stomdevice

Dentsply Sirona

Endo IQ® Accessories

Directions For Use



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Dentsply Sirona

RX ONLY

Introduction

Dear Customer,

These Directions for Use (DFU) are kept up-to-date by Dentsply Sirona. The most current version can be accessed at **dentsplysirona.com** and is also available from **Endo IQ®** App. **We strongly recommend that you periodically check this website for updates of this DFU.**

The DFU is available in other languages upon request. If a printed version in your language is not enclosed, Dentsply Sirona will send a free copy to any address in North America. To order a free copy of the DFU, send a request to tulsacustserv@dentsplysirona.com.

We would appreciate your feedback. If any errors or discrepancies are noted with the DFU, the packaging or the accessories, please contact Dentsply Sirona Endodontics Customer Service.

Manufactured For:
Dentsply Tulsa Dental Specialties
Dentsply International Inc.
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tulsacustserv@dentsplysirona.com
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1 INDICATIONS FOR USE

Endo IQ® iPad stand is an iPad® support designed to facilitate the use of Dentsply Sirona **IQ®** devices and to fit all sizes of iPad®.

Disposable Barrier Sleeves and Covers are intended to serve as a disposable barrier for dental instruments and equipment. **Endo IQ®** Barrier Sleeve for iPad is non-sterile and intended for single patient use only.

2 CONTRAINDICATIONS

There are no known contraindications.

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3 WARNINGS

Read the following warnings before use.



Some sections / texts of this DFU are dedicated uniquely to readers from a specific territory. When this happens the section / text will be clearly identified with a sentence similar to: For US / EU readers.
If nothing is indicated, the text is applicable to all of the intended territories.

- **Endo IQ®** Accessories are supplied un-disinfected. You must reprocess the **Endo IQ®** iPad stand prior to first use and before each treatment (Follow instructions given in section **7 Cleaning, Disinfection and Sterilization**).
- It is mandatory to reprocess the **Endo IQ®** iPad stand before shipping it to the service center (follow instructions given in section **7 Cleaning, Disinfection and Sterilization**).
- Always place **Endo IQ®** iPad stand on a flat, steady surface during treatment.
- Always ensure a stable positioning of the iPad® on **Endo IQ®** iPad stand during treatment or if they must be displaced.
- **Do not use an iPad® on Endo IQ® iPad stand with accessories other than the Endo IQ® Disposable Polyethylene Barrier Sleeve for iPad.**
- Protect the **Endo IQ®** iPad stand with appropriate, clean and dry packaging when sending it for service.

4 PRECAUTIONS

There are no known precautions to take before use.

5 ADVERSE REACTIONS

There are no known adverse reactions.

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6 STEP BY STEP INSTRUCTIONS

Refer to the section **3 Warnings** to verify any special care to exercise before starting to use the **Endo IQ®** Accessories.

6.1 Accessories compatibility

Specification	Description
iPad®	iPad Mini™ 2 iPad Mini™ 3 iPad Mini™ 4 iPad® (6th gen) iPad Pro® 10.5" iPad® 12.9" (2nd gen)

*Apple®, the Apple logo, iPad®, iPad Pro® and iPad Mini™ are trademarks of Apple Inc., registered in the U.S. and other countries. App Store® is a service mark of Apple Inc..

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6.2 Package content

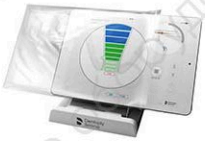
List of components	
Endo IQ® iPad Stand	
DFU	

Components not included		
iPad with iOS Operating System		
Endo IQ® Disposable Polyethylene Barrier Sleeve for iPad and Unit Numbers (for separate supply)		
	For iPad Mini™	T 00 IQ00 079 BAR
	For iPad® (6th gen)	T 00 IQ00 097 BAR
	For iPad Pro® 10.5"	T 00 IQ00 105 BAR
	For iPad Pro® 12.9" (2nd gen)	T 00 IQ00 129 BAR

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6.3 Using Endo IQ® iPad Stand and Sleeves

Place **Endo IQ®** iPad Stand on a clean, dry, flat surface. Place the iPad® horizontally on **Endo IQ®** iPad Stand. Ensure that the iPad® and the stand are stable.

N°	Action
A	Remove carefully the accessories from their packaging and place them on a flat surface.
B	Use the appropriate **Endo IQ®** Barrier Sleeve for iPad for your iPad® size and insert your device into that sleeve. 
C	Close the sleeve and place your iPad® horizontally onto the **Endo IQ®** iPad Stand, ensuring that the lower side of the iPad® is securely inserted into the mechanical stop of the **Endo IQ®** iPad Stand. 

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7 CLEANING, DISINFECTION AND STERILIZATION

7.1 General

The **Endo IQ®** iPad stand shall be reprocessed before and after each treatment.

Clean and disinfect the **Endo IQ®** iPad stand.



Dentsply Sirona accepts no liability in the event that these instructions are disregarded or processes that have not been validated are used to reprocess the accessories.



Use only properly maintained equipment and approved materials according to national laws and/or regulations.



Do not sterilize.

7.2 Cleaning Procedure of Endo IQ® iPad Stand

Cleaning is intended to remove all the visible soiling (e.g. organic and inorganic) from the surface of **Endo IQ®** iPad Stand so that the subsequent disinfection process can be efficient.

N°	Cleaning steps
A	Always wear protective clothes for your own safety (gloves, mask, glasses and a waterproof gown) for the reprocessing process.
B	Clean **Endo IQ®** iPad Stand paying special attention to grooves of the device. Use a single-use wipe or soft clean cloth lightly soaked in disinfectant containing Alcohol Quaternary Ammonium active ingredients (e.g. VoloWipes™ or CaviWipes™ or CaviCide™).
C	Clean the grooves and device screws by using a clean brush with soft bristle (e.g. nylon) slightly soaked in cleaning solution.
D	Continue steps B and C until no debris appear on the wipe / brush. Replace the wipe and clean the brush as necessary.

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7.3 Disinfection procedure for Endo IQ® iPad Stand

Disinfection shall be done immediately after cleaning using the following procedure:

N°	Disinfection steps
A	Always wear protective clothes for your own safety (gloves, mask, glasses and a waterproof gown) for the reprocessing process.
B	Disinfect the surface of **Endo IQ®** iPad Stand paying special attention to grooves of the device. Use a single-use wipe or soft clean cloth lightly soaked in disinfectant containing Alcohol Quaternary Ammonium active ingredients (e.g. VoloWipes™ or CaviWipes™ or CaviCide™).
C	Remove all disinfectant residue. No visible impurities or liquid should remain on the **Endo IQ®** iPad Stand after disinfection.
D	If the **Endo IQ®** iPad Stand is not being used immediately after the reprocessing process, keep it in a safe and clean environment and follow the instructions for storage and transport.



Use only disinfectants with Alcohol Quaternary Ammonium active ingredients (e.g. VoloWipes™ or CaviWipes™ or CaviCide™).
Use only disinfectants, which are FDA-approved and compatible with the device and accessories (see **8 Technical Characteristics**).



Leave the disinfectant to act in accordance to manufacturer's instructions. Avoid leaving the disinfectant in contact with the device surfaces for a time longer than that recommended by the manufacturer of the disinfectant product. It can result in damage to the device.

7.4 Use of Endo IQ® Barrier Sleeves

The **Endo IQ®** Disposable Polyethylene Barrier Sleeves are single-use barriers. Remove and discard the Barrier Sleeve from the iPad® after each patient and replace it with a new, unused Sleeve before starting the next treatment. Use of the **Endo IQ®** Disposable Polyethylene Barrier Sleeves does not replace cleaning of the iPad® in accordance with the manufacturer's instructions.

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8 TECHNICAL CHARACTERISTICS

Specification	Description
Manufacturer	Dentsply Tulsa Dental Specialties Dentsply International Inc. 608 Rolling Hills Drive Johnson City,Tennessee 37604 USA Phone 1-800-662-1202 Fax 1-800-597-2779 tulsacustserv@dentsplysirona.com dentsplysirona.com
Model	**Endo IQ®** iPad Stand **Endo IQ®** Barrier Sleeve for iPad
Dimensions	**Endo IQ®** iPad Stand: Length: 160 mm Width: 165 mm Height: 72 mm
Weight	iPad stand: 200 g (0.44 lbs)
Material	**Endo IQ®** iPad Stand: ABS
	Disposable Barrier Sleeve: LDPE/LLDPE
Ambient conditions	• Use: in enclosed spaces • Ambient temperature: 15°C - 35°C (59°F - 95°F) • Relative humidity:< 80%
Conditions for transport and storage	• Ambient temperature: -20°C - +50°C (-4°F - 122°F) • Relative humidity: 20% - 80%, • Pressure: 50 kPa - 106 kPa Not to use or store system in a flammable environment
Endo IQ® iPad Stand usage lifetime	1 year

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9 ERROR CODES

N/A

10 TROUBLESHOOTING

N/A

11 WARRANTY

Dentsply Sirona Endodontics offers customers the following product warranty:

- Dentsply Sirona Endodontics guarantees proper manufacturing of the product, the use of top quality materials, performance of all required tests and compliance with all applicable relevant laws and regulations relating to the product. The full functionality of the **Endo IQ®** iPad Stand is covered by a 12-month warranty. Warranty period begins on the date of equipment purchase. The customer is only entitled to warranty services within the warranty period and under the condition that Dentsply Sirona has been informed of the defect within a one-month period from the date of discovery of the defect

Component	Warranty period
Endo IQ® iPad Stand	12 months

- This warranty covers only the exchange or repair of individual components or parts affected by manufacturing defects. The cost for personnel to be dispatched for purposes of technical assistance from the dealer to the customer, and / or packaging expenses of the customer will not be covered by Dentsply Sirona. Any customer claims beyond the realm of repair, such as claims for damages, will not be covered. This warranty does not include any compensation for direct or indirect personal injuries or material damage of any kind. The customer will not be entitled to damages covering downtime of the equipment.
- The warranty does not extend to damage for which evidence can be provided by Dentsply Sirona that such damage has been caused by negligence on the part of the user as related to Directions For Use. The warranty explicitly excludes any defects arising on the basis of:
  - damage occurring during transportation to Dentsply Sirona for the purposes of repair;
  - damage occurring through environmental events such as lightning strikes, fire and / or humidity. This warranty shall automatically become cancelled and void if the product has been improperly repaired, modified or manipulated in any manner by the user, by non-authorized persons or by third party personnel.
- Legal claims, such as under product liability law remain unaffected.

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12 DISPOSAL OF THE PRODUCT

Comply with your national and regional regulations, guidelines and requirements for the disposal of this product.
Endo IQ® Barrier Sleeves for iPad are single-use sleeves and must be discarded after each patient.

13 IDENTIFICATION OF SYMBOLS

Normative Symbols

Symbol	Identification
	Batch Code
	Catalogue number
	Consult Instructions for Use
	Electronic Instructions for Use (relevant information for use of the product is available in electronic format from dentsplysirona.com).
	Date of manufacture
	Temperature limit
	Humidity limitation
	Keep dry
	Do not steam sterilize
	Do not re-use
	Caution, consult instructions for use
	Do not use if package is damaged
	Accessory
	Open packages are not replaced
	Polyethylene
	Latex free

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