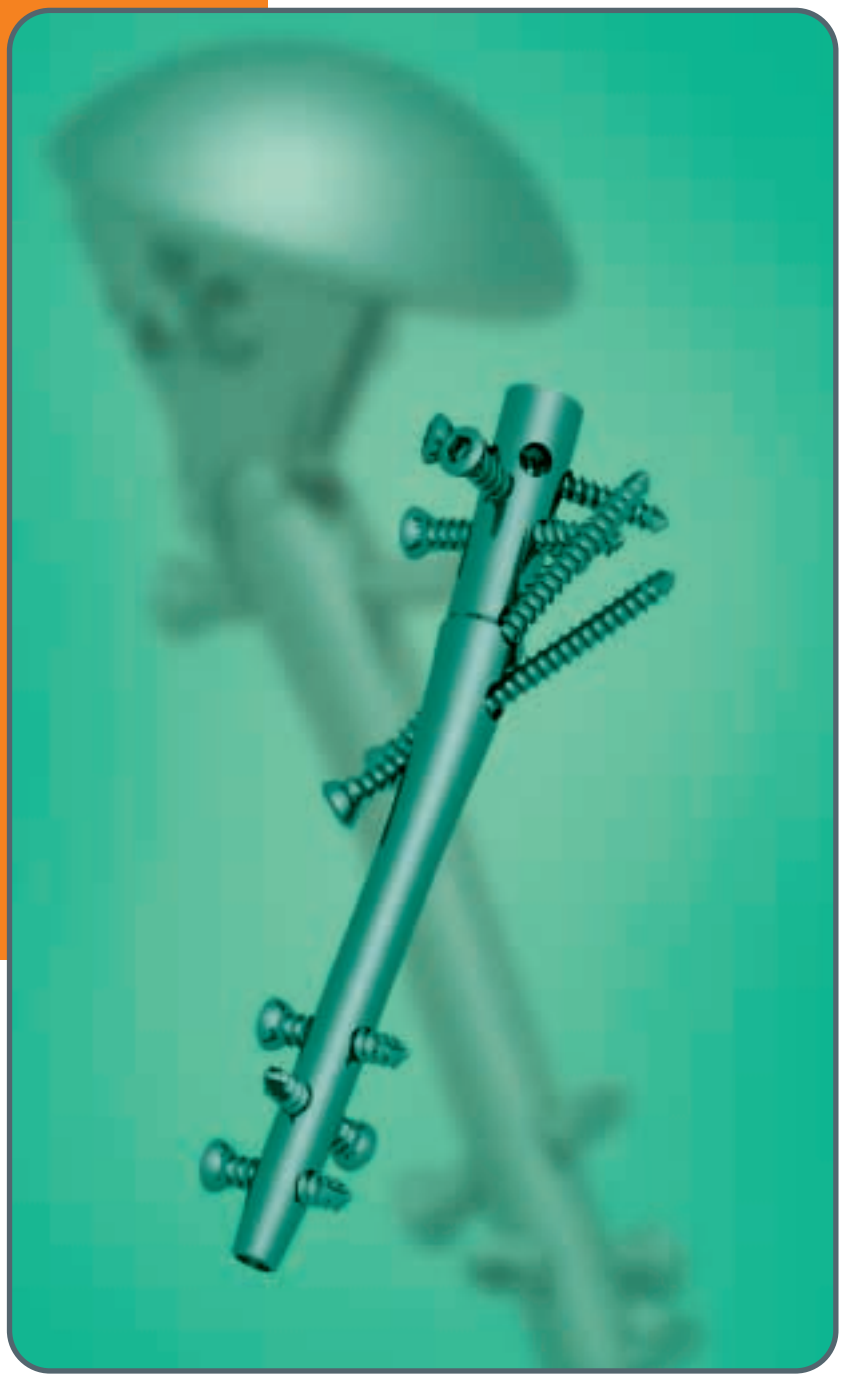
Operative Technique

VARION



tantum

the medical people

))) VARION Humeral Nail System

The new VARION system from tantum is a variable and thus cost-effective humeral nailing system. Its suitability for patients, especially those at an advance biological age with markedly impaired bone quality, is ideal. At this stage of life the incedence of fractures in the proximal third is very high.

There is currently a wide variety of intra- and extramedullary systems on the market for managing the increasing number of fractures encountered in the subcapital and humeral head region, and which indeed account for approx. 70% of all humeral fractures. Without a doubt, intramedullary treatments offer more favorable biomechanical support. Among the systems of this type available on the market, orthograde or retrograde approaches can be used optionally.

The high number of iatrogenic complications involved with the retrograde approach as well as the rising incidence of fractures in the proximal third were motivating factors driving the development team at tantum AG. They cooperated with surgeons from the many performance centers to design an implant system especially for this anatomical region which builds on the experience gained with different modalities for treating proximal humeral fractures.

Their result is the new VARION system. With its two variants, the VARION stands out against existing systems by virtue of its variability, because it gives surgeons the option, if required, of switching to a head replacement intraoperatively. Thus, surgeons are afforded the possibility of adapting their strategy to fit the situation and, in many cases, obviating the need for preoperative CT-guided diagnostics.

During the operation, the surgeon may deem it is necessary to switch from an osteosynthesis procedure to a head replacement. With other conventional systems, this intraoperative modification can increase considerably the procedural costs and implant expenditure – for example costs incurred by opening new implant trays or even having to postpone or reschedule surgeries. Under such circumstances, the result for already stretched hospital budgets is obviously negative. The new VARION systems allow surgeons all the variability needed to modify the operative procedure in the best interests of the patient, thereby ensuring the most favorable outcome in both medical and economic terms.

For accurate implantation, every VARION humeral nail system is supplied with instruments of high precision.

Indications
Osteosynthesis Treatment with VARION

The VARION humeral nail system is indicated for the treatment of subcapital and proximal humerus fractures.

Indications
VARION Head Replacement

Non head-preserving reconstructable fractures in very elderly patients.

Implant Selection

Nails, screws and fracture heads are supplied in various sizes to fit the anatomical situation.

Features and Advantages of the New VARION System at a Glance.

1. Symmetrical VARION humeral nail (for left or right use)

2. Cannulated Nail for insertion over guide wire

3. 7.5° lateral inclination ensures easy access and optimal implant positioning in bone

4. The proximal nail diameter of 11 mm allows optional adaption of fracture head

5. Proximal locking for angular and rotational stability

6. Secure fixation of tuberculum majus and tuberculum minus fragments is possible on both right and left

7. 4.5 mm screws with highly profiled threads allow excellent retention in cancellous and cortical bone

8. 10 mm washers for optional fixation of tendons or bone fragments and to prevent the screw heads from penetrating through bone of poor quality

9. Distal stop for fracture head

10. Distal nail diameters of 8.5 and 10 mm, to avoid reaming the medullary cavity

11. Ascending screws ensure good fixation of humeral head

12. Reliable distal locking with up to 3 screws

13. Tapered nail tip for easy insertion

14. Six different head sizes available

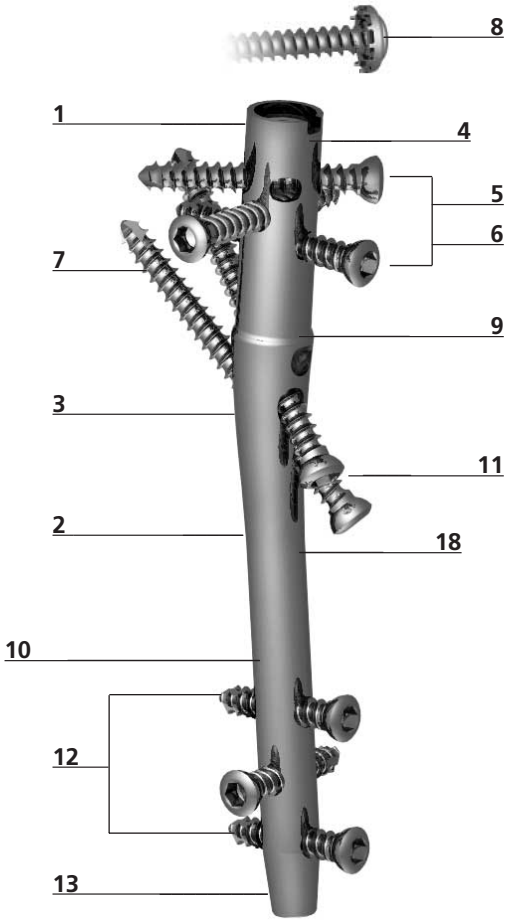
15. Intraoperative fixation of the head from the anterior

16. Fin allows additional fixation of rotator cuff with suture material

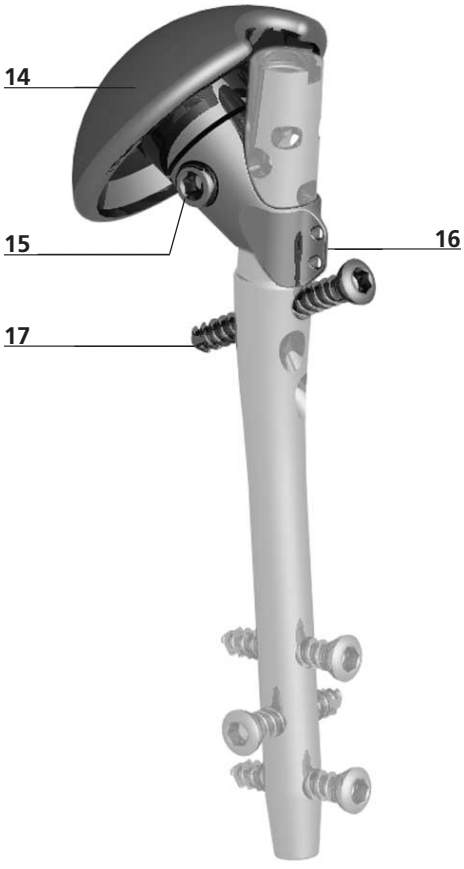
17. Descending screw for nail stabilization

18. 120-mm nail length allows targeting device-guided insertion of all locking options

VARION Fracture Management



VARION Head Replacement



Operative Technique of Osteosynthesis Treatment

VARION Humeral Nail

1. Positioning of the patient

The patient is placed in a beach-chair position. The position is supine with the upper body at a 30° angle. For x-ray imaging in the vertical plane, the upper arm is extended over the operating table. It is important to ensure that the shaft can be moved back without impairment in case it becomes necessary to expose the humeral head anteriorly.

2. Approach

A short anterolateral incision (deltoid split) is made. After longitudinal splitting of the muscles and the subacromial bursa, the rotator cuff is split from the greater tuberosity along the line of the fibers of the supraspinatus muscle. Reduction of the head is carried out under radiographic guidance with a Steinmann pin or a hook, temporary fixation with K wires, if needed.

3. Opening of the medullary cavity

Under a/p fluoroscopy, using the chuck, the guide wire is placed laterally at the edge of the head and in the sagittal plane should be located in the middle of the greater tuberosity. The guide wire is then advanced into the medullary cavity (Fig. 1.1).

With the obturator attached, the tissue protection sleeve is slid over the guide wire (Fig. 1.2). The obturator is removed and the 12-mm cannulated drill is inserted over the guide wire for opening the medullary cavity and advanced until it stops (Fig. 1.3).

Fig. 1.1 Fig. 1.2 Fig. 1.3

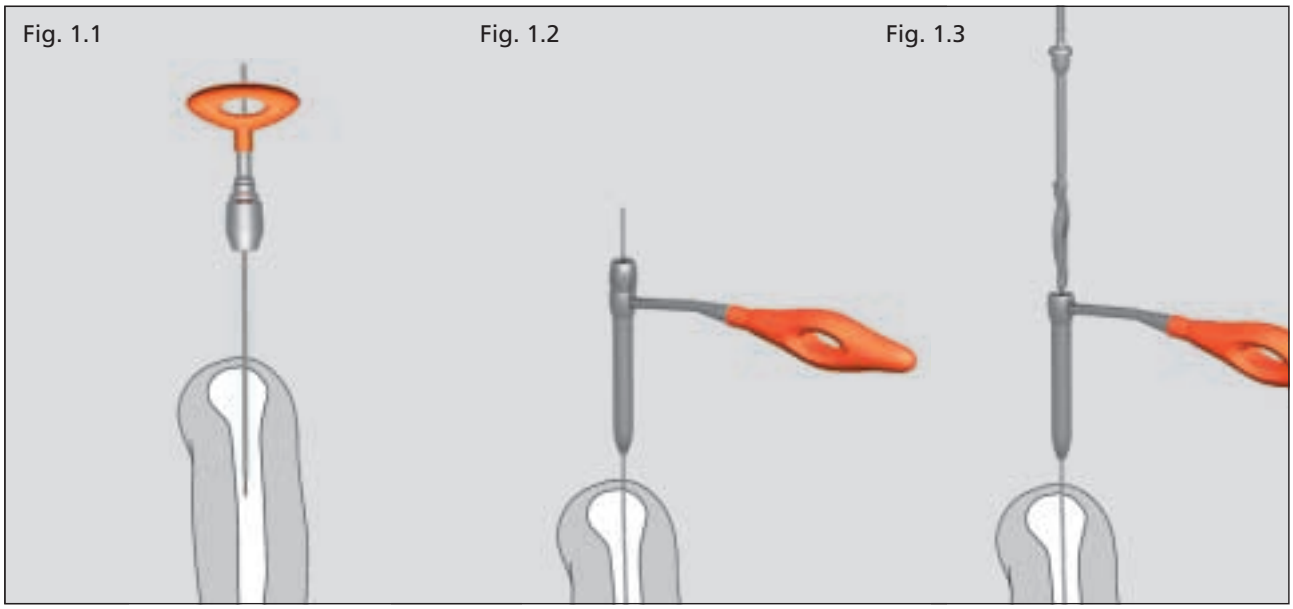


Fig. 2

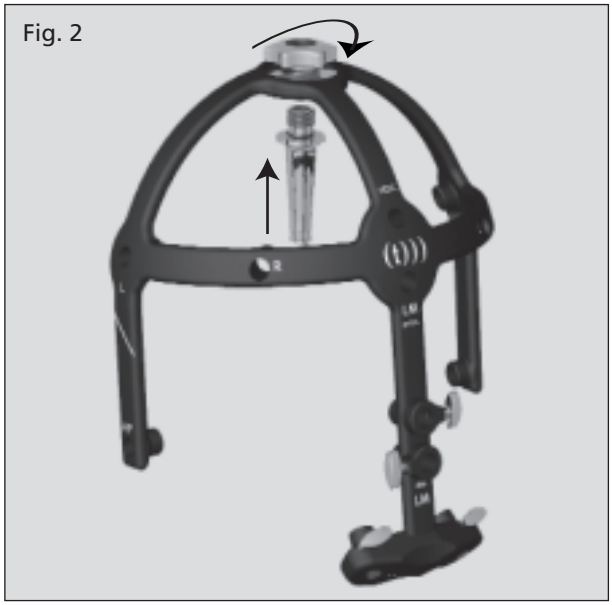


Fig. 3.1

Fig. 3.2

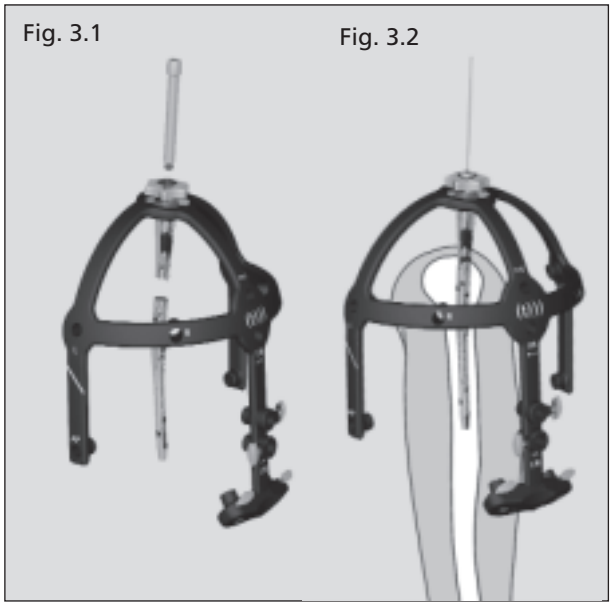
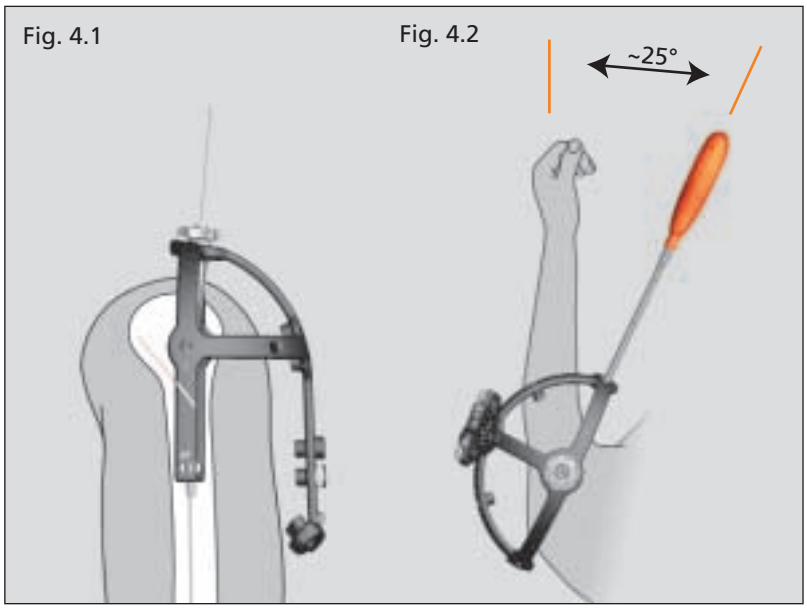


Fig. 4.1

Fig. 4.2



4. Preparation of the Targeting Device

The targeting device is designed for intraoperative removal. Prior to use, the nail adapter should be assembled onto the targeting device with the fixation nut (Fig. 2).

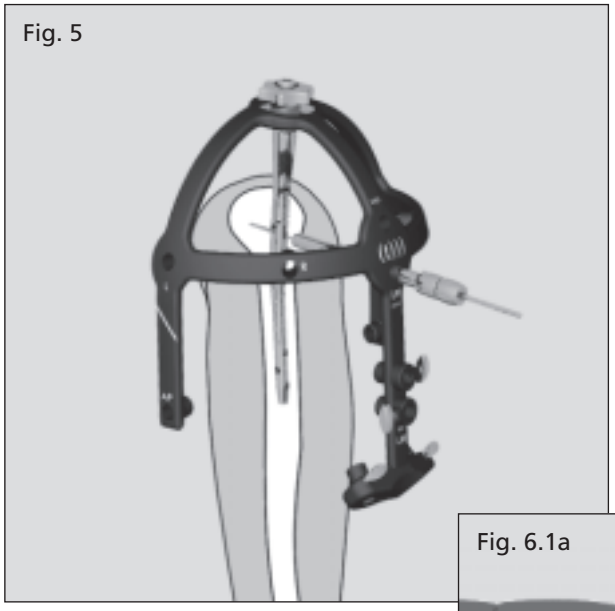
5. Nail Insertion

The nail holding screw is used to fasten the nail to the targeting device; the nail is advanced over the guide wire and completely inserted into the medullary cavity (Fig. 3.1 – 3.2). A circumferential groove on the targeting device can be used for orientational alignment on the x-ray. To avoid any impingement, the proximal end of the nail must be placed approx. 2 – 3 mm subchondrally. The later position of the distal ascending screw should be checked on the X-ray according to the markings on the targeting device (Fig. 4.1). It is important that the nail holding screw remains firmly tightened throughout the entire implantation procedure. Manual insertion of the nail should never be carried out with force – for example by hitting it with a hammer. Remove the guide wire after the nail has been inserted.

When adjusting the retrotorsion, it is recommended to place the lower arm at a 90° angle and, when looking from the cranial, to set the A/P arch of the targeting device at an inner rotation angle of approx. 25° in relation to the lower arm (Fig. 4.2).

Tip: *The SW 5 screwdriver inserted in the anterior targeting hole can serve as a pointer.*

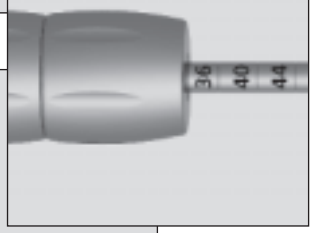
Fig. 5



The adjusted reduction is maintained by inserting the drill for proximal L/M locking into the bone where it remains while the distal locking screws are inserted. (Fig. 5)

To achieve this, after puncture incision and blunt dissection, the tissue protection sleeve Ø 9, Ø 7, L 110 is advanced up to the bone with the obturator Ø 7, L 130. Then, while advancing the tissue protection sleeve slightly, the obturator is removed and the guide sleeve Ø 3.2, L 124 introduced into the tissue protection sleeve. The cortex is breached using the drill Ø 3.2, L 205. (Fig. 5)

Fig. 6.1a



6. Locking of the nail

Distal locking

Likewise, when distal locking is performed, after puncture incision and blunt dissection, the tissue protection sleeve Ø 9, Ø 7, L 110 is advanced up to the bone with the obturator Ø 7, L 130 (Fig. 6.1 – 6.2). After the obturator is removed and the guide sleeve Ø 3.2, L 124 introduced into the tissue protection sleeve, the cortex can be breached with the drill Ø 3.2, L 205. Markings on the drill at the end of the guide sleeve indicate the required screw length. (Fig. 6.1a)

Fig. 6.1

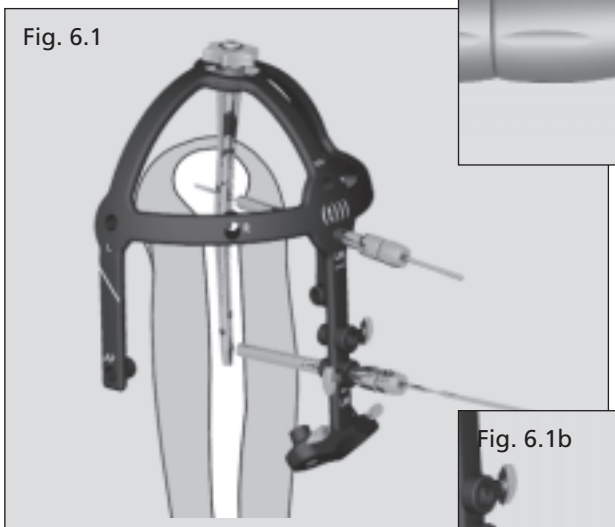
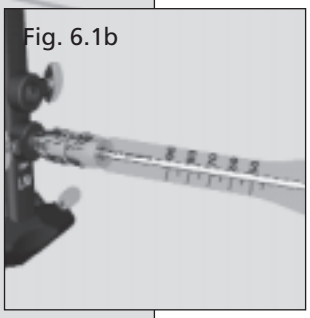


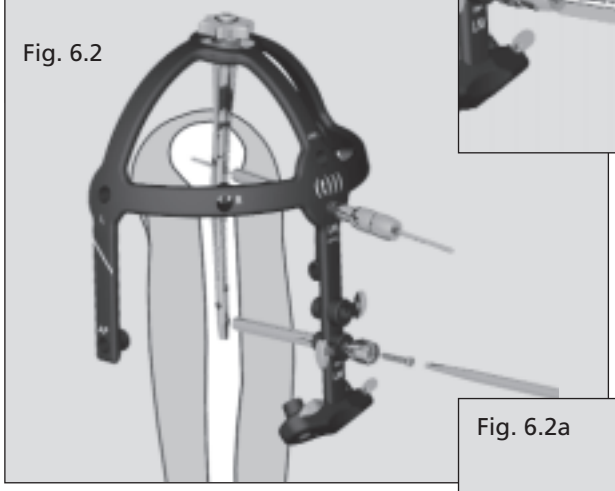
Fig. 6.1b



Tip: for bicortical locking: When the screw length is read off where the drill tip comes up against the opposing cortical bone, then a screw should be selected that is 8 –10 mm longer than the value read off the gauge.

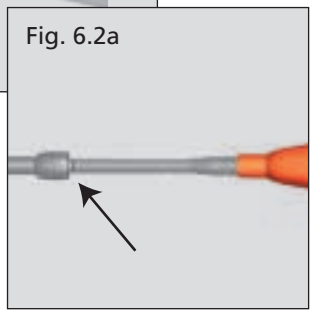
Alternatively, after monocortical reaming, the probe Ø 2.5, L 300 can be inserted into the drill hole and the screw length read off the screw depth gauge (Fig. 6.1b). Here as well, when the probe encounters opposing cortical bone, select a screw that is 8 –10 mm longer than the value read off the gauge.

Fig. 6.2



After bicortical reaming, the guide sleeve is removed and, using the SW 3.5 screwdriver, the locking screw is inserted through the tissue protection sleeve (Fig. 6.2). The screw head is flush with the cortex when the circular marking on the screwdriver shaft has reached the end of the tissue protection sleeve (Fig. 6.2a).

Fig. 6.2a



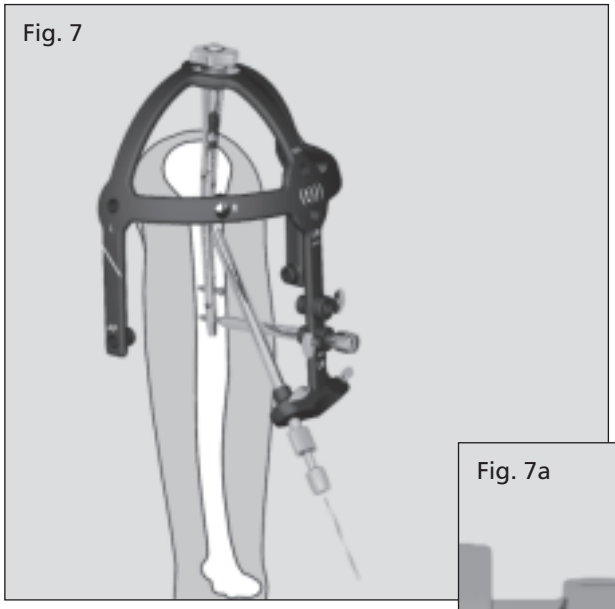


Fig. 7

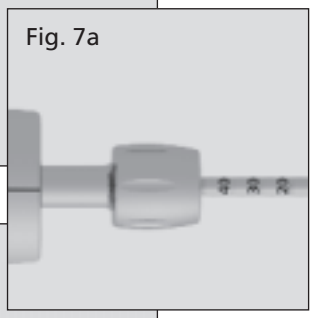


Fig. 7a

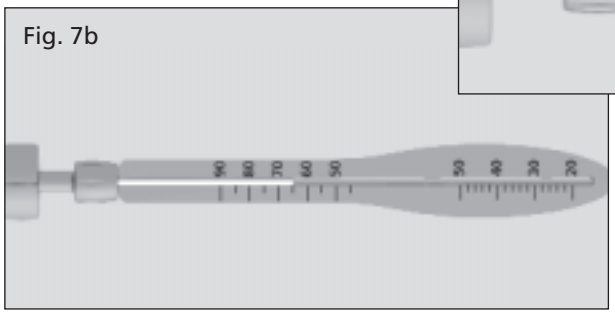


Fig. 7b

Note: *To prevent fissure formation, do not tighten the distal screws too firmly into the cortical bone.*

Up to three locking screws can be inserted distally. For each one, repeat the described procedure accordingly.

The inserted drill used for temporary fixation of the reduction can be removed after distal locking.

The tissue protection sleeve of a lateral/medial locking screw should be left on the screw head and fastened with the set screw (Fig. 7).

Ascending locking

After puncture incision and blunt dissection, the tissue protection sleeve Ø 9, Ø 7 L 160 is advanced on to the bone with the obturator Ø 7, L 180. Particular effort should be taken to avoid the axillary nerve. The obturator is removed and the tissue protection sleeve advanced. The tissue protection sleeve is beveled on the medial side. To ensure that the sleeve is flush with bone, the marking line on the lateral side of the sleeve should be aligned to the cranial and fastened to the targeting device with the set screw.

Carefully center punch the lateral cortical bone using the center drill Ø 7, Ø 3.15, L 200.

Tip: When reaming, press the tissue protection sleeve on the medial side slightly caudal. This will prevent reaming towards the cranial.

Insert the guide sleeve Ø 3.2, L 183 into the tissue protection sleeve and bring the drill Ø 3.2, L 300 to the position where the tip of the ascending screw is to be located (Fig. 7). The screw length is read off the drill shaft at the edge of the guide sleeve (Fig. 7a). After reaming, the probe Ø 2.5, L 300 can alternatively be inserted into the drill hole and the screw length read off the screw depth gauge (Fig. 7b). To avoid inaccurate measurements, the guide sleeve must be flush with the bone. Now, the guide sleeve is removed and, using the SW 3.5 screwdriver, the fully threaded screw is inserted through the tissue protection sleeve. It should be ensured that the screw does not penetrate through the medial cortical bone, but that its tip is positioned 3 – 5 mm subcortically.

The second ascending screw should be inserted in the same way.

Fig. 8

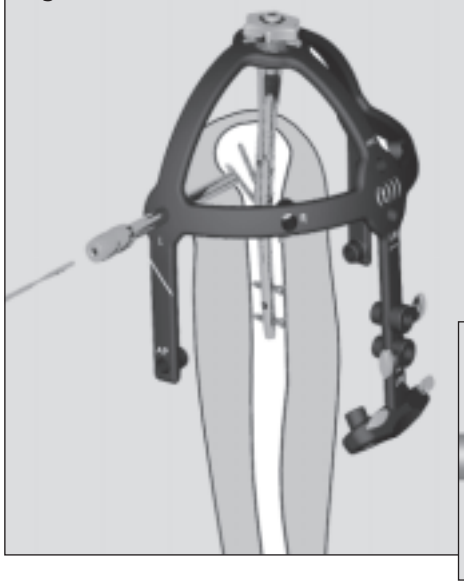
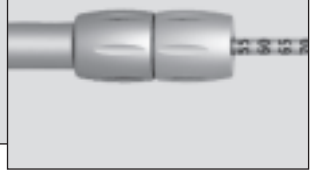


Fig. 8a



Proximal locking

After puncture incision and blunt dissection, the tissue protection sleeve Ø 9, Ø 7, L 110 is advanced to the bone with the obturator Ø 7, L 130. Then while advancing the tissue protection sleeve slightly the obturator is removed and the guide sleeve Ø 3.2, L 124 introduced into the tissue protection sleeve. The first cortex is opened using the drill Ø 3.2, L 205. (Fig. 8).

The screw length is read off the drill at the end of the guide sleeve (Fig. 8a). To avoid inaccurate measurements, the tissue protection sleeve must be flush with the bone.

Alternatively, after reaming, the probe Ø 2.5, L 300 can be inserted into the drill hole and the screw length read off the screw depth gauge.

Fig. 9.1

Fig. 9.2

Fig. 9.3

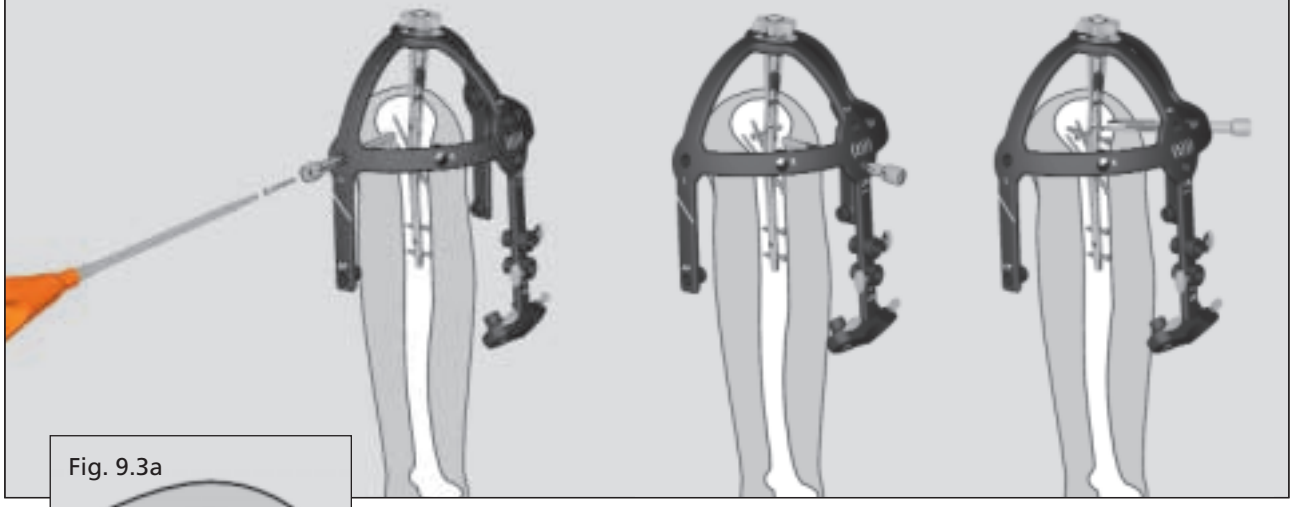
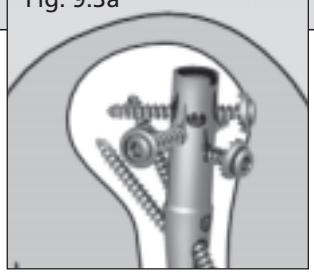


Fig. 9.3a



Note: *For checking the screw's position, the targeting device can be detached from the nail adaptor prior to the proximal locking. Without the targeting arch, it is possible to carefully turn the upper arm under image intensifier guidance. Before doing, however, ensure fixation of all fragments at this time. Otherwise the outcome of reduction may be jeopardized.*

With the screwdriver SW 3.5, each locking screw is inserted through the tissue protection sleeve one after the other (Fig. 9.1 – 9.3). If bone quality is poor, the use of a washer is recommended. To insert the washer, the tissue protection sleeve must be retracted somewhat. The washer is placed between the tissue protection sleeve and the bone and fastened with the locking screw (Fig. 9.3a).

Fig. 10

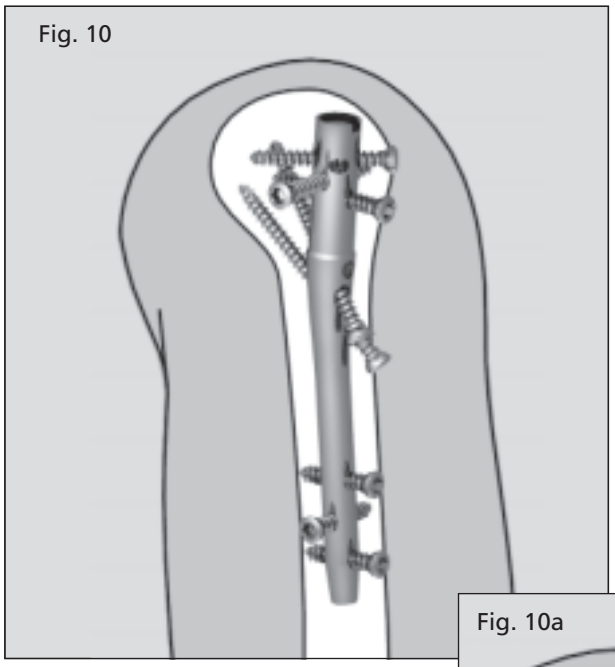
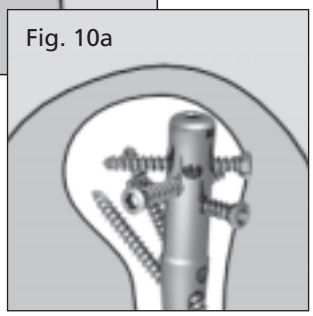


Fig. 10a



After removing the targeting device (Fig. 10), the proximal plug can be optionally inserted into the proximal end of the nail with screwdriver SW 3.5. (Fig. 10a)

7. Follow-up Care and Management

Postoperative management should be based on the principles of functional treatment:

Time frame	*Treatment*	*Recommendations*
1 – 2 weeks	Passive/functional	No rotation
3 – 6 weeks	Active/functional	Including rotation
6 months	Nail removal	Optional

Note: *As with other osteosynthesis procedures, the postoperative course in patients with VARION systems should be followed at regular intervals to check that the implants are seated properly. If any signs of implant loosening emerge, countermeasures can be taken in a timely manner.*

Fig. 11

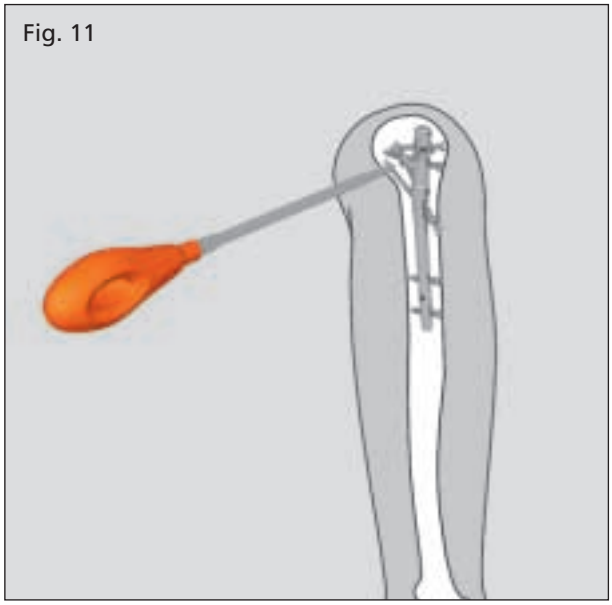


Fig. 12

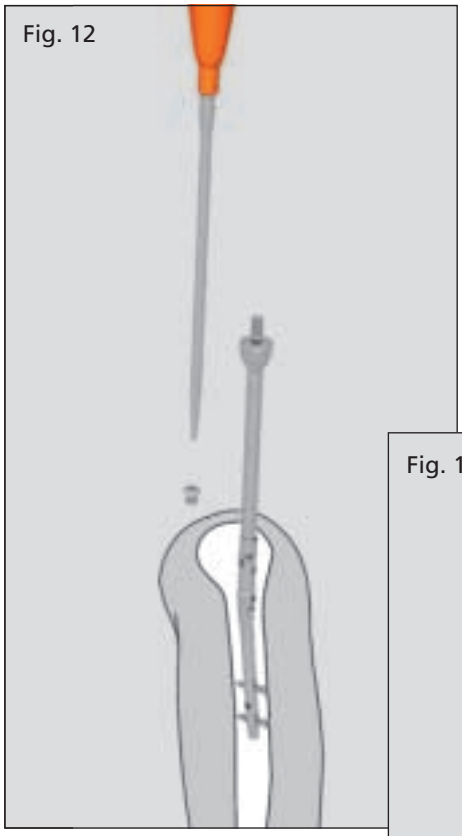
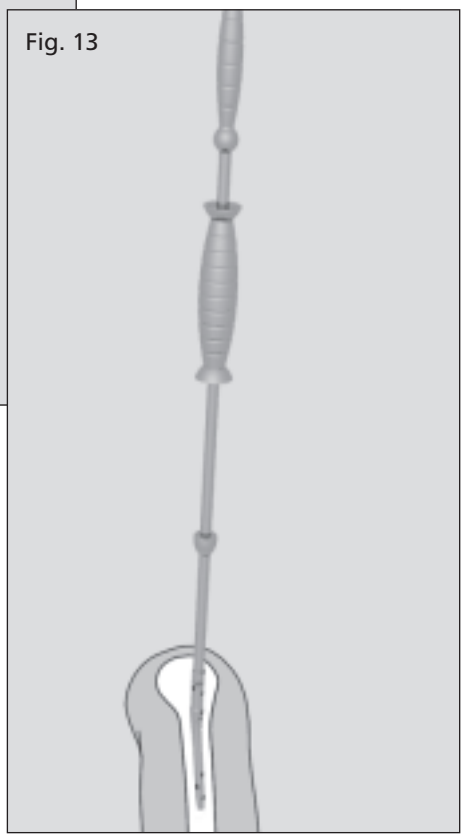


Fig. 13



8. Removal of the Implant

8a. Removal of the Proximal and Ascending Locking Screws

The old scar is excised and the screw head must be located. After palpation of its exact position, incision and dissection are performed. The locking screws are removed using screwdriver SW 3.5. (Fig.11)

8b. Removal of the Proximal Plug

The upper scar is excised. After palpation of the end of the nail, the muscles are split longitudinally and the rotator cuff split along the line of the fibers. The proximal end of the nail is exposed and the proximal plug is removed using screwdriver SW 3.5.

The extraction adapter (M 8) is screwed into the proximal nail plug. (Fig. 12)

8c. Removal of the Distal Locking Screws

The distal locking screws are removed as described under 8a.

8d. Removal of the Varion nail

After sliding on the impact weight (460g), the extraction rod (M 8) is screwed on the extraction adapter (M 8, L 420) and tightened firmly with the open-ended wrench SW 10.

Then, the nail is carefully pulled out with light blows. (Fig.13)

Operative Technique – Head Replacement

VARION Humeral Nail with Fracture Head

Fig. 14

1. Placement of the Fracture Head
The new VARION humeral head nailing system offers the surgeon the option of easily switching intraoperatively to a head replacement.

2. Screw Fixation or Cementation
The VARION humeral nail with head can either be anchored with screws with bone cement. Cementation can make sense if the humeral head has to be replaced and the medullary cavity is extremely wide and/or there is significant osteoporosis. The decision about whether to cement in the steel nail is left up to the discretion of the surgeon and is only recommended after scrupulously weighing its merits.

3. Patient Positioning
The patient is positioned as described for osteosynthesis treatment (see page 4).

4. Preparation and Approach
The VARION nail is implanted according to the operative technique for osteosynthesis treatment and distal locking performed. Any ascending or proximal locking screws must be removed. The incision should be extended slightly to the distal.

Note: *Here it is important to avoid any impingement of the axillary nerve.*

The head fragment is removed or the head resected as required. The targeting device must be attached on the nail again and fixated with the nail holding screw.

5. Locking of Nail
Descending Locking
Descending locking is required to stabilize the nail in the humeral shaft. After puncture incision and blunt dissection – with particular effort being made to avoid the axillary nerve – the tissue protection sleeve Ø 9, Ø 7, L 110 is advanced with the obturator Ø 7, L 130 on to the bone (Fig. 14). While advancing the tissue protection sleeve slightly, the obturator is removed and the guide sleeve Ø 3.2, L 124 is introduced into the tissue protection sleeve. The cortical layer is reamed using the drill Ø 3.2, L 205.

Fig. 15

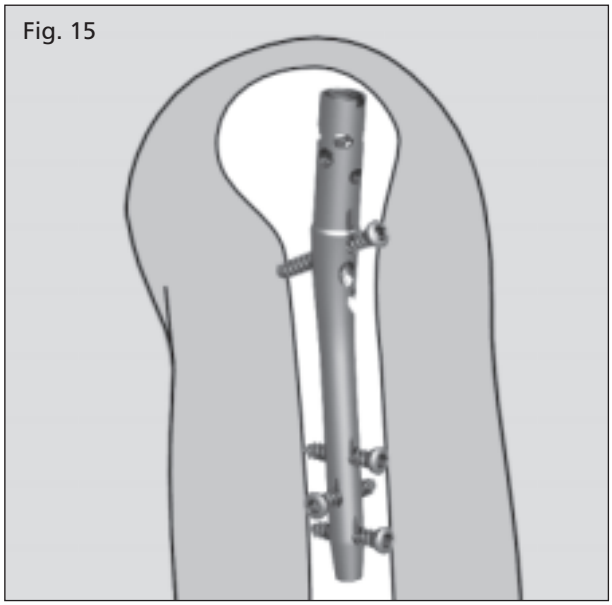
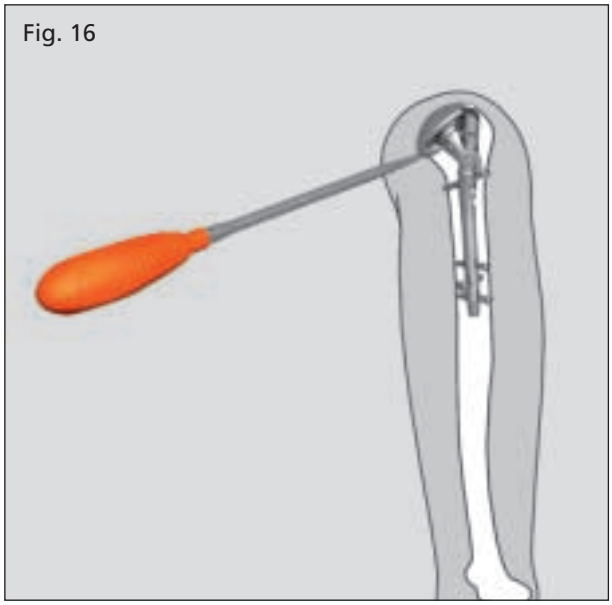


Fig. 16



Tip: When the drill bit encounters opposing cortical bone, the screw length is read off from the drill at the end of the guide sleeve. A screw should be selected that is 8 –10 mm longer than the length gauged. The tissue protection sleeve must be flush with the bone during this process.

Alternatively, after monocortical reaming, the probe Ø 2.5, L 300 can be introduced into the drill hole and the screw length read off the screw depth gauge. Here as well: a screw should be selected that is 8 –10 mm longer than the value read off the gauge. After bicortical reaming, the guide sleeve is removed and the locking screw is screwed through the tissue protection sleeve into bone using the screwdriver SW 3.5.

The targeting device should be removed. (Fig. 15)

6. Assembly of the Fracture Head

The fixation screw is screwed into the fracture head from the anterior (Fig. 16). The fracture head is slid over the proximal end of the nail to allow correct anatomical reconstruction of the humerus length while respecting retrotorsion of the humeral head. The head is set by firmly tightening the clamping screw with screwdriver SW 3.5.

Horizontally, the tuberosities are fixated with the sutures placed around the neck of the prosthesis and through the tendon insertion. Additionally, fixation sutures can be attached through the eyes of the fin on the lateral side of the fracture head.

7. Follow-up Care and Management

Postoperative management should be based on the principles of functional treatment:

Time frame	*Treatment*	*Recommendations*
1 – 2 weeks	Passive/functional	No rotation
3 – 6 weeks	Passive/functional	Rotation permitted
From week 6 onward	Active	Muscle build up

Note: *When the fracture head is used, the primary aim is to achieve freedom from pain and stability of movement in biologically elderly patients.*

Here as well, the postoperative course should be followed at regular intervals to check that the implants are seated properly. If any signs of implant loosening emerge, countermeasures can be taken in a timely manner.

VARION Instrumentarium

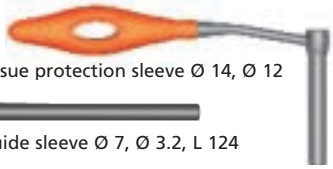
200-110 Chuck

201-100 Screwdriver SW 5

201-112 Screwdriver SW 3.5, L 305

201-140 Open-ended wrench SW 10

202-109 Tissue protection sleeve Ø 9, Ø 7, L 110



202-113 Tissue protection sleeve Ø 14, Ø 12

202-115 Guide sleeve Ø 7, Ø 3.2, L 124

202-118 Guide sleeve Ø 7, Ø 3.2, L 183

202-119 Tissue protection sleeve Ø 9, Ø 7, L 160

203-109 Drill Ø 3.2, L 205

203-111 Obturator Ø 7, L 130

203-112 Obturator Ø 7, L 180

203-117 Drill, cannulated Ø 12, Ø 3.5

203-118 Obturator Ø 12

203-124 Drill Ø 3.2, L 300

203-127 Center drill Ø 7, Ø 3.15, L 200

204-101 Targeting device

204-102 Nail Holding Screw

205-106 Extraction adapter M 8

205-107 Extraction rod M 8, L 420

205-108 Impact weight 460 g

206-103 Guide wire Ø 2.5, L 450

206-106 Probe Ø 2.5, L 300

208-102 VARION Length gauge

VARION Components

VARION Humeral Nail

Material: ISO 5832-9

Dimensions	Art. No. non-sterile	Art. No. sterile
Ø 8.5, L 120	107-100	107-140
Ø 10, L 120	107-101	107-141

Bone Screws

Screws, fully threaded
Material: ISO 5832-1

Dimensions	Art. No. non-sterile	Art. No. sterile	Dimensions	Art. No. non-sterile	Art. No. sterile
Ø 4.5, L 20	101-200	101-270	Ø 4.5, L 44	101-212	101-282
Ø 4.5, L 22	101-201	101-271	Ø 4.5, L 46	101-213	101-283
Ø 4.5, L 24	101-202	101-272	Ø 4.5, L 48	101-214	101-284
Ø 4.5, L 26	101-203	101-273	Ø 4.5, L 50	101-215	101-285
Ø 4.5, L 28	101-204	101-274	Ø 4.5, L 55	101-216	101-286
Ø 4.5, L 30	101-205	101-275	Ø 4.5, L 60	101-217	101-287
Ø 4.5, L 32	101-206	101-276	Ø 4.5, L 65	101-218	101-288
Ø 4.5, L 34	101-207	101-277	Ø 4.5, L 70	101-219	101-289
Ø 4.5, L 36	101-208	101-278	Ø 4.5, L 75	101-220	101-290
Ø 4.5, L 38	101-209	101-279	Ø 4.5, L 80	101-221	101-291
Ø 4.5, L 40	101-210	101-280	Ø 4.5, L 85	101-222	101-292
Ø 4.5, L 42	101-211	101-281			

VARION Fixation Screw

Material: ISO 5832-1

Dimensions	Art. No. non-sterile	Art. No. sterile
L 16	107-110	107-150

VARION Fracture Head

Material: ISO 5832-1

Dimensions	Art. No. non-sterile	Art. No. sterile
Ø 43, H 16	107-114	107-154
Ø 46, H 16	107-116	107-156
Ø 46, H 19	107-117	107-157
Ø 49, H 16	107-118	107-158
Ø 49, H 19	107-119	107-159
Ø 52, H 19	107-121	107-161

VARION Proximal Plug

Material: ISO 5832-1

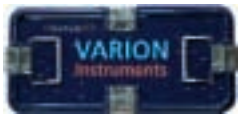
Dimensions	Art. No. non-sterile	Art. No. sterile
M 8	107-131	107-171

VARION Washer

Material: ISO 5832-1

Dimensions	Art. No. non-sterile	Art. No. sterile
Ø 10 teethed	107-130	107-170
Ø 10 plain	107-132	107-172

209-106 Implant box (empty)



209-107 Instumentarium box (empty)

The figures are schematic representations and do not correspond with the original dimensions.
The manufacturer reserves the right to make technical modifications. Status March 05

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the medical people

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