Instructions for Use: Non-Sterile Reusable Orthopaedic Surgical Instruments

WARNING: The instruments described may only be used in combination with OrthoMedFlex products!

Instructions for Use OMF-IFU-004 RevD Issue Date: Sept-17

Caution:

Carefully read all the instruction and be familiar with the surgical technique(s) prior to use of the system. This product must only be used by trained, qualified persons, aware of the directions for use.

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

1 General Instructions

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the parts, but must also be aware of their mechanical limitations. OrthoMedFlex instruments and implants should only be used with approved devices and accessories.

2 Applicable Devices

This document is applicable to all reusable surgical instruments designed and manufactured solely by/for OrthoMedFlex LLC comprising fixed assemblies (no moving parts) and simple hinged assemblies.

For instruments not designed and manufactured solely by/for OrthoMedFlex, refer to the specific instructions supplied with the device. These devices are listed below for reference. OrthoMedFlex retains and will provide current copies of these instructions for use. For more information, contact the manufacturer of the part numbers listed.

Part No.	Manufacturer	Description
101-318	Greatbatch Medical	Offset Cup Impactor
101-319	Greatbatch Medical	Offset Reamer Assembly
101-190-01	Bradshaw Medical	Ratcheting Screwdriver
101-203-01	Bradshaw Medical	T-Handle
112-153-2XX	Precimed	Acetabular Reamers

3 Warnings

a) Long narrow cannulations and blind holes require particular attention during cleaning.

b) Enzymatic or other cleaning agents with neutral pH are recommended

c) Instruments should be thoroughly inspected to ensure that they are in good condition and operating order following reprocessing. Instruments should be returned to OrthoMedFlex at least once every 2 years for review / repair / replacement. Instruments may be returned for review / repair / replacement earlier if the user deems necessary.

4 Cleaning and Decontamination

a) CLEANING AT POINT OF USE

Remove excess soil with disposable non-shedding wipes.

b) CONTAINMENT AND TRANSPORTATION

It is recommended that instruments are reprocessed as soon as is reasonably practical following use. OrthoMedFlex recommends cleaning within 30 minutes of completion of use

c) PREPARATION PRIOR TO CLEANING

Disassemble instruments prior to cleaning. Do not clean instruments with products containing Sodium Hypochlorite (NaOCl) and Sodium Hydroxide (NaOH). Corrosive products or abrasive instruments should not be used.

d) Rinse water should be highly purified water (treated by reverse osmosis or distillation) or deionized water (if there is not an endotoxin issue).

e) MANUAL CLEANING

- Prepare a decontaminant solution according to manufacturer's recommendations using lukewarm water. Fully immerse the articles in the prepared solution, actuating them through their full range of motion, flushing all hard to reach areas using an appropriately sized syringe with a minimum of 50 mL of the prepared detergent per article, and then allow the article to soak for the minimum amount of time as stated in the precautions for the use of the decontaminant.
- After the minimum soak, brush the articles thoroughly using a soft bristled brush (M16) beneath the surface of the prepared solution until all visible soil had been removed. Pay special attention to hard to reach areas
- Remove the articles from the solution and thoroughly rinse under running water until all solution residues are removed. Actuate the articles through their full range of motion while rinsing. During rinsing, thoroughly brush the articles using a soft bristled brush (M16), paying special attention to hard to reach areas. Actuate the articles through their full range of motion while brushing. During rinsing, flush the articles thoroughly using an appropriately sized syringe with a minimum of 50 mL of water per article, paying special attention to hard to reach areas. Actuate the articles through their full range of motion while flushing.
- Dry the articles using a clean, soft cloth and filtered pressurized air (≤ 40 psi). Visually inspect the articles for cleanliness.

f) AUTOMATED CLEANING

- Automated cleaning of instruments is not recommended in isolation. A combination of manual and automated cleaning is required. Automated cleaning cycles should be validated to equal or exceed the cleaning process as specified in the Manual cleaning section above.
- Thoroughly rinse the articles under running water using a disposable paper towel to remove gross contamination.
- Transfer the articles into the automatic washer/disinfector for processing. Orient the articles at an incline to facilitate drainage.
- Select the cleaning cycle set to the following set of parameters, set to high:

Phase	Recirculation Time	Temperature	Detergent, Concentration
Pre-wash 1	2 minutes	Cold water	N/A
Enzyme Wash	2 minutes	Hot water	Enzol®, 1 oz/gal
Wash 1	2 minutes	151° F (66° C)	Valsure® Neutral, ¾ oz/gal
Rinse 1	2 minutes	Hot water	N/A
Drying	7 minutes	187° F (86° C)	N/A

- Remove the articles from the automatic washer/disinfector. If moisture remains on the articles, dry them using a clean, soft cloth and filtered pressurized air.

g) PACKAGING

In sets: Instruments may be loaded into dedicated instrument trays, or general-purpose sterilization trays. Ensure that cutting edges are protected. Wrap the trays using Disposable Surgical Instrument Wrap following AAMI double wrap method (ANSI/AAMI ST46-1993)

5 Sterilization and Resterilization

Unless specifically labelled sterile, the instruments are supplied non-sterile and must be sterilized prior to use. The following sterilization method is recommended:

Steam Autoclave Pre-Vacuum
Condition: Double-Pouched
Temperature: 270° F (132° C)
Time: 4 minutes
Drying Time: 30 minutes

Note: Drying time is subject to variation depending on machine load.

6 Maintenance, Storage, and Handling

a) Instruments are to be stored in dry, clean surroundings at room temperature, in their original packaging or sterilization tray respectively, and in accordance with AS4187:2003.

b) Ancillary surgical instruments should be handled and stored with care. Instruments should be carefully stored in an appropriate, dry, clean environment. Instruments must not be stored in contact with, or close to, products that may have a corrosive effect.

c) Procedures to be implemented after use: it is the hospital's responsibility to decontaminate, clean and sterilize the ancillary instrumentation (full box or single instrument) in accordance with the recommendations of the manufacturer. Any missing or damaged instrument should be reported to your representative or distributor, or directly to the manufacturer.

7 Inspection and Function Testing

OrthoMedFlex reusable instruments are designed to be used for many procedures and endure many sterilization cycles. Before each sterilization cycle, visually inspect for damage and wear. An instrument should be considered at its end of use if it shows signs of deterioration, corrosion, discoloration, pitting, cracking, nicking of edges, or excessive deformation. Confirm the smooth movement of hinged instruments without excessive "play". Locking (ratchet) mechanisms should be checked for action. Check instruments with long slender features (particularly rotating instruments) for distortion. Where part of a larger assembly, check assembly with mating components.

8 Limited Warranty / Liability

a) OrthoMedFlex products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

b) OrthoMedFlex LLC shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. OrthoMedFlex LLC neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. OrthoMedFlex LLC intends that these instruments should be used only by physicians with appropriate training in orthopaedic surgical techniques.

9 Contact Information

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact the appropriate OrthoMedFlex location for current information. For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate OrthoMedFlex location as listed below:

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10 Label Symbol Legend