1.0 INTRODUCTION

HPF instrumentation is made up of class I and class IIa medical devices (D.L. 24/02/97 n. 46 “Implementaion of Directive 93/42/CEE concerning Medical Devices”) utilized in the implantation procedures of Customers prosthesis.

1.1 Warnings, precautions and restrictions

a) HPF has designed a set of specific instruments for each type of implantable component: other instruments are not to be used if not specified by the surgical technique for that implant.

b) As most of the instruments are intended for reuse, general wear is expected. If wearing (i.e. scratches) does not alter instrument properties, they can be reused. Otherwise, **if the defects worsen the instruments performance** (i.e. edge loss, metals strain), please contact HPF for substitution. HPF recommends **not to resharpen instruments autonomously**.

c) Pay attention to friction between metal instruments and tissues: if the heat generated is too high and/or prolonged can cause necrosis of the tissue and lead to a faster decay of the instruments.

d) Some instruments, such as drill bits and other cutting devices are intended for **SINGLE USE ONLY and must not be reused**. Check the label of the instrument to see if it is a single use instrument.

e) **Personal Protective Equipment** (i.e. gown, mask, goggles or face shield, gloves and shoe covers) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment.

f) **Do not place heavy instruments on top of delicate devices**.

g) **Metal brushes or scouring pads must not be used** during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.

h) **Do not allow contaminated devices to dry prior to reprocessing**. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on used devices.

i) **Use of hard water should be avoided**. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments. One or more of the following processes may be used to purify water: ultra-filter (UF), reverse-osmosis (RO), deionized (DI), or equivalent.

NOTE. The user has to validate the equipment and the processes for cleaning/disinfection and sterilization.

NOTE. These instructions are not applicable to trays of other manufacturers or containing devices that are not manufactured and/or distributed by HPF.

2.0 ASSEMBLY AND USE OF INSTRUMENTS

Before performing any surgical operation, the surgeon should be familiar with the surgical technique, the use of the instruments and devices to be implanted. It is recommended neither modify nor alter any instrument; furthermore instruments should not be used for surgical operations other than those indicated.

2.1 Shipping conditions

HPF instruments are shipped clean but NOT sterile. HPF advise against the sterilization of instruments with ethylene oxide (EtO), gas plasma and dry-heat. Steam sterilization (autoclave) is suitable for the sterilization of HPF instruments.
A list of codes and this instructions for use leaflet are included inside the instrument trays.
In case of complex instruments instructions for their disassembly/assembly are available on the HPF website.
Instruments shipped singularly are packaged in a closed pouch.
All instruments must be checked, in order to be sure they are suitable for the surgical operation, and then washed and sterilized.

3.0 CLEANING AFTER USE

Before starting the cleaning and sterilization procedures check the label of the instrument to see if it is a single use instrument.

3.1 Indications

Instruments must be washed and disinfected as soon as possible after use, in order to minimize hazards of infections (formedical staff) and corrosion (for instruments).
Immediately after surgery remove excess body fluids and tissue with a suitable disposable, non-shedding wipe.
Instruments should be cleaned within 30 minutes after their use to reduce the probability of drying. **After cleaning instruments are to be dried** with a suitable non-shedding wipe.
Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.
Enzymatic and cleaning agents with a neutral pH or between 4.5 and 8.5 are recommended for cleaning HPF reusable devices. Do not use strong acids nor oxidizing agents or corrosive chemicals which can alter the instrument surface (i.e. chlorine, iodine, fluorine, organic solvents, ammonia, mercury, especially if they are plastic or other polymeric components).
Do **not** soak instruments in **Ringer solution or similar saline solutions**. Alkaline agents with pH < 12 may be used to clean stainless steel and some polymer instruments in countries where required by law or local ordinance; or where prior diseases such as Transmissible Spongiform Encephalopathy (TSE) and Creutzfeldt-Jakob Disease (CJD) are a concern. **It is critical that alkaline cleaning agents be completely and thoroughly neutralized and rinsed from devices**.
Strong basis must be avoided for the cleaning of trays made of aluminium and aluminium alloy.
Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.

NOTE. Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/orturbid).

NOTE. After their use, boxes and instruments are to be washed separately; place the instruments in the boxes only after the cleaning and disinfection phase.

3.2 Manual Cleaning/Disinfection Procedure

Phase 1	**Disassembly all instruments** and check all threads are drawn back. It's recommended to keep together the parts of the disassembled instruments tofacilitate the assembly. When in doubt follow the instruction for the disassembly/assembly made available by HPF.
Phase 2	Completely submerge instruments for 20 minutes in a water solution with the proper cleaning agent (i.e. : enzymatic detergent for surgical instruments) following the specifications of the manufacturer of the solution. While the instruments are submerged, scrub them with a soft brush, paying special attention to remove all organic residuals and clean also the difficult to reach areas (threads, pivots, hinges) Do not use metal or abrasive brushes! **Note. Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.**
Phase 3	**Rinse instrument in tap water** for at least 3 minutes flushing thoroughly lumens, holes and other difficult to reach areas.
Phase 4	**Place prepared cleaning agents in a sonication unit**. Completely submerge device in cleaning solution and sonicate (≥ 24 kHz) for 10 minutes. Temperatures higher than 50°C can cause encrustations when blood is still present.
Phase 5	**Soak the instruments in a disinfecting solution** specific for surgical instruments, following the instructions of the manufacturer for concentration, temperature of solution and length of soak.
Phase 6	**Rinse instrument in distilled or demineralised water** for at least 5 minutes paying attention to flush thoroughly and aggressively lumens, holes and other difficult to reach areas.
Phase 7	**Immediately dry the instruments in a hot air oven (70°C minimum) for at least 10 minutes or with a suitable disposable, non-shedding wipe** paying special attention to slots, lumens, mated surfaces, connectors and difficult to dry areas (i.e.laser-markings). Long and thin brushes can be used to dry lumens. Completing this significantly reduces the risk of corrosion caused by drops of water on the parts surface is reduced.

3.3 Manual/Automated Cleaning/Disinfection Procedure

Before starting with the automated cleaning/disinfection procedure it's advisable to perform an accurate manual cleaning by carrying out phases 1 to 3 as indicated at point 3.2.
Put the instruments inside a cleaning/disinfection system and start with a standard cleaning/ disinfection cycle.

Phase 1	Pre Wash; Softened Tap Water; 2 minutes minimum
Phase 2	Enzyme Spray (1), Hot (2) Softened Tap Water
Phase 3	Enzyme Soak (1)
Phase 4	Rinse (X2); Tap Water; 15 seconds minimum
Phase 5	Detergent Wash (1) in water solution
Phase 6	Rinse (X2); Hot (2) Softened Tap Water; 15 seconds minimum
Phase 7	Rinse; Hot (2) Softened Tap Water; 3 minutes minimum
Phase 8	Purified Water Rinse; 1minute minimum
Phase 9	Hot Air Dry; 70°C minimum; 10 minutes

(1) see the manufacturer specifications for temperatures and treatment duration
(2) water temperature ≥ 50°C

HPF advises against the performance of the sole automated cleaning/disinfection by using manual cleaning /disinfection equipment as this procedure can be inefficacious for orthopaedic instruments.

4.0 INSPECTION, MAINTENACE, AND LUBRICATION

Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
Check the action of moving parts (e.g. hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
Check instruments with long slender features (particularly rotating instruments) for distortion.
Where instruments form part of a larger assembly, ensure a check is completed that devices assemble readily with compatible components.
Hinged, rotating, or articulating instruments should be lubricated with a water soluble product (e.g. Lubrimilk or equivalent lubricant) **intended for surgical instruments that must be sterilized**. Some water-based instrument lubricants contain bacteriostatic agents which are beneficial. Manufacturer's expiration dates should be adhered to for both stock and use-dilution concentrations.
Follow the instructions provided by HPF for instruments disassembly/assembly.

4.1 Packaging

After inspection the instruments are to be placed in the proper slots of the boxes, trays suitable for steam sterilization. **All devices must be arranged to ensure steam penetration** to all instrument surfaces. Instruments should not be stacked or placed in close contact.
The user must ensure that the instrument case is not tipped or the contents shifted once the devices are arranged in the case.
Commercially available, medical grade steam sterilization pouches or wrap may be used to package individual instruments.
Trays and cases with lids may also be wrapped in standard medical grade, steam sterilization wrap or placed in an approved sterilization container with gasket lid for sterilization. Follow the sterilization containers' manufacturer's instructions for inserting and replacing sterilization filters within sterilization containers.
NOTE. Areas designated for specific devices shall contain only devices specifically intended for these areas.

5.0 STERILIZATION PROCEDURE

The instruments produced by HPF are to be sterilized by means of steam sterilization (autoclave) according to the requirements of EN 285 and European Pharmacopoeia. In case the user chooses another sterilization method the individual and/or hospital location takes on the responsibility for the sterilization
efficacy and possible damages of HPF instruments.
Make sure your sterilizing facility is properly serviced and process validated.
NOTE: each sterilization equipment has its own operating parameters. The suitability of the parameters has to be validated by qualified and skilled personnel on sterilization procedures. Each change to the sterilization procedures is at the risk of the user.

Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contact with all surfaces.
When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.
Disinfection is only acceptable as a precursor to full sterilization for reusable surgical instruments.

The following minimum sterilization parameters are recommended to provide a 10^{-6} sterility assurancelevel (SAL):

	Description	Temperature	Pressure	Time
Phase 1	Pre-vacuum	-	-0,80 Bar	240 sec
Phase 2	Fractioned Phase (Omogeneization)	-	4 pulses from -0,80 Bar to +0,55 Bar	-
Phase 3	Sterilization	134°	+2.1 Bar	6 min
Phase 4	Drying	-	-0.80 Bar	180 sec
Phase 5	Drying Pulses	-	3 pulses from -0,80 Bar to +0,00 Bar	-
Phase 6	Balancing	-	-	100 sec

NOTE. The instructions of the sterilization equipment use, configuration and maximum load issued by the manufacturer must be strictly followed.
Once sterilized the instruments must be handled with aseptic procedures.

6.0 STORAGE

Instruments are to be kept and carried in their boxes, this will provide suitable protection from impacts and damages, and at the same time will shield users' from risks of cuts.
Instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/ humidity extremes.
Note. Store instruments in their boxes. Protect components from involuntary contact with other instrument as it may lead to damaging their finishing. Before use check possible visible damages of each instrument.

7.0 HOSPITAL RESPONSIBILITIES FOR HPF LOANER INSTRUMENTS

Instruments which no longer perform properly because of long use, mishandling, or improper care should be returned to HPF who will provide of their maintenance or disposal.
Loaner sets should undergo all steps of decontamination, cleaning, disinfection, inspection,and terminal sterilization before being returned to HPF. **Documentation of decontamination should be provided** with instruments being returned to HPF.
Instruments are to be returned in their boxes and the boxes are to be properly packaged inside a cardboard box suitable for preventing possible damages during transport.

8.0 FURTHER INFORMATION

For further investigation and questions contact HPF S.r.l. (http://www.hpfgroup.it).

9.0 BIBLIOGRAPHY

ISO 17664: 2005
European Pharmacopoeia