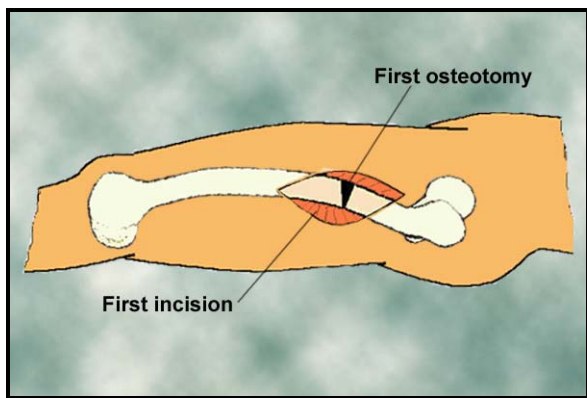
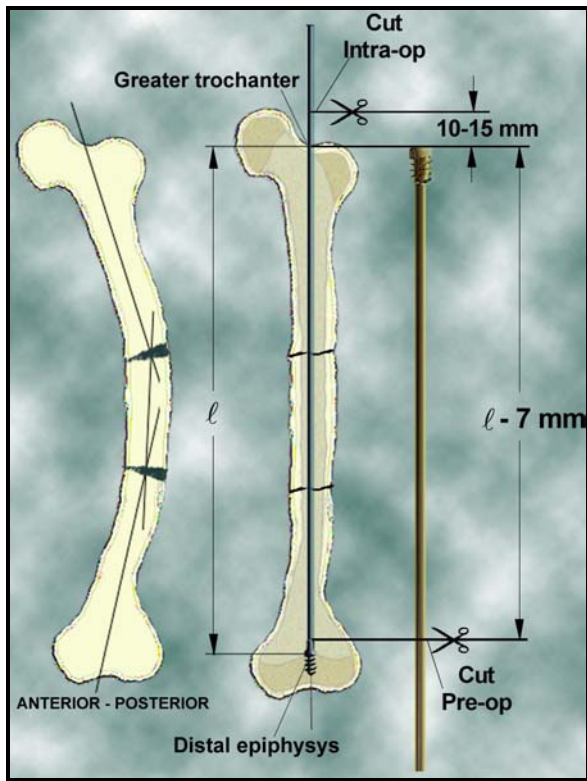

PRELIMINARIES FEMORAL NAIL

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 **percutaneous** 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 growthplate. **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 $l - 7$ 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) or S (short), which defines the length of the distal thread, should be based on the length of the distal epiphysis as measured from A-P x-ray film.



OPEN OSTEOTOMY TECHNIQUE

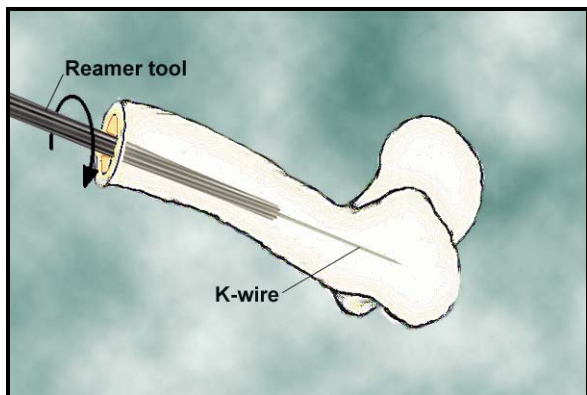
STEP 1

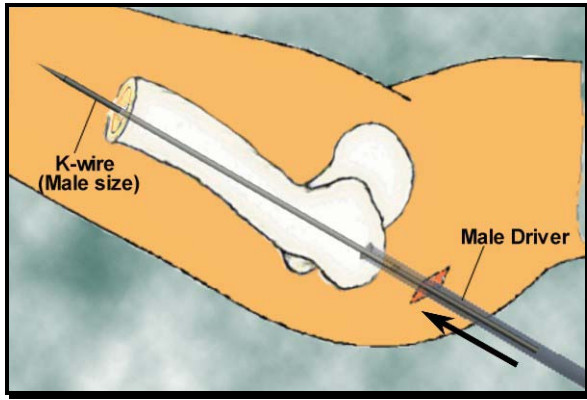
Through a classic postero-lateral approach, the femur is exposed sub-periostally. Subsequently the first osteotomy is executed under C-arm guidance.

STEP 2

Reaming of the proximal fragment is done with a cannulated reamer or drill up to the greater trochanter over a small diameter K-wire for guidance. The diameter of the reamer should be 0.25 to 0.35mm larger than the diameter of the Fassier-Duval Nail implant size chosen.

The distal fragment is prepared in the same fashion. If the K-wire guide does not reach the distal epiphysis, a second osteotomy should be performed after reaming the intermediate fragment.

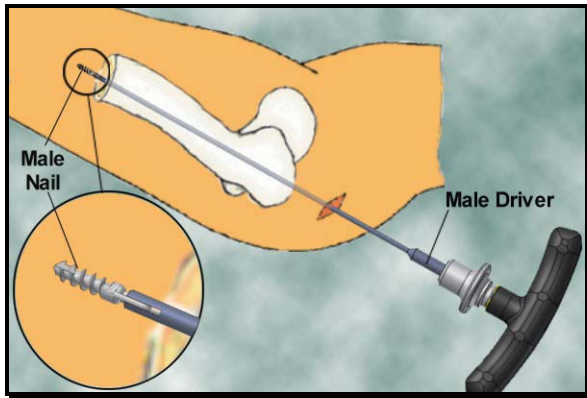




STEP 3

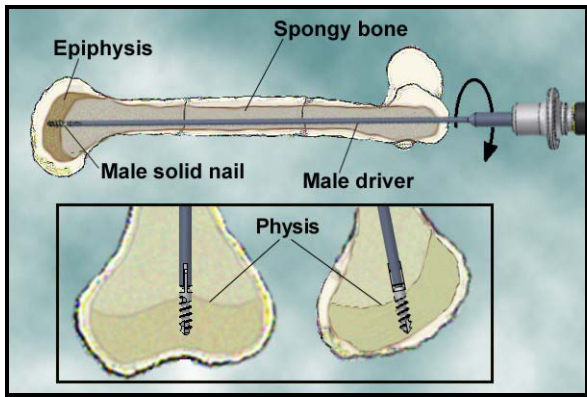
A male-size K-wire is inserted on the retrograde direction from the osteotomy through the proximal fragment. (in case for a need of a second osteotomy, the male nail is inserted from the distal osteotomy). A second incision will be done at the buttock to allow the extremity of the K-wire to exit proximally.

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



STEP 4

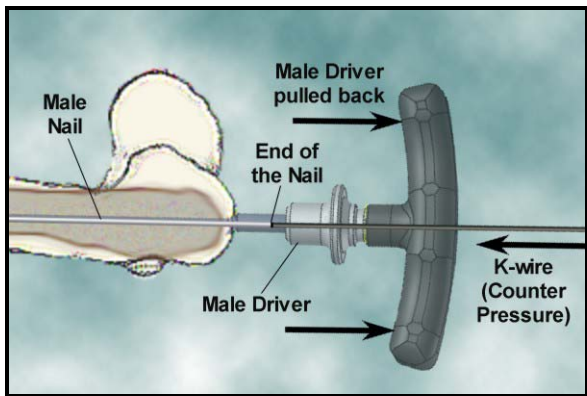
The K-wire is removed and the male solid nail is placed in the male driver, making sure that the wings of the male solid nail are fitted into the male driver slot. **WARNING:** *The male driver is designed only to screw the male component. Do not use the male driver to reduce the fracture. Align the bone segments before advancing the driver into the canal. Incorrect use of the male driver could result in instrument damage.*



STEP 5

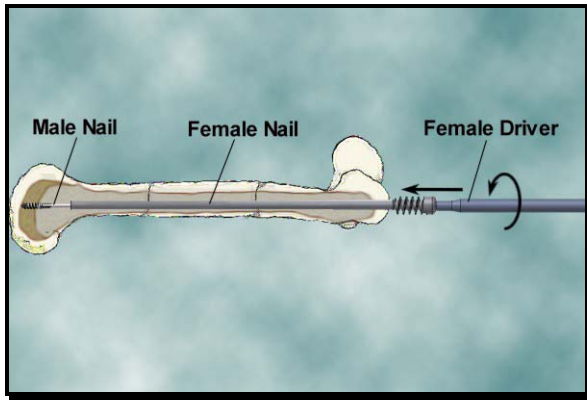
The male solid nail is pushed distally after reduction of the osteotomy(ies) and screwed into the distal epiphysis. Verify under fluoroscope that the distal thread is positioned beyond the growth plate (otherwise normal growth may be affected.)

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 components see "Specifics on the Short Thread" below.



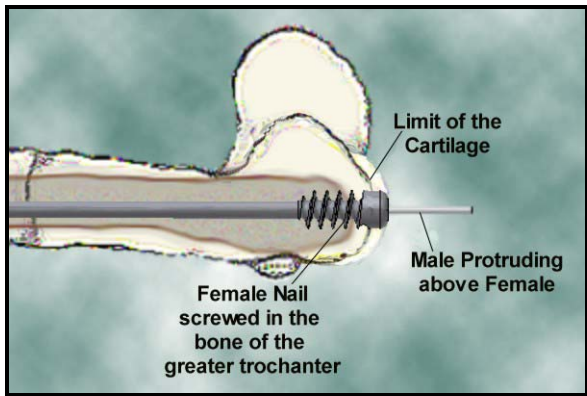
STEP 6

Removal of the male driver is done with the assistance of a small diameter K-wire to reduce stressing of the nail fixation while the driver is pulled back.



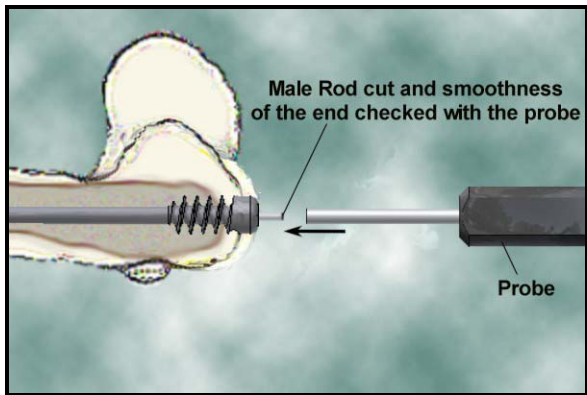
STEP 7

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



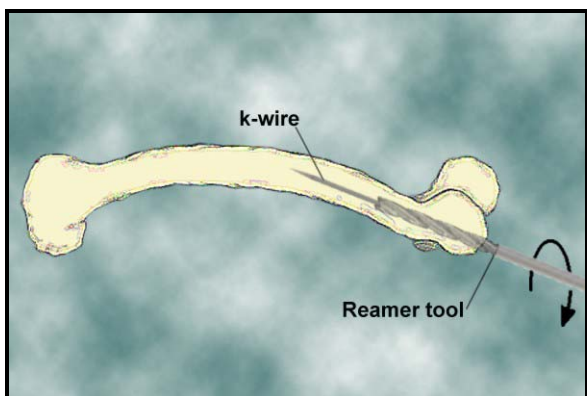
STEP 8

The threaded portion of the female head should be **completely** inserted in bone, 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.**



STEP 9

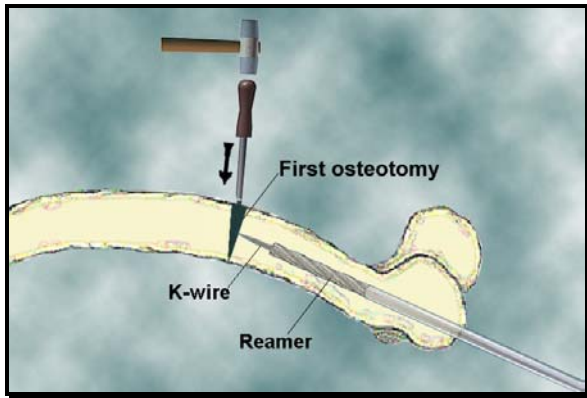
The female driver is then removed and the male solid nail is cut 10 to 15mm above the female head. The smoothness of the cut end of the male is checked with the probe (PRO132-140, PRO148-156 or PRO164) of appropriate size. Then, incisions are finally closed.



PER CUTANEOUS TECHNIQUE

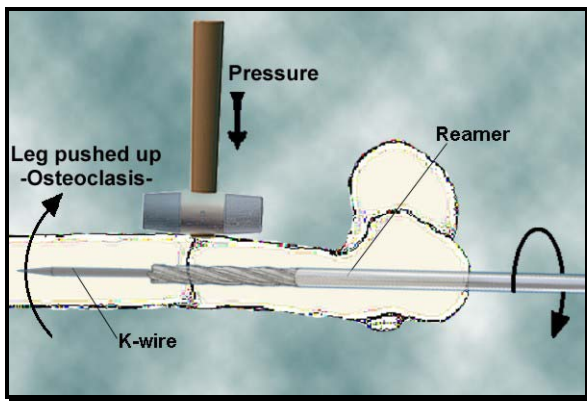
STEP 1

After insertion through the greater trochanter of a small diameter K-wire to the apex of the deformity, the femur is reamed to the appropriate size using the provided cannulated reamers. All corresponding reamers of the system are in fact 0.25 to 0.35mm larger than the diameter of the Fassier-Duval System implant in use.



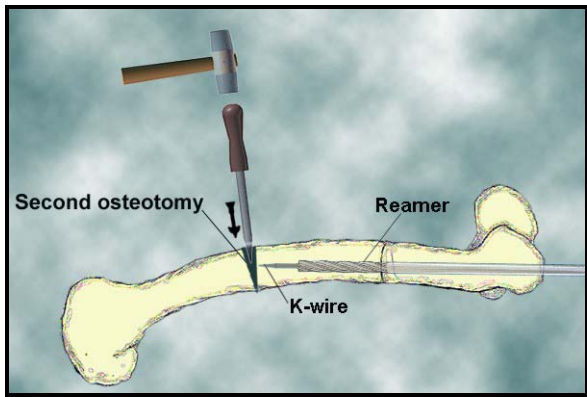
STEP 2

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 hammer for example) the deformity is progressively corrected (osteoclasis) by gentle manipulation. When the bone is straightened, the guiding K-wire is pushed distally and the reamer advanced accordingly.

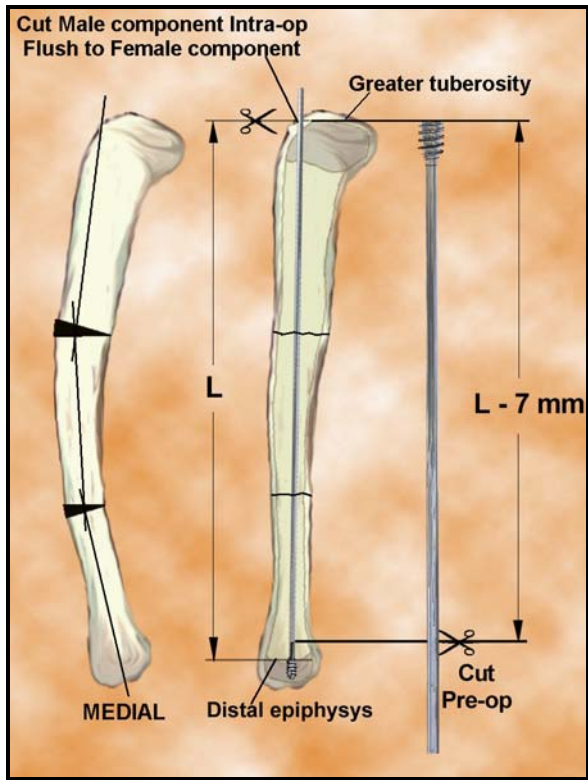


STEP 4

The guiding K-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).



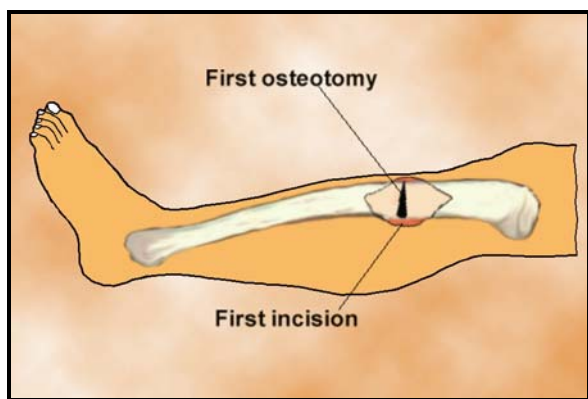
PRELIMINARIES TIBIAL NAIL

CHOICE OF THE TECHNIQUE

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

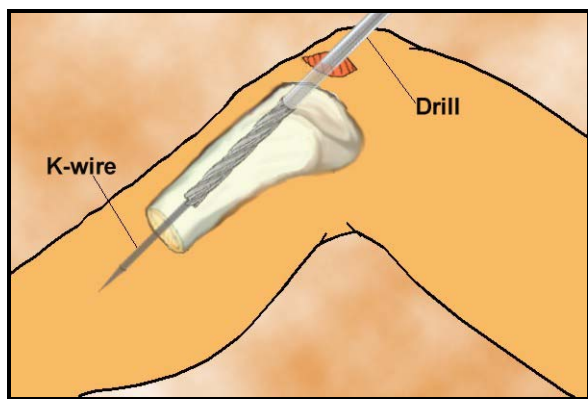
CHOICE OF NAIL SIZE

Estimate the length (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 growthplate. 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 16.5 mm for standard series or more than 12 mm for the SPS series. The choice of L (long) or S (short) LON series, which defines the length of the distal thread or non-threaded fixation, should be based on the length of the distal epiphysis as measured from A-P x-ray film.



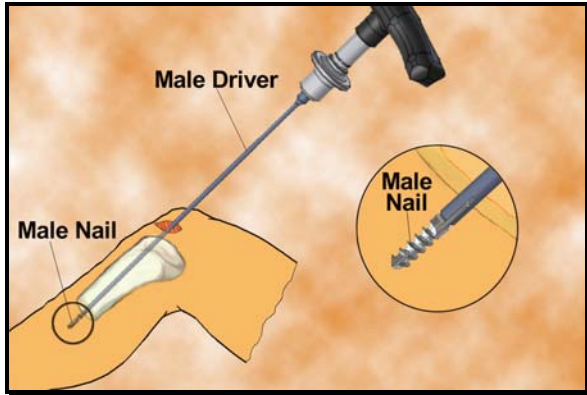
STEP 1

Through a classic antero-medial 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.



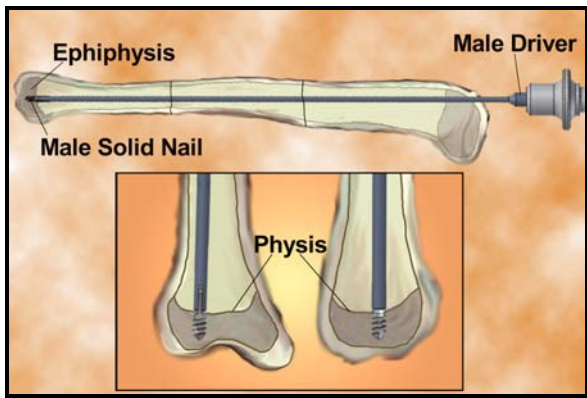
STEP 2

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



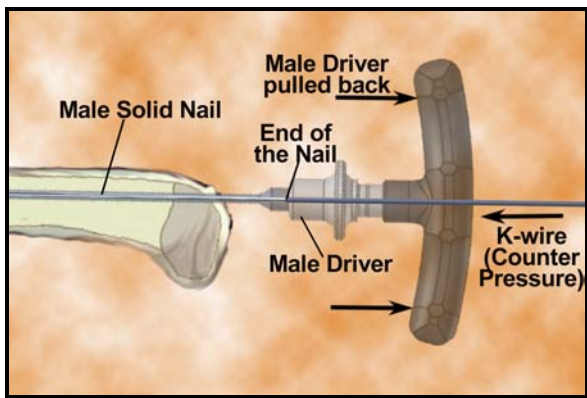
STEP 3

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. 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. WARNING¹



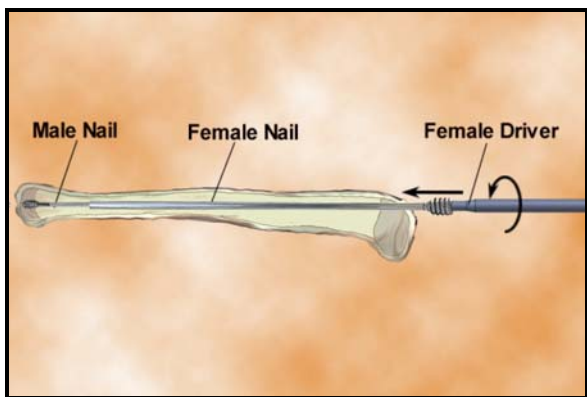
STEP 4

The fixation differs with the type of implant chosen: a) the thread must be screwed beyond the distal tibial growth plate, and in cases of poor bone quality, additional fixation can be achieved in the short-thread types by means of 0.9 mm locking wire; b) the non-threaded fixation is pushed into the epiphysis and locked with a 1.5 mm 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.



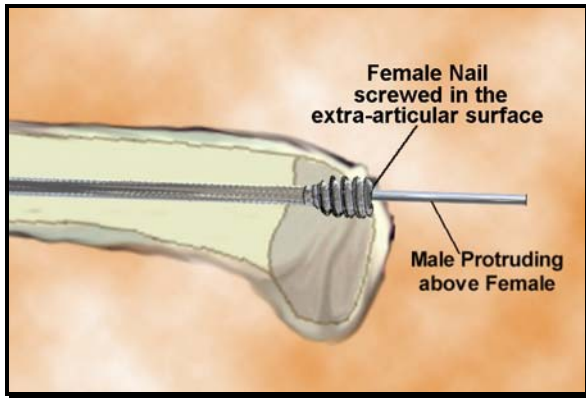
STEP 5

Removal of the male driver 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.



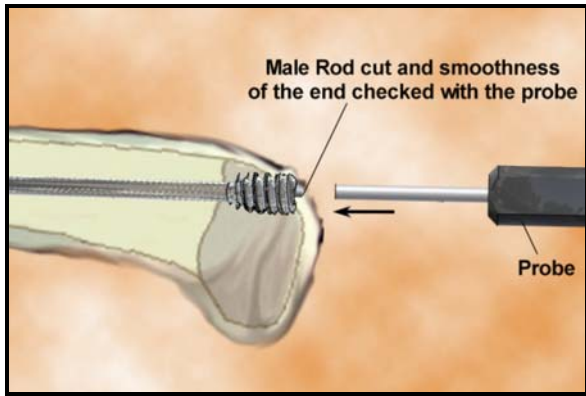
STEP 6

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).



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.



STEP 8

The female driver is then removed and the male solid nail is cut 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. 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.

¹ *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.*

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 larger 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 L-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 an oscillating saw or lathe. The Stryker # 5110-80-30 3.2 mmx18.3 mm Helicoidal short rasp or similar is recommended. **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.

MALE NAIL SIZE & LENGTH

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.

The length of the male solid nail is cut intraoperatively after both components are implanted, leaving 10 to 15 mm protruding n 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 (MC100) if available; 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

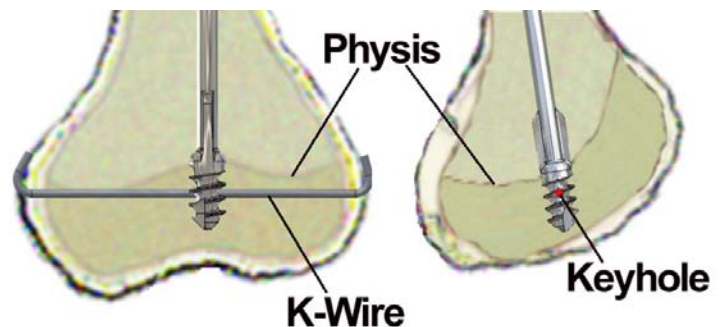
cutters and a deburring power tool (Midax Rex or Stryker burr types) used to remove all sharp edges and burrs created during the cutting operation. Make sure that the wound area is cover while these operations are performed to avoid particulate contamination of the surgical site.

TABLE I – DISTAL THREAD LENGTHS

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
6.4mm	L	15 mm
	S / SPS	10 mm

SPECIFICS ON THE SHORT THREAD

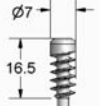
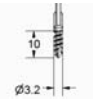
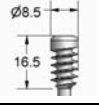
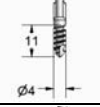
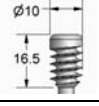
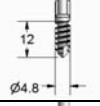
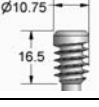
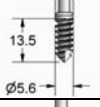
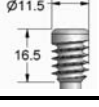
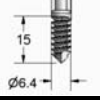
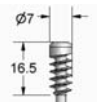

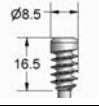

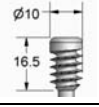
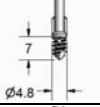
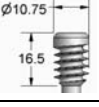
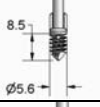
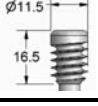
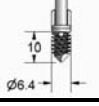
The short thread males components are designed to resist maximum pull-out forces due to growth and distraction forces. Although in most cases no extra fixation is required, a small keyhole has been added to the distal end to achieve added strength to the distal fixation. Under C-arm and before the male 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 for all the other implant sizes) introduced and locked on both corteces.

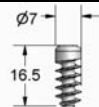

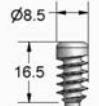

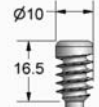

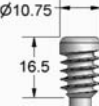
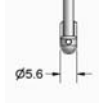
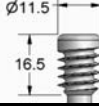
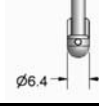
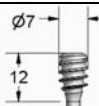

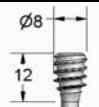

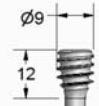



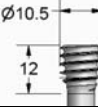
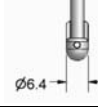


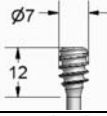

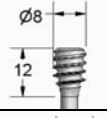

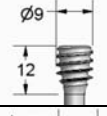
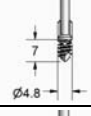
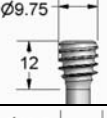
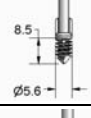
GUIDING K-WIRES FOR CANNULATED REAMERS

REAMER	DIAMETER AND LENGTH
DR132	Kirschner wire 0.062" (1.6 mm) x 9 inch
DR140	Kirschner wire 0.062" (1.6 mm) x 12 inch
DR148	Steinmann pin 5/64" (2.0 mm) x 12 inch
DR156	Steinmann pin 5/64" (2.0 mm) x 12 inch
DR164	Steinmann pin 5/64" (2.0 mm) x 12 inch

IMPLANTS

CATALOGUE#	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		
FD-040(L)-SS	Ø4.0 x 338		
FD-048(L)-SS	Ø4.8 x 409		
FD-056(L)-SS	Ø5.6 x 410		
FD-064(L)-SS	Ø6.4 x 412		
Small Femoral or Tibial Implants (Short Threaded Distal Fixation)			
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		

CATALOGUE#	SIZE Ø X LENGTH [MM]	PROXIMAL FIXATION [MM]	DISTAL FIXATION [MM]
LON Femoral Implants (Non-threaded Distal Fixation)			
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		
LON Tibial and Humeral Implants (Non-threaded distal Fixation)			
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		

CATALOGUE#	SIZE Ø X LENGTH [MM]	PROXIMAL FIXATION [MM]	DISTAL FIXATION [MM]
Standard Tibial and Humeral Implants (Short Distal Threaded Fixation)			
FD-032(SPS)-SS	Ø 3.2 x 197		
FD-040(SPS)-SS	Ø 4.0 x 333		
FD-048(SPS)-SS	Ø 4.8 x 404		
FD-056(SPS)-SS	Ø 5.6 x 405		
FD-064(SPS)-SS	Ø 6.4 x 407	