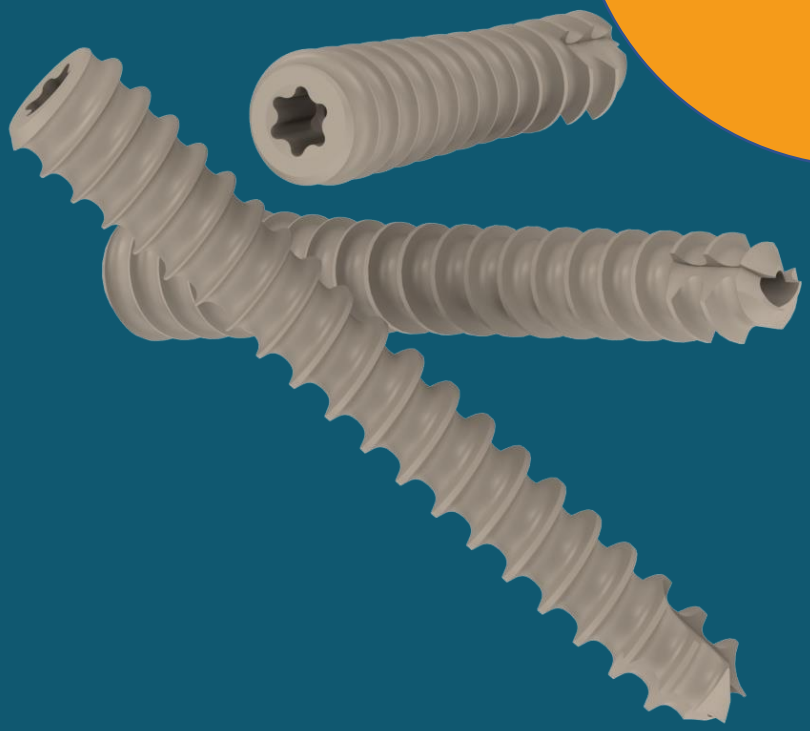
Surgical Technique

EXray®

First Forefoot PEEK Screw



SynchroMedical

The interphalangeal reference

Product description

EXray®

EXray® 20

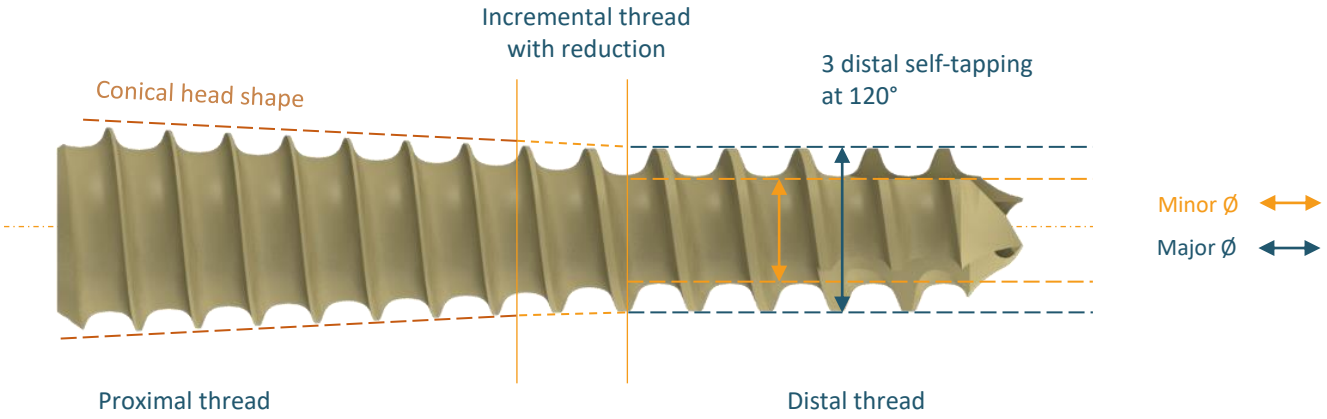
EXray® 20 screws has a threaded portion and a connector portion with a narrower diameter which is connected to a surgical power tool.

EXray® 20 screws are non-compressive 2.5 mm screws with a continuous thread. The screw site is prepared with 2 mm drill.
The length of the screw can be resected after insertion with a clamp or an oscillating saw.

EXray® screws are manufactured in PEEK as per standard ASTM F2026.

EXray® 30 and 35

EXray® 30 and 35 screws are monobloc screws. These 3 mm self-compressive headless screws are available in several different lengths.



Indications and Contraindications

EXray® screws are designed to relieve pain and disability of the forefoot by attaching and stabilizing bone segments in elective osteotomies on metatarsal bones and phalanges of the foot, in order to optimize the correct bone fusion of the segments concerned. These devices are only intended for use for the forefoot of a mature skeleton

Indications:
The EXray® screw system is indicated as an attachment system for small bone fractures or minor bone reconstruction in mature skeleton in the following cases:

- monocortical or bicortical osteotomies of the foot
- metatarsal or distal or proximal metacarpal osteotomies
- fusion of the first metatarsophalangeal and interphalangeal joint
- attachment in the case of treatment of Hallux Valgus (e.g. scarf osteotomy, chevron osteotomy, etc.)
- Akin osteotomy

CAUTION: to be used by or on the order of a surgeon. The surgeon must take note of the documents accompanying the device. No specific training is required for the understanding and use of the device. The surgeon's qualifications and the reading of the accompanying documents are enough.

Contraindications:

A non-exhaustive list of contraindications is as follows:

1. Any sign of generalised or local infection

2. Pathological obesity

3. Pregnancy

4. Any other medical or surgical condition that may compromise the success of surgery with instruments, such as the presence of malignant tumours, or serious congenital anomalies, an increase in sedimentation rates that cannot be attributed to other diseases, an increase in the number of white blood cells or a downward trend in such blood cells

5. Suspected or known allergy or intolerance to the implant's component materials

6. Any situation requiring the use of different materials

7. Any case not listed in the indications

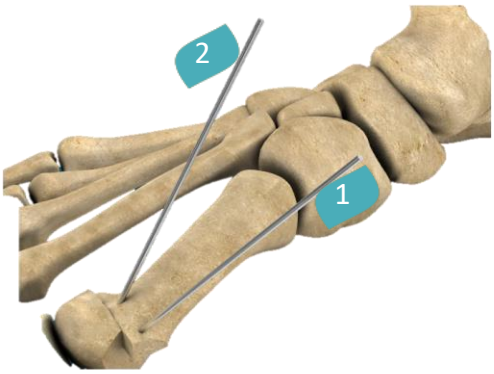
8. Any patient who is not willing to follow the postoperative instructions

9. Any patient in whom use of the implant may interfere with anatomical organs or some expected physiological function

The contraindications related to these devices are similar to those related to other osteosynthesis instruments. These osteosynthesis instruments have not been designed for, intended or sold for any use other than those indicated

→ For more information please refer to EXray® instruction for use reference SUP_ 7.016

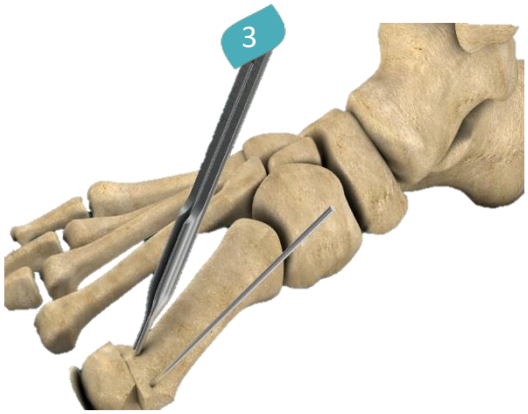
Surgical Technique
EXray® 30/35



PREPARATION

1 Bone osteotomy stabilization with Kirschner wire Ø 1,5 mm.

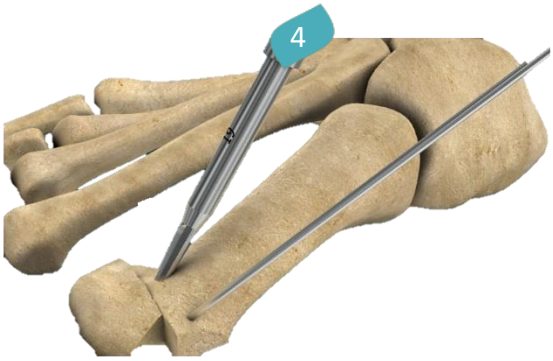
2 Kirschner wire Ø1mm insertion (Ref: KW10100TR) as guide for instruments and implants insertion.



3 Measurement of the screw length on Kirschner wire thanks to gauge length instrument (Ref: HV9005).

Note: for bicortical fixation, perform the length measurement with the depth gauge instrument (Ref: HV9020).

HV9020 – Depth gauge

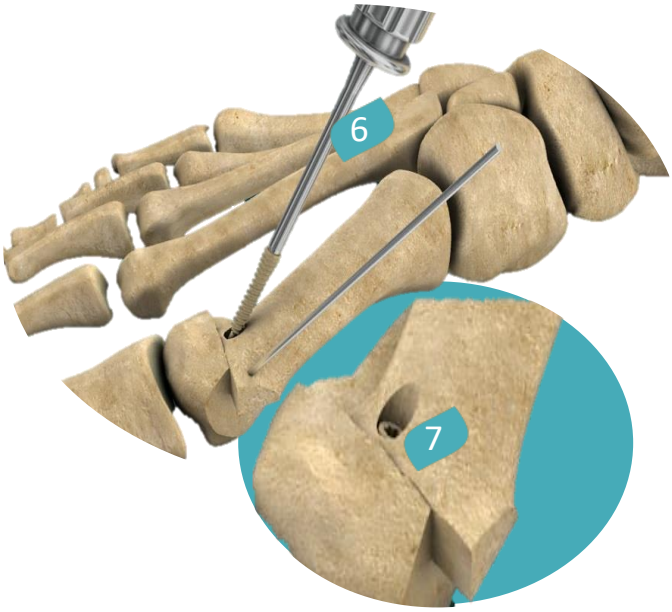


4 Drill the bone over the Kirschner wire with the adapted cannulated step drill (Ref: HV9040-XX) until the shaft shoulder.

Surgical Technique
EXray® 30/35

PREPARATION

5 Perform manually the screw tapping into bone over the Kirschner wire with the adapted cannulated tap instrument (Ref: HV9131-XX).



6 Insert the screw over the Kirschner wire with the screwdriver.

(Ref: HV9140)

7 *EXray® 30 / 35 self compressive screw implanted*

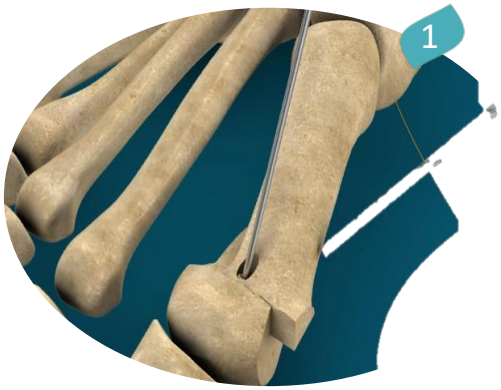
REMOVAL / REVISION

Should removal or revision of the implant be required:

Use the screw extractor (Ref HV9050). Connect the screw extractor to the AO handle (Ref: HV9010). Place the screw extractor over the EXray® 30/35 screw implanted and unscrew properly directly into the peek screw. Target the cannula of the screw with the screw extractor trocard tip. The screw extractor is left threaded instrument. Therefore, keep unscrewing and the EXray® 30/35 will be removed.

Surgical Technique

EXray® 20



1 After osteotomy stabilization, drill the bone with the drill Ø 2mm (Ref: AO20ST100).

2 Insert the EXray® 20 snap-off threaded pin with surgical power tool over the protective barrel (Ref: PW9010) in order to protect soft tissues.

PW9010 – Protective barrel

3 Cut the EXray® 20 snap-off threaded pin with surgical sawblade or surgical clamp flush to the bone surface.

4 *EXray® 20 implanted*

REMOVAL / REVISION

Should removal or revision of the implant be required:

Use the screw extractor (Ref HV9016). Connect the screw extractor to the AO handle (Ref: HV9010). Place the screw extractor over the EXray® 20 snap-off threaded pin implanted and unscrew properly. First the teeth of the screw extractor will rasp the bone. The screw extractor is left threaded instrument. Therefore, keep unscrewing and the EXray® 20 will be removed.

HV9016 – Screw extractor

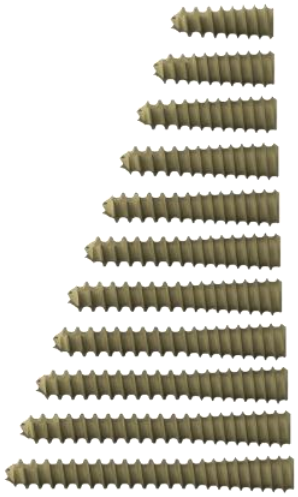
Implants

EXray® 20, 30 and 35

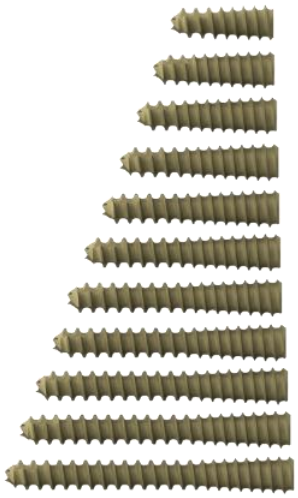
EXray® 20 - IMPLANT REFERENCE - Snap-off threaded pin

REFERENCE		Ø	Length
PW2060		2,5	60
PW20100			100

EXray® 30 - IMPLANT REFERENCE - Self-compressive cannulated screw

REFERENCE		Ø	Length
HVP3011		3	11
HVP3013			13
HVP3015			15
HVP3017			17
HVP3019			19
HVP3021			21
HVP3023			23
HVP3025			25
HVP3027			27
HVP3029			29
HVP3031			31

EXray® 35 - IMPLANT REFERENCE - Self-compressive cannulated screw *(only available on request)*

REFERENCE		Ø	Length
HVP3511		3.5	11
HVP3513			13
HVP3515			15
HVP3517			17
HVP3519			19
HVP3521			21
HVP3523			23
HVP3525			25
HVP3527			27
HVP3529			29
HVP3531			31

Instruments

EXray® 20, 30 and 35

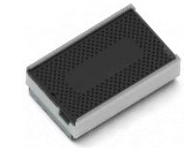
HV9010	AO HANDLE

HV9140	LONG CANNULATED T7 SCREWDRIVER
HV9005	GAUGE LENGTH
HV9011-1	K-WIRE CASE
HV9016	SCREW EXTRACTOR

HV9131-013 HV9131-015 HV9131-017 HV9131-019 HV9131-021 HV9131-023 HV9131-025 HV9131-027 HV9131-029 HV9131-031	CANNULATED TAP

PW9010	PROTECTIVE BARREL
KW10100TR	KIRSCHNER WIRE WITH TROCAR TIP

HV9040-013 HV9040-015 HV9040-017 HV9040-019 HV9040-021 HV9040-023 HV9040-025 HV9040-027 HV9040-029 HV9040-031	CANNULATED STEP DRILL



HV9115	EXray® INSTRUMENT TRAY
HV9020	DEPTH GAUGE
AO20ST100	DRILL

Instruments

EXray® 20, 30 and 35

HV9050 — SCREW EXTRACTOR

HV9132-013
HV9132-015
HV9132-017
HV9132-019
HV9132-021
HV9132-023
HV9132-025
HV9132-027
HV9132-029
HV9132-031

TAP

HV9041-013
HV9041-015
HV9041-017
HV9041-019
HV9041-021
HV9041-023
HV9041-025
HV9041-027
HV9041-029
HV9041-031

STEP DRILL

EXray® instruments kit

Legal and regulatory disclaimers

This material is intended for health care professionals. Distribution to any other recipient is prohibited. For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert. Check for country product clearances and reference product-specific instructions for use (SUP_7.016). This is intended for professionals authorized to perform lower limb surgery. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon.

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.

EXray® is registered trademarks of ADSM.

EXray® products are manufactured using PEEK material as per ASTM F2026.

MEDICAL DEVICES:

- EXray® implants Class IIb
- EXray® instruments Class IIa
- EXray® instruments Class Ir
- EXray® instruments Class I

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