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OSSEOINTEGRATION SYSTEM

CE Quality Management System
for Medical Devices
ISO 13485:2016

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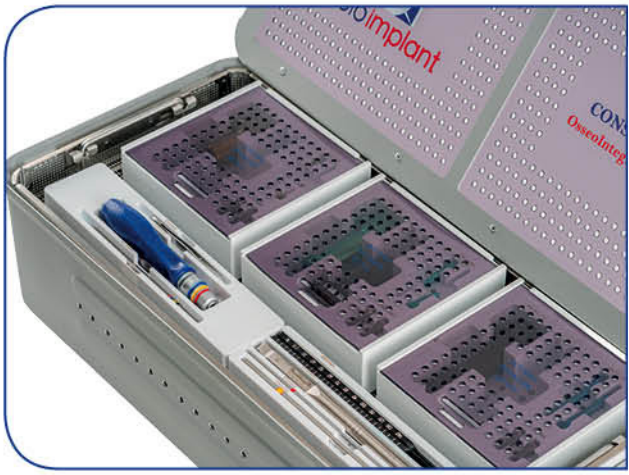
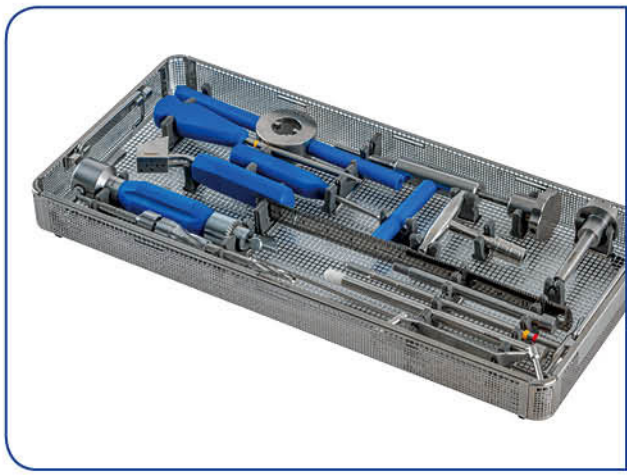
INSTRUMENT SETS

S.N.	Product Code	Product
1	EWOI.6010	CANNULATED T QUICK HANDLE
2	EWOI.6011	QUICK KEY
3	EWOI.6012	CANNULATED MOD. DRILL 8 mm & 12 mm
4	EWOI.6013	BONE AWL FIBRE HANDLE
5	EWOI.6014	STEM AND EXTENSION PUSHER
6	EWOI.6015	STEM AND EXTENSION REMOVER
7	EWOI.6016	STEM EXTENSION ATTACHMENT
8	EWOI.6017	HAMMER
9	EWOI.6018	SCREWDRIVER 3.5 mm
10	EWOI.6019	QUICK HANDLE
11	EWOI.6020	BONE CORRECTION HAND DEVICE
12	EWOI.6021	DIAMETER MEASURING SCALE
13	EWOI.6022	KIRSCHNER WIRE 2 mm
14	EWOI.6023	T HANDLE
15	EWOI.6024	CANNULATED DEPTH MEASURING GAUGE
16	EWOI.6025	DEPTH MEASURING GAUGE
17	EWOI.6037	3.2 mm BONE DRILL
18	EWOI.6038	4.3 MM CANNULATED BONE DRIL
19	EWOI.6039	MATERIALS: TWEEZERS
20	EWOI.6040	EXTERNAL EXTENSION POSITIONER
21	EWOI.6041	ANGLED GUIDE
22	EWOI.7010	REAMER T HANDLE
23	EWOI.7012	BONE REAMER 12 mm
24	EWOI.7013	BONE REAMER 13 mm
25	EWOI.7014	BONE REAMER 14 mm
26	EWOI.7015	BONE REAMER 15 mm
27	EWOI.7016	BONE REAMER 16 mm
28	EWOI.7017	BONE REAMER 17 mm
29	EWOI.7018	BONE REAMER 18 mm
30	EWOI.7019	BONE REAMER 19 mm
31	EWOI.7020	BONE REAMER 20 mm
32	EWOI.6034	IMPLANT PET TRAY
33	EWOI.6035	CONTAINER TRAY
34	EWOI.6036	CONTAINER





CEMENTLESS STEM DOUBLE COATING

PRODUCT CODE	DIAMETER (mm)	LENGTH (mm)	MATERIAL
CEMENTLESS STEM DOUBLE COATING	12	60	Ti/HA
CEMENTLESS STEM DOUBLE COATING	12	130	Ti/HA
CEMENTLESS STEM DOUBLE COATING	12	160	Ti/HA
CEMENTLESS STEM DOUBLE COATING	14	60	Ti/HA
CEMENTLESS STEM DOUBLE COATING	14	130	Ti/HA
CEMENTLESS STEM DOUBLE COATING	14	160	Ti/HA
CEMENTLESS STEM DOUBLE COATING	16	60	Ti/HA
CEMENTLESS STEM DOUBLE COATING	16	130	Ti/HA
CEMENTLESS STEM DOUBLE COATING	16	160	Ti/HA
CEMENTLESS STEM DOUBLE COATING	18	60	Ti/HA
CEMENTLESS STEM DOUBLE COATING	18	130	Ti/HA
CEMENTLESS STEM DOUBLE COATING	18	160	Ti/HA
CEMENTLESS STEM DOUBLE COATING	20	60	Ti/HA
CEMENTLESS STEM DOUBLE COATING	20	130	Ti/HA
CEMENTLESS STEM DOUBLE COATING	20	160	Ti/HA
CEMENTLESS STEM DOUBLE COATING	22	60	Ti/HA
CEMENTLESS STEM DOUBLE COATING	22	130	Ti/HA
CEMENTLESS STEM DOUBLE COATING	22	160	Ti/HA
CEMENTLESS STEM DOUBLE COATING	24	60	Ti/HA
CEMENTLESS STEM DOUBLE COATING	24	130	Ti/HA
CEMENTLESS STEM DOUBLE COATING	24	160	Ti/HA

EXTERNAL EXTENSION

P. CODE	DIAMETER (mm)	LENGTH (mm)	MATERIAL
EW.EEA.FT01	22	60	Ti
EW.EEA.FT02	22	85	Ti
EW.EEA.FT03	22	110	Ti
EW.EEA.FT04	22	60	Ti
EW.EEA.FT05	22	85	Ti
EW.EEA.FT06	22	110	Ti

EXTERNAL EXTENSION LOCKING SCREW

P. CODE	DIAMETER (mm)	LENGTH (mm)	MATERIAL
EW.CS.580	5.8	24	Ti

EXTERNAL EXTENSION END CUPS

P. CODE	DIAMETER (mm)	LENGTH (mm)	MATERIAL
EW.SS.600	0	0	Ti
EW.SS.850	5.7	25	Ti
EW.SS.1100	5.7	50	Ti

6.5 MM CANNULATED SCREWS WITH 16 MM HALF-THREAD

P. CODE	DIAMETER (mm)	LENGTH (mm)	MATERIAL
TRV11778	6.5	75	Ti
TRV11780	6.5	80	Ti
TRV11782	6.5	85	Ti
TRV11784	6.5	90	Ti
TRV11786	6.5	95	Ti
TRV11788	6.5	100	Ti

6.5 MM CANNULATED SCREWS WITH 32 MM HALF-THREAD

P. CODE	DIAMETER (mm)	LENGTH (mm)	MATERIAL
TRV11777	6.5	75	Ti
TRV11781	6.5	80	Ti
TRV11783	6.5	85	Ti
TRV11785	6.5	90	Ti
TRV11787	6.5	95	Ti
TRV11789	6.5	100	Ti

4.5 MM CORTICAL SCREWS

P. CODE	DIAMETER (mm)	LENGTH (mm)	MATERIAL
TRV11349	4.5	34	Ti
TRV11351	4.5	38	Ti
TRV11353	4.5	42	Ti
TRV11355	4.5	46	Ti
TRV11357	4.5	50	Ti

STEP 1

Surgical Preparation and Bone Access

Anatomical Dissection & Intramedullary Entry

✦Surgical Incision ✦Awl ✦Bone Rasp

Procedure: Following the planned surgical incision, anatomical layers are carefully dissected to reach the residual bone (femur or tibia).

Intramedullary Entry: The bone end is perforated using an awl to ensure safe entry into the intramedullary canal.

Surface Preparation: The bone surface is smoothed using a rasp to create a suitable contact surface for implant placement.

⚠ **Caution:** Pay attention to neurovascular structures; fluoroscopic control is recommended.

Intramedullary Canal Expansion (Reaming)

STEP 2

Sequential Reaming & Press-Fit Preparation

✦ Sequential Reamers ✦ Fluoroscopy ✦ Cortical Contact

Gradual Expansion: The canal is gradually widened using reamers of increasing diameter, starting from the smallest size.

Fluoroscopic Guidance: The procedure is performed under real-time fluoroscopy, with continuous monitoring of axial alignment.

Measurement: The reaming length should match the implant stem length; the final reamer diameter determines the implant diameter and ensures press-fit contact.

⚠ **Caution:** Excessive reaming may cause cortical perforation. Proceed slowly and in a controlled manner.

STEP 3

Implant Assembly and Conical Locking

Stem–Connector Integration & Torque Application

SURGICAL APPLICATION TECHNIQUE GUIDE

✦ Conical Connection ✦ 12 Nm Torque ✦Impactor

Implant Selection: The osseointegration implant (stem) of the appropriate size and diameter is connected component via a conical connection system.

Conical Locking: The osseointegration implant (stem) of the appropriate size and diameter is connected

Torque Fixing: The connecting screw is securely fastened by tightening with a calibrated torque wrench to 12 Nm. Correct torque setting is critical for long-term stability.

⚠ The torque value should not be exceeded. Overtightening can cause micro-cracks in the conical interface.

Implant Placement into the Canal
Press-Fit Placement

STEP 4

Axial Alignment & Penetration Depth Control

SURGICAL APPLICATION TECHNIQUE GUIDE

✦ Press-Fit ✦ Fastening Device ✦ Fluoroscopy Control

Placement: The prepared implant is inserted into the canal using a press-fit technique with the aid of a triggering device and a surgical hammer under fluoroscopy guidance.

Fluoroscopic Verification: Imaging confirms the axial alignment and penetration depth of the implant within the medullary canal.

Stability Check: Correct press-fit contact is essential for the initiation of osseointegration and long-term implant stability.

⚠ The implant must be perfectly seated in the axial direction. Varus/valgus angulation should not be allowed.

STEP 5

SistemExternal Prosthetic Attachment and Modular System

Quick-Swappable Adapter Interface & Rehabilitation

✦ Quick-Change ✦ Modüler Tasarım ✦ Adaptör Sistemi

Interface: The Quick-Change adapter system provides an interface between the implant's connecting element and the external prosthesis component.

Modular Advantage: This system allows for easy attachment and removal of the external prosthesis from the surgical implant.

Rehabilitation: Modular design allows for quick adjustments and replacement of components as needed during the rehabilitation process.

⚠ Prior to initial activation, the adapter locking mechanism must be verified with a torque gauge.

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SURGICAL TECHNIQUE GUIDE

For more information and technical support, please contact your manufacturer's representative.

5 SURGICAL STEPS

STEP 1

Surgical Preparation and Bone Access

Anatomical Dissection & Intramedullary Entry

STEP 2

Intramedullary Canal Expansion (Reaming)

Sequential Reaming & Press-Fit Preparation

STEP 3

Implant Assembly and Conical Locking

Stem–Connector Integration & Torque Application

STEP 4

Implant Placement into the Canal Press-Fit Placement

Axial Alignment & Penetration Depth Control

STEP 5

SistemExternal Prosthetic Attachment and Modular System

Quick-Swappable Adapter Interface & Rehabilitation

This document is intended for educational and surgical reference purposes only. The clinical decision always rests with the surgeon.

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