

## Drill Bit Instructions for Use and Reprocessing

### INTENDED USE

- General surgical instrument for the rotary cutting of a hole to size and depth in bone or tissue.

### INTENDED USER PROFILE

- Surgical procedures should be performed only by persons having adequate training and familiarity with surgical techniques.
- Consult medical literature relative to techniques, complications and hazards prior to performance of any surgical procedure. Before using the product, all instructions regarding its safety features must be read carefully.

### DEVICE DESCRIPTION

- Surgical instruments composed of medical grade stainless steel.
- Devices labeled as SurgiBit® use the SurgiBit® technology.
- Instruments are supplied NON-STERILE and must be inspected, cleaned and sterilized before each use.
- Devices are critical and require terminal sterilization per FDA guidelines and the Spaulding Classification scheme.
- Devices are not implantable.

### WARNINGS



- Avalign recommends thorough manual and automated cleaning of medical devices prior to sterilization. Automated methods alone may not adequately clean devices.
- Devices should be reprocessed as soon as possible following use. Instruments must be cleaned separately from cases and trays.
- All cleaning agent solutions should be replaced frequently before becoming heavily soiled.
- Prior to cleaning, sterilization and use, all instruments should be inspected to ensure proper function and condition. Do not use instruments if they do not perform satisfactorily.
- Risk of damage – The surgical instrument is a precision device. Careful handling is important for the accurate functioning of the product. Improper external handling can cause product malfunction.
- Use caution when handling sharp instruments to avoid injury.
- If a device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination.

### CAUTION



Federal U.S. Law restricts this device to sale, distribution, and use, by, or on order of a physician.

### LIMITATIONS ON REPROCESSING

Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

### DISCLAIMER

- The SurgiBit® technology is protected under US Patent 7,892,235 and associated US patents, foreign patents, design patents and patents pending. Used with permission of Orthopaedic Innovation Pty Ltd, Sydney, Australia, under license.
- It is the responsibility of the reprocessor to ensure reprocessing is performed using equipment, materials and personnel in the reprocessing facility and achieves the desired result. This requires validation and routine monitoring of the process. Any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.

## Reprocessing Instructions

### TOOLS AND ACCESSORIES

Water	Cold Tap Water (< 20°C / 68°F) Hot Tap Water (> 40°C / 104°F) Deionized (DI) or Reverse Osmosis (RO) Water (ambient)
Cleaning Agents	Neutral Enzymatic Detergent pH 6.0-8.0 i.e. MetriZyme, EndoZime, Enzol
Accessories	Assorted Sizes of Brushes and/or Pipe Cleaners with Nylon Bristles Absorbent, Low Lint Disposable Cloths or equivalent Soaking Pans
Equipment	Medical Compressed Air Ultrasonic Cleaner (Sonicator) Automated Washer

### POINT-OF-USE AND CONTAINMENT

- 1) Follow health care facility point of use practices. Keep devices moist after use to prevent soil from drying and remove excess soil and debris from all surfaces and hard-to-clean design features.
- 2) Follow universal precautions and contain devices in closed or covered containers for transport to central supply.

### MANUAL CLEANING

- 3) Prepare neutral pH enzymatic detergent as per vendor's directions. Enzol® enzymatic detergent is recommended at a preparation of 1 oz./gallon using lukewarm water.
- 4) Fully immerse device in the prepared detergent per labeling instructions. Allow device to soak for a minimum of 1 minute.
- 5) Scrub the device, using a soft bristled brush, paying particular attention to hard to reach areas until all visible soil has been removed.
- 6) Prepare neutral pH enzymatic detergent in the sonicator (as per vendor directions) and sonicate the devices for a minimum of 10 minutes. Note: Enzyme solution shall be changed when it becomes grossly contaminated (bloody and/or turbid).
- 7) Rinse all surfaces in running reverse osmosis or deionized (RO/DI) water for a minimum of 3 minutes to remove any residual detergent or debris.
- 8) Dry the device with a clean, soft cloth. Filtered, compressed air may be used to aid drying.
- 9) Visually examine each device for cleanliness. If visible soil remains, repeat cleaning procedure.

### AUTOMATED CLEANING

Note: All devices must be manually pre-cleaned prior to any automated cleaning process, follow steps 1-5. Steps 6-9 are optional but advised.

- 10) Clean devices within a washer/disinfector utilizing the equipment and detergent manufacturers' instructions per the below minimum parameters.

Phase	Time (minutes)	Temperature	Detergent Type & Concentration
Pre-wash 1	02:00	Cold Tap Water	N/A
Enzyme Wash	02:00	Hot Tap Water	Enzyme Detergent
Rinse 1	01:00	Hot Tap Water	N/A
Purified Water Rinse	00:10	146-150°F / 63-66°C	N/A
Drying	15:00	194°F / 90°C	N/A

- 11) Dry excess moisture using an absorbent cloth. Filtered, compressed air may be used to aid drying.
- 12) Visually examine each device for cleanliness. If visible soil remains, repeat cleaning procedure.

### DISINFECTION

- Devices must be terminally sterilized (See § Sterilization).
- Aalign instruments are compatible with washer/disinfector time-temperature profiles for thermal disinfection per ISO 15883.

### INSPECTION AND FUNCTIONAL TESTING

- Visually inspect devices for damage or wear. Instruments with broken, cracked, chipped or worn parts or surfaces should not be used, but should be replaced immediately.
- Check that drill cutting edges are smooth and continuous, free from large cracks or chips that may impair cutting performance.
- Verify mating surfaces function as intended and device interfaces with power without complications.

### PACKAGING

- Only FDA cleared sterilization packaging materials should be used by the end user when packaging the devices.

- The end user should consult ANSI/AAMI ST79 or ISO 17665-1 for additional information on steam sterilization.
- **Sterilization Wrap**
  - Individual instruments may be wrapped in a standard, medical grade sterilization wrap using the AAMI double wrap method or equivalent.

#### STERILIZATION

Sterilize with steam. The following are minimum cycles required for steam sterilization of Aalign devices:

##### Double Wrapped Instruments:

Cycle Type	Temperature	Exposure Time	Pulses	Drying Time
Prevacuum	132°C (270°F)	4 minutes	4	25 minutes

- The operating instructions and guidelines for maximum load configuration of the sterilizer manufacturer should be followed explicitly. The sterilizer must be properly installed, maintained, and calibrated.
- Time and temperature parameters required for sterilization vary according to type of sterilizer, cycle design, and packaging material. It is critical that process parameters be validated for each facility's individual type of sterilization equipment and product load configuration.
- A facility may choose to use different steam sterilization cycles other than the cycle suggested if the facility has properly validated the cycle to ensure adequate steam penetration and contact with the devices for sterilization. Note: rigid sterilization containers cannot be used in gravity steam cycles.
- Water droplets and visible signs of moisture on sterile packaging or the tape used to secure it, may compromise sterility of processed loads or be indicative of a sterilization process failure. Visually check outside wrapper for dryness. If there are water droplets or visible moisture on the exterior of the package or on the tape used to secure it, the pack or instrument tray is considered unacceptable. Repackage and re-sterilize sterilization packages with visible signs of moisture.

#### STORAGE

- After sterilization, instruments should remain in sterilization packaging and be stored in a clean, dry cabinet or storage case.
- Care should be taken when handling devices to avoid damaging the sterile barrier.

#### MAINTENANCE

- Discard damaged, worn or non-functional devices.
- Drills cannot be resharpened.

#### WARRANTY

- All products are guaranteed to be free from defects in material and workmanship at the time of shipping.
- Aalign instruments are reusable and meet AAMI standards for sterilization. All our products are designed and manufactured to meet the highest quality standards. We cannot accept liability for failure of products which have been modified in any way from their original design.







#### CONTACT



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### Symbols Glossary

Symbol	Title	Symbol	Title
	Manufacturer		Consult Instructions for Use
	Lot Number / Batch Code		Caution
	Catalogue Number		Federal Law (USA) restricts this device to sale by or on the order of a physician

### Parts List

#### Avalign SurgiBit® Drills

Part Number	Description	GTIN
10-2030145	SurgiBit® 2.0mm 3-fluted SQC drill bit, 145mm	00190776144524
10-2530145	SurgiBit® 2.5mm 3-fluted SQC drill bit, 145mm	00190776144531
10-2730145	SurgiBit® 2.7mm 3-fluted SQC drill bit, 145mm	00190776144548
10-3230145	SurgiBit® 3.2mm 3-fluted SQC drill bit, 145mm	00190776144555
10-4030145	SurgiBit® 4.0mm 3-fluted SQC drill bit, 145mm	00190776144562
10-4230145	SurgiBit® 4.2mm 3-fluted SQC drill bit, 145mm	00190776144579
10-4545145	SurgiBit® 4.5mm 3-fluted SQC drill bit, 145mm	00190776144586
10-5045145	SurgiBit® 5.0mm 3-fluted SQC drill bit, 145mm	00190776144593
10-2530230G	SurgiBit® 2.5mm 3-fluted SQC drill bit, 230mm, 200mm graduated	00190776144609
10-3230230G	SurgiBit® 3.2mm 3-fluted SQC drill bit, 230mm, 200mm graduated	00190776144616
10-4030230G	SurgiBit® 4.0mm 3-fluted SQC drill bit, 230mm, 200mm graduated	00190776144623
10-5045230G	SurgiBit® 5.0mm 3-fluted SQC drill bit, 230mm, 200mm graduated	00190776144630

#### Avalign Drills

Part Number	Description	GTIN
85-116020	AO Coupling Drill Ø1.1mm, 60/20mm	00190776118198
85-158523	AO Coupling Drill Ø1.5mm, 85/23mm	00190776118204
85-1511023	AO Coupling Drill Ø1.5mm, 110/23mm	00190776118211
85-2010023	AO Coupling Drill Ø2.0mm, 100/23mm	00190776118228
85-2012523	AO Coupling Drill Ø2.0mm, 125/23mm	00190776118235
85-2211035	AO Coupling Drill Ø2.2mm, 110/35mm	00190776118242
85-2518035	AO Coupling Drill Ø2.5mm, 180/35mm	00190776118259
85-2511035	AO Coupling Drill Ø2.5mm, 110/35mm	00190776118266
85-2711035	AO Coupling Drill Ø2.7mm, 110/35mm	00190776118273
85-2712535	AO Coupling Drill Ø2.7mm, 125/35mm	00190776118280
85-3214542	AO Coupling Drill Ø3.2mm, 145/42mm	00190776118297
85-3219542	AO Coupling Drill Ø3.2mm, 195/42mm	00190776118303

Part Number	Description	GTIN
85-1517127	Jacobs Chuck Drill 1.5mm, 17/127mm	00190776118365
85-2023127	Jacobs Chuck Drill 2.0mm, 23/127mm	00190776118372
85-2423127	Jacobs Chuck Drill Ø2.4mm, 23/127mm	00190776118389
85-2523127	Jacobs Chuck Drill Ø2.5mm, 23/127mm	00190776118396
85-2730127	Jacobs Chuck Drill Ø2.7mm, 30/127mm	00190776118402
85-3242127	Jacobs Chuck Drill Ø3.2mm, 42/127mm	00190776118419
85-3542127	Jacobs Chuck Drill Ø3.5mm, 42/127mm	00190776118426
85-4034127	Jacobs Chuck Drill Ø4.0mm, 34/127mm	00190776118433
85-4534127	Jacobs Chuck Drill Ø4.5mm, 34/127mm	00190776118440
85-4734127	Jacobs Chuck Drill Ø4.7mm, 34/127mm	00190776118457
85-5042127	Jacobs Chuck Drill Ø5.0mm, 42/127mm	00190776118464

Part Number	Description	GTIN
85-3511042	AO Coupling Drill Ø3.5mm, 110/42mm	00190776118310
85-3519542	AO Coupling Drill Ø3.5mm, 195/42mm	00190776118327
85-4019542	AO Coupling Drill Ø4.0mm, 195/42mm	00190776118334
85-4514542	AO Coupling Drill Ø4.5mm, 145/42mm	00190776118341