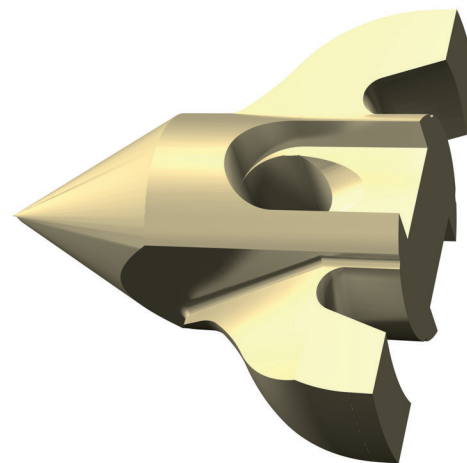




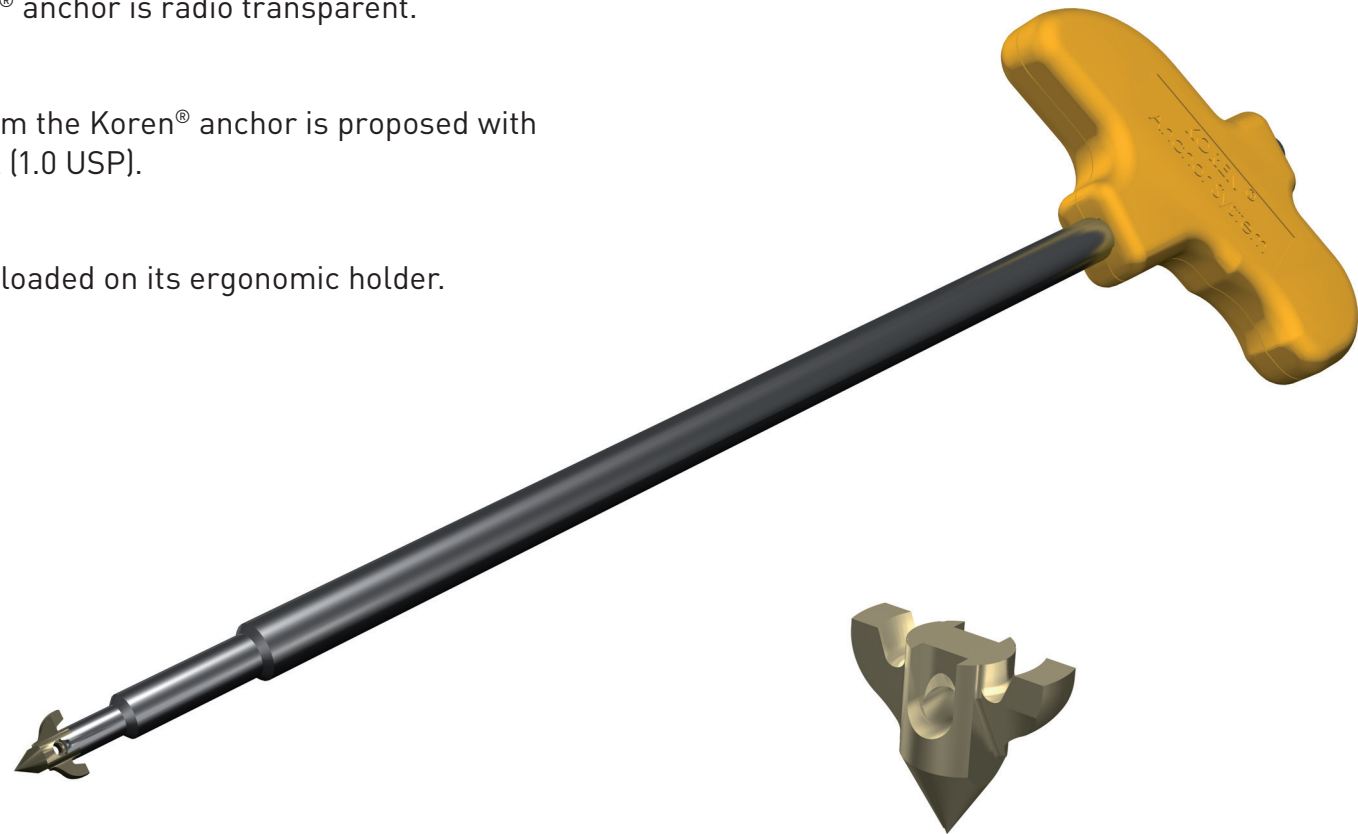
Koren[®]

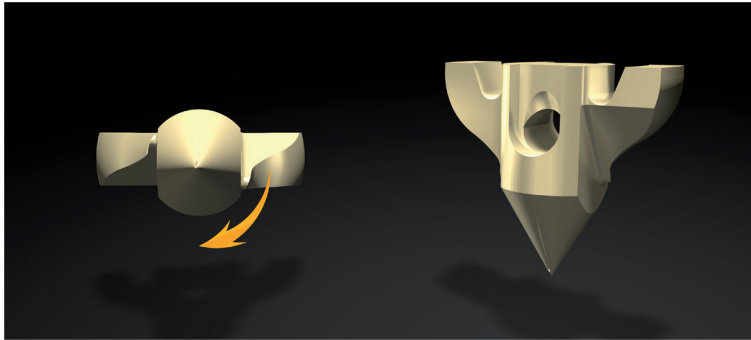
SUTURE ANCHOR



> PRODUCT DESCRIPTION	3
> INDICATIONS	5
> SURGICAL TECHNIQUE	6
1 - PREPARATION	7
2 - ANCHOR INSERTION	7
3 - ANCHOR LOCKING	8
> REFERENCES	9

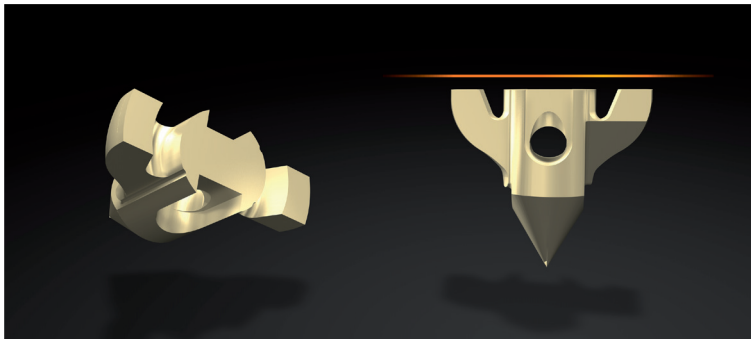
- ▶ The arrow shaped Koren® anchor's design has two side fins with inverted sections that :
 - ▶ facilitates the insertion in the cortical bone,
 - ▶ allows a fast and safe locking of the anchor,
 - ▶ guarantees a high grip in the bone.
- ▶ Made in PEEK, the Koren® anchor is radio transparent.
- ▶ Available in 2mm and 3mm the Koren® anchor is proposed with one suture of 4.0 decimal (1.0 USP).
- ▶ The Koren® anchor is preloaded on its ergonomic holder.





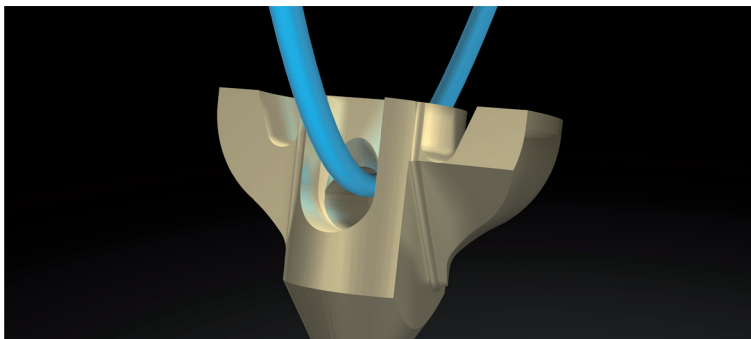
LATERAL FINS

- ▶ The fins of the anchor present two inverted tilted sections facilitating insertion and rotation of the anchor in the bone.
- ▶ The elasticity of the PEEK facilitates the fins penetration into the cortical bone.
- ▶ The helix shape of the Koren® anchor eases locking by $\frac{1}{4}$ of tour after the insertion.



PRIMARY STABILITY

- ▶ The flat base of the Koren® anchor guarantees a good retaining wall under the cortical bone and thus primary stability.



SUTURE

- ▶ The edges of the suture hole are smoothen in order to:
 - ▶ Limit the risk of damaging the suture,
 - ▶ Facilitate the insertion of a different suture if needed.

INDICATIONS

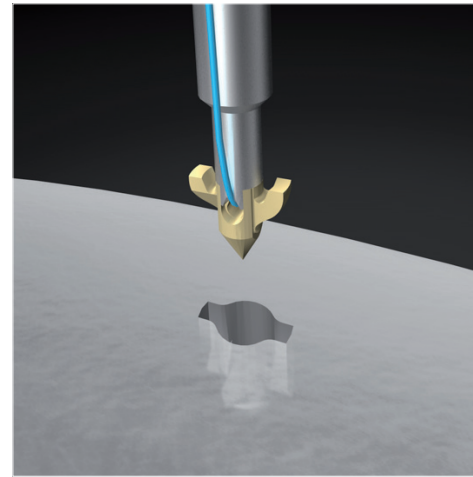
In the fixation of soft tissues to bone, in association with appropriate post-operative immobilization, in particular in the following cases:

- ▶ ELBOW:
 - ▶ Reinsertion of the biceps tendon
 - ▶ Cubital and radial ligament reinsertion
- ▶ FOOT - ANKLE:
 - ▶ Repair / reconstruction of the Achilles tendon
 - ▶ Lateral instability
 - ▶ Median instability at the medial level of the talus
 - ▶ Reinsertion of the tendons in the bone of the fore-, mid- and hindfoot

CONTRAINDICATIONS

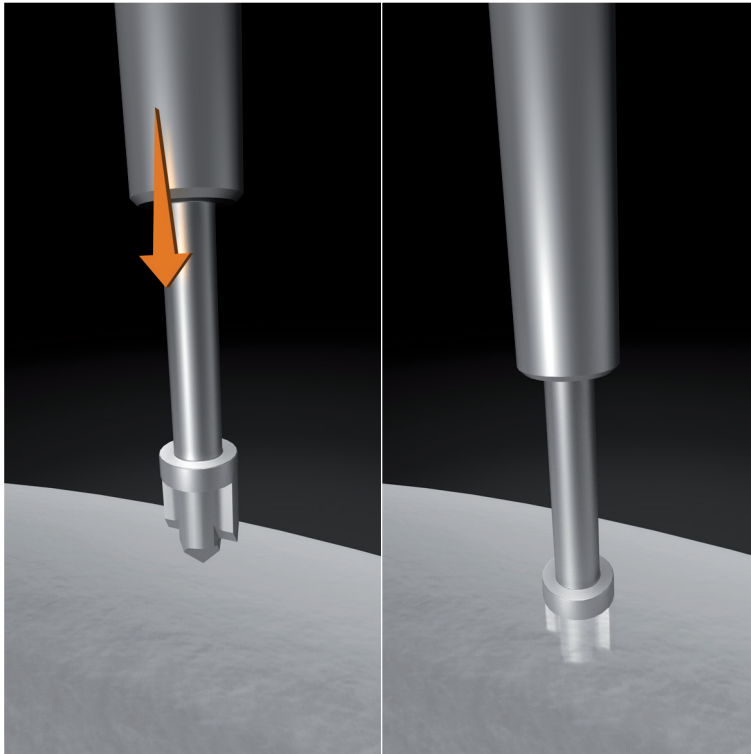
- ▶ The implant should not be implanted in patients who currently have or have had:
 - ▶ acute or chronic inflammations, whether local or systemic,
 - ▶ active infections,
 - ▶ vascularization disorders; a pathological condition of the soft tissues to be sutured to the bone, liable to undermine the rigidity of the fixation by the structure,
 - ▶ bone deviation, severe osteoporosis, loss of bone mass,
 - ▶ bone pathologies such as acute cystic developments or acute osteopenia that risk preventing proper drilling of a clean hole or compromising the rigidity of the fixation of the implant.
- ▶ Anchorage systems are not intended for use for the fixation of artificial ligaments or other implants.

SURGICAL TECHNIQUE

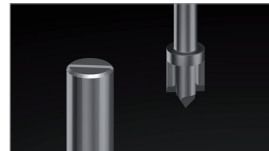


In2Bones® as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

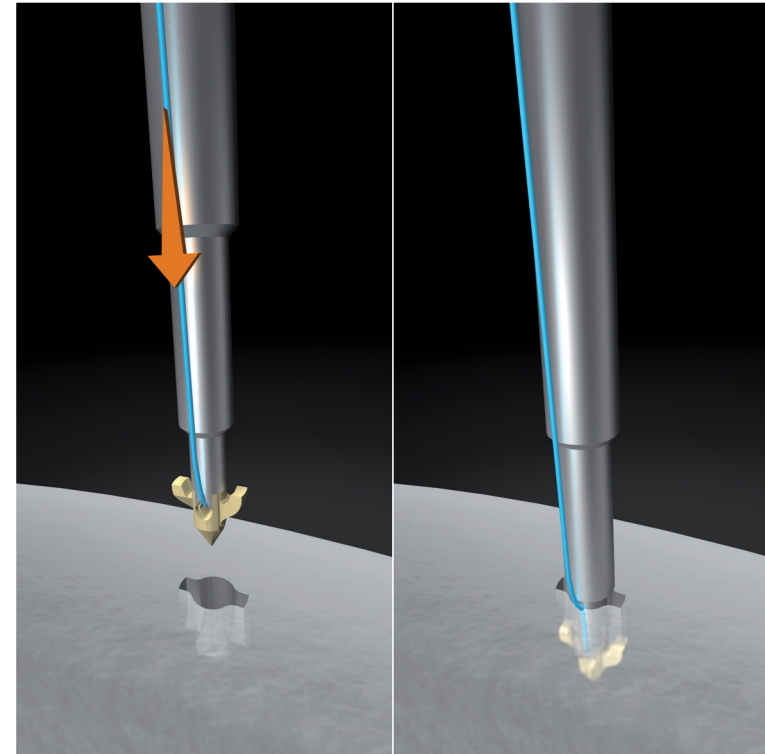
1 - PREPARATION



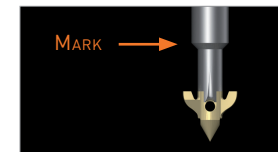
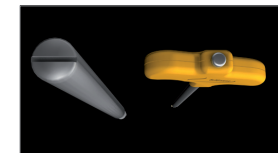
- ▶ The cortical bone drilling is performed with the Koren® anchor broach matching the selected size of the anchor.
- ▶ The mark at the top of the tool indicates the orientation of the anchor broach.
- ▶ The anchor broach is impacted with a mallet.



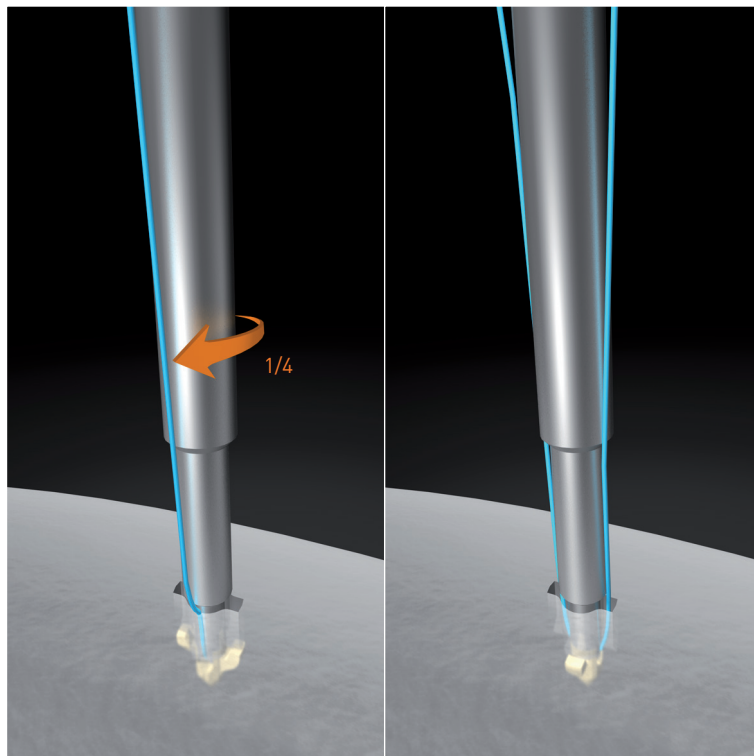
2 - ANCHOR INSERTION



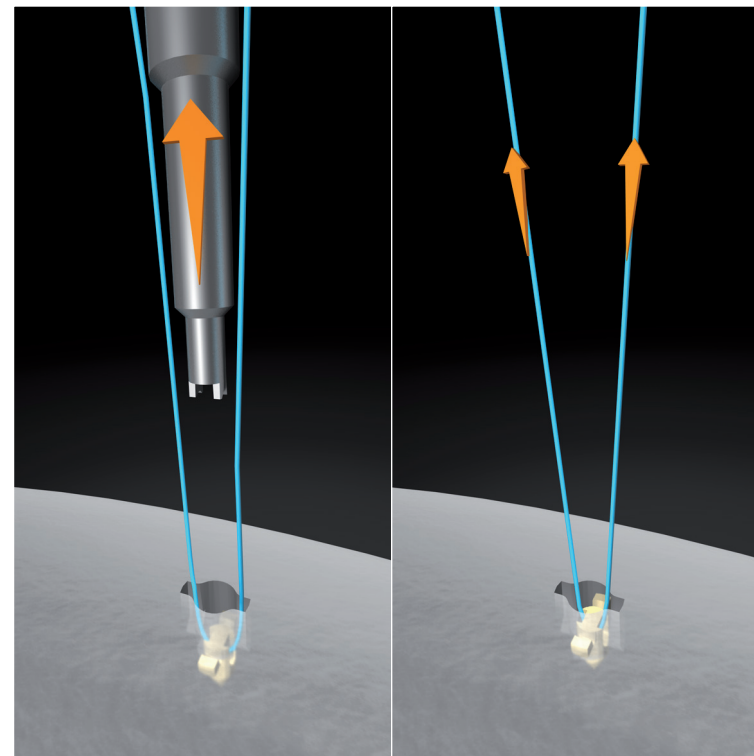
- ▶ The anchor is inserted in the imprint of the anchor broach.
- ▶ The orientation of the handle must be aligned to the mark of the previously used anchor broach.
- ▶ The holder is introduced up to its abutment.



3 - ANCHOR LOCKING



- ▶ To lock the anchor, turn the holder quarter turn clockwise.



- ▶ Pull back the holder to release the anchor. Pay attention not to pull sutures while removing the holder.
- ▶ To lock the anchor against the cortical wall, pull both suture ends.

IMPLANTS

▶ Koren®

A20 SP020Koren® - Suture anchor PEEK Sterile - Non resorbable Suture . . . Diam. 2.0mm

A20 SP030Koren® - Suture anchor PEEK Sterile - Non resorbable Suture . . . Diam. 3.0mm

▶ Sutures

Koren® Diam. 2.0mm	1 suture / 2 strand	Non resorbable	4.0 decimal / 1 USP
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Koren® Diam. 3.0mm	1 suture / 2 strand	Non resorbable	4.0 decimal / 1 USP
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Note : the sutures are not supplied separately but pre-assembled with the Koren® anchor.

INSTRUMENTS

A01 00071Anchor Broach - Lg 150mm - Diam. 2.0mm

A01 00061Anchor Broach - Lg 150mm - Diam. 3.0mm

G01 20021Set Koren®

RECOMMANDATION

- ▶ It is recommended to carefully read the instructions for use available in the package insert.


DEVICES

- ▶ Implants :
 - ▶ Anchors : Class IIb - CE0499
- ▶ Instruments :
 - ▶ Anchor Broach : Classe I

REIMBURSEMENT

- ▶ Reimbursement may vary from countries to countries. Check with local authorities.

MANUFACTURER

- ▶  In2Bones SAS
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DOCUMENT

- ▶ Référence : ST-Koren-Eng-032013
- ▶ Date de révision: 03/2013
- ▶ Version 01



Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

Always refer to the appropriate instructions for use for complete clinical instructions.

Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.

WARNING: Applicable laws restrict these products to sale by or on the order of a physician.

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