.0 x 333	18.5	1 5 5 6 6 7		
FD-048(S)-SS	Ø4.8 x 404	16.5	7		
FD-056(S)-SS	Ø5.6 x 405	g110.75	8.5 		
FD-064(S)-SS	Ø6.4 x 407	911.5 16.5	10 M		

#### FEMORAL IMPLANT SPECIFICATIONS

Catalog #	Size Ø x Length [mm]	PROXIMAL FIXATION [MM]	DISTAL FIXATION [MM]
	LON femoral ir	nplants (non-threaded distal fixe	ation)
FDLON-F032-SS	Ø3.2 x 194	d7	g13.2
FDLON-F040-SS	Ø4.0 x 330	18.5	84.0
FDLON-F048-SS	Ø4.8 x 400	(\$10 16.5	g44.8
FDLON-F056-SS	Ø5.6 x 411	14.5	Ø5.6
FDLON-F064-SS	Ø6.4 x 411	011.5 16.5	ph.4

#### **PRELIMINARIES TIBIAL NAIL**

#### Choice of the technique

The standard technique usually employed is the open osteotomy technique. Percutaneous technique is not recommended for the tibia.

#### Choice of nail size

Estimate the length ( $\ell$ ) of the rectified bone after osteotomy(ies) and x-ray magnification correction if necessary.  $\ell$  is the distance between the superior margin of the ossified proximal epiphysis and the distal growth plate. The maximum length of the uncut nail of the chosen size should be long enough to reach the distal epiphysis. The length of the female hollow component is cut pre-operatively to a length of  $\ell$ -7 mm. The length of the male solid nail is cut intraoperatively after both components are implanted. Check that the thickness of the proximal tibial epiphysis is more than 12 mm. The choice of L (long), SPS (short) or LON series, which defines the length of the distal thread or non-threaded fixation, should be based on the height of the distal epiphysis as measured from A-P x-ray film (see page 17).



**Mediolateral view** 

#### Step 1

Through a classic anteromedial approach, the patellar tendon is retracted laterally to expose the proximal tibia. The pre-spinal extra-articular surface of the tibial plateau should be exposed. Create an entry portal using a tibial awl or a K-wire. The apex of the tibial deformity is exposed through an anterior approach. The periosteum is elevated and after checking the level of the first osteotomy wit the C-arm, the osteotomy is done. Once completed, an osteoclasis or osteotomy of the fibula is done.

#### STEP 2

A small diameter guide-wire (G-wire 016 or G-wire 020) is inserted anterograde from the tibial plateau with special care not to bend it. Preparation of the proximal fragment is done with a size-specific cannulated reamer of the appropriate size (DR132, DR140, DR148, DR156 and DR164). All reamers provided in the system are 0.25 to 0.35 mm larger than the diameter of the Fassier-Duval Nail implant size chosen. The distal fragment is prepared in the same fashion. If the guide-wire guide does not reach the distal epiphysis, a second (or third) osteotomy should be performed after reaming the intermediate fragment.





Male driver

#### STEP 3

Once the proper alignment of the fragments is achieved over the reamer with the position of the distal fixation defined in a neutral position (nail axis must be perpendicular to the joint line on the AP view and in the middle of the epiphysis on the lateral view), the reamer and guiding wire are replaced by the male and its driver (MDr132-L, MDr140-L, MDr148-L, MDr156-L or MDr164-L). The male is once again inserted on the anterograde direction from the proximal entry point and pushed through the reduced osteotomy (ies) making sure the male wings are properly fitted into the driver's slots at all times.

The male drivers have the possibility to lock the

male component to facilitate maneuvering the nail upon insertion. To lock the male implant component after it is inserted inside the male driver, simply rotate the eccentric ring to the LOCK position.

#### Step 4

The male solid nail is pushed distally after reduction of the osteotomy(ies) and screwed into the distal epiphysis.

Male solid nail

The fixation differs with the type of implant chosen. For short thread and LON components see "Specifics on distal fixation" on page 17. Verify the position of the distal fixation under image intensifier.

**Epiphysis** 

Once the male implant component has been fixed into the distal epiphysis, unlock the male by rotating the eccentric ring to the UNLOCK position before removing the male driver.

# WARNING: Failure to unlock the male driver from the male, may result in the male implant component being pulled out of the epiphysis and consequently lack of secure fixation.

WARNING. The male driver is designed only to screw the male component. Do not use the male driver to reduce the fracture. Align the bone segments before advancing the driver into the canal. Incorrect use of the male driver could result in instrument damage.



**Male nail** 

#### STEP 5

Removal of the male driver (unlock position) is done with the assistance of the Pushrod (PSR100) or a small diameter K-wire to reduce stressing of the nail fixation while the driver is pulled back.

End of the nail Male solid nail

**Female nail** 

**Male Rod cut** 

Male driver pulled back

Limit of the cartilage

Male Cútter

Probe

#### Step 6

The female component, previously cut to size, is then placed over the male and screwed into the proximal tibial epiphysis using the female driver (FDr100 or FDr101).

Push rod

(Counter pressure)

Female driver

#### Step 7

The threaded portion of the female head should be completely inserted in tibial epiphysis, making sure no threads are left across the proximal growth plate. The female driver is then removed and the male solid nail is cut using the male cutter (MC200) flush with the head of the female nail to prevent

interference with the patella tendon and articular surfaces. A full range of motion of the knee must be obtained before closing the wound.

#### Step 8

The smoothness of the cut end of the male is checked with the probe (PRO132-140, PRO148-156 or PRO164) of appropriate size. Then, incisions are finally closed.





#### **PRELIMINARIES HUMERAL NAIL**

#### Choice of nail size

Estimate the length  $(\ell)$  of the rectified bone after osteotomy(ies).  $\ell$  is the distance between the tip of the humeral head and the growth plate of the lateral condyle. The maximum length of the uncut nail of the chosen size should be long enough to reach the distal epiphysis. The length of the female hollow component is cut pre-operatively to a length of  $\ell$ -7 mm. The length of the male solid nail is cut intraoperatively but, unlike femoral rodding, the nail should not protrude above the female hollow nail -due to a risk of interference with the rotator cuff.

The choice of SPS (short) or LON series which defines the length of the distal thread or non threaded fixation should be based on the size of the epiphysis on the lateral condyle as measured from A-P x-ray film (see page 17).



Step 1

Through a classic anterolateral approach between the Brachialis anterior and the wrist extensors, the radial nerve is identified and protected. The humerus is then approached subperiosteally and the first osteotomy is executed under C-arm guidance.



K-wire

#### Step 2

Reaming of the proximal fragment is done with a cannulated reamer or drill up to the Greater Tuberosity over a small diameter guidewire (G-wire 016 or G-wire 020) . The diameter of the reamers included in the instrument set (DR132, DR140, DR148, DR156 and DR164) are 0.25 to 0.35 mm larger than the diameter of the Fassier-Duval Nail implant size chosen. The distal fragment is prepared in the same fashion with the K-wire directed to the lateral condyle.

#### Humeral

Male driver

**Physis** 

#### STEP 3

Additional proximal osteotomies may be required and should be performed percutaneously whenever possible, with the guide wire exiting just anterior to the acromion in the middle of the humeral head in the AP view. A male-size K-wire is inserted on the retrograde direction from the osteotomy through the proximal fragment (in case for a need of a second osteotomy, the male nail is inserted from the distal osteotomy). A second incision is done at the shoulder to allow the extremity of the K-wire to exit proximally.



**Male nail** 

#### Step 4

The male driver (MDr132-L, MDr140-L, MDr148-L, MDr156-L or MDr164-L) is introduced over the male-size K-wire. The K-wire is removed and the male solid nail is placed in the male driver, making sure that the wings of the male solid nail are fitted into the male driver slot.

The male drivers have the possibility to lock the male component to

facilitate maneuvering the nail upon insertion. To lock the male implant component after it is inserted inside the male driver, simply rotate the eccentric ring to the LOCK position.



#### STEP 5

The male solid nail is pushed distally after reduction of the osteotomy(ies) and screwed into the lateral condyle. Verify under fluoroscope that the distal thread is positioned beyond the growth plate (otherwise normal growth may be affected.)

Optimal position of the male solid nail on the distal humeral epiphysis is achieved by centering the distal tip on the Mediolateral view. For Short thread and LON components see "Specifics on distal fixation" on page 17.

Once the male implant component has been fixed into the distal epiphysis, unlock the male by rotating the eccentric ring to the UNLOCK position before removing the male driver.

WARNING: Failure to unlock the male driver from the male, may result in the male implant component being pulled out of the epiphysis and consequently lack of secure fixation.

Removal of the male driver (unlock position is done with the assistance of the Pushrod (PSR100) or a small diameter K-wire to reduce stressing of the nail fixation while the driver is pulled back.



IMPORTANT. Cutting the male component flush with the cartilage of the humeral head is mandatory to avoid damage to the rotator cuff, therefore the preferred technique is to pre-cut the male component with the appropriate length. Alternatively, the male nail could be cut once positioned 5 to 10 mm above the ideal fixation site by removing the male driver, cutting the male component in situ at the desired level, and then continue driving the male until its final optimal position. Once the male has been place in its final position, only the proximal tip will be visible to place the female component over it.

#### Step 7

The female hollow nail is then screwed into the greater tuberosity using the female driver (FDr100 or FDr101) until it seats flush with the cartilage. A full range of motion of the shoulder must be obtained before closing the wound.





#### TIBIAL & HUMERAL IMPLANT SPECIFICATIONS

Catalog #	Size Ø x Length [mm]	PROXIMAL FIXATION [MM]	DISTAL FIXATION [MM]	
Standard tibial and humeral implants (short distal threaded fixation)				
FD-032(SPS)-SS	Ø3.2 x 197	¢7 12	6 8 (83.2	
FD-040(SPS)-SS	Ø4.0 x 333	498 12 7	6 9 94.0	
FD-048(SPS)-SS	Ø4.8 x 404	(50) 12	1 7 1948	
FD-056(SPS)-SS	Ø5.6 x 405	gf0.75	8.5 ; (4 (5.6	
FD-064(SPS)-SS	Ø6.4 x 407	(\$10.5 12	10 Mil 190.4 -	
LON	l tibial and hum	eral implants (non-threaded dist	tal fixation)	
FDLON-T032-SS	Ø3.2 x 194	¢7 12	gi3.2 • •	
FDLON-T040-SS	Ø4.0 x 330	498 12 1	84.0	
FDLON-T048-SS	Ø4.8 x 400	(50) 12	g44.8	
FDLON-T056-SS	Ø5.6 x 411	g60.75	p5.6	
FDLON-T064-SS	Ø6.4 x 411	¢10.5	p1.4 -	

#### Female nail size & length

Once the estimated length (l) of the rectified bone after osteotomy (ies) is calculated and the diameter of the medullary canal measured, the implant size is determined. Choose the largest diameter of the nail that fits the patient's medullary canal. Refer to the implants catalogue for maximum non-extended length of each implant size available. The maximum length of the uncut nail of the chosen size should be long enough to reach the distal epiphysis The length of the Female hollow nail is cut pre-operatively to a length of  $\ell$ -7 mm. Pega Medical offers to customize the Fassier Duval Nail to your patients requirements if you advice us one week before shipping. Otherwise cutting could be done at the same medical facility where the appropriate tools are available. The Female nail should be cut with the diamond disc (FC-DISC) or similar. Do not try to cut the female with a standard surgical rod or wire cutter because it will crimp the end of the nail and obstruct normal telescoping. Verify that the cut end results in a clean, non-deformed cut. Deburr all sharp edges and remove loss particles. Introduce the male in the female component and verify that there is a smooth telescoping of the parts relative to each other. Clean both components ultrasonically and sterilize according to manufacturer instructions located in the packaging insert of the device.

After the implant maximum diameter (female diameter) has been chosen, verify that the distal epiphysis can accommodate the full length of the male distal thread. Avoid by all means leaving the thread across the physis. The distal thread length is indicated in TABLE I.

#### Male NAIL SIZE & LENGTH

The length of the male solid nail is cut intraoperatively after both components are implanted, leaving 10 to 15 mm protruding in the case of the femur from the proximal end to accommodate for future growth, whereas the male nail should be cut flush with the female head in tibial and humeral nailing.

The Male nail can be cut with the Pega Medical Male Cutter (MC200); this tool is specially designed for the Fassier Duval system and produces a clean cut which needs no further care. Otherwise standard surgical rod or wire cutters and a deburring power tools used to remove all sharp edges and burrs created during the cutting operation. Make sure that the wound area is cover while these operations are performed to avoid particulate contamination of the surgical site. Table I

SIZE	ТҮРЕ	DISTAL THREAD LENGTH
2.5 mm	L	10 mm
5.2 11111	S / SPS	5 mm
10	L	11 mm
4.0 mm	S / SPS	6 mm
4.8 mm	L	12 mm
	S / SPS	7 mm
Γίραρο	L	13.5 mm
5.6 MM	S / SPS	8.5 mm
6.4.00.00	L	15 mm
0.4 MM	S / SPS	10 mm

#### Specifics on distal fixation

The short thread males components are designed to resist maximum pull-out forces due to growth and distraction forces. Although in most cases no extra fixation is required, a small keyhole has been added to the distal end to achieve added strength to the distal fixation. Under C-arm and before the male driver is withdrawn, the keyhole can be visualized and a K-wire of appropriate size (0.7 mm for the Ø3.2 implant, 0.9 mm for the Ø4.0 implant and 1.1 mm for all the other implant sizes) introduced and locked on both cortices.

Non-threaded (LON) male components are used when the distal epiphysis is too small or of poor quality for a threaded fixation. The non-threaded fixation is pushed into the epiphysis and locked with a 1.5mm locking wire which is engaged in the lateral cortex and bent on the medial cortex. Verify the final position of the distal fixation under image intensifier.



#### Instrumentation

DESCRIPTION	<b>R</b> EFERENCE #
Female driver for Ø3.2 mm	FDr100
Female driver for Ø4.0 mm / Ø4.8 mm / Ø5.6 mm / Ø6.4 mm	FDr101
Male driver Ø3.2 mm in SS	MDr132-L
Male driver Ø4.0 mm in SS	MDr140-L
Male driver Ø4.8 mm in SS	MDr148-L
Male driver Ø5.6 mm in SS	MDr156-L
Male driver Ø6.4 mm in SS	MDr164-L
Male Rod Cutter	MC200
Probe Ø3.2 mm and Ø4.0 mm	PRO132-140
Probe Ø4.8 mm and Ø5.6 mm	PRO148-15
Probe Ø6.4 mm	PRO164
Pushrod	PSR100
Drill Set	DR132, DR140, DR148, DR156 and DR164
Diamond disc	FC-DISC
Guide wires	G-wire 016, G-wire 020
Quick Lock Silicone T Handles	FD-HANDLE
Quick Lock Silicone Axial Handles	FD-AXIALHANDLE
Sterilization Case	FD-CASE
Implant case	FD-IMPLCASE

# Guide wires for cannulated reamers

REAMER	DIAMETER
DR132	G-wire 016 - 1.6 x 450 mm
DR140	G-wire 016 - 1.6 x 450 mm
DR148	G-wire 020 - 2.0 x 450 mm
DR156	G-wire 020 - 2.0 x 450 mm
DR164	G-wire 020 - 2.0 x 450 mm





#### **ORDER FORM**

#### SURGERY INFORMATION

Name of surgeon

Patient ID information

Date of surgery

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#### Pega Medical

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#### **MATERIAL NEEDED**

QIY V	FEMORAL IMPLANTS	QIY •	TIRIAL & HOMERAL IMPLANTS	QIY	INSTRUMENTATION
	FD-032(L)-SS		FD-032(SPS)-SS		PR0132-140
	FD-040(L)-SS		FD-040(SPS)-SS		PR0148-156
	FD-048(L)-SS		FD-048(SPS)-SS		PRO164
	FD-056(L)-SS		FD-056(SPS)-SS		PSR100
	FD-064(L)-SS		FD-064(SPS)-SS		DR132
	FD-032(S)-SS		FDLON-T032-SS		DR140
	FD-040(S)-SS		FDLON-T040-SS		GWIRE - 016
	FD-048(S)-SS		FDLON-T048-SS		DR148
	FD-056(S)-SS		FDLON-T056-SS		DR156
	FD-064(S)-SS		FDLON-T064-SS		DR164
	FDLON-F032-SS				GWIRE - 020
	FDLON-F040-SS	QTY 🔻	INSTRUMENTATION		FD-HANDLE
	FDLON-F048-SS		MDr132-L		FD-AXIALHANDLE
	FDLON-F056-SS		MDr140-L		FD-CASE
	FDLON-F064-SS		MDr148-L		FD-DISC
			MDr156-L		MC200
			MDr164-L		FD-INSTRENT
			FDr100		FD-INSTSET

FDr101

Please photocopy this form, fill out information and submit to Purchasing department

To Purchasing department, please fax Purchase Order along with this form to:

International distributor

FD-IMPLCASE

In North America: Pega Medical Fax: 450-688-1977

#### NOTES


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## Pega Medical

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