

Astra Tech Implant System® Surgical manual OsseoSpeed® TX



## Astra Tech Implant System®

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Clinical and laboratory procedures for cement-retained restorations utilizing Astra Tech Implant System<sup>®</sup>.

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This manual is designed for use by clinicians who have undergone appropriate education and training in surgical and prosthetic implant treatment. Staying current on the latest trends and treatment techniques in implant dentistry through continued education is the responsibility of the clinician.

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## Drilling sequence overview OsseoSpeed® TX

Implants	Drilling protocol - soft bone	Drilling protocol – standard	Drilling protocol – dense bone
OsseoSpeed* TX 3.0 S	Guide Twist Drill Drill 2.0 Z	Guide Twist Twist Drill Drill Drill 2.0 2.7	Guide Twist Twist Cortical Twist Drill Drill Drill Drill Drill 2.0 2.7 2.7/3.0 2.85
OsseoSpeed* TX 3.5 S	Guide Twist Twist Drill Drill Drill Drill 2.0 2.7	Guide Twist Twist Drill Drill Drill 2.0 3.2	Guide Twist Twist Cortical Twist Drill Drill Drill Drill Drill 2.0 3.2 3.2/3.5 3.35
OsseoSpeed* TX 4.0 S	Guide Twist Twist Drill Drill Drill Drill 3.7	Guide Twist Twist Twist Drill Drill Drill Drill Drill 2.0 3.2 3.7	Guide Twist Twist Twist Cortical Twist Drill Drill Drill Drill Drill Drill Drill 2.0 3.2 3.7 3.7/4.0 3.85
OsseoSpeed* TX 4.5	Guide Twist Twist Conical Drill Drill Drill Drill 2.0 2.7 2.7/4.5	Guide Twist Twist Conical Drill Drill Drill Drill 2.0 3.2 3.2/4.5	Guide Twist Twist Conical Twist Drill Drill Drill Drill Drill 2.0 3.2 3.2/4.5 3.35
OsseoSpeed* TX 5.0	Guide Twist Twist Conical Drill Drill Drill Drill 2.0 3.2 3.2/5.0	Guide Twist Twist Twist Conical Drill Drill Drill Drill Drill 2.0 3.2 3.7 3.7/5.0	Guide Twist Twist Twist Conical Twist Drill Drill Drill Drill Drill Drill Drill 2.0 3.2 3.7 3.7/5.0 3.85
OsseoSpeed* TX 5.0 S	Guide Twist Twist Twist Twist Drill Drill Drill Drill Drill Drill Drill Drill	Guide Twist Twist Twist Twist Drill Drill Drill Drill Drill Drill Drill A.7	Guide Twist Twist Twist Twist Twist Cortical Twist Drill Drill Dri

# OsseoSpeed® TX 3.0 S





OsseoSpeed® TX

3.0 S

13 mm

Guide

Drill

Twist

Drill

2.0

Twist

Drill

2.7

Cortical

Drill

2.7/3.0

Twist

Drill

2.85

OsseoSpeed\*TX

3.0 S

13 mm

Guide

Drill

Twist

Drill

2.0

Twist

Drill

2.7

DRILLING SEQUENCES OsseoSpeed® TX 3.5 S

# • OsseoSpeed® TX 3.5 S

#### **Drilling protocol - STANDARD**



#### **Drilling protocol - SOFT BONE**

#### **Optional drill**









#### Drilling protocol - SOFT BONE

## **Optional drills**







## OsseoSpeed® TX 4.0 S - 6 mm

#### **Drilling protocol - STANDARD**



#### **Drilling protocol - SOFT BONE**



**Optional drill** 

Pilot Drill is available as an optional step within the drilling sequence. Ø 2.0/3.2 mm



# OsseoSpeed® TX 4.5



#### Drilling protocol - SOFT BONE



Guide	Twist	Twist
Drill	Drill	Drill
	2.0	2.7

- Drill 2.7/4.5
  - 4.5 13 mm

#### **Optional drill**



### **Drilling protocol - DENSE BONE**



Twist	Twist	Conical	Twist	OsseoSpeed <sup>®</sup> TX
Drill	Drill	Drill	Drill	4.5
2.0	3.2	3.2/4.5	3.35	13 mm
	Drill	Drill Drill	Drill Drill Drill	Drill Drill Drill Drill

#### 10

DRILLING SEQUENCES OsseoSpeed® TX 5.0



#### **Drilling protocol - STANDARD**



Drill Drill Drill Drill Drill 5.0 2.0 3.2 3.7 3.7/5.0 13 mm

#### **Drilling protocol - SOFT BONE**



5.0

13 mm

2.0 3.2

Guide	Twist	Twist	Conical	Oss
Drill	Drill	Drill	Drill	
	2.0	3.2	3.2/5.0	

#### **Drilling protocol - DENSE BONE**



Iwist	Conical	Iwist	OsseoSpeed® I X
Drill	Drill	Drill	5.0
3.7	3.7/5.0	3.85	13 mm

#### **Optional drills**



Pilot Drills are available as an optional step within the drilling sequence.

Ø 2.0/3.2 mm Ø 3.2/3.7 mm



#### Drilling protocol – STANDARD



Guide Twist Twist Twist Twist Twist Drill Drill Drill Drill Drill Drill 2.0 3.2 3.7 4.2 4.7

OsseoSpeed® TX 5.0 S 13 mm

#### **Drilling protocol - SOFT BONE**



#### **Optional drills**



Pilot Drills are available as an optional step within the drilling sequence.

Ø 2.0/3.2 mm Ø 3.2/3.7 mm Ø 3.7/4.2 mm

#### Drilling protocol - DENSE BONE



## Implant installation - standard drilling protocol

## Step-by-step procedures for placement of OsseoSpeed® TX 4.5 and 4.0 S, 13 mm

Regardless of the pre-operative planning and choice of surgical protocol, the treatment with dental implants includes a site preparation and installation of the implant. The following is a overview of a implant site preparation according to the standard drilling protocol for the installation of OsseoSpeed TX implants 4.5 and 4.0 S.

Note: All drilling should be performed at a speed of 1500 rpm and under profuse irrigation.





#### Guide Drill

Mark out the planned position of the implant site. This will also provide valuable information about the bone quality.

(Use of an acrylic stent shown here)



### Twist Drill 2.0

Drill in the planned direction to the appropriate depth.

**Note:** Depth should allow implant to be level or slightly submerged in relation to adjacent marginal bone.

Place Direction Indicator in the site to facilitate the direction of the subsequent drilling.



## Twist Drill 3.2

Drill the implant site to the appropriate depth.



#### **Conical Drill 4.5**

Finalize the osteotomy for the OsseoSpeed TX 4.5 implant, with the Conical Drill 4.5.

In standard and soft bone: drill to the beginning of the depth indication line. In dense bone: drill to the full depth of the depth indication line.



Make sure there is enough depth provided for the entire implant. Sometimes additional drilling with a twist drill is needed. Always measure the depth using the Implant Depth Gauge.

#### Implant Depth Gauge

It is important to verify the drilling depth after the drilling with the Conical Drill is completed. Place the Depth Gauge against the wall of the osteotomy to verify the drilling depth.



#### Implant installation – OsseoSpeed® TX 4.5

Install the implant with a contra angle at low speed (25 rpm) under profuse irrigation. Set the maximum torque to 35 Ncm. Let the implant work its way into the osteotomy and avoid applying unnecessary pressure.



#### Implant installation continue

The Ratchet Wrench, in combination with the Driver Handle, may be used for the final manual seating of the implant.

Use light finger force when leveling the implant. Excessive force with the Ratchet Wrench must be avoided as this will cause too much compression in the bone. A too high torque indicates that the implant needs to be retrieved for additional drilling.



#### Positioning the implant

Position the implant at the marginal bone level or slightly below. The objective is to get the implant in contact with as much cortical bone as possible.

Position one of the flat surfaces of the Implant Driver buccally to facilitate optimal placement of the chosen abutment. This especially applies to pre-designed abutments, such as TiDesign and ZirDesign.

Release the Implant Driver from the implant by shifting it slightly from side to side.





Use a Twist Drill 3.7 to finalize the osteotomy for an OsseoSpeed TX 4.0 S implant.

**Note:** This sequence is not applicable for the 4.5 implant, where the final twist drill is 3.2 mm.



#### Implant installation – OsseoSpeed® TX 4.0 S

Install the implant with a contra angle at low speed (25 rpm) under profuse irrigation. Set the maximum torque to 35 Ncm. Let the implant work its way into the osteotomy and avoid applying unnecessary pressure.



#### One-stage procedure Healing Abutment

Using light finger force (5–10 Ncm), seat the Healing Abutment.

Adapt and suture back the soft tissue flaps for a tight seal around the abutments.

They remain in place during the soft tissue healing phase and should then be replaced by permanent abutments.



#### **One-stage procedure** Temporary or permanent abutment

#### **Optional:**

A one-stage surgical procedure may include a temporary prosthetic restoration attached to temporary or permanent abutments.



#### Two-stage procedure Installation of Cover Screw

Insert the Cover Screw into the implant and tighten with only light finger force or with a contra angle preset at 25 rpm and 5–10 Ncm torque.

Reposition the mucoperiosteal flaps carefully and suture tightly together.



#### Two-stage procedure Installation of abutment

After an appropriate healing phase the Cover Screw is exposed and removed using the Hex Screwdriver. Install the selected abutment into the implant.

For abutment selection and details, please refer to Cement-, Screw- or Attachment-retained manuals.

## Pre-operative procedures

#### **Pre-operative examination**

The pre-operative examination should include a general evaluation of the patient's health and a clinical and oral radiographic examination. Particular attention should be given to mucous membranes, jaw morphology, dental and prosthetic history, and signs of dysfunction.

A radiographic analysis should be used to evaluate bone quality and the topography of the residual alveolar process. The initial radiographic evaluation, together with the clinical examination, is the basis for determining whether or not a patient is a candidate for implant treatment.

If the patient is found to be suitable, a more thorough clinical examination of the area for treatment and the opposing jaw should be performed. Any local pathology in the jaws should be treated before implant placement.

#### Pre-operative planning

Models from both jaws should be mounted on an articulator and the relationship between the alveolar ridges and teeth studied. A diagnostic wax-up, replacing the missing teeth, should be made on the model.

An analysis to evaluate the occlusal table, force distribution, and preferred sites for the implants should then be performed. When an optimal situation is achieved on the articulator, a duplicate model of the wax-up should be fabricated and an acrylic stent produced from this model. The stent should then be used during implant installation to guide the placement of the implants in terms of both position and inclination, taking into account anatomical, functional, esthetic, hygienic, and phonetic factors.

A transparent Radiographic Implant Guide, presenting implants in different magnifications, is helpful for planning optimal implant position and direction.

A Computer Guided Implant Treatment software can also be helpful in order to ensure accurate planning for optimized implant position and placement.

For more information please refer to the Facilitate Procedures Manual.

Even though the final treatment approach is usually not determined until the time of surgery the following should be considered based on the quality of supporting bone and initial stability of the implants:

- Whether a one- or two-stage surgical procedure will be preformed
- If an immediate or early loading protocol will be used
- What is the expected healing time before loading

Before treatment begins, the patient should be informed about the results of the pre-operative examination and given a clear explanation of what is entailed by the planned treatment, including the expected outcome and risks involved.





#### Implant-bone relationship

Factors influencing the implant-bone relationship are:

- Bone quantity
- Bone quality
- Diameter of the drilled implant site
- Depth of the drilled implant site

The implant site must be prepared in such a way that:

- The installed implant can achieve primary stability
- No harmful stress to the bone is induced during implant placement

Limited vertical dimension of bone for implant support may be compensated for by an increased implant diameter, provided that sufficient bone support around the implant is present. Optimal bone support can be additionally gained through the use of OsseoSpeed TX implants. The surgical methods, together with prosthetic flexibility for different implant positions, can often compensate for reduced bone quantity.

When bone quality and quantity are compromised, the utilization of osteotome techniques can help to improve the conditions for implant placement and the soft bone drilling protocol provides a perception of increased torque resistance during implant installation.

#### Loading guidelines

A three-month healing period in the mandible and a six-month healing period in the maxilla before loading were originally advocated for implants. Extensive research and product development have shown that reduced healing times can be applied which has been documented in numerous clinical studies. However, when a shorter healing time before loading is being considered, the assessment must always be based on the individual clinical situation.

Bone quality and quantity, design of superstructure, loading conditions, and primary stability achieved, should be carefully examined and assessed.

#### Immediate loading protocol may be utilized when:

- Good primary stability can be achieved
- There is no risk of traumatic loading
- A one-stage protocol can be recommended
- There is no need for grafting procedures in close relation to implant surgery

#### Early loading protocol

When the prerequisites for immediate loading cannot be met, an early loading protocol (six weeks or more healing period) may be considered. It is the responsibility of the clinician to determine which loading protocol to use based on each invidividual case.

#### Surgical considerations

Supported by Computer Guided Surgery the implant installation is sometimes performed without flaps being raised. This reduced surgical intervention is reported to give less postoperative swelling and pain than the conventional surgical protocol with incision and flap elevation, however it must be stressed that there is no documentation available evaluating risks for surgical errors and other complications using this method. It is up to the discretion and responsibility of each individual clinician which surgical approach to choose.

## Implant overview

The OsseoSpeed TX implants have been developed and extensively documented for both one- and two-stage surgical procedures. The Conical Seal Design of the Astra Tech Implant System allows for a strong and stable implant-abutment connection.

#### Intended use

- In replacing missing teeth in single or multiple unit applications within the mandible or maxilla
- Indicated for immediate placement in extraction sites and partially or completely healed alveolar ridge situations
- Especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective
- Suitable for immediate loading\* in all indications, except in single tooth situations in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate \*Immediate loading of single-tooth restorations with OsseoSpeed TX Implant 4.0 S 6 mm is not recommended.

It is important that the clinician takes loading conditions into consideration when determining the number and spacing of short implants. Considering the reduced bone support provided by short implants, it is important for the purpose of early diagnosis and treatment that the clinician closely monitor soft tissue and supporting bone health status by means of probing and radiographic evaluation when indicated.

From a mechanical strength point of view it is recommended to always place as wide an implant as possible. This is particularly important in the posterior regions of the jaws where loading forces are high and considerable bending moments could be generated.



## Drill overview

Implant sites are prepared in a step-by-step procedure using drills of different diameters to ensure an efficient and atraumatic widening of the implant site. All drilling of the bone tissue should be carried out under profuse external irrigation with saline solution and with an intermittent drilling technique to prevent heating of the bone and to create a pumping effect for efficient removal of bone tissue. All drills have laseretched depth indication lines that allow for distinct and clear depth reading.

Drills are available in two options:

#### **Single Patient Drills**

- Packaged sterile and opened as needed at time of surgery
- Optimized cutting properties and contamination-free ease of use
- Disposed after each surgery

#### **Multiple-use Drills**

- Optimal cutting properties
- Designed for multiple-use provided that they are carefully cleaned and sterilized after each surgery

Must be replaced as needed to ensure optimal cutting properties for each surgery.

#### **Drill types**

There are five basic drill types:



#### **Guide Drill**

To mark out and create the insertion point penetrating cortex to evaluate bone quantity and quality.



To prepare the installation site, reaching final width and depth.



#### **Pilot Drill**

**Twist Drill** 

Optional drill to guide succeeding with twist drills, e.g. suitable to facilitate soft bone situation.



#### **Cortical Drill**

Drill for cervical preparation for OsseoSpeed TX 3.0 S, 3.5 S, 4.0 S and 5.0 S implants when the bone is dense. Used to enlarge the opening of an implant site to the exact implant diameter to reduce the pressure in the bone around the implant neck.



#### **Conical Drill**

The apical boarder of the indication line indicates the minimum depth needed to fit the implant. The recommendation is to drill to this depth in standard and soft bone situations. When the bone is dense the recommendation is to drill to the marginal border of the depth indication line. Make sure there is enough depth provided for the entire implant. Sometimes additional drilling with a twist drill is needed. Always make a check-up with the Implant Depth Gauge.

## OVERVIEW AND CONSIDERATIONS Drill overview



Twist Drill, 6-13 mm

#### **Implant Depth Gauge**

The depth indications on the Implant Depth Gauge correspond to the laser markings on the Twist Drills for the different implant lengths. A waist is available on the depth gauge to facilitate the identification of the 13–15 mm indication band. The lower part of the gauge has indications for 2–3, 4–5 mms and can be used for measuring soft tissue height.

When measuring the final prepared implant site, rest the depth gauge against the wall of the osteotomy. **Note:** If the Implant Depth Gauge is placed in the deeper central part of the prepared implant site, the additional depth should be taken into account.





#### **Color-coding**

For easy identification of the implant-abutment connection size the product packaging is color-coded:

- 🛑 X-Small connection Yellow: Implant diameter 3.0 mm
  - Small connection Aqua: Implant diameters 3.5 and 4.0 mm
  - Large connection Lilac: Implant diameters 4.5 and 5.0 mm



#### Peel off

Peel off the perforated section of the label and use it for documentation and/or communication with your restorative partner.



#### Open

Slide the sterile inner container onto a sterile surgical area. Lift the cap to expose the implant.



#### Pick up

Attach the appropriate Implant Driver to the Contra Angle.

Make sure that the driver is properly seated. Pick up the implant from the inner container.



## Preparation of the Healing Abutment and Cover Screw

The Healing Abutment as well as the Cover Screw and other sterile abutments are packed in the same type of container as implants, with color-coded labels that indicate the implant-abutment connection size. They are mounted in a convenient plastic insert for direct access with a Hex Screwdriver.



#### Peel off and open

Peel off the perforated section of the label and use it for documentation and/or communication with your restorative partner. Open the container and slide the sterile inner insert onto a sterile surgical area.



#### Connect

Hold the inner insert steady and connect the Hex Screwdriver to the Healing Abutment or the Cover Screw with a friction fit.



#### Lift out

Split the insert open and lift out the Healing Abutment or Cover Screw.

## Surgical Tray and instruments

The Surgical Tray is designed to conveniently and easily manage the required drills, instruments, and implants for surgery. The layout of the tray navigates the surgeon through the drilling progression.





for each individual patient and give you the confidence of predictably sharp drills every time.

collector for harvesting bone The unique design of the filter allows for efficient collection of bone particles without clogging.

## Cleaning and sterilization guidelines

#### **Drills**

Astra Tech Implant System provides Multiple-use and Single Patient Drills.

- Dispose of the Single Patient Drills into a sharps container immediately after the implant procedure is completed
- Do not re-sterilize the Single Patient Drills
- Reusable drills are designed to be cleaned, disinfected, placed back in the tray and sterilized after each use

### Instruments, Multiple-use Drills and trays

Choose between the following two cleaning techniques

#### **Cleaning technique 1:**

 Clean Multiple-use Drills and instruments and then use an ultrasonic cleaner to ensure all the debris is removed. Rinse thoroughly

#### **Cleaning technique 2:**

 Clean and disinfect all Multiple-use Drills, instruments and trays within an instrument dishwasher

#### Sterilization

- Thoroughly dry Multiple-use Drills, instruments and trays before the sterilization process to prevent possible corrosion of the metal components
- Steam sterilize Multiple-use Drills, instruments and trays at 134°C/270-275°F for minimum 3 minutes (or corresponding method in accordance with autoclave manufacturers instruction)

Note: Ensure that both the Ratchet Wrench and/or combination Torque Wrench is dismantled before the cleaning and sterilization process.

#### **Contra Angle**

Choose between the following two cleaning techniques (please refer to manufacturer's instructions).

#### **Cleaning technique 1:**

- Disassemble the contra angle
- Clean with a soft brush under cold running water or in a dishwasher
- Thoroughly dry the contra angle
- Lubricate the contra angle according to the manufacturer's instruction

#### **Cleaning technique 2:**

• Clean and lubricate in an automatic unit for contra angles

#### Sterilization

• Steam sterilize the disassembled contra angle









### References supporting the Astra Tech Implant System®

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#### **Placement in extraction sockets**

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#### Early loading protocol

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Maiorana C, King P, Quaas S, et al. Clinical and radiographic evaluation of early loaded narrow-diameter implants: 3 years follow-up. Clin Oral Implants Res 2015;26(1):77-82. Abstract in PubMed

Mertens C, Steveling HG. Early and immediate loading of titanium implants with fluoride-modified surfaces: Results of 5-year prospective study. Clin Oral Implants Res 2011;22(12):1354-60. Abstract in PubMed

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#### About Dentsply Sirona Implants

Dentsply Sirona Implants offers comprehensive solutions for all phases of implant therapy, including Ankylos\*, Astra Tech Implant System\* and Xive\* implant lines, digital technologies, such as Atlantis\* patient-specific solutions and Simplant\* guided surgery, Symbios\* regenerative solutions, and professional and business development programs, such as STEPPS™. Dentsply Sirona Implants creates value for dental professionals and allows for predictable and lasting implant treatment outcomes, resulting in enhanced quality of life for patients.

#### About Dentsply Sirona

Dentsply Sirona is the world's largest manufacturer of professional dental products and technologies, with a 130-year history of innovation and service to the dental industry and patients worldwide. Dentsply Sirona develops, manufactures, and markets a comprehensive solutions offering including dental and oral health products as well as other consumable medical devices under a strong portfolio of world class brands. As The Dental Solutions Company<sup>™</sup>, Dentsply Sirona's products provide innovative, high-quality and effective solutions to advance patient care and deliver better, safer and faster dentistry. Dentsply Sirona's global headquarters is located in York, Pennsylvania, and the international headquarters is based in Salzburg, Austria. The company's shares are listed in the United States on NASDAQ under the symbol XRAY.

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