

ARBUTUS MEDICAL

DrillCover PRO System

INSTRUCTIONS FOR USE

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Do not modify this equipment.

LBL-093(06)

REF: SYS-015

CONTENTS

1. Warnings	4
2. Intended Use and Technical Description	5
3. DrillCover PRO System Components	6
4. Sterile Loading Procedure	8
5. Sterile Unloading Procedure	16
6. Use in Surgery	19
7. Reprocessing	21
8. Battery, Charger and DF032D Power Tool	27
9. Storage	27
10. Disposal	27

1. WARNINGS



Solutions that contain or release chlorine (eg. chlorine bleach, Presept by J&J) or hydrogen peroxide will damage the product. Refer to the instructions in Section 7: Reprocessing.



Handle with care. Dropping the device on a hard surface can permanently damage the sterile barrier. Impacting the device into pins and K-wires or placing the device over sharps (e.g. drill bits, reamers, saw blades) will cause damage. Follow guidelines for preventing mechanical damage outlined in Section 6.3. Inspect device after each use following procedure outlined in Section 7.4 and replace if integrity has been compromised.



Drilling into bone can produce heat at the drilling site and damage surrounding bone. Control bone temperature. Drill only in short bursts and use irrigation.



The device is not suitable for use in oxygen rich environments. Ensure staff have been trained on surgical fire prevention associated with electrical equipment, and have a plan of action in the case of fire.



For electrical safety, consult the enclosed Makita DF032D tool manual. This device generates electromagnetic interference within approved limits for medical devices. If interference were to occur in a particular application, stop operation of the device. Reorient or relocate the affected equipment. There is no significant risk of reciprocal interference posed by the device during specific investigations or treatments.

For more information regarding these warnings, contact Arbutus Medical.

2. INTENDED USE AND TECHNICAL DESCRIPTION

The DrillCover PRO System is a battery powered orthopaedic drill/reamer indicated for trauma and reconstructive orthopaedics. The DrillCover PRO System is comprised of the DrillCover PRO Power Tool used with one of the two adapters, InLine Adapter for non-cannulated drilling and reaming or Cannulated Adapter for either cannulated or non-cannulated drilling and reaming. Each adapter accepts reamers and drill bits with either Hudson or Zimmer (also referred to as Stryker, Hall-Jacobs or Modified Trinkle) quick-connect shanks. A selection of different drill chucks and quick-connect attachments is available for use with either adapter. All components of the system are intended to be used together.

The device is intended for use by trained orthopaedic surgeons. Surgical staff require training in sterile technique and surgical fire prevention.

Contraindications: oxygen rich environments or patients not indicated for orthopaedic procedures.

Specifications:

Storage/Transport	10-40°C (50-104°F) and 700-1060 hPA, 30-70% humidity.
Use Environment	10-40°C (50-104°F) and 700-1060 hPA, 30-70% humidity.
Sterilization Specification	Prevacuum or gravity displacement autoclave.

In this instructions for use,


conveys a general warning message which describes a foreseen risk.


conveys mandatory action.


tells the user to refer to these instructions for use.

Classification of device when assembled for use: Internally powered ME equipment. Adapters and attachments are Type B applied parts. We do not claim IPXX ingress protection (IPX0). Sterilization of patient-contacting components by moist heat. Not suitable for use in oxygen rich environment. Not suitable for continuous operation.

3. DRILLCOVER PRO SYSTEM COMPONENTS

DrillCover PRO Linen and Cover Guard



Linen



Cover Guard

DrillCover PRO Power Tool



Drill/Reamer



12V battery



Charger

Adapters and Attachments



Cannulated Adapter



InLine Adapter



AO Small
Quick Connect



3mm Drill
Chuck Keyless



7.4mm Drill Chuck



7.4mm Drill
Chuck Keyless



10mm Drill Chuck

4. STERILE LOADING PROCEDURE

The following step-by-step procedure describes the sterile loading process for the DrillCover PRO System. Two team members are required for loading. Observe when a sterile or nonsterile team member should perform each step.

Arbutus Medical recommends practicing the sterile loading procedure before clinical use.

The purpose of the loading procedure is to install the non-sterile power tool into the sterile linen without contaminating the outside of the linen. Complete the loading procedure before the sterile team member is contaminated by biohazard during the procedure.

4.1. Obtain Sterile Equipment

Sterile Team Member

1. Collect sterile parts, including: DrillCover PRO linen, required adapters and attachments, and appropriate chuck keys.
2. Check parts for cleanliness (unremoved traces of blood or tissue from previous procedures).
3. If soiled, send soiled components for reprocessing and replace with clean and sterilized components.



⚠ *Chuck keys are not interchangeable between different size chucks. Ensure the correct chuck key is available for the procedure.*

4.2. Prepare the Drill/Reamer

Always put the Forward/Reverse switch in "Lock" position before attaching and removing adapters, attachments, drill bits, and reamers.



Nonsterile Team Member

1. Install a charged battery and confirm that the tool is functioning by pressing the trigger and observing if it turns on. The operation of the drill/reamer can be terminated at any time by letting go of the trigger.
2. Set the tool mode to the desired setting using the drill/ream switch. Push forward for drilling or pull backward for reaming.

   NOTE: Tool mode can be changed during the procedure by adjusting the switch through the linen.
3. Set forward/reverse switch to "lock" by sliding it to the middle position.



4.3. Prepare Sterile DrillCover Linen

Sterile Team Member

1. Hold linen by buckles from the top.
2. Rotate both hands palm-up to roll the edge back.

*Make sure the gloves are **tucked under** fabric and **away** from the opening when holding the linen.*





4.4. Transfer the Power Tool to the Linen

Sterile Team Member

1. Present the rolled linen while holding it in the air.

Nonsterile Team Member

1. Hold drill/reamer near battery pack, and ensure the distal end of the drill is facing the grommet.
2. Drop the drill/reamer inside the linen. **The inside of the linen is now contaminated and non-sterile.**



There is a risk of contaminating the sterile team member's gloves during the transfer of the drill/reamer. Ensure that the transfer only occurs after the linen has been rolled back and the sterile team member's gloves are protected by the cuff.

Ensure that the sterile team member is prepared to accept the drill/reamer without dropping the device.

If the drill/reamer is inserted in the wrong orientation it could be difficult to reorient the device while preserving sterility of the cover.

4.5. Close the DrillCover Linen

Sterile Team Member

1. Rotate hands palms-down to unfold linen in air.
2. Carefully lay linen on a sterile surface. Roll the webbing 3 times.
3. Buckle **away** from the direction of roll.
4. Loop the rolled up end over the battery.

⚠ *If the closure is not rolled 3 times and buckled away from the roll direction, it may unfold during use.*

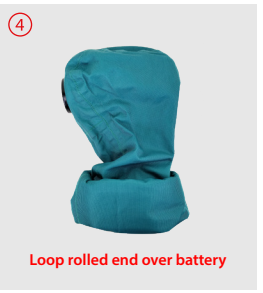
The opening in the Grommet leads to the non-sterile inner side of linen. Avoid touching the grommet area while handling device in this step. Handle carefully until the adapter is connected.









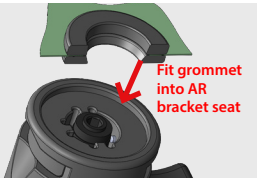


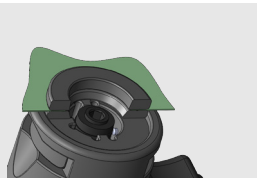
4.6. Connect the InLine Adapter or Cannulated Adapter

⚠ *Adapters cannot be exchanged during surgery. Select the adapter that is most appropriate for the procedure.*

Sterile Team Member

1. Place the device on its proximal end so that the grommet and the opening are facing upward. Align and fit the grommet into the AR bracket seat. Handle the Grommet carefully to avoid contacting the non-sterile inner side of the device.





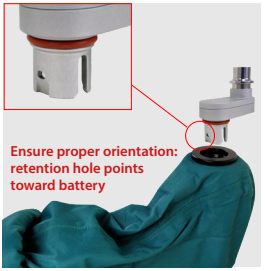
2. Determine correct orientation of the adapter – retention hole points toward the battery. Insert the adapter through the grommet **(do not withdraw!)** and firmly press it into the AR Bracket until a click is heard.
3. If the click is not heard, continue applying light pressure to the adapter and at the same time turn the Hudson/ Zimmer sleeve. This will realign the engaging shafts and the adapter will drop in and lock (indicated by the click).

INLINE ADAPTER:





CANNULATED ADAPTER:





4. Verify that the adapter is locked by tugging on it. **If the adapter pulls out, beware that the inserted end is no longer sterile** and may contaminate the outside of the linen or the rest of the sterile field. To mitigate this risk, always have a spare sterile adapter available.
5. Pull the fabric taut on the drill/reamer. Pull the opening of the cover guard over the adapter, then pull the other end over the drill. Tuck excess fabric underneath the cover guard.



⚠ *Once inserted, the inserted portion of the adapter is no longer sterile. Do not hesitate or withdraw the adapter once the insertion has begun. Ensure the adapter is fully inserted and locked (indicated by the click)*



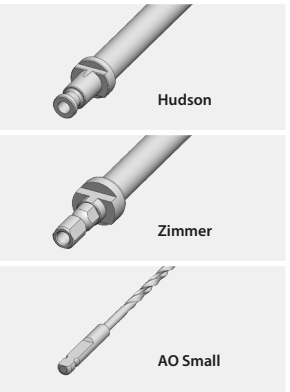
❗ *Do not remove the Cover Guard from the device. Cover Guard protects the DrillCover PRO linen from impacting pins, K-wires or other hardware during use, from puncture by K-wire while loading or use, from accidentally contacting sharps or being dropped too hard on hard surface, etc..*



4.7. Select Appropriate Attachment

Sterile Team Member

1. Without an attachment, adapters can accept drill bits and reamers with either Hudson or Zimmer (also referred to as Stryker, Hall-Jacobs or Modified Trinkle) quick-connect shanks.
2. For drill bits with round shanks, use the appropriate drill chuck attachment, 7.4mm, 10mm or 7.4mm keyless. The keyless chuck allows for faster exchange of round shank drill bits and faster re-chucking of K-wires. The 10mm chuck provides better gripping force for large diameter shanks.
3. For drill bits with AO Small quick-connect shanks, use the AO Small quick-connect attachment.



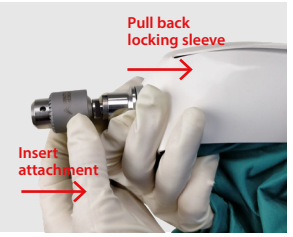
4. For all other quick-connects and for large diameter round shank drill bits, Arbutus Medical recommends the 10mm drill chuck attachment. This attachment allows for a greater gripping force sufficient for most demanding applications, such as acetabular reaming.

4.8. Install or Exchange Attachments or Zimmer and Hudson Drill Bits and Reamers

Sterile Team Member

1. Ensure the Forward/Reverse Switch is in the middle ("Lock") position.
2. Pull back the locking sleeve on the adapter and fully insert the attachment, drill bit or reamer.
3. Release the locking sleeve.
4. Ensure the attachment/drill bit/reamer is locked by tugging on it.
5. To remove attachment/drill bit/reamer, put the Forward/Reverse Switch in the middle ("Lock") position, then pull back the sleeve and pull out the attachment/ drill bit/reamer.





4.9. Install or Exchange Round Shank Drill Bits in Drill Chucks

Sterile Team Member

1. Ensure the Forward/Reverse Switch is in the middle ("Lock") position.
2. Turn the chuck collar by hand in counter-clockwise direction until the chuck is open enough to accept the drill bit.
3. Insert the drill bit and close the chuck by hand by turning it clockwise to lightly grip the drill bit.
4. Lock the chuck by fully inserting the chuck key and turning it in the clockwise direction, or tighten by hand for keyless chucks.
5. To remove the drill bit, put the Forward/ Reverse Switch in the middle ("Lock") position, then loosen the collar by inserting and turning the chuck key in counter-clockwise direction, or by twisting the collar in counter-clockwise direction by hand for keyless chucks.

⚠ *Ensure the chuck key is fully inserted to avoid stripping of the key teeth or chuck collar teeth.*







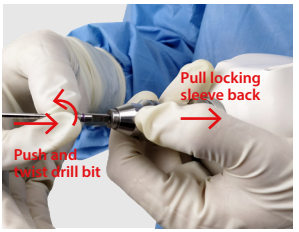


4.10. Install or Exchange AO Small Drill Bits

Sterile Team Member

1. Ensure the Forward/Reverse Switch is in the middle ("Lock") position.
2. Insert the drill bit into the AO quick-connect attachment.
3. Pull back on the locking sleeve and twist the drill bit while simultaneously trying to insert it further into the attachment. When the shank is properly aligned, it will advance further into the quick connect.
4. Release the locking sleeve when the drill bit is fully inserted.
5. Ensure the drill bit is locked by tugging on it.
6. To remove drill bit, put the Forward/ Reverse Switch in the middle ("Lock") position, then pull back the sleeve and pull out the drill bit.





5. STERILE UNLOADING PROCEDURE

The following step-by-step procedure describes the aseptic unloading process for the DrillCover PRO System. Two team members are required for unloading. Note when a sterile or a nonsterile team member should perform each step.

The purpose of the unloading procedure is to remove the power tool from the DrillCover PRO linen without contaminating it with biohazardous material. This ensures the power tool remains clean and safe to handle.

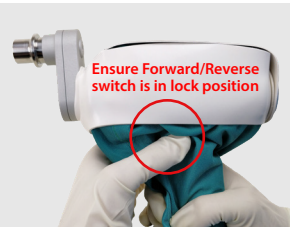
Only unload the power tool after the procedure has been completed and maintaining sterile field is no longer required.

To control biohazard, the sterile team member must avoid contacting the power tool while unloading.

5.1. Remove Sharps and Attachments

Sterile Team Member

1. Put the Forward/Reverse Switch in the middle ("Lock") position.
2. Remove drill bit or reamer from the device.
3. Remove any attachments. Grip the chuck key in the chuck to keep them together.
4. **Leave the adapter attached to the tool.**





Removing the adapter would open the path for the biohazard to contaminate the tool. Keep the adapter attached to the tool.

5.2. Open Linen for Power Tool Removal

Sterile Team Member

1. Remove the cover guard from the power tool and lay the tool down on a flat surface.
2. Unbuckle the clip and unroll the linen.
3. Open linen, hold device by the buckles, and roll back the cuff while taking care not to contact the power tool or the interior of the linen. This step is easier to perform if the weight of the tool is still resting on the surface.
4. Reveal drill/reamer to non-sterile team member.





Treat the outside (dark green fabric, webbing, and buckles) as contaminated and the inside (light green) fabric as clean.

5.3. Invert Linen

Nonsterile Team Member

1. Grab drill/reamer near the battery pack.
2. Hold the tool steady while sterile team member pulls off and inverts the linen.

Sterile Team Member

1. Pull linen off the drill/reamer, only touching the outside, until the linen is inverted.





Nonsterile Team Member

1. Hold the the power tool by the AR Bracket with one hand and hold the adapter through the linen with the other hand.
2. Press on the adapter release button on the AR Bracket and simultaneously pull out the adapter.
3. Hand linen with adapter still inside to the sterile team member.



The inside of the linen is not sterile. Perform this step only if maintaining sterile field is no longer required.

Sterile Team Member

1. Remove adapter from linen.
2. Send linen, adapters and attachments for reprocessing. Keep linen separate from sharps, adapters and attachments to prevent damage to linen.

6. USE IN SURGERY

The following directions indicate how to use the drill/reamer during surgery. Arbutus Medical recommends first becoming familiar with the location and use of switches and buttons with the DrillCover PRO linen off.

6.1. Drill/Reamer Controls

1. The drill/reamer is activated by squeezing the trigger. When the trigger is released, the drill/reamer turns off. The amount of trigger squeeze modulates the speed.
2. The Drill/Ream button switches the tool mode between drilling and reaming modes. In Drilling mode, the tool runs at 1500 rpm. In Reaming mode, the tool runs at 450 rpm. Only use the tool in the appropriate mode for each operation.
3. The Forward/Reverse switch reverses the direction of rotation. When the switch is placed in the middle, the trigger is locked and cannot be squeezed. Ensure the spin direction is correct before squeezing the trigger.
4. The Adapter Release button enables the detachment of adapters from the power tool.



⚠ *Reaming while in Drilling mode may cause injury or bone necrosis due to high speed.*

❗ *Driving some flexible intramedullary reamers in reverse may cause the reamer to get stuck. Ensure the spin direction is always set to forward when using unidirectional IM reamers.*

⚠ *Accidental actuation of the Adapter Release Button during use may result in breach of sterility.*

6.2. Controlling Heat and Plunge

Always use sharp drill bits and reamers. Dull drill bits and reamers create more friction and generate more heat. The plunge through the posterior cortex increases greatly when dull drill bits are used because greater force must be applied to drill the hole.

To reduce the risk of thermal necrosis, Arbutus Medical recommends using irrigation and drilling in short bursts to prevent excessive heating of bone tissue.

For reaming, it is recommended to avoid increasing reamer sizes in large increments. Always ream with the tool switched to reaming mode.

⚠ *Always use sharp drill bits and reamers to reduce thermal necrosis and plunge.*

6.3. Guidelines for Preventing Mechanical Damage to the DrillCover PRO Linen

If the reprocessing instructions are followed , the textile is expected to maintain the level IV liquid barrier rating for 75 autoclave cycles. Aside from incorrect reprocessing, the primary cause of premature end of life of DrillCover Linen is mechanical damage. Always inspect the integrity of DrillCover PRO Linen (Section 7.4) before the next use. The following guidelines will help reduce the likelihood of accidental mechanical damage.

- Always use the cover guard with the DrillCover PRO power tool.
- Avoid impacting pins, K-wires, and other hardware with the power tool.
- Do not place the device over sharps (e.g. drill bits, reamers, saw blades). Arbutus Medical recommends that the device is kept in a dedicated stainless steel tray or basin during surgery to prevent accidental contact with sharps.
- Do not drop the device onto a hard surface from any height if the cover guard is not in place.

⚠ ***Breach of sterility can occur if the DrillCover linen is damaged during use.***

7. REPROCESSING

The following step-by-step instructions describe the reprocessing procedure for the DrillCover PRO components. It is important to carefully follow these steps to ensure the device is not damaged and remains safe to use.

Timely reprocessing is important as it will prevent the soil from drying and setting.

Separate DrillCover linen from adapters, attachments, sharps and other instruments before reprocessing. The lifetime of the DrillCover PRO linen is 75 uses when following these guidelines. Reprocessing has a minimal effect on adapters and attachments and their lifetime is typically determined by mechanical wear and damage due to use.

Reprocessing linen together with sharps and hard objects may result in damage to the linen and compromised sterility.

This device is not suitable for automated cleaning.

Do not exceed 75 uses for the DrillCover PRO linen and always reprocess in accordance with these guidelines.

7.1. Cleaning of the Power Tool

1. If the prescribed unloading procedure is used, there is no need to disinfect the power tool as it never contacts biohazard. If required, the outside of the power tool can be wiped with isopropyl, ethanol, or a similar disinfectant that does not require rinsing. Wipe the battery first, then remove battery prior to wiping the rest of the device. Do not wipe over the metal contacts of the battery to avoid damaging the battery. Ensure that no liquid penetrates the inside of the power tool as this may cause permanent damage. If the liquid penetrates the power tool, allow sufficient time to dry before reconnecting the battery and using the device.
2. Remove drill battery and place in charger. The battery takes approximately 30 minutes to charge. Keep the charger away from biohazard. Do not allow any liquid to come into contact with the charger.

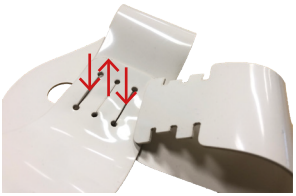
The electrical components of the drill and battery cannot withstand water. Use caution to avoid getting water inside the plastic casing of the drill.

For additional electrical safety information and operating instructions regarding the use of the charger, battery and power tool, consult the enclosed Makita DF032D tool manual.

7.2. Cleaning and Disinfection of DrillCover Linen and Cover Guard

Clean DrillCover linen and cover guard in pH-neutral enzymatic solution designed for surgical instruments (eg. Medzyme) to remove blood and tissue from the device. Clean linen and cover guard separately from sharps, adapters, attachments and other instruments to prevent damage to the device.

If the cover guard is excessively soiled, it may be disassembled for cleaning. To disassemble the cover guard, unweave the end of the top strap from the slots in the lateral straps. To reassemble the cover guard after cleaning, overlap the lateral straps and line up the slots. Then, weave the end of the top strap through the slots.



1. Prepare enzymatic solution using manufacturer's instructions. Immerse linen and cover guard and soak for the prescribed amount of time.



⚠ *Any solution with a high or low pH may damage the instrument. Enzyme concentration should follow manufacturer recommendations. Do not use dish soap, iodine, bleach, cold-soak solution, chlorhexidine-based solution, laundry soap or surgeons hand scrub.*

2. Scrub soiled areas of linen and cover guard in the enzymatic solution using a soft-bristled, non-abrasive brush under the surface of the solution to minimize splashing. Pay special attention to crevasses on the buckles, between the grommet and fabric, and between the sheets of the cover guard. Remove all visible soil.

⚠ *Metal brushes or scouring pads must be avoided as this will damage the linen.*
⚠ *Do not scrub the linen fabric against itself as this will reduce its expected lifetime.*

3. Rinse thoroughly in water and allow excess water to drain.
4. Disinfect DrillCover linen and cover guard using an appropriate pH-neutral disinfectant solution (e.g. Cydex OPA) to make it safe to handle for inspection.

⚠ *Solutions that contain or release chlorine (eg. chlorine bleach, Presept by J&J) or hydrogen peroxide will damage the device.*

5. Prepare disinfecting solution using manufacturer's instructions.
6. Soak linen and cover guard in the solution and ensure all areas of the device are submersed. Keep submersed for the prescribed amount of time to disinfect the device.
7. Rinse thoroughly in water and allow excess water to drain.
8. Allow device to dry completely before sterilization. Remove excess moisture with lint-free, soft absorbent towel to speed up drying. Do not wring or twist the device. Hang linen in a drying cabinet, or on a drying rack in front of a fan.

⚠ *Autoclaving the linen while wet will reduce its expected lifetime.*

7.3. Cleaning and Disinfection of Attachments and Adapters

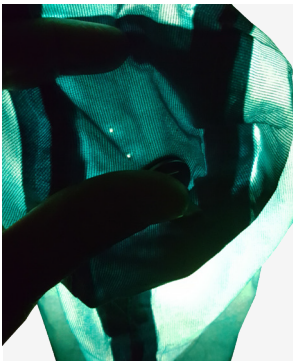
1. Clean and disinfect attachments and adapters in the same manner as the linen. Keep hardware separate from linen to prevent damage to linen.
2. Pay special attention to crevices and hard to reach areas. Scrub adapter and attachment bores with a channel-cleaning brush.
3. While cleaning chucks, open and close the jaws in order to reach all areas inside the chuck.
4. While cleaning quick-connects, open and close the locking sleeve in order to clean the area underneath it.

7.4. Inspection

1. Inspect all components of the device for visible soil under good lighting conditions.
2. Ensure that the chuck keys engage with the chucks and that the chucks fully open and close. Leave the chuck in fully open position.
3. Ensure that quick-connect sleeves fully retract and close. Ensure that quick-connects engage with respective quick-connect shanks.
4. Ensure that the attachments properly engage with adapters and that adapters properly engage with the Drill/Reamer.
5. Inspect adapters for presence and integrity of O-rings. Inspect the cover guard for through cuts and tears.

6. Inspect linen for obvious tears and rips in fabric or seams, check for integrity of the buckles, and ensure that the grommet is still firmly attached to fabric. Invert the linen and inspect integrity of seam tape.
7. Invert the linen back to the right side and place it over a light fixture with bright cold light source (eg. fluorescent light bulb). Look for pin holes in fabric. Move the linen around on the light fixture to ensure all areas are inspected. Preferably, do this step in a dark room to make it easier to spot pin holes.
8. If linen passes inspection, record use on the tracking grid located on the inside of the linen, by marking one square using a laundry pen. If linen fails inspection, remove it from clinical use.

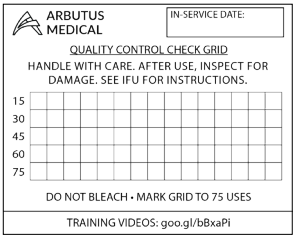




***DAMAGED COMPONENTS:** If a part is damaged, discard and contact Arbutus Medical for replacement information.*

***BLOOD:** Check for blood residue/other stains. If found, send for re-cleaning. (Note: Dye residue is acceptable).*

***STERILIZATION TAPE:** Remove any tape and adhesive residue. If you cannot remove, send for re-cleaning.*



7.5. Sterilization

7.5.1 Gravity Displacement Sterilizer

Sterilize linen in a separate wrapper from sharps, adapters, atachments, and other hard instruments to prevent damage.

1. Wrap DrillCover Linen and Cover Guard:

    i. Lay linen flat.
    ii. Fold lengthwise once.
    iii. Fold widthwise twice, webbing side first, then grommet side on top with the grommet facing upward.
    iv. Place cover guard on top of linen.
    v. Wrap in two 18" x 18" sterilization wrappers using sequential envelope folding technique. Include a sterile indicator or sterile indicator tape.



Do not fold linen along the same lines after each use as this will create concentrated areas of wear at crease lines, reducing the lifetime of the DrillCover linen.

1. Wrap adapters, attachments, and chuck keys:

    i. Individually wrap each adapter and attachment in two 12" x 12" sterilization wrappers using sequential envelope folding technique. Wrap chuck keys with chucks. Include a sterile indicator or sterile indicator tape.



2. Place wrapped components in autoclave and run the autoclave using these sterilization settings:



TEMPERATURE	121ºC (249.8ºF)
EXPOSURE TIME	30 minutes
DRY TIME	60 minutes

7.5.2 Prevac (Dynamic Air Removal) Sterilization

1. Fold DrillCover linen once lengthwise and insert into a sterilization case (3/4 Aesculap case or equivalent).
2. Add cover guard to the container.
3. Separate metal components from linen by using a separate sterilization container or partitions within the same container.
4. Sterilize per parameter set 1 or 2.

Parameter Set 1:

TEMPERATURE	132ºC (269.8ºF)
EXPOSURE TIME	4 minutes
DRY TIME	30 minutes

Parameter Set 2:

TEMPERATURE	134ºC (273.2ºF)
EXPOSURE TIME	3 minutes
DRY TIME	30 minutes

8. BATTERY, CHARGER AND DF032D POWER TOOL

The power tool is supplied with two 1.5Ah batteries. Higher capacity, 2Ah or 4Ah, replacement batteries are available to order.

For detailed information on battery, charger and the DF032D power tool, consult the enclosed Makita DF032D tool manual. Ensure all relevant safety and use information covered by the manual is read and fully understood before using the device.

9. STORAGE

Store device in a cool, dry place to maximize the lifetime of the product.

10. DISPOSAL

DrillCover linen and hardware can be disposed with other biohazardous waste or it can be sterilized and then disposed as regular non-biohazardous waste.

Protected by US Patent US20170027658A1

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