OVERFIX®

TRAUMA

TÉCNICA QUIRÚRGICA

Clavo de Húmero

bioadvance

CERTIFIED ISO 13485 · CE · FDA 510(k) Cleared · Cofepris Comisión Federal para la Protección contra Riesgos Sanitarios

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TÉCNICA QUIRÚRGICA
CLAVO DE HÚMERO OVERFIX

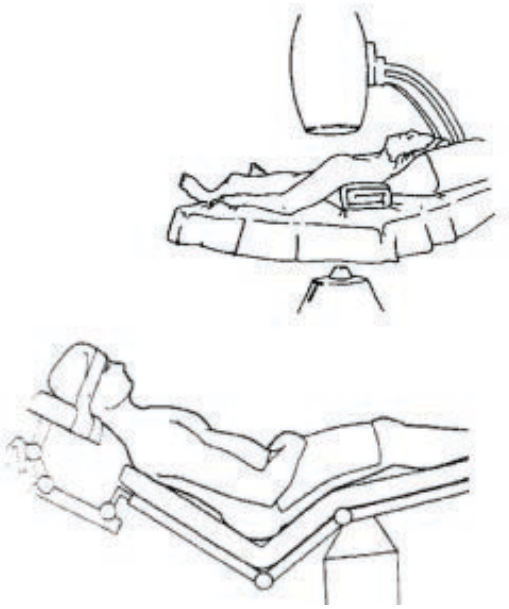
INDICATION:

-Proximal Humeral Fracture
-Humeral Shaft Fracture
-Humeral Pathologic Fracture

1. POSITION PATIENT

Position the patient supine on an extension table or a radiolucent operating table.

Abduct the affected arm and place it on the support pad under image intensification. Or lay the patient with beach-chair position.



2. APPROACH

Make a 3~4mm longitudinal incision, slightly anterior lateral acromion, to cleave the deltoid.

Note: To protect the axillary nerve, cleave the deltoid with less than 5cm to the distal acromion.

3. DETERMINE ENTRY POINT

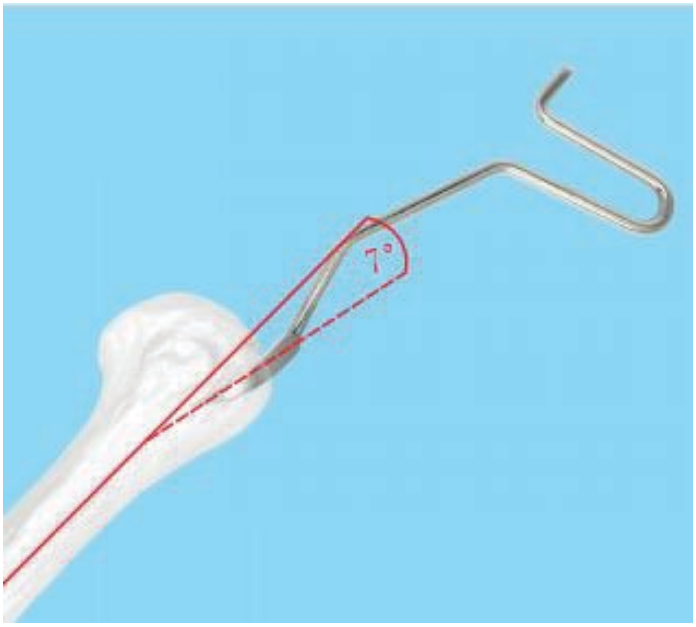
Select an entry point in the medial tip of humeral tuberculum majus, approximate 5mm of sulcus tendon in the posterior musculus biceps brachii.

Note: Ensure that the entry point is accurate so as to protect the axillary nerve.

4. OPEN MEDULLARY CANAL

Open and drill into the medullary canal using the 15044-018 reverse awl.

Note: The axis of the reverse awl shape an angle of 7° the sagittal plane with the sagittal plane and overlap with the coronal plane.



5. REDUCE FRACTURE AND INSERT GUIDE WIRE

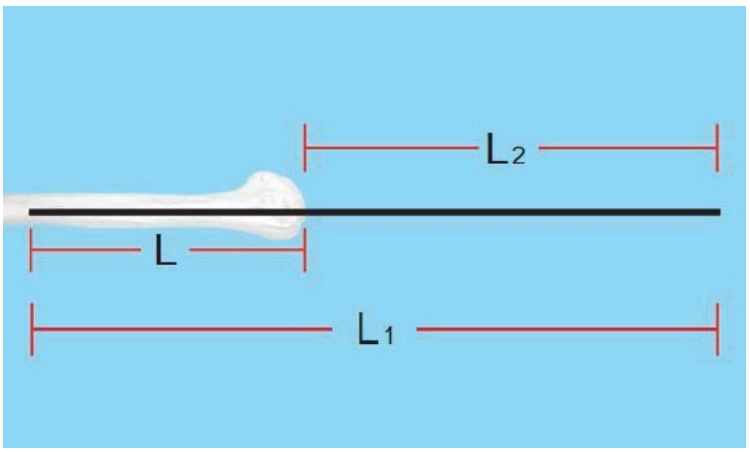
Insert the 15044-030 guide wire into the medullary canal after closed fracture reduction.

Note: Ensure that the guide wire is in the correct position of the medullary canal under image intensification.

6. DETERMINE NAIL LENGTH

Measure the length of L2, the length of the exposed guide wire. Subtract L2 from the overall length of the guide wire (L1), and the appropriate nail length L= L1- L2.

Note: Reconfirm the preoperative measured nail length.



7. REAM

Gradually enlarge the canal with the flexible medullary reamer along the guide wire up to the desired diameter, generally starting from the smallest size. Ream to a diameter of 0.5mm greater than the nail diameter. Do not move the guide wire when removing the medullary reamer.

8. CALIBRATE NAIL

Mount the selected nail on aiming device to calibrate.

(1) Connect the nail and 15044-001 inserting handle with the 15044-025 locking screw for main nail.

(2) Assemble the 15044-027 straight aiming arm on 15044-001 inserting handle and lock the straight aiming arm using the 15044-029 locking screw for arming arm at the appropriate mark according to the nail length.

(3) Install the 15044-002 curved aiming device on the distal end of the straight aiming arm, and screw it up with the locking screw. Calibrate the nail after the assembling process.

9. INSERT NAIL

Remove the guide wire with olive head, and insert guide wire without olive head.

Verify fracture reduction and insert the nail by hand as much as possible. Slightly rotate the insertion handle so to facilitate the nail insertion. If there is great resistance, ream or select a nail of smaller size. Ensure that the canal is at least 1mm wider than the nail diameter. Optionally, attach the inserter-extractor on the insertion handle and use light hammer blows on the connector to insert the nail.

Note: Ensure that the nail is advanced into 5mm below the proximal humeral bone surface.

10. PROXIMAL LOCKING

A. Install the 15044-003 proximal oblique aiming device. Assemble the 15044-004 protection sleeve and 15044-008 trocar. Make an incision at the fixed position in the bone cortex and cleave the soft tissue to bone surface. Then insert the protection sleeve and trocar to bone surface.

B. Remove the trocar and insert the 15044-007 inner sleeve, then drill hole with the 15044-015 3.2mm drill bit through the inner sleeve.

Note: Pre-estimate the depth and install the fixation sleeve at the appropriate mark tick before drilling or drill under image intensification.

C. After drilling the hole, remove the drill bit and inner sleeve. Confirm the length of the nail using the 15044-011 depth gauge.

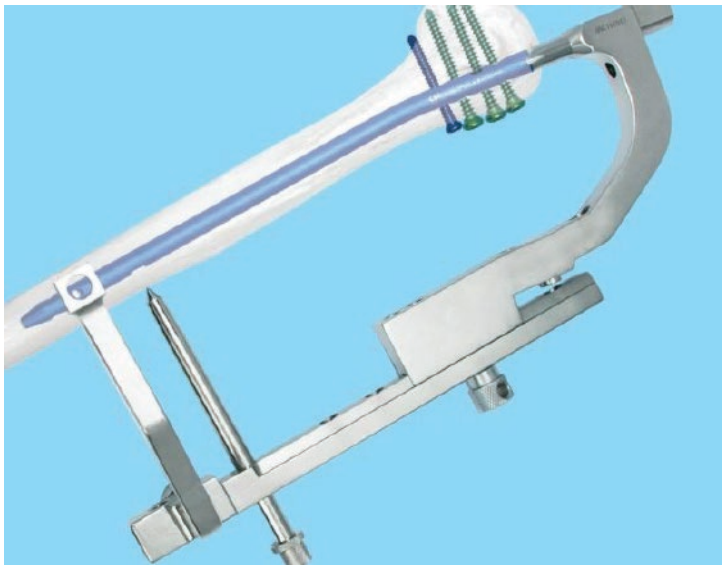
Note: Ensure that the protection sleeve is tightly pressed on the bone cortex during measuring.

D. Insert 5.0mm locking screw of appropriate length using 15044-017 hexagonal screwdriver through the outer protection sleeve till the 0 tick mark parallels with the sleeve.

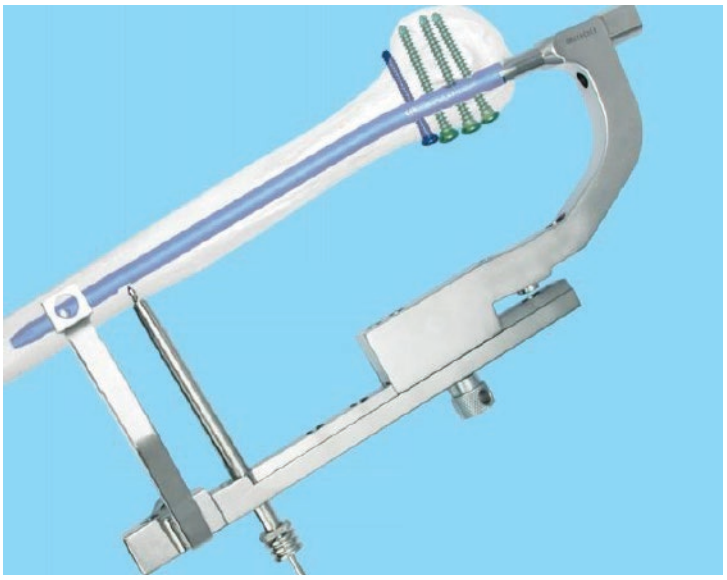
E. Repeat the same operation as described above to insert the other two locking screws. Remove the oblique aiming device and insert a 3.6mm locking screw like the above operation. Verify locking screw length under image intensification to ensure a correct position.

11. ASSEMBLE CALIBRATING PIN

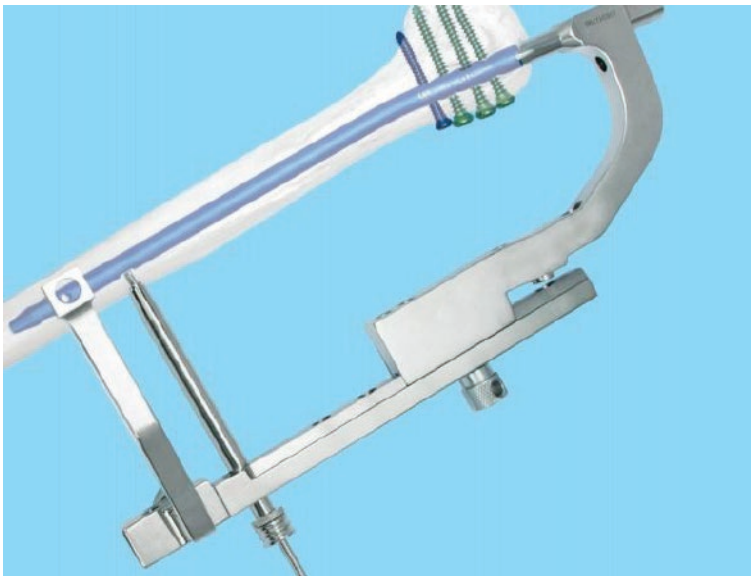
A. Connect the straight aiming arm and tighten with locking screw. Insert the outer sleeve and trocar to the bone cortex.



B. Remove the trocar, and place the outer sleeve. Insert the φ3.2mm drill bit along the sleeve and penetrate through the single bone cortex.



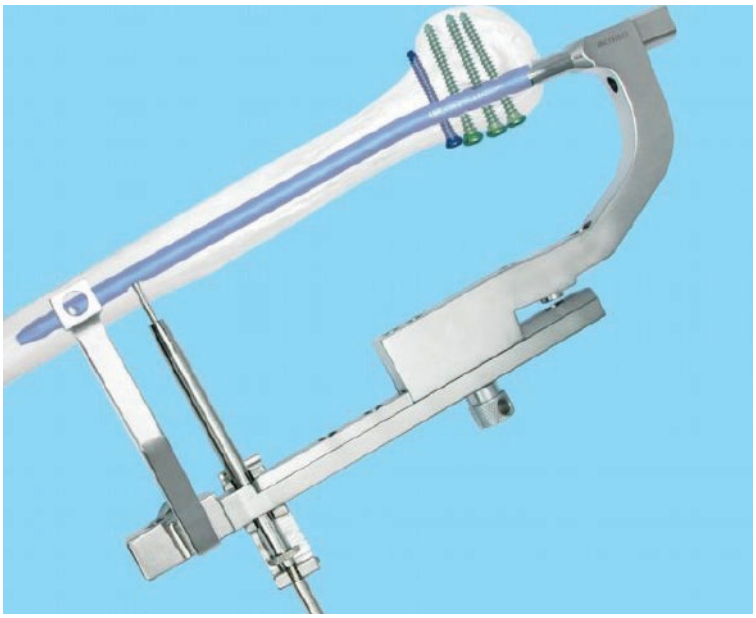
C. Remove the drill bit, and then insert a 15044-020 φ3.2mm drill bit with flat head to clear the bone debris on the operation plateau.



D. Remove the flat-headed drill bit and sleeve, and then insert the calibrating pin.

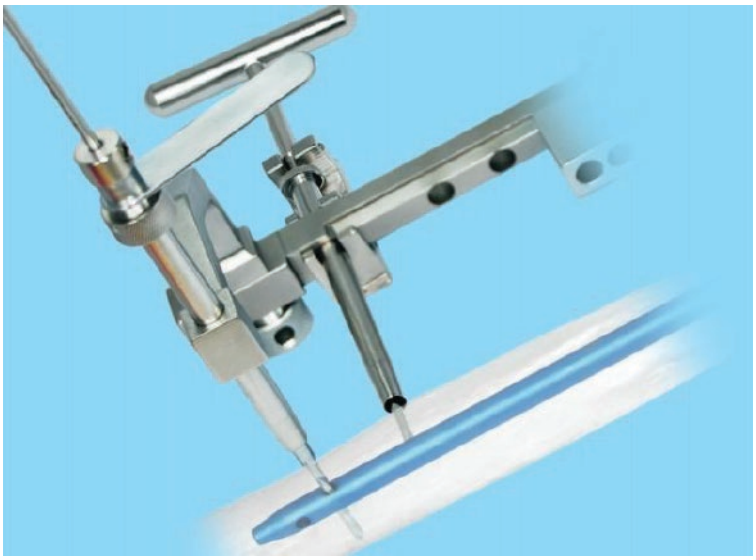
Ensure that the calibrating pin could contact with the nail plateau. Connect the calibrating pin and the straight aiming arm using the 15044-028 U-clip.

Note: The accurate implantation of locking screws is determined by the direct contact of calibrating pin and the nail plateau.



12. INSERT DISTAL LOCKING SCREW

A. Install the protection sleeve and trocar at the 15044-002 curved aiming arm. Make an incision in the fixed position of the bone cortex and cleave the soft tissue to bone surface. Then insert the protection sleeve and trocar to bone surface. Remove the trocar and position the inner sleeve. Drill through the inner sleeve using 3.0mm drill bit.

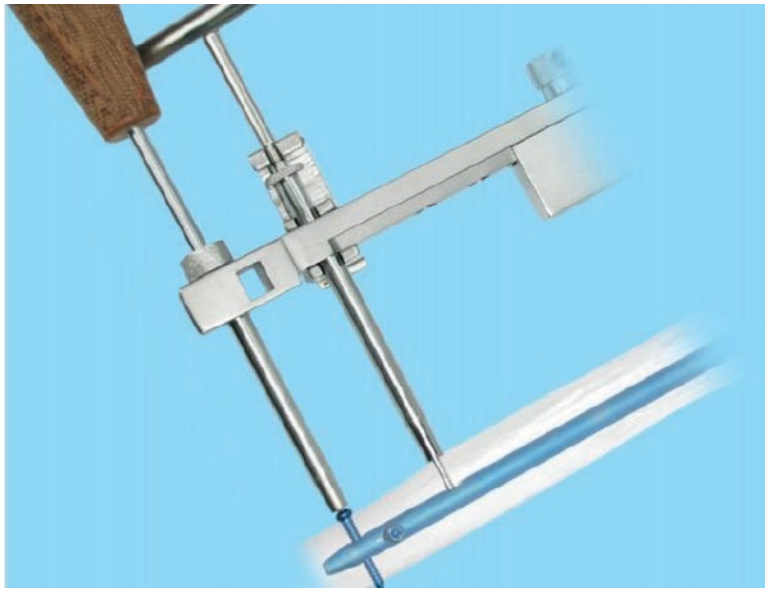


B. Drill through both cortices until the tip of the drill bit just breaks through the medial cortex. Remove the drill bit and inner sleeve. The required length of the locking screw can be determined directly by measuring with the 15044-011 depth gauge for locking screw.

C. Insert an appropriate 3.6mm locking screw using 15044-017 hexagonal screwdriver through outer sleeve till the 0 tick mark reaches end of the sleeve.

D. Repeat the same operation as described above to insert the other 3.6mm locking screw.

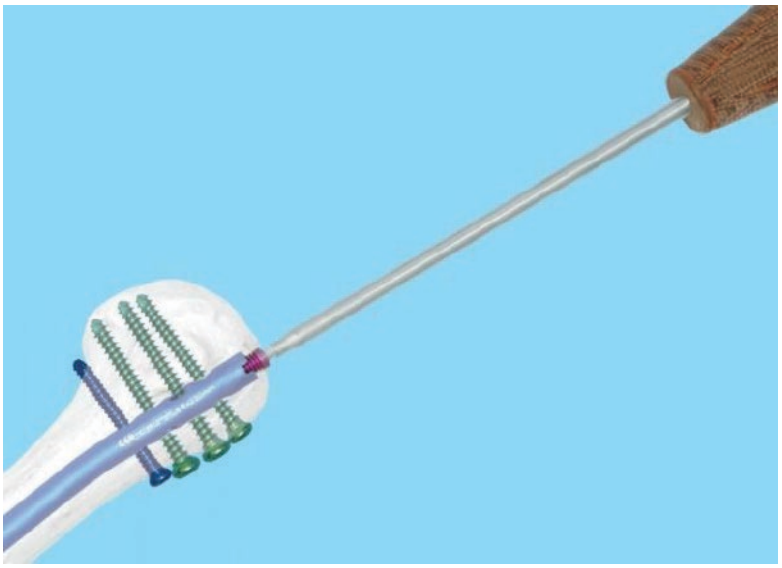
Note: Protect the brachial artery and radial nerve when inserting the distal locking screw. It will be more stable to place two locking screws. Accordingly, just insert one locking screw if it is difficult to lock.



13. INSTALL TEND CAP INTO NAIL

The end cap protects the inner thread of the nail from tissue ingrowth and facilitates subsequent implant removal. Remove the proximal aiming arm and insertion handle.

Pick up the end cap with the hexagonal screwdriver shaft and slightly screw it into the nail end. Tighten the end cap using the hexagonal screwdriver. Ensure that the nail and the end cap are fully countersunk in the humeral head, so that shoulder function remains unhindered, including during abduction. For this reason, an end cap without extension should be used where possible.



13. IMPLANT REMOVAL

Remove each locking screw and end cap successively with hexagonal screwdriver.

Mount the universal joint and ail using ratchet wrench, and connect the universal joint on inserter-extractor. Ensure that every component is completely tightened. Perform the slide hammer to remove the nail.

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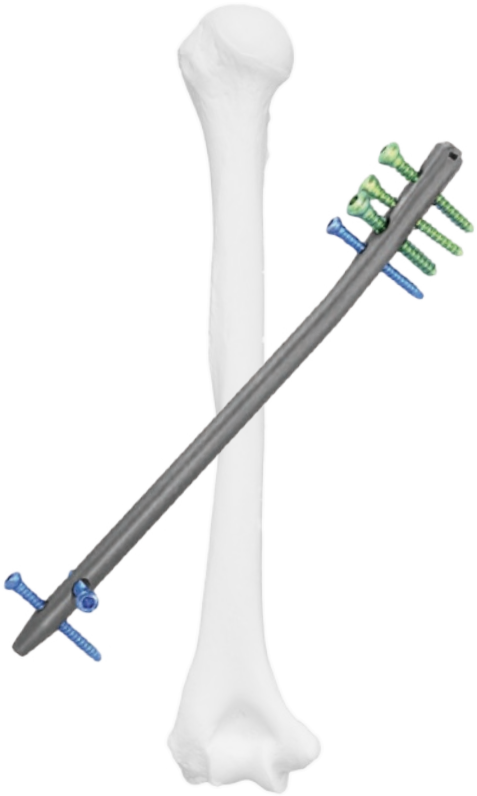
Diámetro: 7.0mm/8.0mm
Material: Aleación de Titanio
Canulado

CÓDIGO	DIÁMETRO (mm)	LARGO (mm)
10638-016	7.0	160
10638-018	7.0	180
10638-020	7.0	200
10638-022	7.0	220
10638-024	7.0	240
10638-026	7.0	260
10638-116	8.0	160
10638-118	8.0	180
10638-120	8.0	200
10638-122	8.0	220
10638-124	8.0	240
10638-126	8.0	260



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3.5MM TORNILLO DE BLOQUEO PARA CLAVO DE HÚMERO

Diámetro: 3.5mm

Material: Aleación de Titanio

CÓDIGO	DIÁMETRO (mm)	LARGO (mm)
10648-018	3.5	18
10648-020	3.5	20
10648-022	3.5	22
10648-024	3.5	24
10648-026	3.5	26
10648-028	3.5	28
10648-030	3.5	30
10648-032	3.5	32
10648-034	3.5	34
10648-035	3.5	35
10648-036	3.5	36
10648-038	3.5	38
10648-040	3.5	40
10648-045	3.5	45
10648-050	3.5	50

5.0MM TORNILLO DE BLOQUEO PARA CLAVO DE HÚMERO

Diámetro: 5mm

Material: Aleación de Titanio

CÓDIGO	DIÁMETRO (mm)	LARGO (mm)
10649-020	5.0	20
10649-025	5.0	25
10649-030	5.0	30
10649-035	5.0	35
10649-040	5.0	40
10649-045	5.0	45
10649-050	5.0	50

TAPÓN PARA CLAVO DE HÚMERO

Diámetro: 5mm

Material: Aleación de Titanio

CÓDIGO	DIÁMETRO (mm)
10650-000	5.0

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SET DE INSTRUMENTAL

Reverse Awl

Drill Bit, φ3.0, length 200mm

Drill Bit, φ3.2, length 200mm

Protection Sleeve, φ8.0, length 85mm

Protection Sleeve, φ10.0, length 85mm

Trocar, φ6.0

Trocar, φ8.0

Inner Sleeve, φ6.0

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Inner Sleeve, φ8.0

Screwdriver Shaft, hexagonal, φ3.0

Screwdriver, hexagonal, φ3.0

Fixation Sleeve for Drill Bits

L-Wrench, hexagonal, φ3.0

Inserter-Extractor for Humeral Nail

Universal Joint

Radiographic Ruler
for Humeral Nail

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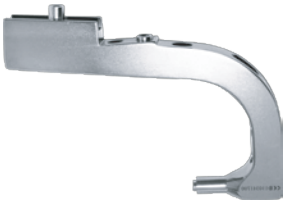
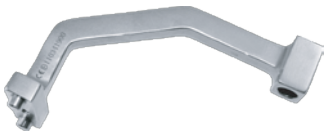
Insertion Handle for Humeral Nail



Aiming Arm, straight

Distal Aiming Device, curved



Proximal Aiming Device, oblique

Locking Screw for Aiming Arm

Connecting Shaft for Aiming Arm

Ratchet Wrench

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Depth Gauge

Guide Wire, φ2.0, length 660mm, with olive head

Guide Wire, φ2.0, length 660mm, without olive head

Calibrating Pin

U-Clip

Drill Sleeve

Protection Sleeve, for Calibrating Pin

Trocar, φ6.0, length 96mm

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Locking Screw for Aiming Arm II

Drill Bit with flat head

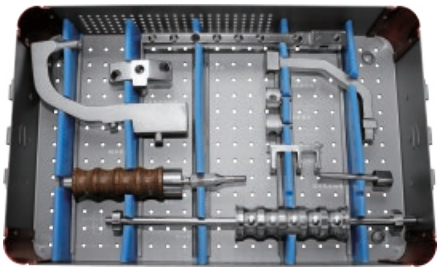
Flexible Reamer, φ6.5

Flexible Reamer, φ7.0

Flexible Reamer, φ7.3

Flexible Reamer, φ8.3

Instrument Case



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