Low-Temperature Sterilizer

Frequently Asked Questions

Tuttnauer

Innovation · Legacy · Partnership

13 Questions to ask before buying a low-temperature plasma sterilizer

We know that the thought of purchasing a sterilizer can be daunting. There are so many questions and angles to consider, and you don't want to make the wrong decision. You are hoping to choose a machine that is top-of-the-line, safe, durable, and reliable for many, many years to come. How should you proceed?

In this document we will answer important questions to consider when purchasing a plasma low-temperature sterilizer.

Information Questions about Plasma H_2O_2 Technology

1. Why plasma sterilization?
2. What is plasma sterilization?
3. How does a plasma sterilizer work?
4. How is the hydrogen peroxide (H_2O_2) disposed during the cycle?
5. Is plasma sterilization safe?

Product Questions about Plasma Sterilizers

6. What size plasma sterilizer do you need?
7. What are the utility and installation considerations?
8. What consumables are needed in order to operate your sterilizer?
9. Why does Tuttnauer use only 50% concentration of H_2O_2 while other manufacturers use a higher concentration?
10. How do you ensure effective sterilization and penetration of H_2O_2?
11. How many times I can use the PCD for PlazMax?
12. Sterilization in a PCD of 4 meters length works also in other plasma sterilizer manufacturers even though they say the longest tube is 1.4m. Why is that?
13. Are there equipment tracing records for endoscopes?

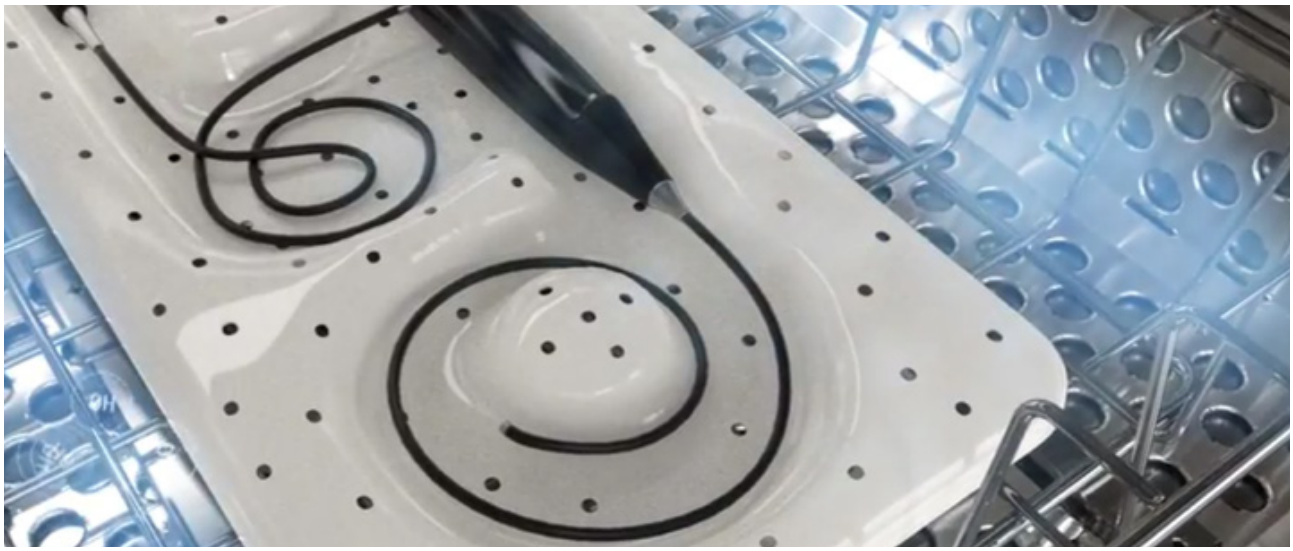
01.

Why plasma sterilization?

Plasma sterilizers are the go-to option for delicate equipment and instruments.

Steam is a smart way to sterilize many standard devices, but for others it would ruin or damage them. In other words, not all medical equipment can be sterilized in an autoclave. The most common autoclave is one that uses high-pressurized, high-temperature steam to sterilize medical and scientific devices like forceps, scalpels, and beakers.

Basically the more technologically advanced an item, the less likely it could be safely autoclaved. The classic example of this scenario is an endoscope, which is an expensive device often outfitted with a camera that sits at the end of a long tube meant to "scope" the body in a procedure called an endoscopy.



Given that autoclaving an endoscope would most likely damage it, or, over time, destroy it, how is it possible to sterilize it? Enter low-temperature sterilization. As medical devices became more technologically-sophisticated and sensitive to high temperatures and humidity, the need for a more delicate alternative to autoclaves grew. For over twenty years, plasma sterilizers have been one of the most effective and safest solutions for the unique demands of low temperature sterilization, and are often the low temperature sterilizer of choice.

02.

What is plasma sterilization?

Plasma. Most of us learned in school that there are three states of matter: liquid, solid, and gas. However, there is a fourth state of matter, plasma. Out of the other three states of matter, plasma is the most similar to gas by not having a definite shape or volume. But unlike most gases, plasma is a highly unstable state of matter.

A plasma can be created by heating a gas or subjecting it to a strong electromagnetic field, applied with a laser or microwave generator. This decreases or increases the number of electrons, creating positive or negative charged particles called ions, and is accompanied by the dissociation of molecular bonds, if present.[1]

Here are a few examples of popular plasmas:

Natural Plasmas	Man-made Plasmas
Lightning, fire, the sun, stars, tails of comets, the Northern Lights, auroras, more than 99% of the galaxy.	Neon signs, fluorescent light bulbs, plasma displays used for televisions and computers, and plasma lamps.

Now that you are more familiar with the concept of plasmas, let's take a look at what the U.S. Centers for Disease Control and Prevention (the CDC) has to say about plasma sterilization.

1 - https://en.wikipedia.org/wiki/plasma_(physics)

> “Gas plasmas are generated in an enclosed chamber under deep vacuum using radio frequency or microwave energy (or by adding heat)* to excite the gas molecules and produce charged particles, many of which are in the form of free radicals.
>
> A free radical is an atom with an unpaired electron and is a highly reactive [unstable] species. The proposed mechanism of action of this device is the production of free radicals within a plasma field that are capable of interacting with essential cell components (e.g., enzymes, nucleic acids) and thereby disrupt the metabolism of microorganisms.[2]”

It is this ionized gas, or plasma, which is able to sterilize medical devices, i.e., kill all microorganisms, by a process called oxidation. That is another way of saying that plasma causes a chemical reaction in which microorganisms are deactivated -- from resistant bacterial spores to viruses, fungi, and yeasts.

How does that work?

In short, the plasma sterilizer uses hydrogen peroxide (H_2O_2) as its sterilizing agent. By increasing the heat, the sterilizer converts the liquid hydrogen peroxide into a gas. Further heating of the hydrogen peroxide gas turns some of the gas into plasma. The high heat disperses the molecules into free radicals, which are highly unstable. The free radicals want to return to their natural stable state, so they “search” for matter to attach themselves to in order to accomplish this. What matter do they easily find inside the sterilizer? The microorganisms on your load of endoscopes. When the free radicals attach themselves to the microorganisms on the load of endoscopes, oxidation takes place, and this is what effectively destroys the essential cell components of the germs, e.g., enzymes, nucleic acids, and DNA.

2 - http://www.cdc.gov/hicpac/disinfection_sterilization/13_02sterilization.html

* text was added by Tuttnauer

03.

How does a plasma sterilizer work?

Although different manufacturers have different cycle parameters, they all share the basic commonality of using hydrogen peroxide as the sterilizing agent, which kills the microorganisms on the load in the sterilizer chamber. Let's take a look at what happens inside the sterilizer with a normal cycle.

1. After inserting the load and starting the cycle, the air is extracted from inside the sterilizer chamber by vacuum (approximately zero mbar). In addition, the temperature increases to about 55°C in order to prevent the condensation of hydrogen peroxide on the load during the diffusion/sterilization stage.
2. In some sterilizers, the dosing pump then extracts hydrogen peroxide from the hydrogen peroxide tank and puts it into a vaporizer, where it is converted to gas and plasma states, and is prepared for diffusion.[3]
3. Now begins the actual sterilization stage. Hydrogen peroxide gas and plasma enter in short pulses and diffuse into the sterilizer chamber. The number of pulses and the amount of hydrogen peroxide entering the chamber depend on the cycle, the size of the chamber, and the volume of the load. This step usually takes a couple of minutes. Oxidation begins (sterilization).
4. Gas and plasma are extracted from the chamber into the exhaust channel, where they are exposed to a high-energy electrical plasma field (outside the chamber), where they are "cracked." This means that the gas and plasma are broken into small amounts of water and oxygen. The water evaporates and the oxygen escapes into the air.
5. Vacuum (step 1), preparation for diffusion (step 2), and diffusion/sterilization (step 3) stages are repeated as an extra stringency for ensuring sterilization. [Some manufacturers do not repeat these steps.]
6. The chamber is aerated, readying it for cycle completion.
7. Finally, the chamber is returned to atmospheric pressure. Cycle ends.

3 - In other machines, the hydrogen peroxide is extracted directly into the chamber where it is vaporized. Some manufacturers do not adjust dosage according load.

04.

How is the hydrogen peroxide disposed during the cycle?

There are three common methods for safely removing the hydrogen peroxide from the chamber after sterilization is completed.

1. To “scrub” it. This means extracting it with a vacuum and then processing it in a filter.
2. To “crack” it. This means to break it into its most basic components of water and oxygen, which safely evaporate into the air.
3. Perform both methods above.

Depending on the manufacturer, cracking can take place inside or outside the chamber. The disadvantage of cracking inside the chamber is that it uses up chamber space resulting in less usable chamber volume.

✦ *Tuttnauer’s PlazMax cracks the hydrogen peroxide outside the chamber and allows for more usable chamber volume.*

05.

Is plasma sterilization safe?

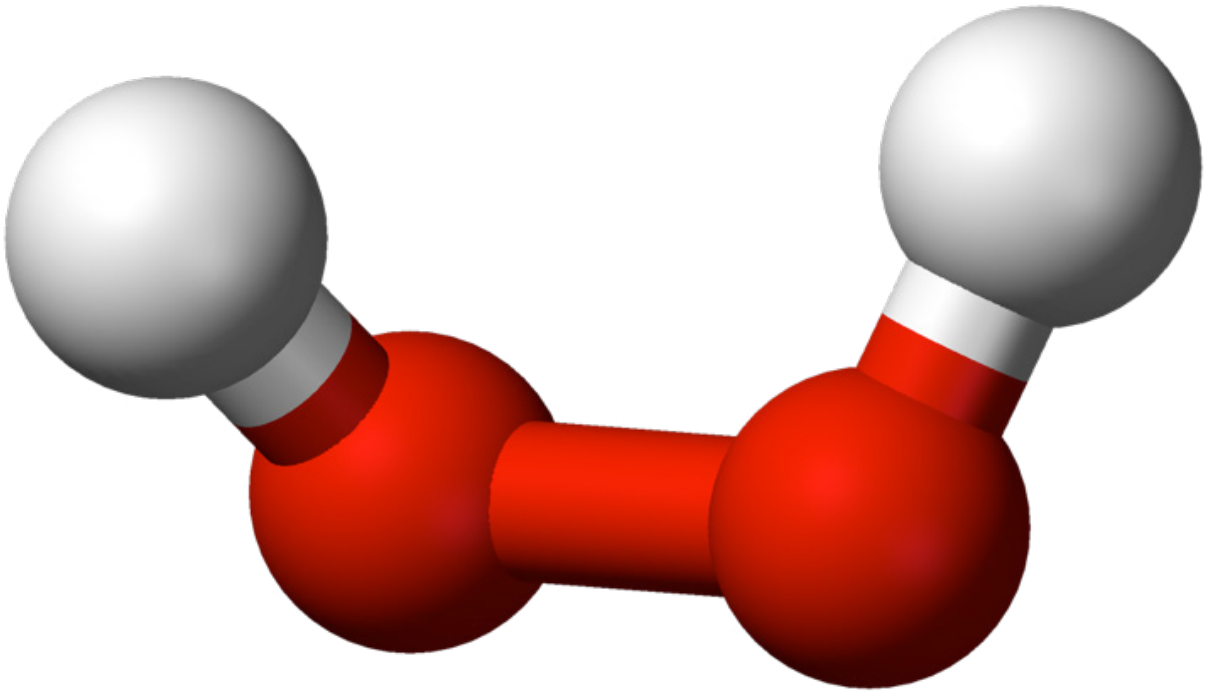
Yes. And here is why.
Plasma sterilization uses hydrogen peroxide as its sterilant. Hydrogen peroxide (H_2O_2), in weaker concentrations, is widely available in pharmacies and used to disinfect wounds and surfaces. It is generally believed to be a safer alternative to chlorine-based bleaches, and the US Food and Drug Administration (FDA) recognizes it as a safe antimicrobial agent.

Hydrogen peroxide is safe for the staff operating the sterilizer, as well as the devices that are exposed to the hydrogen peroxide during sterilization. By ensuring thorough removal of hydrogen peroxide and proper aeration, the load is left without any chemical residues, and is, therefore, safe to handle.

It is recommended to use a low concentration of H_2O_2 in the chamber, so that the load is not significantly affected by the sterilant. It's important to check the level of concentration of H_2O_2 that will be used in the sterilizer you plan to purchase.

✦ *Tuttnauer's PlazMax plasma sterilizer uses a 50% concentration of H_2O_2, which is strong enough to act as an effective sterilant, but not too strong to damage the load. Other manufacturers use a higher concentration of H_2O_2.*

Visual representation of an H_2O_2 molecule



Let's take a side-by-side look at safety concerns with hydrogen peroxide plasma, and the two other main types of low temperature sterilants on the market: ethylene oxide and formaldehyde.

	H_2O_2 Gas Plasma	Ethylene Oxide (EtO)	Formaldehyde
Chemical residues		✓	✓
Safe to handle	✓		
Safe for the environment	✓		
Short aeration time	✓		
Carcinogenic to humans		✓	
Long cycle time due to long aeration time		✓	
Possible toxic residues on surgical instruments		✓	
Flammable		✓	
Toxic gas			✓
Solution irritates skin and can cause allergy			✓
Vapor is irritating to the eyes, nose, and throat			✓
Must be neutralized immediately after use			✓

As you can see from this chart, hydrogen peroxide plasma is the clear winner for safest sterilant on the market, with its non-toxic nature and short aeration time.

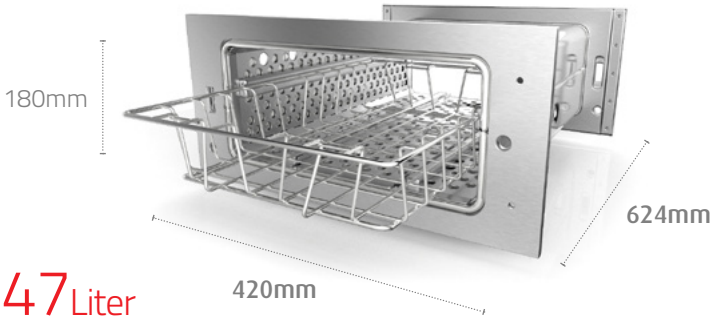
07.

What size plasma sterilizer do you need?

Plasma sterilizers range in size from about 30 liter chamber volume to 200 liters. Here are three questions to consider when figuring out what size is right for you:

1. What size chamber you need will depend on the anticipated size and volume of your loads. What specific equipment do you plan to sterilize and how often? Refer to the manufacturer's instructions on how many lumened and non-lumened devices can be sterilized at one time.
2. How much room do you have available in your Central Sterile Supply Department (CSSD) / Sterile Processing Department (SPD) or Operating Room (OR) for additional sterilizers? Keep in mind that sterilizers of different chamber volume may actually take up the same floor space. Consult your building managers and the manufacturer's options for which model would best suit your needs. [See page 11 below for PlazMax chamber sizes]
3. Consider whether you require the use of loading equipment if you plan to process high volumes, which would require loading containers and transfer carriages. Will the sterilizer chamber volume be large enough to accommodate such equipment? Will you have room to access the front of the sterilizer in order to load and unload the equipment comfortably? And will technicians be able to service and maintain your sterilizer in a tight spot?

✦ Tuttnauer offers a wide range of chamber sizes: 47, 110, and 162 liter volumes.



47 Liter Chamber

110 Liter Chamber

162 Liter Chamber

07.

What are the utility & installation considerations?

UTILITY

Unlike autoclaves, which often require special piping and connections to water, steam, and electricity, the plasma sterilizer is essentially a “plug-and-play” machine. This means all you need to do to operate this sterilizer is to plug it in. There are no special drainage or ventilation requirements. In other words, the only utility necessary to operate the plasma sterilizer is electricity.

It is also worth noting that some plasma sterilizers are built with 1-phase electrical supply whereas others are built with 3-phase electrical supply. The former is more energy-efficient, and will ultimately cost less money to run. It’s important to investigate whether the plasma sterilizer you would like to buy uses 1-phase or 3-phase electrical supply.

INSTALLATION

Plasma sterilizers can be installed quite easily since they are on wheels, and therefore can be moved from one room to another without transport equipment. In addition, as we explained above, once you plug them in, they are ready to sterilize. Most plasma sterilizers are narrow enough to fit through hospital doors, thus making these sterilizers quite mobile.

Tuttnauer’s PlazMax sterilizers use 1-phase electrical supply.

08.

What consumables are needed in order to operate your sterilizer?

Here is the basic list of consumables you will need to operate your sterilizer:

- Hydrogen peroxide sterilant cassettes, bottles, or cartridges
- Filters
- Tyvek sterilization wrapping/pouches
- Chemical and biological indicators
- Incubators for biological indicators

By far, the most important consumable, both in terms of functionality and cost, is the hydrogen peroxide sterilant. Manufacturers supply the H_2O_2 sterilant in cassettes, bottles, or cartridges. Just like when you buy laundry detergent, you want to know which detergent is most economical based on how many cycles you can get out of one bottle, so too, it's important to research how many cycles your sterilizer will run per cassette/bottle/cartridge of hydrogen peroxide sterilant. The amount of H_2O_2 used per cycle depends on the size of the chamber, type and size of the load. Since the sterilant is the major consumable, it is also the most important one to investigate in terms of total cost of ownership.

✦ *Tuttnauer's PlazMax sterilizer efficiently uses available hydrogen peroxide, adjusting the amount of H_2O_2 used according to the load in the chamber while maintaining necessary concentration levels. This ultimately translates to a cost-effective use of the H_2O_2, thus keeping ongoing running costs low. When purchasing a plasma sterilizer make sure to find out if the sterilizer adjusts the amount of H_2O_2 used per load and the cost of the H_2O_2.*

The rest of the consumables are secondary and, depending on the sterilizer manufacturer, may be purchased from third party distributors, or from the manufacturer itself. It is also worthwhile to look into the economics here of who will be your main supplier of consumables, and how much you expect your annual consumable costs to be.

✦ *With PlazMax sterilizers, customers are able to purchase commonly available consumables such as indicators and pouches from any third-party distributor. The only consumable that Tuttnauer requires its customers to purchase directly from its suppliers is the hydrogen peroxide sterilant, in order to maintain the integrity of the H_2O_2.concentration.*

09.

Why does Tuttnauer use only 50% concentration of H_2O_2 while other manufacturers use a higher concentration?

Tuttnauer's PlazMax sterilizer agent uses a 50% concentration of hydrogen peroxide (H_2O_2).

This concentration is strong enough to act as an effective sterilant, but not too strong to damage endoscopes and other flexible heat-sensitive equipment. **This is Tuttnauer's advantage** by using a low concentration of (H_2O_2) in the chamber, so that the load is not significantly affected by the sterilant. Other manufacturers work with cassettes or cartridges. These two are physically small and therefore contain a low volume of liquid. The Hydrogen Peroxide consumption differs by the volume, program and load. By using a cassette or cartridge you will not have the adequate quantity of H_2O_2 for a proper sterilizing process, therefore, the low volume of liquid dictates the necessity of using a higher concentration for having the same effect of sterilization.
In this case, the less concentration of H_2O_2, the more prolonged the endoscope's longevity. **Less is more!**
For instance, think about if you had used the same quantity of water in a normal steam sterilizer, regardless the chamber size, the program and the load, would you have received the same results?

10.

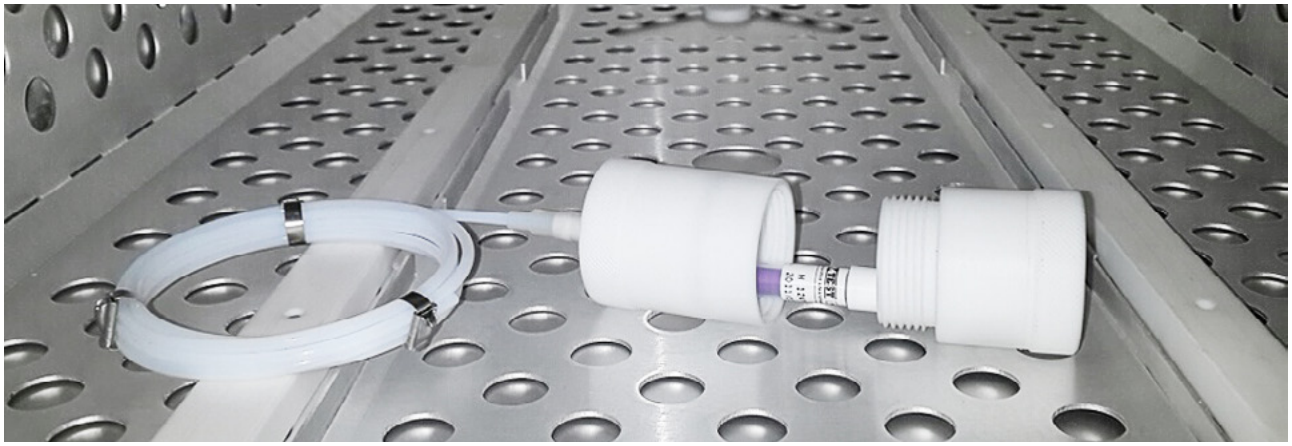
How do you ensure effective sterilization and penetration of H_2O_2?

There are two general tests that can be performed:

1. The Leak Test detects if the chamber is totally sealed and that there are no leaks from outside the machine to the inside. In addition the performance of the vacuum pump is checked during this test.

2. The Penetration Test uses a chemical indicator. This is a quick test to run on the sterilizer first thing in the morning to make sure that conditions for sterilization are being met. This will be verified by a chemical indicator, which shows whether sterilization has been successful. Some manufacturers provide a Process Challenge Device (PCD), which is a kit that includes lumens, connected to a cavity designed to hold an indicator. Successful penetration will be verified by the indicator result.

✦ Tuttnauer's PCD kit is comprised of 1 mm diameter lumens with lengths of 4 meters with both sides open, and 1.4 meter lumens with one side open. These lumens are more difficult to penetrate than your typical load. Thus we know that if we have successfully sterilized the PCD load, all the more so have we sterilized a lesser difficult-to-penetrate load. This is the most reliable test since your typical load won't be as difficult to sterilize as the PCD lumens.

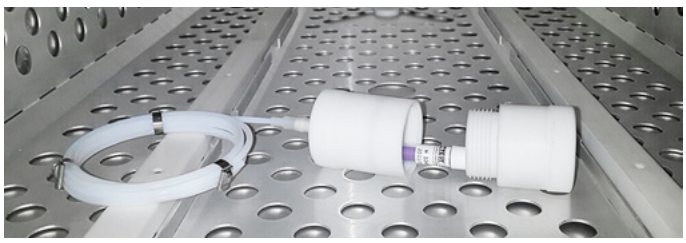


Tuttnauer PCD Kit

11.

How many times I can use the PCD for PlazMax?

The PCD kit for PlazMax is a hardware tool without a predefined shelf life. When working according to the operation manual, you can use this PCD as long as it undamaged.



12.

Sterilization in a PCD of 4 meters length works also in other plasma sterilizer manufacturers even though they say the longest tube is 1.4m. Why is that?

The PCD kit for PlazMax is a hardware tool without a predefined shelf life. When working according to the operation manual, you can use this PCD as long as it undamaged.
There are two PCD types:

1.4m length, only one side is opened, 1mm diameter
4m length, two sides are opened, 1mm diameter
It is a common belief that the longer the tube is, the more challenging it can be. Unfortunately, this is a frequent misconception.
When dealing with such a test, the length is not the critical factor, but the opening setting dictates the challenge scale. When the tube has both sides open (two-way tube), it serves as a straw, suction forces act from both sides and makes it very easy to vacuum all air out along its entire length.

When the tube is blocked on one side, suction forces act from the open side only, therefore, a powerful vacuum is required to remove air from the far dead end.
When running a PCD test, using the 1.4m with one side blocked, it provides an ultimate indication of entire air removal and ensures maximum vaporized hydrogen peroxide spreading into the entire volume. **This is the true challenge.**

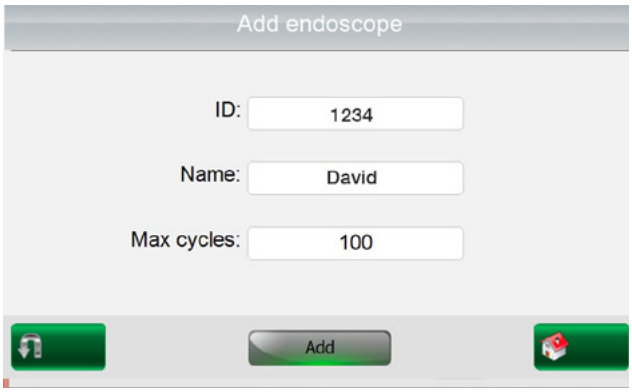
13.

Are there equipment tracing records for endoscopes?

An important question to ask when considering which plasma sterilizer to buy is whether or not the machine comes with the ability to record the sterilization history of the endoscopes.

Tracing endoscope sterilization doesn't just mean verifying whether a particular endoscope was sterilized or not; rather, it means using the endoscope's unique identification number at the start of each cycle in order to track how many times the endoscope has been sterilized. This information is crucial for the proper maintenance and care of your endoscopes. After a certain number of sterilization cycles -- that number depends on the device and the manufacturer -- the endoscopes must be returned to the manufacturer or distributor for a regular maintenance check, which ensures the long life of these delicate and sophisticated devices.

How is it possible to keep track of so many different devices in a busy Sterile Supply Department (SPD) or Operating Room (OR)? If equipment tracking is a necessary feature required for the endoscopes you plan to sterilize, be sure to take that into account when purchasing your next low-temperature sterilizer.

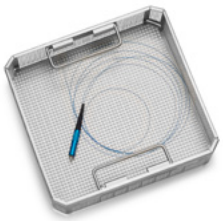


Commonly sterilized devices

Non-Hollow Loads

Electrocautery Instruments

Dopplers



Laser probe

Defibrillator paddles

Thermometer

Ophthalmic lenses

Harmonic cable

Hollow Loads

Laryngscope blade

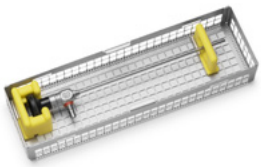
Shaver hand pieces

Fiber optic light cable

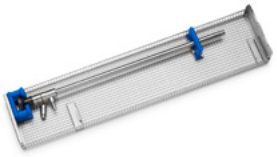
Laryngscope & blades

Laryngscope & blades

Endoscopes

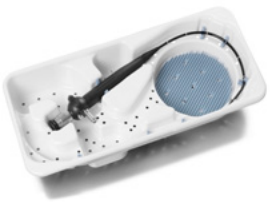


Rigid scope for optics



Rigid scope

Flexible endoscope



Flexible endoscope

Commonly sterilized materials

Common Materials	Metals	Non-Metals
• Stainless Steel • Polyethylene • Teflon	• Stainless steel 300 series • Aluminum 6000 series • Titanium	• Acryl nitrite butadiene styrene (ABS) • Delrin, EVA (Etheyl vinyl acetate) • Fluorinated ethylene propylene (PTFE) • Glass • USP type I borosilicate • Low density polyethylene • Latex • Low density polyethylene • Monel • Neoprene rubber (polychloroprene) • Nylon • Phenolic resin • Polycarbonate • Polyethylene terephthalate (PET) • Polymethyl methacrylate (PMMA) • Polyphenyl sulfone • Polypropylene • Polystyrene • Polysulfone • Teflon (PTFE) • Polyurethane • Polyvinyl chloride (PVC) • Silicone

Materials that cannot be sterilized

• Paper (but very small amounts of paper are possible, e.g. small barcode label)
• Absorbent materials (cellulose)
• Wood, linen, paper, spongy materials
• Liquids
• Powder
• Oil
• Instruments with lumen, having less than 1 mm diameter and/or over 10 m length

Thanks for joining us in our low temperature plasma sterilizer ebook. We hope you have learned a lot and clarified many of the questions you and your team are grappling with in this major and exciting purchase. If we can be of more assistance to you during your research, please contact us.

Your Sterilization & Infection Control Partners

Company Profile

For over 90 years, Tuttnauer's sterilization and infection control products have been trusted by hospitals, universities, research institutes, clinics and laboratories throughout the world. Supplying a range of top-quality products to over 100 countries, Tuttnauer has earned global recognition as a leader in sterilization and infection control.

Global Partnership

At Tuttnauer we feel that business means people dealing with people. We pride ourselves on our reputation for having long-lasting relationships with our customers based on commitment and trust, spanning over decades and distances.

Our Flexibility is Your Advantage

Beyond our wide range of products and ability to customize products to customer requirements, we also manage complete turnkey solutions, including planning, design and installation of equipment, as well as consultation and feasibility studies, for projects of all sizes.

Learn from our Experts

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