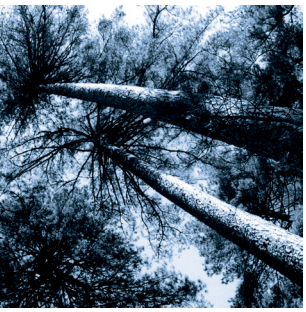
POWERED BY: SURFIX™

PSH • ENGLISH

PSH

Proximal Humeral Plate



Surgical technique

ORTHOPAEDICS
LOWER
EXTREMITY

INTEGRA™
EXTREMITY RECONSTRUCTION

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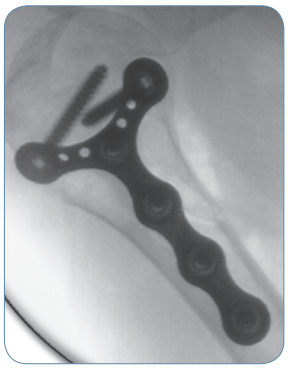
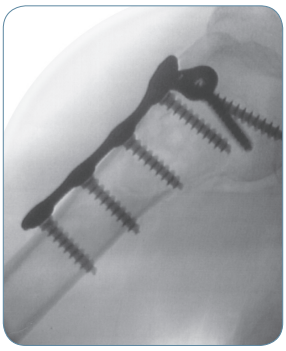




Concept

The SURFIX® implants for bone fixation take advantage of a new and outstanding principle, which consists in fixing the screw to the implants. Fixation is secured through to a threaded lipped socket integrated in the plate and to a lock screw wich is fitted into it.

"This technique modifies and improves considerably the mechanical qualities of plate fixation."

Indication

The PSH is indicated for internal fixation of proximal humeral fractures with the SURFIX® plate.

Benefits

• Great stability. The different elements, wich were seperate, now constitute a single unit system.

• No damage of blood vessels in the periosteum. A close contact between the bone and the plate is no longer necessary to ensure a reliable fixation.

• Elasticity and stability of the assembly.
Screw/plate solidity provides better force distribution over the assembled unit.

Excellent resistance to forces:
- leverage forces
- shearing forces
- «ploughing» forces

Implant details

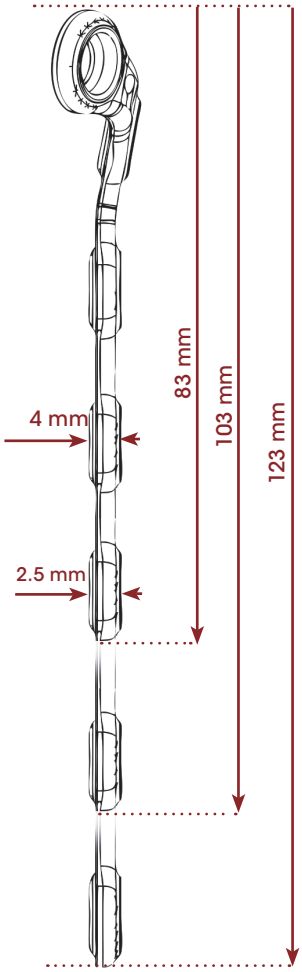
Materials:

- Plate: Stainless Steel 316L
- Screw and lock-screw: Titanium TA6V

• *Shapeable plate*

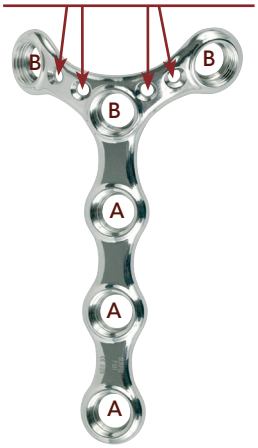
• *Stabilisation of the lesser and greater tubercle plate*

• *Low profile design:*
- protection of tissues
- protection of periosteal vascularisation



• *Crossed screwing in the humeral head works in two different planes and provides increased stability to tearing off of the cephalic fragment during rotatory movements of the arm.*

Holes for pins and sutures



A 

•*Cortical bone screw and lock-screw:*
- Asymmetrical thread
- Nominal diameter 4.5 mm
- Core diameter 3.0 mm
- Self-tapping screw

B 

• *Cancellous bone screw and lock screw:*
- Symmetrical thread
- Nominal diameter 6.5 mm
- Core diameter 3.5 mm
- Non self-tapping screw

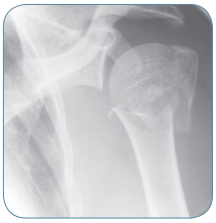
PSH

Surgical technique

Surfix® as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Operative technique performed by the Department of Orthopaedic-trauma Surgery, University Hospital, 49033 Angers.
Dr. A. Talha • Dr. J.L. Toulemonde • Dr. P. Cronier • Dr. L. Hubert • Pr. Ph. Massin

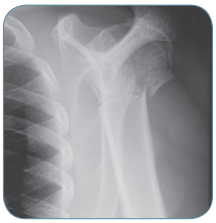
1 • History



As applies to the neck of femur, ageing of the population is the major cause for proximal humeral fractures.

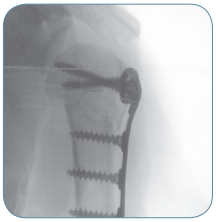
These fractures are rarely simple and usually occur in a poor quality porotic bone. These fractures may also affect young adults (generally in the setting of a violent injury). The possible complications are then frequently incapacitating.

The surgeon generally has the choice of one of four solutions:



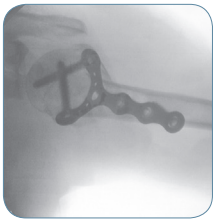
1 • Functional treatment which is indicated for non-displaced fractures, some piecemeal fractures or conversely for comminuted disorganised fractures in frail inoperable elderly people

2 • (Non-surgical) orthopaedic treatment is generally reserved for not severely displaced, stable fractures.



3 • Internal fixation is reserved for displaced or unstable fractures which may be maintained and stabilised by nail, screw, pins or band such as, for example, certain Neer II and Neer III fractures.

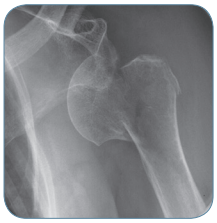
4 • Arthroplasties are proposed for complex fractures which are at very high risk of necrosis, such as for Neer grade IV fractures or certain fracture dislocations.

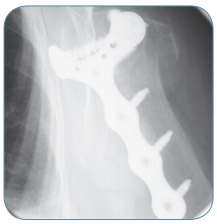


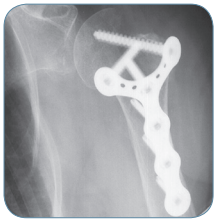
Regardless of the treatment chosen, the aim is to obtain a painless shoulder with the best possible mobilities.

In contrast to the hip, there is no reference internal fixation material currently for fractures of the proximal end of the humerus which allows tailored, reproducible epiphyseal-diaphyseal internal fixation with sufficient primary stability to begin early habilitation.

The lack of primary stability with conventional internal fixations in fractures of porotic bone or in comminuted fractures in young people has led us to develop a plate designed to restore the neck-tuberosity anatomy, which has the following theoretical objectives:







1 • To obtain crossed screwing in the humeral head to increase stability:

Whereas almost all current plates are implanted in the lateral position with neck screwing, mostly in the frontal plane, crossed screwing in the humeral head which works in two different planes should provide increased stability, countering tearing off of the neck fragment during rotation movements of the arm.

2 • To avoid conflict between the proximal part of the plate and the acromion and/or coracoid process

3 • To repair and stabilise parts of the rotator cuff: lesser tuberosity (trochin) and sub-scapular tuberosity, greater tuberosity (trochiter), and the supra and infraspinatus

4 • To develop a baseline surgical technique with reproducible stages to enable young surgeons to learn the operative technique relatively quickly.

2 • Pre-operative assessment

• Emergency basis : the assessment involves a postero-anterior film of the shoulder and a Lamy view. A scan has become systematic for us.
Three-dimensional reconstruction is particularly useful to assess the size and displacement of the fragments. In addition the scan helps to assess the bone density of the neck fragment and to predict screw holding.

3 • Indications for internal fixation

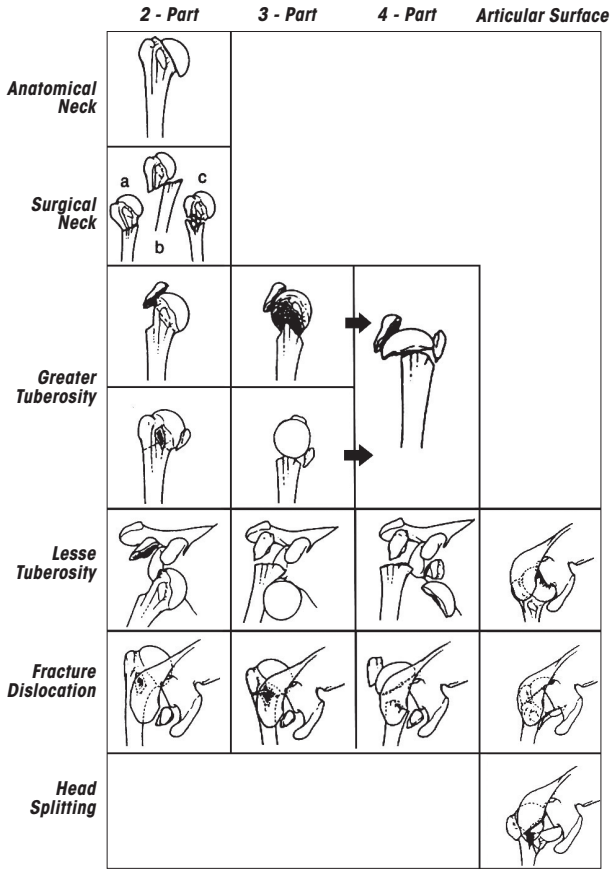
These are based on :

• the type of fracture; these are usually displaced Neer type II, Neer type III, and more rarely Neer type IV fractures,

• displacement of the fragments or their potential instability and fear of subsequent infra-acromial conflict,

• the age, general condition and particularly the capacity of the patient to take part in re-education,

• whether or not the dominant side is affected.



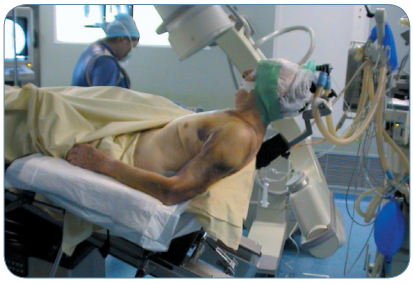
4 • Surgical technique

Common points of the technique

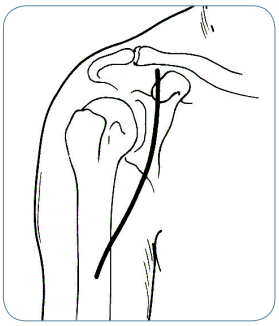
It is important to stress from the outset that this is a technique which must in no case "dismantle" the fragments and worsen the risk of necrosis of the neck.

The reduction procedures will for the most part be guided by radioscopy control.

1 • Positioning the patient : dorsal decubitus position, slightly seated in the so-called beach-chair position.



2 • Positioning of the fluroscope : the C-arm is placed opposite the surgeon so it has the permanent capacity to obtain a postero-anterior image. The lateral image is obtained by rotating the arm laterally. With certain operating tables which require the patient to be positioned eccentrically, in order for the shoulder to project beyond the table, the C-arm must occasionally be positioned in the sagittal plane on the side of the patient's head.



3 • Delto-pectoral incision passing outside of the cephalic vein and extending sufficiently inferiorly to position the diaphyseal screws without hindrance:

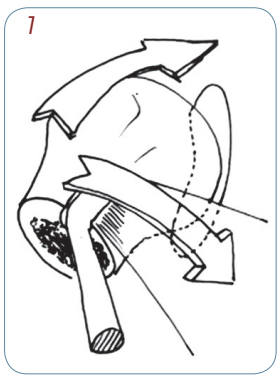
• Positioning the retractors. Generally we use an autostatic retractor in the middle part of the approach route and a counterelbow retractor at the upper part of the approach route on the lateral edge of the acromion which is then slid behind the humeral head.

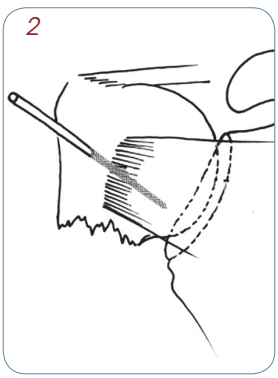
• The assessment of the injury examines the state of the tuberosity, rotator cuff, and tests for free fragments which may cause subsequent conflict.

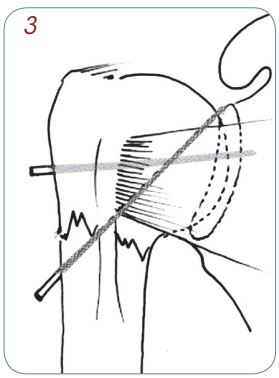
Difficult case of a 2 fragments fracture : diaphyseal head

• The problem raised is that of repositioning the head in the "0 position" with reference to the glenoid *(Diagram 1)*.

• If there are no criteria indicating reduction at the head-diaphysis junction we position the head facing the glenoid, manipulating it with a pin or pointed cramp forceps as required, until the rotator cuff is sufficiently tight *(Diagram 2)*. The diaphysis is then fixed to the head (cramp forceps rising pins) in a position close to "elbow to body". The head is often unsteady and very mobile and it may be useful to fix it temporarily onto the glenoid with a pin (see red arrow), pending the phase of fixing it to the diaphysis *(Diagram 3)*.







• The position of the long head of biceps and the tension of the subscapularis provide an indirect idea of the retroversion of the head before fixing it to the diaphysis. If, by C-arm, the appearances of the circumference of the humeral neck is satisfactory all that remains to be done is to gently test rotations of the shoulder in the 90° abduction position (Patte position), to exclude conflicting callus.

• We position the plate on the reduced fragments:
(Diagrams 4a - 4b)

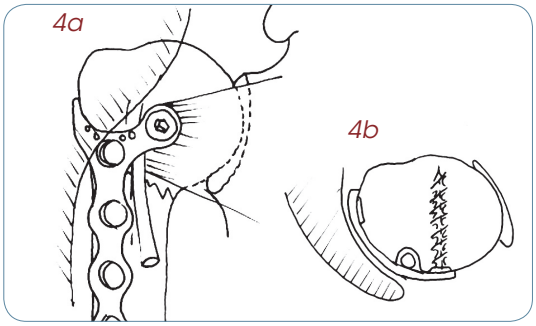
- Positioning the plate requires it to be fitted to the local anatomy per-operatively.

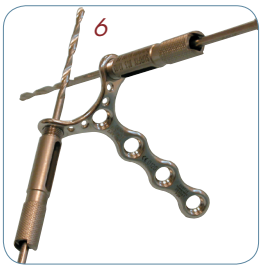
- The proximal branches of the plate may be orientated in the different spatial planes. They may be distanced if the humeral head is large or brought together if the humeral head is small *(Diagram 5).* The right and left branches of the plate must be curved gently to avoid the proximal screws touching each other. Using drills and drilling guides it is possible to confirm that the screws do not come into conflict *(Diagram 6).* The branches may also be orientated in order that the screws are ascending allowing where necessary the plate to be positioned relatively low on the humeral head to limit any infra-acromial conflict.

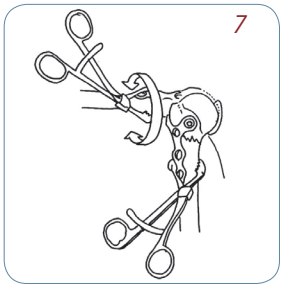
- fixation of the plate onto the trochin with 1 antero-posterior screw,

- the plate is not screwed onto the diaphysis, but is maintained with a cramp forceps,

- the rotations are then retested before definitive fixation of the implant *(Diagram 7).*





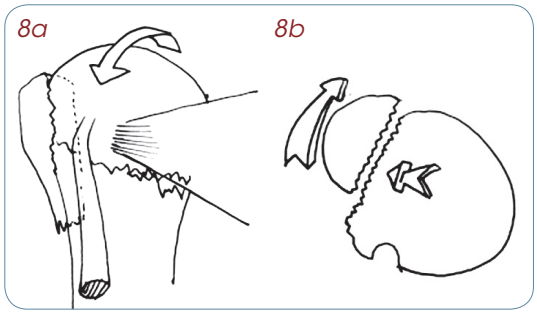


Intermediary case of a three fragments fractures :
Head and lesser tubercle, greater tubercle and diaphysis

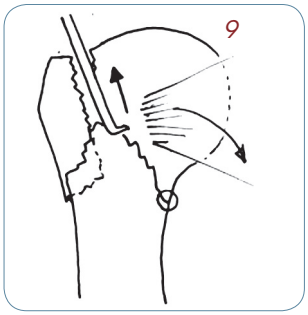
• The first phase is designed to assess the injury, to prepare for any refixation of the tuberosities *(Diagrams 8a-8b).*

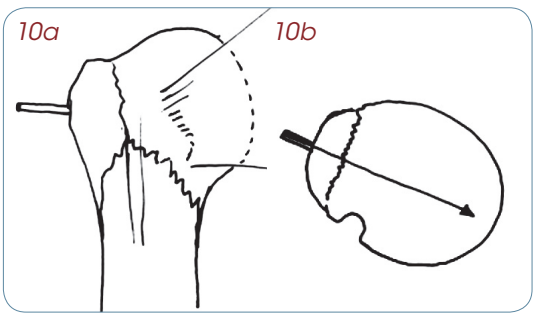
• The humeral head must then be carefully positioned against the scapula and where necessary fixed onto the glenoid with a pin. This stage is facilitated by use of C-arm.

• The greater tuberosity is manipulated either with a «joystick» pin or using wire passing through the bone in order to place it in a position close to the reduction controlled under C-arm. This temporary reduction with the neck fragment may be assisted either with pointed cramp forceps or with pins passing percutaneously through the deltoid and then re-cut to a few millimetres from the surface of the bone to allow mobilisations.



Before this reduction the neck fragment can then be cautiously lifted using a spatula or clamp which is often covered over in the valgus position *(Diagram 9).*





Once the epiphyseal fragment has been reconstructed we are back in the case of the previous situation and it must then be fixed to the diaphysis
(Diagrams 10a - 10b).

We have found that reduction of the humeral head with the diaphysis is "easier" if the arm is positioned alongside the body, as the weight of the arm and the forces on the neck fragment are reduced. Conversely, in this position the visual field does not allow us to see clearly that the anterior surface of the head of the humerus and the diaphyseal area against the lateral edge of the log head of biceps. The locked plate is then slid beneath the deltoid with the arm position practically parallel with the body. We ensure during this stage of positioning of the trochiter that the plate is positioned above.

The whole of the anterior neck screw is positioned in front of the tendon of the long handed biceps on the middle part of the trochin with X-ray control to achieve hold in the central part of the humeral head. In this position it is very easy to insert the first neck screw, as the plate is fixed onto the diaphysis with a cramp forceps. Positioning this first screw then allows the arm to be positioned in abduction and internal rotation without fear of dismantling (head-diaphysis) and relatively easily visualising the tearing off of the infra-spinatous and its fixation. The angle of direction of this second screw is almost 90° to the first neck screw.

Implanting the diaphyseal screws. Reinsertion of any isolated tearing off of the supra-spinatous using additional holes in the superior concavity of the plate.

Complicated case of a four fragments fracture :

It usually involves prosthetic surgery but in some cases it may be treated by internal fixation, particularly in the young.

The underlying technique is similar to the previous situation, although the conditions are more difficult still because of the lack of hold on the fragments. The humeral head is generally the only part on which the repair is built. The first phase involves bringing the wires passing through the bone into the lesser tuberosity and then into the greater tuberosity in order to be able to bring these together on each side of the neck fragment. The reduction landmarks are based on the overall shape of the epiphysis reconstructed around the neck fragment by temporary pins, helped in this by radioscopy control.

It is sometimes useful to stabilise the humeral head initially on the glenoid using a Kirschner pin before moving to the epiphyseal reconstruction.

This epiphyseal phase is often laborious because of tissue fragility, making it very complicated to keep the tuberosities in place.

Subsequent phase: Positioning the plate is identical to the case in the previous figure.

Closure is onto a drain. The patient is immobilised in the operating theatre in a arm waistcoat, elbow to body.

5 • Post-operative protocole

Immobilisation of the arm is different depending on the case:

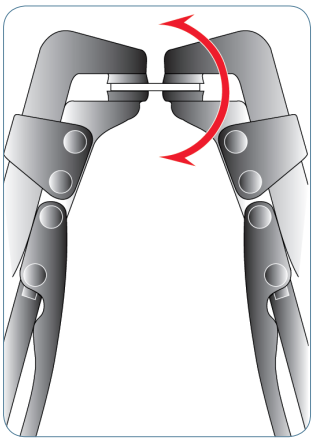
• Either very limited, simply with a sling and immediate re-education (passive for 21 days then active and passive beyond that): Neer II, good hold of the assembly tested per-operatively.

• Or restraining with an abductor for 3 weeks in cases in which it was necessary to repair the cuff with a degree of tension. At the end of these 3 weeks passive re-education is started keeping the shoulder in abduction for a further three weeks.

• In patients in which increased monitoring is required such as, for example, cases of complex fractures with fragile tuberosities or poorly compliant patients, temporary immobilisation for 3 to 4 weeks with a Dujarrier before starting re-education in a re-education centre is proposed.

Fitting technique

1 • Modeling plate

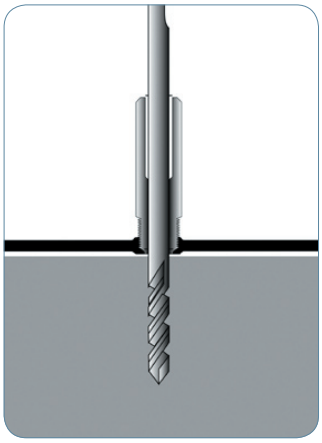


• Do not leave the pegs free between the plate benders.

• Only use Surfix plate benders.
• Avoid excessive or repeated bending.

• Ensure that the screws are not touching once the plate has been contoured.

2 • Drilling



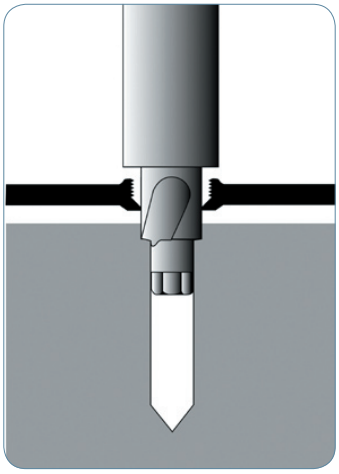
Use the drill guide:

• screw diam 6.5 mm: Drill and drill guide diam 3.5 mm for cancellous bone.

• screw diam 6.5 mm: Drill and drill guide diam 4.5 mm for cortical bone.

• screw diam 4.5 mm: Drill and drill guide diam 3.5 mm.

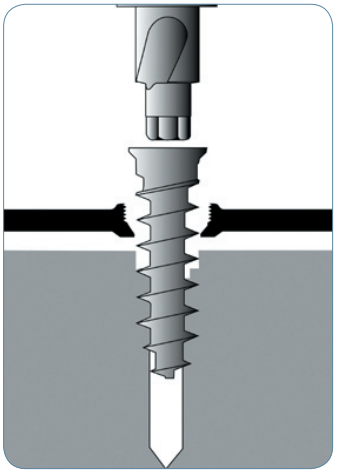
3 • Chamfering



• Chamfer the head of the screw with the screwdriver.

• Ensure that the threaded hole is not damaged when performing the chamfering.

4 • Positioning the screw

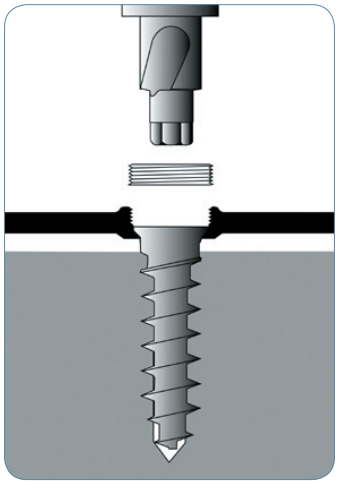


• Insert the screw into the prepared cavity until it reaches the end.

• Clean the threaded hole before and after introducing the screw.

• Maintain co-axiliality between the screw and the threaded hole.

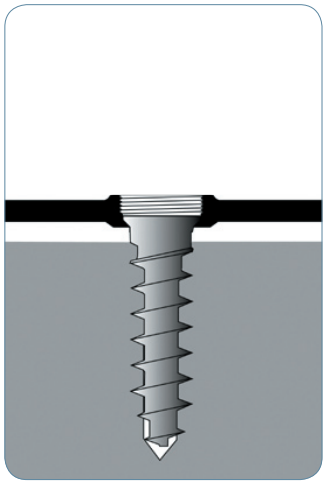
5 • Positioning the lock-screw



• Insert the lock-screw in the peg which is designed for this purpose.

• The screw and lock-screw must be inserted in the same phase of the procedure.

6 • Locking



• Lock the lock-screw tightly in its cavity.

PSH Instructions for use

Edition : 3.0 du 19/06/03 du DT/Notice-GB

Instructions for use SURFIX® Osteosynthesis System
In accordance with ECC directive 93/42 related to medical devices, this product must be handled and/or implanted by well-trained, qualified persons, aware of these directions for use.

1. Packaging and traceability
- Most SURFIX® implants are supplied sterile. The sterilization method is specified on the packaging. Components sterilized by radiation are exposed to a minimum of 25 kGy of g irradiation.
- References and batch numbers are engraved on each implant to facilitate traceability.
- For sterile implants, several copies of labels are provided for the patient's record in each package.

2. Warnings and precautions for handling
- SURFIX® implants must be stored in a dry, cool place away from dust and UV radiation.
- Check that the packaging is intact before using sterile implants. Implants from damaged packages should not be implanted and are considered to be non-sterile. It is recommended that the implant be re-run through the sterilization procedure (see §3).
- The sterility expiration date is limited to five years from the sterilization date (see label).
- Check that the implant matches the specifications mentioned on the package (reference and size) when you unpack it.
- Do not put the implant in contact with objects or substances that might alter its surface or chemical composition. Perform a visual check of each implant before use to detect damage (such as warping, scratches, etc…). In such cases, do not use the implant.
- Inner packing should be handled under sterile conditions.

3. Recommendation for (re)sterilization
SURFIX® brand products are sold sterile. Products sold sterile, whose sterility is no longer guaranteed (see §2), are considered to be non-sterile and must be (re)sterilized.

- Recommendations for decontamination and cleaning
SURFIX® brand products considered as non-sterile must be unpacked and decontaminated before implanting, in compliance with current regulations. Any stained and/or damaged instruments should be removed from the operating area. Sterilization is not a substitute for cleaning and decontamination.

- Recommendations for (re)sterilization
Re-sterilization is only allowed for non implanted products. Remove delivery packaging in compliance with current regulations to (re)sterilize non-sterile products. SURFIX's osteosynthesis implants are recommended to be sterilized by the steam autoclaving procedure regularly used in the hospital. The suggested method is based on HIMA or AORN recommended pratices. The implants can be sterilized several times in the same conditions :

- 270°F/132°C - 45 minutes
- 298.8°F/134°C – 18 minutes

Warning : SURFIX® cannot guarantee sterility for implants that have been cleaned or (re) sterilized by the purchaser or user.

4. Product description
SURFIX® osteosynthesis plates are made of 316 L stainless steel for implants in compliance with standard NF ISO 5832-1 and ASTM F138 & F139.
SURFIX® osteosynthesis screws and lock screws are made of a TA6V titanium alloy for implants in compliance with standard NF ISO 5832-3 and ASTM F136.
. SURFIX® fixation system
The SURFIX® system creates extemporaneously a single implant/screw unit fixed into the bone. The osteosynthesis screws must be driven into the bone through the holes in the plate. The system is locked by means of lock screws drilled into the threaded lipped socket at the top of each hole, thus blocking each screw head. The system looses some of its mechanical qualities if not properly locked and much more if it is not locked at all. The SURFIX® plate will then have the same mechanical features as those of a standard screwed plate. The synthesis of the plate onto the bone with the SURFIX® system is not only secured by a tight union between the plate and the bone - as is the case with an ordinary screwed plate - but also because of the good adjustment of the screws into the bone. The screws must be adjusted into the bone as accurately as possible. The screws must be driven through both cortical areas in the case of a synthesis in the metaphyso-diaphysiary area.

5. Combined implants
A SURFIX® osteosynthesis implant consists of a plate, as many screws as threaded lipped sockets on the plate and as many lock screws as implanted screws. All these components must bear the SURFIX® trademark. All SURFIX® implants must be fitted with instruments and accessories from the same manufacturer and designed for that purpose. The choice of the best-fitting SURFIX® screw-plate combination is the responsibility of the surgeon.

6. Device performance
- Good stability and seal-like fixation on the two fragments to be synthesised.
- Consolidation of the focus without any compression of the plate on the bone.
- Suppression of the lever effect where the screw and the plate are in contact.

7. Precautions to be taken for fixation
The SURFIX® system is fully effective only if the screw is perfectly tightened to the implant. The following steps are essential:
- Maintain the performance of the locking system by using only suitable instruments. The bottom of the lipped socket and its thread must be protected so as to avoid damaging the fixation. The oval-shaping of the lipped sockets, when bending the plates into shape, is particularly risky. Some plates have thinner and smaller bendable sections so that screws can be better adjusted. The bending of these sections is carried out with SURFIX® pliers designed for this purpose. It is imperative that the bending be implemented between two consecutive lipped sockets. If this is not the case, the intermediary socket might become oval-shaped. Bend the plates only once and not excessively. The screws must not touch each other once the lipped sockets have been shaped. Bend the plate slightly between two sockets outside the bendable sections to adapt the shape of a plate onto the bone. Plate benders should be used, provided the sockets are not twisted, as mentioned above.
- Drive the screw co-axially through the threaded lipped socket, by using SURFIX® drill guides, which can be fitted into any SURFIX® plates. The drill guide and the drill must have the same diameter.
- The screw must remain co-axial until it has been locked by the lock screw. Consequently, it is necessary to:
- Make sure that the screw can be easily driven into the bone until its collar has reached the bottom of its hole. It may be necessary to widen the top of the hole in the bone. Be careful not to damage the threaded lipped socket, if this is the case.
- Stop screwing as soon as the screw head has reached the bottom of its hole.
Further screwing could draw the plate against the bone by exerting a pull-in effect if the implant is not in contact with the bone. This could change the axis of both the screw and the socket.
- Implement each fixation in succession, from the guided drilling to the tightening of the lock screw. The tightening of the screw by the lock screw should always be carried out immediately after the positioning of the screw and before implementing any other operation that could alter the position of the plate against the bone and, consequently, against the screw.
- Remove any foreign bodies that may be found between the implant, the screw and the lock screw.
- Tighten the lock screw.

8. Safety instructions for an osteosynthesis
A strain is created on the screws if the system is fitted to a non-reduced focus and is actually used to reduce it. This can deteriorate the bone and even result in a spiroid fracture or weaken and even break the screws. Therefore, it is strongly recommended to reduce the fracture first, and then fix it with a SURFIX® implant, as described above.

9. Indications
The indications for surgery of the whole range of SURFIX® implants are described in the attached document Indications of these directions for use and in the SURFIX leaflet®.

10. Contraindications
- Acute or chronic, local or systemic infections.
- Lack of musculo-cutaneous cover, severe vascular deficiency touching the focus.
- Bone deterioration preventing a good fixation of the screws in the bone.
- Muscular deficit, neurological deficiency or behavioural disorders, which could submit the osteosynthesis to abnormal mechanical strains.

11. Factors likely to compromise the success of implantation
- Serious vascular deterioration, bone devitalization, severe osteoporosis, loss of bone substance.
- Deformity or severe traumatism with loss of bone substance or soft parts.
- Local bone tumor.
- Systemic, metabolic or genetic disorders.
- Infectious diseases.
- Drug and/or alcohol and/or smoke and/or medications addiction and/or abuse.
- Obesity.
- Intense physical activity (e.g., competitive sports or strenuous work).

WARNING : The stability of SURFIX® osteosynthesis lessens the painful effect and may therefore induce the patient to move carelessly. The surgeon must warn the patient of the risks of such careless behavior. The risks in connection with these injuries include, for example, torsional stress of the plate and breaking of the screw. These risks would be caused by the abnormally high strain sustained by the osteosynthesis material, particularly with regard to synthesis of highly comminuted fractures with loss of bony substance.

It is important to warn patients having such contraindications about the influence these factors may have on the successful outcome of the operation. Patients should be given advice about the measures to be taken to reduce the effects of these contraindications.

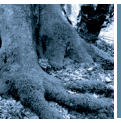
12. Adverse reactions
The most typical and common adverse reactions following the fitting of osteosynthesis implants are the following:
- Delayed consolidation, pseudoarthrosis.
- Loosening of the implant.
- Rupture or deformity of all or part of the implant.
- Infection, hematoma, venous thrombosis, pulmonary embolism, cardiovascular problems.

13. Liability
SURFIX TECHNOLOGIES shall not be liable for any accidental or consequential loss, damage or expense, directly or indirectly arising from the use of this product. SURFIX TECHNOLOGIES neither assumes nor authorizes any other person to assume for it any other or additional liability or responsability in connection with the product. SURFIX TECHNOLOGIES intends that these devices should be used only by physicians having received appropriate training in orthopedic and traumatologic surgery techniques.

INFORMATION : Please contact your supplier for further information concerning the use of this product.

WARNING : Federal law (USA) restricts this device to sale by or on the order of a physician.

WARNING : This device is not approved for screw attachement or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.



PSH
Proximal humeral plate

Implants

Reference	Designation
PSH	Humeral proximal plate
PSH2	Humeral proximal plate size 2
PSH3	Humeral proximal plate size 3

Cortical bone screw + lock screw diam. 4.5 mm

Reference	Length
CC 014	14 mm
CC 016	16 mm
CC 018	18 mm
CC 020	20 mm
CC 022	22 mm
CC 024	24 mm
CC 026	26 mm
CC 028	28 mm
CC 030	30 mm
CC 032	32 mm
CC 035	35 mm
CC 040	40 mm
CC 045	45 mm

Cancellous bone screw + lock screw diam. 6.5 mm

Reference	Length
SP 020	20 mm
SP 025	25 mm
SP 030	30 mm
SP 035	35 mm
SP 040	40 mm
SP 045	45 mm
SP 050	50 mm
SP 055	55 mm
SP 060	60 mm
SP 065	65 mm

Instruments

Reference	Designation
MA003	Plate benders
MA004	Hexagonal screwdriver 3.5 mm
MA005	Length gauge
MA006	Drill guide diam. 3.5 mm
MA007	Drill guide diam. 4.5 mm
MA008	Drill diam. 3.5 mm

Reference	Designation
MA009	Drill diam. 4.5 mm
MA038	K-wire diam. 1.8 mm
MA041	K-wire guide diam. 1.8 mm for drill guide diam. 3.5mm
FPSH	Humeral proximal template
FPSH2	Humeral proximal template size 2
FPSH3	Humeral proximal template size 3

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- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
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- *See instructions for use*
- *Single use*
- *Sterile* — STERILE | R

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