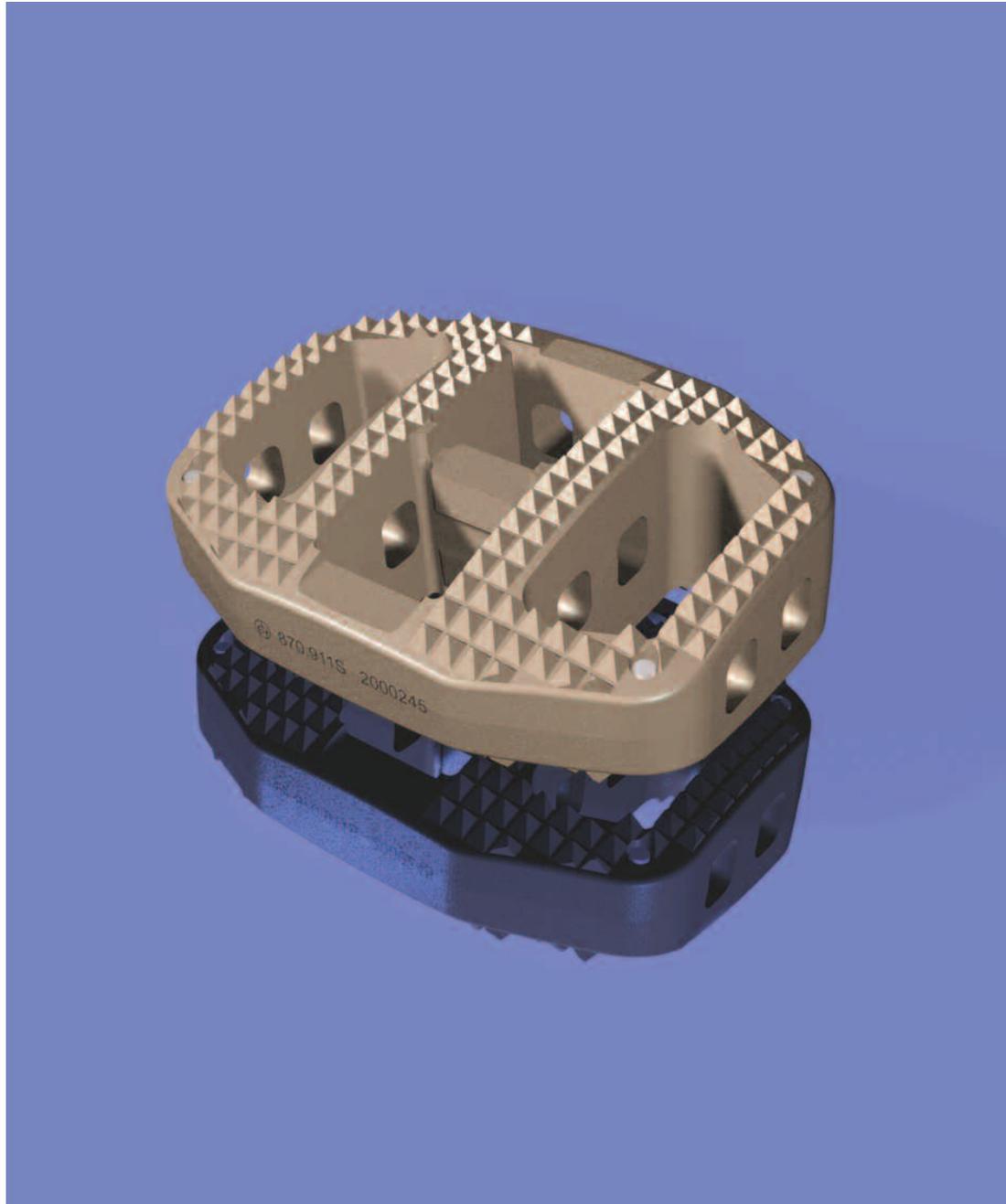


SynCage-LR. Operationstechnik für den anterioren Zugang.

Operationstechnik



Dieses Dokument ist nicht zur
Verteilung in den USA bestimmt.

Instrumente und Implantate
geprüft und freigegeben von
der AO Foundation.

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Warning

This description is not sufficient for an immediate application of the instrumentation. An instruction by an experienced surgeon in handling this instrumentation is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to: www.synthes.com/reprocessing

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to: www.synthes.com/reprocessing

Introduction

The SynCage system is the SYNTHES® implant and instrumentation solution for anterior lumbar interbody fusion (ALIF), designed in accordance with the AO/ASIF principles of interbody fusion:

1. Provide adequate stability
2. Restore disc height
3. Restore lordosis
4. Maintain the integrity of the endplates
5. Provide an optimised fusion bed
6. Atraumatic technique

Indications/contraindications

Indications

Lumbar and lumbosacral pathologies which may require anterior segmental arthrodesis, including:

- degenerative disc disease and instability
- revision surgery for failed decompression syndrome or pseudoarthrosis
- reduced spondylolisthesis

Contraindications

- spinal fractures
- spinal tumour
- osteoporosis
- infection

System overview

The SynCage-LR is an evolutionary development of the proven SynCage concept

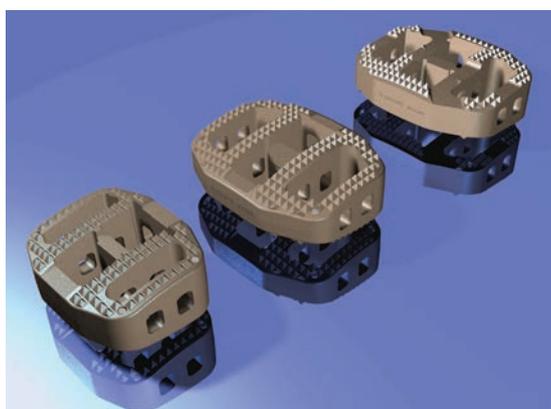
The titanium SynCage system's wedge-shaped, bi-convex design offers



SynCage (Titanium)

- **Reduced risk of subsidence**
The optimal anatomical shape and supportive superior and inferior surface design reduces the risk of subsidence into the adjacent vertebral bodies
- **Enhanced fusion**
The perforated structure allows for bony ingrowth through the cage, and the bi-convex design ensures optimal implant-to-endplate contact
- **Stability**
SynCage is designed to fit snugly into the natural concavity between two adjacent vertebral bodies. The tension of the longitudinal ligaments and annulus fibrosus provide stability; the teeth on the superior and inferior surfaces provide additional initial stability

The new PEEK SynCage-LR¹ system offers all the benefits of the titanium version, and



SynCage-LR (PEEK)

- **Radiolucency**
PEEK facilitates radiographic assessment of fusion
- **Superior biocompatibility**
SynCage-LR consists of pure medical grade PEEK (Polyetheretherketone). It contains no carbon fibre, thereby reducing the risk of systemic uptake and local connective tissue formation
- **Bone integration**
The injection moulded PEEK SynCage-LR has a roughened surface, which is superior to a machined PEEK surface in that it promotes bone integration and ongrowth
- **Optimal fit**
An expanded range of implants including 3 profiles, 5 heights and 2 footprints to ensure an optimal fit in all patients
- **Specialised L5-S1 implant**
A specific implant for optimal fit of the L5-S1 level

¹⁾ Patent pending



Fig. 1

AO Instrumentation - Swiss precision and quality

The SynCage-LR instrument set contains relatively few instruments, but nevertheless provides the surgeon with many unrivalled benefits:

- **Unequaled flexibility**
Free choice of the surgical approach and insertion technique
- **Ergonomics**
The unique distraction/insertion assembly facilitates simultaneous distraction of the vertebral bodies and insertion of the trial implants. However, Fig.1 depicts an implant and not a trial implant.

This distraction is also maintained during insertion of the cage, thus

- reducing the force required to insert the cage
- reducing the fiddle-factor and
- saving time



Fig. 2

The LSR implant (for L5-S1 application) has its own dedicated angled instruments, which may be used in cases where the anatomy makes access difficult with straight instruments. This ensures consistent user-friendly handling in all situations. (Fig. 2)

- **Safety**
Requires no drilling, tapping or broaching of the endplates
- **Tactility**
The SynCage-LR system provides tactile distraction feedback, allowing the surgeon to accurately achieve optimal distraction to ensure stability of the implant

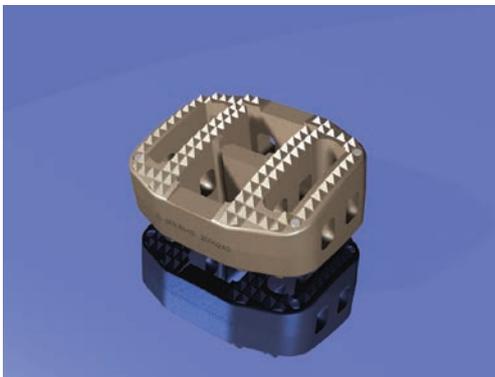
Implant & trial implant overview

SynCage-LR Cage and Trial Implant overview

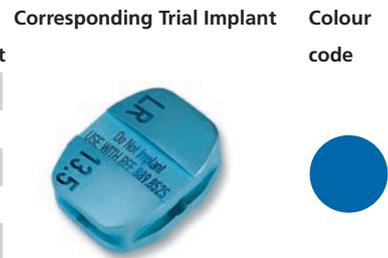
Implant sterile packaging and trial implants are colour coded to avoid mismatching.

SynCage-LR

Dimensions: 24mm (depth) x 30mm (width)
for smaller and normal vertebral bodies

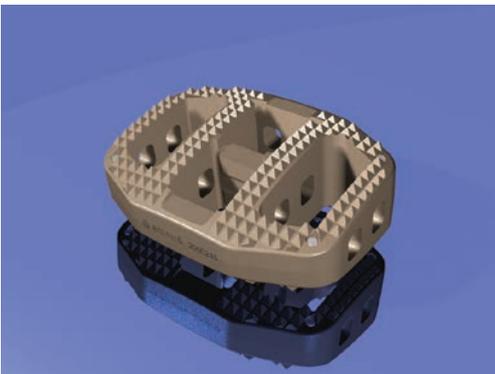


Anterior Height	Cat. no. Implant	Cat. no. Trial Implant
12mm	889.851S	357.160
13.5mm	889.852S	357.161
15mm	889.854S	357.162
17mm	889.856S	357.163
19mm	889.858S	357.164

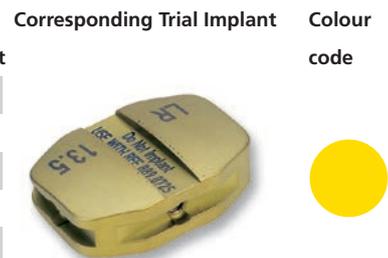


SynCage-LR, large

Dimensions: 28mm (depth) x 38mm (width)
for larger vertebral bodies

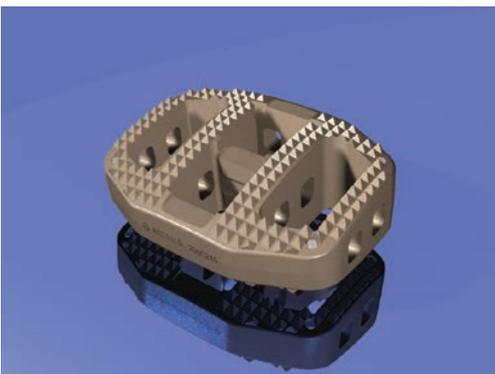


Anterior Height	Cat. no. Implant	Cat. no. Trial Implant
12mm	889.871S	397.121
13.5mm	889.872S	397.101
15mm	889.874S	397.102
17mm	889.876S	397.103
19mm	889.878S	397.104



SynCage-LSR

Dimensions: 28mm (depth) x 38mm (width)
for application in L5-S1



Anterior Height	Cat. no. Implant	Cat. no. Trial Implant
12mm	870.909S	357.150
13.5mm	870.910S	357.151
15mm	870.911S	357.152
17mm	870.912S	357.153
19mm	870.913S	357.154



Surgical technique

Surgical technique for anterior approach

Step 1

Preoperative planning

The surgical approach is dependent on the level to be treated and the surgeon's preference.

Determine the optimal implant size by comparing the relevant SynCage-LR Radiographic Template (Fig. 3) with a lateral radiograph of the adjacent intervertebral discs.

Note: the height indicated on the template is approximately 1mm lower than that of the actual cage to account for penetration of the teeth into the vertebral bone.

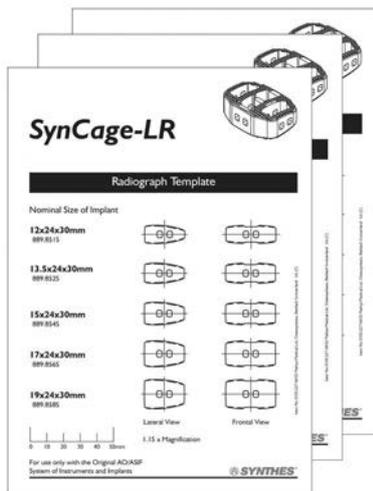


Fig.3

With the segment fully distracted, the SynCage-LR must fit firmly with a tight press-fit between the endplates.

It is therefore recommended that the maximum size SynCage-LR be selected to optimise the stability of the segment through tension in the annulus fibrosus and/or longitudinal ligaments.

Step 2

Patient positioning

For the anterior approach to the lower lumbar levels, the patient is placed in a Trendelenburg position.

Step 3

Attain exposure

For anterior insertion, the intervertebral disc is exposed such that there is a clear space on either side of the vertebral midline equal to half the width of the SynCage-LR.

If the vessels and/or tissues cannot be retracted sufficiently, insertion from an anterolateral direction may be indicated.



Fig.4

Step 4

Cut the anterior window

A rectangular window the width of the SynCage-LR is cut in the anterior longitudinal ligament and annulus fibrosus. (Fig. 4)

A trial implant (see page 7) may be used as a template to indicate the width of the annular window required.

Care is taken to retain as much of these structures as possible as they are important for the stability of the instrumented segment.

Step 5

Prepare the disc space

Through the window in the anterior longitudinal ligament and annulus fibrosus, the disc material is excised and the superficial layers of the cartilaginous endplates removed such that bleeding bone is attained.

Adequate cleaning of the endplate is important to enable the provision of a vascular supply to the bone graft; excessive cleaning or use of a rasp may however, weaken the endplate and result in subsidence of the cage.

Once the endplates have been prepared and any additional surgical procedures completed, the SynCage-LR is introduced into the intervertebral space as per the following steps.

Note: It is essential to remove all nuclear material and the inner annulus in order not to hinder bone ingrowth. This also prevents displacement of disc material into the canal.



Fig.5

Step 6
Distract the segment

Distraction of the segment is essential for restoration of disc height, opening of the neural foramina and stability of the SynCage-LR.

Distraction is achieved prior to insertion of the SynCage-LR using the appropriate distractor.

Note: There are two distractors

397.113 for SynCage-LR and SynCage-LR, large

397.126 for SynCage-LSR (optional; for use when anatomy makes access difficult with straight instruments)

To ensure that the SynCage-LR is inserted symmetrically into the disc space, the line on the blades indicating the vertebral midline is aligned with the anterior midline of the vertebral bodies. (Fig. 5)

Compressing the Distractor Handle opens the disc space.

Note: Due to the wedge shaped configuration of the disc and the distractor blades, the distractor must be held in place during distraction and the insertion of the trial or implant to prevent its displacement and possible injury to adjacent structures.



Fig.6

Step 7
Trial for implant size

Select the trial implant that corresponds with the SynCage-LR size determined during the preoperative planning and attach it to the appropriate Handle for Trial Implants.

Note: *There are two Handles for Trial Implants*

397.035 *For SynCage-LR and SynCage-LR, large*

397.034 *For SynCage-LSR (optional; for use when anatomy makes access difficult with straight instruments)*

The Trial implant is then slid between the Distractor blades into the disc space. (Fig. 6)

If a tight fit is not achieved, repeat the process using incrementally larger sizes of trial implants. Conversely, if the trial implant cannot be inserted, repeat using incrementally smaller sizes of trial implants.

With the segment fully distracted, the SynCage or Trial Implant must fit firmly with a tight press-fit between the endplates such that disc height is not lost once the distractor is removed.

Once the optimal size of SynCage-LR has been determined, the distraction is temporarily relaxed.

The image intensifier can now be used to check the trial implant position.



Fig.7

Step 8 Select the implant

The SynCage-LR corresponding to the Trial Implant is then selected.

The Trial Implants are laser etched with the nominal height of the cages, and both Trial Implants and cage packaging are colour-coded. Refer to the „SynCage-LR Cage and trial implant overview“ on page 7.

With the SynCage-LR (or LSR) of the correct height chosen, it is then secured on the appropriate Implant Holder. (Fig. 7)

Note: There are two Implant Holders

397.114 for SynCage-LR and large SynCage-LR

397.117 for SynCage-LSR (optional; for use when anatomy makes access difficult with straight instruments)

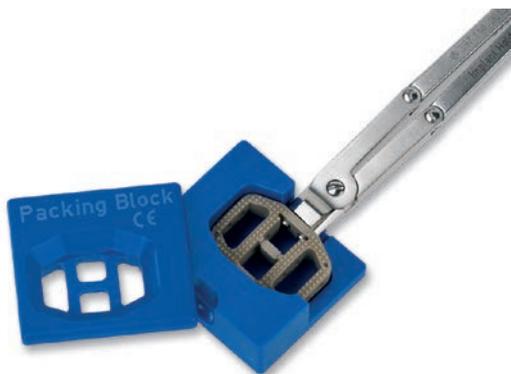


Fig.8

Step 9 Pack implant with bone graft

To assist packing the graft, the SynCage-LR with the Implant Holder attached is inserted into the appropriate Packing Block. (Fig. 8)

The Cancellous Bone Impactors (nos. 394.585 and 394.586) are used to firmly pack the graft material into the implant. (Fig. 9)



Fig.9

It is important to fill the cage until the graft protrudes from the perforations in the cage, to ensure optimal contact with the vertebral endplates.

Note: There are two Packing Blocks

397.131 for SynCage-LR (Standard)

397.132 for SynCage-LR, large and LSR



Fig.10

Step 10 Insert implant

With the SynCage-LR ready for insertion, the segment is again distracted.

The distraction is fixed by tightening the locking nut on the handle.

The SynCage-LR is then introduced into the disc space by sliding it between the distractor blades. (Fig. 10)

The SynCage-LR will require light hammering to fully introduce it into the disc space.

Note: The distractor should be held firmly in place during this stage of the procedure.



Fig.11

Step 11 Remove instruments

Once the SynCage-LR is in the correct position, the locking nut on the Distractor Handle is loosened and the distraction released. (Fig. 11)

The Distractor is gently removed while the SynCage-LR is held in position by the Implant Holder.

Additional hammer blows will ensure a secure fit.

The Implant Holder-LR is then released from the SynCage-LR by loosening the locking nut, leaving the SynCage-LR in its optimal position.

The Cage Repositioner for ALIF (no. 389.157) may be used once the distractor has been removed to manipulate the cage within the disc space if required.



Fig.12

Step 12
Verify placement

The optimal position for the SynCage-LR is centred within the periphery of the vertebral endplate. (Fig. 12)

Depending on the size of the vertebrae, the anterior edge of the SynCage-LR will usually be approximately three to four millimetres posterior from the anterior edge of the adjacent vertebrae.



Fig.13

The location of the SynCage-LR relative to the vertebral bodies in the AP direction should be verified using an image intensifier.

Three x-ray markers are incorporated into the implant to allow for an intra-operative and postoperative assessment of the position of the cage. (Fig. 13)

Supplemental posterior procedure

The SynCage-LR is not designed or intended to be used as a stand-alone device; the use of supplementary posterior instrumentation is therefore strongly recommended.

When used in the treatment of spondylolisthesis, posterior pedicle screw assisted reduction is usually performed prior to the insertion of the SynCage-LR. (Fig. 14)



Fig.14

Postoperative care

The patients can be mobilised one day after surgery; however, patients should be cautioned against activities that place unreasonable stress on the low back.

Excessive physical activity and trauma may result in failure, with subsidence of the implant and/or the development of a non-union.

Notes and warnings

The following is a brief description of additional information on the SynCage-LR system. Please consult the package insert for further information.

- Use caution in handling the SynCage-LR. Damage to the surface finish and/or teeth can lead to fatigue failure or displacement of the SynCage
- It is essential that enough material is removed from the intervertebral disc to accommodate the SynCage-LR, otherwise disc material may be displaced posteriorly during insertion of the implant
- The Trial Implants are not for implantation and must be removed before insertion of the SynCage-LR
- Consult the package insert for a complete description of the handling of the SynCage-LR
- Indications and contraindications for its use are listed above

Additional Instruments

Other instruments which may be useful during the SynCage-LR procedure include:

- Cancellous Bone Impactor (397.730) and Handle with quick coupling (397.700)
- A larger version of the Cancellous Bone Impactor (394.570)
- Bone Spreaders (399.100, 399.130) can be used to distract the vertebral segment
- Hammers (399.420, 399.430) for final seating of the implant and for packing bone graft into the implant
- Spinal Instruments for Anterior Surgery: a range of instruments specifically designed for the requirements of anterior spinal surgery. Included are Punches, Rongeurs and Curettes
- Cage Repositioner ALIF (389.157) may be used to manipulate the cage into the optimal position after insertion

Suggested reading

Aebi, M., Thalgott, J.S., Webb, J.K. AO/ASIF Principles in Spine Surgery. Springer-Verlag, Germany, 1998.

Heiden, E.A., Montesano, P.X. Translaminar Facet Screw Fixation in Manual of Internal Fixation of the Spine, eds.

J.S. Thalgott, M. Aebi. Lippincott-Raven Publishers, Philadelphia, 1996.
Heggeness, M.H., Esses, S.I. Translaminar Facet Joint Screw Fixation for Lumbar and Lumbosacral Fusion. A Clinical and Biomechanical Study. Spine 16(6S):S266-S269, 1991.

Jacobs, R. R., Montesano, P.X., Jackson, R.P. Enhancement of Lumbar Spine Fusion by Use of Translaminar Facet Joint Screws. Spine 14(1):12-15, 1989.

Oxland TR, Hoffer Z, Nydegger T, Rathonyi GC, Nolte LP; A comparative biomechanical investigation of anterior lumbar interbody cages: central and bilateral approaches; J Bone Joint Surg Am 2000 Mar; 82(3):383-93

Lund T, Oxland TR, Jost B, Cripton P, Grassmann S, Etter C, Nolte LP; Interbody cage stabilisation in the lumbar spine: biomechanical evaluation of cage design, posterior instrumentation and bone density; J Bone Joint Surg Br 1998 Mar;80(2):351-9

Steffen T, Tsantrizos A, Aebi M; Effect of implant design and endplate preparation on the compressive strength of interbody fusion constructs; Spine 2000 May 1;25(9):1077-84

Watkins, R.G. Anterior Lumbar Interbody Fusion: Surgical Technique in Lumbar Interbody Fusion, eds. P.M. Lin, K. Gill. Aspen Publishers, Inc., Rockville

Schlegel, J., Green, S. Polyetheretherketones (PEEK) - A Biocompatible High Performance Plastic Medical Plastics 2000, vol. 14, 12.1-12.10, ©Hexagon Holding ApS, DK-1460 Copenhagen, Denmark, ISBN 87-89753-32-1

Müller, M.E., Allgöwer, M., Schneider, R., Willenegger, H. Manual of Internal Fixation. Techniques Recommended by the AO/ASIF Group. Third edition, Springer-Verlag, Berlin, 1991.

Rüedi TP, Murphy WM;
AO Principles of Fracture Management;
Thieme Stuttgart New York 2000.

