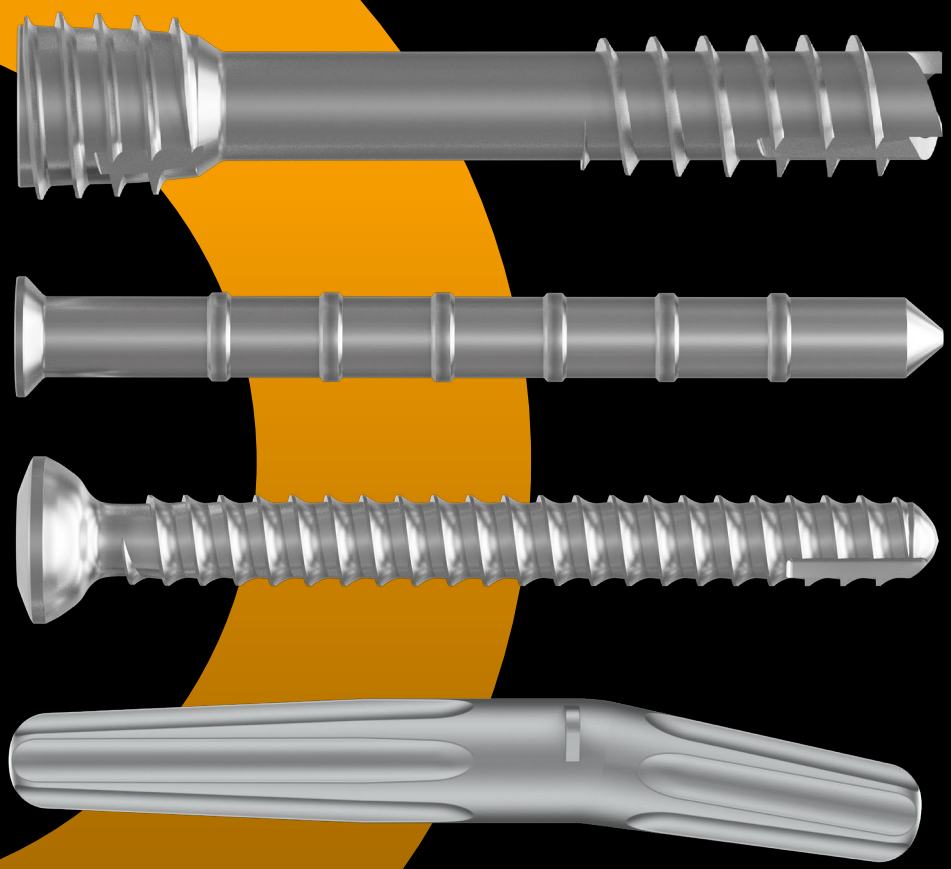
MAGNEZIX

THE NEW STANDARD OF IMPLANTS!

MAGNEZIX® PRODUCT OVERVIEW



Intelligent innovations for a better life.
www.syntellix.com

SYNTELLIX

ADVANTAGES AT A GLANCE

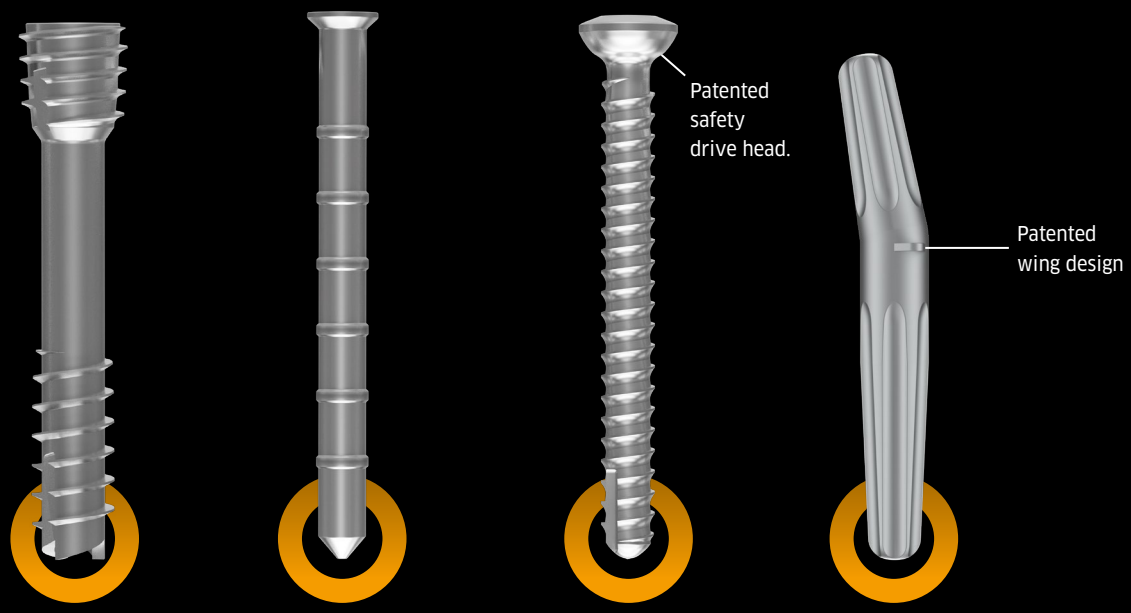
„CLINICALLY SUPERIOR“
COMPARED TO TITANIUM IMPLANTS[1]

Similar stability to comparable titanium implants.

Greater stability than PLA/PGA implants.

Superior stability compared to PLA/PGA implants.

Ideal properties – stable and elastic.



Osteoconductive properties.
Metallic and transformable.
Reduced risk of infection.

No remaining foreign material.
Prevents „stress shielding“.

Suitable for MRI and CT diagnostics.
Virtually no radiological artifacts.

Free of nickel, cobalt, chrome, and aluminium.
Excellent biocompatibility, no known allergies.

[1] *Reference: Klauser H. (2018): Internal fixation of three-dimensional distal metatarsal I osteotomies in the treatment of hallux valgus deformities using biodegradable magnesium screws in comparison to titanium screws; Foot and Ankle Surgery, DOI: 10.1016/j.fas.2018.02.005.*

MAGNEZIX

THE NEW STANDARD OF IMPLANTS

METAL THAT TURNS INTO BONE – MAGNEZIX®

Innovation has no end: MAGNEZIX®, the worldwide unique material and basis for simultaneously stable and transformable magnesium-based metal implants, is becoming increasingly versatile. In addition to the well-proven compression screw CS, the unrivalled Pin and the versatile cortical screw CBS, the MAGNEZIX® StarFuse® (PIP arthrodesis) and the MAGNEZIX® CS^{c} 4.8 as the largest dimension are now also available.

No compromises: MAGNEZIX® implants are metallic and stable, and therefore much more resilient than conventional polymer implants based on PGA or PLA. And unlike conventional metal screws or wires, they do not have to be removed again because they dissolve, are rebuilt by the body and form the basis for new mineralized bone substance.

The ideal solution: MAGNEZIX® implants are suitable for indications that require a temporary fixation of the bone, but for which remaining material or a surgical removal of the metal following the healing process is not desirable.

MAGNEZIX® implants offer you:

Stability: MAGNEZIX® products are metallic and offer significantly greater stability than conventional resorbable implants.

Transformation: Implants made of MAGNEZIX® are rebuilt in the body and replaced by endogenous bone tissue.

Osteoconductive properties: Magnesium stimulates bone growth.

Inhibition of infection: The degradation of magnesium creates an alkaline, anti-bacterial environment.

Compatibility: MAGNEZIX® has an excellent biocompatibility, no allergies are known for the components of the alloy.

THE MAGNEZIX®-PRINCIPLE

First healing, then dissolving! *MAGNEZIX® implants are metallically stable and are transformed into endogenous bone tissue, setting new standards for implants.*

THIS METAL SCREW TURNS INTO BONE

MAGNEZIX® CS/CS^{c}

INTENDED USE

The MAGNEZIX® CS/CS^{c} is a bioabsorbable compression screw that is used to restore the bone continuity after fractures and osteotomies (osteosynthesis) as well as for treatment of pseudarthroses. Specifically, the MAGNEZIX® CS/CS^{c} is intended to achieve anatomical retention of bone sections that have been joined together by surgical splinting following prior reduction until the bone has healed. The implant is designed for single use.

INDICATIONS

The indications for MAGNEZIX® CS/CS^{c} implants are reconstruction procedures after fractures and malalignment in the human skeleton. The surgeon must determine the degree of injury and the scope of the required surgical procedure and then select the correct surgical procedure and the appropriate implant. This is particularly important when using bioabsorbable MAGNEZIX® implants. The surgeon is always responsible for the decision to use these implants.

Depending on the chosen size, the MAGNEZIX® CS/CS^{c} can be used as a bone screw for children, adolescents or adults for the adaptation-capable or exercise-capable fixation of bones and bony fragments.

MAGNEZIX® CS 2.0, 2.7, 3.2:

- Intra- and extraarticular fractures of small bones and bony fragments
- Arthrodeses, osteotomies and pseudarthroses of small bones and joints
- Small bony ligament and tendon ruptures
- Similar indications

MAGNEZIX® CS 2.0:

- Phalangeal and metacarpal bones
- Processus styloideus radii et ulnae
- Capitulum humeri and caput radii
- Osteochondrosis dissecans
- Similar indications

MAGNEZIX® CS 2.7, 3.2:

- Carpal, metacarpal, tarsal and metatarsal bones
- Processus styloideus radii et ulnae
- Capitulum humeri and caput radii
- Epicondylus humeri
- Hallux valgus corrections
- Similar indications

MAGNEZIX® CS^{c} 4.8:

- Intra- and extraarticular fractures of small and medium-sized bones and bony fragments
- Arthrodeses, osteotomies and pseudarthroses of small- and medium-sized bones and small joints
- Similar indications at distal tibia, calcaneus, talus and metatarsus
- Re-fixiation of bony fragments also on distal femur and proximal tibia

CONTRAINDICATIONS

MAGNEZIX® implants are contraindicated (absolute contraindication) in specific clinical situations or they should only be planned and used after careful consideration (relative contraindication).

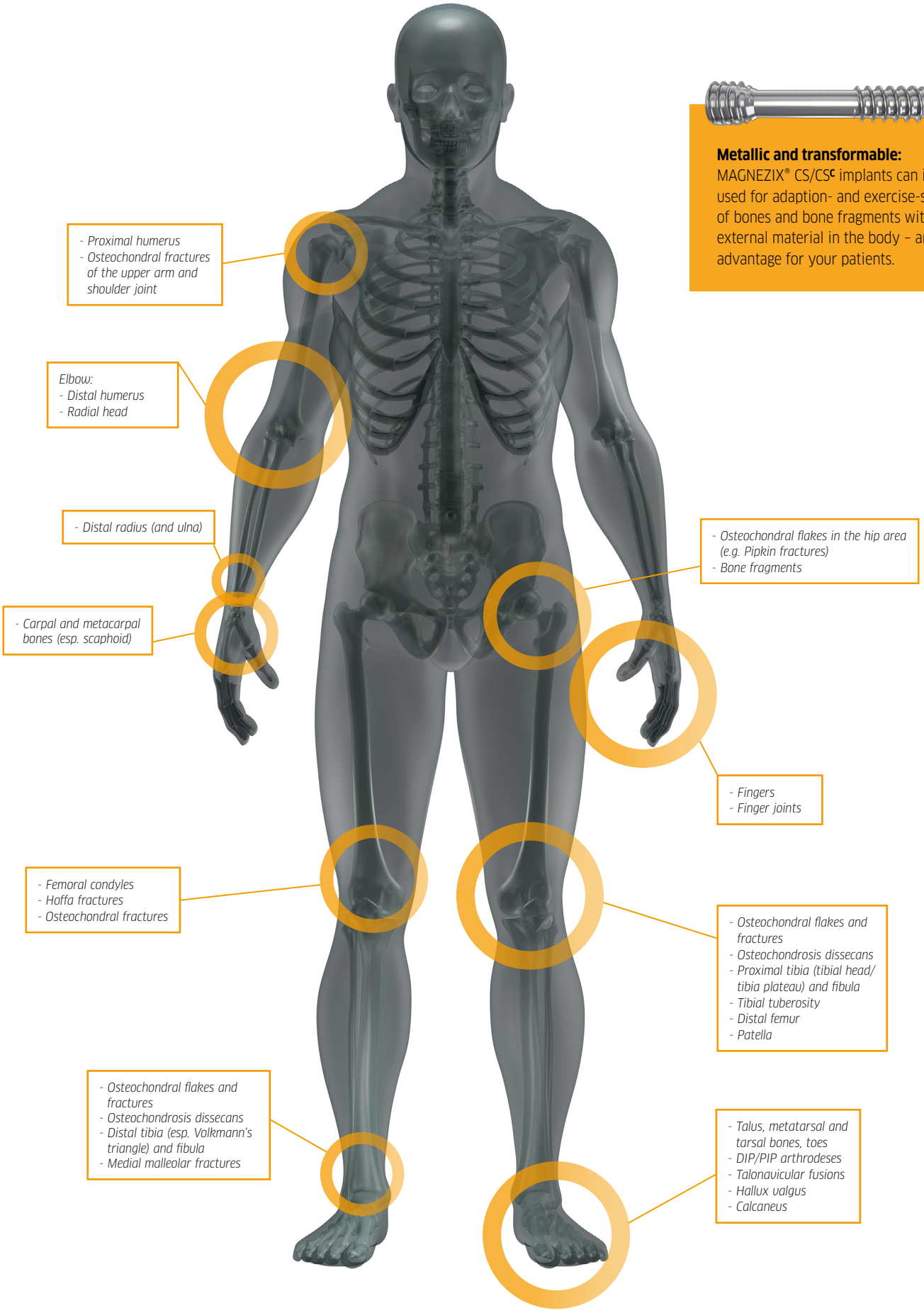
Absolute contraindications

- Insufficient or avascular bone mass for anchorage of the implant, except osteochondral fractures and dissecates
- Confirmation or suspected septic infectious surgical site
- Application in the area of the epiphyseal plates
- Load-bearing stable osteosynthesis
- Radioscaphoid and/or midcarpal arthrosis
- Arthrodeses of medium-sized and large joints
- Applications on the spinal column

Relative contraindications

- Options for conservative treatment
- No options for adequate postoperative treatment (e.g. temporary strain relief)
- Uncooperative patient or patient with restricted intellectual capacity
- Alcohol, nicotine and/or drug abuse
- Poor skin/soft tissue conditions
- Osteoporosis
- Acute sepsis
- Epilepsy

Application examples



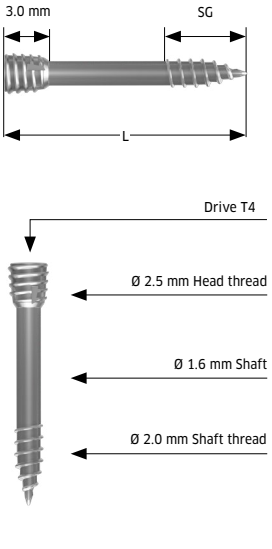
Metallic and transformable:
MAGNEZIX® CS/CS^{C} implants can ideally be used for adaption- and exercise-stable fixation of bones and bone fragments without leaving external material in the body – an outstanding advantage for your patients.

MAGNEZIX® CS/CS^{C}

PRODUCT OVERVIEW

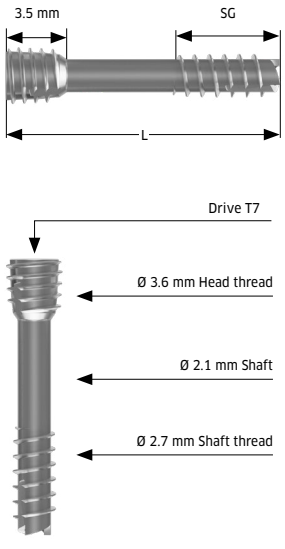
DIMENSIONS

MAGNEZIX® CS 2.0



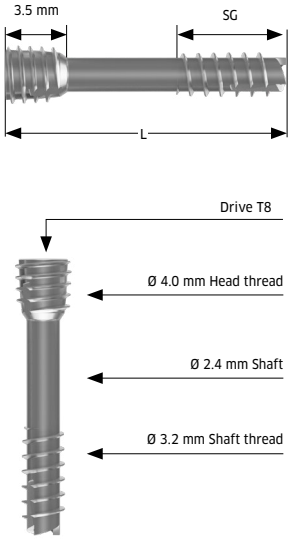
Art. No.	Threaded shaft length SG [mm]	Screw length L [mm]
1020.008	4	8
1020.010	4	10
1020.012	4	12
1020.014	5	14
1020.016	5	16
1020.018	5	18
1020.020	6	20
1020.022	6	22
1020.024	6	24

MAGNEZIX® CS 2.7



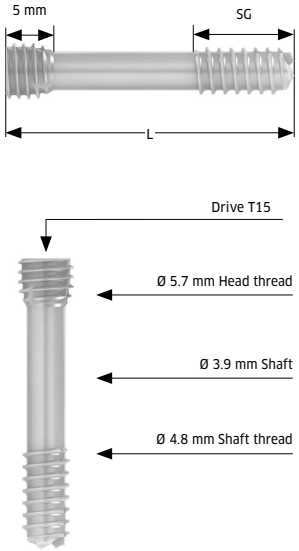
Art. No.	Threaded shaft length SG [mm]	Screw length L [mm]
1027.010	4	10
1027.012	5	12
1027.014	5	14
1027.016	7	16
1027.018	7	18
1027.020	7	20
1027.022	7	22
1027.024	7	24
1027.026	7	26
1027.028	7	28
1027.030	7	30
1027.032	9	32
1027.034	9	34

MAGNEZIX® CS 3.2



Art. No.	Threaded shaft length SG [mm]	Screw length L [mm]
1032.010	4	10
1032.012	5	12
1032.014	5	14
1032.016	7	16
1032.018	7	18
1032.020	7	20
1032.022	7	22
1032.024	7	24
1032.026	7	26
1032.028	7	28
1032.030	7	30
1032.032	9	32
1032.034	9	34
1032.036	9	36
1032.038	9	38
1032.040	9	40

MAGNEZIX® CS^{C} 4.8

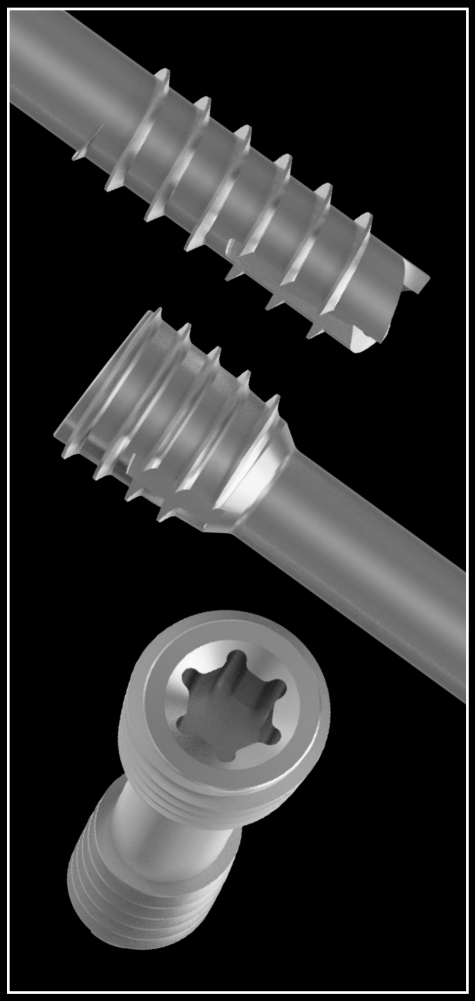


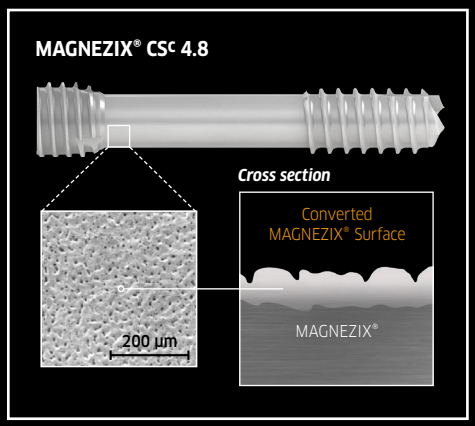
Art. No.	Threaded-shaft length SG [mm]	Screw length L [mm]
2048.014	6	14
2048.016	6	16
2048.018	6	18
2048.020	6	20
2048.022	8	22
2048.024	8	24
2048.026	8	26
2048.028	8	28
2048.030	10	30
2048.032	10	32
2048.034	10	34
2048.036	10	36
2048.038	14	38
2048.040	14	40
2048.042	14	42
2048.044	14	44
2048.046	14	46
2048.048	14	48
2048.050	14	50
2048.055	20	55
2048.060	20	60
2048.065	20	65
2048.070	20	70

The illustrations are not to scale.

ADVANTAGES AND FEATURES

MAGNEZIX® CS/CS^{C} IMPLANTS





Unique, bioabsorbable magnesium alloy

The use of MAGNEZIX® implants makes any subsequent implant removal unnecessary, and moreover, it supports the osseous healing process. MAGNEZIX® is bioabsorbable and biocompatible.

Self-tapping screw tip

The self-tapping properties of the screw tip reduce the operation time and simplify the surgical application technique.

Cannulated screw

The screw is cannulated (hollow) to allow controlled positioning of the screw using the guide wire. This feature supports minimal invasive surgery.

Self-tapping head thread

The self-tapping design of the screw head simplifies insertion and countersinking of the screw head.

Different thread pitches

The threads of the head and the shaft have different thread pitches. This adapted design of the screw generates compressive forces and supports the intended inter-fragmentary compression.

Self-holding screwdriver

The screw head is equipped with a T4/T7/T8/T15 (ISO 10664-4/7/8/15). The advantages of this ISO standardized technology are:

- ➔ Enlarged contact area
- ➔ Improved self-retaining mechanism
- ➔ Improved torque transmission

Innovative surface design MAGNEZIX® CS^{C} 4.8

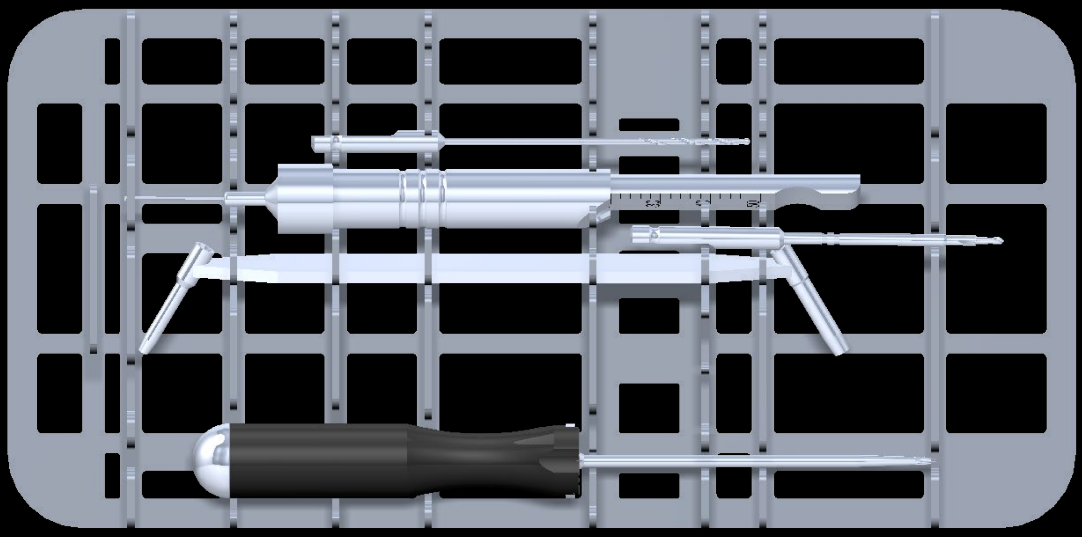
MAGNEZIX® CS^{C} 4.8 includes a highly innovative modification of the implant surface. This deliberately delays the transformation process and additionally ensures the stability required during the healing process.

WARNINGS

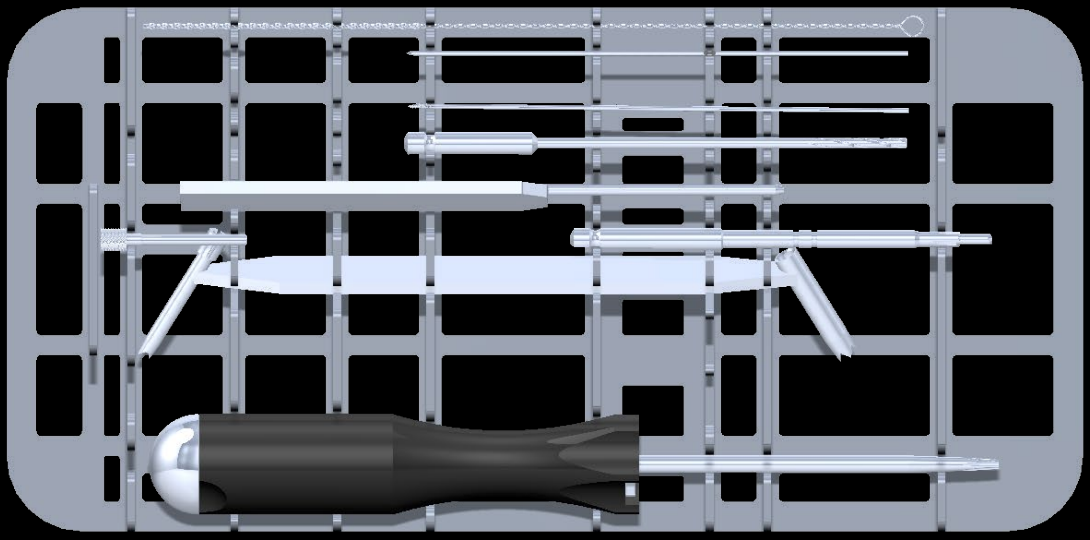
In the case of concurrent use of third party implants it must borne in mind that steel, titanium and cobalt-chromium alloys may not remain in direct contact with a MAGNEZIX® implant at the intervention site (i.e. no physical contact of implants). Since the implants are designed for single use only, reuse of MAGNEZIX® implant devices is grossly negligent and can result in an increased risk of infection and loss in implant stability. In general, re-sterilization alters the implant's functionality in an unpredictable way.

MAGNEZIX® CS

PRODUCT OVERVIEW INSTRUMENTS



MAGNEZIX® CS 2.0



MAGNEZIX® CS 2.7 (LIKE CS 3.2)

INSTRUMENTS
MAGNEZIX® CS/CS^{C}

PRODUCT OVERVIEW

Art. No.	Description
6020.104	Screwdriver T4, One-Piece Handle, consisting of:
	9099.001 One-Piece Handle for Screwdriver, 9020.015 Screwdriver btlade T4
6027.107	Screwdriver T7, One-Piece Handle, Ø 1.1 mm cannulated, consisting of:
	9099.001 One-Piece Handle for Screwdriver, 9027.015 Screwdriver blade T7
6032.108	Srcewdriver T8, One-Piece Handle Ø 1.3 mm cannulated, consisting of:
	9099.001 One-Piece Handle for Screwdriver: 9032.015 Screwdriver blade T8

6020.204	Screwdriver T4, Multi-Part Handle, consisting of:
	9099.002 Multi-Part Handle for Screwdriver, 9020.015 Screwdriver blade T4
6027.207	Screwdriver T7, Multi-Part Handle Ø 1.1 mm cannulated, consisting of:
	9099.002 Multi-Part Handle for Screwdriver, 9027.015 Screwdriver blade T7
6032.208	Screwdriver T8, Multi-Part Handle Ø 1.3 mm cannulated, consisting of:
	9099.002 Multi-Part Handle for Screwdriver, 9032.015 Screwdriver blade T8

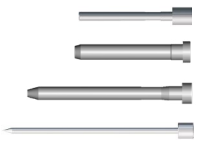
9099.003	Screwdriver Handle with Quick Coupling
9048.015	Screwdriver Blade T15, self-holding, for Quick Coupling

9020.020	Drill Bit Ø 1.5 mm, length 88/63 mm, for Quick Coupling
9027.020	Drill Bit Ø 2.2/1.1 mm, cannulated, length 100/75 mm, for Quick Coupling
9032.020	Drill Bit Ø 2.5/1.3 mm, cannulated, length 160/135 mm, for Quick Coupling
9048.020	Drill Bit Ø 4.0/1.9 mm, cannulated, length 160/135 mm, for Quick Coupling

9020.021	Countersink Ø 2.2/1.5 mm, cannulated, for Quick Coupling
9027.021	Countersink Ø 3.1/1.1 mm, cannulated, for Quick Coupling
9032.021	Countersink Ø 3.5/1.3 mm, cannulated, for Quick Coupling
9048.021	Countersink Ø 5.0/1.9 mm, cannulated, for Quick Coupling

9048.030	Protection Sleeve, Ø 5.0 mm

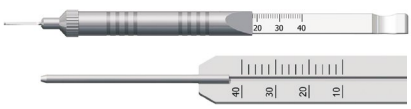
9020.033	Double Drill Guide, Ø 2.2/1.5 mm
9027.033	Double Drill Guide, Ø 3.1/2.2 mm
9032.033	Double Drill Guide, Ø 3.5/2.5 mm



9027.034	Drill Sleeve, Ø 2.2/1.1 mm
9032.034	Drill Sleeve, Ø 2.5/1.3 mm
9048.031	Drill Sleeve, Ø 5.0/4.0 mm
9048.032	Drill Sleeve, Ø 4.0/1.9 mm
9048.033	Trocar, Ø 1.8 mm

9027.040	Guide Wire Ø 1.0 mm, with trocar tip, length 100 mm
9032.040	Guide Wire Ø 1.2 mm, with trocar tip, length 150 mm
9048.043	Guide Wire Ø 1.7 mm, with trocar tip, length 150 mm

9027.041	Guide Wire Ø 1.0 mm, with threaded tip, length 100 mm
9032.041	Guide Wire Ø 1.2 mm, with threaded tip, length 150 mm
9048.044	Guide Wire Ø 1.7 mm, with threaded tip, length 150 mm



9020.042	Depth Gauge for screws
9027.042	Measuring Device, for Guide Wire Ø 1.0 mm, Guide Wire length 100 mm
9032.042	Measuring Device, for Guide Wire Ø 1.2 mm, Guide Wire length 150 mm
9048.042	Measuring Device, for Guide Wire Ø 1.7 mm, Guide Wire length 150 mm

9027.050	Cleaning Stylet Ø 1.05 mm, for Ø 1.1 mm, cannulated instruments
9032.050	Cleaning Stylet Ø 1.25 mm, for Ø 1.3 mm, cannulated instruments
9048.050	Cleaning Stylet Ø 1.85 mm, for Ø 1.8 mm, cannulated instruments

Not Shown:

Sterilizing Tray, without content				Lid for Sterilizing Tray			
CS Ø 2.0 mm	8020.001	CS Ø 3.2 mm	8032.001	CS Ø 2.0 mm	8020.002	CS Ø 3.2 mm	8032.002
CS Ø 2.7 mm	8027.001	CS^{c} Ø 4.8 mm	8048.001	CS Ø 2.7 mm	8027.002	CS^{c} Ø 4.8 mm	8048.002

The illustrations are not to scale.
The latest generation of instruments can additionally have color codes.

A KIND OF ITS OWN

MAGNEZIX® Pin

INTENDED USE

The MAGNEZIX® Pin is a bioabsorbable bone pin that is used to restore the bone continuity of bone fragments that are subjected to low loads and dimensionally stable after fractures, for the treatment of bony avulsion fractures, and for the refixation of bone fragments and osteochondral fragments. Specifically, the MAGNEZIX® Pin is intended to achieve anatomical retention of bone sections that have been joined together by surgical splinting following prior reduction until the bone has healed. The implant is designed for single use.

INDICATIONS

The indications for MAGNEZIX® Pin implants are reconstruction procedures after fractures and malalignment in the human skeleton. The surgeon must determine the degree of injury or changes in the bone and the scope of the required surgical procedure and then select the correct surgical procedure and the correct implant. This is particularly important for the use of bioabsorbable MAGNEZIX® implants. The surgeon always remains responsible for the decision to use these implants.

Depending on the chosen size, the MAGNEZIX® Pin can be used as a bone pin for children, adolescents or adults for the adaptation-capable or exercise-capable fixation of bones, bone fragments or osteochondral fragments for areas that are only subjected to minor loads. The relevant medical literature and corresponding guidelines of the professional associations must be observed when selecting the pin size that is going to be used.

MAGNEZIX® Pin 1.5, 2.0, 2.7, 3.2 for example:

- ➔ Intra-articular and extra-articular fractures of small bones and bone fragments
- ➔ Arthrodeses and osteotomies of small bones and joints
- ➔ Small osseous ligament and tendon ruptures
- ➔ Osteochondral fractures and dissecates
- ➔ Similar Indications

MAGNEZIX® Pin 1.5 among others:

- ➔ Phalangeal and metacarpal bones
- ➔ Osteochondrosis dissecans
- ➔ Similar indications

MAGNEZIX® Pin 2.0 among others:

- ➔ Carpal, metacarpal, tarsal and metatarsal bones
- ➔ Ulnar and radial styloid processes
- ➔ Radial head and capitulum
- ➔ Similar indications

MAGNEZIX® Pin 2.7 and 3.2 among others:

- ➔ Pipkin fractures
- ➔ Metaphyseal fractures of the radius and ulna
- ➔ Hallux valgus corrections
- ➔ Similar indications

CONTRAINDICATIONS

MAGNEZIX® implants are contraindicated (absolute contraindication) in specific clinical situations or they should only be planned after careful consideration (relative contraindication).

Absolute contraindications

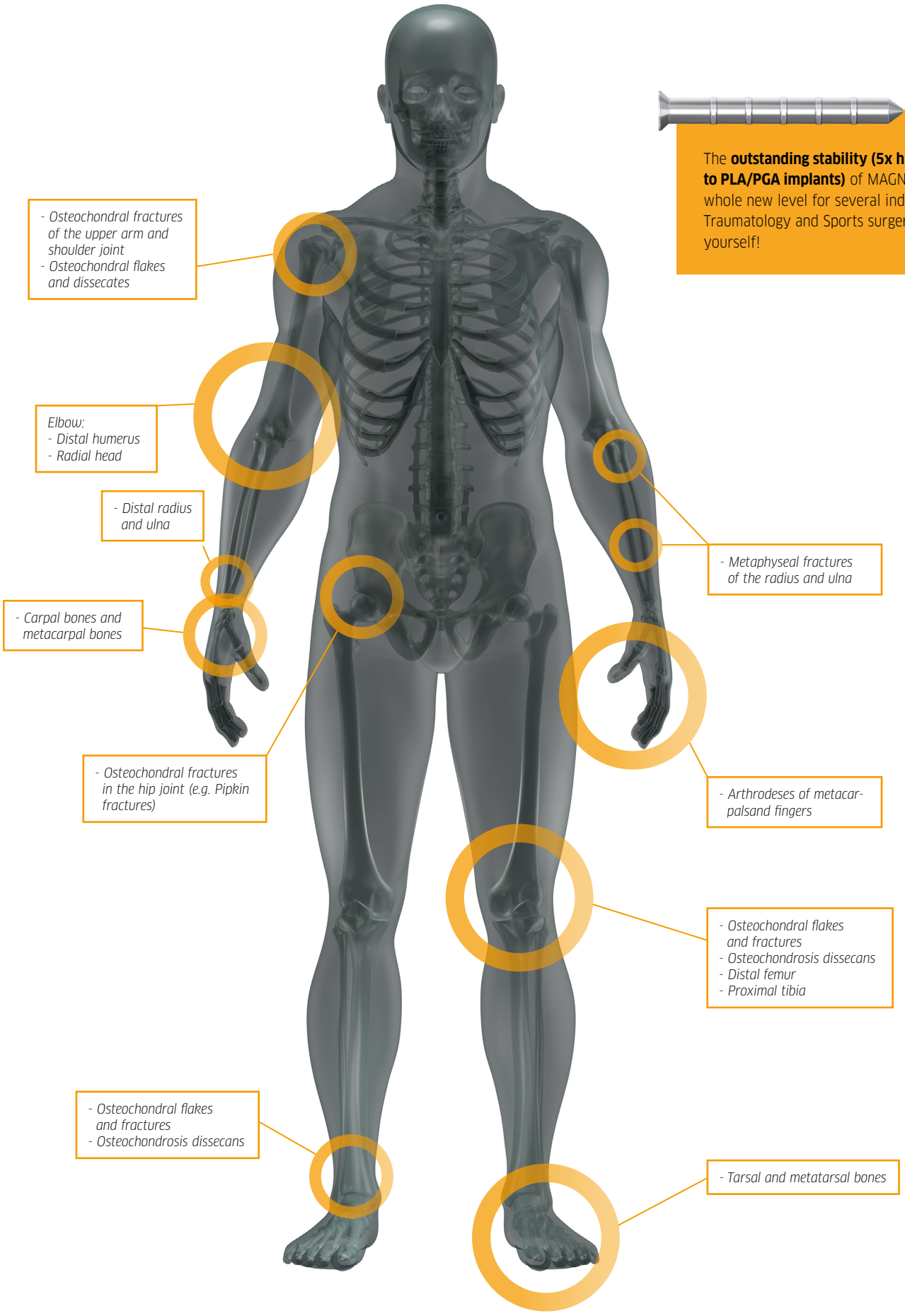
- ➔ Insufficient or avascular bone tissue for anchorage of the implant
- ➔ Confirmation or suspected septic infectious surgical site
- ➔ Application in the area of the epiphyseal plates
- ➔ Functionally stable osteosynthesis
- ➔ Arthrodeses of medium to large joints
- ➔ Applications on the spinal column

Relative contraindications

- ➔ Options for conservative treatment
- ➔ Acute sepsis
- ➔ Osteoporosis
- ➔ Continuous stretching of tendons and ligaments with foreseeable secondary dislocation
- ➔ Alcohol, nicotine and/or drug abuse
- ➔ Epilepsy
- ➔ Poor skin/soft tissue conditions
- ➔ Uncooperative patient or patient with restricted intellectual capacity
- ➔ No options for adequate postoperative treatment (e.g. temporary strain relief)

MAGNEZIX

Application examples



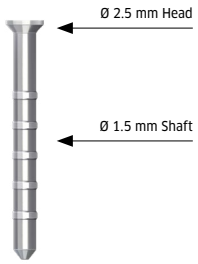
The **outstanding stability (5x higher compared to PLA/PGA implants)** of MAGNEZIX® Pins sets a whole new level for several indications in Traumatology and Sports surgery. Convince yourself!

MAGNEZIX® Pin

PRODUCT OVERVIEW

DIMENSIONS

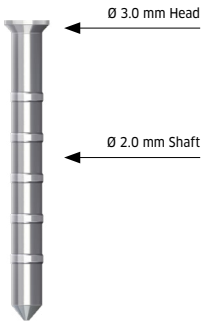
MAGNEZIX® Pin 1.5



Head height is 1.0 mm.

Art. No.	Length [mm]
1115.008	8
1115.010	10
1115.012	12
1115.014	14
1115.016	16
1115.018	18
1115.020	20
1115.022	22
1115.024	24
1115.026	26
1115.028	28
1115.030	30

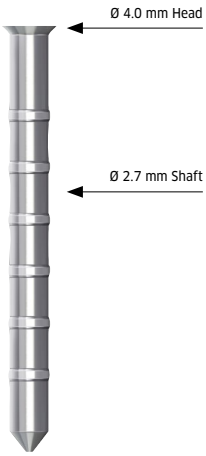
MAGNEZIX® Pin 2.0



Head height is 1.0 mm.

Art. No.	Length [mm]
1120.008	8
1120.010	10
1120.012	12
1120.014	14
1120.016	16
1120.018	18
1120.020	20
1120.022	22
1120.024	24
1120.026	26
1120.028	28
1120.030	30
1120.032	32
1120.034	34
1120.036	36
1120.038	38
1120.040	40

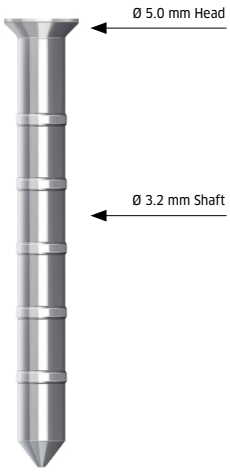
MAGNEZIX® Pin 2.7



Head height is 1.1 mm.

Art. No.	Length [mm]
1127.012	12
1127.014	14
1127.016	16
1127.018	18
1127.020	20
1127.022	22
1127.024	24
1127.026	26
1127.028	28
1127.030	30
1127.032	32
1127.034	34
1127.036	36
1127.038	38
1127.040	40
1127.042	42
1127.044	44
1127.046	46
1127.048	48
1127.050	50

MAGNEZIX® Pin 3.2



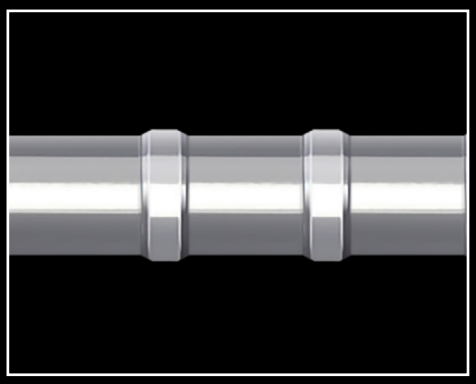
Head height is 1.3 mm.

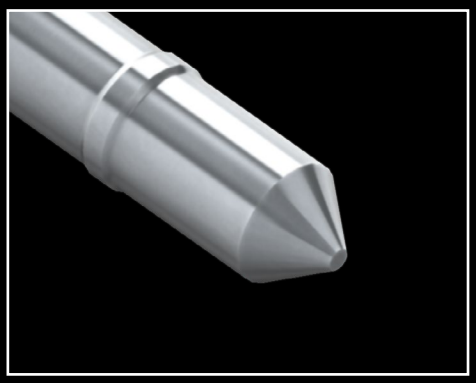
Art. No.	Length [mm]
1132.012	12
1132.014	14
1132.016	16
1132.018	18
1132.020	20
1132.022	22
1132.024	24
1132.026	26
1132.028	28
1132.030	30
1132.032	32
1132.034	34
1132.036	36
1132.038	38
1132.040	40
1132.042	42
1132.044	44
1132.046	46
1132.048	48
1132.050	50

The illustrations are not to scale.

ADVANTAGES AND FEATURES

MAGNEZIX® PIN IMPLANTS





Unique, transformable magnesium alloy

The use of MAGNEZIX® implants makes any subsequent implant removal unnecessary, and moreover, it supports the osseous healing process. MAGNEZIX® is bioabsorbable and biocompatible.

Head design

The flat designed head of the MAGNEZIX® Pin enables stable reduction of the bone fragment. Prominent protrusion of the implant involving possible damage to proximal structures can thus be avoided and the pin head can be completely countersunk.
In addition, a recess in the pin head improves positioning of the impactor and the impactor is prevented from slipping off the pin head during impaction.

Axially stabilising shaft design

The symmetric collars on the pin shank result in compression of the free bone fragment during impaction of the implant. In addition, the collars increase the axial positioning precision of the implant and thus ensure reduction during the healing process.

Design of the pin tip

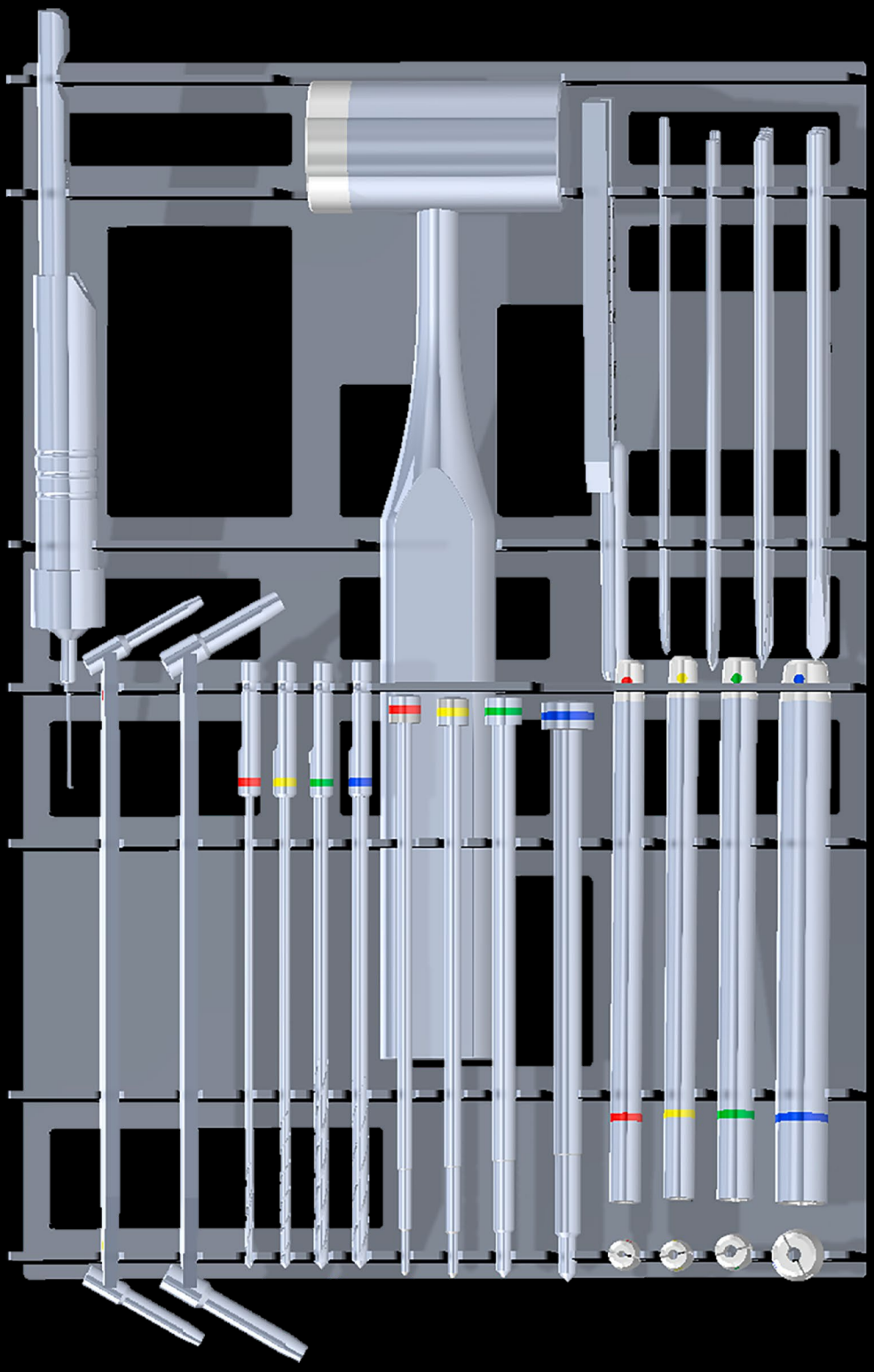
The tip design of the MAGNEZIX® Pin displaces cancellous bone and thus compresses the implant bed. The pin tip without any collars facilitates positioning of the MAGNEZIX® Pin in the pre-drilled implant bed.

WARNINGS

In the case of concurrent use of third party implants it must borne in mind that steel, titanium and cobalt-chromium alloys may not remain in direct contact with a MAGNEZIX® implant at the intervention site (i.e. no physical contact of implants). Since the implants are designed for single use only, reuse of MAGNEZIX® implant devices is grossly negligent and can result in an increased risk of infection and loss in implant stability. In general, re-sterilization alters the implant's functionality in an unpredictable way.

MAGNEZIX® Pin

PRODUCT OVERVIEW INSTRUMENTS



INSTRUMENTS MAGNEZIX® Pin

PRODUCT OVERVIEW

Art. No.	Description
6115.010	Impactor for MAGNEZIX® Pin Ø 1.5 mm, consisting of:
9115.010	Impactor Sleeve for MAGNEZIX® Pin Ø 1.5
9115.011	Impactor Insert for MAGNEZIX® Pin Ø 1.5
9115.012	Impactor Tip for MAGNEZIX® Pin Ø 1.5
6120.010	Impactor for MAGNEZIX® Pin Ø 2.0 mm, consisting of:
9120.010	Impactor Sleeve for MAGNEZIX® Pin Ø 2.0
9120.011	Impactor Insert for MAGNEZIX® Pin Ø 2.0
9120.012	Impactor Tip for MAGNEZIX® Pin Ø 2.0
6127.010	Impactor for MAGNEZIX® Pin Ø 2.7 mm, consisting of:
9127.010	Impactor Sleeve for MAGNEZIX® Pin Ø 2.7
9127.011	Impactor Insert for MAGNEZIX® Pin Ø 2.7
9127.012	Impactor Tip for MAGNEZIX® Pin Ø 2.7
6132.010	Impactor for MAGNEZIX® Pin Ø 3.2 mm, consisting of:
9132.010	Impactor Sleeve for MAGNEZIX® Pin Ø 3.2
9132.011	Impactor Insert for MAGNEZIX® Pin Ø 3.2
9132.012	Impactor Tip for MAGNEZIX® Pin Ø 3.2

9115.020	Drill Bit Ø 1.5 mm, length 115/90 mm, for Quick Coupling
9120.020	Drill Bit Ø 2.0 mm, length 115/90 mm, for Quick Coupling
9127.020	Drill Bit Ø 2.7 mm, length 115/90 mm, for Quick Coupling
9132.020	Drill Bit Ø 3.2 mm, length 115/90 mm, for Quick Coupling

9115.033	Double Drill Guide, for MAGNEZIX® Pin Ø 1.5/2.0 mm
9127.033	Double Drill Guide, for MAGNEZIX® Pin Ø 2.7/3.2 mm

9115.040	Reduction Wire Ø 1.5 mm, spade point tip, length 100 mm
9120.040	Reduction Wire Ø 2.0 mm, spade point tip, length 100 mm
9127.040	Reduction Wire Ø 2.7 mm, spade point tip, length 100 mm
9132.040	Reduction Wire Ø 3.2 mm, spade point tip, length 100 mm

9100.042	Measuring Device, for reduction wires, up to Ø 3.2 mm, for length 100 mm

9100.045	Depth Gauge for MAGNEZIX® Pin

Not shown:

8100.001	Sterilizing Tray for MAGNEZIX® Pin, without contents
8100.002	Lid for Sterilizing Tray, for MAGNEZIX® Pin
9100.000	Hammer 230 g, with plastic insert, optional
9100.001	Plastic Insert, spare part

The illustrations are not to scale.

UNIQUE ADVANTAGES, VERSATILE APPLICATIONS

MAGNEZIX® CBS

INTENDED USE

The MAGNEZIX® CBS is a bioabsorbable bone screw that is used to restore the bone continuity after fractures and osteotomies (osteosynthesis) as well as for treatment of pseudarthroses. Specifically, the MAGNEZIX® CBS is intended to achieve anatomical retention of bone sections that have been joined together by surgical splinting following prior reduction until the bone has healed. The implant is designed for single use only.

INDICATIONS

The indications for MAGNEZIX® CBS implants are reconstruction procedures after fractures and malalignment in the human skeleton. The surgeon must determine the degree of injury or changes in the bone and the scope of the required surgical procedure and then select the correct surgical procedure and the correct implant. This is particularly important for the use of bioabsorbable MAGNEZIX® implants. The surgeon is always responsible for the decision to use these implants.

Depending on the chosen size, the MAGNEZIX® CBS can be used as a bone screw for children, adolescents or adults for the adaptation-capable or exercise-capable fixation of bones and bone fragments.

MAGNEZIX® CBS 2.0, 2.7, 3.5:

- ➔ Intra- and extra-articular fractures of small bones and bone fragments
- ➔ Arthrodeses, osteotomies or pseudarthroses of small bones and joints
- ➔ Small bony ligament and tendon ruptures
- ➔ Osteochondral fractures and dissecates
- ➔ Similar indications

MAGNEZIX® CBS 2.0:

- ➔ Phalangeal and metacarpal bones
- ➔ Osteochondrosis dissecans
- ➔ Similar indications

MAGNEZIX® CBS 2.7 and 3.5:

- ➔ Carpal, metacarpal, tarsal and metatarsal bones
- ➔ Epicondylus humeri
- ➔ Metaphyseal fractures of small and medium-sized bones and bone fragments
- ➔ Similar indications

CONTRAINDICATIONS

MAGNEZIX® implants are contraindicated (absolute contraindication) in specific clinical situations or they should only be planned and used after careful consideration (relative contraindication).

Absolute contraindications

- ➔ Insufficient or avascular bone mass for anchorage of the implant, except osteochondral fractures and dissecates
- ➔ Confirmation or suspected septic infectious surgical site
- ➔ Application in the area of the epiphyseal plates
- ➔ Loadbearing stable osteosynthesis
- ➔ Arthrodeses of medium to large joints
- ➔ Applications on the spinal column
- ➔ Applications in combination with osteosyntheses plates, consisting of foreign material

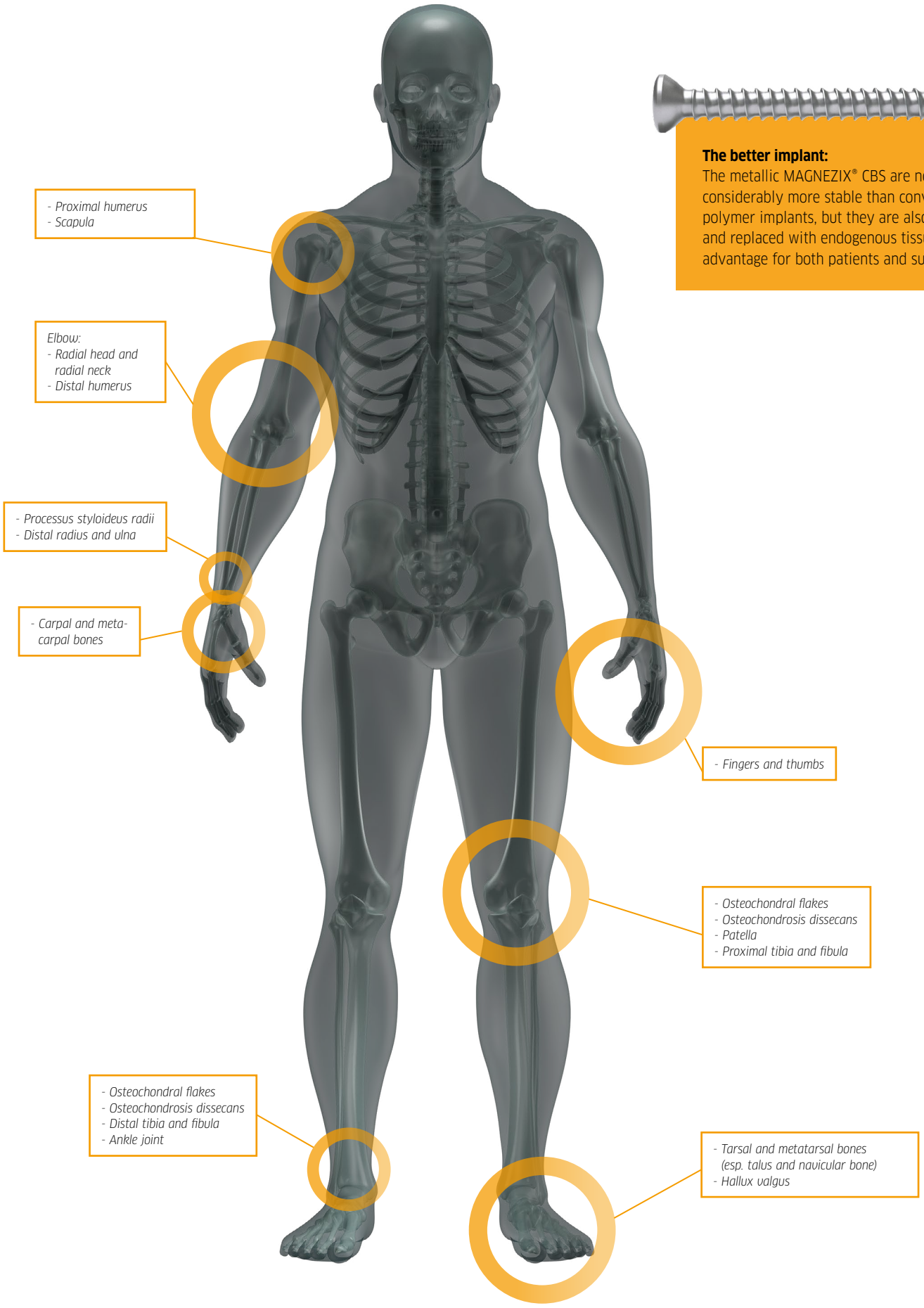
Relative contraindications

- ➔ Options for conservative treatment
- ➔ Acute sepsis
- ➔ Osteoporosis
- ➔ Alcohol, nicotine and/or drug abuse
- ➔ Epilepsy
- ➔ Poor skin/soft tissue conditions

Application examples

MAGNEZIX

The better implant:
The metallic MAGNEZIX® CBS are not only considerably more stable than conventional polymer implants, but they are also transformed and replaced with endogenous tissue – a clear advantage for both patients and surgeons.

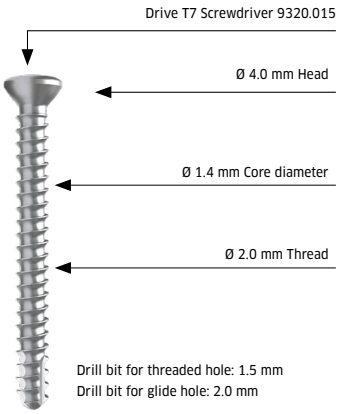


MAGNEZIX® CBS

PRODUCT OVERVIEW

DIMENSIONS

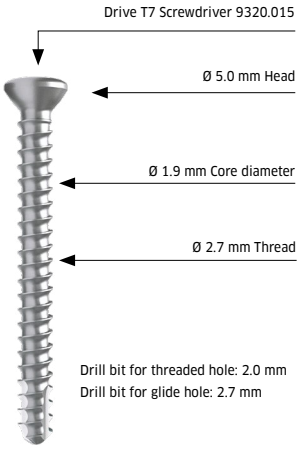
MAGNEZIX® CBS 2.0



Head height is 1.9 mm.

Art. No.	Length [mm]
1320.006	6
1320.008	8
1320.010	10
1320.012	12
1320.014	14
1320.016	16
1320.018	18
1320.020	20

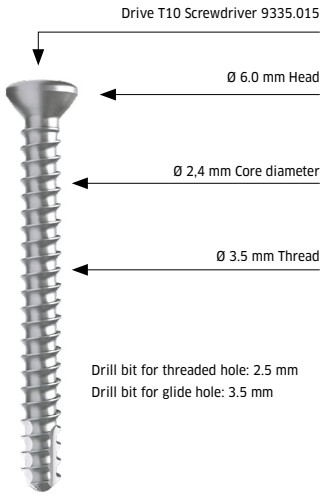
MAGNEZIX® CBS 2.7



Head height is 2.3 mm.

Art. No.	Length [mm]
1327.006	6
1327.008	8
1327.010	10
1327.012	12
1327.014	14
1327.016	16
1327.018	18
1327.020	20
1327.022	22
1327.024	24
1327.026	26
1327.028	28
1327.030	30

MAGNEZIX® CBS 3.5



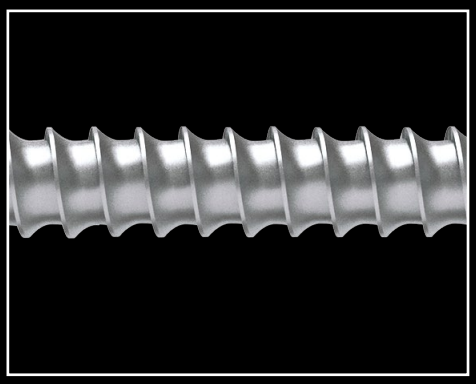
Head height is 2.6 mm.

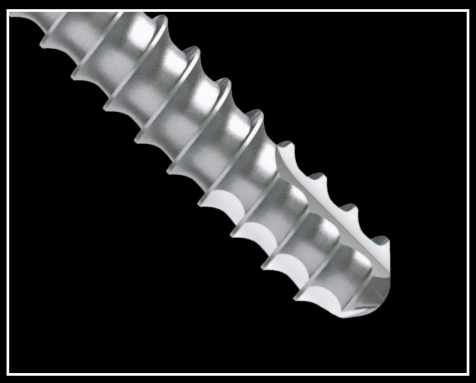
Art. No.	Length [mm]
1335.008	8
1335.010	10
1335.012	12
1335.014	14
1335.016	16
1335.018	18
1335.020	20
1335.022	22
1335.024	24
1335.026	26
1335.028	28
1335.030	30
1335.032	32
1335.034	34
1335.036	36
1335.038	38
1335.040	40

The illustrations are not to scale.

ADVANTAGES AND FEATURES

MAGNEZIX® CBS IMPLANTS





Unique, transformable magnesium alloy

The use of MAGNEZIX® implants makes any subsequent implant removal unnecessary, and moreover, it supports the osseous healing process. MAGNEZIX® is bioabsorbable and biocompatible.

Head design

The head of the MAGNEZIX® CBS, with a typical cortical screw design, allows for stable repositioning of the bone fragment, with good compression characteristics.

Patented safety drive design

The special design of the TORX-based drive protects the implant in the shaft and head area from failure. If the torsional load is too high during the insertion process, a targeted deformation of the screw head drive takes place. As a result, subsequent steps can be continued using a hexagonal screwdriver blade.

Thread design

The thread design, which is typical for cortical screws, produces a strong fixation in cortical bone. A dimension-dependent thread pitch supports the controlled compression of bone fragments.

Screw tip

The additionally existing chip flutes improve the thread quality and ease the screwing-in. However, a precutting of the thread in cortical bone is required.

WARNINGS

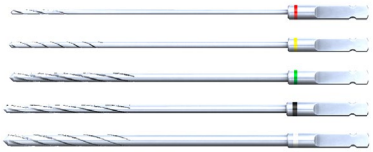
When using other makes of implant at the same time, it is important to note that steel, titanium and cobalt-chromium alloys in the surgical site must not be in direct contact with a MAGNEZIX® implant for an extended period (physical contact between implants). Since the implants are intended for single use only, reuse of MAGNEZIX® implants constitutes gross negligence. It may lead to increased risk of infection and especially loss of implant stability. Re-sterilization will have an unpredictable impact on the product.

MAGNEZIX® CBS

PRODUCT OVERVIEW INSTRUMENTS

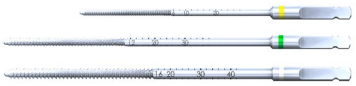
INSTRUMENTS MAGNEZIX® CBS

PRODUCT OVERVIEW



Art. No.	Description
9115.020	Drill Bit Ø 1.5 mm, Length 115/90 mm, for Quick Coupling
9120.020	Drill Bit Ø 2.0 mm, Length 115/90 mm, for Quick Coupling
9127.020	Drill Bit Ø 2.7 mm, Length 115/90 mm, for Quick Coupling
9325.020	Drill Bit Ø 2.5 mm, Length 115/90 mm, for Quick Coupling
9335.020	Drill Bit Ø 3.5 mm, Length 115/90 mm, for Quick Coupling

9320.021	Countersink CBS Ø 2.0, for Quick Coupling
9327.021	Countersink CBS Ø 2.7/3.5, for Quick Coupling



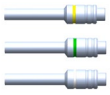
9320.022	Tap CBS Ø 2.0, for Quick Coupling
9327.022	Tap CBS Ø 2.7, for Quick Coupling
9335.022	Tap CBS Ø 3.5, for Quick Coupling

9115.033	Double Drill Guide, Ø 1.5/2.0 mm
9327.033	Double Drill Guide, Ø 2.0/2.7 mm
9335.033	Double Drill Guide, Ø 2.7/3.5 mm

9327.034	Insert Drill Sleeve Ø 2.7/2.0
9335.034	Insert Drill Sleeve Ø 3.5/2.5

9300.045	Depth Gauge for MAGNEZIX® CBS

9320.015	Screwdriver Blade T7, for Quick Coupling
9335.015	Screwdriver Blade T10, for Quick Coupling



9320.016	Holding Sleeve CBS Ø 2.0, for 9320.015
9327.016	Holding Sleeve CBS Ø 2.7, for 9320.015
9335.016	Holding Sleeve CBS Ø 3.5, for 9335.015

9099.004	Small Screwdriver Handle with Quick Coupling

Not shown:

8300.001	Sterilizing tray for MAGNEZIX® CBS, without contents
8300.002	Lid sterilizing tray MAGNEZIX® CBS
8300.003	Insert sterilizing tray MAGNEZIX® CBS

The illustrations are not to scale.

PROGRESS IN FOREFOOT SURGERY

MAGNEZIX® StarFuse®

INTENDED USE

The MAGNEZIX® StarFuse® is a bioabsorbable intramedullary arthrodesis implant that is intended for adaptation-capable or exercise-capable fixation of small bone reconstruction limited to interphalangeal fusion of the lesser toes. The implant is designed for single use.

INDICATIONS

The indications for MAGNEZIX® StarFuse® implants are small bone reconstruction procedures after malalignment in the human skeleton. The surgeon must determine the degree of the deformity and the scope of the required surgical procedure and then select the correct surgical procedure and the appropriate implant. This is particularly important when using bioabsorbable MAGNEZIX® implants. The surgeon is always responsible for the decision to use these implants.

Depending on the chosen size and angulation, the MAGNEZIX® StarFuse® can be used for adaptation-capable or exercise-capable fixation of osteotomies and reconstruction procedures limited to interphalangeal arthrodesis of the lesser toes.

CONTRAINDICATIONS

MAGNEZIX® implants are contraindicated (absolute contraindication) in specific clinical situations or they should only be planned after careful consideration (relative contraindication).

Absolute contraindications:

- PAOD (peripheral arterial occlusive disease)
- Insufficient or avascular bone mass for anchorage of the implant
- Confirmation or suspected septic infectious surgical site
- Load-bearing stable osteosynthesis
- Arthrodeses of medium-sized and large joints

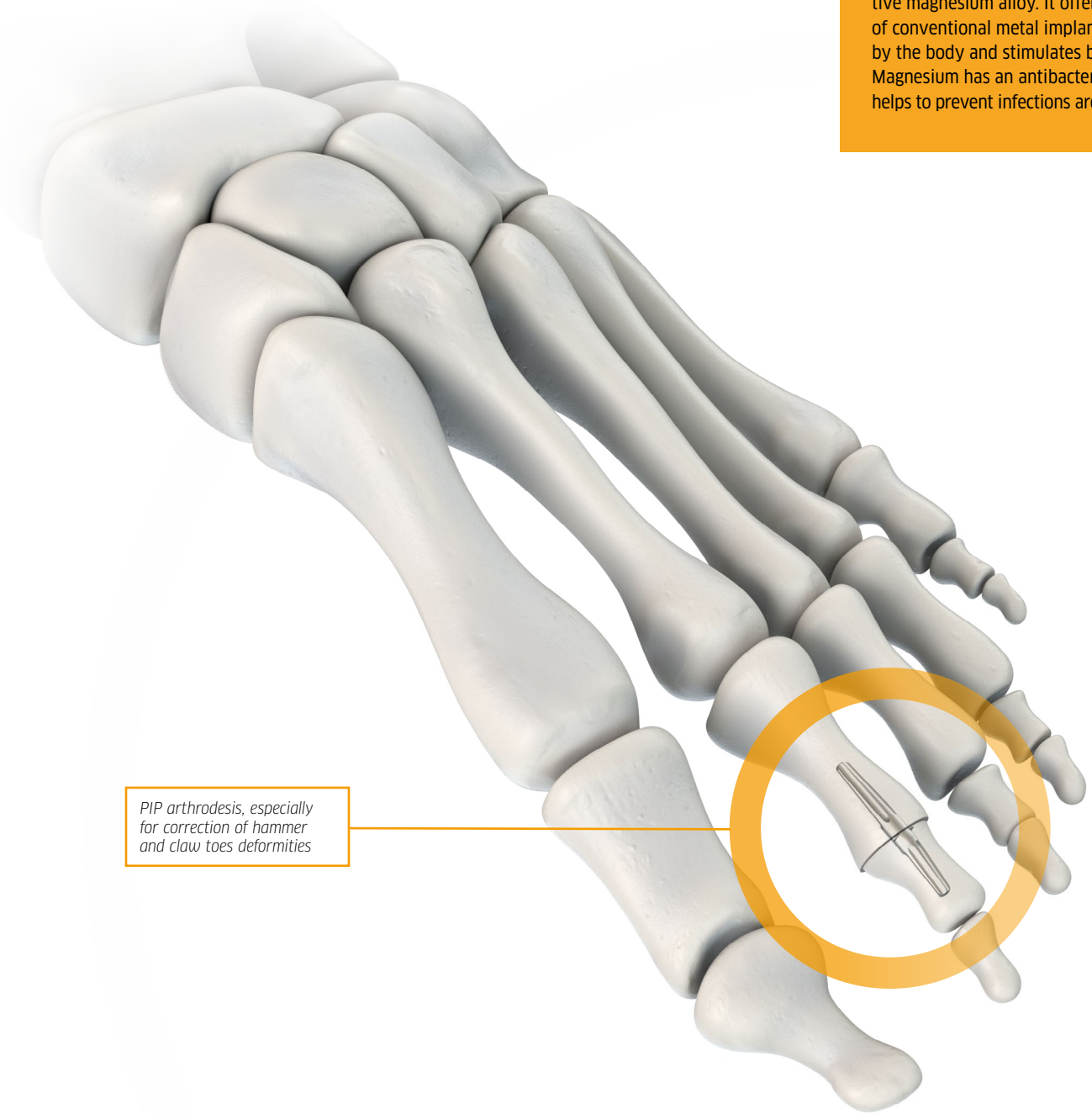
Relative contraindications:

- Options for conservative treatment
- No options for adequate postoperative treatment (e.g. temporary strain relief)
- Application in the area of the epiphyseal plates
- Uncooperative patient or patient with restricted intellectual capacity
- Alcohol, nicotine and/or drug abuse
- Poor skin/soft tissue conditions
- Osteoporosis
- Acute sepsis
- Epilepsy

Application examples

Ideal for forefoot surgery – this metal implant turns into bone!

MAGNEZIX® StarFuse® consists of an innovative magnesium alloy. It offers the stability of conventional metal implants, but is rebuilt by the body and stimulates bone growth. Magnesium has an antibacterial effect and helps to prevent infections around the implant.



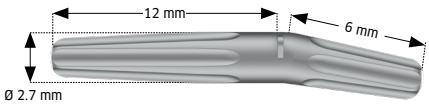
PIP arthrodesis, especially for correction of hammer and claw toes deformities

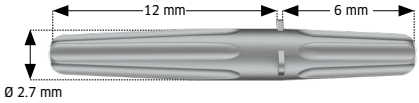
MAGNEZIX® StarFuse®

PRODUCT OVERVIEW

DIMENSIONS

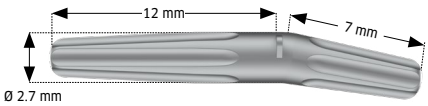
MAGNEZIX® StarFuse® Short

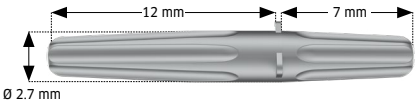




Art. No.	Proximal/Distal length [mm]	Angle
1427.126.00	12/6	0°
1427.126.10	12/6	10°

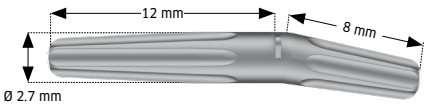
MAGNEZIX® StarFuse® Medium

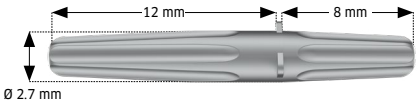




Art. No.	Proximal/Distal length [mm]	Angle
1427.127.00	12/7	0°
1427.127.10	12/7	10°

MAGNEZIX® StarFuse® Large



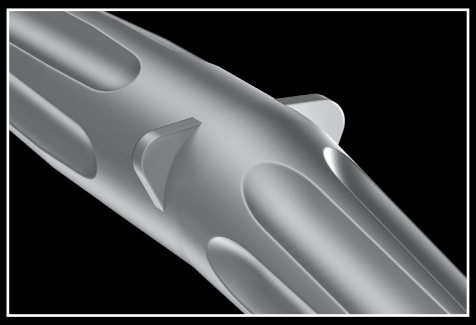


Art. No.	Proximal/Distal length [mm]	Angle
1427.128.00	12/8	0°
1427.128.10	12/8	10°

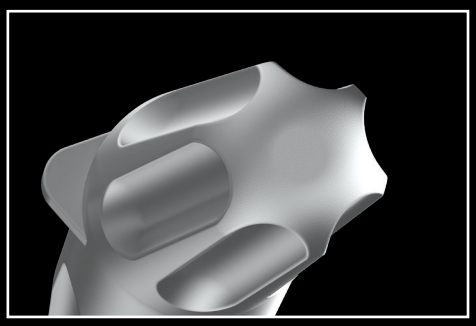
The illustrations are not to scale.

ADVANTAGES AND FEATURES

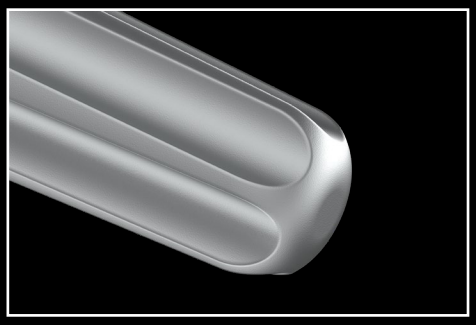
MAGNEZIX® StarFuse® IMPLANTS



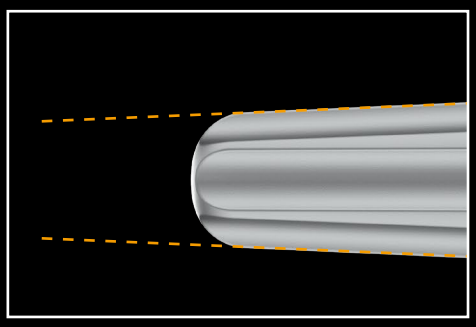
Patented wing design
Two small-sized wings act as a mechanical stop during insertion and following reduction of the more distal phalanx. This innovative design feature ensures stable axial implant positioning.



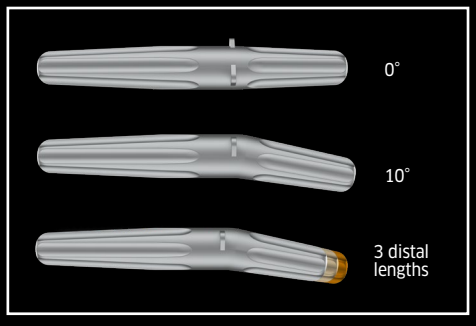
Star-shaped profile
Deep cutting longitudinal flutes guarantee proper rotational stability for optimal fixation.



Blunt ends
The blunt end design ensures secure implant position via reducing the risk of axial implant displacement.



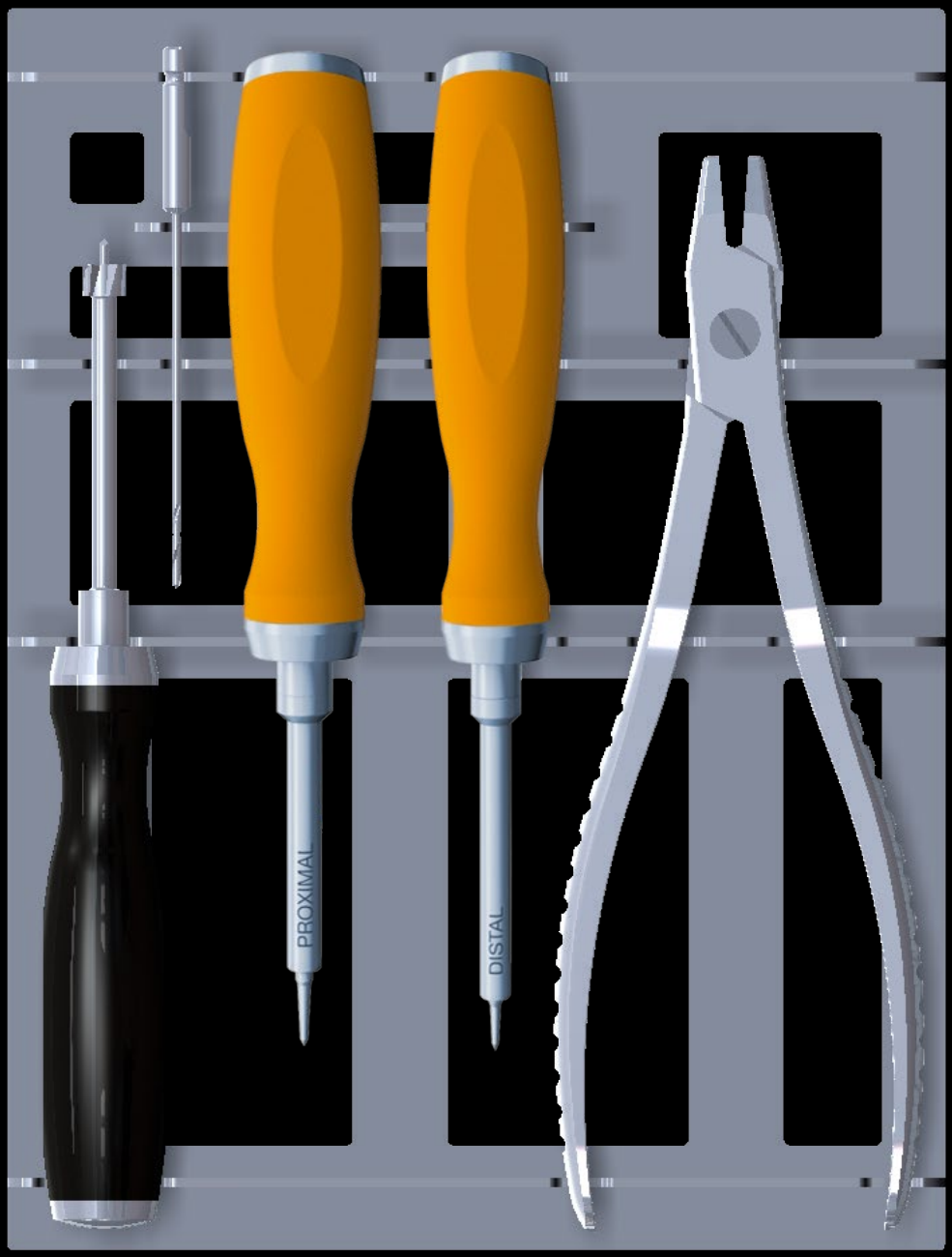
Tapered design
The conical shape of the proximal and distal end allows fast and easy insertion. This design aspect further achieves proper intra-medullar press-fit anchoring.



Multiple sizes
The implants are available in two angles, 0° and 10°, with three different distal lengths each.

MAGNEZIX® StarFuse®

PRODUCT OVERVIEW INSTRUMENTS



INSTRUMENTS
MAGNEZIX® StarFuse®

PRODUCT OVERVIEW

Art. No.	Description
9427.001	StarFuse® Calcar Reamer
9427.020	Drill Bit Ø 1.5 mm, length 85/60 mm, for Quick Coupling
9427.003	Punch, proximal, with depth stop
9427.004	Punch, distal, with depth stop
9427.002	StarFuse® Holding Forceps

Not shown:	8400.001	Sterilization Tray for StarFuse®, without contents
	8400.002	Lid for Sterilization Tray for StarFuse®
	8400.003	Insert for Sterilizing Tray for StarFuse®

The illustrations are not to scale.

ADDITIONAL REFERENCES

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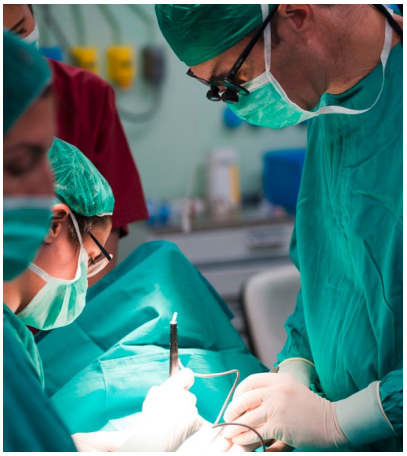

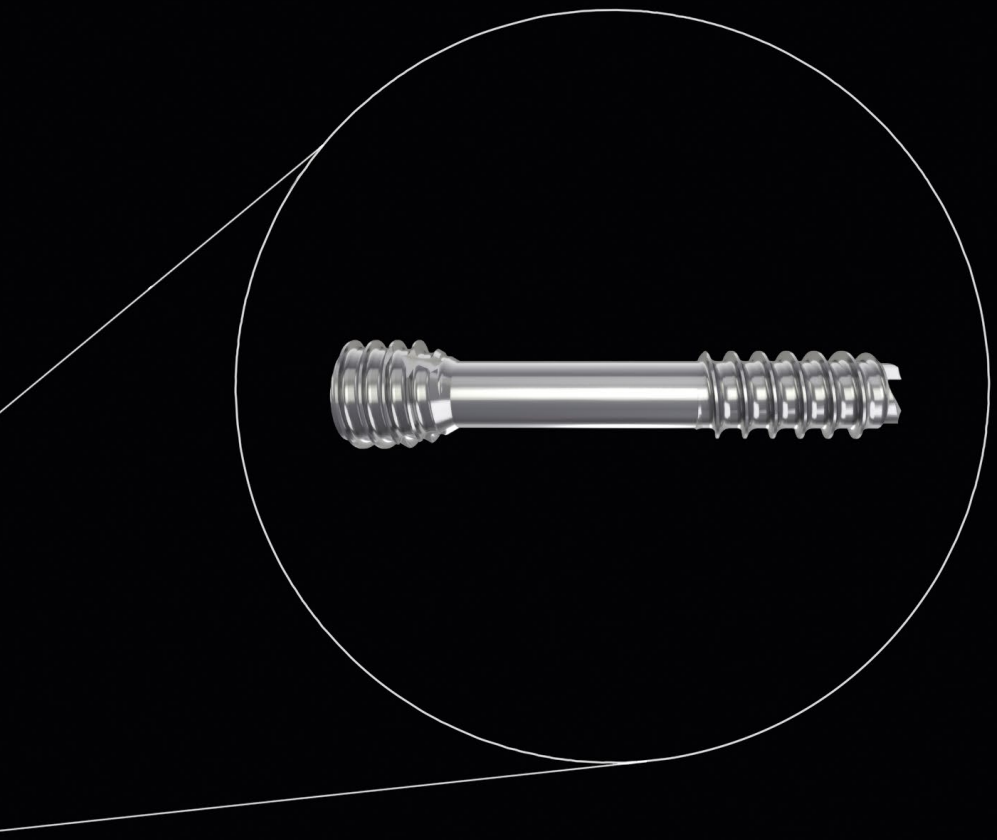

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M 7031.001.004 05/19