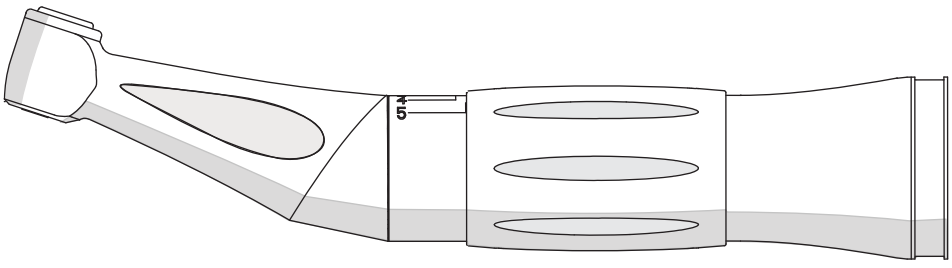
New as of: 09.2017

sirona
The Dental Company

SIRONiTi APEX
SIRONiTi Air+ APEX

Operating Instructions

English



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1 Before you begin …

SIRONiTi APEX / SIRONiTi Air + APEX complies with state-of-the-art technical regulations. SIRONiTi APEX / SIRONiTi Air + APEX complies with the ISO 14457 standard.

1. Read the operating instructions prior to using SIRONiTi APEX / SIRONiTi Air + APEX.
2. Only use SIRONiTi APEX / SIRONiTi Air + APEX for the applications described in the operating instructions.
3. Observe the applicable hygiene standards, occupational safety regulations and accident prevention measures for SIRONiTi APEX / SIRONiTi Air + APEX.

Intended use

The contra-angle handpieces are used to hold and drive burr instruments for the purposes of rotary processing. The handpieces are intended for dental applications in endodontics and for root canal measurement and are used by trained dental personnel in dental practices and laboratories. The T1 Spray is intended to be used to clean and lubricate dental handpieces.

Contraindications

The instrument generates magnetic fields that can affect cardiac pacemakers. Therefore, the instrument must **not** be used on patients or operated by users who have cardiac pacemakers!

Target group

This product is intended only for use by trained dental personnel in dental practices and laboratories.

1.1 Structure of the document

1.1.1 Labeling of information

Warnings

➢ To prevent injuries, please observe the warnings.

Warnings are labeled as follows:

DANGER! indicates a danger **leading** to death or serious injury if not avoided.

WARNING! indicates a danger that **may lead** to death or serious injury if not avoided.

CAUTION! indicates a danger that **may lead** to injury if not avoided.

Instructions for use

➢ To prevent material damage and additional expenses, please observe all instructions for use.

Instructions for use are labeled as follows:

NOTICE! indicates measures for the prevention of material damage.

IMPORTANT: indicates information on the avoidance of additional expenses and other important information.

Tip: indicates information for facilitating work.

1.1.2 Formats and symbols

The formats and symbols used in this document have the following meaning:

✓ Prerequisite **1.** First action step **2.** Second action step or ➢ Alternative action ↳ Result ➢ Individual action step	Requests you to do something.
Use of formats and symbols [→ 5].	Identifies a reference to another text passage and specifies its page number.
• List	Identifies a list.

1.2 Service life of Sirona instruments

When used as intended:

- Non-moving parts of Sirona instruments have a typical service life of approx. 5 years
- Moving parts of Sirona instruments have a typical service life of approx. 3 years

No warranty claim can be inferred here, as wear may occur earlier or later than indicated above depending on use, frequency of sterilization, and frequency of maintenance.

Elastomers, e.g. O-rings, must be replaced depending on their degree of wear.

For safety and technical reasons, check the clamping system of the contra-angle and straight handpiece burs on an annual basis.

2 Safety information

Obligations of the user

- Use only fault-free materials that do **not** deviate from the specified data [→ 8].
- Protect yourself, patients, and others against any foreseeable dangers. To do this, follow the safety information.
- Comply with the Intended use of the equipment.
- You should always keep these operating instructions within reach for further reference.

Preventing the spread of infections and cross contamination

Prevent the spread of infections and cross contamination between patients, users, and third parties. Sterilize equipment after each patient.

Take the appropriate hygiene measures, e.g. wear protective gloves.

Magnetic fields

The SIRONiTi APEX / SIRONiTi Air + APEX instrument generates magnetic fields that can affect cardiac pacemakers. Therefore, the SIRONiTi APEX / SIRONiTi Air + APEX instrument must **not** be used on patients or operated by users who have cardiac pacemakers!

Direct contact of the instrument with magnetic storage media can lead to data loss.

The instrument is therefore marked with the following symbol:

Instrument head overheating

If the instrument is defective, the area around the instrument head may heat up, thus creating a risk of burning the patient's oral mucosa.

Malfunction or damage

Discontinue use immediately in case of malfunction, unusual or different sounds or damage. Damaged instruments may cause injury. Notify the dental dealer or the manufacturer.

Repair

Do **not** repair the instrument yourself.

Spare and accessory parts

Use only original Sirona parts or parts approved by Sirona. Safe operation is **not** guaranteed for parts that have not been approved by Sirona.

First aid measures in the case of lubricant accidents

General information:	Immediately remove any clothing soiled by the product.
After inhalation:	Supply fresh air; consult doctor in case of complaints.
After skin contact:	If skin irritation continues, consult a doctor.
After eye contact:	Rinse opened eye for several minutes under running water.
After swallowing:	If symptoms persist consult doctor.

For details download the Sirona T1 Spray Material Safety Data Sheet from the Sirona homepage: www.sirona.com

Operating conditions:

Temperature: +10 °C – +30 °C

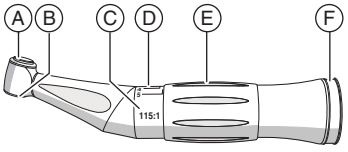
If you have any questions, please contact your dental depot or the manufacturer.

3 Technical description

3.1 Task

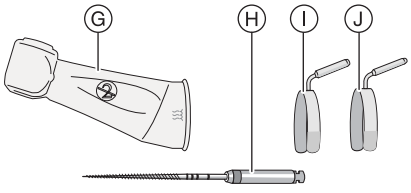
The instrument serves for transmitting the driving power and speed of the electric motor or air motor (handpiece coupling according to ISO 3964) to the preparation tool.

3.2 Contra-angle handpiece configuration



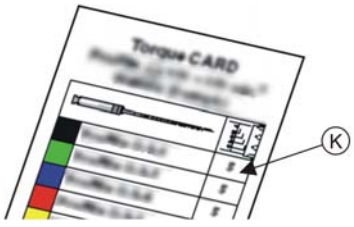
A	Pushbutton
B	Opening of chuck system
C	Gear ratio
D	Torque levels
E	Control ring
F	Joint for clip

Accessories



G	Insulating sleeve
H	NiTi file
I	Clip Ø 2.0mm
J	Clip Ø 1.5mm

Torque CARD



For the file assortment of each manufacturer, corresponding Torque CARDs are included in the delivery.

Here you can read the torque levels (K) recommended for the files used.

The Torque CARDs are available on the Internet under www.sirona.com.

3.3 Technical data

Instrument

		SIRONiTi APEX	SIRONiTi Air+ APEX
Gear ratio		115:1	66:1
Maximum motor speed in rpm		40000	40000
Maximum operating speed in rpm (must be chosen according to the file manufacturer)		approx. 350	approx. 600
Motion		360° (fully rotating)	360° (fully rotating)
Clamping system		NiTi files	NiTi files
Internal cooling media		-	-
Back suction stop		-	-
Light function		-	-
Apex measurement function		x	x
Clips available for standard endometer connections			
	⌀ 1.5mm	x	x
	⌀ 2mm	x	x
Instrument coupling		ISO 3964	ISO 3964
Available for use in the US		x	-

File

	SIRONiTi APEX / SIRONiTi Air + APEX
Shank diameter in mm	2.334 - 2.35
Maximum total length in mm	25
Maximum working diameter in mm (ISO 2157)	2.1
Gripping length in mm	≥ 11
Standard	ISO 1797-1, Type 1

CE
0123

This product bears the CE mark in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices (MDD).

4 Preparation

4.1 Initial start-up and longer breaks in use

➢ Sterilize the instrument and accessories prior to startup.

➢ Clean and maintain the instrument after longer breaks in use.

5 Operation

NOTICE! Use only faultless files in order to prevent fatigue fractures of the files as far as possible.

CAUTION! A loose or partially removed file can detach itself from the head or break off. This may cause injury! Therefore, only use the instrument if the file is at least 10 mm deep and clamped securely in place.

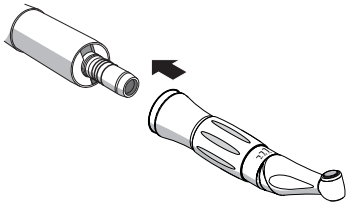
CAUTION! Do not pull the patient's cheek back with the contra-angle handpiece while the motor is running. This would actuate the pushbutton, thus creating a risk of burning the patient's oral mucosa.

IMPORTANT: For application details and operating data of the different preparation tools, please refer to the information provided by the manufacturer.

5.1 Replacing the instrument

CAUTION! The instrument should only be fitted or removed when the motor is at standstill.

Attaching the instrument



✓ The motor is at a standstill.

➢ Insert the instrument until it snaps into place.

Removing the instrument

✓ The motor is at a standstill.

➢ Detach the instrument. Do not pull on the supply hose while doing this.

5.2 Attaching and removing a file

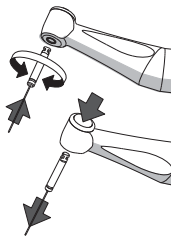
NOTICE! Use only faultless files in order to prevent fatigue fractures of the files as far as possible.

IMPORTANT: Check the push button to make sure it moves freely!

Please take the following points into consideration when selecting files:

- The NiTi file is designed for fully rotating use.
- A torque CARD is available for the NiTi file.

Attaching a file



✓ The drive has come to a stop.

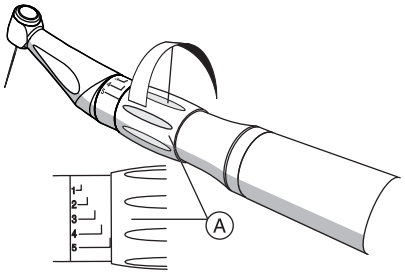
1. Insert the file by gently rotating it until it snaps into place. In doing so, do **not** press the pushbutton.
2. Then pull and turn the file to check that it is firmly seated.

Removing a file

✓ The file has come to a stop.

➢ Remove it while pressing and holding down the pushbutton.

5.3 Setting the torque

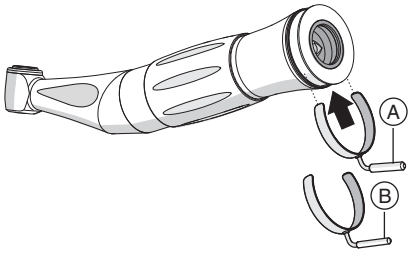


✓ The required NiTi file is inserted [→ 11].

✓ The speed set at the supply unit corresponds to the file manufacturer's specifications.

1. Read out the recommended torque level from the torque CARD of the file used.
2. Turn the ring (A) until its front edge is located opposite the mark corresponding to the desired level 1 - 5.

5.4 Attaching the APEX clip



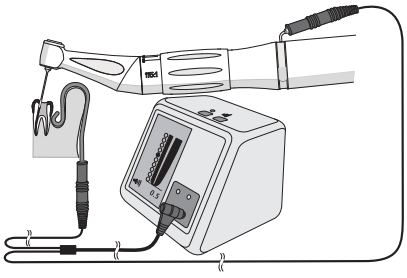
Attach the clip whose pin diameter matches the endometer being used as shown.

For SIRONiTi APEX and SIRONiTi Air+ APEX, 2 clips are available for connecting a measuring cable to an apex locator for example SIROEndo (Sirona) or Root ZX (Morita).

The contact pins on these clips vary in diameter.

A	Clip dia. 2.0 mm
B	Clip dia. 1,5 mm

5.5 Connecting the instrument to an apex locator



The SIRONiTi APEX / SIRONiTi Air + APEX makes it possible to connect a measuring cable for an apex locator by means of a clip in order to check the exact position of the file in the root canal.

NOTICE! The apex locator must comply with the requirements of IEC 60601.

1. Please observe the operating instructions pertaining to the apex locator being used.
2. Attach an APEX clip [→ 11].
3. Connect the measuring cable of the apex locator to the clip's contact pin.
4. Perform the measurement in accordance with the equipment manufacturer's specifications.

Based on in vitro studies, we recommend defining the maximum preparation depth at the coronal end of the apex interval on the display of the apex locator used.

Calibration

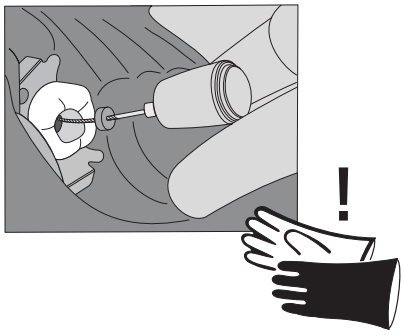
✓ The manufacturer of the apex locator stipulates that a calibration must be performed.

1. Insert a file into the contra-angle handpiece [→ 11].
2. Connect the cable of the file clamp (without the actual file clamp) onto the clip of the contra-angle handpiece.
3. Perform the calibration in accordance with the equipment manufacturer's specifications.

5.6 Recommendation for the treatment procedure

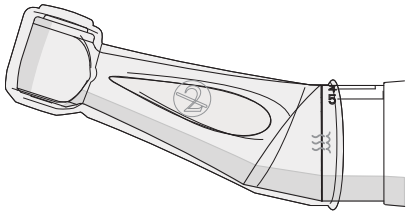
NOTICE! Use only faultless files in order to prevent fatigue fractures of the files as far as possible.

- The different file systems require different working techniques. For this reason, please always observe the information provided by the file manufacturer.
- Work without exerting any pressure on the file.
- Prior to the first treatment, we recommend performing conditioning tests on resin blocks or extracted teeth.
- Due to the special characteristics of the nickel-titanium material, the crown down technique should be preferred when preparing the root canal.
- The ApexLocator function is used to support the root canal preparation process in combination with a treatment center with the apex measurement function. The number of X-rays can be reduced with SIRONiTi APEX / SIRONiTi Air + APEX. However, you must always take at least one X-ray to determine the depth for preparatory work. A clinical evaluation including knowledge of the anatomy of root canals is important for interpreting the results.



- When performing the APEX measurement, wear appropriate insulated gloves. We recommend performing the treatment with a cofferdam, while using an insulating sleeve. This will prevent inaccurate measurements caused by undesired leakage currents. During the measurement, the instrument must not come into contact with the patient's mucosa, metallic tooth restorations, or the mucosal electrode.
- If the limit torque is exceeded, a gentle creaking may be heard and vibrations felt. Remove the file by gently pulling it toward the coronal end. If this is not possible, switch the drive to counterclockwise rotation and pull the file out of the channel.
  IMPORTANT: Check the file afterwards for damage or deformation (untwisting) and replace it, where necessary.

5.7 Mounting and removing the insulating sleeve



NOTICE! Insulating sleeves are only used once. Change the insulating sleeve after each patient.

Fitting an insulating sleeve

✓ You have sterilized the insulating sleeve.
✓ The motor is at a standstill.
✓ A file is **not** clamped in place.
1. Twist the insulating sleeve carefully this way and that and pull the insulating sleeve fully over the instrument.
2. Attach the file [→ 11].

Removing an insulating sleeve

✓ The motor is at a standstill.
1. Remove the file.
2. Remove the insulating sleeve.
3. Dispose of the insulating sleeve [→ 21].

6 Follow-up

6.1 After each treatment session

NOTICE! Condition immediately, or at the latest, one hour after treatment.

NOTICE! Only use Sirona T1 Spray.

✓ Wear appropriate protective clothing.

1. Remove the file with tweezers.
2. Pre-disinfect directly at the treatment center [→ 15].
3. Detach the instrument from the drive.
4. Transport the instrument to the hygiene room in a suitable transport container.
5. Conduct automatic conditioning. Manual conditioning [→ 16] is possible in exceptional cases if the national/local regulations are followed.
6. Apply spray to the instrument [→ 16].
7. Sterilize the instrument and accessories [→ 17].

6.2 At the end of the work day

➢ Apply spray to the instrument [→ 16].

NOTICE! Do not leave any instruments on the motor overnight, in order to prevent oil from leaking into the electric motor. Never lubricate the electric motor.

7 Conditioning

7.1 Conduct pre-disinfection

✓ Wear appropriate protective clothing.

✓ All disinfectants must be approved in your country and have proven bactericidal, fungicidal and virucidal properties. Only use disinfectants with **no** protein-fixing properties.

1. Spray the surface with disinfectant.
2. Wipe the disinfectant off with a cloth.

↳ For further conditioning, the instrument should be dry and free of residue.

In the USA and Canada, for example, you can use:

- CAVICIDE®
- CAVIWIPES ™

Please observe the manufacturer's instructions for using instrument disinfectants.

7.2 Automated cleaning and disinfecting

The cleaning and disinfection equipment used must be approved by its manufacturer for the cleaning and disinfection of dental instruments and comply with EN ISO 15883-1 (e.g. 95°C (203°F) and 10 min. holding time).

For further details, refer to the operating instructions supplied with the unit.

✓ The instrument is conditioned with a cleaning and disinfection device.

1. Check whether the instrument is clean after conditioning under good lighting (min. 500 lux) and color rendering index (min. 80 Ra).
2. If it is still dirty, repeat the process.

   ↳ For further conditioning, the instrument should be dry and free of residue.
3. Blow the instrument out with max. 3 bar.
4. Manual care of mechanical parts [→ 16].
5. Manual care of the push button chuck [→ 17].
6. Pack the instrument in packaging material suitable for sterilization and storage. e.g. paper/plastic composite packaging.
7. Sterilize the instrument [→ 17].

7.3 Manual cleaning and disinfection

IMPORTANT: Manual conditioning is possible in exceptional cases if the national/regional regulations are followed. The national/regional regulations are to be checked before.

NOTICE! Condition immediately, or at the latest, one hour after treatment.

NOTICE! Never clean in an ultrasound bath!

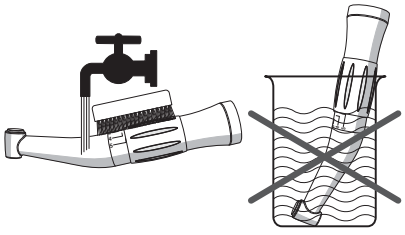
NOTICE! Never immerse in disinfectant solution!

NOTICE! Only use Sirona T1 Spray.

IMPORTANT: Use a soft, clean, and disinfected brush for cleaning.

✓ Wear appropriate protective clothing.

✓ All disinfectants must be approved in your country and have proven bactericidal, fungicidal and virucidal properties. Only use disinfectants with **no** protein-fixing properties.



1. Brush the instrument under running water (< 38 °C, < 100 °F, at least drinking water quality) and good lighting (min. 500 lux) and color rendering index (min. 80 Ra) until no more dirt can be seen, for at least 10 seconds.
2. Flush the drive channels with spray.
3. Conduct thermal disinfection or unwrapped steam sterilization.
4. Maintain mechanical parts manually [→ 16].
5. Maintain the push button chuck manually [→ 17].
6. Pack the instrument in packaging material suitable for sterilization and storage. e.g. paper/plastic composite packaging.
7. Conduct sterilization [→ 17].

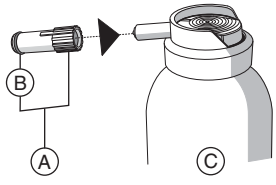
7.4 Manual maintenance

7.4.1 Maintenance of mechanical parts

Intervals

- At least every noon and evening
- Prior to each sterilization
- After every thermal disinfection without integrated maintenance

Required accessories



A	Spray adapter
B	O-ring for spray adapter
C	T1 Spray

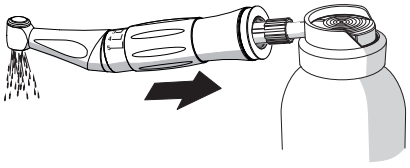
NOTICE! Only use Sirona T1 Spray.

Process

✓ The spray adapter is disinfected.

✓ The O-ring on the spray adapter is intact.

1. Fit the spray adapter onto the nozzle of the spray can.



2. Insert the instrument until it snaps into place and hold it.
3. Spray the instrument for 1 - 2 seconds.
   IMPORTANT: Hold the spray can upright.
4. Wipe any spray that comes out with a disinfection cloth.
5. Repeat the process until the spray is clear.

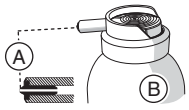
7.4.2 Care of the push button chuck

Use Sirona T1 Spray on the push button chuck to remove deposits and ensure proper functioning of the clamping system.

Interval

- At least once a week

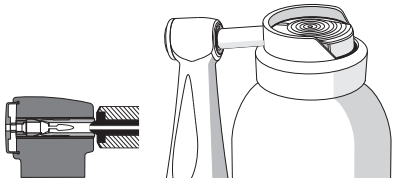
Required accessories



A	Black nozzle insert
B	Sirona T1 Spray

NOTICE! Only use Sirona T1 Spray.

Process



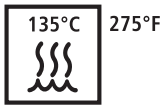
✓ The instrument is clean and disinfected.
1. Press the contra-angle handpiece head with the chuck firmly against the spray can nozzle.
2. Spray the chuck for 1 - 2 seconds.
   IMPORTANT: Hold the spray can upright.
3. Wipe any spray that comes out with a disinfection cloth.

7.5 Sterilizing

Intervals:

- Prior to initial operation
- Prior to each subsequent use

Process



✓ The instrument is clean and disinfected.
✓ Instrument maintenance is complete.
✓ The instrument can be sterilized in packaging suitable for sterilization and storage: paper/plastic composite packaging according to ISO 11607.
➢ Sterilize the instrument in the steam sterilizer with saturated water vapor.

Temperature:	135° C (275° F)
Overpressure:	2.13 bar (30.89 psi)

Article	Holding time at 135 °C (275° F)	Drying time
Wrapped instruments	10 minutes	30 minutes
Unpackaged instruments	3 minutes	0 - 1 minute

Gravity displacement steam sterilizers are permitted.

NOTICE! Do not exceed 140°C (284°F), even during the drying phase.

After sterilizing

1. Remove the instrument from the steam sterilizer immediately.
   CAUTION! The instrument is hot. Risk of burns!
   NOTICE! Do **not** attempt to accelerate the cooling process by immersing the instrument in cold water. This can damage your instrument.
2. Store all instruments so that they are protected from contamination.
3. Sterilize again once the storage period has elapsed.

8 Spare parts and consumables

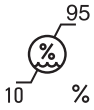
Use only original Sirona parts or parts approved by Sirona.

	REF			REF
T1 spray (6 x 250 ml cans)	59 01 665		Clip dia. 2.0 mm	61 73 681
Spray adapter (ISO) for spray can	89 17 858		Clip dia. 1,5 mm	61 73 699
O-ring for spray adapter	70 36 353		SIRONiTi torque CARDs	59 63 322
Insulating sleeve for Endo	63 24 631			

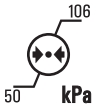
9 Storage and transport conditions

Protect from moisture

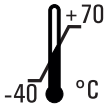
Sensitive contents



Relative humidity



Air pressure



Temperature

After a severe change in temperature, allow sufficient time for acclimation.

10 Disposal

- According to current information, the product does not contain any substances that are hazardous to the environment.
- Disinfect the product prior to disposal.
- Observe the applicable disposal regulations for your area.

We reserve the right to make any alterations which may be required due to technical improvements.

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