



CE ISO 9001:2008 ISO 13485:2003

Introduction

Indications

- Indicated for osteogenesis imperfecta diagnosed children who are 18 months and older aged.
- Used for Children's long bone deformity corrections.
- Fracture stabilization
- Prevent of fracture and also for lengthening associated with external fixators.
- In osteoporotic bone.

Features

It is made of medical stainless steel.

Consists of 3 parts; one D profile Bar (male nail), suitable D profile tube (female nail) and an end cap which is connected to the proximal part of the tube.

The male and the female and the angled female nails have five different diameter choices. The male nail has for each diameter one length choice because during the surgery it could be cut. The female nails have 5 different choices for each diameter and the angled female nails have 3 different length choices for each diameter.

During the growing of the child's bone, due to the engagement (telescopic) of the male and female nails, the nails also grow without any hindering.

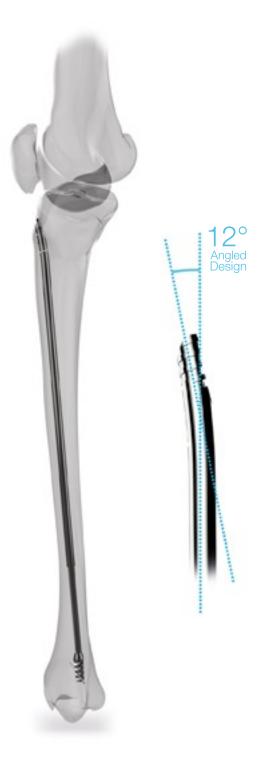
There is a special designed corkscrew end on the distal part of the male nails which gives a minimal damage to the growth plate and also holds the bone very well.

The end cap fixes, with a hexagonal screwdriver, the female nails with its self taping threads to the bone. There are grooves on the side of the end cap on which Kirschner wires can be send to prevent sliding back of the screw and to strengthen the fixation.

In this way the male and the female nails are fixed behind the distal and proximal bone growth plate into the epiphysis part of the bone.

There is a female D profile nail with 12 degree Angled proximal part which is Designed For Tibia. The angled part has a gap (opening) on which the male nail can go through out. Two slots and a hole, on which Kirschner wire can be used for fixing, are on the angled proximal part. The threads on the proximal part allows to screw the end cap and for not to exceed the bone there is a cut on the top of the nail.

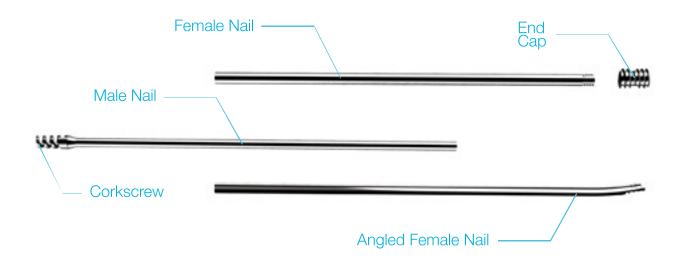
The application of the nail for tibia and humerus is from the proximal part and for femur is from proximal and distal part of the bones.



Special Angled Design For Tibia.

Implants

FEMALE NAIL DIAMETER	FEMALE NAIL	ANGLED FEMALE NAIL LENGTH CHOICE	MALE NAIL	END CAP
3.5 mm	110 mm 120 mm 130 mm 140 mm 150 mm	110 mm 130 mm 150 mm	2x180 mm	7 mm
4.0 mm	150 mm 170 mm 180 mm 190 mm 200 mm	150 mm 180 mm 200 mm	2.5x250 mm	8 mm
5.0 mm	150 mm 200 mm 210 mm 230 mm 250 mm	150 mm 210 mm 250 mm	3.5x300 mm	9.5 mm
6.0 mm	250 mm 270 mm 280 mm 290 mm 300 mm	150 mm 210 mm 250 mm	4x350 mm	10.5 mm
6.5 mm	190 mm 200 mm 250 mm 280 mm 300 mm	150 mm 210 mm 250 mm	5x350 mm	11.5 mm

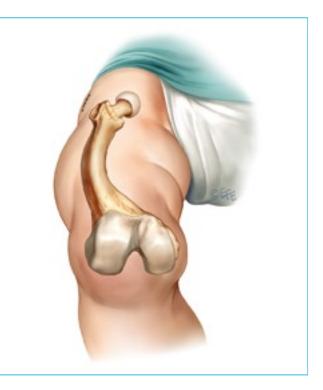


3 —

Surgical Technique

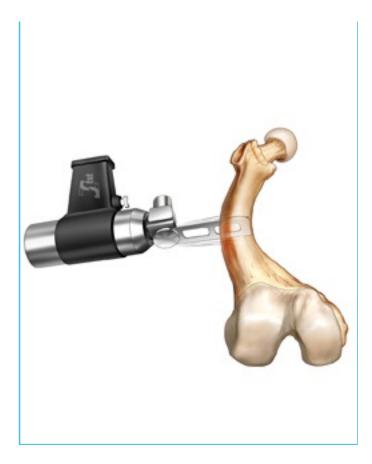
1.1 ANTEGRADE TECHNIQUE

A ENTRY POINT: From the tip of the trochanter major at the proximal femur, approximately 2 cm incision is performed.

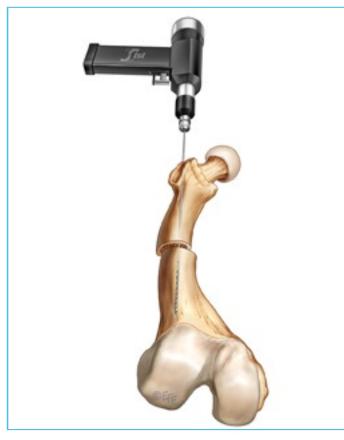


B GUIDE WIRE INSERTION:From the tip of the trochanter major at the proximal femur a guide wire is advanced into the medullary canal.





C OSTEOTOMY: The osteotomy is applied at the center of rotation and angulation (CORA) of deformity (the point where the guide wire tap cortex) then the guide wire is advanced distally.





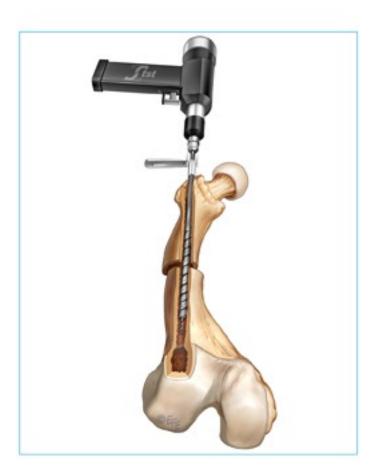
1.2 RETROGRADE TECHNIQUE

A GUIDE WIRE INSERTION: Procedure is began with osteotomy that is applied to center of the deformity rotation and angulation (CORA). After the osteotomy the guide wire is entered from the center point of the osteotomy line and advanced to the proximal. After fluoroscopic control the canal is opened with an appropriate reamer.

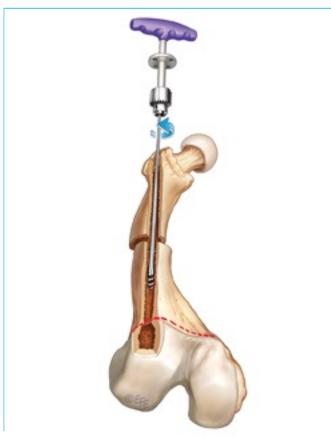


B The guide wire is send from the distal to the medullary canal. The wire end must reach the distal epiphysis. If the wire contact the cortex or remove because of the bone curve, a second osteotomy is done and the wire is orientated to the center of the bone.





Reaming is began with the smallest cannulated reamer over the wire. Reaming process is done until metaphysis, do not perforate to epiphysis.



SPLACEMENT MALE NAIL The male nail is forwarded by turning clockwise through to the distal

segment.

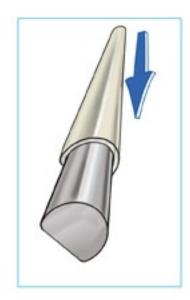
4 CUTTING MALE NAIL

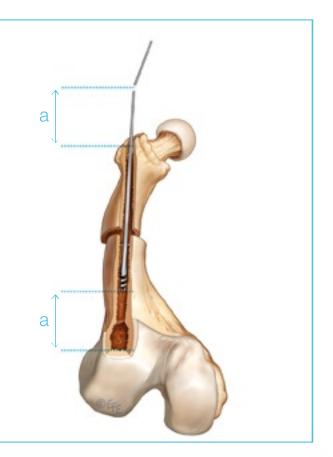
The length of the outer part of the male nail the level of fossa trochanterica is controlled by fluoroscopy. The distance between the tip of the male nail and the joint surface which was measured at the previous step is left and the exceeding part is cut.



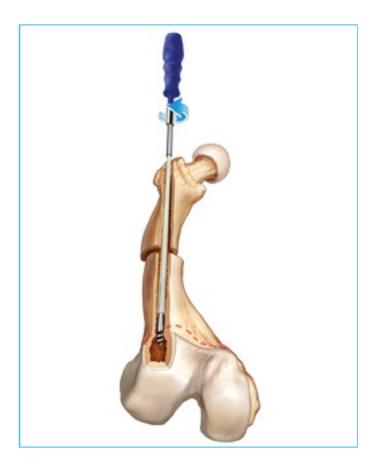
5 PLACEMENT FEMALE

Appropriate size of the Female Nail of the telescopic nail is chosen and entered into the proximal femur by sliding over the male nail.









6 POSITIONING OF TELESCOPIC NAIL

By turning the female nail holder which is mounted to the threads at the proximal part of the female nail, the male nail is advanced through the medullary canal. The corkscrew tip is placed to the distal metaphysis under the control of fluoroscopy.



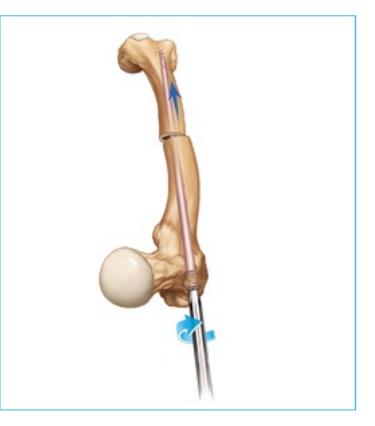
7END CAP PLACEMENT

The end cap is placed on the proximal part of the female nail while the proximal part is outside.

8 LOCKING PROXIMAL END CAP

The female nail should be send without turning until the screw part touches the bone. The turning process is began when the end cap insert the trochanteric fossa to enter the screw into the bone and to provide passing of the corkscrew through the growth plate.

In this stage the placement of the tip of the male nail to the distal epiphysis should be controlled.

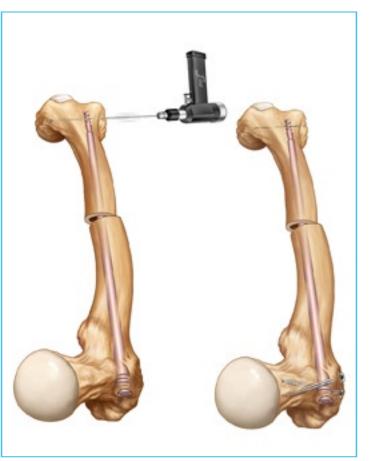


9 DISTAL LOCKING

The fixation to the distal epiphysis is increased by sendig two threaded Kirschner wire into the corkscrew tip.

10 PROXIMAL LOCKING

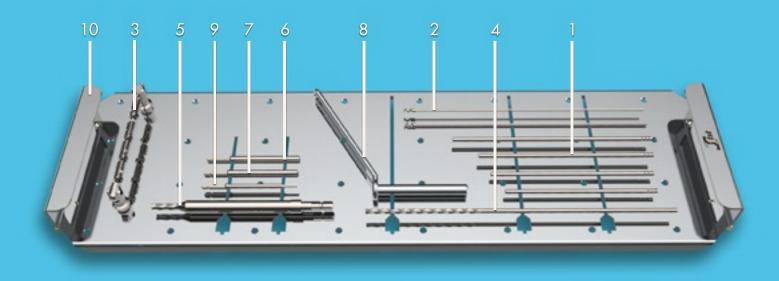
Extra locking screws from the notch on the proximal locking screws can be applied to increase stability.

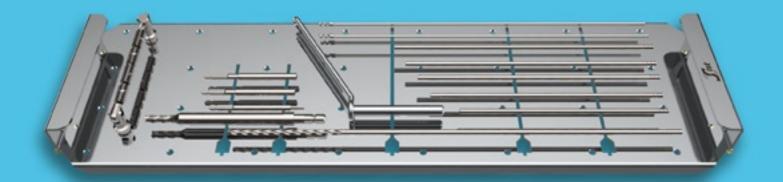


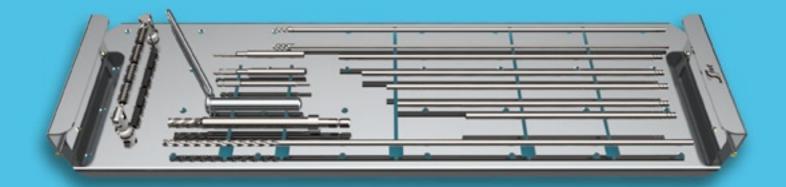
Instruments Implants

NO CATALOG NO **UBB NO** DESCRIPTION QTY TELESCOPIC INTRAMED, NAIL-FEMALE SS Ø3.5X110 MM TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø3.5X120 MM TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø3.5X130 MM TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø3.5X140 MM 80710350140 8680858405565 TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø3.5X150 MM 80710350150 8699931033090 TELESCOPIC INTRAMED. NAIL-MALE SS Ø2.0X180 MM TELESCOPIC I.M. NAIL END CAP SS 3.5 MM CANNULATED DRILL FOR Ø3.5 MM NAIL DRILL FOR END CAP Ø3.5 MM SPECIAL FEMALE NAIL DRIVER 3.5 MM SPECIAL MALE NAIL DRIVER 2.0 MM Ø 3.5 MM DRILL GUIDE (TELES) Ø 3.5 MM FEMAIL NAIL TURNING TIP 10 801001 TELESCOPIC NAIL DESIGN TRAY 1 (480x145x33) 80710400150 8699931033106 TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø4.0X150 MM 80710400170 8680858405572 TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø4.0X170 MM 80710400180 8699931033113 TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø4.0X180 MM TELESCOPIC INTRAMED, NAIL-FEMALE SS Ø4.0X190 MM 80710400190 8680858405589 TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø4.0X200 MM 80710400200 8699931033120 TELESCOPIC INTRAMED. NAIL-MALE SS Ø2.5X250 MM TELESCOPIC I.M. NAIL END CAP SS 4.0 MM CANNULATED DRILL FOR Ø4.0 MM NAIL DRILL FOR END CAP Ø4.0 MM 04010000040 8680858400164 08750000040 8699931033380 SPECIAL FEMALE NAIL DRIVER 4.0 MM SPECIAL MALE NAIL DRIVER 2.5 MM 00760000025 8680858406470 Ø 4 MM DRILL GUIDE (TELES) Ø 4 MM FEMAIL NAIL TURNING TIP 10 801002 TELESCOPIC NAIL DESIGN TRAY 2 (480x145x33) TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø5.0X150 MM 80710500150 8680858406432 TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø5.0X200 MM TELESCOPIC INTRAMED, NAIL-FEMALE SS Ø5.0X210 MM 80710500210 8680858405596 TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø5.0X230 MM 80710500230 8699931033144 TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø5.0X250 MM TELESCOPIC INTRAMED. NAIL-MALE SS Ø3.5X300 MM TELESCOPIC I.M. NAIL END CAP SS 5.0 MM 3 80710000050 CANNULATED DRILL FOR Ø5.0 MM NAIL DRILL FOR END CAP Ø5.0 MM SPECIAL FEMALE NAIL DRIVER 5.0 MM SPECIAL MALE NAIL DRIVER 3.5 MM 8 02010050050 Ø 5 MM DRILL GUIDE (TELES) Ø 5 MM FEMAIL NAIL TURNING TIP TELESCOPIC NAIL DESIGN TRAY 3 (480x145x33)

10 801003

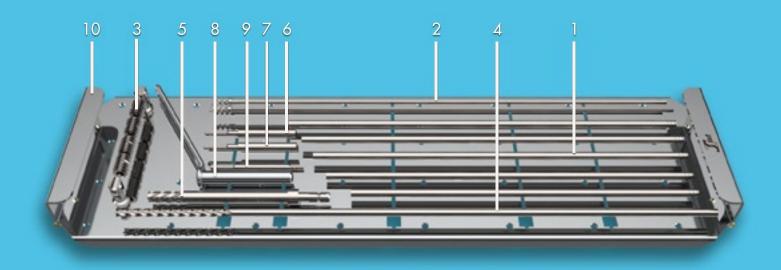


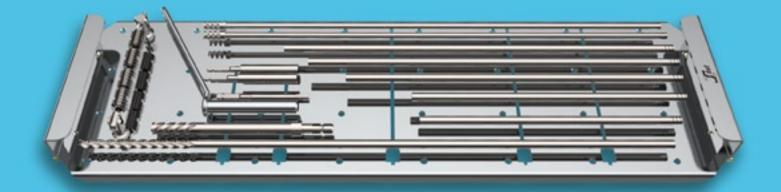


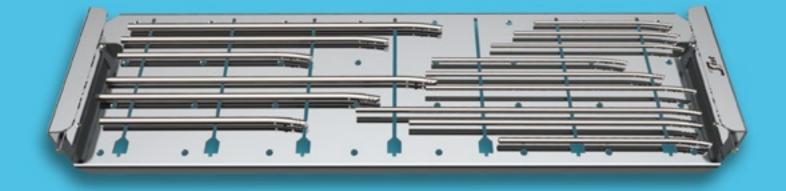


Instruments

NO 1 2 3 4 5 6 7 8 9 10	CATALOG NO 80710600250 80710600280 80710600290 80710600290 80710600300 80711400350 8071000060 0201000060 0401000060 0401000060 0076000040 0201006060 02010003060 801004	UBB NO 8699931033168 8680858405619 8699931033175 8680858405626 8699931033250 8699931033250 8699931033359 868085840096 8680858400188 8699931033403 8680858406494 8680858408948 8680858408955	DESCRIPTION TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø6.0X250 MM TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø6.0X270 MM TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø6.0X280 MM TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø6.0X290 MM TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø6.0X300 MM TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø6.0X300 MM TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø6.0X300 MM TELESCOPIC INTRAMED. NAIL-FEMALE SS Ø4.0X350 MM TELESCOPIC I.M. NAIL END CAP SS 6.0 MM CANNULATED DRILL FOR Ø6.0 MM NAIL DRILL FOR END CAP Ø6.0 MM SPECIAL FEMALE NAIL DRIVER 6.0 MM SPECIAL FEMALE NAIL DRIVER 4.0 MM Ø 6 MM DRILL GUIDE (TELES) Ø 6 MM FEMAIL NAIL TURNING TIP TELESCOPIC NAIL DESIGN TRAY 4 (480x145x33)	QTY 1 1 1 1 4 4 2 1 1 1 1 1 1
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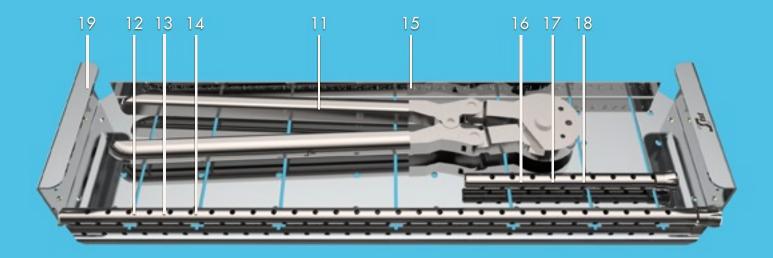


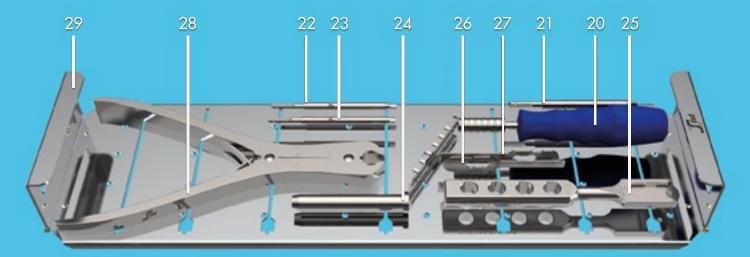
Instruments

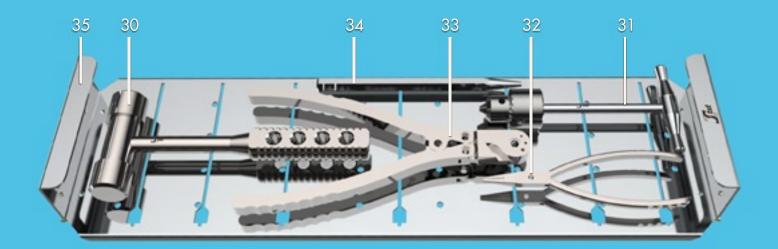
NO	CATALOG NO	UBB NO	DESCRIPTION	QTY
11	03210004050		SPECIAL ROD CUTTER FOR Ø 4.0,5.0 MM	1
12	23410450115	8698673457935	KIRSCHNER WIRE TROCAR POINT 1.5X450 MM	6
13	23410450120	8698673457928	KIRSCHNER WIRE TROCAR POINT 2X450 MM	6
14	04551008460	8699931029796	K-WIRE TUBE Ø10XØ8X460 MM	1
15	08050000011	8698673496507	RADIOGRAPHIC RULER 400 MM	1
16	04551006160	8699931029796	K-WIRE TUBE Ø10XØ6X160 MM	1
17	23412125015	8698673452619	KIRSCHNER WIRE TREADED POINT 1.5X125 MM	4
18	23410120150	8698673452978	KIRSCHNER WIRE TROCAR POINT 1.5X120 MM	2
19	801006		TELESCOPIC NAIL DESIGN TRAY 6 (480x145x33)	1

21	02010101002 02010010050	8698673493308 8680858400140	SOFT SCREW DRIVER QUICK (TORNAVIDA) LARGE SCREW DRIVER QUICK TIP HEGZAGONAL Ø5.0x100 MM	1
	02010010035 02010010040	8680858400126 8680858400133	SCREW DRIVER QUICK TIP HEGZAGONAL Ø3.5x100 MM SCREW DRIVER QUICK TIP HEGZAGONAL Ø4.0x100 MM	1
	08750009010	0087500090106	PROTECTION SLEEVE (END CUP DRILL)	1
25	03381000001	8699931023770	CHISEL HANDLE	1
26	03381016030	8699931023800	CHISEL BLADE 16x30mm Straight	1
27	03381011030	8699931023794	CHISEL BLADE 11x30mm Straight	1
28	02345020000	8698673493506	PLATE WIRE CUTTER UP TO 3MM	1
29	801007		TELESCOPIC NAIL DESIGN TRAY 7 (480x145x33)	1
				1

30	01193003009	8699931028133	BONE HAMMER SMALL (HAFIF CEKIC)	1
31	08050000100	8680858409174	T-HANDLE FOR CANNULATED DRILL	1
32	08201000004	8698673495036	LOCKING PLIERS (KILITLI CIKARMA PENSESI)	1
33	03210202535	8680858408986	SPECIAL ROD CUTTER FOR Ø 2.0,2.5,3.5 MM	1
34	02271000003		PIN IMPACTOR	1
35	801008		TELESCOPIC NAIL DESIGN TRAY 8 (480x145x33)	1







Radiographic Samples



pre op



post op







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