ARBUTUS MEDICAL

DrillCover Hex System

INSTRUCTIONS FOR USE

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Safe Surgery for All

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Do not modify this equipment. Do not service the device. Service is not intended to be performed by the operator. If troubleshooting, contact Arbutus Medical.

LBL-003(12)

CONTENTS

1. Warnings	4
2. Intended Use and Technical Description	5
3. DrillCover Hex System Components	6
4. Sterile Loading Procedure	7
5. Aseptic Unloading Procedure	12
6. Use in Surgery	14
7. Reprocessing	15
8. Battery, Charger and DCF610 Power Tool	21
9. Storage	21
10. Disposal	21

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. 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. Insert a strong, cool light inside of the Drill Cover linen to inspect for damage.

Drilling of bone can produce heat at the cutting 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 Dewalt 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.

Do not oil or lubricate unless with biocompatible lubricant.

For more information regarding these warnings, contact Arbutus Medical.

2. INTENDED USE AND TECHNICAL DESCRIPTION

This instructions for use gives users essential information to prepare the device for use and to reprocess for re-use. The DrillCover Hex System is a battery powered drilling system equipped with a standard hex quick-change drive and reusable aseptic enclosure. The device is meant for use by orthopaedic surgeons. Surgical staff require training in sterile technique and surgical fire prevention. The intended patient population is patients indicated for trauma or reconstructive procedures involving orthopaedic bone drilling.

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

Specifications

Drill Specification	DCF610
Charger Specification	DCB113 or DCB115
Battery Specification	DCB120 or DCB127 See charger and battery manual for associated charger and battery specification.
Storage Environment	10-40°C and 700-1060 hPA, 30-70% humidity.
Use Environment	10-32°C 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.

 signifies a type B applied part, not suitable for cardiac applications.

This equipment has been evaluated for compliance with IEC60601-1. Any modification will require evaluation to the requirements of this standard.

Classification of device when assembled for use: Internally powered ME equipment. DrillCover linen and chuck adapter components 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. Suitable for continuous operation.

3. DRILLCOVER HEX SYSTEM COMPONENTS

4. STERILE LOADING PROCEDURE

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.

Two team members are required for loading. Note when a sterile or nonsterile team member should perform each step. Complete the loading procedure before the sterile team member is contaminated by biohazard during the procedure.

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

4.1. Obtain Sterile Equipment

Sterile Team Member

1. Collect sterile parts, including: DrillCover linen, chuck adapter, and chuck key.
2. Check parts for cleanliness (unremoved traces of blood or tissue from previous procedure).
3. If soiled, send soiled components for reprocessing and use a cleaned and sterilized DrillCover.

4.2. Prepare the Drill

Nonsterile Team Member

1. Install a charged battery and confirm that the drill is functioning by pressing the trigger and observing if it turns ON.
2. Ensure toggle switch is set to forward position.
3. Ensure torque is set to "MAX".

⚠ *A torque setting less than 'MAX' may be insufficient to drill holes in cortical bone.*

4.3. Prepare Sterile Linen

Sterile Team Member

1. Hold the linen by the buckle tabs.
2. Roll the linen edge back. Only expose the inside lining of the linen to the non-sterile team member.
3. Hold the linen so that your sterile gloves are tucked under the folded fabric cuff and protected by the fold.

4.4. Transfer the Drill to the Linen

Sterile Team Member

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

Nonsterile Team Member

2. Hold the drill by the battery and pay attention to the orientation of the drill.
3. Drop the drill inside the linen so that it only touches the fabric on the inside. **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.*

❗ *Ensure that the sterile team member is prepared to accept the drill **without dropping** the device.*

⚠ *If the drill is inserted in the wrong orientation, it could be diffficult to reorient the device while preserving the 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.
3. Roll the webbing 3 times.
4. Buckle **away** from the direction of roll.

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

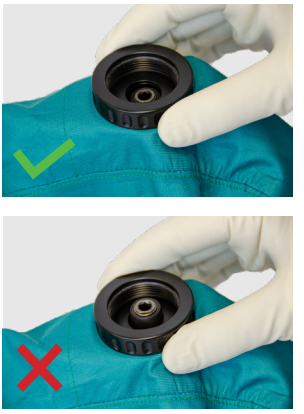
❗ *Keep nose piece facing up at all times. Do not let it touch sterile field.*

4.6. Connect the Chuck Adapter

Sterile Team Member

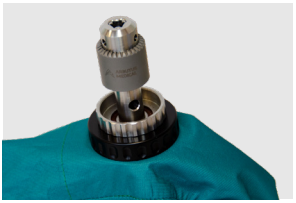
❗ *Do not let quick-release chuck come out of nose opening.*

1. Keep nose piece facing up.
2. Pull back excess fabric so the quick-release chuck can be seen.



3. Insert chuck adapter into quick-release chuck. You should hear a click sound.
4. Screw the chuck adapter and the nose piece together until O-ring is no longer visible.
5. Check the engagement between Chuck Adapter and drill by pulling up on the chuck.

⚠ *Mind that the inside of the chuck adapter is contaminated once it contacts the drill.*



4.7. Install the Drill Bit

Sterile Team Member

1. Insert drill bit into the chuck.
2. Tighten with chuck key.

5. ASEPTIC UNLOADING PROCEDURE

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

Two team members are required for unloading. Note when a contaminated or a clean team member should perform each step.

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

5.1. Remove Drill Bit

Contaminated Team Member

1. Remove the drill bit from the chuck.

5.2. Open Linen for Power Tool Removal

Contaminated Team Member

1. Lay the tool down on a flat surface.
2. Unbuckle the clip and unroll the linen.

Do not unscrew chuck adapter from the nose piece.

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3. Open linen, hold device by the buckles, and roll back the cuff without touching the inside of the linen. This step is easier to perform if the weight of the tool is still resting on the surface.
4. Reveal drill to non-sterile team member.

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

5.3. Invert Linen

Clean Team Member

1. Grab drill near the battery pack and hold steady.

Contaminated Team Member

2. With the drill and the chuck adapter still connected, pull linen off the drill, only touching the outside, until the linen is inverted.

Clean Team Member

3. Hold quick-release chuck collar and push forward to disengage the Chuck Adapter (see red arrow in picture). No turning is required. Pull drill back.

Contaminated Team Member

4. Invert the linen back to the right side so that the nose is visible. Unscrew the chuck adapter from the nose piece.
5. Send soiled components for reprocessing.

Keep linen separate from chuck adapter and other metal components to prevent damage to linen.

6. USE IN SURGERY

6.1. Drill Controls

1. The drill is activated by squeezing the trigger. The amount of trigger squeeze modulates the speed.
2. 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 use.

6.2. Controlling Heat and Plunge

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

To reduce the risk of thermal necrosis, Arbutus Medical recommends using irrigation and drilling in short bursts.

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

6.3. Guidelines for Preventing Damage to the DrillCover Hex Linen

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

- 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.

⚠ ***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 Hex. It is important to carefully follow these steps to ensure the device is not damaged and remains safe to use.

Separate DrillCover Linen a from hardware and other sharp and hard objects before reprocessing.

⚠ *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.*

⚠ *The lifetime of the DrillCover linen is 75 uses when following these guidelines.*

7.1. Cleaning of the Power Tool

1. 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.
2. Remove drill battery and place in charger. The battery takes approximately 30 minutes to charge. Do not allow any liquid to come into contact with the charger. The battery may be stored in the charger.

⚠ *The electrical components of the drill and battery cannot withstand liquids. Use caution to avoid getting liquid inside the plastic casing of the drill.*

7.2. Cleaning and Disinfection of DrillCover Linen

7.2.1. Cleaning

Clean DrillCover linen in pH-neutral enzymatic solution designed for surgical instruments (eg. Medzyme) to remove blood and tissue from the device.

Clean the linen separately from the chuck adapter, chuck key, and other sharps or instruments to prevent damage to the device.

1. Scrub soiled areas of the DrillCover components in the enzymatic solution using a soft-bristled brush under the surface of the solution to minimize splashing. Pay special attention to crevasses on the buckles, between the nose piece and fabric.

⚠ *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, presept, cold-soak solution, chlorhexidine-based solution, laundry soap or surgeons hand scrub.*

2. Carefully inspect for any signs of residual soils. Repeat step 2 until no residuals remain.

⚠ *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.

7.2.2. Disinfection

Disinfect DrillCover linen using an appropriate pH-neutral disinfectant solution (e.g. Cydex OPA).

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

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1. Prepare disinfecting solution using manufacturer's instructions.
2. Soak linen in the solution for the prescribed amount of time.
3. Rinse thoroughly in water and allow excess water to drain.
4. 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.

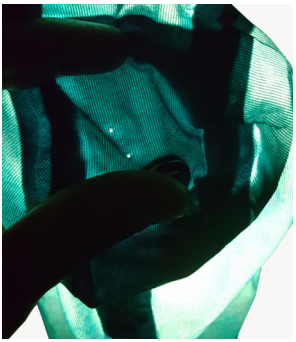
⚠ *Autoclaving the linen while wet will reduce its expected lifetime.*

7.3. Cleaning and Disinfection of Chuck Adapter and Chuck Key

1. Clean and disinfect the chuck adapter and chuck key 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 the inside of the chuck and shaft using a channel cleaning brush.
3. Open and close the chuck while flushing irrigation through the chuck in order to remove any residual soil. When done, leave the chuck in fully open position.

7.4. Inspection

1. Inspect all components of the device for visible soil under good lighting conditions.
2. Ensure that the chuck key engages with the chuck and that the chuck fully opens and closes. Leave the chuck in fully open position.
3. Inspect chuck adapter for presence and integrity of O-ring.
4. Inspect linen for obvious tears and rips in fabric or seams and check for integrity of the buckles. Invert the linen and inspect integrity of seam tape.
5. Invert the linen back to the right side and place it over a light fixture with 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.
6. Record use on the tracking grid located on the inside of the linen, by marking one square using a laundry pen.



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IN-SERVICE DATE:

QUALITY CONTROL CHECK GRID

HANDLE WITH CARE. AFTER USE, INSPECT FOR DAMAGE. SEE IFU FOR INSTRUCTIONS.

15
30
45
60
75

DO NOT BLEACH • MARK GRID TO 75 USES

TRAINING VIDEOS: goo.gl/bBxaPi

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

7.5. Sterilization

7.5.1. Gravity Displacement Autoclave Sterilization

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

1. Wrap DrillCover Linen:
    i. Lay linen flat.
    ii. Fold lengthwise once.
    iii. Fold widthwise twice, webbing side first, then nose side on top with the nose facing upward.
    iv. Wrap in two 18 inch x 18 inch sterilization wrappers using sequential envelope folding technique. Include a sterile indicator or sterile indicator tape.

2. Wrap chuck adapter and chuck key
    i. Wrap the chuck adapter and chuck key together in two 10 inch x 10 inch sterilization wrappers using a sequential envelope fold. Include a sterile indicator or sterile indicator tape.

Ensure chuck is in a fully-open position.

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3. Place packages in autoclave and run the autoclave using these sterilization settings:

TEMPERATURE	121ºC
EXPOSURE TIME	30minutes
DRY TIME	60minutes

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. Separate the metal components from the linen by using a separate sterilization container or partitions within the same container.
3. Sterilize per parameter set 1 or 2

Parameter Set 1:

TEMPERATURE	132ºC
EXPOSURE TIME	4 minutes
DRY TIME	30minutes

Parameter Set 2:

TEMPERATURE	134ºC
EXPOSURE TIME	3 minutes
DRY TIME	30minutes

8. BATTERY, CHARGER, AND DCF610 POWER TOOL

The power tool is supplied with two batteries.

For detailed information on battery, charger and the DCF610 power tool, consult the enclosed DeWalt DCF610 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

At end of life, dispose of drill, battery, and charger in common electronics recycling. DrillCover linen and hardware can be disposed with other biohazardous waste or it can be sterilized and then disposed as regular non-biohazardous waste.

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