Scan-Anchor®

...Not just another soft tissue bone anchor,
.....but a new reference!

Presentation booklet

Pre-Loaded Soft Tissue Bone Anchors

A little history about soft tissue anchors.

We have come a long way since drilling holes in the recipient bone and passing sutures through. This technique led to numerous complications from suture breakage even to bone fracturing. If some still use staples or screws and plates these techniques have relatively unpredictable clinical issues.

The rationale for soft tissue anchors is to procure superior fixation strength to recipient bone while at the same time simplifying surgical protocols.

Soft tissue bone anchors were first introduced in the late 80's in order to enhance reattachment of tendons and ligaments to bone.

The probing results of such devices was the signal for most of the worlds leading orthopaedic companies to look into the possibilities of developing their own respective devices.

THE SCAN-ANCHOR© FROM SCANOS

With the **SCAN-ANCHOR©28**, **SCAN-ANCHOR©35** and the **SCAN-ANCHOR©50** SCANOS® has taken into account all comments and criticisms put forward by surgeons using past and present soft tissue bone anchors, SCANOS® then designed and developed this anchor incorporating *"into one"* all major prominent features suggested by surgeons.

SCAN-ANCHOR© soft tissue bone anchors are the first self-tapping, self-drilling, preloaded soft tissue anchors with two separate identifiable sutures each in separate eyelets.

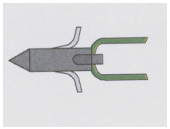
SCAN-ANCHOR© anchors come sterile with a disposable insertion device. The different versions of the **SCAN-ANCHOR©** soft tissue bone anchors are easily identifiable each version or size having a different coloured handle, corresponding both to the size of the device and to the colour code on the box label.

MEDICAL SURVEYS

Different independent medical surveys have evidenced a fast expanding use for such devices. The current estimated rate for use is around 1.600.000 anchors per year with a growth rate of 30-40% a year. The reasons for such a rapid growth reside in the fact that such devices reduce surgery time, simplify surgical protocols and improve clinical results of such 'repairs' and 'reattachments'.

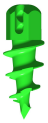
DIFFERENT TYPES OF BONE ANCHORS AVAILABLE

Non-threaded harpoon type anchors:
such as Mitek's GII, Arthrotek's Harpoon or Linvatec's Ultra-fix.



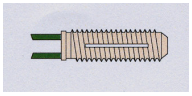
Mitek

Threaded anchors: such as Zimmer's Statak, OBL's PeBA C or RC5, Wright Medical's Questus, Orthofix's Ogden, Howmedica's Mainstay, Arthrex's Corkscrew or Fasttak etc… and of course the SCAN-ANCHOR® from ScanOs shown here.



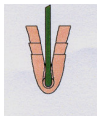
Scan-Anchor

Polymer anchors: such as Innovasive's ROC or ROCxs anchors.



Innovaisive

Resorbable soft tissue bone anchors:
such as Acuflex's Suretak or Wedge, Surgical Dynamics' Lacto-Sorb or Bionix's SmartTack



Acuflex

WHICH THEN IS THE BEST TECHNOLOGY ? *"To be or not to be, that is the question".*

Polymer anchors: have a very weak pull out strength, less than ½ the pull-out strength of non-threaded harpoon type anchors, harpoon anchors themselves being half that of screw type anchors. Moreover polymer anchors cannot be seen correctly on X-rays. Then suture choice is very limited.

Bioresorbable anchors: This type of anchor has in fact only two advantages. They are resorbed and are radiolucent. However they have the lowest pull out strength of all categories of bone anchors and above all lose more than 50% of their already low pullout resistance within less than 30 days. In fact during the most crucial 30 days after surgery often inducing insufficient fixation before resorption.

Non-threaded impacted anchors: mainly destined for sub-cortical applications where a sufficient cortical shelf is available. In such applications impacted anchors have reasonable pullout strength even though much weaker than treaded anchors, especially when used in cancellous bone. After implantation this type of anchor does not allow for revision and requires trephine drilling to remove.

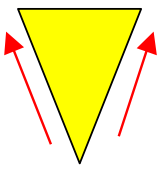
Threaded anchors: The most popular type of anchor with the best clinical results. This is the technology that was decided upon for designing and developing **Scan-Anchors**.

THEN WHAT IS THE DIFFERENCE BETWEEN ONE TITANIUM THREADED SOFT TISSUE BONE ANCHOR AND ANOTHER ?

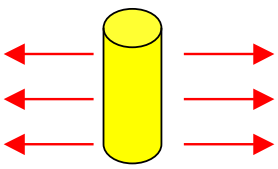
Basically the thread, threaded devices exist not only in the medical world, but also in hundreds of other sectors of activity. A soft tissue bone anchor looks very much like an **AO** bone screw and are **AO** screws not unanimously considered to be *a must* in orthopaedics?

What conclusions can one come to ?
Bone screw thread differs whether the screw is intended for use in cortical bone or in cancellous bone. However **AO** does have an intermediate screw for both cancellous and cortical use. This is the thread solution adopted for our Scan-Anchor.

The dilemma then is should a bone anchor be straight or conical ?
Mechanical explanation of lines of force on round cylindrical and conical shapes



Forces pushing upwards along side the cone and therefore theoretically pushing the device 'out' but making insertion and positioning much easier.



Forces pushing outwards, conferring superior fixation capacities and blocking the screw or anchor.

WHAT THEN SHOULD BE THE CONCLUSION ?

Conical screws are easier to insert and allow for oblique insertion and better positioning while 'straight' screws have a better fixation strength and ensure better long-term fixation.

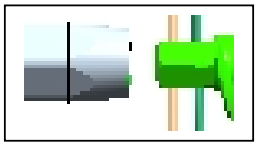
The **SCAN-ANCHOR©** profile and choice of thread are therefore a compromise taking each of these aspects into account. The Scan-Anchor is a '*two in one*'. The profile of the distal two thirds of the anchor is conical, self-tapping and self-drilling allowing for easy implanting, in-depth anchoring and steep angle insertion, whilst the proximal third of the anchor is cylindrical, or 'straight', allowing for better long-term and final fixation.

WHICH TYPE OF THREAD PITCH ?

The final element influencing 'fixation' is the pitch of the screw thread itself. Should the pitch be a 'cortical' pitch or a 'cancellous' pitch? **AO** have long since shown the way by manufacturing intermediate threads for screws for both cortical and cancellous use. We have simply inspired ourselves from this most appropriate pitch from **AO**.

SUTURES & EYELETS

Each Scan-Anchor has two independent eyelets and is preloaded with 2 polyester braided non-resorbable sutures. The unique feature of having independent eyelets for each suture allows easier suturing and knotting without one suture being blocked by the other. The sutures are identifiable, one being white the other green.



Differentiated sutures

BRAID

Suture braid

INDICATIONS FOR USE

SCAN-ANCHOR© 28

FOOT & ANKLE
Lateral ankle stabilization
Medial stabilization
Achilles tendon repair
Hallux Valgus corrections
Midfoot reconstruction surgery
Metatarsal ligament repair

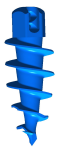
HAND & WRIST
Scapho-lunate ligament repair
Ulnar collateral ligament repair [Game keeper's thumb]
Radial collateral ligament reconstruction

ELBOW
Lateral epicondylitis repair
Ulnar collateral ligament repair
Radial collateral ligament repair

SCAN-ANCHOR© 35

FOOT & ANKLE
Lateral stabilization
Medial stabilization
Achilles tendon repair
Hallux Valgus corrections
Midfoot reconstruction surgery
Metatarsal ligament repair

KNEE
Medial collateral ligament repair
Lateral collateral ligament repair
Fibular tear
Patellar tendon repair
Posterior oblique ligament repair
Iliotibial band tendodesis



SHOULDER
Bankart or Putti-Platt shoulder dislocation
SLAP repair
Bicep Tendon repair
Rotator cuff repair
AC Separation repair [acromio-clavicular]
Deltoid repair
Capsular shift [capsulolabral reconstruction]

ELBOW
Bicep tendon reattachment
Tennis elbow repair
Ulnar collateral ligament reconstruction
Radial collateral ligament reconstruction

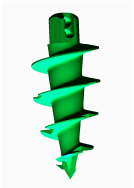
Scan-ANCHOR© 50

[The SCAN-ANCHOR© 50 anchor is mainly used in older patients when a 'wider' thread is required for stronger fixation].

SHOULDER
Rotator cuff repair
In older patients
Bicep tendon repair

FOOT & ANKLE
Retro calcaneal Exostosis repair
Retro calcaneal Haglunds repair
In older patients
Achilles tendon repair

KNEE in older patients
Lateral collateral ligament repair
Fibular tear [75% of occurrences]
Femoral tear [25% of occurrences]
Medial collateral ligament repair
Femoral tear [65% of occurrences]
Joint line tear [10% of occurrences]
Combination tear [only occasional]
Patella tendon repair [quadriceps tendon repair]



Number of anchors generally used per surgery

Hereunder is an indication as to how many anchors are generally used.

FOOT & ANKLE SURGERY

Lateral ankle stabilization	[1-4 anchors]
Achilles tendon repair	[1-2 anchors]

HAND & WRIST SURGERY

Scapho-lunate ligament repair	[1-2 anchors]

KNEE SURGERY

Lateral collateral ligament repair in older patients	
Fibular tear (75% of occurrences)	[1-2 anchors]
Femoral tear (25% of occurrences)	[1-2 anchors]
Medial collateral ligament repair in older patients	
Femoral tear (65% of occurrences)	[1-2 anchors]
Joint line tear (10% of occurrences)	[2-4 anchors]
Combination tear (only occasional)	[2-4 anchors]
Patella tendon repair (quadriceps tendon repair)	[1-3 anchors]

SHOULDER SURGERY

Rotator cuff repair	[1-6 anchors]
Bankart or Putti-Platt shoulder dislocation	[normally 3 anchors]
AC Separation repair (acromio-clavicular)	[3-6 anchors]

SCAN-ANCHOR© DETAILS

A Scan-Anchor is *not simply just another soft tissue bone anchor*, it features innovating and essential aspects to such a device.

A SCAN-ANCHOR© ANCHOR ENLARGED DETAILS

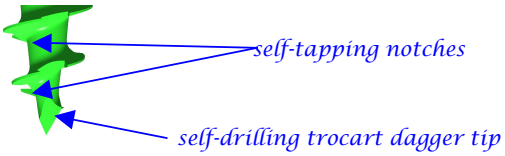
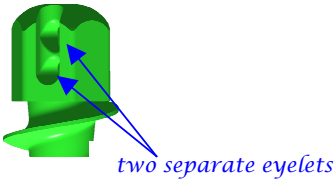


Fig 1

In this drawing can be seen details of the self-taping system. The conical distal dagger-tip ensures precision for initial insertion and positioning. The **SCAN-ANCHOR©** dagger-tip is designed to allow for steep angled insertion limiting skidding or sliding.

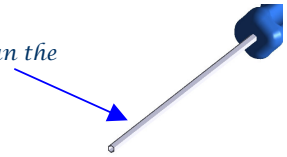
Fig 2

This drawing shows another distinctive feature of the **SCAN-ANCHOR©** soft tissue bone anchor, the two individual eyelets for the two separate pre-loaded sutures. Having **two separate eyelets** confers to the device the advantages of multiple suture anchors, spreading of the load of the suture and secures a safety margin in case of suture breakage. Having individual eyelets avoids blockage of one suture by the other.



All versions of **SCAN-ANCHORS©** come mounted on a disposable single use hollow hex shaft screwdriver up which run the sutures allowing perfect positioning without having to be preoccupied with the sutures during insertion of the anchor. The sutures are inside the device and therefore both protected and momentarily 'out of the way'.

Hollow hex shaft with 2 depth indicators up which run the two protected sutures. Anchor affixed ready for use.



To differentiate the 3 sizes each **SCAN-ANCHOR©** has a different colour screwdriver handle.

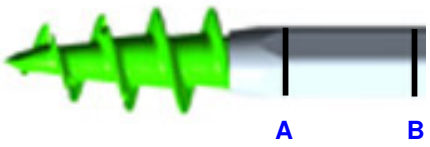
The anchor reference is moulded on each handle, Scan-Anchor 28, Scan-Anchor 35 or Scan-Anchor 50.

DEPTH INDICATORS

All Scan-Anchors have 2 depth indicators marked on the distal part of the disposable insertion device.

Depth indicator A shown below indicates a depth of 3mm which indicates to the surgeon that the anchor and anchor head are embedded to bone surface level.

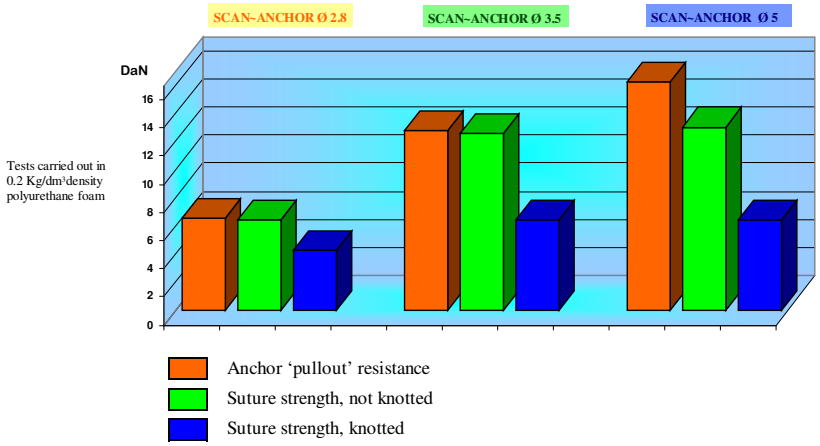
Indicator B is situated 7mm above indicator A and therefore10mm from the distal tip of the screwdriver allowing for the surgeon to adjust depth below bone surface level.



SUTURE ORIENTATION INDICATION

The visible 'ladder' structure seen through the screwdriver indicates suture orientation. Sutures are always layout perpendicular to the 'ladder'.

MECHANICAL TESTS :



IMPLANTING INFORMATION

Number of screwdriver turns to embed an anchor

SCAN-ANCHOR 28……..3.73
SCAN-ANCHOR 35……..3.5
SCAN-ANCHOR 50……..4

SCAN-ANCHOR® PACKAGING SPECIFICATIONS:

Each Scan-Anchor® is packed in a filmed box. Three different labels are to be found on the box. **A label on the top** of each box briefly describes, in French and English, the contents. **The right hand side** end label has a bar code, the name and address of manufacturer, the CE certification logo and states the mode of sterilization. This label also displays the single use sign and a warning sign. **The left hand side label** indicates the size of the anchor enclosed with a colour code specific to each anchor size and describes the product. It also indicates the lot number, the product reference and expiry date.

OVERALL SIZE AND WEIGHT OF EACH BOX:

Length	**29.5 cm**	**Scan-Anchor® 50 & 35**	**109g**
Width	**6.6 cm**	**Scan-Anchor® 28**	**104g**
Height	**4.2 cm**		

INSIDE A SCAN-ANCHOR® BOX ARE TO BE FOUND:

One Scan-Anchor® double wrap vacuum packed in a medical grade foam, the Scan-Anchor® itself protected with a silicone cap. The anchor is affixed to a disposable insertion device with the same colour code handle as the colour code to be found on the box label. In the bottom of the packaging, are to be found four patient labels and an “instructions for use leaflet for temporary internal orthopaedic implants”.

SCAN-ANCHORS ARE DOUBLE VACUUM PACKED AND FILM WRAPPED:

This again is a Scan-Anchor unique feature for such devices. This ensures great safety, guarantees sterility, and prevents oxidization. The packaging system also allows for a ‘no touch’ use operating technique.

Note: compared to most bone anchors from competition a Scan-Anchor® box is some 60% less in volume. This is greatly appreciated for storage purposes and transport costs.

Comparison with other anchors currently available.

	ScanOs	ScanOs	ScanOs	Mitek	Mitek	Mitek	DePuy
Name	Scan-Anchor 25	Scan-Anchor 35	Scan-Ancor 50	GII	Super	RC	Anchor
Size	2.8mm	3.5mm	5mm	7mm	8mm	10.2mm	3.5 &4.5mm
Material	titanium	titanium	titanium	titanium	titanium	titanium	titanium
Double eyelet	yes	yes	yes	no	no	no	no
Preloaded sutures	yes	yes	yes	yes	yes	yes	yes
Multiple sutures	yes	yes	yes	no	no	no	no
Suture[s]	2Ea #2	2Ea #2	2Ea #2	1Ea #2	1Ea #2	1Ea #2	1Ea #2
Sutures fail at	**7 DaN**	**14.2 DaN**	**14.2 DaN**	**7 DaN**	**7 DaN**	**7 DaN**	**7 DaN**

	Linvatec	Linvatec	Smith & Nephew	Smith & Nephew	Smith & Nephew	Zimmer	Zimmer
Name	Ultrafix	Revo	OBL HS	OBL Ti 3.5	OBL RC5	Statak	Statak
Size	5.9mm	2.8 & 4mm	2.8mm	3.5mm	5mm	2.5mm	5.2mm
Material	Stainless steel	titanium	titanium	titanium	titanium	titanium	titanium
Double eyelet	-	-	no	no	no	no	no
Preloaded sutures	no	no	yes	yes	yes	yes	yes
Multiple sutures	limited	limited	yes	yes	yes	no	no
Suture[s]	2 Ea #2	1 Ea #2	1 Ea #2	2 Ea #2	2 Ea #2	1 Ea #2	1 Ea #2
Sutures fail at	**14.2 DaN**	**7 DaN**	**7 DaN**	**14.2 DaN**	**14.2 DaN**	**7 DaN**	**7 DaN**

	Innovaisive	BIOMET	Wright Medical	ARTHREX	Howmedica	ACUFEX
Name	ROC xs	Harpoon	Questus	Corkscrew	Mainstay	Tag Wedge
Size	3.5mm	2mm	2.5mm	5mm	3.5 & 4.5mm	3mm
Material	polyethylene	Stainless steel	titanium	titanium	titanium	polyglyconat
Double eyelet	no	no	no	no	no	no
Preloaded sutures	yes	yes	yes	yes	optional	yes
Multiple sutures	no	no	no	yes	no	no
Suture[s]	1 Ea. #2	1 Ea. #2	1 Ea. #2	2 Ea. #2	1 Ea #2	1 Ea #2
Sutures fail at	**7 DaN**	**7 DaN**	**7 DaN**	**14.2 DaN**	**7 DaN**	**7 DaN**

DaN = Deca Newton = kilograms

It is interesting to note that all bone anchor manufacturers claim high anchor pull out strengths [so do we]. However suture fail strength is far below any anchor pull out strength claimed excepting for resorbable devices or some of the polyethylene anchors. This denotes if needed that the pull out strength has no real significant meaning in terms of "surgery".

For this reason pull out strengths are not shown in the above charts, but the Scan-Anchor pull out strength, and also knotted suture resistance, can be seen on the graph in this dossier.