

XO Osseo in XO 4 Unit User Guide



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Introduction

Introduction

Your new XO Osseo is a build-in micro motor unit intended for bone surgery in general and for dental implantology in particular.

In your own interest we kindly ask and recommend that you take the time to carefully study this manual in order to familiarize yourself with XO Osseo and its operation.

By doing so you will be able to take full advantage of the qualities of XO Osseo and to operate without problems in actual practice.

We are confident that you will find that XO Osseo will be a major adjunct to your daily practice. We thank you for choosing XO Osseo.

XO CARE A/S

1 XO 4 documentation

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This document describes how XO Osseo in XO 4 Unit functions in general.

More details can be found in:

- XO 4-2 / XO 4-6 Quick Guide
- XO 4-2 / XO 4-6 Configuration Guide
- XO Smart Link Quick Guide

2 XO Osseo features

2 XO Osseo features

XO Osseo is a build-in micro motor unit intended for bone surgery in general and for dental implantology in particular.

XO Osseo is delivered with a low speed/high torque brushless micro motor.

The micro motor is maintenance free, and runs from 300RPM to 40.000RPM.

XO Osseo is intended for use together with XO Peristaltic Pump, which supplies irrigation.

3 Preparation and set-up

3 Preparation and set-up

3.1 General preparation

Connect the peristaltic pump to XO 4 Unit, as explained in the User Guide for XO Peristaltic Pump.

XO Peristaltic Pump is automatically detected by XO 4 unit and controlled by XO Osseo motor.

The parameters speed (RPM) and irrigation flow rate can be configured in 3 different levels.

Please refer to **XO 4 Configuration Guide** for details.



The handmotor and contra-angle will operate at maximum torque (value depending on the used contra-angle).

If you need to control the maximum torque we recommend our software solution XO Smart Link.

3.2 Set-up for general bone surgery

The following instructions will prepare the XO Osseo for bone surgery.



Appropriate sterile handling procedures must be observed to ensure and maintain sterile conditions.

3.2.1 Handmotor and Cord

- a. Remove the sterilized handmotor and cord from the autoclave bag or wrapping just prior to surgery. Regarding sterilization – see chapter 5, Cleaning and sterilization.
- b. Connect the hand motor cord to the matching connector at the rear of the instrument bridge. The suspension shall be configured as OSSEO in the unit menu, and peristaltic pump shall be selected to operate with this suspension.
- c. Place the handmotor on the sterile field.

3.2.2 Contra-angle handpiece

- a. Remove the sterilized handpiece from the autoclave bag just prior to surgery. Regarding sterilization, see chapter **Error! Reference source not found.5**, Cleaning and sterilization.
- b. Slide the handpiece or contra-angle firmly in place on the handmotor shaft and place the handmotor with handpiece on the sterile field.

3.2.3 XO Peristaltic pump

Connect the irrigation tubing according to the instructions in the User Guide for XO Peristaltic Pump.



The tubing's are for one time use only. Do not re-sterilize.

NOTE:

If your XO 4 Unit is running with XO Smart Link, please refer to XO Smart Link Quick Guide for further details.

Your XO Osseo is now ready for general bone surgery.

3.3 Implant surgery

Implant surgery demands our software solution XO Smart Link. With XO Smart Link you can set-up instrument programs and configure all relevant parameters.

4 Operation controls

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All functions are controlled from XO Foot control. Please refer to XO 4 Quick Guide, section **XO Osseo** for details.

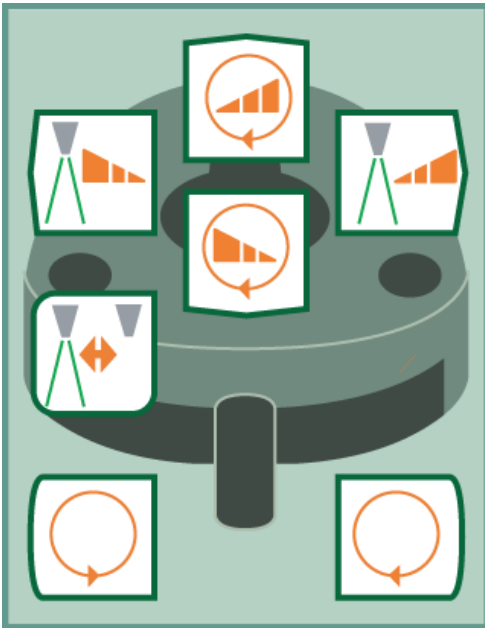


Figure 1 XO Foot control

5 Cleaning and sterilization

5 Cleaning and sterilization

5.1 Irrigation tubing

The irrigation tubing kit is for one time use only. Discard after use. Cannot be re-sterilized.

5.2 Handpiece/contra-angle

Handpieces and contra-angles must be cleaned, maintained and sterilized strictly in accordance with the handpiece manufacturer's specifications and recommendations. Failure to do so may result in reduced torque performance and shortened lifetime of the handpiece.

5.3 Handmotor with cord

The handmotor is supplied with a sealing plug which has an O-ring at the end.

Prior to autoclaving, push the end of the sealing plug into the open center of the handmotor shaft.



Failure to autoclave the handmotor with the sealing plug in place may cause damages to the handmotor.

The recommended infection control procedure is to autoclave the handmotor with cord between patients.

The handmotor with cord can be sterilized by steam autoclaving (maximum temperature 135°C/275°F and with a holdtime of at least 4 min.).



Higher autoclave temperatures (flash autoclaving) and other sterilization methods may damage the equipment beyond repair.

Instrument suspensions can be washed in a thermo disinfectant (90°C).



Double wrapping is recommended.



Do not leave the handmotor and cord overnight in the autoclave.



Do not lubricate through the open front end of the handmotor.



Do not wash handmotor & cord in a thermo disinfectant!

6 Accessories

6 Accessories

Delivered with XO Osseo:

Ref. No.: Part:

AO-187 Handmotor with cord, complete

160095 Handmotor sealing plug

Extras:

XO-055 Pre-sterilized, disposable surgical tubing kit,
50 pcs.

IT-100 XO Smart Link

7 Maintenance and safety

7 Maintenance and safety

Please observe the following instructions at all times:

1. XO Osseo must be operated in accordance with this Manual.
2. XO Osseo and its accessories must not be taken into use, if signs of operational, electrical or mechanical defects are found.
3. XO Osseo is engineered to meet the general safety requirements of IEC 60601-1 (IEC 60601-1-2) and particular requirements of
4. Technical changes including repairs, adjustments/calibrations and modifications may only be made by XO CARE A/S or specialists approved by XO CARE A/S.
5. Do not attempt to disassemble the handmotor and cord.
6. XO Osseo should be checked in connection with general unit check-up at least every two years.

8 Important Notes and Warnings

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The Medical Device Vigilance System imposes on manufacturers the duty to promptly report to Competent Authorities in case a medical device made by the manufacturer has caused an incident that led to a serious deterioration of the state of health of a patient or user.

In the improbable event that your XO Osseo should be involved in such an incident, it is therefore very important that you:

1. Promptly inform XO CARE A/S,
2. Immediately stop using the Osseo unit, and
3. Immediately store the Osseo unit separately and exactly in the condition it was in, i.e. without any kind of cleaning or disassembling.

9 Technical specifications

9 Technical specifications

Product name:

XO Osseo

Classification:

Class 1, type B (IEC 601-1)

Class IIa (M.D.D. 93/42/EEC)

Max. output power:

125 W

Max. torque, handmotor (without contra-angle):

5,6 Ncm

Manufacturer:

XO CARE A/S

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