



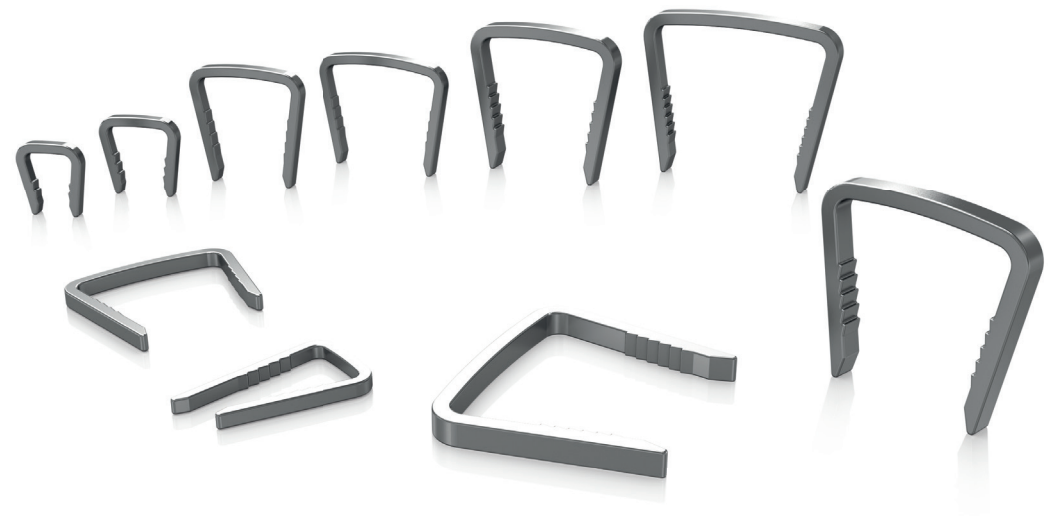
SURGICAL
TECHNIQUE

enovis™

ARCAD[®]

OSTEOSYNTHESIS COMPRESSIVE STAPLES

STAPLE SYSTEMS



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Novastep® S.A.S is a manufacturer of orthopedic implants and does not practice medicine. This surgical technique was prepared in conjunction with licensed health care professionals. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.

See package insert for complete list of potential adverse effects, contraindications, warnings and precautions.

A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.


Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions, if applicable. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient.

Some implants / instruments are not available in all territories. For more information, please contact your local sales representative.

INDICATIONS

Osteosynthesis compressive staples are indicated for the correction of bone deformities (Hallux valgus, Lesser ray deformities, Hammertoe deformity, Coalitions, Rheumatoid foot deformity, Cavovarus foot, Flatfoot), and treatment of foot joint stiffness (Hallux rigidus, Foot arthritis).

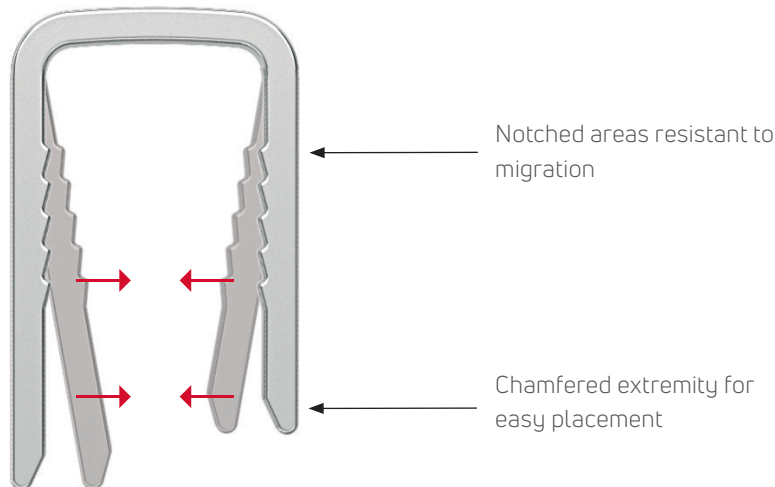
 **NOTE:** Detailed information on each medical device is provided in the instruction for use. Refer to the instruction for use for a complete list of side effects, warnings, precautions for use and directions for use.

CONTRAINDICATIONS

- . Severe muscular, neurological or vascular deficiency in the extremity concerned
- . Bone destruction or poor bone quality, likely to impair implant stability
- . Hypersensitivity to NiTiInol

Made of Nitinol, osteosynthesis compressive staples are indicated for the correction of bone deformities (Hallux valgus, Lesser ray deformities, Hammertoe deformity, Coalitions, Rheumatoid foot deformity, Cavovarus foot, Flatfoot), and treatment of foot joint stiffness (Hallux rigidus, Foot arthritis). Designed to facilitate fast and easy fixation, memory metal staples provide dynamic compression at the osteotomy and arthrodesis site.

KEY FEATURES



Superelastic effect



Nitinol is an alloy made of 50% Nickel and 50% Titanium. Nitinol implants have the ability to return to their original shape immediately after unloading, inducing immediate and dynamic inter-fragmentary compression.

FEATURES

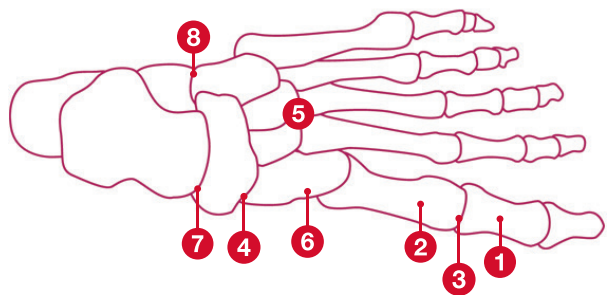
- . Shape Memory Alloy for immediate and dynamic compression.
- . No temperature management.
- . Compressive strength is generated by mechanical stress by means of Arcad® insertion forceps.
- . Low profile / atraumatic contours.

RANGE

- Size range allows for precise fitting and anatomic compatibility.
- Width options : 8 / 10 / 15 / 18 / 20 / 25 mm.
 - Mono-Cortical or Bi-Cortical Anchorage.

Raw Material: Nitinol.

SIZES EXAMPLE BY PROCEDURE*



FOREFOOT :

1. Akin Osteotomy.....	08/10
2. Bunion.....	10
3. MTP Arthrodesis.....	15/18

MIDFOOT :

4. Naviculocuneiform Arthrodesis.....	15/18
5. Lisfranc Arthrodesis.....	15/18
6. Lapidus Arthrodesis.....	15/18

REARFOOT :

7. Talo-Navicular Arthrodesis.....	20/25
8. Calcaneo-Cuboidal Arthrodesis.....	20/25

MTP ARTHRODESIS



AKIN OSTEOTOMY



LISFRANC ARTHRODESIS

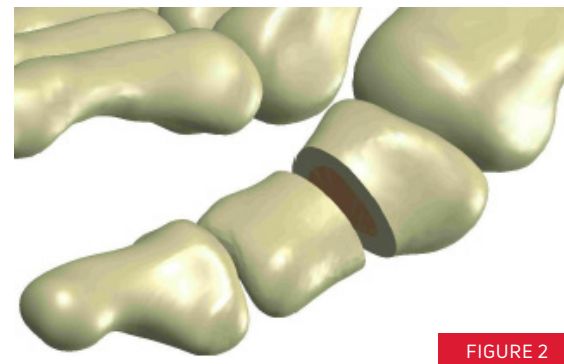
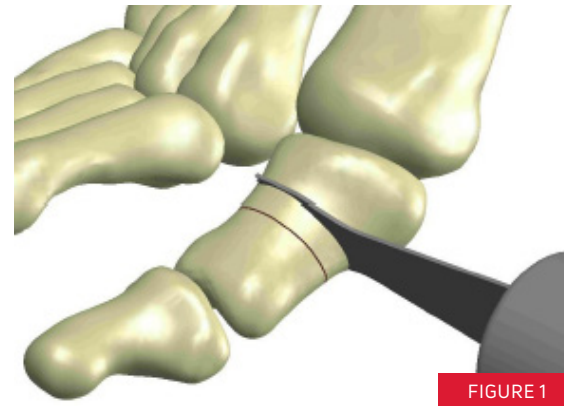


*Size choice example to be adjusted at the surgeon's discretion according to the patient anatomy

P1 SHORTENING OSTEOTOMY

1. JOINT PREPARATION

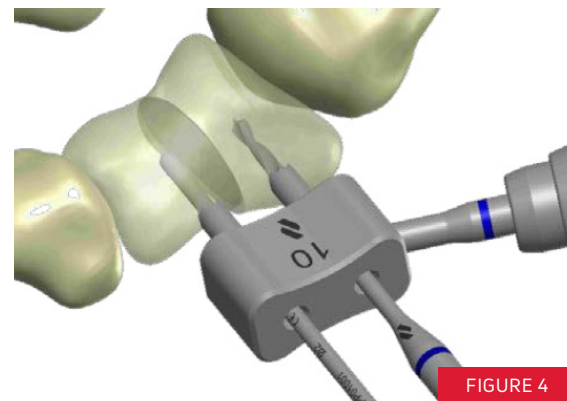
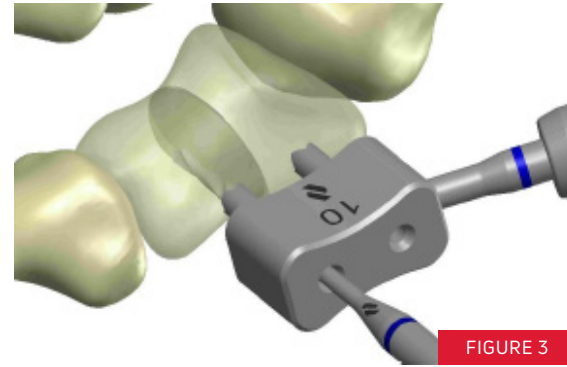
Perform the P1 shortening osteotomy (Akin) using an oscillating saw and shift the distal fragment (**FIGURE 1 & 2**).



2. SITE PREPARATION

Drill the first hole using the drill guide and the drill bit (FIGURE 3).

Insert the positioning pin and drill the second hole (FIGURE 4).



3. STAPLE INSERTION

Position the staple into the forceps and close the arms until locking position (staple legs are then parallel) (FIGURE 5).

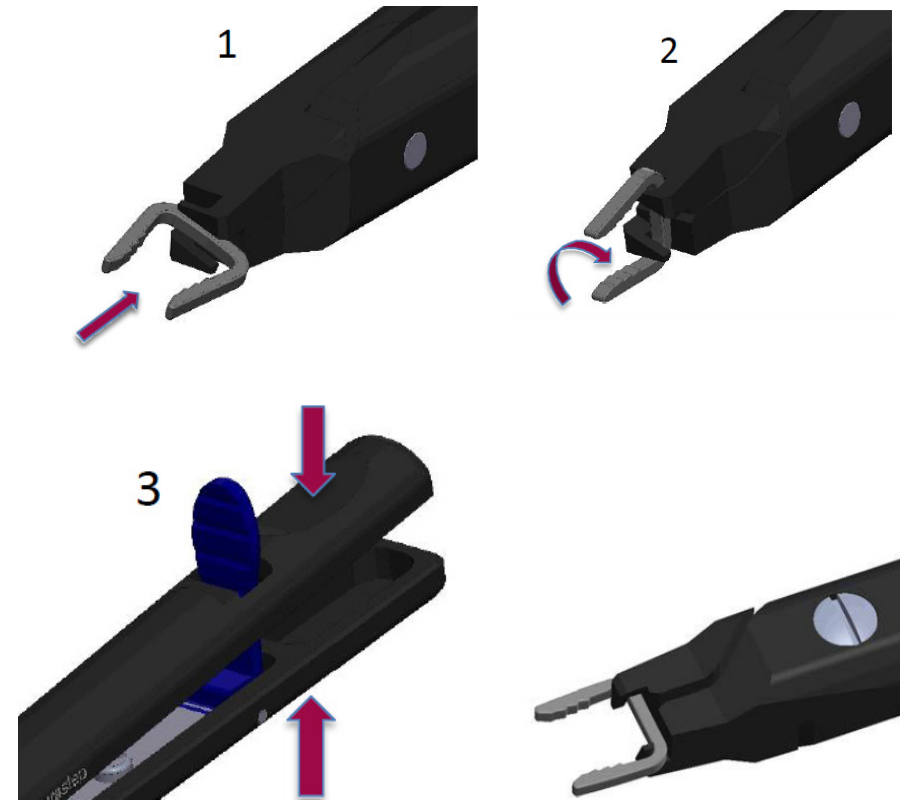


FIGURE 5

Insert the staple and then remove the forceps (**FIGURE 6**).

Finish the staple insertion using the impactor (**FIGURE 7**).

Check the stability of the osteotomy.

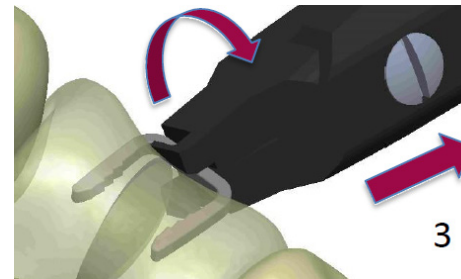
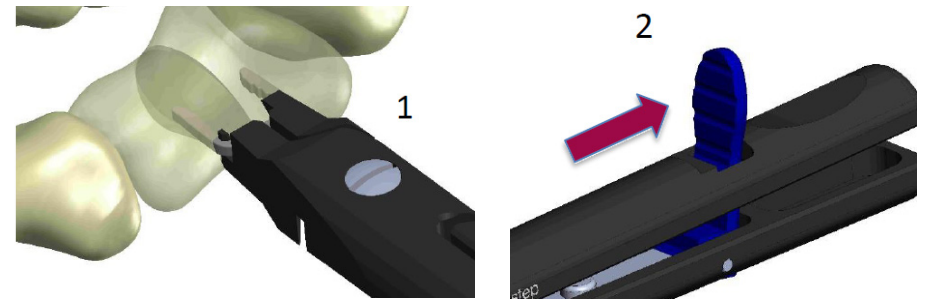


FIGURE 6

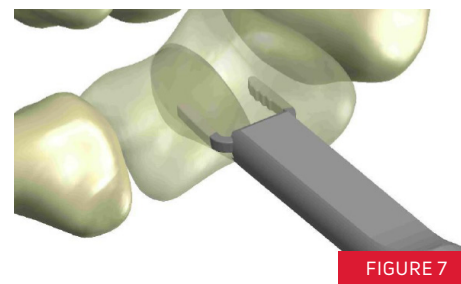


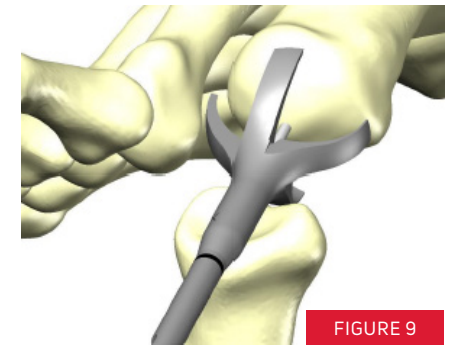
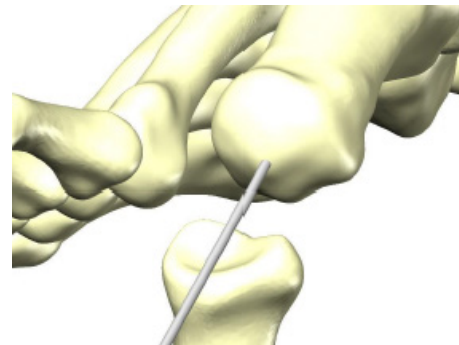
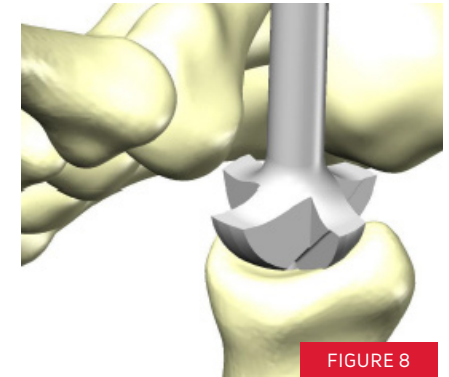
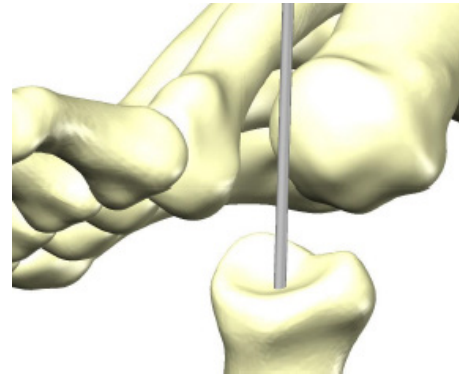
FIGURE 7

METATARSAL ARTHRODESIS

1. JOINT PREPARATION

Prepare the bone site and surface the proximal phalanx using the appropriate size of convex reamer (FIGURE 8).

Repeat this on the metatarsal head with the same size of concave reamer (FIGURE 9).



2. SITE PREPARATION

Stabilize the articulation and drill the first hole using the drill guide and the drill bit (**FIGURE 10**).

Insert the positioning pin and drill the second hole. (**FIGURE 11**).

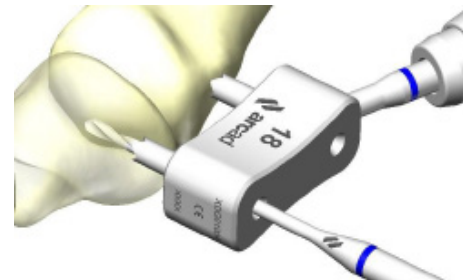


FIGURE 10



FIGURE 11

3. STAPLE INSERTION

Position the staple into the forceps and close the arms until locking position (staple legs are then parallel) (FIGURE 12).

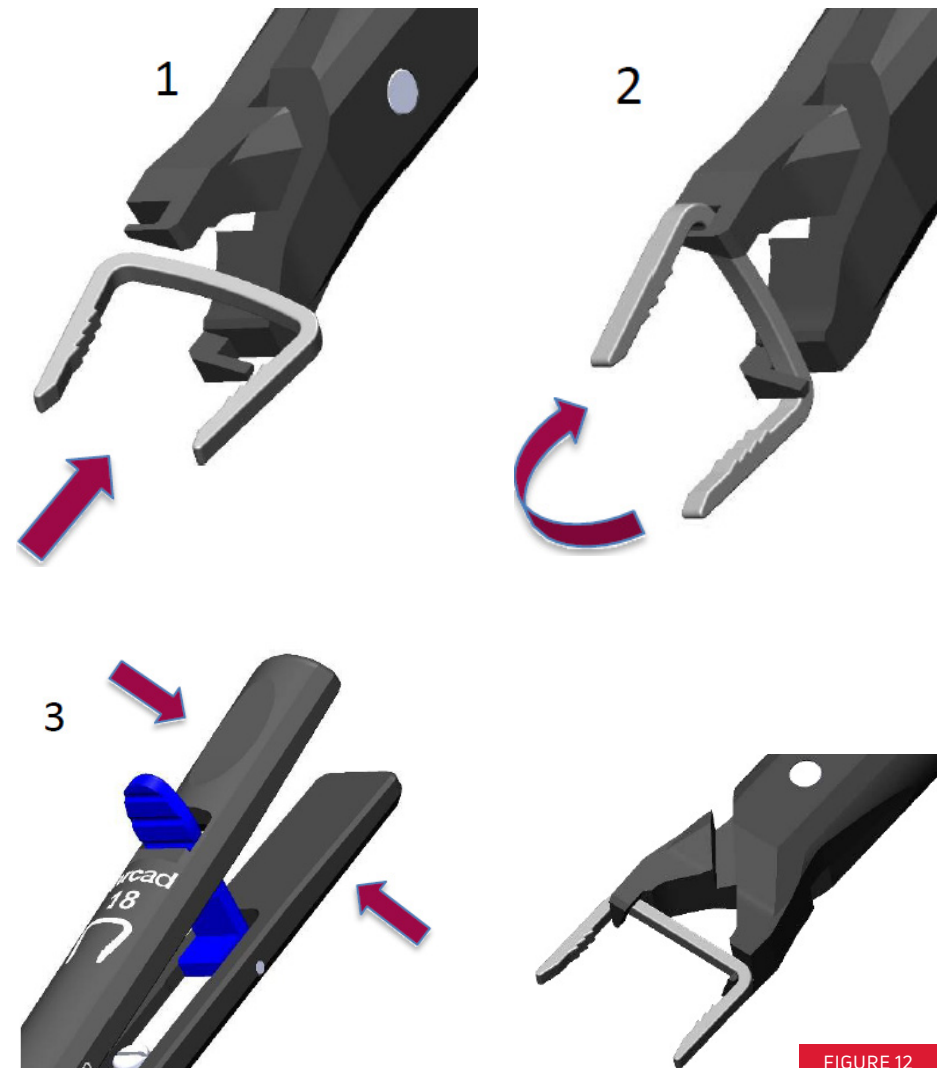
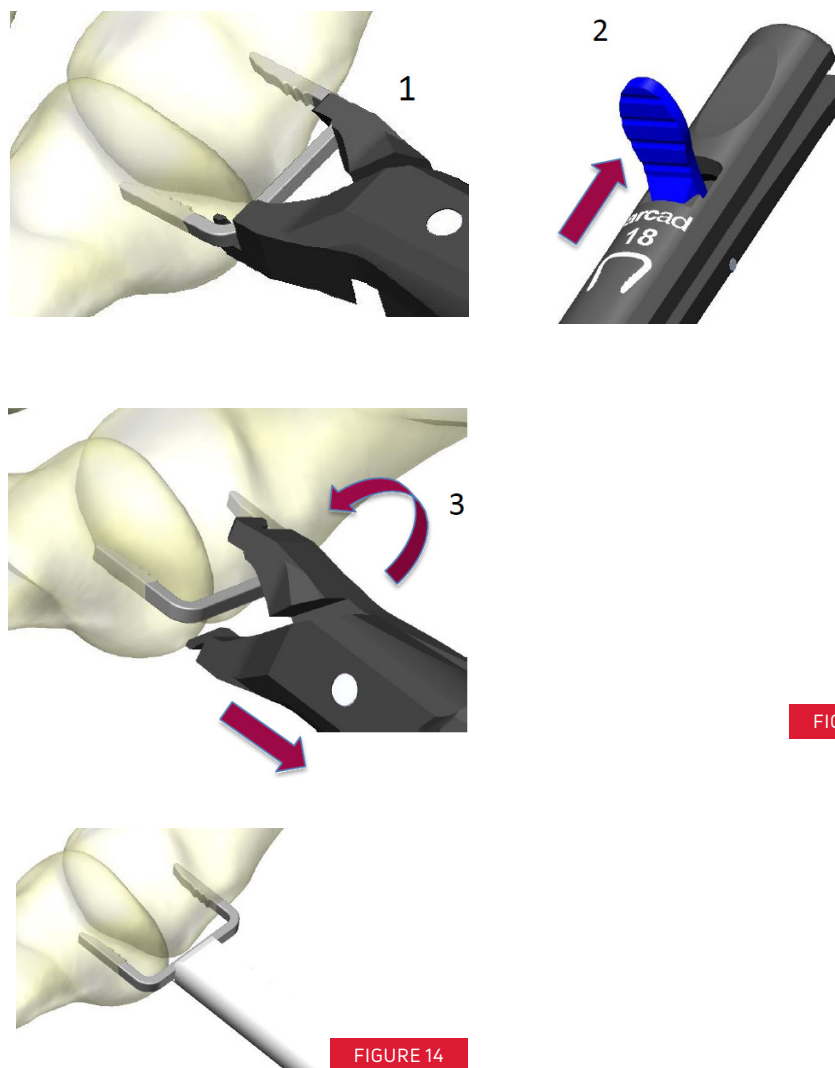


FIGURE 12

Insert the staple and then remove the forceps (**FIGURE 13- 1,2 &3**).

Finish the staple insertion using the impactor (**FIGURE 14**).

Position a second staple in the dorsal plane and check the stability of the arthrodesis.



ARCAD® COMPRESSIVE STAPLES

REFERENCE	DESCRIPTION	BRIDGE WIDTH (mm)	LEG LENGTH (mm)	WIRE DIMENSIONS (mm)
CS020808	COMPRESSIVE STAPLE 08-08-08	8	8-8	1,2 X 1,5
CS010909	COMPRESSIVE STAPLE 10-09-09	10	9-9	1,2 X 1,5
CS011214	COMPRESSIVE STAPLE 10-12-14	10	12-14	1,2 X 1,5
CS011416	COMPRESSIVE STAPLE 10-14-16	10	14-16	1,2 X 1,5
CS011518	COMPRESSIVE STAPLE 10-15-18	10	15-18	1,2 X 1,5
CS031212	COMPRESSIVE STAPLE 15-12-12	15	12-12	1,3 X 1,8
CS031414	COMPRESSIVE STAPLE 15-14-14	15	14-14	1,3 X 1,8
CS041212	COMPRESSIVE STAPLE 18-12-12	18	12-12	1,3 X 1,8
CS041414	COMPRESSIVE STAPLE 18-14-14	18	14-14	1,3 X 1,8
CS041416	COMPRESSIVE STAPLE 18-14-16	18	14-16	1,3 X 1,8
CS041618	COMPRESSIVE STAPLE 18-16-18	18	16-18	1,3 X 1,8
CS041818	COMPRESSIVE STAPLE 18-18-18	18	18-18	1,3 X 1,8
CS051818	COMPRESSIVE STAPLE 20-18-18	20	18-18	2,5 X 1,6
CS062020	COMPRESSIVE STAPLE 25-20-20	25	20-20	2,5 X 1,6

ARCAD® FOREFOOT MODULE

#	DESCRIPTION	PART NO.	QTY
-	MODULE	ACC1001P0003	1
14	ARCAD® 10 - FORCEPS	XFP03001	1
15	ARCAD® 10 - DRILL GUIDE	XDG01001	1
16	DRILL BIT Ø 2	XDB01008	1
17	ANGLED STAPLES FORCEPS	XFP02001	1
18	IMPACTOR	XMS01002	1
19	POSITIONING PIN Ø 2	XPP01001	2
20	STRAIGHT STAPLES - FORCEPS	XFP05001	1

ARCAD® 15-18-20-25

#	DESCRIPTION	PART NO.	QTY
-	MODULE	ACC1005P0007	1
6	DRILL GUIDE - ARCAD® 15	XDG01003	1
6	DRILL GUIDE - ARCAD® 18	XDG01004	1
7	DRILL GUIDE - ARCAD® 20	XDG01005	1
7	DRILL GUIDE - ARCAD® 25	XDG01006	1
8	POSITIONING PIN Ø 2	XPP01001	2
9	POSITIONING PIN Ø 3	XPP01002	2
10	IMPACTOR	XMS01002	1
8	DRILL BIT Ø 2	XDB01008	1
9	DRILL BIT Ø 3	XDB01004	1
11	FORCEPS - ARCAD® 15	XFP03003	1
11	FORCEPS - ARCAD® 18	XFP03004	1
12	FORCEPS - ARCAD® 20	XFP03005	1
12	FORCEPS - ARCAD® 25	XFP03006	1

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Carefully read the enclosed Instructions For Use (IFU) and all packaging label information. Devices: Implants: Class IIb-CE1639 / Instruments: Class I / Class Ir-CE1639 / Class IIa-CE1639.

REFERENCE: ARC-ST-ED4-03-26-EN