



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™

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FD-ST-EN REV H

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 OI, pseudoarthrosis and can also 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.

TABLE OF CONTENTS

Femoral nail

Choice of technique	3
Choice of nail size	3
Open osteotomy technique	3
Per cutaneous technique	6
Femoral implant specifications	7

Tibial nail

Choice of nail size	9
Open osteotomy technique	9

Humeral nail

Choice of nail size	13
Open osteotomy technique	13
Tibial and Humeral implant specifications	16

Important notes on sizing of the F-D nail	17
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Instrumentation	18
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Order form	21
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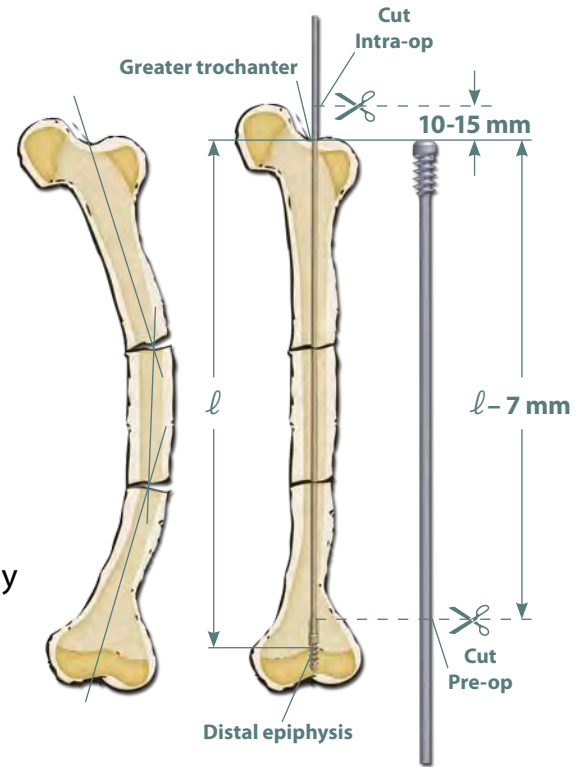
PRELIMINARIES FEMORAL NAIL

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 (ℓ) of the rectified bone after osteotomy(ies). ℓ 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).

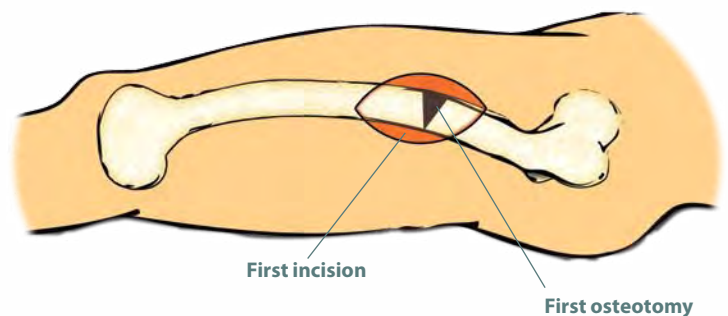


Antero-posterior view

OPEN OSTEOTOMY TECHNIQUE

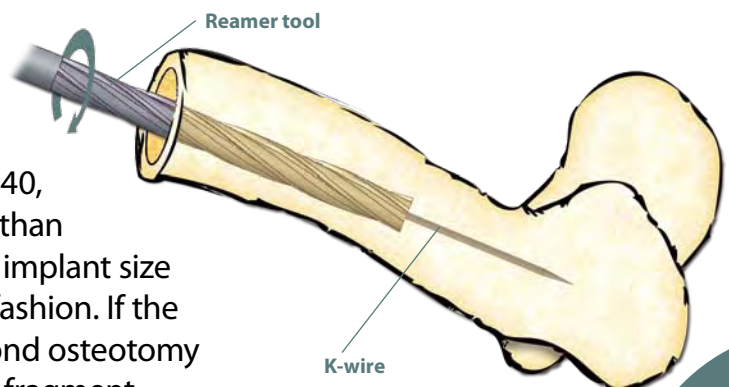
Step 1

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



Step 2

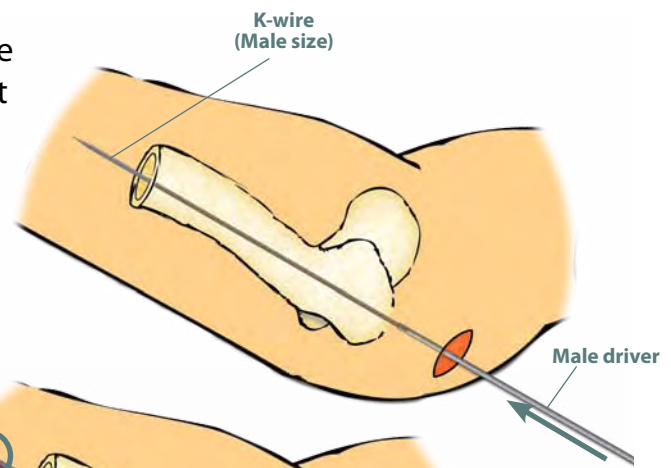
Reaming of the proximal fragment is done with a cannulated reamer or drill up to the Greater Trochanter over a small diameter guide wire (G-wire 016 or G-wire 020). The diameter of the reamer provided with the instrument set (DR132, DR140, DR148, DR156 and DR164) are 0.25 to 0.35 mm larger than the diameter 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.



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.

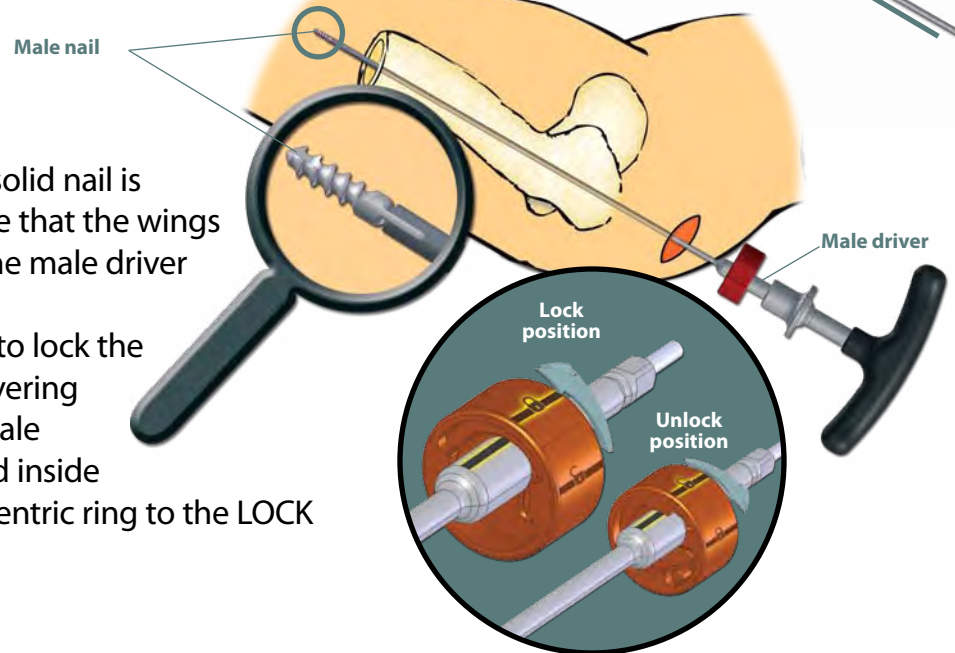
The male driver (MDr132-L, MDr140-L, MDr148-L, MDr156-L or MDr164-L) is introduced over the male-size K-wire.



STEP 4

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.

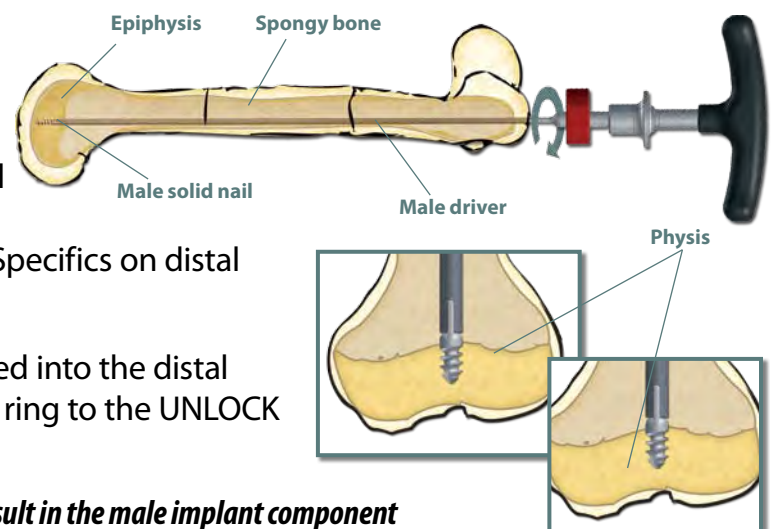


STEP 5

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.

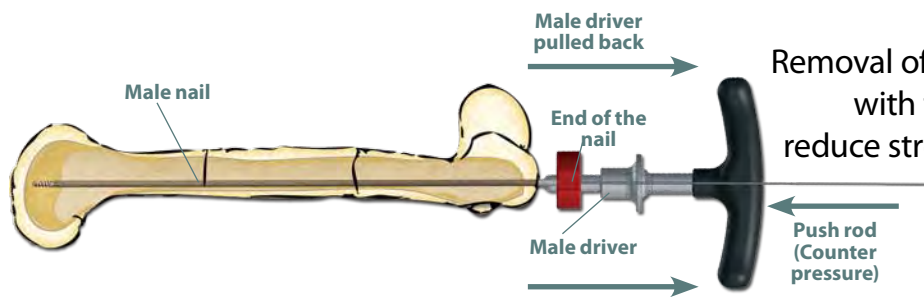
Once the male implant component has been screwed into the distal epiphysis, unlock the male by rotating the eccentric ring to the UNLOCK position before removing the male driver.



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.

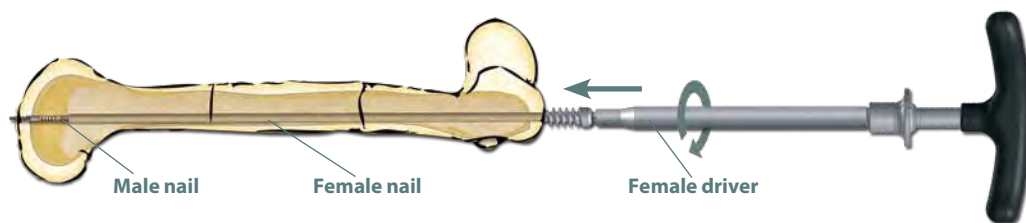
The male driver is designed only to screw the male component. Do not use the male driver to reduce the fracture. Align the bone segments before advancing the driver into the canal. Incorrect use of the male driver could result in instrument damage.

STEP 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



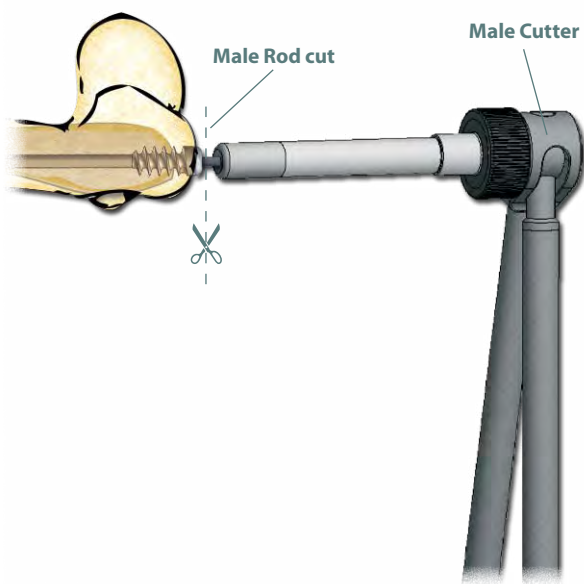
The female hollow nail is screwed into the Greater Trochanter using the female driver (FDr100 or FDr101).

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.

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

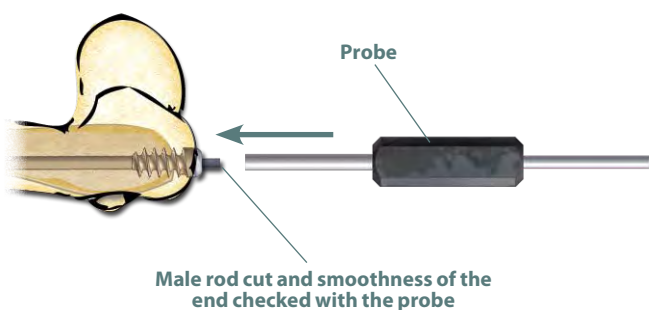
The Female Driver should be kept aligned with the Female Nail during insertion. Lateral forces (bending) may cause the failure of the hexagonal tip of the Female Driver.

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



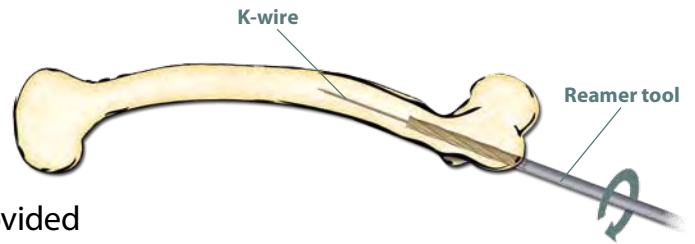
The smoothness of the cut end of the male is checked with the probe (PRO132-140, PRO148-156 or PRO164) of appropriate size. Then, incisions are finally closed.



PER CUTANEOUS TECHNIQUE

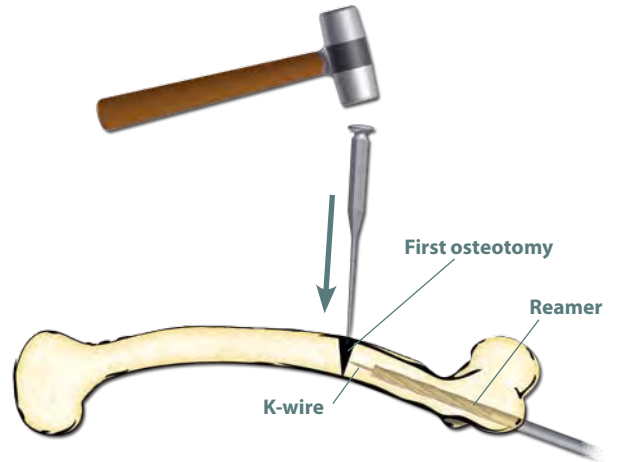
STEP 1

After insertion through the Greater Trochanter of a small diameter guide-wire to the apex of the deformity, the femur is reamed to the appropriate size using the provided cannulated reamers.



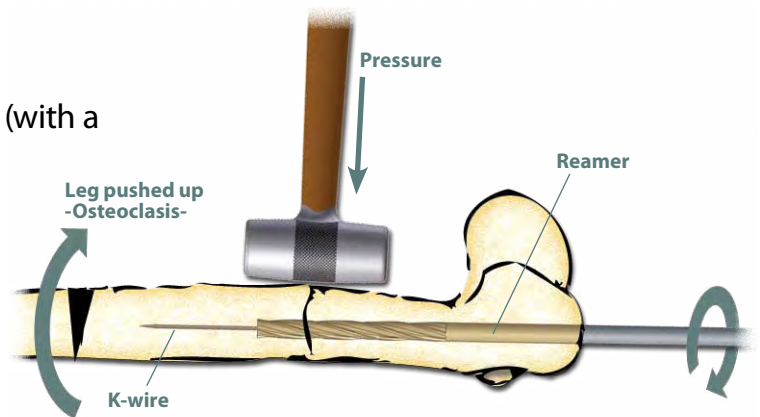
STEP 2

The first osteotomy is done (through a 0.5 cm incision) in the convexity of the deformity, just distal to the reamer.



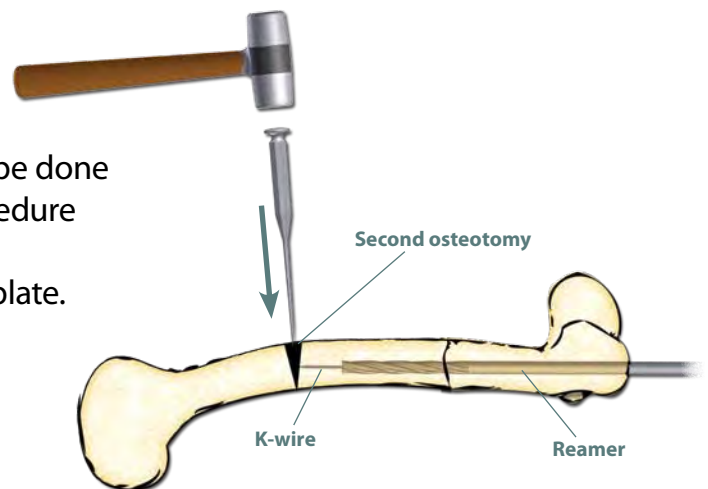
STEP 3

With counter pressure applied at the osteotomy site (with a mallet for example) the deformity is progressively corrected (osteoclasis) by gentle manipulation. When the bone is straightened, the guide wire is pushed distally and the reamer advanced accordingly.



STEP 4



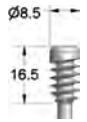

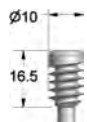

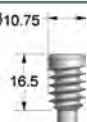

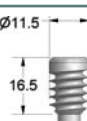
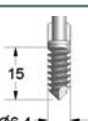
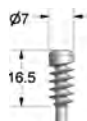

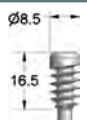
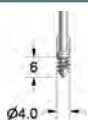
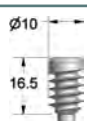

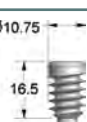

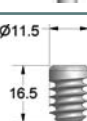

The guide wire is pushed distally to the apex of the second deformity. Then, the second osteotomy should be done at the extremity of the reamer, following the same procedure described in steps 2 and 3 until the whole length of the medullary canal is reamed until just before the growth plate.



STEPS 5 TO 10

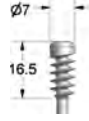

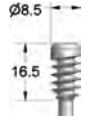

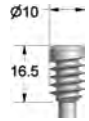

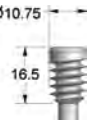

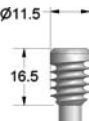

See the Open osteotomy technique (steps 4 to 9)

FEMORAL IMPLANT SPECIFICATIONS

CATALOG #	SIZE Ø x LENGTH [MM]	PROXIMAL FIXATION [MM]	DISTAL FIXATION [MM]
<i>Standard femoral implants (long threaded distal fixation)</i>			
FD-032(L)-SS	Ø3.2 x 202		
FD-040(L)-SS	Ø4.0 x 338		
FD-048(L)-SS	Ø4.8 x 410		
FD-056(L)-SS	Ø5.6 x 410		
FD-064(L)-SS	Ø6.4 x 412		
<i>Small femoral implants (short threaded distal fixation)</i>			
FD-032(S)-SS	Ø3.2 x 197		
FD-040(S)-SS	Ø4.0 x 333		
FD-048(S)-SS	Ø4.8 x 404		
FD-056(S)-SS	Ø5.6 x 405		
FD-064(S)-SS	Ø6.4 x 407		



FEMORAL IMPLANT SPECIFICATIONS

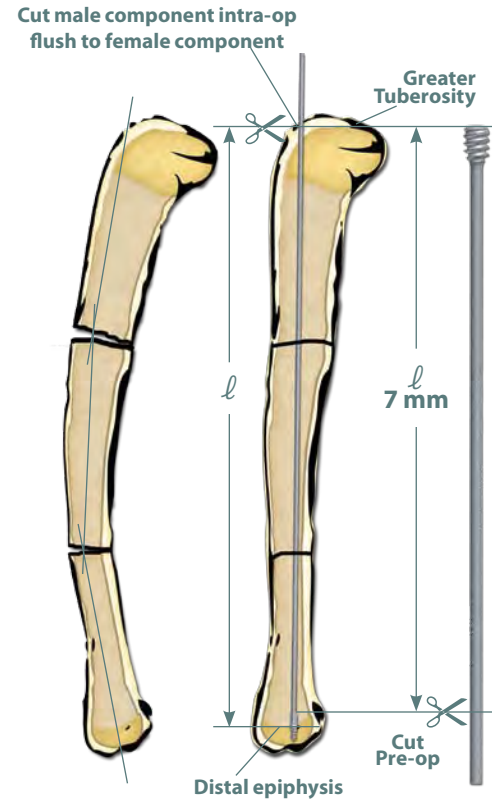
CATALOG #	SIZE Ø x LENGTH [MM]	PROXIMAL FIXATION [MM]	DISTAL FIXATION [MM]
<i>LON femoral implants (non-threaded distal fixation)</i>			
FDLON-F032-SS	Ø3.2 x 194		
FDLON-F040-SS	Ø4.0 x 330		
FDLON-F048-SS	Ø4.8 x 400		
FDLON-F056-SS	Ø5.6 x 411		
FDLON-F064-SS	Ø6.4 x 411		

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

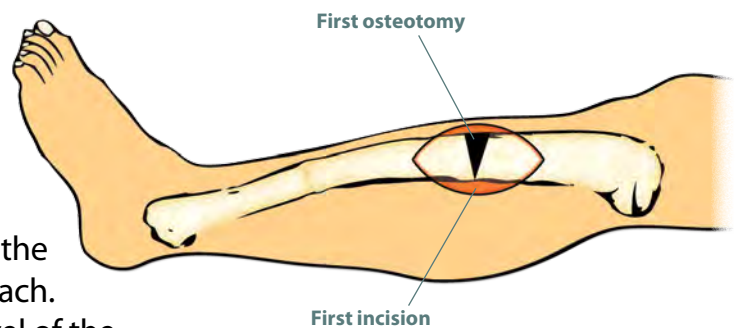
Estimate the length (ℓ) of the rectified bone after osteotomy(ies) and x-ray magnification correction if necessary. ℓ is the distance between the superior margin of the ossified proximal epiphysis and the distal growth plate. The maximum length of the uncut nail of the chosen size should be long enough 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 SPS (short) or LON series, which defines the type of distal fixation, should be based on the height of the distal epiphysis as measured from A-P x-ray film (see page 17)



Mediolateral view

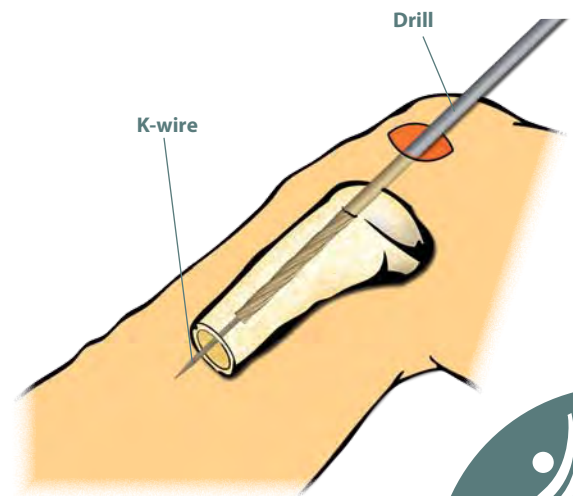
STEP 1

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 with the C-arm, the osteotomy is done. Once completed, an osteoclasis or osteotomy of the fibula is done.



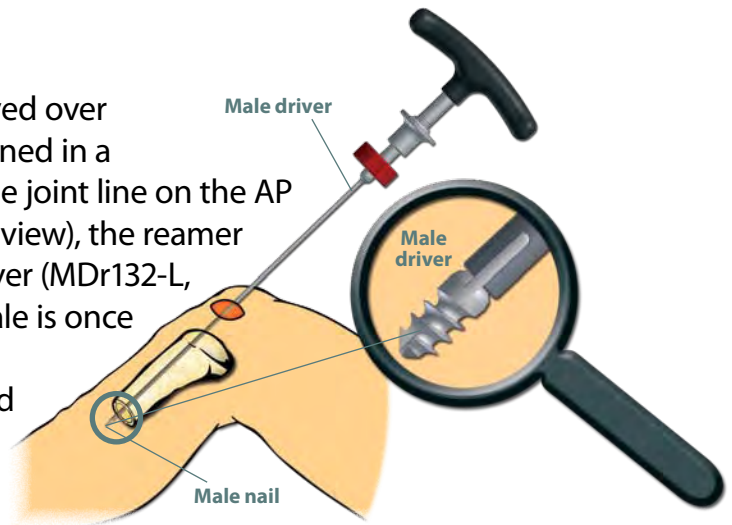
STEP 2

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.



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.



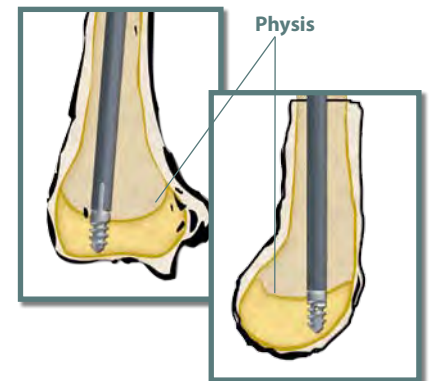
The fixation differs with the type of implant chosen. For short thread and LON components see "Specifics on distal fixation" on page 17. Verify the position of the distal fixation under image intensifier.

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.

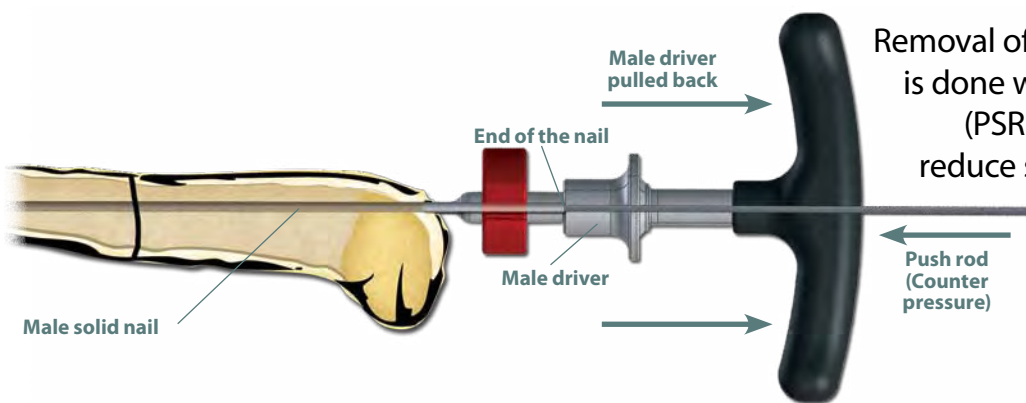


Failure to unlock the male driver from the male, may result in the male implant component being pulled out of the epiphysis and consequently lack of secure fixation.

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.

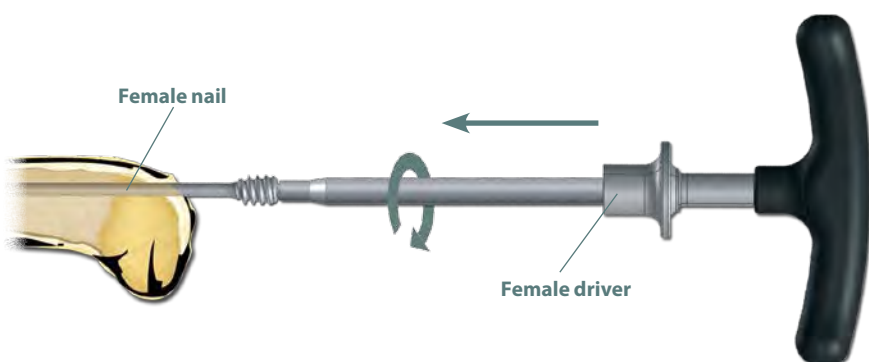


STEP 5



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.

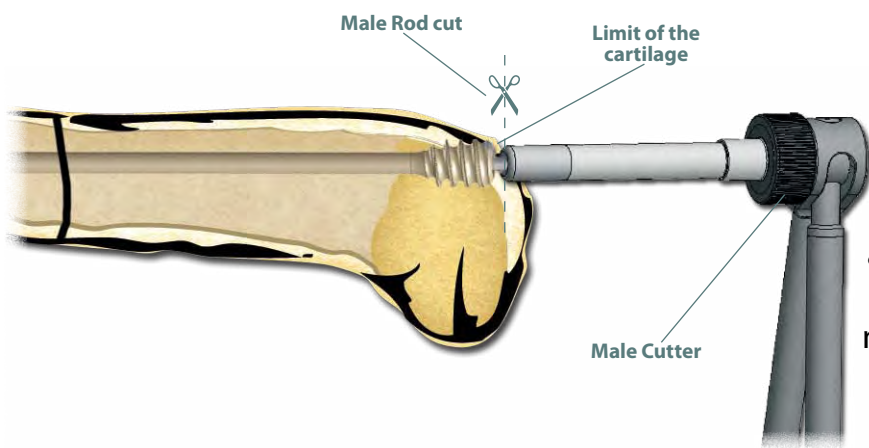
STEP 6



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).

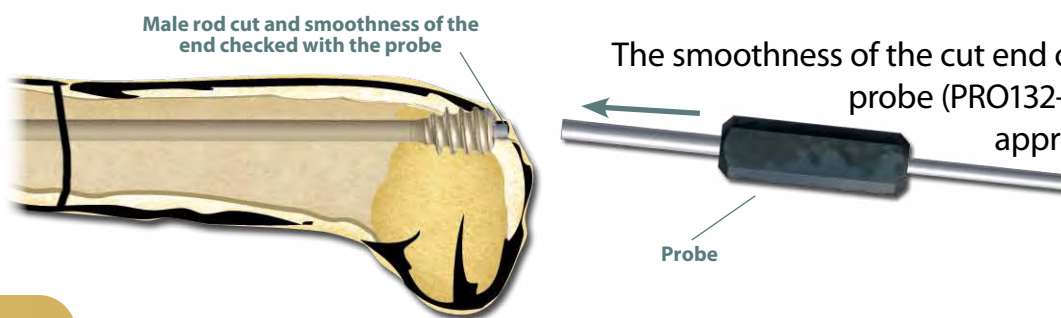
The Female Driver should be kept aligned with the Female Nail during insertion. Lateral forces (bending) may cause the failure of the hexagonal tip of the Female Driver.

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

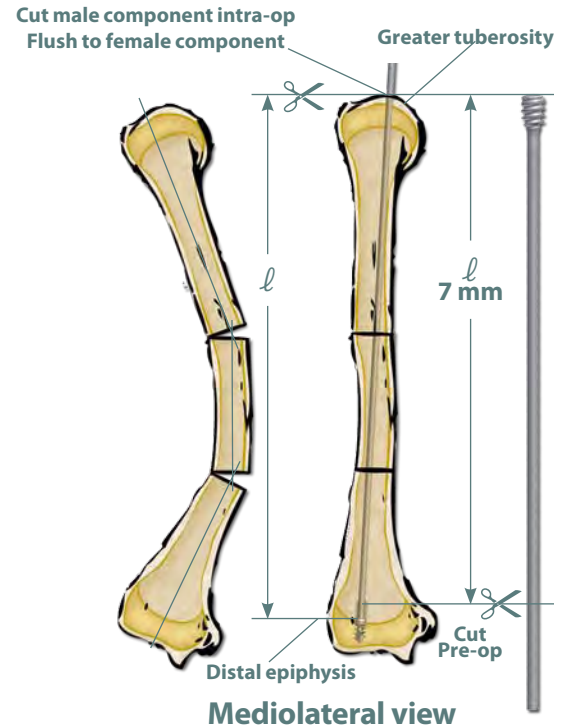


The smoothness of the cut end of the male is checked with the probe (PRO132-140, PRO148-156 or PRO164) of appropriate size. Then, incisions are finally closed.



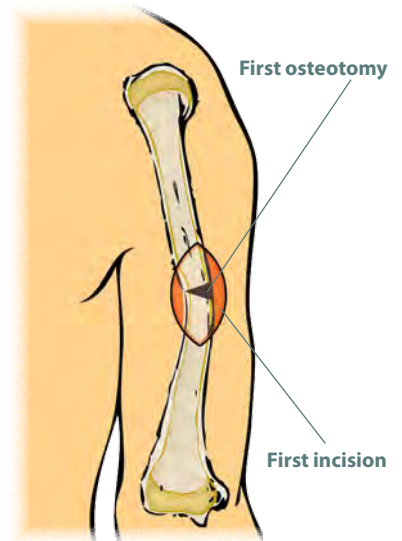
Choice of nail size

Estimate the length (ℓ) of the rectified bone after osteotomy (ies). ℓ 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 type of distal 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).



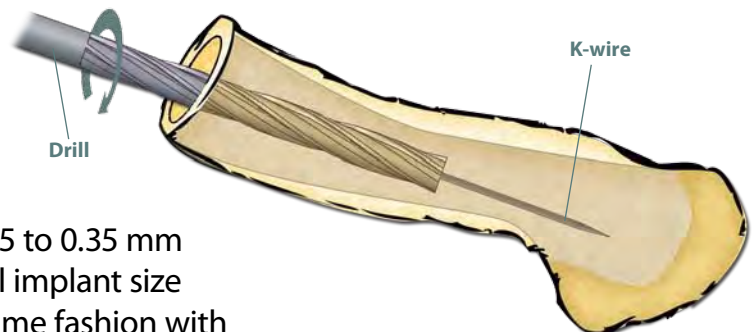
Step 1

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.



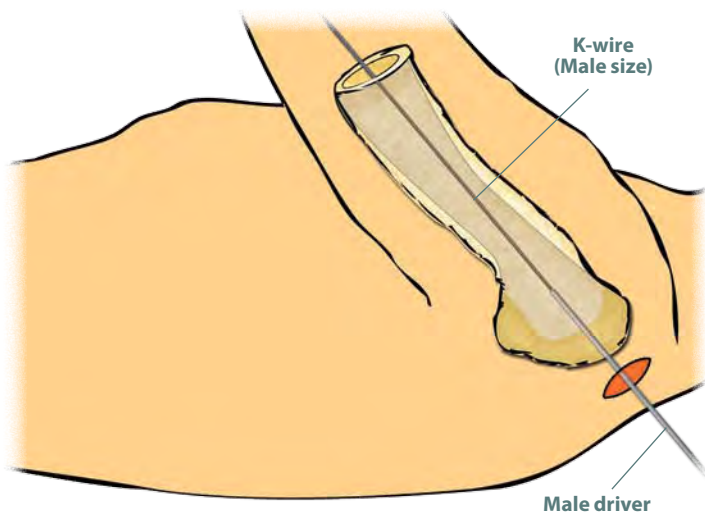
Step 2

Reaming of the proximal fragment is done with a cannulated reamer or drill up to the Greater Tuberosity over a small diameter guide-wire (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.



STEP 3

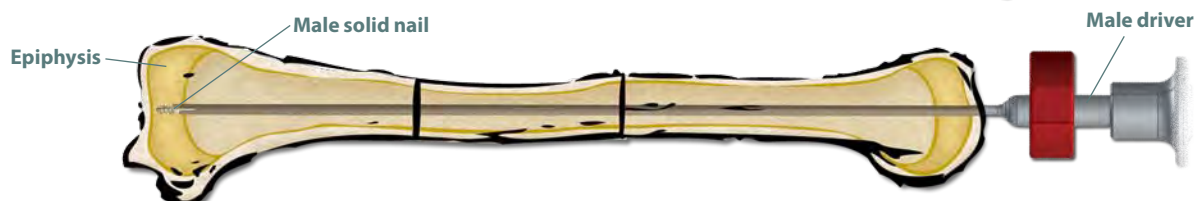
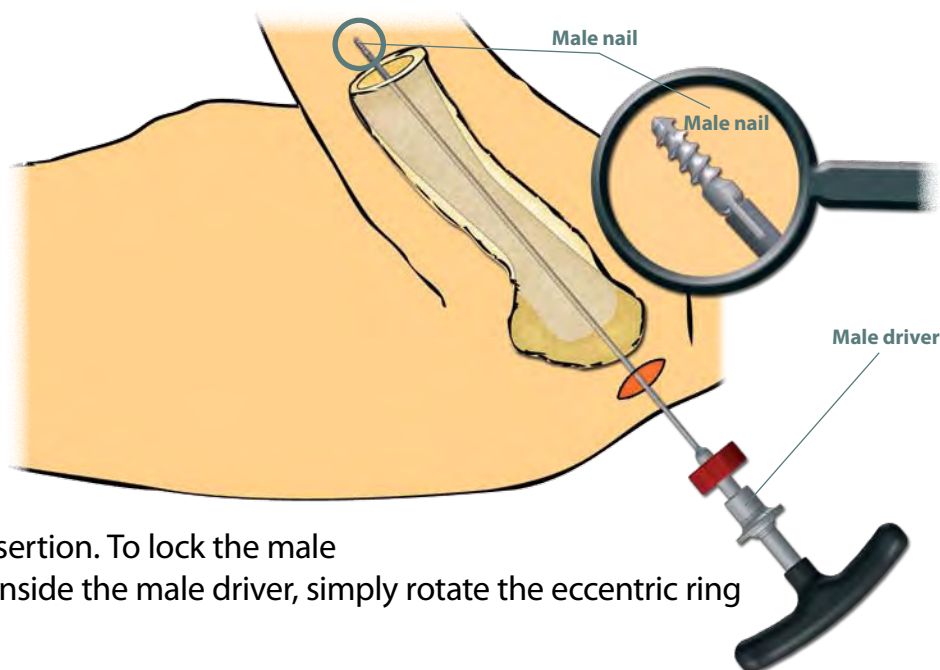
Additional proximal osteotomies may be required and should be performed percutaneously whenever possible, with the guide wire exiting just anterior to the acromion in the middle of the humeral head in the AP view. A male-size K-wire is inserted on the retrograde direction from the osteotomy through the 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.



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.

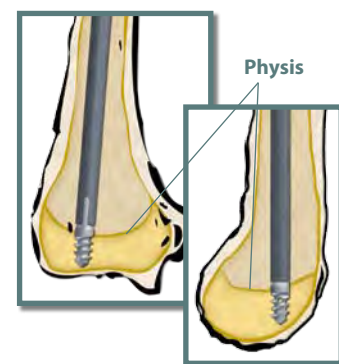
The male drivers have the possibility to lock the male component to facilitate maneuvering the nail upon insertion. To lock the male implant component after it is inserted inside the male driver, simply rotate the eccentric ring to the LOCK position.



STEP 5

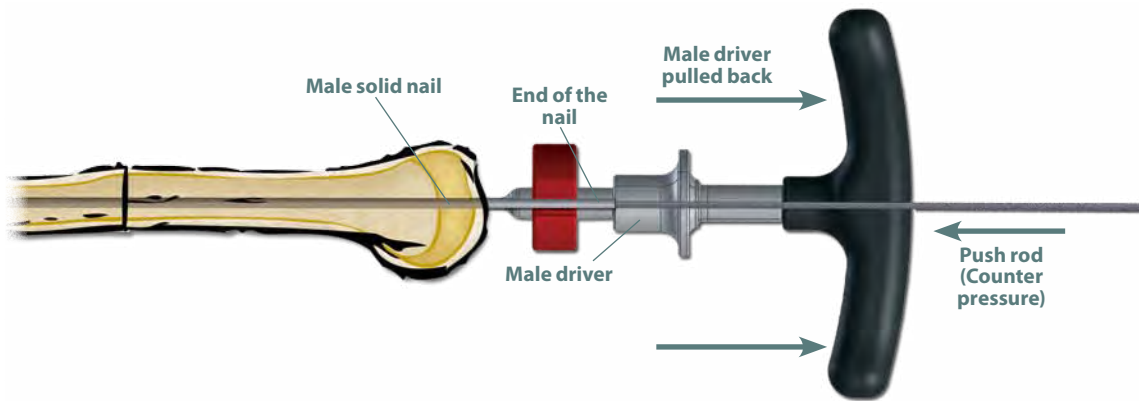
The male solid nail is pushed distally after reduction of the osteotomy(ies) and screwed into the lateral condyle. Verify under fluoroscope that the distal thread is positioned beyond the growth plate (otherwise normal growth may be affected.) Optimal position of the male solid nail on the distal humeral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



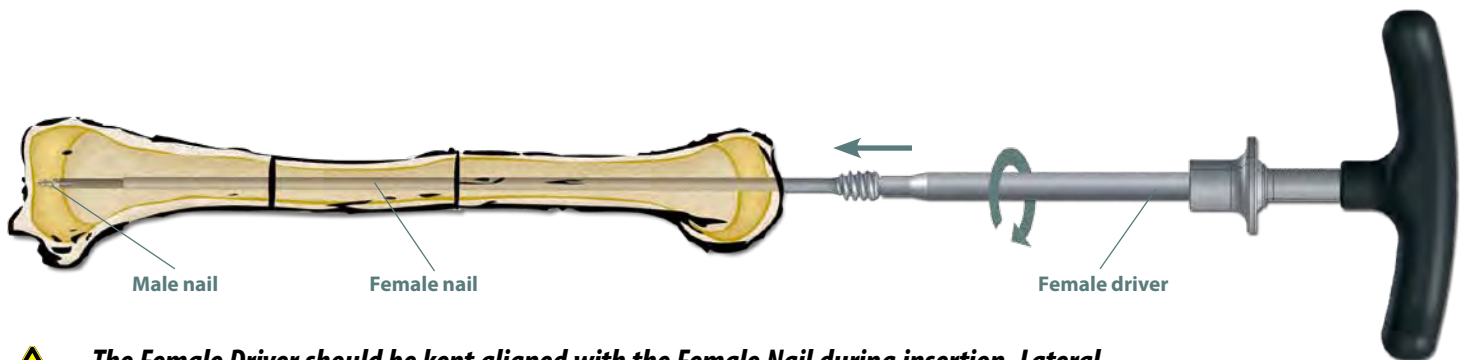
Failure to unlock the male driver from the male, may result in the male implant component being pulled out of the epiphysis and consequently lack of secure fixation.

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.



! *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 placed in its final position, only the proximal tip will be visible to place the female component over it.*

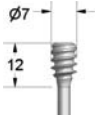
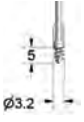

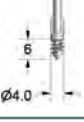

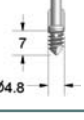

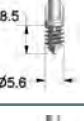

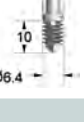
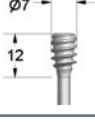




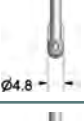




The female hollow nail is then screwed into the greater tuberosity using the female driver (FDr100 or FDr101) until it seats flush with the cartilage. A full range of motion of the shoulder must be obtained before closing the wound.



! *The Female Driver should be kept aligned with the Female Nail during insertion. Lateral forces (bending) may cause the failure of the hexagonal tip of the Female Driver.*



TIBIAL & HUMERAL IMPLANT SPECIFICATIONS

CATALOG #	SIZE Ø x LENGTH [MM]	PROXIMAL FIXATION [MM]	DISTAL FIXATION [MM]
<i>Standard tibial and humeral implants (short distal threaded fixation)</i>			
FD-032(SPS)-SS	Ø3.2 x 197		
FD-040(SPS)-SS	Ø4.0 x 333		
FD-048(SPS)-SS	Ø4.8 x 404		
FD-056(SPS)-SS	Ø5.6 x 405		
FD-064(SPS)-SS	Ø6.4 x 407		
<i>LON tibial and humeral implants (non-threaded distal fixation)</i>			
FDLON-T032-SS	Ø3.2 x 194		
FDLON-T040-SS	Ø4.0 x 330		
FDLON-T048-SS	Ø4.8 x 400		
FDLON-T056-SS	Ø5.6 x 411		
FDLON-T064-SS	Ø6.4 x 411		

IMPORTANT NOTES ON SIZING OF THE F-D NAIL

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.

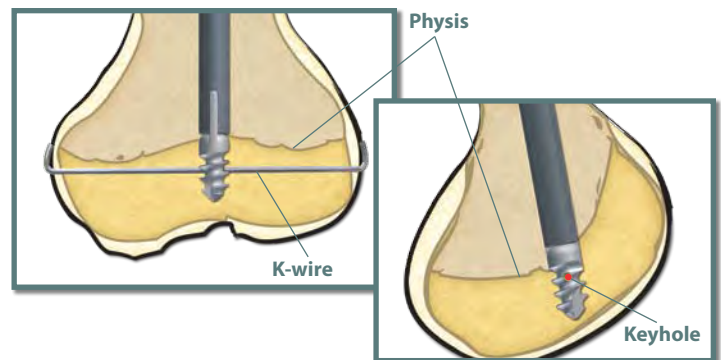
Table I

SIZE	TYPE	DISTAL THREAD LENGTH
3.2 mm	L	10 mm
	S / SPS	5 mm
4.0 mm	L	11 mm
	S / SPS	6 mm
4.8 mm	L	12 mm
	S / SPS	7 mm
5.6 mm	L	13.5 mm
	S / SPS	8.5 mm
6.4 mm	L	15 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.



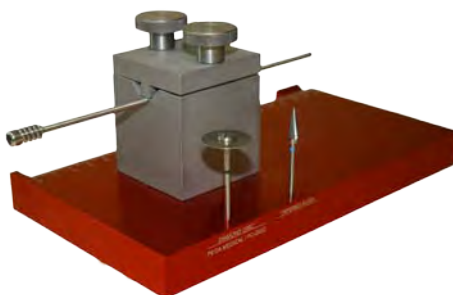
Instrumentation

DESCRIPTION	REFERENCE #
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	MDr132-L
Male driver Ø4.0 mm	MDr140-L
Male driver Ø4.8 mm	MDr148-L
Male driver Ø5.6 mm	MDr156-L
Male driver Ø6.4 mm	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-L, DR140-L, DR148, DR156 and DR164
Diamond disc	FC-DISC
Tapered Burr	FC-BURR
Female Cutter Jig	FC-JIG100
Guide wires	G-wire 016-PKG6, G-wire 020-PKG6
Quick Lock Silicone T Handles	FD-HANDLE
Quick Lock Silicone Axial Handles	FD-AXIALHANDLE
Sterilization Case	FD-CASE-3
Implant case	FD-IMPLCASE
Small Implant Case	SI-CASE



GUIDE WIRES FOR CANNULATED REAMERS

REAMER	DIAMETER
DR132-L	G-wire 016 - 1.6 x 450 mm
DR140-L	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





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